

EFSA Conclusions on the Peer Review of the Pesticide Risk Assessment for Bees for the Active Substance Thiamethoxam: Syngenta Overview of EFSA Conclusions

On behalf of the European Commission, the European Food Safety Authority (EFSA) conducted a risk assessment for bees from the use of imidacloprid, clothianidin, and thiamethoxam seed treatment and granular products on a variety of crops. These assessments were based on the “EFSA Scientific Opinion on the science behind the development of a risk assessment of plant protection products on bees”, published in 2012. This opinion is the current scientific basis for the development of a new EFSA “Guidance document on the risk assessment of Plant Protection Products on bees”, for use by notifiers and regulatory authorities in the context of the review and approval of plant protection products (PPPs) and their active substances under Regulation (EC) 1107/2009.

However, the completion of this new bee guidance document has been delayed until March 2013, in order to allow EFSA to consider the many hundreds of comments received during the consultation period and the need to revise the document accordingly. This enforced delay shows that the EFSA’s theoretical approach on bee risk assessment, utilized for the neonicotinoid reviews, is still very far from being accepted or complete. In addition, existing and legally valid risk assessment and testing schemes such as EPPO 170 are not being considered.

Assessments were conducted for exposure to dust and systemic residues in nectar, pollen and guttation droplets. In addition, exposure via honeydew, systemic residues from succeeding crops, and the risk to non-*Apis* pollinators were also discussed.

In summary, the EFSA conclusions for thiamethoxam are as follows:

- For dust exposure from seed treatment products, risks are concluded for cereals, cotton, maize and oilseed rape (OSR). Data gaps were considered in other crops and only sugar beet was considered safe. Risk mitigation measures and progress related to seed treatment quality and sowing machinery, which are already in place at MS level, were acknowledged by EFSA in principle but not taken into consideration for the risk assessment.
- A data gap was identified for risk to bees from systemic residues in nectar and pollen for all flowering, bee-attractive crops. However, EFSA concluded that a further analysis of the existing data might address this data gap. EFSA acknowledged Syngenta’s state of the art long-term field studies investigating 4 years’ consecutive exposure of bees to Thiamethoxam seed-treated flowering OSR, which had no effect on honeybee colonies.
- Guttation is also concluded as a potential risk and data gaps are concluded for all uses in all crops.
- EFSA suggests that only limited information is available for non-*Apis* pollinators, honeydew as an exposure pathway, and systemic residues in succeeding crops; therefore data gaps are concluded here for all uses.

Beyond these points, data from a few monitoring projects are discussed, but they only seem to have been considered where they substantiate a potential concern and not where no effect on honeybees colonies was reported, eg for the French regulatory authority maize dust monitoring programme in 2008-2011.

EFSA concludes that the critical areas of concern for thiamethoxam are: a high acute risk to honey bees from dust in cereals, cotton, oilseed rape (except for uses with the lowest application rate authorised in the EU), maize, and sunflowers (except for uses with the lowest application rate authorised in the EU); and a high acute risk for exposure via guttation fluid for the authorised uses in maize. However, there is no interpretation provided by EFSA as to the acceptability of these reported risks.

For both of these critical areas of concerns (dust and guttation), Syngenta has just completed an additional field testing programme on thiamethoxam seed-treated maize in France, which reported no effect on bee colonies from exposure to both dust during drilling and exposure to guttation. This field programme investigated 19 treatment sites and 3 control sites. Syngenta believes that it will provide more reassuring field-based evidence to address EFSA's concerns in these critical areas.

In addition, a very recent study by the University of Hohenheim concluded that the guttation of OSR was not a relevant risk for bees. We would be grateful for advice on how this new field data and the public data could be integrated into the EFSA thiamethoxam review.

Not surprisingly, when measured against the untested science standards set out in the "EFSA Opinion on the science behind the development of a risk assessment of plant protection products on bees", there were data gaps concluded for nearly all registered uses of thiamethoxam. It is both scientifically and procedurally wrong to claim these as data gaps since the science standards used for both the neonicotinoid reviews and the current draft of the new bee guidance document are still under review and considered at least debatable and at most highly controversial.

The large number of data gaps identified in the EFSA review incorrectly infers that the industry has been negligent and has ignored risk, when in fact the companies have been working closely with Member State authorities to address any new risks identified, fill any data gaps and comply with the requests that authorities have made.

In conclusion: EFSA performed an evaluation of available regulatory data on bees and thiamethoxam based on the scientific opinion, as mandated by the Commission. EFSA has taken an extremely critical and highly conservative approach to this data, to such an extent that it admits that a guidance document would have been a more suitable document for such a process. It appears that even minor, open points have invalidated comprehensive data sets, and overall evidence that suggests the absence of health impacts also appear to have been disregarded.

Even in areas where there is no hint of the existence of a health impact, data gaps have been concluded simply because no established testing and risk assessment procedures existed for the respective aspects. Practically all available higher-tier studies were factually invalidated, or considered not relevant for the risk assessment partly on the basis of what appear to be arbitrary criteria. Evaluation was focused on individual

studies and their potential shortcomings, and overall evidence was not taken into consideration.

It is hard to see how this EFSA review document will help the Commission and the Member States to develop pragmatic measures to optimize the protection of bees, whilst allowing the invaluable use of seed treatment technology to European farmers.

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