# Commission Implementing Regulation (EU) No 578/2012 of 29 June 2012 concerning the non approval of the active substance diphenylamine, 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)

## COMMISSION IMPLEMENTING REGULATION (EU) No 578/2012

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concerning the non approval of the active substance diphenylamine, 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)

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 80(1)(c) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC[(2)] is to apply, with respect to the procedure and the conditions for approval, to active substances for which completeness has been established in accordance with Article 16 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I[(3)]. Diphenylamine is an active substance for which completeness has been established in accordance with that Regulation.

(2) Commission Regulations (EC) No 451/2000[(4)] and 1490/2002[(5)] lay down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list included diphenylamine. By Commission Decision 2009/859/EC[(6)] it was decided not to include diphenylamine in Annex I to Directive 91/414/EEC.

(3) In agreement with the original notifier, another person (hereinafter 'the applicant') submitted a new application pursuant to Article 6(2) of Directive 91/414/EEC requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008.

**Changes to legislation:** *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 578/2012. 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*

(4) The application was submitted to Ireland, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2009/859/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) Ireland evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 3 December 2010.

(6) The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on the risk assessment of diphenylamine to the Commission on 5 December 2011[7]. The draft assessment report, the additional report 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 1 June 2012 in the format of the Commission review report for diphenylamine.

(7) The additional data and information provided by the applicant did not permit to eliminate the specific concerns that led to the non-inclusion. In particular, it was not possible to perform a reliable consumer exposure assessment because information concerning residues in raw and processed apples was missing and because the presence of nitrosamines in apples could not be excluded. Specifically, three metabolites could not be identified and, consequently, their toxicological properties could not be assessed. Furthermore, the processing study submitted by the applicant was not representative of the standard hydrolytic conditions and did not allow to identify breakdown and reaction products including the three unknown metabolites. Finally, the additional evidence submitted on nitrosamines was inconclusive as the analytical method was not validated and had an insufficient resolution and a lack of selectivity.

(8) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with Article 21(1) of Regulation (EC) No 33/2008, the Commission invited the applicant to submit comments on the draft review report. The applicant submitted its comments, which have been carefully examined.

(9) However, despite the arguments put forward by the applicant, the concerns referred to in recital 7 could not be eliminated. Consequently, it has not been demonstrated that it may be expected that, under the proposed conditions of use, plant protection products containing diphenylamine satisfy in general the requirements laid down in Article 5(1) (a) and (b) of Directive 91/414/EEC.

(10) Diphenylamine should therefore not be approved pursuant to Article 13(2) of Regulation (EC) No 1107/2009.

(11) In the interest of clarity, Decision 2009/859/EC should be repealed.