EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10834/2016 Rev. 8
[…](2017) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

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) …/...

of XXX

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 the second alternative of 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 of 15 July 1991 concerning the placing of plant protection products on the market by Commission Directive 2007/6/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 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;

---

1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2007/6/EC of 14 February 2007 amending Council Directive 91/414/EEC to include metrafenone, Bacillus subtilis, spinosad and thiamethoxam as active substances (OJ L 43, 15.2.2007, p. 13).

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) 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[5].

(7) The draft assessment report, the addendum and the Technical Report 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 13 December 2017 in the form of a revised addendum to the Commission review report for thiamethoxam.

(8) 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.

(9) Having reviewed the information submitted by the applicant, the Commission has concluded that the further confirmatory information required by Regulation (EU) No 485/2013 has not been provided and that an unacceptable risk to bees and other pollinators 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.

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

(11) 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 in a permanent greenhouse during its entire life cycle.

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

[5] EFSA (European Food Safety Authority), 2016. Technical report on the outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for thiamethoxam in light of confirmatory data. EFSA supporting publication 2016:EN-1020. 27 pp.

(13) 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 *[Office of Publications please insert date 6 months from the date of entry into force]*.

(14) 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.

(15) 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.

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 thiamethoxam 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

Article 2 of Regulation (EU) No 485/2013 is deleted as of [*Office of Publications please insert date 6 months from the date of entry into force*] as regards seeds which have been treated with plant protection products containing thiamethoxam.

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 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