



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Dichlobenil
SANCO/11296/2011 final
11 March 2011

Review report for the active substance **dichlobenil**

in support of a decision concerning the non-inclusion of dichlobenil 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 dichlobenil, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Dichlobenil is a substance that was covered by the third stage 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 market¹, with a view to the possible inclusion of this substance in Annex I to the Directive.

At the outcome of that evaluation, dichlobenil was not included through Commission Decision 2008/754/EC² as, on the basis of the available information, there was a substantial lack of data to assess the risk to earthworm eating birds and mammals and concerns were identified with regard to the consumer exposure from drinking water and the leaching to groundwater. All information as regards this initial evaluation is recorded in the relevant Commission Review Report (document SANCO/1342/08 final of 25 April 2008).

In accordance with Article 13 of Regulation (EC) No 33/2008³, Chemtura Netherlands B.V., the sole data submitter presented, on 16 March 2009 a request to the United Kingdom, the designated rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

¹ OJ L 230, 19.8.1991

² OJ L 258, 26.09.2008

³ OJ L 15, 18.1.2008

The United Kingdom finalised in September 2009 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was received by the Commission and the European Food Safety Authority on 7 October 2009.

In accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Chemtura Netherlands B.V., being the sole data submitter, on 9 October 2009 by making it available.

The EFSA organised a focused consultation of scientific experts from a certain number of Member States, to review the additional report, the draft assessment report and the comments received thereon (peer review) and to deliver its conclusion..

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008, on the basis of the draft assessment report, additional report and comments received through the above consultation, the Commission asked EFSA to deliver its conclusion on the substance. [Conclusions regarding the peer review of the pesticide risk assessment of the active substance dichlobenil (issued on 29 July 2010)⁴]. This conclusion refers to background document A (draft assessment report and additional report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 21 of Regulation (EC) No 33/2008, the Commission referred 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 11 March 2011.

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 and appendices hereto, has been developed and finalised in support of Commission **Decision 2011/234/EU**⁵ concerning the non-inclusion of dichlobenil in Annex I to Directive 91/414/EEC.

In accordance with the provisions of Article 22 of Regulation (EC) No 33/2008, this review report will be made available for public consultation by any interested parties.

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

The overall conclusion of this evaluation, 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:

⁴ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance dichlobenil. EFSA Journal 2010; 8(8):1705. [68 pp.]. doi:10.2903/j.efsa.2010.1705. Available online: www.efsa.europa.eu

⁵ OJ L 98, 13.4.2011, p. 14–15

- specification of the technical material
 - nature of residues in processed commodities for the metabolite 2,6-dichlorobenzamide (BAM)
- **concerns were identified with regard to**
- very high potential of groundwater exposure by non-relevant metabolite BAM over a wide range of geo-climatic conditions even with applications only every third year
 - potential for long-range transport of the metabolite BAM
 - high risk to the aquatic environment
 - high acute risk to birds from uptake of granules as grit
 - high long-term risk to earthworm-eating birds and mammals.

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.

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