EUROPEAN
COMMISSION

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

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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

(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[1], and in particular Article 20(1) in conjunction with Article 24(1) thereof,

Whereas:

(1) Commission Directive 2006/74/EC[2] included metconazole 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 metconazole, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 March 2025.

(4) An application for the renewal of the approval of the active substance metconazole was submitted to Belgium, the rapporteur Member State, and the United Kingdom, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[5] and within the time period provided for in that Article.

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1 OJ L 309, 24.11.2009, p. 1, ELI: http://data.europa.eu/eli/reg/2009/1107/oj.

2 Commission Directive 2006/74/EC of 21 August 2006 amending Council Directive 91/414/EEC to include dichlorprop-P, metconazole, pyrimethanil and triclopyr as active substances (OJ L 235, 30.8.2006, p. 17, ELI: http://data.europa.eu/eli/dir/2006/74/oj).

3 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, ELI: http://data.europa.eu/eli/dir/1991/414/oj).

4 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).

5 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26, ELI: http://data.europa.eu/eli/reg_impl/2012/844/oj).

(5) The applicant submitted the supplementary dossiers required to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be admissible by the rapporteur Member State.

(6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 26 February 2018. In its draft renewal assessment report the rapporteur Member State proposed to renew the approval of metconazole.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the draft renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.

(8) On 12 July 2019, the Authority requested additional information from the applicant on the endocrine disrupting properties of metconazole pursuant to Article 13(3a), first subparagraph, of Implementing Regulation (EU) No 844/2012. The applicant submitted information to allow the Authority to conclude the assessment as regards whether the scientific criteria for the determination of endocrine disrupting properties set out in point 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as introduced by Commission Regulation (EU) 2018/605[6], are met.

(9) In April 2022, the rapporteur Member State made an updated draft renewal assessment report available to the Authority, the Member States and the Commission. In its updated draft renewal assessment report, the rapporteur Member State considered the additional information regarding the criteria to identify endocrine disrupting properties and proposed renewing the approval of metconazole.

(10) On 11 July 2023, the Authority communicated to the Commission its conclusion[7] which indicated metconazole can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(11) The Commission presented a renewal report and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 11 and 12 December 2023 and on 30 and 31 January 2024 respectively.

(12) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined and taken into consideration.

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

(14) The risk assessment for the renewal of the approval of the active substance metconazole is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing metconazole may

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6 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, ELI: http://data.europa.eu/eli/reg/2018/605/2018-04-20).

7 EFSA Journal 2023, doi: 10.2903/j.efsa.2023.8141. Available online: www.efsa.europa.eu.

be authorised. It is therefore appropriate not to maintain the restriction to use as a fungicide and plant growth regulator.

(15) The Commission, however, considers that metconazole is a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Metconazole is considered a persistent and toxic substance in accordance with points 3.7.2.1 and 3.7.2.3 respectively, of Annex II to Regulation (EC) No 1107/2009, given that the half-life of metconazole is higher than 40 days in fresh water and higher than 120 days in fresh water sediment, that the substance is classified as toxic for reproduction (category 2) pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[8] and that the long-term no-observed effect concentration for freshwater organisms is less than 0.01 mg/L. Therefore, it fulfils the condition set in the second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.

(16) It is therefore appropriate to renew the approval of metconazole as a candidate for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009.

(17) 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 and the outcome of the risk assessment, it is, however, necessary to provide for certain conditions and restrictions.

(18) In the light of the potential concern for an increasing prevalence of azole-resistant strains in *A. fumigatus* and taking into account the precautionary principle, it is in particular appropriate to restrict the use of products containing metconazole to professional users only.

(19) Furthermore, it is appropriate to require further confirmatory information on the assessment of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water to be submitted once the relevant guidance becomes applicable. In addition, to increase confidence in this decision, information should be requested to confirm the appropriate toxicological reference values applicable to certain metabolites and the residue definition for risk assessment.

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

(21) Commission Implementing Regulation (EU) 2015/408[9] listed metconazole as a candidate for substitution. In the light of the renewal of approval of metconazole as a candidate for substitution and the corresponding move of that substance to Part E of the Annex to Implementing Regulation (EU) No 540/2011, the entry for metconazole should be deleted from the Annex to Implementing Regulation (EU) 2015/408.

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8 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/2023-12-01).

9 Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution. (*OJ L 67, 12.3.2015, p. 18,* ELI: http://data.europa.eu/eli/reg_impl/2015/408/oj

(22) Commission Implementing Regulation (EU) 2023/689[10] extended the approval period of metconazole to 15 March 2025 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply earlier than that date.

(23) 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 metconazole, as specified in Annex I to this Regulation, is renewed, subject to the conditions laid down in that Annex.

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

Amendment to Implementing Regulation (EU) 2015/408

The entry for metconazole is deleted from the Annex to Implementing Regulation (EU) 2015/408.

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 September 2024.

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

[10] Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances Bacillus subtilis (Cohn 1872) strain QST 713, Bacillus thuringiensis subsp. Aizawai strains ABTS-1857 and GC-91, Bacillus thuringiensis subsp. Israeliensis (serotype H-14) strain AM65-52, Bacillus thuringiensis subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, Beauveria bassiana strains ATCC 74040 and GHA, clodinafop, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, pyridaben, pyrimethanil, rimsulfuron, spinosad, Trichoderma asperellum (formerly T. harzianum) strains ICC012, T25 and TV1, Trichoderma atroviride (formerly T. harzianum) strain T11, Trichoderma gamsii (formerly T. viride) strain ICC080, Trichoderma harzianum strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram **(**OJ L 91, 29.3.2023, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2023/689/oj).

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN