Commission Implementing Regulation (EU) No 807/2011 of 10 August 2011 approving the active substance triazoxide, 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, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 807/2011

of 10 August 2011

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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 Articles 13(2) and 78(3) 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 to active substances for which completeness has been established in accordance with Article 16 of Commission Regulation (EC) No 33/2008[(3)], with respect to the procedure and the conditions for approval. Triazoxide is an active substance for which completeness has been established in accordance with that Regulation.

(2) Commission Regulations (EC) No 451/2000[(4)] and (EC) No 1490/2002[(5)] lay down the detailed rules for the implementation of the third stage 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 triazoxide. By Commission Decision 2009/860/EC[(6)] it was decided not to include triazoxide in Annex I to Directive 91/414/EEC.

(3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the application of the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Regulation (EC) No 33/2008 laying down detailed rules for the application of 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.

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(4) The application was submitted to the United Kingdom, 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 those that were the subject of Decision 2009/860/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) The United Kingdom evaluated the new information and 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 10 June 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 additional report was peer reviewed by the Member States and the Authority. The Authority then presented its conclusion on triazoxide to the Commission on 15 February 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 17 June 2011 in the format of the Commission review report for triazoxide.

(7) The additional report by the rapporteur Member State and the new conclusion by the Authority concentrate on the concerns that led to the non-inclusion. Those concerns were in particular that it was not possible to perform a reliable consumer risk assessment as data were missing to determine the nature of residues in plant commodities and the possible transfer of residues in animal products.

(8) The new information submitted by the applicant shows that the exposure of consumers may be considered as acceptable.

(9) Consequently, the additional information provided by the applicant permit to eliminate the specific concerns that led to the non-inclusion. No other open scientific questions have arisen.

(10) It has appeared from the various examinations made that plant protection products containing triazoxide may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular as regards the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve triazoxide in accordance with Regulation (EC) No 1107/2009.

(11) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions and restrictions.

(12) Without prejudice to the conclusion that triazoxide should be approved, it is, in particular, appropriate to require further confirmatory information.

(13) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of

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the Council as regards the list of approved active substances[8], should be amended accordingly.

(14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance triazoxide, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

It shall apply from 1 October 2011.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 August 2011.

For the Commission

The President

José Manuel BARROSO

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ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Triazoxide CAS No 72459-58-6 CIPAC No 729	7-chloro-3-imidazol-1-yl-1,2,4-benzotriazine 1-oxide	≥ 970 g/kg Impurities: toluene: not more than 3 g/kg	1 October 2011	30 September 2021	PART A Only uses as fungicide for seed treatment may be authorised. PART B For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on triazoxide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 17 June 2011, shall be taken into account. In this overall assessment Member States: (a) shall pay particular attention to

a Further details on identity and specification of active substance are provided in the review report.

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					the protection of operators and workers and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate; (b) shall pay particular attention to the risk to granivorous birds and shall ensure that conditions of authorisation include risk mitigation measures. The applicant shall submit to the Commission, the Member States and the Authority confirmatory

a Further details on identity and specification of active substance are provided in the review report.