Commission Implementing Regulation (EU) 2020/2087 of 14 December 2020 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/2087

of 14 December 2020

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)

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.

(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.

(9) Following the withdrawal of the United Kingdom from the EU on 31 January 2020, Greece agreed to take over the responsibility as rapporteur Member State.

(10) According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report to the Standing Committee on Plants, Animals, Food and Feed, for examination in March 2020. During the discussions in the Standing Committee, the new rapporteur Member State Greece informed that it considered as appropriate to evaluate data that in its view had been omitted by the earlier rapporteur Member State. Greece sent its evaluation to the Commission on 2 September 2020 in the form of an updated renewal assessment report. The evaluation was also made available to EFSA, the other Member States and the applicant.

(11) The draft renewal report was finalised by the Standing Committee on 23 October 2020.

(12) 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. Given the concerns identified the derogation provided for in Article 4(7) to Regulation (EC) No 1107/2009 cannot apply.

(13) 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.

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

(15) 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.

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

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

(18) 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 4 January 2022.

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

(20) 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.

(21) 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 at the latest by 4 July 2021.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire at the latest by 4 January 2022.