



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/2016/12106  
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**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

**amending Implementing Regulation (EU) 540/2011 as regards the conditions of approval  
of the active substance clothianidin**

(Text with EEA relevance)

**EN**

**EN**

# COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

## amending Implementing Regulation (EU) 540/2011 as regards the conditions of approval of the active substance clothianidin

(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, and in particular the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

- (1) The active substance clothianidin 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) 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<sup>1</sup>.
- (3) Regulation (EU) 485/2013<sup>2</sup> amended the conditions of approval of the substance clothianidin 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;

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<sup>1</sup> 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).

<sup>2</sup> 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).

- (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 applicants submitted additional information concerning bees (ie. honey bees, bumble bees and solitary bees) to the rapporteur Member State Belgium within the time period provided for its submission. They provided an updated dossier in March 2015 and June 2015.
  - (5) Belgium assessed the additional information submitted by the applicants. 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, hereinafter 'the Authority', on 31 August 2015.
  - (6) The Commission consulted the Authority which presented its conclusion on the risk assessment of clothianidin on 13 October 2016. The Authority identified for most crops high acute risks for bees from plant protection products containing the active substance clothianidin. In particular, as regards exposure via dust, the Authority identified high acute risks for bees for winter cereal and high chronic risks to bees cannot be excluded for sugar beets. For the consumption of residues in contaminated pollen and nectar high acute and chronic risks were identified or a high risk cannot be excluded for most field uses. Chronic and acute risks to bees were also identified in the succeeding crops for all field uses. For forestry nursery, no data was provided by the applicants and risks to bees can therefore not be excluded. Furthermore the Authority identified a number of data gaps.
  - (7) The draft assessment report, the addendum 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 [...] in the format of the Commission addendum to the review report for clothianidin.
  - (8) The Commission invited the applicants to submit their comments on the addendum to the review report for clothianidin. The applicants submitted their comments which have been carefully examined.
  - (9) The Commission has concluded that further risks to bees cannot be excluded and that the use of clothianidin has to be further restricted. In particular, the use of clothianidin should be limited to permanent greenhouses where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside.
  - (10) In order to minimise the exposure of bees to clothianidin, it is appropriate to amend the conditions of use of this active substance.
  - (11) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
  - (12) Also the placing on the market and use of the seeds treated with plant protection products containing clothianidin should be further restricted.
  - (13) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing clothianidin.

- (14) For plant protection products containing clothianidin and seeds treated with plant protection products containing clothianidin, where Member States grant any grace period in accordance with 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].
- (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*

By way of derogation to Article 2 of Implementing Regulation (EU) No 485/2013, seeds treated with plant protection products containing clothianidin may not be placed on the market or used, with the exception of seeds to be used in permanent greenhouses where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside.

*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 clothianidin 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*  
*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*.

Article 2 shall apply as of [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*

[Annex]

The column 'Specific provisions' of row 121, clothianidin, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

'PART A

**EN**

Only uses as insecticide, in permanent greenhouses or for the treatment of seeds to be used in permanent greenhouse, where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside, may be authorised.

## PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on clothianidin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 and the conclusions of the revised addendum of the review report on clothianidin as finalised in the Standing Committee on the Food Chain and Animal Health on XXX 2017 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

- the protection of groundwater;
- the risk to bees and bumble bees released for pollination in permanent greenhouses;
- the exposure of bees via the consumption of contaminated water from the permanent greenhouses.

Member States shall ensure that:

- the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised;

Conditions of use shall include risk mitigation measures, where appropriate.'



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/2016/12105  
[...] (2016) **XXX** draft

**COMMISSION IMPLEMENTING REGULATION (EU) .../...**

**of **XXX****

**amending Implementing Regulation (EU) 540/2011 as regards the conditions of approval  
of the active substance imidacloprid**

(Text with EEA relevance)

**EN**

**EN**

# COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

## **amending Implementing Regulation (EU) 540/2011 as regards the conditions of approval of the active substance imidacloprid**

(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, and in particular the second alternative of Article 21(3) 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) 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<sup>1</sup>.
- (3) Regulation (EU) 485/2013<sup>2</sup> amended the conditions of approval of the 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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<sup>1</sup> 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).

<sup>2</sup> 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 (ie. 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, hereinafter '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. 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 the consumption of residues in contaminated pollen and nectar a high risk was identified or a high risk cannot be excluded for potatoes and winter cereals. For almost all field uses also a high risk to bees was identified in the succeeding crops. Furthermore the Authority identified a number of data gaps.
- (7) Bearing in mind the need to ensure a level of safety and protection consistent with the high level of protection that is sought within the Union, from the risk management perspective, it is appropriate to restrict all outdoor uses.
- (8) The draft assessment report, the addendum 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 [...] in the format of the Commission addendum to the review report for imidacloprid.
- (9) The Commission invited the applicant to submit its comments on the addendum to the review report for imidacloprid. The applicant submitted its comments which have been carefully examined.
- (10) The Commission has concluded that further risks to bees cannot be excluded and that the use of imidacloprid has to be further restricted. In particular, the use of imidacloprid should be limited to permanent greenhouses where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside.
- (11) In order to minimise the exposure of bees to imidacloprid, it is appropriate to amend the conditions of use of this active substance.
- (12) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (13) Also the placing on the market and use of the seeds treated with plant protection products containing imidacloprid should be further restricted.

- (14) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing imidacloprid.
- (15) For plant protection products containing imidacloprid and seeds treated with plant protection products containing imidacloprid, where Member States grant any grace period in accordance with 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 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*

By way of derogation to Article 2 of Implementing Regulation (EU) No 485/2013, seeds treated with plant protection products containing imidacloprid may not be placed on the market or used, with the exception of seeds to be used in permanent greenhouses where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside.

*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*

#### *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*.

Article 2 shall apply as of [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*

#### **[Annex]**

The column 'Specific provisions' of row 216, imidacloprid, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

#### **'PART A**

Only uses as insecticide, in permanent greenhouses or for the treatment of seeds to be used in permanent greenhouse, and where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside, may be authorised.

#### **PART B**

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on imidacloprid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 26 September 2008 and the conclusions of the revised addendum of the review report on imidacloprid as finalised in the Standing Committee on the Food Chain and Animal Health on **XXX 2017** shall be taken into account.

**EN**

In this overall assessment Member States must pay particular attention to:

- the risk to bees and bumble bees released for pollination in permanent greenhouses;
- the impact on aquatic organisms;
- the exposure of bees via the consumption of contaminated water from the permanent greenhouses.

Member States shall ensure that:

- the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised;

Conditions of use shall include risk mitigation measures, where appropriate.



EUROPEAN  
COMMISSION

Brussels, **XXX**  
SANTE/10834/2016 Rev. 2  
[...](2014) **XXX** draft

**COMMISSION IMPLEMENTING REGULATION (EU) No .../..**

**of **XXX****

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

(Text with EEA relevance)

**EN**

**EN**

# COMMISSION IMPLEMENTING REGULATION (EU) No .../..

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<sup>1</sup>, and in particular the second alternative of Article 21(3) 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<sup>2</sup>.
- (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<sup>3</sup>.
- (3) Regulation (EU) No 485/2013<sup>4</sup> 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;

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<sup>1</sup> OJ L 309, 24.11.2009, p. 1.

<sup>2</sup> 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).

<sup>3</sup> 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).

<sup>4</sup> 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)

- (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;
- (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 notifier submitted some additional information with a view to confirm the risk assessment for bees and other pollinators to the rapporteur Member State Spain.
- (5) Spain assessed the additional information submitted by the notifier. It submitted its assessment, in the form of addendum to the draft assessment report, to the other Member States, the Commission and the European Food Safety Authority, hereinafter 'the Authority', on 12 November 2015.
- (6) The further confirmatory information is considered not sufficient to address the risks and therefore demonstrate that an unacceptable risk to bees and other pollinators could not be excluded unless further restrictions would be provided.
- (7) The Commission invited the applicant to submit its comments on the addendum to the review report for thiamethoxam. The applicant submitted its comments which have been carefully examined.
- (8) The Commission has concluded that the applicant failed to submit the required confirmatory data and that the use of thiamethoxam has to be further restricted. In particular, the use of thiamethoxam should be limited to permanent greenhouses where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside.
- (9) In order to minimise the exposure of bees to thiamethoxam, it is appropriate to amend the conditions of use of this active substance.
- (10) The Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (11) Also the placing on the market and use of the seeds treated with plant protection products containing thiamethoxam should be further restricted.
- (12) Member States should be provided with time to amend or withdraw authorisations for plant protection products containing thiamethoxam.
- (13) For plant protection products containing thiamethoxam and seeds treated with plant protection products containing thiamethoxam, where Member States grant any grace period in accordance with 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 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*

By way of derogation to Article 2 of Implementing Regulation (EU) No 485/2013, seeds treated with plant protection products containing thiamethoxam may not be placed on the market or used, with the exception of seeds to be used in permanent greenhouses where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside.

*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*

*Period of grace*

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 [*Office of Publications please insert date 6 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*.

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*

**EN**

**EN**



## **ANNEX**

The column 'Specific provisions' of row 140, thiamethoxam, of Part A of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

### **PART A**

Only uses as insecticide, in permanent greenhouses or for the treatment of seeds intended for permanent greenhouse, where the crop stays its entire life cycle within the greenhouse and is thus not replanted outside, may be authorised.

### **PART B**

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on thiamethoxam, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 14 July 2006 and the conclusions of the revised addendum of the review report on thiamethoxam as finalised in the Standing Committee on the Food Chain and Animal Health on xx xxx 2017 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

- the risk to groundwater,
- the risk to aquatic organisms,
- the risk to bees and bumble bees released for pollination in permanent greenhouses,
- the exposure of bees via the consumption of contaminated water from the permanent greenhouses.

Member States shall ensure that:

- the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised;

Conditions of use shall include risk mitigation measures, where appropriate. '

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