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COMMISSION IMPLEMENTING REGULATION (EU) 2023/2456

of 7 November 2023

concerning the non-renewal of the approval of the active substance clofentezine, 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)

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 2010/39/EU ([2]) included clofentezine 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 clofentezine, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 December 2023.

(4) An application for the renewal of the approval of the active substance clofentezine was submitted to Spain, the rapporteur Member State, and the Netherlands, the co-rapporteur Member State, 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 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.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2010/39/EU of 22 June 2010 amending Annex I to Council Directive 91/414/EEC as regards the specific provisions relating to the active substances clofentezine, diflubenzuron, lenacil, oxadiazon, picloram and pyriproxyfen (OJ L 156, 23.6.2010, p. 7).

([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), which continues to apply to the procedure for the renewal of the approval of this active substance pursuant to Article 17 of Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 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, and repealing Commission Implementing Regulation (EU) No 844/2012 (OJ L 392, 23.11.2020, p. 20).

(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 6 March 2018. In its draft renewal assessment report, the rapporteur Member State proposed that the approval of clofentezine could only be renewed if the applicant submitted additional data to further address certain issues during the subsequent peer review process.

(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) In accordance with Article 13(3a), third subparagraph, of Implementing Regulation (EU) No 844/2012, the applicant was given the opportunity to submit additional information to address the approval criteria concerning endocrine disrupting properties set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009.

(9) On 29 July 2021, the Authority communicated to the Commission its conclusion ([6]) on whether clofentezine can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(10) In its conclusion, the Authority identified several concerns. In particular, it concluded that based on the available information submitted in the dossier, clofentezine has endocrine disrupting properties that may cause adverse effects in humans, as set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009. According to the Authority, residues of clofentezine are expected to be above the value set in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009. Therefore, the requirement set out in point 3.6.5 of Annex II to Regulation (EC) No 1107/2009 is not fulfilled.

(11) Furthermore, the Authority identified a high long-term risk to birds and wild mammals for the representative uses on crops not grown in permanent greenhouses. The Authority also concluded that the consumer risk assessment could not be performed and that maximum residue levels could not be proposed based on the available data and that the risk assessment for non-target arthropods could also not be finalised for the representative uses on crops not grown in permanent greenhouses.

(12) In its evaluation of whether clofentezine is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods in accordance with Article 4(7) of Regulation (EC) No 1107/2009, the Authority concluded that, despite the fact that there may be an insufficient number of chemical alternatives available for some uses of clofentezine and in some Member States, some non-chemical methods are also available, and that a combination of chemical and non-chemical methods may be possible to control the pests in some crops. In addition, no serious danger to plant health has been identified. Therefore, the Commission considers that the conditions for the application of the derogation in Article 4(7) of Regulation (EC) No 1107/2009 are not fulfilled.

(13) The Commission presented a renewal report on 24 May 2023 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 12 July 2023.

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

(15) Despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.

(16) 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 clofentezine in accordance with Article 20(1), point (b), of that Regulation.

([6]) Conclusion on the peer review of the pesticide risk assessment of the active substance clofentezine (*EFSA Journal* 2021;19(8):6817; https://doi.org/10.2903/j.efsa.2021.6817).

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

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

(19) For plant protection products containing clofentezine, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 12 months from the date of entry into force of this Regulation. Commission Implementing Regulation (EU) 2022/1480 ([7]) extended the approval period of clofentezine to 31 December 2023 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance.

(20) Taking into account that the current approval of clofentezine expires on 31 December 2023, this Regulation should enter into force as soon as possible.

(21) This Regulation does not prevent the submission of another application for the approval of clofentezine pursuant to Article 7 of Regulation (EC) No 1107/2009.

(22) 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 the approval of the active substance

The approval of the active substance clofentezine 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 171 on clofentezine is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing clofentezine as an active substance by 11 May 2024.

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 11 November 2024.

([7]) Commission Implementing Regulation (EU) 2022/1480 of 7 September 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2-phenylphenol (including its salts such as the sodium salt), 8-hydroxyquinoline, amidosulfuron, bensulfuron, bifenox, chlormequat, chlorotoluron, clofentezine, clomazone, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, dimethachlor, esfenvalerate, etofenprox, fenoxaprop-P, fenpropidin, fenpyrazamine, fludioxonil, flufenacet, flumetralin, fosthiazate, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, paraffin oil, penconazole, picloram, prohexadione, propaquizafop, prosulfocarb, quizalofop-P-ethyl, quizalofop-P-tefuryl, sodium 5-nitroguaiacolate, sodium o-nitrophenolate, sodium p-nitrophenolate, sulphur, tebufenpyrad, tetraconazole, tri-allate, triflusulfuron and tritosulfuron (OJ L 233, 8.9.2022, p. 43).

Article 5

Entry into force

This Regulation shall enter into force on the third 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.

Done at Brussels, 7 November 2023.

For the Commission
The President
Ursula VON DER LEYEN