



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain
Unit E.3 - Chemicals, contaminants, pesticides

Diphenylamine
SANCO/191/08 – final
1 December 2009

FINAL

Review report for the active substance **diphenylamine**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting
on 26 February 2009

in support of a decision concerning the non-inclusion of diphenylamine in Annex I of
Directive 91/414/EEC and the withdrawal of authorisations for plant protection products
containing this active substance

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of diphenylamine, made in the context of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 451/2000⁽¹⁾ laying 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 Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1490/2002⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Diphenylamine is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 10 of Regulation (EC) No 451/2000, Cerexagri s.a. and Pace International notified to the Commission of their wish to secure the inclusion of the active substance diphenylamine in Annex I to the Directive.

Under Annex I to Regulation (EC) No 1490/2002, Ireland has been designated by the Commission as rapporteur Member State to carry out the assessment of diphenylamine on the basis of the dossiers submitted by the notifier. In Regulation (EC) No 1490/2002 the Commission specified furthermore that the deadline for the notifier with regard to the

¹ OJ No L 55, 29.02.2000, p.25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p.32).

² OJ No L 224, 21.8.2002, p.23. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.09.2007, p. 19).

submission to the rapporteur Member States of the dossiers required under Article 7(1) of Regulation (EC) No 1490/2002, as well as for other parties with regard to further technical and scientific information was 30 November 2004.

Cerexagri s.a. and Pace International submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore, Cerexagri s.a. and Pace International were considered to be the main data submitters.

In accordance with the provisions of Article 10(1) of Regulation 1490/2002, Ireland submitted on 20 June 2007 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of diphenylamine in Annex I to the Directive. Moreover, in accordance with the provisions of Article 10(2) of Regulation (EC) 1490/2002, the Commission and the Member States received also the summary dossier on diphenylamine from the notifier.

In accordance with the provisions of Article 11c of Regulation (EC) No 1490/2002, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Cerexagri s.a. and Pace International being the main data submitters, on 8 October 2007 by making it available.

In accordance with the provisions of Article 11c (1) of Regulation (EC) No 1490/2002, the EFSA organised an intensive consultation of technical experts from a certain number of Member States, to review the draft assessment report and the comments received thereon.

In accordance with the provisions of Article 11c of Regulation (EC) No 1490/2002, the EFSA sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance diphenylamine (finalised 30 September 2008)]³. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 12 of Regulation (EC) No 1490/2002, the Commission referred on 2 December 2008 a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 26 February 2009.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of the Decision **2009/859/EC** concerning the non-inclusion of diphenylamine in Annex I to Directive 91/414/EEC.

³ EFSA Scientific Report (2008) n 188.

In accordance with the provisions of Article 13 of Regulation (EC) No 1490/2002, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion of this examination, based on the information available and the proposed conditions of use, is that:

- **the information available is insufficient** to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC in particular with regard to:
 - the risk to consumers.

- **concerns were identified with regard to**
 - the lack of data on the levels and toxicity of unidentified metabolites of the substance;
 - the possible formation of nitrosamines during storage of the active substance and during processing of treated apples;
 - the lack of data on the potential breakdown or reaction product of diphenylamine residues in processed commodities;
 - the lack of data to finalise the specification.

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC.

Diphenylamine should therefore not be included in Annex I to Directive 91/414/EEC.