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)

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)

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 thiamethoxam was included in Annex I to Council Directive 91/414/EEC[(2)] by Commission Directive 2007/6/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 thiamethoxam and required the applicant 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) 2018/785. 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) The applicant submitted additional information concerning bees (i.e. honey bees, bumble bees and solitary bees) to the rapporteur Member State Spain.

(5) Spain assessed the additional information submitted by the applicant. 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 12 November 2015.

(6) The Member States, the applicant and the Authority were consulted and asked to provide comments on the assessment of the rapporteur Member State. The Authority published a Technical Report summarising the outcome of this consultation for thiamethoxam on 20 April 2016[(6)].

(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 thiamethoxam 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 thiamethoxam considering the uses as seed treatment and granules on 28 February 2018[(8)]. The applicant was given the opportunity to comment on this conclusion. The applicant submitted its comments which have been carefully examined.

(9) The draft assessment report, the addendum, the Technical Report and the conclusion 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 thiamethoxam.

(10) The Commission invited the applicant to submit its comments on the revised addendum to the review report for thiamethoxam. The applicant submitted its comments which have been carefully examined.

(11) Having reviewed the information submitted by the applicant, 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 thiamethoxam

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 thiamethoxam should be subject to the same restrictions as the use of thiamethoxam. It is therefore appropriate to provide that seeds treated with plant protection products containing thiamethoxam 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 thiamethoxam.

(15) For plant protection products containing thiamethoxam, 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.

Article 2

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

Seeds treated with plant protection products containing thiamethoxam 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.