Commission Implementing Regulation (EU) 2018/1981 of 13 December 2018 renewing the approval of the active substances copper compounds, as candidates for substitution, 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) 2018/1981

of 13 December 2018

renewing the approval of the active substances copper compounds, as candidates for substitution, 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)

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 24 in conjunction with Article 20(1) thereof,

Whereas:

(1) Commission Directive 2009/37/EC[(2)] included copper compounds as active substances in Annex I to Council Directive 91/414/EEC[(3)].

(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 approval of the active substances copper compounds, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2019.

(4) An application for the renewal of the approval of copper compounds was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[(5)] within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 16 December 2016.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1981. 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*

(7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(8) On 20 December 2017 the Authority communicated to the Commission its conclusions[6] on whether copper compounds can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report for copper compounds to the Standing Committee on Plants, Animals, Food and Feed on 25 May 2018.

(9) The applicant was given the opportunity to submit comments on the draft renewal report.

(10) It has been established with respect to one or more representative uses of at least one product for each of the copper compounds that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of copper compounds.

(11) The risk assessment for the renewal of the approval of copper compounds is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing copper compounds may be authorised. It is therefore appropriate to remove the restriction for use only as fungicide and bactericide.

(12) The Commission, however, considers that copper compounds are candidates for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009. Copper compounds are persistent and toxic substances in accordance with points 3.7.2.1 and 3.7.2.3, respectively, of Annex II to Regulation (EC) No 1107/2009, given that the half-life in soil is greater than 120 days and the long-term no-observed effect concentration for aquatic organisms is less than 0,01 mg/L. Copper compounds therefore fulfil the condition set in the second indent of point 4 of Annex II to Regulation (EC) No 1107/2009.

(13) It is therefore appropriate to renew the approval of copper compounds as candidates for substitution pursuant to Article 24 of Regulation (EC) No 1107/2009.

(14) In accordance with Article 14(1) 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.

(15) It is, in particular, appropriate to restrict the use of plant protection products containing copper compounds to a maximum application rate of 28 kg/ha of copper over a period of 7 years (i.e. on average 4 kg/ha/year) in order to minimise the potential accumulation in soil and the exposure for not target organisms, while taking into account agro-climatic conditions occurring periodically in Member States leading to an increase of the fungal pressure. When authorising products Member States should pay attention to certain issues and strive for the minimisation of application rates.

(16) It is also appropriate to limit the maximum content of certain impurities of toxicological concern.

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

(18) Commission Implementing Regulation (EU) 2018/84[7] extended the approval period of copper compounds to 31 January 2019 in order to allow the renewal process to be completed before the expiry of the approval of these substances. However, given that a decision on renewal has been taken ahead of this extended expiry date, this Regulation should apply from 1 January 2019.

(19) 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

Renewal of the approval of the active substances as candidates for substitution

The approval of the active substances copper compounds, as a candidate for substitution, is renewed as set out in Annex I.

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 third day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2019.

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

Done at Brussels, 13 December 2018.

For the Commission

The President

Jean-Claude JUNCKER

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1981. 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*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity**[a]	**Date of approval**	**Expiration of approval**	**Specific provisions**
Copper compounds:			1 January 2019	31 December 2025	Only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years shall be authorised. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council, the conclusions of the review report on copper compounds and in particular Appendices I and II thereto, shall be taken into account. In their overall assessment Member States shall pay particular attention to: — the operator,
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 shall not exceed the following levels: Arsenic max. 0,1 mg/g Cu Cadmium max. 0,1 mg/			

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

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		g Cu Lead max. 0,3 mg/g Cu Nickel max. 1 mg/g Cu Cobalt max. 3 mg/kg Mercury max. 5 mg/kg Chromium max. 100 mg/kg Antimony max. 7 mg/kg			worker and bystander safety and ensure that conditions of use prescribe the application of adequate personal protective equipment and other mitigation measures as appropriate; — the protection of water and non-target organisms. In relation to these identified risks, risk mitigation measures, such as buffer zones, shall be applied where appropriate; — the amount

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