



2024/1718

20.6.2024

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

(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) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2020/617 ⁽²⁾ renewed the approval of the active substance metalaxyl-M and restricted the use of seeds treated with plant protection products containing it.
- (2) The approval of the active substance metalaxyl-M, as set out in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾, included 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 as regards the treatment of seeds, i.e. the use of metalaxyl-M is 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 designated rapporteur Member State, Belgium, seeking an amendment of 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 contained therein. The application was found to be admissible by the designated rapporteur Member State.
- (4) The designated rapporteur Member State assessed the request for an amended use of the active substance metalaxyl-M in relation to the potential effects on human and animal health and the environment in accordance with the provisions of 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. Belgium evaluated the additional information and submitted a revised renewal assessment report to the Commission and to the Authority in 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 14 August 2023, the Authority communicated to the Commission its conclusion ⁽⁴⁾ on whether the amended conditions of approval 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.
- (7) 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.
- (8) The applicant was invited to submit comments on the addendum to the review report.
- (9) It has been established that, with a maximum level of less than 10 g/kg for impurity CGA226048 (2-[(2,6-dimethylphenyl)-(2-methoxyacetyl)-amino]-propionic acid 1-methoxycarbonyl-ethyl ester), the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to update the maximum level of that impurity and to amend the conditions of approval.
- (10) Concerning the restriction concerning the sowing of seeds, following the outcome of the application for amendment of conditions of approval, the Commission has requested the Authority to further review certain issues and to update the risk assessment. Therefore, currently that restriction is maintained.
- (11) Furthermore, it is necessary that the applicant submits to the Commission, the Member States and the Authority further confirmatory information on the effect of water treatment processes on the nature of residues of the active substance or its metabolites in water abstracted for the production of drinking water.
- (12) Implementing Regulations (EU) 2020/617 and (EU) No 540/2011 should therefore be amended accordingly.
- (13) 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.

⁽⁴⁾ EFSA (European Food Safety Authority), Alvarez F., Arena M., Auteri D., Leite S. B., Binaglia M., Castoldi A. F., Chiusolo A., Colagiorgi A., Colas M., Crivellente F., De Lentdecker C., De Magistris I., Egsmose M., Fait G., Ferilli F., Gouliarmou V., Halling K., Nogareda L. H., Villamar-Bouza, L. (2023). Peer review of the pesticide risk assessment of the active substance metalaxyl-M (amendment of approval conditions). *EFSA Journal*, 21(10), 1–21. <https://doi.org/10.2903/j.efsa.2023.8373>.

*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, 19 June 2024.

For the Commission
The President
Ursula VON DER LEYEN

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

‘ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (%)	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-dimethyl-phenyl)-(2-methoxyacetyl)-amino]-propionic acid 1-methoxy-carbonyl-ethyl ester: max. content < 10 g/kg	1 June 2020	31 May 2035	When used for seed treatment, only the treatment of seeds intended to be sown in greenhouses may be authorised. 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 an updated assessment of the information submitted and, where relevant, further information to confirm the absence of endocrine disrupting properties in accordance with points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605, by 26 May 2022.

					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.'					

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-(methoxyacetyl)-N-(2,6-xylyl)-D-alaninate	<p>≥ 920 g/kg</p> <p>The following impurities are of toxicological concern and must not exceed the following levels in the technical material:</p> <p>2,6-dimethylphenylamine: max. content: 0,5 g/kg</p> <p>4-methoxy-5-methyl-5H-[1,2]oxathiole 2,2-dioxide: max. content: 1 g/kg</p> <p>2-[(2,6-dimethyl-phenyl)-(2-methoxyacetyl)-amino]-propionic acid 1-methoxycarbonyl-ethyl ester: max. content < 10 g/kg</p>	1 June 2020	31 May 2035	<p>When used for seed treatment, only the treatment of seeds intended to be sown in greenhouses may be authorised.</p> <p>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.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — 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. <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

						<p>The applicant shall submit to the Commission, the Member States and the Authority an updated assessment of the information submitted and, where relevant, further information to confirm the absence of endocrine disrupting properties in accordance with points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605, by 26 May 2022. 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.</p>
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(¹) Further details on the identity and the specification of the active substance are provided in the review report.'