Commission Implementing Regulation (EU) 2015/232 of 13 February 2015 amending and correcting Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance copper compounds (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/232

of 13 February 2015

amending and correcting Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance copper compounds

(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 the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Directive 2009/37/EC[(2)] included copper compounds as active substance in Annex I to Council Directive 91/414/EEC[(3)], under the condition that the Member States concerned ensure that the notifier at whose request copper compounds were included in that Annex provides further confirmatory information on the risk from inhalation and on the risk assessment for non-target organisms and for soil and water.

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[(4)].

(3) The notifier submitted additional information taking the form of studies on the risk from inhalation and on the risk assessment for non-target organisms and for soil and water to the rapporteur Member State France within the time period provided for its submission.

(4) France assessed the additional information submitted by the notifier. It submitted its assessment, in the form of an addendum to the draft assessment report, to the other Member States, the Commission and the European Food Safety Authority, hereinafter 'the Authority', on 8 June 2012.

(5) The Commission consulted the Authority which presented its opinion on the risk assessment of copper compounds on 22 May 2013[(5)].

(6) The Commission invited the notifier to submit its comments on the review report for copper compounds.

(7) In the light of the additional information provided by the notifier, the Commission considered that the further confirmatory information required had not been fully

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/232. 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*

provided and that, in particular, the specific provision of row 277 of Part A of the Annex to Implementing Regulation (EU) No 540/2011, concerning monitoring programmes for contamination by copper, is not sufficient to conclude on the environmental risk assessment.

(8) It is confirmed that the active substance copper compounds is to be deemed to have been approved under Regulation (EC) No 1107/2009. It is, in particular, appropriate to require that the notifier presents to the Commission, the Authority and the Member States a monitoring programme for areas where the contamination of soil and water (including sediments) by copper is a concern or may become one, in order to verify whether further limitations of use are necessary to prevent any unacceptable environmental effect. The results of that monitoring programme should also be presented.

(9) The maximum levels for certain heavy metals, as set in row 277 of Part A of the Annex to Implementing Regulation (EU) No 540/2011, were by mistake set with wrong measurement unit from those set in the respective FAO specifications. The maximum level set in the Annex to that Implementing Regulation should therefore be corrected.

(10) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(11) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing copper compounds.

(12) For plant protection products containing copper compounds, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest 18 months after the entry into force of this Regulation.

(13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendment to Implementing Regulation (EU) No 540/2011

Part A of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

Article 2

Transitional measures

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing copper compounds as active substance by 6 September 2015.

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Article 3

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire on 6 September 2016 at the latest.

Article 4

Entry into force

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

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

Done at Brussels, 13 February 2015.

For the Commission

The President

Jean-Claude JUNCKER

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ANNEX

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 277 on the active substance Copper Compounds is replaced by the following:

Number	Common Name,Identification Numbers	IUPAC Name	Purity	Date of approval	Expiration of approval	Specific provisions
‘277	Copper compounds:			1 December 2009	31 January 2018	PART A Only uses as bactericide and fungicide may be authorised. PART B In assessing applications to authorise plant protection products containing copper for uses other than on tomatoes in greenhouses, Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. For the implementation
	Copper hydroxide CAS No 20427-59-2 CIPAC No 44.305	Copper (II) hydroxide	≥ 573 g/kg			
	Copper oxychloride CAS No 1332-65-6 or 1332-40-7 CIPAC No 44.602	Dicopper chloride trihydroxide	≥ 550 g/kg			
	Copper oxide CAS No 1317-39-1 CIPAC No 44.603	Copper oxide	≥ 820 g/kg			
	Bordeaux mixture CAS No 8011-63-0 CIPAC No 44.604	Not allocated	≥ 245 g/kg			
	Tribasic copper sulphate CAS No 12527-76-3 CIPAC No 44.306	Not allocated	≥ 490 g/kg The following impurities are of toxicological concern and must not exceed the levels below (expressed in g/g):			

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			Lead max 0,0005 g/g of copper content; Cadmium max 0,0001 g/g of copper content; Arsenic max 0,0001 g/g of copper content.		of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on copper compounds, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 January 2009, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the specification of the technical material as commercially manufactured which