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

**of **XXX****

**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)

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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<sup>1</sup>, and in particular Article 20(1) and 49(2) thereof,

Whereas:

- (1) Commission Directive 2002/64/EC<sup>2</sup> included metalaxyl-M as an active substance in Annex I to Council Directive 91/414/EEC<sup>3</sup>.
- (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<sup>4</sup>.
- (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 Council Directive 91/414/EEC<sup>5</sup> was submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010<sup>6</sup> within the time period provided for in that Article.

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<sup>1</sup> OJ L 309, 24.11.2009, p. 1.

<sup>2</sup> Commission Directive 2002/64/EC of 15 July 2002 amending Council Directive 91/414/EEC to include cinidon-ethyl, cyhalofop butyl, famoxadone, florasulam, metalaxyl-M and picolinafen as active substances (OJ L 189, 18.7.2002, p. 27).

<sup>3</sup> 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).

<sup>4</sup> 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).

<sup>5</sup> 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).

<sup>6</sup> Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).

- (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.
- (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<sup>7</sup> 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<sup>8</sup>.
- (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.

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<sup>7</sup> EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance metalaxyl-M. EFSA Journal 2015;13(3):3999, 105 pp. doi:10.2903/j.efsa.2015.3999.

<sup>8</sup> Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/i.efsa.2018.5311>.

- (16) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (17) Commission Implementing Regulation (EU) 2019/707<sup>9</sup> extended the approval period of metalaxyl-M to 30 June 2020 in order to allow the renewal process to be completed before the expiry of that approval period. However, given that a decision on renewal of the approval is taken ahead of the expiry of that extended approval period, this Regulation shall apply as soon as possible.
- (18) The restriction to the use of treated seeds should apply as of 1 November 2020 in order to allow for a sufficient period of transition.
- (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*

***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 April 2020.

However, Article 3 shall apply as of 1 November 2020.

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<sup>9</sup> Commission Implementing Regulation (EU) 2019/707 of 7 May 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, bentiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, desmedipham, dimethoate, dimethomorph, diuron, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, metalaxyl-m, methiocarb, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, s-metolachlor and tebuconazole (OJ L 120, 8.5.2019, p. 16).

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

Done at Brussels,

*For the Commission*

*The President*

*(Name to be added)*