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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/617

of 5 May 2020

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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/EEC[(1)], and in particular Article 20(1) and 49(2) thereof,

Whereas:

(1) Commission Directive 2002/64/EC[(2)] included metalaxyl-M 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 metalaxyl-M, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 June 2020.

(4) An application for the renewal of the inclusion of metalaxyl-M in Annex I to Directive 91/414/EEC was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010[(5)] within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 9 of Regulation (EU) No 1141/2010. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 13 November 2013.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2020/617. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(8) On 30 January 2015, the Authority communicated to the Commission its conclusion[(6)] on whether metalaxyl-M can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented an initial draft review report for metalaxyl-M to the Standing Committee on Plants, Animals, Food and Feed on 14 July 2015 and a revised version on 16 July 2019.

(9) The applicant was given the opportunity to submit comments on the draft review report.

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing metalaxyl-M that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(11) It is therefore appropriate to renew the approval of metalaxyl-M.

(12) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions.

(13) Risks for birds and mammals from consumption of treated seeds have been identified by the Authority. Taking into consideration those risks, the use of seeds treated with plant protection products containing metalaxyl-M should be restricted. It is therefore appropriate that seeds treated with plant protection products containing metalaxyl-M should only be sown in greenhouses.

(14) The Commission considers that metalaxyl-M does not have endocrine disrupting properties based on the available scientific information summarised in the conclusion of the Authority. However, in order to increase the confidence in this conclusion, the applicant should provide an updated assessment, in accordance with point 2.2(b) of Annex II to Regulation (EC) No 1107/2009, of the criteria laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605, and in accordance with the guidance for the identification of endocrine disruptors[(7)].

(15) The risk assessment for the renewal of the approval of metalaxyl-M is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing metalaxyl-M may be authorised. It is therefore appropriate not to maintain the restriction to uses as a fungicide.

(16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(17) The restriction to the use of treated seeds should apply as of 1 June 2021 in order to allow for a sufficient period of transition.

(18) 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:

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Article 1

Renewal of the approval of the active substance

The approval of the active substance metalaxyl-M is renewed as set out in Annex I.

Article 2

Amendments 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

Restriction to the use of treated seeds

Seeds treated with plant protection products containing metalaxyl-M shall only be sown in greenhouses.

Article 4

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 June 2020.

However, Article 3 shall apply as of 1 June 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 May 2020.

For the Commission

The President

Ursula VON DER LEYEN

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ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Metalaxyl-M	methyl N-(methoxyacetyl)-N-(2,6-xylyl)-D-alaninate	≥ 920 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.
CAS No 70630-17-0 (R) CIPAC No 580		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-			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

a Further details on the identity and the specification of the active substance are provided in the review report.

b Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

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			methoxyacetyl)-amino]-propionic acid 1-methoxycarbonyl-ethyl ester: max. content 0,18 g/kg		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

a Further details on the identity and the specification of the active substance are provided in the review report.

b Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).