Commission Implementing Regulation (EU) No 993/2011 of 6 October 2011 approving the active substance 8-hydroxyquinoline, 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 993/2011

of 6 October 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 Article 13(2) and Article 78(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 6 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)]. 8-hydroxyquinoline 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 second and third stages of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish lists of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. These lists included 8-hydroxyquinoline.

(3) For 8-hydroxyquinoline no complete dossier was submitted within the prescribed time limit. Consequently, Commission Decision 2006/797/EC of 22 November 2006 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 993/2011. 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*

products containing these substances[6] was adopted on the non-inclusion of 8-hydroxyquinoline.

(4) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the regular procedure to be applied, as provided for in Articles 3 to 12 of Regulation (EC) No 33/2008.

(5) The application was submitted to Spain, which had been designated rapporteur Member State by Regulation (EC) No 1490/2002. That application complies with the substantive and procedural requirements of Articles 3 and 4 of Regulation (EC) No 33/2008.

(6) Spain evaluated the information submitted and prepared a draft assessment report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 3 August 2009. The Authority communicated the draft assessment report to the other Member States and the applicant for comments and forwarded the comments received to the Commission. The Authority also made the draft assessment report available to the public. In accordance with Article 10 of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on the risk assessment of 8-hydroxyquinoline to the Commission on 17 December 2010[7]. The draft assessment 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 15 July 2011 in the format of the Commission review report for 8-hydroxyquinoline.

(7) It has appeared from the various examinations made that plant protection products containing 8-hydroxyquinoline 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 8-hydroxyquinoline in accordance with Regulation (EC) No 1107/2009.

(8) 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.

(9) Without prejudice to the conclusion that 8-hydroxyquinoline should be approved, it is, in particular, appropriate to require further confirmatory information.

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

(11) 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:

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Article 1

Approval of active substance

The active substance 8-hydroxyquinoline, 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 January 2012.

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

Done at Brussels, 6 October 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**
8-hydroxyquinoline CAS No 148-24-3 (8-hydroxyquinoline) CIPAC No 677 (8-hydroxyquinoline)	8-quinolinol	≥ 990 g/kg	1 January 2012	31 December 2021	PART A Only uses as fungicide and bactericide in greenhouses 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 8-hydroxyquinoline, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 July 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the operator safety

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

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					and shall ensure that conditions of use include the application of adequate personal protective equipment, where appropriate. The applicant shall submit confirmatory information on 8-hydroxyquinoline and its salts as regards: (1) the method of analysis for air; (2) a new storage stability covering the storage time periods of samples from both the metabolism study and from the supervised reidue trials. The applicant shall submit to the Commission,

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