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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance imidacloprid

(Text with EEA relevance)

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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 imidacloprid was included in Annex I to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market by Commission Directive 2008/116/EC[2].

(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[3].

(3) Regulation (EU) No 485/2013[4] amended the conditions of approval of the active substance imidacloprid 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;

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1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include aclonifen, imidacloprid and metazachlor as active substances (OJ L 337, 16.12.2008, p. 86).

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 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 (OJ L 139, 25.5.2013, p. 12).

(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;

(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 applicant submitted additional information concerning bees (i.e. honey bees, bumble bees and solitary bees) to the rapporteur Member State Germany within the time period provided for its submission.

(5) Germany 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 18 January 2016.

(6) The Commission consulted the Authority which presented its conclusion on the risk assessment of imidacloprid on 13 October 2016[5]. The Authority identified for most crops high acute risks for bees from plant protection products containing the active substance imidacloprid. In particular, as regards exposure via dust, the Authority identified high risks for bees for several field uses. For bees foraging in the treated crop, a high risk was identified for the use on potatoes and winter cereals. For almost all field uses, a high risk to bees was also identified in the succeeding crops. In addition, the Authority identified a number of data gaps.

(7) As foreseen in recital 16 of 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[6].

(8) On 13 November 2015, the Commission requested EFSA to provide conclusions concerning an updated risk assessment for bees as regards the use of imidacloprid 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 imidacloprid considering the uses as seed treatment and granules on 28 February 2018[7]. 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 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

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5 EFSA (European Food Safety Authority), 2016. Peer review of the pesticide risk assessment for the active substance imidacloprid in light of confirmatory data submitted. EFSA Journal 2016;14(11):4607. doi: 10.2903/j.efsa.2016.4607.

6 EFSA (European Food Safety Authority), 2015. Technical report on the open call for new scientific information as regards the risk to bees from the use of the three neonicotinoid pesticide active substances clothianidin, imidacloprid and thiamethoxam applied as seed treatments and granules in the EU. EFSA supporting publication 2015:EN-903. 8pp.

7 EFSA (European Food Safety Authority), 2018. Conclusions on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid considering the uses as seed treatments and granules. EFSA Journal 2018;16(2):5178. 113 pp.

finalised on 27 April 2018 in the form of a revised addendum to the Commission review report for imidacloprid.

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

(11) Having reviewed the information submitted by the applicant in 2014 the Commission has concluded that the further confirmatory information required by 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 imidacloprid 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 imidacloprid should be subject to the same restrictions as the use of imidacloprid. It is therefore appropriate to provide that seeds treated with plant protection products containing imidacloprid 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 in 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 imidacloprid.

(15) For plant protection products containing imidacloprid, 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 [*Office of Publications please insert date 6 months from the date of entry into force*].

(16) The prohibition of placing on the market and use of treated seeds should apply only as of [*Office of Publications please insert date 6 months from the date of entry into force*] 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 imidacloprid 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 imidacloprid as active substance by [*Office of Publications please insert date 3 months from the date of entry into force*] 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 [*Office of Publications please insert date 6 months from the date of entry into force*] at the latest.

Article 5
Amendment to Regulation (EU) No 485/2013

As regards seeds which have been treated with plant protection products containing imidacloprid, Article 2 of 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 [*Office of Publications please insert date 6 months from the date of entry into force*].

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

Done at Brussels,

For the Commission
The President
Jean-Claude JUNCKER