# Commission Implementing Regulation (EU) No 781/2013 of 14 August 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance (Text with EEA relevance)

## COMMISSION IMPLEMENTING REGULATION (EU) No 781/2013

## of 14 August 2013

## amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active substance fipronil, and prohibiting the use and sale of seeds treated with plant protection products containing this active substance

## (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 first alternative of Article 21(3), Article 49(2) and Article 78(2) thereof,

Whereas:

(1) The active substance fipronil 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[(2)] by Commission Directive 2007/52/EC[(3)].

(2) Commission Directive 2010/21/EU[(4)] amended Annex I to Directive 91/414/EEC as regards the specific provisions relating to fipronil.

(3) Active substances included in Annex I to Directive 91/414/EEC are deemed to be approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to 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[(5)].

(4) Based on new information received from Italy concerning risks to honeybees caused by coated maize seeds treated with plant protection products containing fipronil, the Commission decided to review the approval of that active substance. The Commission, in accordance with Article 21(2) of Regulation (EC) No 1107/2009, asked the European Food Safety Authority, hereinafter 'the Authority', for scientific and technical assistance to assess this new information and to review the risk assessment of fipronil as regards its impact on bees.

(5) The Authority presented its conclusion on the risk assessment of fipronil as regards bees on 27 May 2013[(6)].

**Changes to legislation:** *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 781/2013. 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*

(6) The Authority identified for the use as seed treatment in maize, high acute risks for bees from plant protection products containing the active substance fipronil. The Authority identified, in particular, a high acute risk for bees resulting from dust. In addition, unacceptable risks due to acute or chronic effects on colony survival and development could not be excluded for several crops. Furthermore, the Authority identified some missing information for each of the evaluated uses, in particular as regards long term risk to honeybees from dust exposure, from potential exposure to residues in pollen and nectar, from potential exposure to guttation fluid and from exposure to residues in succeding crops, weeds and soil.

(7) In the light of the new scientific and technical knowledge, the Commission considered that there are indications that some approved uses of fipronil do not satisfy the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 with respect to the impact on bees and that the high risk for bees could not be excluded except by imposing further restrictions.

(8) The Commission invited the notifier to submit comments.

(9) The conclusion of the Authority was reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 16 July 2013 in the format of an addendum to the review report for fipronil.

(10) The Commission has come to the conclusion that a high risk for bees cannot be excluded except by imposing further restrictions.

(11) It is confirmed that the active substance fipronil is deemed to have been approved under Regulation (EC) No 1107/2009. In order to minimise the exposure of bees, it is, however, appropriate to restrict the use of plant protection products containing fipronil and to provide for specific risk mitigation measures for the protection of bees. In particular the use of plant protection products containing fipronil should be limited to the treatment of seeds intended to be sown in greenhouses and to the treatment of seeds of leek, onions, shallots and the group of *Brassica* vegetables intended to be sown in fields and harvested before flowering. Crops which are harvested before flowering are not considered attractive to bees.

(12) Concerning applications of fipronil which may be authorised under Implementing Regulation (EU) No 540/2011, it is appropriate to require further confirmatory information.

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

(14) Risks for bees from treated seeds have been identified in particular from exposure via dust as regards the use in maize. Taking into consideration the risks linked with the use of treated seeds, the use and the placing on the market of seeds treated with plant protection products containing fipronil should be prohibited except for seeds sown in greenhouses and for treatment of seeds of leek, onions, shallots and the group of *Brassica* vegetables sown in fields and harvested before flowering. Pending submission of missing information regarding the use of treated sunflower seeds, it is appropriate to apply similar measures as for maize.

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(15) Member States should be provided with time to withdraw authorisations for plant protection products containing fipronil.

(16) For plant protection products containing fipronil, where Member States grant any period of grace in accordance with Article 46 of Regulation (EC) No 1107/2009, this period should expire on 28 February 2014 at the latest. Accordingly, the prohibition of placing on the market of treated seeds should apply as of 1 March 2014 in order to allow for a period of transition.

(17) Within two years from the date of entry into force of the present Regulation the Commission will initiate a review of the new scientific information, including new studies, information on new product formulations provided by the applicants, which it has received.

(18) Article 36(3) of Regulation (EC) No 1107/2009 provides that Member States may, under certain circumstances, impose further risk mitigation measures or restrictions to the placing on the market or use of the plant protection products containing fipronil. Concerning the placing on the market and use of the seeds treated with plant protection products containing fipronil, Regulation (EC) No 1107/2009 provides for the possibility of Member States to take emergency measures pursuant to Article 71 thereof.

(19) Seeds treated with plant protection products containing fipronil, which are subject to the restrictions referred to in Article 1 of this Regulation, may be used for experiments or tests for research or development purposes pursuant to Article 54 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 the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Amendment to Implementing Regulation (EU) No 540/2011**

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with the Annex to this Regulation.

*Article 2*

**Prohibition of placing on the market of treated seeds**

Seeds of crops which have been treated with plant protection products containing fipronil shall not be used or placed on the market with the exception of seeds intended to be sown in greenhouses and seeds of leek, onions, shallots, and the group of *Brassica* vegetables intended to be sown in fields and harvested before flowering.

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*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 fipronil as active substance by 31 December 2013.

*Article 4*

**Period of grace**

Any period of grace granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire on 28 February 2014 at the latest.

*Article 5*

**Entry into force**

This Regulation shall enter into force and apply from the day following that of its publication in the *Official Journal of the European Union*.

However, Article 2 shall apply from 1 March 2014.

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

Done at Brussels, 14 August 2013.

*For the Commission*

*The President*

José Manuel BARROSO