



Brussels, **XXX**
PLAN/2023/1253
[...](2023) **XXX** draft

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

of **XXX**

concerning the non-renewal of the approval of the active substance metiram, 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)

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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 2005/72/EC² included metiram 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 metiram, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2024.
- (4) Applications for the renewal of the approval of metiram were submitted to Italy, the rapporteur Member State, and to the United Kingdom, 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 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances (OJ L 279, 22.10.2005, p. 63).

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).

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), which continues to apply to the procedure for the renewal of the approval of this active substance pursuant to Article 17 of Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in

- (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 applications were 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 2 November 2017.
- (7) The Authority communicated 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. The Authority made the supplementary summary dossier available to the public.
- (8) On 20 March 2023, the Authority communicated to the Commission its conclusion⁶ on whether metiram can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority identified several critical areas of concern. In particular, it concluded that the reference values of metiram and its relevant fungicidally active metabolites for operator, bystander and resident exposures are exceeded in all representative uses. In addition, the Authority identified a high risk to aquatic organisms and high in-field risk for non-target arthropods for all representative uses. The Authority also concluded that metiram meets the criteria to be identified as endocrine disruptor for humans for the T modality.
- (9) In accordance with Article 13(3a), third subparagraph, of Implementing Regulation (EU) No 844/2012, the applicant was given the opportunity to submit additional information to address the approval criteria concerning endocrine disrupting properties set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009.
- (10) The Commission presented a draft renewal report regarding metiram and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 24 May 2023.
- (11) The Commission invited the applicants to submit their comments on the conclusions 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 applicants submitted their comments, which have been carefully examined.
- (12) Despite the arguments put forward by the applicants, the concerns regarding the active substance metiram could not be eliminated.
- (13) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product containing metiram 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 that active substance.
- (14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20).

⁶ Peer review of the pesticide risk assessment of the active substance metiram. EFSA Journal 2023;21(4):7937.

- (15) Member States should be given sufficient time to withdraw authorisations for plant protection products containing metiram.
- (16) For plant protection products containing metiram, 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.
- (17) Commission Implementing Regulation (EU) 2023/114⁷ extended the approval period of metiram to 31 January 2024 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 has been taken ahead of the expiry of that extended approval period, this Regulation should start to apply earlier than that date.
- (18) This Regulation does not prevent the submission of a further application for the approval of metiram pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (19) 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 metiram 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 115 on metiram, is deleted.

Article 3

Transitional measures

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

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 [...] *[Office of Publications: please insert date 12 months from the date of entry into force of this implementing regulation]*.

⁷ Commission Implementing Regulation (EU) 2023/114 of 16 January 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benzovindiflupyr, buprofezin, cyflufenamid, fluazinam, flutolanil, lambda-cyhalothrin, mecoprop-P, mepiquat, metiram, metsulfuron-methyl, phosphane and pyraclostrobin (OJ L 15, 17.1.2023, p 9).

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,

For the Commission
The President
Ursula VON DER LEYEN