EUROPEAN
COMMISSION

Brussels, XXX
SANTE/11110/2019 Rev 1
[…](2019) XXX draft

ANNEXES 1 to 2

ANNEXES

to the

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

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

ANNEX I

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-dimethyl-phenyl)-(2-methoxyacetyl)-amino]-propionic acid 1-methoxycarbonyl-ethyl ester: max. content 0.18 g/kg	1 April 2020	31 March 2035	Use as seed treatment is permitted, however, treated seeds shall only be sown in greenhouses. 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 activity 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 … *[Publication Office please insert the date corresponding to 2 years from the date of entry into force]*.

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

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 37 on metalaxyl-M is deleted;

(2) in Part B, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity[2]	Date of approval	Expiration of approval	Specific provisions
'XXX	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-methoxycarbonyl-ethyl ester: max. content 0.18 g/kg	1 April 2020	31 March 2035	Use as seed treatment is permitted, however, treated seeds shall only be sown in greenhouses. 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 activity in accordance with points 3.6.5. and 3.8.2. of Annex II to

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

No.	Common Name, Identification Numbers	IUPAC Name	Purity[2]	Date of approval	Expiration of approval	Specific provisions
						Regulation (EC) No 1107/2009, as amended Regulation (EU) 2018/605 by *…[Publication Office please insert the date corresponding to 2 years from the date of entry into force]*.'