European Food Safety Authority

EFSA Conclusions on neonicotinoids

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Structure

- The Commission's mandate (question)
- The process
- EFSA (2012)
- Data
- Risk assessment (routes of exposure, tiered approach)
- Results
- Conclusion

The Commission's mandate

- EFSA has undertaken its work upon receipt of a mandate from the European Commission
- The key elements of the mandate
  - ✓ Deadline on **31/12/12**
  - ✓ Substances: **imidacloprid, clothianidin, thiamethoxam**
  - ✓ **all authorised uses** as **seed treatment** and as **granules** are to be considered

The Commission's mandate

- To revise the risk assessment for bees by considering:
  - ✓ Acute and chronic risk on colony survival and development (including bee larvae and bee behaviour)
  - ✓ Sublethal effects
- To focus on the following routes of exposure:
  - ✓ Dust
  - ✓ Residue in pollen and nectar
  - ✓ Guttation
- EFSA PPR Panel Opinion (2012)

EFSA's review process

- **Data collection** (specified in the mandate):
  - ✓ studies from the applicants
  - ✓ information on the authorised uses (**GAP tables**), and monitoring data from the Member States
  - ✓ published literature

Data evaluation*

Draft Conclusions

Tiered risk assessment*

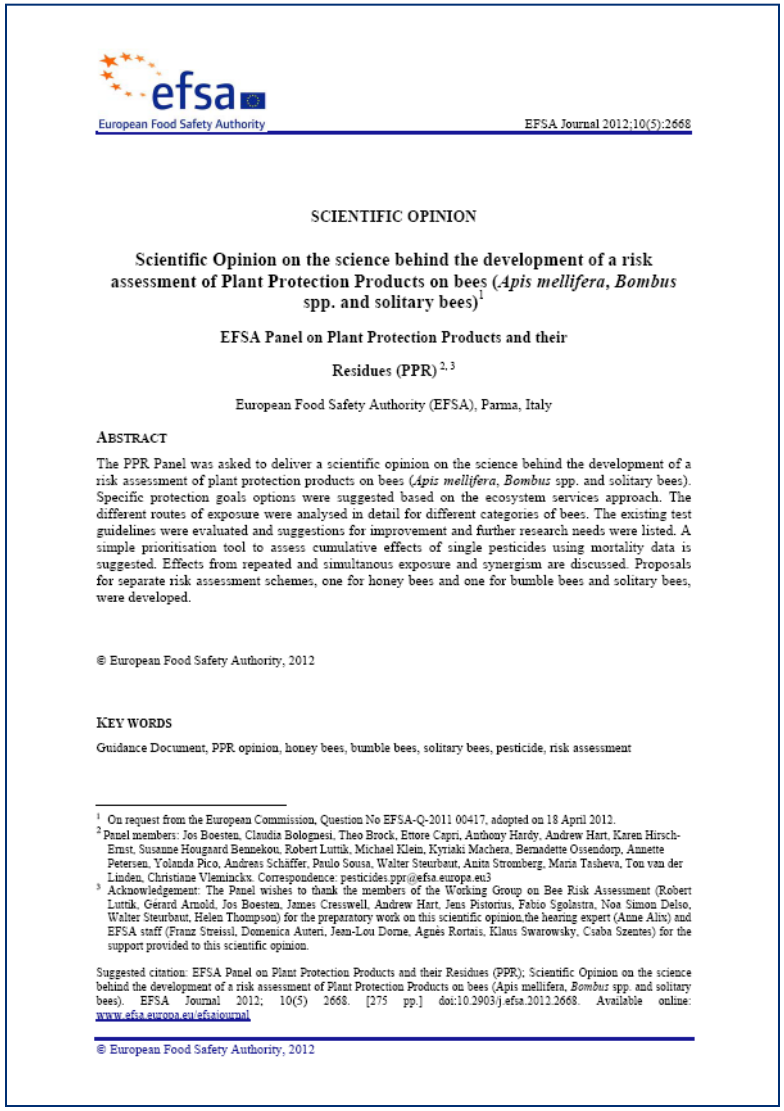
MSs consultation

Final Conclusions

(Adopted the Conclusions on 19/12/12)

***Taking in to account the Scientific Opinion on the science behind the development of a risk assessment of plant protection products on bees (specified in the mandate)**

EFSA PPR Opinion 2012



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EFSA Journal 2012;10(5):2668

SCIENTIFIC OPINION

Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)[1]

EFSA Panel on Plant Protection Products and their Residues (PPR)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The PPR Panel was asked to deliver a scientific opinion on the science behind the development of a risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). Specific protection goals options were suggested based on the ecosystem services approach. The different routes of exposure were analysed in detail for different categories of bees. The existing test guidelines were evaluated and suggestions for improvement and further research needs were listed. A simple prioritisation tool to assess cumulative effects of single pesticides using mortality data is suggested. Effects from repeated and simultanous exposure and synergism are discussed. Proposals for separate risk assessment schemes, one for honey bees and one for bumble bees and solitary bees, were developed.

KEY WORDS

Guidance Document, PPR opinion, honey bees, bumble bees, solitary bees, pesticide, risk assessment

[1] On request from the European Commission, Question No EFSA-Q-2011 00417, adopted on 18 April 2012.

[2] Panel members: Jos Boesten, Claudia Bolognesi, Theo Brock, Ettore Capri, Anthony Hardy, Andrew Hart, Karen Hirsch-Ernst, Susanne Hougaard Bennekou, Robert Luttik, Michael Klein, Kyriaki Machera, Bernadette Ossendorp, Annette Petersen, Yolanda Pico, Andreas Schäffer, Paulo Sousa, Walter Steurbaut, Anita Stromberg, Maria Tasheva, Ton van der Linden, Christiane Vleminckx. Correspondence: pesticides.ppr@efsa.europa.eu3

[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Bee Risk Assessment (Robert Luttik, Gerard Arnold, Jos Boesten, James Cresswell, Andrew Hart, Jens Pistorius, Fabio Sgolastra, Noa Simon Delso, Walter Steurbaut, Helen Thompson) for the preparatory work on this scientific opinion,the hearing expert (Anne Alix) and EFSA staff (Franz Streissl, Domenica Auteri, Jean-Lou Dorne, Agnès Rortais, Klaus Swarowsky, Csaba Szentes) for the support provided to this scientific opinion.

Suggested citation: EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (Apis mellifera, *Bombus* spp. and solitary bees). EFSA Journal 2012; 10(5) 2668. [275 pp.] doi:10.2903/j.efsa.2012.2668. Available online: www.efsa.europa.eu/efsajournal

- Opinion published May 2012
- Extensive document
- New areas of risk assessment
  - other pollinators
  - exposure routes
- Recommendations for improvement:
  - risk assessment methodology (systemic active substances)
  - design of higher tier studies
- No agreed ‘trigger values’

Data considered

- Data submitted by Member States and the applicants
- Residue data
- Laboratory data
- Numerous higher tier studies for exposure via dust, residues in nectar and/or pollen and residues in guttation fluid were available
- Available higher tier data carefully evaluated
- 'Study evaluation notes', background documents (available on the EFSA website)

Data evaluation according to EFSA 2012

- Exposure is **key** in semi-field and field studies
  - Must be proof of exposure
  - Demonstrate 'worst case' conditions
  - Survey of crops/flowering plants surrounding 4 km area
  - Control colonies should be placed at least 4 – 6 km from the experimental field
  - Include assessments of bee pollen loads, bee nectar, residue assessment
  - Ensure study length is sufficient for food stocks to be used
- Interpretation of results - statistical analysis

Routes of exposure (EFSA 2012)

- Imidacloprid, clothianidin, thiamethoxam are systemic active substances

Dust during sowing

Residues in nectar and/or pollen

Residues in succeeding plants/crop

Residues in guttation fluid

Residues in insect honeydew

Routes of exposure (EFSA 2012)

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The risk assessment

- Tiered approach
  - Screening step (dust and guttation exposure)
  - Tier 1 risk assessment
  - Tier 2 risk assessment (dust only)
  - Higher tier risk assessment (semi-field and field studies)

Acute
Chronic
Risk to bee brood
Sublethal

Results: Risks identified (acute risks)

	DUST	Pollen and Nectar	Guttation
Clothianidin	**Maize Cereals OSR**	**OSR**	-
Imidacloprid	**Maize Cereals OSR Cotton**	**OSR Cotton Sunflower**	-
Thiamethoxam	**Maize Cereals OSR Cotton Sunflower ***	-	**Maize**

*only a single authorised use

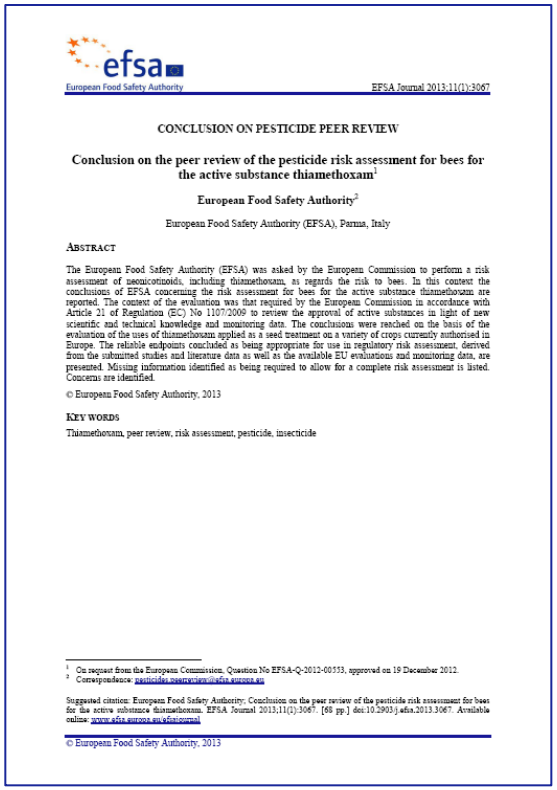
Results: higher tier risk assessment

- Some studies were not considered suitable for risk assessment according to EFSA (2012) criteria
- Some studies were well designed and accounted for many of the issues
  - Problems with 'worst case exposure'
  - Problems with interpretation (lack of statistical analysis, mean colony results, bee brood results etc.)
  - Representativeness of data to all authorised uses in the EU

Issues that could not be finalised

- Long-term risk on colony survival and development
- Risk to pollinators other than honey bees
- Risk to honey bees foraging pollen and nectar in succeeding crops
- Risk to honey bees foraging in honeydew
- Risk following the exposure to sublethal doses
- Risk following the exposure to guttation (except for thiamethoxam, acute risk)

The Conclusions



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CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

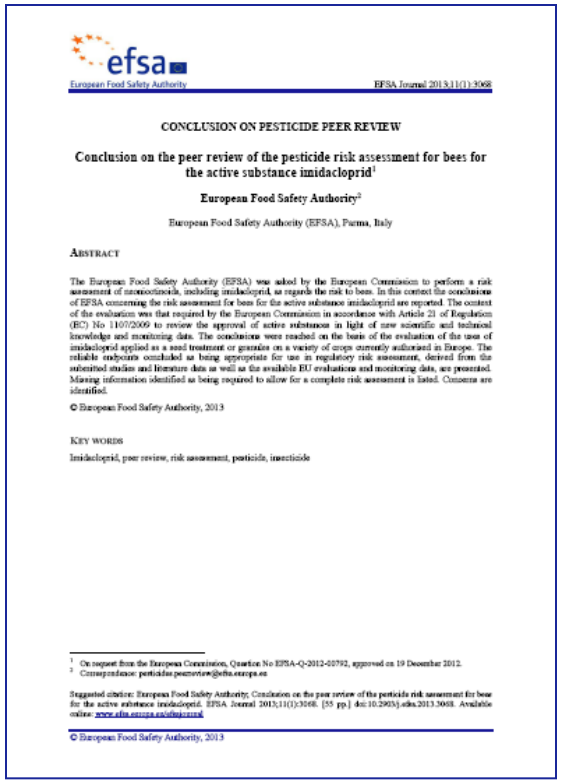
The European Food Safety Authority (EFSA) was asked by the European Commission to perform a risk assessment of neonicotinoids, including thiamethoxam, as regards the risk to bees. In this context the conclusions of EFSA concerning the risk assessment for bees for the active substance thiamethoxam are reported. The context of the evaluation was that required by the European Commission in accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data. The conclusions were reached on the basis of the evaluation of the uses of thiamethoxam applied as a seed treatment on a variety of crops currently authorised in Europe. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the submitted studies and literature data as well as the available EU evaluations and monitoring data, are presented. Missing information identified as being required to allow for a complete risk assessment is listed. Concerns are identified.

KEY WORDS

Thiamethoxam, peer review, risk assessment, pesticide, insecticide

[1] On request from the European Commission, Question No EFSA-Q-2012-00553, approved on 19 December 2012.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu

Suggested citation: European Food Safety Authority. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance thiamethoxam. EFSA Journal 2013;11(1):3067. [68 pp.] doi:10.2903/j.efsa.2013.3067. Available online: www.efsa.europa.eu/efsajournal



European Food Safety Authority EFSA Journal 2013;11(1):3068

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

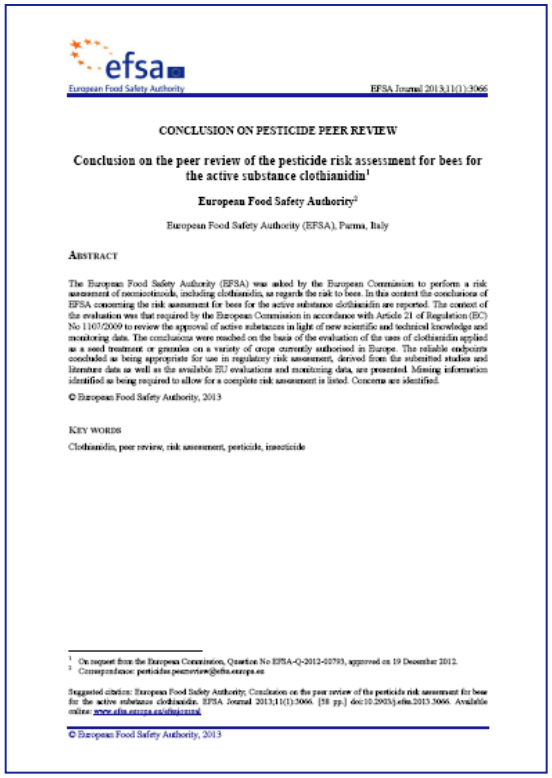
The European Food Safety Authority (EFSA) was asked by the European Commission to perform a risk assessment of neonicotinoids, including imidacloprid, as regards the risk to bees. In this context the conclusions of EFSA concerning the risk assessment for bees for the active substance imidacloprid are reported. The context of the evaluation was that required by the European Commission in accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data. The conclusions were reached on the basis of the evaluation of the uses of imidacloprid applied as a seed treatment or granules on a variety of crops currently authorised in Europe. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the submitted studies and literature data as well as the available EU evaluations and monitoring data, are presented. Missing information identified as being required to allow for a complete risk assessment is listed. Concerns are identified.

KEY WORDS

Imidacloprid, peer review, risk assessment, pesticide, insecticide

[1] On request from the European Commission, Question No EFSA-Q-2012-00792, approved on 19 December 2012.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu

Suggested citation: European Food Safety Authority. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance imidacloprid. EFSA Journal 2013;11(1):3068. [55 pp.] doi:10.2903/j.efsa.2013.3068. Available online: www.efsa.europa.eu/efsajournal



European Food Safety Authority EFSA Journal 2013;11(1):3066

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to perform a risk assessment of neonicotinoids, including clothianidin, as regards the risk to bees. In this context the conclusions of EFSA concerning the risk assessment for bees for the active substance clothianidin are reported. The context of the evaluation was that required by the European Commission in accordance with Article 21 of Regulation (EC) No 1107/2009 to review the approval of active substances in light of new scientific and technical knowledge and monitoring data. The conclusions were reached on the basis of the evaluation of the uses of clothianidin applied as a seed treatment or granules on a variety of crops currently authorised in Europe. The reliable endpoints concluded as being appropriate for use in regulatory risk assessment, derived from the submitted studies and literature data as well as the available EU evaluations and monitoring data, are presented. Missing information identified as being required to allow for a complete risk assessment is listed. Concerns are identified.

KEY WORDS

Clothianidin, peer review, risk assessment, pesticide, insecticide

[1] On request from the European Commission, Question No EFSA-Q-2012-00793, approved on 19 December 2012.
[2] Correspondence: pesticides.peerreview@efsa.europa.eu

Suggested citation: European Food Safety Authority. Conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin. EFSA Journal 2013;11(1):3066. [58 pp.] doi:10.2903/j.efsa.2013.3066. Available online: www.efsa.europa.eu/efsajournal

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Conclusion (1)

- For many of the authorised uses, EFSA did not have enough data available in order to finalise the risk assessment or the data were not sufficient (according to the new criteria). For instance not enough information :
  - ✓ on dust release
  - ✓ on concentration in pollen and nectar
  - ✓ on guttation frequency and use of guttation fluid as a source of water
  - ✓ limited information on other pollinators
- EFSA listed all data gaps, and gave an indication of the uncertainties associated to the risk assessment

Conclusion (2)

- EFSA has summarised the outcome of the evaluations in tables; this outcome can be:
  - ✓ sufficient data was available to perform a risk assessment, and the outcome of this assessment was that a risk is identified.
  - ✓ the risk assessment could not be finalised, because there were no, or not enough data to perform the risk assessment, or because there is no agreed risk assessment scheme available
  - ✓ the risk assessment could be finalised, and no risk was identified

Conclusion (3)

- **Exposure from pollen and nectar**: only uses on crops not attractive to honey bees were considered as presenting a low risk
- **Exposure from dust**: a risk to honey bees was indicated or could not be excluded, with some exceptions, such as use on sugar beet and crops planted in glasshouses, and for the use of some granules
- **Exposure from guttation**: the only risk assessment that could be completed was for maize treated with thiamethoxam. In this case, field studies show an acute mortality effect on honey bees exposed to the substance through guttation fluid

Questions?

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