## CONCLUSION ON PESTICIDE PEER REVIEW

# Conclusion on the peer review of the pesticide risk assessment of post-approval data submitted for the active substance thiamethoxam[1]

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## SUMMARY

Thiamethoxam was included in Annex I to Directive 91/414/EEC on 1 February 2007 by Commission Directive 2007/6/EC[3], and has been deemed to be approved under Regulation (EC) No 1107/2009[4], in accordance with Commission Implementing Regulation (EU) No 540/2011[5], as amended by Commission Implementing Regulation (EU) No 541/2011[6].

The specific provisions of the approval were amended by Commission Directive 2010/21/EU[7], to permit use as a seed treatment only where the seed coating is performed in professional seed treatment facilities, which must apply the best available techniques to ensure that the release of dust during application to the seed, storage and transport can be minimised, and where adequate drilling equipment is used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.

In January 2010 the European Commission received new studies on honeybees from the notifier, Syngenta, which were evaluated by the designated rapporteur Member State (RMS), Spain, in the form of an Addendum to the Draft Assessment Report. The European Commission distributed the Addendum to Member States and the EFSA for comments on 1 July 2011. The RMS collated all comments in the format of a Reporting Table, which was submitted to the Standing Committee on the Food Chain and Animal Health (SCFCAH) in September 2011.

Following consideration of the comments received, and the further discussions in the SCFCAH, the Commission requested the EFSA to organise a peer review of the RMS's evaluation of the new data and to deliver its conclusions on the risk assessment for honeybees.

The conclusions laid down in this report were reached on the basis of the evaluation of the studies submitted, which were conducted with the use of thiamethoxam applied as a seed treatment on maize seeds.

The modification of sowing machines with deflectors was demonstrated to potentially be a useful tool to reduce dust drift and therefore to reduce the exposure of the off-crop areas. However, on the basis

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1 On request from the European Commission, Question No EFSA-Q-2011-01167, approved on 20 February 2012.

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3 OJ L 43, 15.2.2007, p. 13

4 OJ L 309, 24.11.2009, p.1

5 OJ L 153, 11.6.2011, p.1

6 OJ L 153, 11.6.2011, p.187

7 OJ L 65, 13.3.2010, p.27

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of the available data, it was not possible to quantify the effectiveness of the deflectors, or to perform a quantitative risk assessment. Based on the available data, significant exposure of bees (or other pollinators), even if a deflector is used, cannot be excluded.

**KEY WORDS**

Thiamethoxam, peer review, risk assessment, pesticide, insecticide

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## BACKGROUND

Thiamethoxam was included in Annex I to Directive 91/414/EEC on 1 February 2007 by Commission Directive 2007/6/EC[8], and has been deemed to be approved under Regulation (EC) No 1107/2009[9], in accordance with Commission Implementing Regulation (EU) No 540/2011[10], as amended by Commission Implementing Regulation (EU) No 541/2011[11]. The peer review leading to the approval of this active substance was finalised in 2003, and therefore EFSA has not previously been involved in the evaluation of this active substance.

The specific provisions of the approval were amended by Commission Directive 2010/21/EU[12], to permit use as a seed treatment only where the seed coating is performed in professional seed treatment facilities, which must apply the best available techniques to ensure that the release of dust during application to the seed, storage and transport can be minimised, and where adequate drilling equipment is used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.

In January 2010 the European Commission received new studies on honeybees from the notifier, Syngenta, which were evaluated by the designated rapporteur Member State (RMS), Spain, in the form of an Addendum to the Draft Assessment Report (Spain, 2011). The European Commission distributed the Addendum to Member States and the EFSA for comments on 1 July 2011. The RMS collated all comments in the format of a Reporting Table, which was submitted to the Standing Committee on the Food Chain and Animal Health (SCFCAH) in September 2011.

Following consideration of the comments received, and the further discussions in the SCFCAH, the Commission decided to further consult the EFSA. By written request, received by the EFSA on 11 November 2011, the Commission requested the EFSA to organise a peer review of the RMS's evaluation of the new data, and to deliver its conclusions on the risk assessment for honeybees.

The Addendum and the Reporting Table were discussed at the Pesticides Peer Review Experts' Meeting on ecotoxicology in December 2011. Details of the issues discussed, together with the outcome of these discussions were recorded in the meeting report. Following the meeting a further addendum was prepared by the RMS (Spain, 2012).

A final consultation on the conclusions arising from the peer review of the risk assessment for honeybees took place with Member States via a written procedure in February 2012.

The conclusions laid down in this report were reached on the basis of the evaluation of the studies submitted, which were conducted with the use of thiamethoxam applied as a seed treatment on maize seeds. In addition, a key supporting document to this conclusion is the Peer Review Report, which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the compilation of comments in the Reporting Table to the conclusion. The Peer Review Report (EFSA, 2012) comprises the following documents:

- the Reporting Table,
- the report of the scientific consultation with Member State experts,
- the comments received on the draft EFSA conclusion.

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8 OJ L 43, 15.2.2007, p. 13
9 OJ L 309, 24.11.2009, p.1
10 OJ L 153, 11.6.2011, p.1
11 OJ L 153, 11.6.2011, p.187
12 OJ L 65, 13.3.2010, p.27

Given the importance of the Addenda and the Peer Review Report, these documents are considered respectively as background documents A and B to this conclusion.

## CONCLUSIONS OF THE EVALUATION

The information evaluated in the addenda consisted of six field studies addressing the potential exposure of off-crop areas to dust, two studies (a semi-field and a laboratory) considering the toxicity of contaminated dust, and three monitoring studies.

Studies to assess exposure

In all of the six field studies treated maize seeds were sown in small plots (0.32 – 1.0 ha) and the dust deposition was captured and quantified at the neighbouring downwind area. For the quantification of the dust drift, in most of the cases, Petri-dishes with sorbents were placed at ground level at different distances from the edge of the treated field and subsequently analysed for thiamethoxam residues. In one study, similar measurements were done at canopy level of flowering oilseed rape at the edge of the field, as well as residue analysis of whole plant samples from the field. Some additional measurements were also available (e.g. residue analysis of the fan exhaust of the driller, investigation of the dust deposition during the filling of seed hoppers), which confirmed the potential contamination of the environment via dust drift during the sowing operation.

In several trials the sowing machine was equipped with a deflector, while in other trials the machine was unmodified. The exhaust that may contain the dust abraded from the seeds will be emitted at a certain height from the pneumatic machines when no deflector is used. Deflector mode is when the fan exhaust of the pneumatic system is redirected to soil level. When a deflector is used, it is expected that the solid particles will travel shorter distances reducing the exposure of the off-crop areas. Indeed, the results of the field trials (average residues on the Petri-dishes at soil level) indicated that the depositions on the off-crop areas were significantly lower (about an order of magnitude) when a deflector was used. This initial conclusion was however based on only the average values of the measurements from the six studies with different conditions. It was also noted that some individual values significantly deviated from others and from the general trends, indicating the large variability of the data (including some overlap of residue values measured with and without a deflector) that made the interpretation of the results difficult.

The studies and the results were discussed at the Pesticides Peer Review Experts' Meeting 89. Some shortcomings (e.g. small plot size) were noted, however, the meeting agreed that the field trials were useful. It was agreed that several factors of the trials could influence the rate of dust drift and the effectiveness of the deflector. The role and the importance of these parameters were therefore discussed. These factors were the following: formulation type, presence of co-formulants, seed loading, abrasiveness of the treated seeds, drilling rate, method of drilling, drilling equipment, plot size, soil type, soil conditions, wind direction and weather conditions, and type of deflector. The available data did not allow a comprehensive comparison and assessment of the significance of these parameters between the studies. It was also noted that some of the parameters are inter-related and hence not independent. Therefore the meeting considered two studies in closer detail. These studies were selected as they contained results from plots sown with a deflector and from plots sown without a deflector, and therefore it was considered that the impact of the other parameters would be minimised. Since the raw data for only one of the two studies were available for the meeting, only that study was further considered. On the basis of that study, the experts concluded that deflectors had the potential to reduce dust drift when drilling seeds. However, on the basis of this single study, it was not possible to quantify the amount of reduction. The experts agreed that there was a need for further statistical analysis before further conclusions could be drawn. It was noted that there has been much work in the area of dust drift and that some of these additional data (outside of the scope of these assessments) indicated that up to 90% reduction could be achieved by the use of deflectors, which seemed to be in line with the findings in the study considered, however these additional data could not be validated by the experts at the meeting.

Regarding the second study where dust drift was studied with or without using deflectors, more data and data analysis (ranges and extreme values) became available after the meeting. Considering these data, a clear trend could be observed demonstrating that the use of deflectors substantially reduced the contamination of off-crop areas. However it was also apparent, as for the previous study, that the residues were variable and therefore the presence of 'hot spots' cannot be excluded. It seemed to be also likely that the deposition pattern of dust in terms of distance is not as evenly distributed and homogeneous as the spray drift for sprayed products. The available data set was however rather small and no measurements were done closer than 3 meters or further than 50 meters from the edge of the treated field.

Regarding the other factors that may influence the dust formation, the experts noted that the dust already present on the seeds before coating and the quality of the seed dressing are considered to be important. The dust emission during the filling of the seed hoppers could be mitigated through farming practices and user education.

Studies to assess effects

In a laboratory study the oral and contact toxicity of thiamethoxam was studied in dose-response tests. In the oral tests honeybees were fed with contaminated dust or with a formulation of a spray product in sugar solution. In the contact tests honeybees were forced to be in contact with treated cherry leaves. Again contaminated dust or a spray product was used for the preparation of the plant leaves. From the results of this study, under laboratory conditions, it was concluded that the toxicity of thiamethoxam via exposure to contaminated dust or a spray product was comparable.

The potential effects of contaminated dust were also studied in a semi-field trial where honeybees (small colonies confined in meshed tunnels) foraged on treated *Phacelia*. Beside the controls, three thiamethoxam treated groups were studied. One was treated with dust equivalent to 1.0 g a.s./ha, another treated with dust equivalent to 5.0 g a.s./ha, and another where spray application was done that was equivalent to 5.0 g a.s./ha. The dust applications over the flowers were done by hand. The experts noted that the study had some limitations, however, generally it was considered to be useful. An apparent increase in mortality in the dust treatments compared with the control indicated that thiamethoxam applied as a dust at either 1 g/ha or 5 g/ha can result in the mortality of honeybees. The experts noted that it seemed that the effect of dust exposure was longer lasting in comparison to the foliar spray. With regard to flight intensity or brood development, clear evidence of an effect due to the dust applications was not apparent. It was however noted that rainfall was recorded the day after applications and on subsequent days. This could have reduced the exposure and thus the extent of the observed effects. Thiamethoxam residues were found in pollen samples from the dust treated groups (up to 0.015 mg/kg or 0.023 mg/kg) as well as in the spray application group (up to 0.028 mg/kg).

Risk assessment

The meeting agreed that, on the basis of the available information, a quantitative risk assessment was not possible due to uncertainties with both the exposure and toxicity studies. It was noted that the residue values from Petri-dishes cannot directly be compared with the potential exposure of the bees since they are exposed in a more complex three-dimensional compartment during foraging on flowering plants. Moreover, the available trigger value has only been validated for foliar spray applications. There was, however, agreement that honeybee colonies were adversely affected when foraging in fields that had been contaminated with a dust drift equivalent to 5.0 g thiamethoxam/ha. Consensus was not reached regarding the dust contamination at 1.0 g thiamethoxam/ha.

Overall, a tentative risk assessment can be performed considering the available information. The dust contamination of the off-crop area following the use of a deflector can be as high as approximately

0.41 g/ha (based on the highest individual residue values in the two studies considered in detail). This figure is in the same order of magnitude as the lower dose (1.0 g thiamethoxam/ha) that was applied in the semi-field study, which resulted in notable mortality. However it should be borne in mind that this calculation is based on an extreme value and, as discussed above, the residues in a two dimensional measurement (Petri-dish at soil level) cannot be directly extrapolated to a more realistic exposure pattern. Equally, it should be noted that only a limited data set was available for the exposure and did not include measurements closer than 3 meters to the treated area.

Monitoring studies

Some reports concluded that the modification of the sowing machines with deflectors reduced the dust drift. Short summaries of the monitoring studies are included in Appendix A of this conclusion.

## PARTICULAR CONDITIONS PROPOSED TO BE TAKEN INTO ACCOUNT TO MANAGE THE RISK(S) IDENTIFIED

- The modification of the sowing machines with deflectors was demonstrated to be a potentially useful tool to reduce dust drift, and therefore the exposure of the off-crop areas, even though on the basis of the available data it was not possible to quantify the degree of effectiveness.

## REFERENCES

EFSA (European Food Safety Authority), 2012. Peer Review Report to the conclusion regarding the peer review of the pesticide risk assessment of the active substance thiamethoxam.

Spain, 2011. Addendum to the assessment report on the active substance thiamethoxam prepared by the rapporteur Member State Spain in the framework of Directive 91/414/EEC, September 2011.

Spain, 2012. Addendum to the assessment report on the active substance thiamethoxam prepared by the rapporteur Member State Spain in the framework of Directive 91/414/EEC, January 2012.

## APPENDICES

### APPENDIX A – LIST OF END POINTS FOR THE ACTIVE SUBSTANCE AND THE REPRESENTATIVE FORMULATION

**Section 3: Ecotoxicology**

### Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

| Test substance | Acute oral toxicity $LD_{50}$ (48 h) | Acute contact toxicity $LD_{50}$ (72 h)[1] |
|---|---|---|
| a.s. | - | - |
| dust from A9700B (7.24 % thiamethoxam) | 9.36 ng a.s./bee | 13.26 g a.s./ha |
| Actara (25.2 % thiamethoxam) | 6.31 ng a.s./bee | 5.55 g a.s./ha |
| Field or semi-field tests | | |
| - Six field studies addressing the potential exposure of off-crop areas to dust. The maximum average deposition values at 3-5 m distance were between 0.63 – 1.12 % of that applied when no deflector was used. These values were between 0.04 - 0.57 % (3-10 m) when a deflector was used.<br>- In a semi-field study *Phacelia* was treated with dust equivalent to 1.0 g a.s./ha or 5.0 g a.s./ha. In a further treatment group spray application was done equivalent to 5.0 g a.s./ha. In all the three treatment groups increased mortality of honeybees compared to the control was observed. Clear effects on the brood development were not recorded. | | |
| Monitoring studies | | |
| France, 2008-2009<br>Health of bee colonies and exposure due to dust emission were monitored in six French regions with high density of maize fields treated with thiamethoxam (seed dressing with Cruiser). No mortality, sublethal effects or any health problem could be linked with the use of thiamethoxam. Thiamethoxam residues were found in maize pollen samples from the treated plots. The use of deflectors was found to be effective to reduce dust dispersion.<br>Switzerland, 2009<br>The results of the studies indicated that residues of clothianidin (metabolite of thiamethoxam) can be found in matrixes relevant for bees after sowing of maize using deflector. Relatively high residues were found in guttation water of maize seedlings. These results should be considered as only indicative for any assessments for thiamethoxam since clothianidin was used for the treatment of the seeds.<br>Austria, 2009-2010:<br>Bee loss incidences were suspected to be linked to pesticide uses involving maize seed treatment with thiamethoxam. Beside other pesticides (e.g. clothianidin), thiamethoxam residues were found in different matrices including bees or bee bread, but none of the investigated neonicotinoids were detected in honey. Thiamethoxam and clothianidin residues were also found in bee bread samples from honeybee colonies without suspected poisoning incidents. The report concluded that the modification of the sowing machines with deflectors, improved quality of seed coating or compliance of sowing under windy conditions with considerations of the blooming off-crop areas are potential tools to reduce incidences. | | |

[1]: exposure to treated cherry leaves

**Hazard quotients for honey bees (Annex IIIA, point 10.4)**

Crop and application rate

| Test substance | Route | Hazard quotient | Annex VI Trigger |
|---|---|---|---|
| Preparation | contact | Quantification was not possible | n/a |
| Preparation | oral | Quantification was not possible | n/a |

n/a: not applicable

## ABBREVIATIONS

| | |
|---|---|
| µg | microgram |
| a.s. | active substance |
| AF | assessment factor |
| AV | avoidance factor |
| BCF | bioconcentration factor |
| bw | body weight |
| CAS | Chemical Abstract Service |
| d | day |
| DM | dry matter |
| $DT_{50}$ | period required for 50 percent disappearance (define method of estimation) |
| $DT_{90}$ | period required for 90 percent disappearance (define method of estimation) |
| dw | dry weight |
| EAC | environmentally acceptable concentration |
| $EbC_{50}$ | effective concentration (biomass) |
| $EC_{50}$ | effective concentration |
| EEC | European Economic Community |
| $ER_{50}$ | emergence rate/effective rate, median |
| $ErC_{50}$ | effective concentration (growth rate) |
| EU | European Union |
| FAO | Food and Agriculture Organisation of the United Nations |
| FIR | Food intake rate |
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| g | gram |
| GAP | good agricultural practice |
| GM | geometric mean |
| GS | growth stage |
| h | hour(s) |
| ha | hectare |
| L | litre |
| $LD_{50}$ | lethal dose, median; dosis letalis media |
| LOAEL | lowest observable adverse effect level |
| LOD | limit of detection |
| m | metre |
| MAF | multiple application factor |
| mg | milligram |
| mL | millilitre |
| mm | millimetre |
| MTD | maximum tolerated dose |
| MWHC | maximum water holding capacity |
| ng | nanogram |
| NOAEC | no observed adverse effect concentration |
| NOAEL | no observed adverse effect level |
| NOEC | no observed effect concentration |
| NOEL | no observed effect level |
| OM | organic matter content |
| Pa | Pascal |
| PD | proportion of different food types |
| PEC | predicted environmental concentration |
| $PEC_{air}$ | predicted environmental concentration in air |
| $PEC_{gw}$ | predicted environmental concentration in ground water |
| $PEC_{sed}$ | predicted environmental concentration in sediment |
| $PEC_{soil}$ | predicted environmental concentration in soil |

| | |
|---|---|
| $PEC_{sw}$ | predicted environmental concentration in surface water |
| pH | pH-value |
| PHI | pre-harvest interval |
| $pK_a$ | negative logarithm (to the base 10) of the dissociation constant |
| $P_{ow}$ | partition coefficient between *n*-octanol and water |
| ppm | parts per million ($10^{-6}$) |
| ppp | plant protection product |
| PT | proportion of diet obtained in the treated area |
| $r^2$ | coefficient of determination |
| RUD | residue per unit dose |
| SD | standard deviation |
| SFO | single first-order |
| SSD | species sensitivity distribution |
| $t_{1/2}$ | half-life (define method of estimation) |
| TER | toxicity exposure ratio |
| $TER_A$ | toxicity exposure ratio for acute exposure |
| $TER_{LT}$ | toxicity exposure ratio following chronic exposure |
| $TER_{ST}$ | toxicity exposure ratio following repeated exposure |
| TLV | threshold limit value |
| TRR | total radioactive residue |
| TWA | time weighted average |
| UV | ultraviolet |
| W/S | water/sediment |
| w/v | weight per volume |
| w/w | weight per weight |
| WHO | World Health Organisation |
| wk | week |
| yr | year |