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)

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)

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 21(3), Article 49(2) and Article 78(2) thereof,

Whereas:

(1) The active substance clothianidin was included in Annex I to Council Directive 91/414/EEC[(2)] by Commission Directive 2006/41/EC[(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) Commission Implementing Regulation (EU) No 485/2013[(5)] amended the conditions of approval of the active substance clothianidin and required the applicants to provide confirmatory information as regards:

(a) the risk to pollinators other than honey bees;

(b) the risk to honey bees foraging in nectar or pollen in succeeding crops;

(c) the potential uptake via roots to flowering weeds;

(d) the risk to honey bees foraging on insect honey dew;

(e) the potential guttation exposure and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;

(f) the potential exposure to dust drift following drill and the acute and the long-term risk to colony survival and development, and the risk to bee brood resulting from such exposure;

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/784. 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*

(g) the acute and long term risk to colony survival and development and the risk to bee brood for honeybees from ingestion of contaminated nectar and pollen.

(4) In December 2014, the applicants submitted additional information concerning bees (i.e. honey bees, bumble bees and solitary bees) to the rapporteur Member State Belgium within the time period provided for its submission. They provided updated dossiers in March 2015 and June 2015.

(5) Belgium assessed the additional information submitted by the applicants. 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 ('the Authority') on 31 August 2015.

(6) The Commission consulted the Authority which presented its conclusion on the risk assessment of clothianidin on 13 October 2016[(6)]. The Authority identified for most crops high acute risks for bees from plant protection products containing the active substance clothianidin. In particular, as regards exposure via dust, the Authority identified high acute risks for bees for winter cereals and high chronic risks to bees cannot be excluded for sugar beets. For the consumption of residues in contaminated pollen and nectar, high acute and chronic risks were identified or a high risk cannot be excluded for most field uses. Chronic and acute risks to bees were also identified in the succeeding crops for all field uses. For forestry nursery, no data was provided by the applicants and risks to bees can therefore not be excluded. Furthermore the Authority identified a number of data gaps.

(7) As foreseen in recital (16) of Implementing Regulation (EU) No 485/2013, the Commission initiated a review of new scientific information on 11 February 2015 by mandating EFSA to organise an open call for data. EFSA launched an open call for data which ended on 30 September 2015[(7)].

(8) On 13 November 2015, the Commission requested EFSA to provide conclusions concerning an updated risk assessment for bees as regards the use of clothianidin applied as a seed treatment or granules by organising a peer review and taking into account the data collected in the framework of the specific open call for data and any other new data from studies, research and monitoring activities that are relevant to the uses under consideration. The Authority presented its conclusion on the peer review of the updated pesticide risk assessment for bees for the active substance clothianidin considering the uses as seed treatment and granules on 28 February 2018[(8)]. The applicants were given the opportunity to comment on this conclusion. The applicants submitted their comments which have been carefully examined.

(9) The draft assessment report, the addendum to the draft assessment report and the conclusions of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on 27 April 2018 in the form of a revised addendum to the Commission review report for clothianidin.

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(10) The Commission invited the applicants to submit their comments on the revised addendum to the review report for clothianidin. The applicants submitted their comments which have been carefully examined.

(11) Having reviewed the information submitted by the applicants in 2014 and 2015 the Commission has concluded that the further confirmatory information required by Implementing Regulation (EU) No 485/2013 has not been provided, and having also considered the conclusion on the updated risk assessment for bees, the Commission has concluded that further risks to bees cannot be excluded without imposing further restrictions. Bearing in mind the need to ensure a level of safety and protection consistent with the high level of protection of animal health that is sought within the Union, it is appropriate to prohibit all outdoor uses. Therefore, it is appropriate to limit the use of clothianidin to permanent greenhouses and to require that the resulting crop stays its entire life cycle within a permanent greenhouse, so that it is not replanted outside.

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

(13) Taking into account the risks for bees from treated seeds, the placing on the market and the use of seeds treated with plant protection products containing clothianidin should be subject to the same restrictions as the use of clothianidin. It is therefore appropriate to provide that seeds treated with plant protection products containing clothianidin shall not be placed on the market or used, except where the seeds are intended to be used only in permanent greenhouses and the resulting crop stays within a permanent greenhouse during its entire life cycle.

(14) Member States should be allowed sufficient time to amend or withdraw authorisations for plant protection products containing clothianidin.

(15) For plant protection products containing clothianidin, where Member States grant a grace period pursuant to Article 46 of Regulation (EC) No 1107/2009, that period should, at the latest, expire on 19 December 2018.

(16) The prohibition of placing on the market and use of treated seeds should apply only as of 19 December 2018 in order to allow for a sufficient period of transition.

(17) 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.

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Article 2

Prohibition of the placing on the market and use of treated seeds

Seeds treated with plant protection products containing clothianidin shall not be placed on the market or used, except where:

(a) the seeds are intended to be used only in permanent greenhouses, and

(b) the resulting crop stays within a permanent greenhouse during its entire life cycle.

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 as active substance by 19 September 2018 at the latest.

Article 4

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 by 19 December 2018 at the latest.

Article 5

Amendment to Implementing Regulation (EU) No 485/2013

As regards seeds which have been treated with plant protection products containing clothianidin, Article 2 of Implementing Regulation (EU) No 485/2013 is deleted.

Article 6

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*.

However, Article 2 and Article 5 shall apply as of 19 December 2018.

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