



EUROPEAN COMMISSION
HEALTH & CONSUMER DIRECTORATE-GENERAL

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

Triazoxide
SANCO/216/08 – rev. 0
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**COMMISSION WORKING DOCUMENT - DOES NOT NECESSARILY
REPRESENT THE VIEWS OF THE COMMISSION SERVICES**

Final

Review report for the active substance **triazoxide**

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 triazoxide 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 triazoxide, 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. Triazoxide 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, Bayer Crop Science AG. notified to the Commission of their wish to secure the inclusion of the active substance triazoxide in Annex I to the Directive.

Under Annex I to Regulation (EC) No 1490/2002, the United Kingdom has been designated by the Commission as rapporteur Member State to carry out the assessment of triazoxide on the basis of the dossiers submitted by the notifier. In Regulation (EC) No 1490/2002 the

¹ OJ No L 55, 29.02.2000, p.25.

² OJ No L 224, 21.8.2002, p.23.

Commission specified furthermore that the deadline for the notifier with regard to the 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.

Bayer Crop Science AG. 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 Bayer Crop Science AG. was considered to be the sole data submitter.

In accordance with the provisions of Article 10(1) of Regulation 1490/2002, the United Kingdom submitted on 25 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 triazoxide 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 triazoxide from the notifier.

In accordance with the provisions of Article 11 of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by the Bayer Crop Science AG. being the main data submitter, on 4 October 2007 by making it available.

In accordance with the provisions of Article 11c (1) of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, 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 as last amended by Regulation (EC) 1095/2007, the EFSA sent to the Commission its conclusion on the risk assessment³. 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 11c and Article 12(1) b of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, the Commission referred on 1 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.

³ *EFSA Scientific Report (2008), 193. Conclusion regarding the peer review of the pesticide risk assessment of the active substance triazoxide finalised 30 September 2008.*

2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of the Decision **2009/860/EC**⁴ concerning the non-inclusion of triazoxide in Annex I to Directive 91/414/EEC.

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 available metabolism and residue data are not considered appropriate to conduct a robust consumer risk assessment due to the uncertainties identified with regard to the nature of residues in plant commodities and the possible transfer of residues in animal products.
 - the long-term risk for granivorous birds;
 - the long-term risk for granivorous mammals;
 - the long-term risk to fish;
 - the long-term risk to earthworms.

- **concerns were identified with regard to:**
 - the consumer exposure.

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.

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

⁴ OJ No L 314, 1.12.2009, p.81.