# Making sense of the recent EFSA reports on neonicotinoids: What do they really say?


Executive Summary

On February 28, 2018, the European Food Safety Authority (EFSA) published three long-awaited reports concerning their bee risk assessment for the three neonicotinoids imidacloprid, clothianidin, and thiamethoxam as seed treatments and granules.

**A conclusion of high risk was reached for only 5% of more than 500 scenarios** taken through EFSA's tiered risk assessment process. None of these cases involved honey bees. Yet, the results were announced as "Neonicotinoids: risks to bees confirmed", and "Most uses of neonicotinoid pesticides represent a risk to wild bees and honeybees, according to assessments published today by EFSA".

In fact, where EFSA could draw a definitive risk conclusion, **only low risks were found for honey bees**; additionally, while a high risk was found in 19% of the scenarios assessed for bumble bees, and in 1% of those assessed for solitary bees, risk was found to be low in the majority of cases. One risk scenario that is repeatedly highlighted as a potential risk by EFSA is risk from succeeding crops, however, simple mitigation measures could be applied (e.g. only allowing bee unattractive crops to be sown in rotation) that would avoid exposure and remove this risk. So, what EFSA's risk assessment conclusions really suggest is that **relatively few use patterns pose a clear high risk to bees even under the extremely conservative evaluation criteria of EFSA and in these cases mitigation, a common practice in the use of crop protection products, can avoid exposure.** At least most agricultural uses of these products should therefore be eligible for continued registration.

**EFSA's assessment follows the "Bee Guidance Document"** which lays down an approach for carrying out a pollinator risk assessment. Several of its study requirements are not feasible due to a lack of validated study methods, which in turn impacts the outcome of an assessment: **in the absence of data or without clear confirmation of low risk EFSA's conclusion will always be that there is a risk**; and this is the inherent flaw of the document. Applied consistently, this could result in a denial of registration for most crop protection products, including those used in organic agriculture. In light of this, the neonicotinoids actually stood up to the assessment fairly well – which is more in line with the outcomes of risk assessments from other highly regarded authorities.

## 1. Background

On February 28, 2018, the European Food Safety Authority (EFSA) published three long-awaited reports concerning their bee risk assessment for the three neonicotinoids imidacloprid, clothianidin, and thiamethoxam.

EFSA performed this risk assessment on request of the European Commission, and as a follow-up of previous mandates received from the European Commission.

The conclusions were reached based on:

- the evaluation of uses as an insecticide applied as seed treatments and granules
- the new relevant data collected in the framework of the open call organised by EFSA
- and the updated literature review performed by EFSA.

EFSA applied the (draft) bee guidance document developed by EFSA specifically for the risk assessment of pesticides and bees.

Exposure of bees to the substances was assessed via three routes: residues in pollen and nectar of crops; dust drift during the sowing of the treated seeds; and water consumption. Possible risks were evaluated for honey bees, bumble bees and solitary bees.

## 2. Results of the Risk Assessment

The results of the pollinator risk assessments were announced by EFSA as “Neonicotinoids: risks to bees confirmed”, and “Most uses of neonicotinoid pesticides represent a risk to wild bees and honeybees, according to assessments published today by EFSA”.

Numerous media and NGOs subsequently repeated EFSA’s message that neonicotinoid risks to bees “have been confirmed”. The clear message delivered to the public, the scientific community and stakeholders such as beekeepers and farmers was that a comprehensive scientific analysis showed that use of these three neonicotinoids poses a risk to bees.

What do the EFSA conclusions really show?

**A conclusion of high risk was reached for only 5% of more than 500 scenarios** taken through EFSA’s tiered risk assessment process (none of these cases involved honey bees); i**n 70% of the cases where a final risk conclusion could be reached, EFSA concluded a low risk; in 25% of cases a conclusion of uncertain risk was reached.**

A more accurate representation of EFSA’s conclusions could have been that where a definitive risk conclusion could be drawn, only low risks were found for honey bees; additionally, while a high risk was found in 19% of the scenarios assessed for bumble bees, and in 1% of those assessed for solitary bees, risk was found to be low in most cases.

In the bumble bee scenarios for imidacloprid, where risk was found only on succeeding crops, a simple mitigation measure could be avoiding the use on flowering crops the season after use in cereals or sugar beet.

Therefore, what EFSA's risk assessment conclusions really suggest is that even under the extremely conservative criteria of EFSA relatively few use patterns pose a high risk to bees, something that was confirmed independently by Professor Lin Field at Rothamsted Research in the UK. At least most agricultural uses of these products should therefore be eligible for continued registration.

Analysis by active substance

| Neonicotinoid | | | Final EFSA Assessment | | | |
|---|---|---|---|---|---|---|
| | Initial Risk Assessments | Finalized Risk Assessments | Low Risk | Uncertain Risk | High Risk | High Risk Identified Only For |
| **Imidacloprid** | 378 | 153 | 88% | 0% | 12% | Bumble bees in succeeding crops |
| **Clothianidin** | 684 | 239 | 45% | 53% | 2% | Bumble bees in case of oilseed rape seed treatment |
| **Thiamethoxam** | 324 | 121 | 94% | 4% | 1% | Solitary bees in case of oilseed rape seed treatment |

## 3. Understanding EFSA's risk assessment approach

What is the tiered approach?

As other risk assessment systems too, EFSA applies a three-tiered process for its pollinator risk assessments:

- Tier 1 screens out use scenarios that pose a low risk based on laboratory tests.
- The remaining use scenarios undergo a more refined assessment in Tier 2 and Tier 3. These tiers make use of evidence obtained from specialized laboratory experiments, semi-field tests, field residue trials and field effect studies.

**In EFSA's approach the tiered process loses its value because the trigger values are excessively conservative.** In practice, this means that most uses "fail" the Tier 1 assessment – i.e. both products which have an inherent risk and products which are intrinsically harmless. If all of them require complex higher tier studies, this will not only make the exercise incredibly more complex, it also diverts attentions from those uses that may represent a potential concern.

A risk assessment can come to the following conclusions:

- (1) risk is low,
- (2) risk is high (above a regulatory level of concern), or,
- (3) risk is uncertain, meaning that evidence is insufficient to show the risk is low, nor is it sufficient to confirm that it is high.

**While a conclusion of low or *de minimis* risk can be reached in lower tier assessments, confirmation of a risk of concern can only be made after completion of a highly refined Tier 3 assessment.**

EFSA defines a risk of concern as when there is an impact greater than 7 % on bee colonies or populations existing at the edge of treated fields subject to at least 90$^{th}$ percentile exposure levels for the use under consideration. Thus, to conclude there is a low risk, the evidence would have to show that effects are below the level of concern (i.e. less than 7 %) under near worst-case field conditions (i.e. when residue levels which the bees are exposed to are at the 90$^{h}$ percentile or higher).

However, research shows that natural fluctuations in honey bee colony strength due to natural colony dynamics, weather conditions or forage availability, for example, are often much higher. Practically it is impossible to show that honey bee colony strength variability greater than 7% was not due to pesticide use on a crop.

Why are there only so few higher tier conclusions in EFSA's assessment?

There are fewer scenarios evaluated at higher tier because **EFSA's requirements for higher tier testing studies are so demanding that many studies do not fulfill them or they could not be performed.** For example: a single honey bee field study requires field testing areas exceeding the land size of Malta.

Further to that, for some species (e.g. for solitary bees and bumble bees) higher tier studies cannot be performed (or evaluated) as there are no protocols or criteria for how to evaluate the studies. Uncertainties in such studies, e.g. high variability in queen production in bumble bees, render the interpretation impossible.

It is also not possible to perform a higher tier study for every crop. In such a case, unless the evaluator agrees to "read across" between the different crops, a higher tier evaluation cannot be performed. An example is mustard, for which no specific studies are available. Since the crop is virtually identical to spring oilseed rape a read-across could easily be done. However, EFSA treated them as two separate crops.

Finally, some additional higher tier evaluations could have been performed if EFSA had used all available studies, for example the dust drift studies which were judged to be reliable, but were still rejected.

**This is why as a result, EFSA could come to a final risk conclusion only for 513 out of the 1095 assessed scenarios.**

Is EFSA's approach in line with other risk assessment approaches?

No. Other authorities have followed different risk assessment approaches and principles and have come to different risk conclusions regarding the three neonicotinoids – for example the American Environmental Protection Agency (EPA), or the Canadian Pest Management Regulatory Agency (PMRA).

EFSA's assessment follows the "Bee Guidance Document" which lays down an approach for carrying out a pollinator risk assessment, i.e. which studies are required for which species and in which tiers, and at what point higher tier studies need to be included. Several of them are not feasible, for example due to a lack of validated study methods, which in turn impacts the outcome of an assessment: in the absence of data or without clear confirmation of low risk, the conclusion will always be that there is a risk – following the application of the precautionary principle.

In the US EPA system, for example, Tier 1 is a screening assessment that evaluates potential risk to individual bees by comparing results of laboratory tests with individual adult and larval honey bees and assumed exposure levels for the application rate and method. In Tier 2, field-measured residues are used in place of the assumed exposure levels, and results of tests with colonies of bees are used in place of the tests with individual bees. In Tier 2 assessments, most seed and soil applications of neonicotinoids pass the regulatory criteria for acceptable risk because measured exposure levels are found to be below levels that cause effects at the honey bee colony level. Foliar neonicotinoid applications more frequently do not "pass" acceptability criteria at Tier 2, and may require risk mitigation, for example by restricting the timing of applications to ensure only low residues occur in pollen and nectar during bloom. In the North American system, Tier 3 field studies are reserved for rare cases where additional field data are needed to resolve uncertainty about the level of risk. To date, field studies have been used by EPA mainly as an additional line of evidence.

One key difference between the EFSA and EPA approaches occurs at Tier 2, when EPA shifts from a dose-based assessment of risk to individual bees to a concentration-based assessment of risk to colonies of bees. Dose-based risk assessments make overly simplistic, worst-case assumptions about food intake rates, metabolism and detoxification abilities. Comparing concentrations measured in the field to concentrations shown to cause effects in colony-level experiments is a direct, practical approach that is more realistic of what happens if a bee colony is present in or near a field application site. Another difference is that EPA has not yet accepted testing protocols with bumble bees and solitary bees as being robust enough for regulatory use, and so they don't attempt formal risk assessments for these species. Finally, EFSA assessments rely to a much greater extent on the capability of field studies to show that a risk of concern does not occur in the field. EPA relies on field studies to provide measurements of exposure (residue levels) but not to estimate risk directly.

This explains why the outcomes of EFSA's pollinator risk assessment come to conclusions which diverge from those of the US EPA.

**Appendix:**

1) Overview of EFSA's assessment of the three neonicotinoids

EFSA evaluated pollinator risk of:

- 21 uses of imidacloprid-based products,
- 38 uses of clothianidin-based products,
- and 18 uses of thiamethoxam-based products.

**A total of 1386 possible compound-species product use-exposure route scenarios were assessed.** This included consideration of:

- 616 possible cases for honey bees,
- 385 cases for bumble bees
- and 385 cases for solitary bees.

Of these 1386 possible cases, no assessment could be made for 291 because data were lacking or the exposure route was deemed irrelevant. **That left 1095 cases where at least a Tier 1 assessment was performed.**

2) Analysis by tier

For the 1095 cases, the Tier 1 assessment screened out 329 (30%) of these scenarios as posing a clear low risk. Tier 2 assessments screened out an additional 6 scenarios as posing a clear low risk. Data were available to evaluate 178 of the remaining scenarios at the Tier 3 level. Of these, 22 were concluded to pose a clear low risk, 24 were concluded to pose a clear high risk, and 132 were concluded to pose an uncertain risk (meaning that a risk above a level of concern could neither be refuted nor confirmed).

**Therefore, EFSA's assessment for three neonicotinoids evaluated 513 scenarios in which a final risk conclusion could be reached:**

- with 329 of these conclusions reached in Tier 1,
- 6 in Tier 2,
- and 178 in Tier 3.

In 70% of these cases, a conclusion of low risk was reached. In 5% of these cases, a conclusion of high risk was reached. In 25% of these cases a conclusion of uncertain risk was reached.

The only cases where a high-risk conclusion was reached by EFSA's Tier 3 assessment were for bumble bees at clothianidin-seed-treated oil seed rape, solitary bees for thiamethoxam seed-treated winter oil-seed rape, and for bumble bees at succeeding crops after imidacloprid

applications. There were no cases where a high risk was confirmed for honey bees by a Tier 3 assessment.

3) Analysis per active substance

**Imidacloprid**

Eight exposure scenarios for honey bees, 5 exposure scenarios for bumble bees and 5 exposure scenarios for solitary bees were considered for each of 21 product uses. Therefore, there was a possible total of (8 + 5 + 5) x 21 = 378 different risk evaluations. For 66 of these cases, the exposure scenario was either considered not relevant for the species or use, or no data were available to complete the assessment. That left 312 cases where at least a Tier 1 assessment was performed.

For the 312 cases the Tier 1 assessment screened out 113 (36%) of these scenarios as posing a clear low risk. Tier 2 assessments did not screen any additional scenarios as posing a clear low risk. Data were available to evaluate 40 of the remaining scenarios at the Tier 3 level. Of these, 21 (53%) scenarios were concluded to pose a clear low risk, and 19 (48%) were concluded to pose a clear high risk.

For 153 scenarios a final risk conclusion could be reached.

- **In 88% of these scenarios, a conclusion of low risk was reached.**
- In 12% of these scenarios, a conclusion of high risk was reached.
- In none of these cases was a conclusion of uncertain risk reached.

All 19 cases where a high risk was confirmed by EFSA's Tier 3 assessment were for bumble bee exposure in succeeding crops, rather than for the crop to which the product was initially applied. **There were no cases where a high risk was confirmed for honey bees or solitary bees.**

**Clothianidin**

Eight exposure scenarios for honey bees, 5 exposure scenarios for bumble bees and 5 exposure scenarios for solitary bees were considered for each of 38 product uses. Therefore, there was a possible total of (8 + 5 + 5) x 38 = 684 different risk evaluations. For 139 of these cases, the exposure scenario was either considered not relevant for the species or use, or no data were available to complete the assessment. That left 545 cases where at least a Tier 1 assessment was performed.

For the 545 cases, the Tier 1 assessment screened out 102 (19%) of these scenarios as posing a clear low risk. Tier 2 assessments screened out an additional 6 scenarios as posing a clear low risk. Data were available to evaluate 131 of the remaining scenarios at the Tier 3 level. Of these, 4 (3%) scenarios were concluded to pose a clear high risk, and 127 (97%) were concluded to pose an uncertain risk (meaning that a risk above a level of concern could neither be refuted nor confirmed). None of the Tier 3 assessments concluded the scenario posed a clear low risk.

In 239 scenarios a final risk conclusion could be reached.

- **In 45% of these scenarios, a conclusion of low risk was reached.**
- In 2% of these scenarios, a conclusion of high risk was reached.
- In 53% of these scenarios, a conclusion of uncertain risk was reached.

All four of the cases where a high risk was confirmed by a Tier 3 assessment were for bumble bee exposure to clothiandin when used as a seed treatment in oilseed rape. **There were no cases where a high risk was confirmed for honey bees or solitary bees.**

**Thiamethoxam**

Eight exposure scenarios for honey bees, 5 exposure scenarios for bumble bees and 5 exposure scenarios for solitary bees were considered for each of 18 product uses. Therefore, there was a possible total of (8 + 5 + 5) x 18 = 324 different risk evaluation cases. In 86 of these cases, the exposure scenario was either considered not relevant or data were insufficient to do an assessment. That left 238 cases where at least a Tier 1 assessment was performed.

For the 238 cases, the Tier 1 assessment screened out 114 (48%) of these scenarios as posing a clear low risk. Tier 2 assessments did not screen any additional scenarios as posing a clear low risk. Data were available to evaluate 7 of the remaining scenarios at the Tier 3 level. Of these, 1 (14%) scenario was concluded to pose a clear low risk, 1 (14%) was concluded to pose a clear high risk, and 5 (71%) were concluded to pose an uncertain risk (meaning that a risk above a level of concern could neither be refuted nor confirmed).

In 121 scenarios a final risk conclusion could be reached.

- **In 95% of these cases, a conclusion of low risk was reached.**
- In 1% of these cases, a conclusion of high risk was reached.
- In 4% of these cases was a conclusion of uncertain risk reached.

The only case where a high risk was confirmed by EFSA's Tier 3 assessment was for solitary bees exposed to seed-treated winter oil-seed rape. **There were no cases where a high risk was confirmed for honey bees or bumble bees.**