COMMISSION IMPLEMENTING REGULATION (EU) 2017/2065

of 13 November 2017

confirming the conditions of approval of the active substance 8-hydroxyquinoline, as set out in Implementing Regulation (EU) No 540/2011 and modifying Implementing Regulation (EU) 2015/408 as regards the inclusion of the active substance 8-hydroxyquinoline in the list of candidates for substitution

(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)(c), 78(2) and 80(7) thereof,

Whereas:

(1) The active substance 8-hydroxyquinoline was approved in accordance with Regulation (EC) No 1107/2009 by Commission Implementing Regulation (EU) No 993/2011 ([2]) and is listed in Part B of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([3]). In accordance with row 18 of Part B of the Annex to Implementing Regulation (EU) No 540/2011, only uses as fungicide and bactericide in greenhouses may be authorised.

(2) On 31 January 2014, Probelte S.A.U, at whose request 8-hydroxyquinoline had been approved, submitted an application in accordance with Article 7 of Regulation (EC) No 1107/2009 for an amendment to the conditions of approval of the active substance 8-hydroxyquinoline in order to remove the restriction to greenhouse applications and to allow uses of plant protection products containing 8-hydroxyquinoline in fields. The dossier containing information related to the requested extension of uses was submitted to Spain, which had been designated rapporteur Member State by Commission Regulation (EC) No 1490/2002 ([4]).

(3) Spain assessed the information submitted by the applicant and prepared an addendum to the draft assessment report. It submitted that addendum to the Commission, with a copy to the European Food Safety Authority ('the Authority'), on 25 March 2015.

(4) The Authority circulated the addendum to the applicant and the other Member States and made it available to the public, granting a period of 60 days for the submission of written comments.

(5) Taking into account the addendum to the draft assessment report, the Authority adopted its conclusion on 8-hydroxyquinoline on 29 April 2016 ([5]), as regards unrestricted outdoor uses thereof.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) 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 (OJ L 263, 7.10.2011, p. 1).

([3]) 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 (OJ L 153, 11.6.2011, p. 1).

([4]) Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 (OJ L 224, 21.8.2002, p. 23).

([5]) Conclusion on the peer review of the pesticide risk assessment of the active substance 8-hydroxyquinoline. *EFSA Journal* 2016;14(6):4493. Available online: www.efsa.europa.eu/efsajournal.htm

(6) In parallel, Spain submitted a proposal for a harmonised classification and labelling of 8-hydroxyquinoline to the European Chemicals Agency (ECHA) pursuant to Article 37 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([1]). The Committee for Risk Assessment of ECHA issued an opinion ([2]) on that proposal concluding that this active substance should be classified as toxic for reproduction Category 1B.

(7) The Authority identified in its conclusion that some toxic effects were observed on endocrine organs. Therefore 8-hydroxyquinoline should also be regarded as having endocrine-disrupting properties. The Authority communicated its conclusion to the applicant, the Member States and the Commission and made it available to the public.

(8) Taking into account the addendum to the draft assessment report by the rapporteur Member State, the opinion of the Risk Assessment Committee of ECHA and the conclusion of the Authority, the Commission presented an addenddum to the review report and a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed on 6 October 2017.

(9) The applicant was given the possibility to submit comments on the addendum to the review report for 8-hydroxyquinoline. The applicant submitted its comments, which have been carefully examined. However, despite the arguments put forward by the applicant, the concerns referred to in recitals 6 and 7 could not be eliminated.

(10) Consequently, it has not been demonstrated that it may be expected that plant protection products containing 8-hydroxyquinoline satisfy in general the requirements laid down in Article 4 of Regulation (EC) No 1107/2009 unless the restrictions currently provided for that active substance are kept.

(11) The evaluation of the request of the applicant to amend the condition of approval cannot be considered as a review of the approval of 8-hydroxyquinoline. Therefore the conditions of approval of the active substance 8-hydroxyquinoline, as set out in row 18 of Part B of the Annex to Implementing Regulation (EU) No 540/2011, should remain unchanged, and be confirmed.

(12) Pursuant to Article 80(7) of Regulation (EC) No 1107/2009 Commission Implementing Regulation (EU) 2015/408 ([3]) provides for the list of substances included in Annex I to Council Directive 91/414/EEC ([4]) or approved under Regulation (EC) No 1107/2009 pursuant to the transitional provisions of Article 80(1) of Regulation (EC) No 1107/2009, which satisfy the criteria set out in point 4 of Annex II to Regulation (EC) No 1107/2009 ('the list of candidates for substitution'). As 8-hydroxyquinoline, approved pursuant to paragraphs (1) and (2) of Article 80 of Regulation (EC) No 1107/2009, also satisfies the criteria set out in sixth and seventh indent of point 4 of Annex II to Regulation (EC) No 1107/2009, it is appropriate to include that active substance in that list. Implementing Regulation (EU) 2015/408 should therefore be amended accordingly.

(13) Member States should be provided with a reasonable period to adapt to the provisions of this Regulation as some applications for authorisation of plant protection products containing 8-hydroxyquinoline may be close to finalisation without any possibility to conduct the comparative assessment within the deadline provided by Article 37 of the Regulation (EC) No 1107/2009. The obligation to conduct comparative assessment for plant protection products containing candidates for substitution is provided for in Article 50(4) of Regulation (EC) No 1107/2009.

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

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([1]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

([2]) Opinion proposing harmonised classification and labelling at EU level of Quinolin-8-ol; 8-hydroxyquinoline. ECHA 2015. Available online: www.echa.europa.eu.

([3]) Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution (OJ L 67, 12.3.2015, p. 18).

([4]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Confirmation of the conditions of approval

The conditions of approval of the active substance 8-hydroxyquinoline, as set out in Row 18 of Part B of the Annex to Implementing Regulation (EU) No 540/2011, are confirmed.

Article 2

Amendment to the Annex to Implementing Regulation (EU) 2015/408

The name '8-hydroxyquinoline' is inserted between the entry '1-methylcyclopropene' and the entry 'aclonifen'.

Article 3

Deferred application of Article 2

Implementing Regulation (EU) 2015/408 as modified by Article 2 shall apply for the purposes of Article 50(1) of Regulation (EC) No 1107/2009 only to applications for the authorisation of plant protection products containing 8-hydroxyquinoline submitted after 4 April 2018.

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 November 2017.

For the Commission
The President
Jean-Claude JUNCKER