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

**of XXX**

**amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance diflubenzuron**

(Text with EEA relevance)

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**amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance diflubenzuron**

(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 the first alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2008/69/EC[2] included diflubenzuron as 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) In accordance with Commission Directive 2010/39/EU[5], the applicant, at whose request diflubenzuron was included in Annex I to Council Directive 91/414/EEC, was to provide confirmatory information as regards the potential toxicological relevance of the impurity and metabolite 4-chloroaniline (PCA).

(4) The applicant submitted that information to the rapporteur Member State Sweden within the time period provided for its submission.

(5) Sweden assessed the information submitted by the applicant. It submitted its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission and the European Food Safety Authority, hereinafter 'the Authority', on 20 December 2011.

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1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2008/69/EC of 1 July 2008 amending Council Directive 91/414/EEC to include clofentezine, dicamba, difenoconazole, diflubenzuron, imazaquin, lenacil, oxadiazon, picloram and pyriproxyfen as active substances (OJ L 172, 2.7.2008, p. 9).

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 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).

(6) The Commission consulted the Authority, which presented its conclusion on the risk assessment of confirmatory information for diflubenzuron on 7 September 2012[6]. The Authority communicated its views on diflubenzuron to the applicant, and the Commission invited the applicant to submit its comments on the review report. The draft assessment report, the addendum and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 16 July 2013 in the format of the Commission review report for diflubenzuron.

(7) Although the results of genotoxicity studies indicated that PCA is an *in vivo* genotoxic agent, and PCA is a carcinogenic agent, a genotoxic and carcinogenic potential were not observed in studies with an appropriate animal model for human exposure to diflubenzuron, and hence to PCA as a metabolite and impurity. In light of the information submitted by the applicant, the Commission considered that the confirmatory information required had been provided.

(8) In its conclusion, given the genotoxic and carcinogenic properties of PCA and the absence of a threshold for acceptable exposure, the Authority identified a new concern on potential exposure to PCA as a residue.

(9) The Commission considered that the approval of the active substance diflubenzuron should therefore be reviewed in accordance with Article 21 of Regulation (EC) No 1107/2009 to address the new concern raised by the Authority. It invited the applicant to submit information as regards the potential exposure to PCA as a residue and, if exposure is confirmed, consideration of the potential toxicological relevance.

(10) The applicant submitted that information to Sweden within the time period provided for its submission.

(11) Sweden assessed the information submitted by the applicant. It submitted its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission and the Authority on 23 July 2014.

(12) The Commission consulted the Authority, which presented its conclusion on the risk assessment of data submitted for the review of the approval of diflubenzuron on 11 December 2015[7]. The Authority communicated its views on diflubenzuron to the applicant.

(13) The Commission considers that the information submitted in the review process did not demonstrate that the risk from the potential exposure of consumers to PCA as a residue is acceptable. In particular, the presence of PCA in the metabolic pathway has been demonstrated in some plants and livestock and could not be excluded in others. Moreover, studies indicated a significant transformation of diflubenzuron residues into PCA under conditions similar or equal to food sterilisation processes, and such transformation could not be excluded for household processing practices.

(14) Given the genotoxic and carcinogenic properties of PCA and the absence of a threshold for acceptable exposure, the review failed to establish that the exposure of consumers to PCA as a residue, consequent on application consistent with good plant

[6] European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of confirmatory data submitted for the active substance diflubenzuron. EFSA Journal 2012;10(9):2870. [26 pp.] doi:10.2903/j.efsa.2012.2870. Available online: www.efsa.europa.eu/efsajournal.htm.

[7] European Food Safety Authority; Conclusion on the peer review on the review of the approval of the active substance diflubenzuron regarding the metabolite PCA. EFSA Journal 2015;13(8):4222. [30 pp.] doi:10.2903/j.efsa.2015.4222. Available online: www.efsa.europa.eu/efsajournal.htm.

protection practice, has no harmful effects. Since toxicological reference values for PCA cannot be set and as consequently no safe residue levels can be identified, any exposure of consumers to PCA should be prevented.

(15) The Commission invited the applicant to submit its comments on the review report. The comments of the applicant did not alleviate the concerns on consumer safety through exposure to PCA.

(16) The draft assessment report, the addendum and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on [dd-month-yyyy] in the format of the Commission review report for diflubenzuron.

(17) The Commission concluded that exposure of consumers to PCA cannot be excluded except by imposing further restrictions. In particular, the use of diflubenzuron should be limited to non-edible crops only, and crops treated with diflubenzuron should not enter the food and feed chain. In order to minimise the exposure of consumers to PCA, it is therefore appropriate to amend the conditions of use of diflubenzuron.

(18) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(19) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing diflubenzuron.

(20) For plant protection products containing diflubenzuron, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should expire at the latest 15 months after the entry into force of this Regulation.

(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*
*Amendment to Implementing Regulation (EC) No 540/2011*

In the seventh column, 'specific provisions', of entry 174 on diflubenzuron of Part A of the Annex to Implementing Regulation (EU) No 540/2011, the text is replaced by the following:

"Only uses as insecticide in non-edible crops may be authorised.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on diflubenzuron, and in particular Appendices I and II thereof, as amended in the Standing Committee on Plants, Animals, Food and Feed on [dd-month-yyyy] shall be taken into account.

In this overall assessment Member States must pay particular attention to:

– the specification of the technical material as commercially manufactured, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers shall be compared and verified against this specification of the technical material;

– the protection of aquatic organisms, terrestrial organisms and non-target arthropods including bees;

– the potential unintended exposure of food and feed crops to diflubenzuron from uses on non-edible crops (e.g. through spray drift);

– the protection of workers, residents and bystanders.

Member States shall ensure that crops treated with diflubenzuron do not enter the food and feed chain.

Conditions of use shall include adequate risk mitigation measures, where appropriate."

*Article 2*
*Transitional measures*

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing diflubenzuron as active substance by [*Office of Publications please insert date 3 months from the date of entry into force*] at the latest.

*Article 3*
*Grace period*

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by *[Office of Publications please insert date 15 months from the date of entry into force]* at the latest.

*Article 4*
*Entry into force*

This Regulation shall enter into force on the 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.

Done at Brussels,

*For the Commission*
*The President*
*Jean-Claude JUNCKER*