EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10324/2020
[…](2020) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the non-renewal of the approval of the active substance mancozeb, 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[1], and in particular Article 20(1) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2005/72/EC[2] included mancozeb 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 mancozeb, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2021.

(4) Applications for the renewal of the approval of mancozeb were submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[5] within the time period provided for in that Article.

(5) The applicants submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The applications were found to be complete by the rapporteur Member State.

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1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances (OJ L 279, 22.10.2005, p. 63.

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).

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).

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).

(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 27 September 2017.

(7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicants 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 20 June 2019, the Authority communicated to the Commission its conclusion[6] on whether mancozeb can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for mancozeb to the Standing Committee on Plants, Animal, Food and Feed on 23 and 24 March 2020.

(9) The Authority indentified certain specific concerns. In particular, it concluded that mancozeb has been classified as toxic for reproduction category 1B and that the new criteria to identify endocrine disrupting properties are met for humans and most likely for non-target organisms. In addition, it concluded that the non-dietary exposure estimates exceed the reference values for the representative uses in tomatoes, potatoes, cereals and grapevines. Therefore for the representative uses considered, non-dietary exposure to mancozeb also cannot be considered as negligible for the purposes of points 3.6.4 and 3.6.5 of Annex II to Regulation (EC) No 1107/2009.

(10) The Commission invited the applicants to submit their comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the draft renewal report. The applicants submitted their comments which have been carefully examined.

(11) However, despite the arguments put forward by the applicants the concerns regarding the active substance could not be eliminated.

(12) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance mancozeb.

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

(14) Member States should be given sufficient time to withdraw authorisations for plant protection products containing mancozeb.

(15) For plant protection products containing mancozeb, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should at the latest, expire on [*Office of Publications please insert date 6 months from the date of entry into force*].

(16) Commission Implementing Regulation (EU) 2019/2094[7] extended until 31 January 2021 the period of approval of mancozeb in order to allow the renewal

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6 EFSA (European Food Safety Authority), 2019. Conclusion on the peer review of the pesticide risk assessment of the active substance mancozeb. EFSA Journal 2019;17(7):5755 DOI: 10.2903/j.efsa.2019.5755

7 Commission implementing Regulation (EU) 2019/2094 of 29 November 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances

process to be completed before the expiry of the approval period of that substance. Given that a decision on the non-renewal of the approval has been taken ahead of that extended expiry date, this Regulation should apply as soon as possible.

(17) This Regulation does not prevent the submission of a further application for the approval of mancozeb pursuant to Article 7 of Regulation (EC) No 1107/2009.

(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:

Article 1
Non-renewal of approval of active substance

The approval of the active substance mancozeb is not renewed.

Article 2
Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 114, on mancozeb, is deleted.

Article 3
Transitional measures

Member States shall withdraw authorisations for plant protection products containing mancozeb as an active substance by [*Office of Publications please insert date 3 months from the date of entry into force*].

Article 4
Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by *[Office of Publications please insert date 6 months from the date of entry into force]*.

Article 5
Entry into force

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

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

benfluralin, dimoxystrobin, fluazinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (OJ L 317, 9.12.2019, p. 102).

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN