EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2023/2697
[…](2024) XXX draft

ANNEXES 1 to 2

ANNEXES

to the

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

renewing the approval of the active substance metconazole as a candidate for substitution in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending 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
metconazole CAS No: 125116-23-6 (unstated stereochemistry) CIPAC No: 706	(1RS,5RS:1RS,5SR)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	940≥ g/kg (sum of cis- and trans-isomers), with cis-metconazole (CL 354801) level not less than 800 g/kg and not more than 950 g/kg The following impurities shall not exceed the following levels in the technical material: - toluene: 2 g/kg - ethylcyclohexane: 2 g/kg	1 September 2024	31 August 2031	Use shall be limited to professional users. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on metconazole, 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 consumer exposure assessment with regards to residues that may be present in the primary crops and succeeding crops grown in rotation; – the protection of operators and bystanders/residents; – the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water; 2. the general toxicity profile of the metabolites M11 and M21 should be further investigated in order to confirm the appropriate toxicological reference values applicable to them. Moreover, confirmation of the presence of M11 and M21 and their ratio among the monohydroxylated metconazole compounds in crops, in order to confirm the residue definition for risk assessment.

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

Common Name, Identification Numbers	IUPAC Name	Purity[1]	Date of approval	Expiration of approval	Specific provisions
					The applicant shall submit the confirmatory information referred to in point 1 within two years after the date on which the relevant guidance document will become applicable and in point 2 by *[Office of Publications please insert the date two years from the date of entry into force of this Regulation]* to the Commission, Member States and the Authority.

ANNEX II

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

(1) in Part A, entry 134 on metconazole is deleted;
(2) in Part E, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity[1]	Date of approval	Expiration of approval	Specific provisions
"xx	metconazole CAS No: 125116-23-6 (unstated stereochemistry) CIPAC No: 706	(1RS,5RS:1RS,5SR)-5-(4-chlorobenzyl)-2,2-dimethyl-1-(1H-1,2,4-triazol-1-ylmethyl)cyclopentanol	940≥ g/kg (sum of cis- and trans-isomers), with cis-metconazole (CL 354801) level not less than 800 g/kg and not more than 950 g/kg The following impurities shall not exceed the following levels in the technical material: - toluene: 2 g/kg - ethylcyclohexane: 2 g/kg	1 September 2024	31 August 2031	Use shall be limited to professional users. For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on metconazole, 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 consumer exposure assessment with regards to residues that may be present in the primary crops and succeeding crops grown in rotation; – the protection of operators and bystanders/residents; – the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards: 1. the effect of water treatment processes on the nature of residues present in surface water and groundwater, when surface water or groundwater is abstracted for drinking water;

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

No	Common Name, Identification Numbers	IUPAC Name	Purity[1]	Date of approval	Expiration of approval	Specific provisions
						2. the general toxicity profile of the metabolites M11 and M21 should be further investigated in order to confirm the appropriate toxicological reference values applicable to them. Moreover, confirmation of the presence of M11 and M21 and their ratio among the monohydroxylated metconazole compounds in crops, in order to confirm the residue definition for risk assessment. The applicant shall submit the confirmatory information referred to in point 1 within two years after the date on which the relevant guidance document will become applicable and in point 2 by *[Office of Publications please insert the date two years from the date of entry into force of this Regulation]* to the Commission, Member States and the Authority.