Commission Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 485/2013

of 24 May 2013

amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances

(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 first alternative of Article 21(3), Article 49(2) and Article 78(2) thereof,

Whereas:

(1) The active substances clothianidin, thiamethoxam and imidacloprid were included in Annex I to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market[(2)] by Commission Directives 2006/41/EC[(3)], 2007/6/EC[(4)] and 2008/116/EC[(5)].

(2) Commission Directive 2010/21/EU[(6)] amended Annex I to Directive 91/414/EEC as regards the specific provisions relating to the neonicotinoids clothianidin, thiamethoxam and imidacloprid.

(3) Active substances included in Annex I to Directive 91/414/EEC are deemed to be approved under Regulation (EC) No 1107/2009 and are listed in Part A of 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[(7)].

(4) In spring 2012, new scientific information on the sub-lethal effects of neonicotinoids on bees was published. The Commission, in accordance with Article 21(2) of Regulation (EC) No 1107/2009, asked the European Food Safety Authority, hereinafter 'the Authority', for scientific and technical assistance to assess this new information and to review the risk assessment of neonicotinoids as regards their impact on bees.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 485/2013. 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*

(5) The Authority presented its conclusions on the risk assessment for bees for clothianidin, thiamethoxam and imidacloprid on 16 January 2013[8].

(6) The Authority identified for certain crops high acute risks for bees from plant protection products containing the active substances clothianidin, thiamethoxam or imidacloprid. The Authority identified in particular high acute risks for bees from exposure via dust as regards several crops, from consumption of residues in contaminated pollen and nectar as regards some crops and from exposure via guttation fluid as regards maize. In addition, unacceptable risks due to acute or chronic effects on colony survival and development could not be excluded for several crops. Furthermore the Authority identified a number of data gaps for each of the evaluated crops. In particular as regards long term risk to honey bees from dust exposure, from residues in pollen and nectar and from exposure from guttation fluid.

(7) In the light of the new scientific and technical knowledge, the Commission considered that there are indications that the approved uses of clothianidin, thiamethoxam and imidacloprid no longer satisfy the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 with respect to their impact on bees and that the high risk for bees could not be excluded except by imposing further restrictions. In particular, pending the evaluation of the Authority on foliar uses it considered that the risk for bees from foliar applications is similar to the risk identified by the Authority for seed treatment applications and soil treatment, due to the systemic translocation of the active substances clothianidin, thiamethoxam and imidacloprid through the plant.

(8) The Commission invited the notifiers to submit their comments.

(9) The conclusions 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 March 2013 in the format of addenda to the review reports for clothianidin, thiamethoxam and imidacloprid.

(10) The Commission has come to the conclusion that a high risk for bees cannot be excluded except by imposing further restrictions.

(11) It is confirmed that the active substances clothianidin, thiamethoxam and imidacloprid are to be deemed to have been approved under Regulation (EC) No 1107/2009. In order to minimise the exposure of bees, it is, however, appropriate to restrict the uses of those active substances, to provide for specific risk mitigation measures for the protection of bees and to limit the use of the plant protection products containing those active substances to professional users. In particular the uses as seed treatment and soil treatment of plant protection products containing clothianidin, thiamethoxam or imidacloprid should be prohibited for crops attractive to bees and for cereals except for uses in greenhouses and for winter cereals. Foliar treatments with plant protection products containing clothianidin, thiamethoxam or imidacloprid should be prohibited for crops attractive to bees and for cereals with the exception of uses in greenhouses and uses after flowering. Crops which are harvested before flowering are not considered attractive to bees.

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(12) Concerning applications of clothianidin, thiamethoxam or imidacloprid which may be authorised under the present Regulation, it is appropriate to require further confirmatory information.

(13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(14) Risks for bees from treated seeds have been identified in particular from exposure via dust as regards several crops, from consumption of residues in contaminated pollen and nectar as regards some crops and from exposure via guttation fluid as regards maize. Taking into consideration those risks linked with the use of treated seeds, the use and the placing on the market of seeds treated with plant protection products containing clothianidin, thiamethoxam or imidacloprid should be prohibited for seeds of crops attractive to bees and for seeds of cereals except for winter cereals and seeds used in greenhouses.

(15) Member States should be provided with time to withdraw authorisations for plant protection products containing clothianidin, thiamethoxam or imidacloprid.

(16) For plant protection products containing clothianidin, thiamethoxam or imidacloprid, where Member States grant any period of grace in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire at the latest 30 November 2013. Within two years from the date of entry into force of the present Regulation the Commission will initiate without undue delay a review of the new scientific information which it has received.

(17) Article 36(3) of Regulation (EC) No 1107/2009 provides that Member States may, under certain circumstances, impose further risk mitigation measures or restrictions to the placing on the market or use of the plant protection products containing clothianidin, thiamethoxam or imidacloprid. Concerning the placing on the market and use of the seeds treated with plant protection products containing clothianidin, thiamethoxam or imidacloprid, Regulation (EC) No 1107/2009 provides for the possibility of Member States to take emergency measures pursuant to Article 71 thereof.

(18) The prohibition of placing on the market of treated seeds should apply only as of 1 December 2013 in order to allow for a sufficient period of transition. National interim protective measures already taken pursuant to Article 71 of Regulation (EC) No 1107/2009 may be maintained until that date in accordance with Article 71(3) of that Regulation.

(19) Seeds treated with plant protection products containing clothianidin, thiamethoxam or imidacloprid, which are subject to the restrictions referred to in Article 1 of this Regulation, may be used for experiments or tests for research or development purposes pursuant to Article 54 of Regulation (EC) No 1107/2009.

(20) The Standing Committee on the Food Chain and Animal Health did not deliver an opinion. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS REGULATION:

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Article 1

Amendment to Implementing Regulation (EU) No 540/2011

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

F3Article 2

[F1[F2[F3Prohibition of placing on the market of treated seeds]]]

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Textual Amendments

F1 Deleted by Commission Implementing Regulation (EU) 2018/785 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance thiamethoxam (Text with EEA relevance).

F2 Deleted by Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (Text with EEA relevance).

F3 Deleted by Commission Implementing Regulation (EU) 2018/783 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid (Text with EEA relevance).

Article 3

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 clothianidin, thiamethoxam or imidacloprid as active substance by 30 September 2013.

Article 4

Period of grace

Any period of grace granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire 30 November 2013 at the latest.

Article 5

Entry into force

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

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However, Article 2 shall apply as of 1 December 2013.

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