



2026/1353

16.6.2026

COMMISSION IMPLEMENTING REGULATION (EU) 2026/1353

of 15 June 2026

amending Implementing Regulations (EU) 2020/617 and (EU) No 540/2011 as regards the conditions of approval of the active substance metalaxyl-M

(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 13(2)(c) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2020/617 ⁽²⁾ renewed the approval of the active substance metalaxyl-M.
- (2) The conditions of the approval of the active substance metalaxyl-M, as inserted in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾ by Implementing Regulation (EU) 2020/617, include a maximum level of 0,18 g/kg for the impurity CGA226048 (2-[(2,6-dimethyl-phenyl)-(2-methoxyacetyl)-amino]-propionic acid 1-methoxycarbonyl-ethyl ester) as well as a restriction that the use of plant protection products containing metalaxyl-M for seed treatment is to be limited to the treatment of seeds intended to be sown in greenhouses.
- (3) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, on 17 June 2020, Syngenta Crop Protection AG submitted an application to the rapporteur Member State, Belgium, seeking an amendment to the conditions of approval of metalaxyl-M in order to remove the restriction concerning the sowing of seeds and to update the maximum level of the impurity CGA226048. The application was found to be admissible by the rapporteur Member State.
- (4) The rapporteur Member State assessed the proposed new use of the active substance metalaxyl-M and the proposed updated level of the impurity CGA226048 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 revised renewal assessment report which was submitted to the European Food Safety Authority ('the Authority') and the Commission on 9 March 2021.
- (5) In accordance with Article 12(1) of Regulation (EC) No 1107/2009, the Authority circulated the revised renewal 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. The rapporteur Member State evaluated the additional information and submitted the revised renewal assessment report to the Commission and to the Authority on 13 April 2023.

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

⁽²⁾ Commission Implementing Regulation (EU) 2020/617 of 5 May 2020 renewing the approval of the active substance metalaxyl-M, and restricting the use of seeds treated with plant protection products containing it, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 143, 6.5.2020, p. 6; ELI: http://data.europa.eu/eli/reg_impl/2020/617/oj).

⁽³⁾ 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).

- (6) On 3 October 2023, the Authority communicated to the Commission its conclusion ⁽⁴⁾ on whether the proposed new use of the active substance metalaxyl-M and the proposed updated level of the impurity CGA226048 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (7) It was established in the conclusion of the Authority that, with a level of less than 10 g/kg for impurity CGA226048, the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (8) Based on the conclusion of the Authority, the Commission presented an addendum to the review report for metalaxyl-M and a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed on 22 May 2024.
- (9) By Commission Implementing Regulation (EU) 2024/1718 ⁽⁵⁾, The Commission amended the approval of metalaxyl-M setting a revised maximum level for CGA226048.
- (10) With regard to the restriction concerning to the sowing of treated seeds, the Authority identified a critical area of concern. A high acute and long-term risk was identified for birds and wild mammals. However, in the conclusion and its background documents it was indicated that a safe use for treatment and sowing of treated spinach seeds may be possible, when considering precision drilling of seeds. The Commission, in accordance with Article 31 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁶⁾, read in conjunction with Regulation (EC) No 1107/2009, requested that the Authority provide an updated risk assessment for birds and mammals.
- (11) On 4 July 2025, the Authority communicated to the Commission its updated conclusion ⁽⁷⁾ on whether the proposed new use of the active substance metalaxyl-M can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (12) The Authority established in its updated conclusion that the sowing of seeds treated with plant protection products containing metalaxyl-M outside greenhouses does not pose a risk to birds and wild mammals with the application of refined good agricultural practices (GAPs), in particular by limiting the seed sowing rate and by using precision drilling equipment.
- (13) The Commission presented a second addendum to the review report for metalaxyl-M and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 10 December 2025.
- (14) The applicant was invited to submit comments on the second addendum to the review report.
- (15) Based on the outcome of the risk assessment, it is considered appropriate to set a maximum sowing rate that should apply unless the outcome of a risk assessment for sowing of seeds carried out as part of the authorisation for the placing on the market of plant protection products for such use indicates that a higher rate does not lead to any unacceptable effects on birds and mammals. It is also considered appropriate to require the use of precision drilling equipment. It is therefore appropriate to remove the restriction limiting the use of plant protection products containing metalaxyl-M for the treatment of seeds intended to be sown in greenhouses only.
- (16) Implementing Regulations (EU) 2020/617 and (EU) No 540/2011 should therefore be amended accordingly.

⁽⁴⁾ Peer review of the pesticide risk assessment of the active substance metalaxyl-M (amendment of approval conditions). *EFSA Journal* 2023;21:e08373. Available online: <https://doi.org/10.2903/j.efsa.2023.8373>.

⁽⁵⁾ Commission Implementing Regulation (EU) 2024/1718 of 19 June 2024 amending Implementing Regulations (EU) 2020/617 and (EU) No 540/2011 as regards the conditions of approval of the active substance metalaxyl-M (OJ L, 2024/1718, 20.6.2024; ELI: http://data.europa.eu/eli/reg_impl/2024/1718/oj).

⁽⁶⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 031 1.2.2002, p. 1; ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

⁽⁷⁾ Updated peer review of the pesticide risk assessment of the active substance metalaxyl-M (amendment of approval conditions). *EFSA Journal*, 23(7), e9573. Available online: <https://doi.org/10.2903/j.efsa.2025.9573>.

- (17) 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) 2020/617

Annex I to Implementing Regulation (EU) 2020/617 is amended in accordance with Annex I to this Regulation.

Article 2

Amendment 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

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, 15 June 2026.

For the Commission
The President
Ursula VON DER LEYEN

Annex I to Implementing Regulation (EU) 2020/617 is replaced by the following:

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Metalaxyl-M CAS No 70630-17-0 (R) CIPAC No 580	methyl N-(methoxyacetyl)- N-(2,6-xylyl)-D- alaninate	≥ 920 g/kg The following impurities are of toxicological concern and must not exceed the following levels in the technical material: 2,6-dimethylphenylamine: max. content ≤ 0,5 g/kg 4-methoxy-5-methyl-5H-[1,2]oxathiole 2,2-dioxide: max. content ≤ 1 g/kg 2-[(2,6-dimethylphenyl)-(2-methoxyacetyl)-amino]-propionic acid 1-methoxycarbonyl-ethyl ester: max. content < 10 g/kg	1 June 2020	31 May 2035	When used for seed treatment where treated seeds are to be sown outdoors, Member States shall, impose appropriate restrictions concerning the sowing density and require the use of precision drilling equipment. A sowing density above 2 000 000 seeds/ha shall not be exceeded unless the outcome of the risk assessment undertaken for the specific uses for which authorisation is applied for demonstrates that a higher rate does not lead to any unacceptable effects on birds and mammals. 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 metalaxyl-M, 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 specification of the technical material as commercially manufactured; — the protection of operators and workers, ensuring that the conditions of use prescribe the use of adequate personal protective equipment, where appropriate; — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions; — the protection of non-target arthropods, birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water, by 10 July 2026.

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

ANNEX II

Row 140, metalaxyl-M, in Part B of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

No.	Common Name, Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
'140	Metalaxyl-M CAS No 70630-17-0 (R) CIPAC No 580	methyl N-(methoxyace- tyl)-N-(2,6-xylyl)- D-alaninate	920 g/kg The following relevant impurities shall not exceed a certain threshold: 2,6-dimethylphenyla- mine: max. content 0,5 g/kg 4-methoxy-5-methyl- 5H-[1,2]oxathiole 2,2-dioxide: max. content 1 g/kg 2-[(2,6-dimethyl- phenyl)-(2-methoxya- cetyl)-amino]- propionic acid 1-methoxycarbonyl- ethyl ester): max. content 10 g/kg	1 June 2020	31 May 2035	When used for seed treatment where treated seeds are to be sown outdoors, Member States shall, impose appropriate restrictions concerning the sowing density and require the use of precision drilling equipment. A sowing density above 2 000 000 seeds/ha shall not be exceeded unless the outcome of the risk assessment undertaken for the specific uses for which authorisation is applied for demonstrates that a higher rate does not lead to any unacceptable effects on birds and mammals. 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 metalaxyl-M, 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 specification of the technical material as commercially manufactured, — the protection of operators and workers, ensuring that the conditions of use prescribe the use of adequate personal protective equipment, where appropriate, — the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions, — the protection of non-target arthropods, birds and mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in drinking water, by 10 July 2026.'