Commission Implementing Regulation (EU) 2017/855 of 18 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance diflubenzuron (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/855

of 18 May 2017

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.

(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

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/855. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

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 properties of PCA identified on the basis of the confirmatory information, and given the carcinogenic properties of PCA and the absence of a threshold for acceptable exposure, the Authority however identified a new concern on potential exposure to PCA as a residue.

(9) The Commission initiated a review of the approval of the active substance diflubenzuron. The Commission considered that, in the light of the new scientific and technical knowledge described above, there were indications that the approval of the active substance diflubenzuron no longer satisfied the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 with respect to its potential harmful effect on human health, through exposure to PCA as a residue. 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, it was not established that the exposure of consumers to PCA as a residue, consequent on application consistent with good plant 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.

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(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 23 March 2017 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 (EU) 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 23 March 2017 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;