EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the non-approval of the active substance tricyclazole, 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

(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 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, on 21 December 2012, Italy received an application from Dow AgroSciences for the approval of the active substance tricyclazole.

(2) In accordance with Article 9(3) of that Regulation, the rapporteur Member State notified the applicant, the other Member States, the Commission and the European Food Safety Authority (hereinafter 'the Authority') of the admissibility of the application on 4 February 2013.

(3) For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 11(2) and (3) of that Regulation, for the use proposed by the applicant. The rapporteur Member State submitted a draft assessment report to the Commission and the Authority on 7 January 2014.

(4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of that Regulation, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report.

(5) The draft assessment report was reviewed by the Member States and the Authority. The Authority presented to the Commission its conclusion on the risk assessment of the active substance tricyclazole[2] on 18 February 2015. The Authority concluded that the assessment of the genotoxic and carcinogenic potential of the substance was inconclusive and therefore reference values (ADI, ARfD and AOEL) for use in human health risk assessments could not be established. Consequently, the risk assessments for operators, workers, bystanders, residents and consumers could not be conducted. It

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

[2] EFSA Journal 2015;13(2):4032 Available online: www.efsa.europa.eu/efsajournal.

further concluded that the test material used in the toxicity studies was not representative of the proposed technical specification for the active substance and associated impurities. In addition, certain areas of the assessment could not be finalised, including the potential of tricyclazole to act as an endocrine disruptor and the potential for groundwater contamination by metabolites whose toxicological relevance is unknown.

(6) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 13(1) of Regulation (EC) No 1107/2009, on the draft review report. The applicant submitted its comments, which have been carefully examined.

(7) However, despite the arguments put forward by the applicant, the concerns referred to in recital 5 could not be eliminated.

(8) Consequently, it has not been demonstrated that it may be expected that, with respect to one or more representative uses of at least one plant protection product containing tricyclazole, the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The active substance tricyclazole should therefore not be approved pursuant to Article 13(2) of Regulation (EC) No 1107/2009.

(9) This Regulation does not prejudice the submission of a further application for tricyclazole pursuant to Article 7 of Regulation (EC) No 1107/2009.

(10) 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-approval of active substance

The active substance tricyclazole is not approved.

Article 2
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