EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10448/2019 rev 1
[…](2019) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the non-renewal of the approval of the active substance thiacloprid, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the non-renewal of the approval of the active substance thiacloprid, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(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 20(1) and Article 78 (2) thereof,

Whereas:

(1) Commission Directive 2004/99/EC[2] included thiacloprid as an active substance in Annex I to Council Directive 91/414/EEC[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) The approval of the active substance thiacloprid as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2020.

(4) An application for the renewal of the approval of thiacloprid was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012[5] within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

---

1 OJ L 309, 24.11.2009, p. 1.

2 Commission Directive 2004/99/EC of 1 October 2004 amending Council Directive 91/414/EEC to include acetamiprid and thiacloprid as active substances (OJ L 309, 6.10.2004, p. 6).

3 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

4 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).

5 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

(6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 31 October 2017.

(7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

(8) On 22 January 2019 the Authority communicated to the Commission its conclusion[6] on whether thiacloprid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) The Authority identified a critical concern in relation to the contamination of groundwater by metabolites of thiacloprid. In particular, metabolites M30, M34 and M46 are predicted to occur above the parametric drinking water limit of 0,1 μg/L in all pertinent scenarios for all proposed uses of thiacloprid. These metabolites are considered *a priori* of concern since it cannot be excluded that they share the same carcinogenic properties of the parent active substance thiacloprid, which is clasified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council[7] as carcinogenic category 2. Therefore, it cannot currently be established that the presence of metabolites of thiacloprid in groundwater will not result in unacceptable effects on groundwater and in harmful effects on human health. The Authority also concluded that the assessment of the risks to aquatic organisms, bees and non-target terrestrial plants could not be finalised based on the information provided in the dossier.

(10) Additionally, thiacloprid is classified in accordance with Regulation (EC) No 1272/2008 also as toxic for reproduction category 1B. The applicant provided information attempting to demonstrate that exposure of humans to thiacloprid can be considered negligible. The Authority presented the outcome of the assessment of that informaiton in its conclusion. Nevertheless, given the concerns identified in recital 9, a conclusion on whether exposure to humans is negligible for the purposes of point 3.6.4 of Annex II to Regulation (EC) No 1107/2009, is not necessary for the decision on whether the approval of thiacloprid can be renewed.

(11) Furthermore, given the concerns identified, it is also not possible to provide for an approval in accordance with Article 4(7) to Regulation (EC) No 107/2009.

(12) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with the third paragraph of Article 14(1)of Implementing Regulation (EU) No 844/2012, the Commission invited the applicant to submit comments on the draft renewal report. The applicant submitted its comments, which have been carefully examined.

(13) However, despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.

---

6 EFSA Journal (2019). Conclusion on the peer review of the pesticide risk assessment of the active substance thiacloprid. EFSA Journal 2019;17(3):5595. doi: 10.2903/j.efsa.2019.5595

7 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(14) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance thiacloprid in accordance with Article 20(1)(b) of that Regulation.

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

(16) Member States should be given sufficient time to withdraw authorisations for plant protection products containing thiacloprid.

(17) For plant protection products containing thiacloprid, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 12 months.

(18) Commission Implementing Regulation (EU) 2019/168[8] extended the approval period of thiacloprid to 30 April 2020 in order to allow the renewal process to be completed before the expiry of the that approval period. However, given that a decision on the non-renewal of the approval is taken ahead of the expiry of that extended approval period, this Regulation should apply as soon as possible.

(19) This Regulation does not prevent the submission of a further application for the approval of thiacloprid pursuant to Article 7 of Regulation (EC) No 1107/2009.

(20) 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

Non-renewal of the approval of the active substance

The approval of the active substance thiacloprid is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011 row 92, on thiacloprid, is deleted.

[8] Commission Implementing Regulation (EU) 2019/168 of 31 January 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, Bacillus subtilis (Cohn 1872) Strain QST 713, Bacillus thuringiensis subsp. Aizawai, Bacillus thuringiensis subsp. israeliensis, Bacillus thuringiensis subsp. kurstaki, Beauveria bassiana, benfluralin, clodinafop, clopyralid, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, epoxiconazole, fenpyroximate, fluazinam, flutolanil, fosetyl, Lecanicillium muscarium, mepanipyrim, mepiquat, Metarhizium anisopliae var. Anisopliae, metconazole, metrafenone, Phlebiopsis gigantea, pirimicarb, Pseudomonas chlororaphis strain: MA 342, pyrimethanil, Pythium oligandrum, rimsulfuron, spinosad, Streptomyces K61, thiacloprid, tolclofos-methyl, Trichoderma asperellum, Trichoderma atroviride, Trichoderma gamsii, Trichoderma harzianum, triclopyr, trinexapac, triticonazole, Verticillium albo-atrum and ziram (OJ L 33, 5.2.2019, p. 1).

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing thiacloprid as active substance by [*Publications Office please insert date 6 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 expire by *[Publications Office please insert date 12 months from the date of entry into force]* at the latest.

Article 5

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*.

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