Bayer CropScience

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Summary of the ecotoxicological studies Thiacloprid FS 400 (400 g/L)

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According to the guidance document, SANCO 10181/2013, for preparing dossiers for the approval of a chemical active substance

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Version history

Date	Data points containing amendments or additions[1] and brief description	Document identifier and version number

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

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CP 10 ECOTOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

Introduction

The representative formulation submitted in the first Annex I listing process is no longer considered as a representative formulation for the renewal of thiacloprid. One of the new representative formulation used for the submission of the renewal of the Annex I listing of thiacloprid is the seed treatment formulation Thiacloprid FS 400. The summaries of formulation studies and the risk assessment will be presented in this Dossier.

Ecotoxicological endpoints used in the following risk assessment were derived from studies with the formulated product Thiacloprid FS 400, the active substance thiacloprid and the metabolites listed in the residue definition for risk assessment.

In this Dossier only endpoints used for the risk assessment are presented. For an overview of all available endpoints for thiacloprid and its metabolites please refer to the respective section of the MCA document. In order to facilitate discrimination between new and information submitted during the first Annex I inclusion process, the old information is written in grey letters.

Use pattern considered in this risk assessment

Table CP 10- 1: Intended application pattern

Crop	Timing of application	Number of applications	Maximum label rate L product /unit	Maximum label rate [mg as/seed]	Maximum rate U/ha	Maximum application rate [g/ha]
Maize	BBCH 00 (seed treatment)	1	0.125	1	2.2 (1 unit = 50,000 seeds)	110

Definition of the residue for risk assessment for thiacloprid

Due to changes in triggers for metabolites to be further assessed as well as due to new studies on the route of degradation in various environmental compartments, additional metabolites are proposed to be included in the residue definition for the risk assessment. Accordingly, studies have been prepared to describe the ecotoxicological profile of these metabolites in the relevant environmental compartment.

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Table CP 10- 2: Definition of the residue for risk assessment*

Compartment	Residue Definition for Risk Assessment
Soil	Thiacloprid, Thiacloprid amide, Thiacloprid sulfonic acid, Thiacloprid des-cyano
Groundwater	Thiacloprid, Thiacloprid amide, Thiacloprid sulfonic acid, Thiacloprid des-cyano, Thiacloprid sulfonic acid amide, Thiacloprid thiadiazine
Surface water	Thiacloprid, Thiacloprid amide, Thiacloprid sulfonic acid, Thiacloprid des-cyano
Sediment	Thiacloprid,
Air	Thiacloprid

*Justification for the residue definition for risk assessment is provided in MCA Sec 7, Point 7.4.1 and MCA Sec. 6, Point 6.7.1.

A list of metabolites, which contains the structures, the synonyms and code numbers attributed to the compound thiacloprid, is presented in Document N3 of this dossier.

CP 10.1 Effects on birds and other terrestrial vertebrates

The risk assessment has been performed according to "European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA" (EFSA Journal 2009; 7(12):1438), referred to in the following as "EFSA GD 2009".

CP 10.1.1 Effects on birds

Table CP 10.1.1- 1: Endpoints used in risk assessment

Test substance	Test species, test design	EU agreed endpoints		Endpoints used in risk assessment	
Thiacloprid	Japanese quail, acute toxicity	LD_{50}	49 mg a.s./kg bw	LD50	311 mg a.s./kg bw [a] 153 mg a.s./kg bw [b]
	Mallard duck, reproductive toxicity (long-term)	NOEC	60 ppm	NOEC NOEL	140 ppm [d] 11.0 mg a.s./kg bw/d [c]

[a]) Geometric mean LD_{50} as approach recommended in EFSA GD.
[b]) dietary NOEL in Japanese Quail (see below "Toxicity endpoint") as the geomean approach may be not accepted by some Member States
[c]) Conversions based on the respective mean food consumption and mean body weight (see study reports and according to SANCO/4145/2000, final and see below "Toxicity endpoint")
[d]) EU endpoint (60 ppm) in the Annex I List of Endpoints was based on effects on adult body-weight and nominal concentrations; used endpoint (140 ppm) is based on effects on offspring and measured concentrations

Table CP 10.1.1- 2: Relevant generic avian focal species feeding on seeds for risk assessment on Tier 1 level according to EFSA GD (2009)

Type of seeds	Generic focal species	FIR/bw
'Large seeds' (maize, beans or peas)	Large granivorous bird	0.1
'Small seeds' (not maize, beans or peas)	Small granivorous bird	0.3

Table CP 10.1.1- 3: Relevant generic avian focal species feeding on seedlings for risk assessment on Tier 1 level according to EFSA GD (2009)

Generic focal species	Short-cut value (SV) for acute risk*
Small omnivorous bird	0.5 x NAR/5
*For the reproductive assessment, these shortcut values should be combined with appropriate time windows and default degradation/dissipation rates for residues.	

*NAR = nominal loading/application rate of active substance [mg/kg seeds]

ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.1- 4: Tier 1 acute TER calculation for birds feeding on seed treatment

Compound	Generic focal species	Toxicity [mg/kg bw]	Exposure		TER_A	Trigger
			FIR/bw	NAR [mg a.s./kg seeds][1]		
Thiacloprid	Large granivorous bird	311	0.1	2222 - 5000	**0.6 – 1.4**	10

[1]Assuming a thousand grain weight of the seeds of 200-450 g[1]

Table CP 10.1.1- 5: Tier 1 acute TER calculation for birds feeding on crop seedlings

Compound	Generic focal species	Toxicity [mg/kg bw]	Exposure	TER_A	Trigger
			SV*		
Thiacloprid	Small omnivorous bird	311	222 - 500	**0.6 – 1.4**	10

* SV = 0.5 x NAR/5

The TER_A values calculated in the acute risk assessment on Tier 1 level do not exceed the a-priori-acceptability trigger of 10 for all evaluated scenarios. Thus, a refined risk assessment for these scenarios is presented below.

Refined risk assessment

The refined risk assessment presented here follows Guidance of EFSA "Risk Assessment for Birds and Mammals" (2009). This document states in chapter 5.2: "*Tier 1 assumes that granivorous birds and mammals feed entirely on readily available, freshly treated seeds.* ***The failure rate of pesticides used as seed treatments to meet the standard EU triggers for acute and reproductive risks under such a scenario is likely to be high.*** *Therefore, many cases will require refined assessment. At present, it is not possible to recommend standardized approaches for refined assessment. Therefore, a range of options for refinement are presented.*
The outcome of a ***refined assessment*** *would,* ***in most cases****, take the form of* ***a weight-of-evidence*** *approach,* ***rather than a quantitative assessment (e.g. TER)****. Risk managers will have to decide on whether the evidence provided is sufficient to allow for a decision whether the intended level of protection is reached. Guidance is provided on the method for such a weight-of-evidence approach.*"

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[1] Faustzahlen für die Landwirtschaft (2005), published by Kuratorium für Technik und Bauwesen in der Landwirtschaft, Darmstadt, 13th edition, ISBN 3-7843-2194-1

Treated seeds

Focal species

[redacted] ([redacted]; 2001; M-031252-01-1, KCP 10.1.1.2/1) investigated the attractiveness of freshly drilled maize fields for seed eating birds. In this study only large seed eating birds were observed eating maize: Carrion Crow, Pheasant, and Wood Pigeon. Small seed eating birds only exceptionally frequented the fields. In no case was consumption of maize seeds observed.
He also found no evidence that maize seed remaining on the soil after drilling, or the intentionally dispersed maize seed on specific reference fields, were of special attractiveness for seed eating birds.
[redacted] ([redacted]; 2006; M-291204-01-1, KCP 10.1.1.2/2) studied the utilization by birds of freshly drilled sunflower and maize fields in southern France. He found carrion crow, magpie and yellow-legged gull being the most common of the known maize seed eating bird species in freshly drilled maize fields. They are characterized by the largest figures for abundance, frequency of occurrence and dominance.
[redacted] ([redacted]; 2005; M-242960-01-1; KCP 10.1.1.2/8) in a generic field study conducted in maize and sugar beet fields in Austria reported Carrion Crow, Common Pheasant and Grey Partridge as the most common species potentially feeding on maize fields before and/or after germination.
Accordingly, corvids (e.g. Carrion Crow, Magpie), gallinaceous birds (e.g. Pheasant, Partridge) and pigeons (e.g. Wood Pigeon) are considered as the focal species for freshly drilled maize fields feeding on maize seeds. This selection of species is confirmed by [redacted] (2001[2]), who reported these birds feeding on maize. Consequently these species will be addressed in the following risk assessments.

Toxicity endpoint

Acute oral toxicity values are available for four different species, Japanese Quail, Bobwhite Quail, Canary bird and Chicken (MCA, chapter CA 8.1.1). The most sensitive species tested were Canary bird and Japanese Quail with LD_{50}s of 35 and 49 mg/kg bw, respectively. The geometric mean of the acute oral LD_{50}s from all four bird species tested is 311 mg/kg bw. This value is derived following the procedures described in chapters 2.1.2 and 2.4.2 of EFSA (2009).

An acceptable acute risk for all bird species is assumed, if a TER_A greater or equal 10 is demonstrated, i.e. exposure (intake over the relevant period) is no more than one tenth the LD_{50} of the species tested. In other words, intake of a dose equivalent to tenth the LD_{50} over an "acute" time period is considered a (regulatory) acceptable dose. As such, the regulatory margins of safety needed to extrapolate from the LD_{50} in the laboratory test species to a safe exposure level for species in the field are already included in the (regulatory) acceptable dose and do not need to be applied afterwards in a “classical TER calculation”.

Accordingly the toxicity endpoint (LD_{50}) is divided by (the TER_A of) 10 to calculate the regulatory "acceptable dose". This allows a direct comparison of the "acceptable dose", expressed as number of treated maize seeds to achieve the 1/10 of the LD_{50} with the daily intake of maize seeds for that species. Such an approach makes particularly sense in cases where exposure is via distinct "portions" (e.g. treated seeds, granules, bait particles) rather than via a concentration more or less evenly distributed in the diet (e.g. after spraying).

2 [redacted], P. (2001): Project PN0907: Potential exposure of birds to treated seed – Final milestone report (M-091172-01-1)

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A risk clearly can be excluded if a bird would need to ingest more maize seeds to exceed the "acceptable dose" (one tenth of the LD_{50}) than required to satisfy its daily energy needs when feeding exclusively on treated maize.

Two scenarios are considered in this approach, one based on the geometric mean acute oral LD_{50} (311 mg/kg bw) and a second based on the dietary NOLED from most sensitive bird species tested in the short-term dietary studies (Japanese quail, 153 mg/kg bw/d). The "acceptable doses" for these two scenarios are thus 31.1 mg/kg bw and 15.3 mg/kg bw, respectively.
In a second step the doses are related to the body weights of the different bird species that have been observed in field studies on maize fields after drilling and an "acceptable dose" per bird is calculated. These "acceptable doses" per bird are in the third step converted to the corresponding number of treated seeds to achieve this dose (based on nominal loading rates).
The values for the focal species mentioned above are depicted in Table CP 10.1.1-6 below.

Table CP 10.1.1- 6: Acceptable doses of treated seeds for different focal bird species

Focal species	body weight*) [g]	"acceptable dose" [mg/bird]		no. seeds to achieve the "acceptable dose"	
		geomean LD_{50} 311 mg/kg bw	dietary NOLED 153 mg/kg bw/d	geomean LD_{50} 311 mg/kg bw	dietary NOLED 153 mg/kg bw/d
Carrion Crow	570	17.73	8.72	17.73	8.72
Magpie	177.5	5.52	2.72	5.52	2.72
Pheasant	1135	35.30	17.37	35.30	17.37
Grey Partridge	389.5	12.11	5.96	12.11	5.96
Red-legged Partridge	435.5	13.54	6.66	13.54	6.66
Wood Pigeon	490	15.24	7.50	15.24	7.50
*) mean of males and females from Dunning, 1993[3]					

Portion of time (PT)

No "portion of time"-data are available presently for the focal species mentioned above. Therefore this refinement option is not included in the exposure calculation. Nevertheless, all the focal species are known to forage on large areas and in diverse feeding habitats, not exclusively on maize fields. Therefore in reality the PT can be expected to be considerably lower than 1. This expectation is very clearly supported by the low percentage of fixes obtained for those of these species under radio-surveillance by [redacted] & [redacted] (2010; M-371180-01-1, KCP 10.1.1.2/7) in maize fields.

Portion of Diet (PD)

No "portion of diet"-data are available presently for the focal species mentioned above. Therefore this refinement option is not included in exposure calculation. Nevertheless, all the focal species are opportunistic omnivores and therefore (even on drilled maize fields) the PD for maize seeds can be expected to be considerably lower than 1.

[3] Dunning, J.B., Handbook of Avian Body Masses, CRC Press, ISBN 0-8493-4258-9, 1993

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Avoidance (AV)

In the 5-day dietary studies, Japanese and Bobwhite Quail as well as Mallard Duck exhibited increased food avoidance with increasing exposure concentrations. This avoidance, however, is difficult to quantify in such a way that it can be factored into a DDD or TER calculation. Furthermore, avoidance of treated seeds, where the active substance is concentrated on the outside of the seeds, is deemed more pronounced than avoidance at the same (nominal) concentration in dietary studies, where the substance is mixed homogeneously into the diet. Therefore the observed avoidance will only be used as evidence that exposure calculations might overestimate the actual exposure. The fact that avoidance was seen in all three species tested supports the interpretation that avoidance is a general phenomenon with Thiacloprid and hence should occur in all species.
Additionally, in one field study ([redacted]; [redacted]; 2010; M-371180-01-1, KCP 10.1.1.2/7) the availability over time of exposed maize seeds was investigated. The authors found that even at spills maize kernels did rarely vanish. The fact that only individual maize seeds disappeared from spills, together with observations of birds occasionally ingesting individual treated maize seeds, suggests that birds try treated seeds but do not take more than single seeds despite the ready availability of more of these feed items. Contrary to the rare observations of birds eating maize seeds treated with Thiacloprid, the authors report that birds were quite frequently seen feeding on (untreated) maize seeds remaining on the fields from the previous year's maize crop after harvest.
These observations are particularly important since they clearly support the phenomenon of avoidance occurring in the field in relevant species, as has been observed in laboratory experiments with model species (quails, ducks).

Dehusking

Some species, e.g. magpies, were observed breaking or chopping the seeds before eating only the inner parts of it ([redacted].; [redacted]; 2010; M-371180-01-1, KCP 10.1.1.2/7). As a refinement option, however, dehusking of maize seeds cannot be quantitatively factored into the DDD or TER calculation because the extent of exposure reduction after dehusking has not been measured in maize for the species to be considered.

Exposure density

In Europe, maize seeds can be assumed to be almost exclusively precision-drilled which renders their availability on the soil surface to be very limited. This conclusion is supported by the work of De [redacted] *et al.* (1995)[4], who determined in the Netherlands the number of un-incorporated maize seeds on the soil surface (field centre) to be in the range of 0.02 ± 0.04 seeds/m^2 (i.e. a max. of 0.06 and 90th%ile of 0.05 seeds/m^2). For headlands they report 3.1 to 5.8 times higher numbers of exposed seeds (mean 4.0).

These data are well in accordance to the number of un-incorporated maize seeds measured on 10 commercially operated maize fields in the Lower Rhineland (Germany): [redacted] ([redacted].; 2001; M-031252-01-1 KCP 10.1.1.2/1) found un-incorporated maize seeds in the mid-field area to range from a min. of zero to a max. of 0.024 seeds/m^2, with a mean number of 0.007 seeds/m^2. In

[4] de [redacted] J, [redacted] M, de [redacted] GR, [redacted] WLM, [redacted] RJ and R. J. [redacted] RJ. (1995). Risks of granules on treated seeds to birds on arable fields GML report No. 118.Centre of Environmental Science, Leiden University, Leiden, The Netherlands. ISSN 1381-1703

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headland areas (end-rows), the number of un-incorporated maize seeds ranged from a min. of 0.003 to a max. of 0.11 seeds/m^2, with a mean number of 0.042 seeds/m^2. His values are in good agreement with those of De [redacted] et al. (1995) and the differences illustrate the variability to be expected in the field.

Exposure data from three further studies on freshly drilled maize fields ([redacted] 2007, KCP 10.1.1.2/10, [redacted] & [redacted] 2010, KCP 10.1.1.2/7, [redacted] & [redacted] 2010, KCP 10.1.1.2/11; see table below) are available for the assessment of the variability of exposure density. Exposure densities, i.e. number of treated maize seeds exposed on the soil surface per square meter determined in the studies mentioned above are summarized in the table below. The worst case of all five studies is used in the risk assessment with the 90th%ile being used for acute risk assessment scenarios.

Table CP 10.1.1- 7: Number of maize seeds exposed on the soil surface after drilling (seeds/m²)

midfield mean	midfield 90th%ile	end row mean	end row 90th%ile	Reference
0.02	0.02	0.02	0.02	[redacted] & [redacted], 2010 M-371180-01-1, KCP 10.1.1.2/7
0.06	0.10	0.16	0.42	[redacted] & [redacted], 2010 M-369149-01-1, KCP 10.1.1.2/11
0.1	0.1	0.2	0.4	[redacted], 2007 M-286951-01-1, KCP 10.1.1.2/10
0.007	0.016	0.042	0.095	[redacted], 2001 M-031252-01-1, KCP 10.1.1.2/1
0.02	0.05 [a]	0.08 [b]	0.20 [b]	[redacted] et al., 1995
0.028	0.036	0.064	0.137	**geomean**

a) value calculated based on mean and SD given by de [redacted] et al, 1995
b) value estimated based on midfield values and 4x higher number of seeds exposed on headland vs. midfield as presented in de [redacted] et al., 1995

These data show that exposure to treated maize seeds after sowing is very low. This is attributed to the sowing technique (precision drilling) utilized in maize cultivation. Spills may occasionally occur, but the number of seeds exposed on the soil surface is usually low.

In a further weight of evidence approach for the acute risk assessment, the number of seeds a bird has to ingest to achieve the regulatory "acceptable dose" was related to the <u>area</u> a bird has to forage assuming the worst case number of 90th%ile values for midfield and end row exposed seeds. Again, for each species this calculation is done based on the figures for the geomean LD_{50} and the dietary LD_{50}.

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Table CP 10.1.1- 8: Acceptable doses of treated seeds for different focal bird species in relation to the foraging area

Species	no. seeds to achieve "acceptable dose" (LD_{50}/10)		foraging area (m²) to achieve "acceptable dose"			
			midfield area		end row area	
	oral 31.1 mg/kg bw	dietary 15.3 mg/kg bw	oral 31.1 mg/kg bw	dietary 15.3 mg/kg bw	oral 31.1 mg/kg bw	dietary 15.3 mg/kg bw
Carrion Crow	17.73	8.72	492	242	129	64
Magpie	5.52	2.72	153	**75**	40	**20**
Pheasant	35.30	17.37	981	482	258	127
Grey Partridge	12.11	5.96	336	166	88	43
RL Partridge	13.54	6.66	376	185	99	49
Wood Pigeon	15.24	7.50	423	208	111	55

From this table it can be seen, that under the worst-case assumption that magpies would be ten times more sensitive than the most sensitive species tested in the dietary studies, and that the number of exposed seeds is the geometric mean of the 90th%iles of the five studies cited above, they would have to eat each and every seed exposed on an area of 75 m² in the centre of the field or on an area of 20 m² in the end row area to come to an unacceptably high risk.

Further evidence

From various studies it is known that seeds lose some of their active ingredient by degradation and/or dissipation after sowing. The half-life in soil of Thiacloprid and its major metabolites is relatively short, as detailed in the Thiacloprid FS400 Section 5 Core Assessment. For thiacloprid the median DT_{50} is 6.7 days under field conditions (at 20 °C and field capacity), for thiacloprid amide the median DT_{50} is 47.2 days under field conditions (at 20° C and field capacity) and for thiacloprid sulfonic acid the DT_{50} is 16.7 days under field conditions (at 20 °C and field capacity) . It is acknowledged that soil half-lives cannot be translated directly into half-lives in/on seeds, but it can be assumed that while in contact with soil, degradation/dissipation will take place. The time course of disappearance of thiacloprid from seeds was not determined, therefore it will only be used as further qualitative evidence for only a time-limited exposure and a (rapid) decline of the risk to birds.

Field studies

A field study to investigate potential effects on birds of exposure to maize seeds treated with thiacloprid FS 400 was conducted in 2009 in a typical maize-growing area in Southern Germany ([redacted] & [redacted], 2010, KCP 10.1.1.2/7).
Observations conducted included scan sampling (for characterization of bird abundance, activity, and behaviour), radio tracking of species considered to be focal species for freshly drilled maize fields, carcass searches, and counting of seeds exposed on the soil surface (including disappearance from spills over time).
All individuals of four different potential focal bird species that could be trapped (14 grey partridges, one pheasant, four woodpigeons and seven magpies) in the vicinity of the study fields were equipped with radio-transmitters. The birds were trapped as close as possible to the maize fields in order to maximise the probability that these birds would forage in the fields when drilled with Thiacloprid FS 400-treated maize seeds. All individuals were radio-tracked to determine their fate and survival following the drilling procedure.

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Within the monitoring period (onset of drilling until BBCH growth stage 15/16) 21 of the 26 tagged birds stayed verifiable alive. One magpie was found to have lost its tag, and therefore no clarification can be made about the fate of this single bird. Four grey partridges were killed by predation, which is not unexpected for this species. Importantly, all four individuals were "non-users", i.e. they were never located in the fields drilled with Thiacloprid-treated maize. The report clearly states: "*All birds located on the study fields were alive and in good health at the end of the study period*." Therefore it is very unlikely that just these non-users were incapacitated and killed after the consumption of Thiacloprid-treated seeds.

A total of 805 bird contacts, comprising 22 species were recorded during the 775 bird scans carried out. Small songbirds that profit by the facilitated availability of soil invertebrates due to the soil cultivation linked to drilling were by far the most abundant species. As expected these species were not observed feeding on maize seeds. Other species including those able to take maize seeds as food source were much less abundant. The presence of some of the tagged individuals (four grey partridges, the pheasant and three magpies) was verified in fields drilled with Thiacloprid FS 400-treated maize seeds.

Availability, however low, of Thiacloprid FS 400-treated maize seeds on the soil surface was demonstrated by the results of the surface exposure assessment.

The systematic observations of birds foraging on maize fields revealed that the proportion of freshly drilled maize seeds and seedlings were almost negligible in the diet of these species. A tagged magpie, the tagged pheasant and an untagged woodpigeon were observed eating at least once a treated maize seed confirming that birds visiting the study fields may be exposed to Thiacloprid FS 400 via the ingestion of treated maize seeds. However, the portion of ingested untreated maize seeds (remaining from the previous year's crop after harvest) was much higher.

Moore importantly, despite this occasionally observed uptake of maize seeds by birds, no effect of the freshly drilled Thiacloprid FS 400-treated maize seeds on any of the bird species in the study fields could be detected during the scans. During the extensive carcass searches conducted on the study fields and their surroundings, no carcasses were found. Accordingly, despite the obvious utilisation of the study fields by tagged (and untagged) birds no case of death of a bird was related to the ingestion of Thiacloprid FS 400-treated maize seeds.

The various methods applied in this study provided a reasonably robust approach to assess the impact of Thiacloprid FS 400-treated maize seeds on birds foraging on freshly drilled maize fields. Results of all methods consistently show that despite the utilisation of the fields freshly drilled with Thiacloprid FS 400-treated maize seeds, neither the monitored individuals of the focal species nor other species of the local bird population were adversely affected.

Seedlings emerged from treated seeds

Focal species

For the scenario of seedlings emerged from treated seeds EFSA (2009) proposes as relevant indicator species large herbivorous birds and mammals and small omnivorous birds and mammals. For maize at BBCH stages 10 to 29, the Woodpigeon (*Columba palumbus*, medium herbivore, b.w. 490 g, scenario 115) and the lark (small omnivore, scenario 111) as generic focal species are proposed. The body weight of the latter is given as 28.5 g, based on the smallest lark species, the Woodlark (*Lululla arborea*). As the Woodlark is not observed foraging on freshly emerged maize fields, the Skylark (*Alauda arvensis*) with a mean body weight of 40 g (Dunning, 1993) is considered as appropriate focal (lark) species in the following evaluation. Selection of this species is supported by [redacted] ([redacted]B; 2010; M-370696-01-1, KCP 10.1.1.2/9).

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Diet of the focal species

In the risk assessment presented below, a diet of 100% maize seedlings will be assumed for the herbivorous bird. This is an adaptation of the standard scenario proposed by EFSA (2009, A[5]) which assumes a diet of "leaves" only (being non-grass herbs) for the generic focal herbivorous species (represented by the Woodpigeon) in maize at BBCH growth stages 10-29. The scenario described in EFSA (2009 A), "Bird Tier 1 table", no. 115 (maize at BBCH growth stages 10-29), relates to a spray application. For seedlings emerging from treated seeds "spray" RUDs are not relevant. Here according to EFSA (2009) "any information on the amount of substance likely to be present in newly emerged crop shoots should be taken into consideration."
When calculating daily dietary intake for exposure assessment according to EFSA (2009, G) a differentiation is made between "leaves" and "grasses and cereal shoots" with respect to moisture content, assimilation efficiency (for mammals) and energy content. In that respect, (mono-cotyledonous) maize seedlings are deemed better represented by (monocotyledonous) "grasses and cereal shoots". Furthermore, in the case of seed treatments there are only shoots and seedlings that contain residues but no "leaves" in the sense of EFSA (2009, A) for a strictly herbivorous diet. Therefore this adaptation of the standard scenario is deemed appropriate.
Thus, as proposed by EFSA (2009, G) the Woodpigeon is considered to feed only on vegetation (seedling shoots), whereas the lark uses a mixed diet consisting of 25% crop leaves (seedling shoots), 25% weed seeds, and 50% arthropods.

Toxicity endpoint

For the toxicity endpoint refinement the same applies as outlined above in the section on treated seeds. Two scenarios are considered, one based on the geometric mean of the acute oral LD_{50}s from all bird species tested (311 mg/kg bw) and a second, refined, based on the dietary NOLED (153 mg/kg bw/d).

Portion of time (PT)

The "portion of time" for Skylarks in germinating maize fields was determined by [redacted] (2005, KCP 10.1.1.2/8) in a study conducted in Austria. The birds spent 42.1% (PT = 0.421) of their average potential foraging time in or in close vicinity to germinating maize fields. The 90^{th}%ile for PT was 0.954.

The PT value is reported here to support the use of Skylark as appropriate focal species on freshly emerged maize fields, it is, however, not used in the refined risk assessment.

Portion of Diet (PD)

[redacted] (2005) concluded from a study conducted in Austrian maize fields that maize seeds and seedlings were not a relevant food source for birds and mammals. In fact, in no case he found an indication for the ingestion of maize seedlings by skylarks (PD = 0).

[5] European Food Safety Authority; Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA; Appendix A. EFSA Journal 2009; 7(12):1438. [5 pp.]. doi:10.2903/j.efsa.2009.1438. Available online: www.efsa.europa.eu

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The PD value is not used quantitatively in the refined risk assessment. The low number however illustrates that there are significant additional margins of safety that remain unexploited.

Actual residue concentrations

A study was conducted to determine the residue levels of Thiacloprid in seedlings from maize plants which had been grown from seeds dressed with Thiacloprid FS 400 ([redacted], 2009, M-359454-02-1, KCP 10.1.1.2/5). Samples of seedlings were taken for analysis of residues of Thiacloprid and its metabolite between 16 (BBCH 12) and 37 days (BBCH 17) after drilling in the field.
Residue levels were highest at the first sampling occasion (BBCH 12, 16/17 days after sowing) with 17 to 18 mg/kg fresh weight. Thereafter the concentrations declined rapidly with a half-life of less than 3 days ([redacted], 2010; M-370085-01-1, KCP 10.1.1.2/6).
In the acute risk assessment for the herbivorous bird (Woodpigeon), the maximum initial residue level (18 mg/kg fresh weight) will be used.
For the mixed diet of Skylarks, only the seedling part (25%) is considered to contain residues since other feed items like weed seeds or insects are unlikely to come into contact with the active substance to a great extent. Therefore, the concentration in the total diet will be the concentration in the seedlings (initial concentration 18 mg a.s./kg fresh weight) multiplied by 0.25 (corresponding to 25% seedlings in the otherwise uncontaminated diet).

Food intake of Skylark and Woodpigeon

For the Skylark feeding on a mixed diet the standard figures for body weight and food intake rate (for Woodlark) given in EFSA (2009, A) are used. The estimates of food intake for Woodpigeon are based on means of daily energy expenditure for free-ranging animals, energy and moisture content and assimilation efficiencies. The FIR is calculated following EFSA (2009, G) as:

$$FIR = \left(\frac{DEE}{FE * \left(1 - \frac{MC}{100}\right) * \left(\frac{AE}{100}\right)} \right) \quad \text{[g fresh weight/d]}$$

In which:
DEE = Daily energy expenditure of the species [kJ/d]
FE = Food energy [kJ/dry g]
MC = Moisture content [%]
AE = Assimilation efficiency [%]

Daily energy expenditure

Data for the DEE are derived from a research project carried out for DEFRA (Anonymous, 2007). Relationship between body weight (bw in g) and daily energy expenditure (DEE in kJ) in non-passerines can be described by the equation:

$$\log DEE = \log 0.839 + 0.669 \times \log bw$$

According to this formula, a 490 g Woodpigeon would require 435 kJ per day.

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Energy content of food

Seedling shoots have been studied with respect to their energy and moisture content and their assimilation efficiency. The data are used in the table below to calculate the usable energy from these feed sources. The data are taken from Appendix G to the EFSA GD (2009). For seedling shoots no assimilation efficiency for pigeons is given in table 4 of this appendix. Therefore, analogous to the assumed assimilation efficiency in pigeons for the food item "non-grass herbs" given in that table, the mean calculated from "passerines"; "ducks & geese" and "fowl" is used (0.53).

Table CP 10.1.1- 9: Energy content of food

	moisture%	energy content dry (kJ/g)	energy content wet (kJ/g)	ass. eff.% mean	usable energy content wet (kJ/g)
Seedling shoots	76.4	17.6	4.8	53	2.2

Daily food intake

At an energy demand of 435 kJ per day a 490 g Woodpigeon would have to ingest 198 g seedling shoots, containing 2.2 kJ/g of usable energy. This corresponds to a feed intake rate (FIR/bw) of 0.40, approximately 50% of the FIR/bw of 0.79 when feeding exclusively on non-grass herbs.

For the Skylark, a mixed diet of 25% crop leaves (seedlings), 25% weed seeds, and 50% ground arthropods (wet weight) is assumed (EFSA GD, Appendix A, bird scenario 31). With this diet and a body weight of 40 g a FIR/bw of 0.11 for the seedling part of the diet is calculated using the CRD calculator. Since the other dietary components are deemed to be uncontaminated they can be disregarded in the following calculations.

Exposure calculation, Maize seedling shoots

Mean maximum residue concentrations of Thiacloprid in freshly emerged seedling shoots (BBCH 12) were 18 mg/kg fresh weight.
A 490 g Woodpigeon feeding exclusively on such maize seedling shoots could ingest with 138 g seedlings a total dose of 2.48 mg which is equivalent to a dose of 5.1 mg/kg bw.
For the Skylark of 40 g bw and a food intake of 17.63 g (of which 4.41 g consist of maize seedlings), the ingested total dose would be 0.079 mg which is equivalent to a dose of 198 mg/kg bw based on an initial concentration of 18 mg/kg fresh weight in maize seedlings or 4.5 mg/kg fresh weight in the mixed diet.

Table CP 10.1.1- 10: Calculation of the daily dietary dose

	bw [g]	daily food intake [g fresh weight]	concentration in diet [mg/kg fresh weight]	Dose in the daily food intake [mg/bird]	Daily dose [mg/kg bw/d]
Woodpigeon	490	198	18	3.56	7.27
Skylark	40	4.41 (seedlings)	18	0.079	1.98

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<u>Toxicity Exposure Ratios</u>

Taking both scenarios described above, i.e. the geometric mean LD_{50} and the lowest dietary LD_{50} as acute toxicity endpoints, and comparing these to the daily doses calculated for the two generic focal species, the TER_As depicted in the table below are calculated.

Table CP 10.1.1- 11: TER calculations

	Woodpigeon		Skylark	
Acute oral toxicity endpoint [mg a.s./kg bw]	345 (oral)	153 (dietary)	345 (oral)	153 (dietary)
Daily Dietary Dose [mg a.s./kg bw/d]	7.27		1.98	
TER_A	47	21	174	77

An unacceptable acute risk to birds foraging on emerged maize seedlings can be excluded since TER_A exceeds the threshold of 10 for an acceptable risk as laid down in Annex VI to Directive 91/414/EC.

Field studies

A field study to investigate potential effects on birds of exposure to maize seeds treated with Thiacloprid FS 400 was conducted in 2009 in a typical maize-growing area in Southern Germany ([redacted] & [redacted], 2010, KCP 10.1.1.2/7). A detailed description of the study design and findings is given in chapter 10.1.7 of this document and a concise summary is provided in the chapter with the refined risk assessment for birds feeding on treated maize seeds above.

Therefore, as an overall conclusion, the acute risk for birds feeding on maize seeds and seedlings is deemed acceptable. This conclusion is reached by a formal risk assessment with TER calculations for birds feeding on seedlings. For birds potentially feeding on treated seeds the conclusion is supported by a weight of evidence approach including a field study conducted in Germany ([redacted] & [redacted], 2010, KCP 10.1.1.2/7), which covered the period from sowing to BBCH stages 15-16. The different assessment and observation methods applied consistently showed that despite the utilisation of the fields freshly drilled with Thiacloprid FS 400-treated maize seeds, neither the monitored individuals of the focal species nor other species of the local bird population were adversely affected.

Risk assessment for birds drinking contaminated water

EFSA (2009, chapter 5.2.1) proposes to focus the risk assessment for birds and mammals on the dietary route of exposure. An assessment of the risk potentially posed by consumption of contaminated drinking water after the use of a pesticide as seed treatment is not required since this route seems unlikely to be a critical one or to lead to TER greater than direct dietary consumption.

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LONG-TERM REPRODUCTIVE ASSESSMENT

Table CP 10.1.1- 12: Tier 1 reproductive risk assessment for birds feeding on seed treatment

Compound	Generic focal species	Toxicity [mg/kg bw/d]	Exposure			TER_{LT}	Trigger
			FIR/bw	NAR [mg a.s./kg seeds]	f_{twa}		
Thiacloprid	Large granivorous bird	11.0	0.1	2222 - 5000	0.53	**0.042 – 0.093**	5

Table CP 10.1.1- 13: Tier 1 reproductive risk assessment for birds feeding on seedlings

Compound	Generic focal species	Toxicity [mg/kg bw]	Exposure		TER_{LT}	Trigger
			SV*	f_{twa}		
Thiacloprid	Small omnivorous bird	11.0	222 - 500	0.53	**0.042 – 0.093**	5

* SV = 0.5 x NAR/5

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level do not exceed the a-priori-acceptability trigger of 5 for all evaluated scenarios. Thus, a refined risk assessment for these scenarios is presented below.

Refined risk assessment

According to EFSA (2009), chapter 4.3 a screening assessment can be applied to identify quickly those substances that pose very low reproductive risk, for which more detailed assessment is unnecessary.
Step 2 of this screening assessment compares the lowest NOAEL from avian reproduction studies with one tenth of the acute oral LD_{50} used in the acute avian assessment to decide whether the effect could be caused by short-term exposure (STE) or long-term exposure (LTE).
Formally the LD50 used in the acute risk assessment would be the geometric mean from the four species tested (345 mg/kg bw). However, based on the reasons outlined in chapter 10.2 “Selection of the endpoint for the acute risk assessment” as a conservative approach also for the screening assessment, the lowest of the dietary NOLEDs, i.e. 153 mg a.s./kg/d bw is considered the most appropriate value for the acute risk assessment.
$LD_{50}/10$ is proposed as a default for the assessment of reproductive effects from STE based on a review of LD_{50} studies showing that severe signs of toxicity likely to lead to deficits interfering with a bird’s normal activities tend to be recorded at dosing levels greater than 1/10 of the LD_{50} (Callaghan and Mineau, 2000; Appendix 11 of EFSA, 2008[6]).
In reproduction studies, mallard duck is the most sensitive species with a NOAEL of 11 mg a.s./kg bw/d. As 1/10th of the NOLED from the dietary toxicity study on the most sensitive species (15.3 mg/kg bw/d) is higher than the NOAEL from the reproduction study in the most sensitive species it is concluded that reproductive effects are to be expected from long-term exposure rather than from short-term exposure.

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[6] EFSA (2008) Scientific Opinion of the Panel on Plant protection products and their Residues on a request from the EFSA PRAPeR Unit on risk assessment for birds and mammals. The EFSA Journal (2008) 734, 1-181.

Treated Seeds

The refined long-term risk assessment for granivorous birds presented in this document is based on the data and input parameters given in sections 10.1 and 10.1.1.
Focal species and their respective parameters used in the long-term risk assessment are taken from Table CP 10.1.1-3, the application rate is given in table 10.1 and the long-term toxicity endpoint is taken from Table CP 10.1.1- 1 of this document.
Dividing the long-term endpoint of 11 mg/kg bw/d by a factor of 5 (long-term TER trigger value) results in an "acceptable dose" of 2.2 mg/kg bw/d, considering an initial loading of 1 mg thiacloprid/maize kernel and a default 21d-f_{TWA} of 0.53 gives a long-term loading of 0.53 mg thiacloprid/maize kernel.
In the table below the acceptable daily (long-term) doses for the various focal species together with the respective number of kernels required to achieve these doses are given in detail.

Table CP 10.1.1- 14: acceptable daily (long-term) doses for various focal species and number of kernels required to achieve these doses

Focal species	body weight [g]	"acceptable daily dose" per bird: 2.2 mg/kg bw/d	no. seeds per day to achieve the "acceptable daily dose"
Carrion Crow	570	1.25	2.37
Magpie	177.5	0.39	0.74
Pheasant	1135	2.50	4.71
Grey Partridge	389.5	0.86	1.62
Red-legged Partridge	435.5	0.96	1.81
Wood Pigeon	490	1.08	2.03

Based on (mean) exposure of maize seeds on the soil surface after drilling as outlined in above and in particular in Table CP 10.1.1-7, the minimum area granivorous birds would have to forage over a prolonged period to exceed the "acceptable daily dose" is given in the table below.
Since not the effects to the individual but to a population are the scope of ecotoxicological risk assessments, these areas have to be grazed daily by each bird of a whole population in order to potentially provoke any population relevant effects. Following the concept underlying the TWA approach, i.e. that the effect is the product of time and dose, it doesn't matter how the dose is distributed over the time period in question (unless acute effects are provoked). Furthermore it is extremely unlikely that each bird would graze each day the same size of area and find the same number of seeds. Therefore for long-term effects at the population level it is more reasonable to calculate a total area that has to be grazed by each individual within a long-term period, i.e. in this case the default of 21 days. In addition to that it is a fact that if birds would not find or eat each exposed seed within the respective area, the total area would increase accordingly.
The minimum total foraging area for the various focal species is given in the table below.

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Table CP 10.1.1- 15: Minimum total foraging area for various focal species

Focal species	body weight [g]	total minimum foraging area (m²) to achieve "acceptable daily dose"	
		midfield area	end row area
Carrion Crow	570	497	311
Magpie	177.5	155	97
Pheasant	1135	989	618
Grey Partridge	389.5	340	212
Red-legged Partridge	435.5	380	237
Wood Pigeon	490	427	267

While for acute situations the end row area is the realistic worst case, in a chronic/long-term situation the midfield area is more relevant because the end-row area is generally much smaller than the midfield area. This makes it very unlikely that a whole population would feed exclusively in the end-row area for a prolonged period.
Furthermore, the entire field studies presented in this document showed that freshly drilled maize fields are not attractive for birds. This adds further evidence to the notion that a whole bird population would unlikely feed regularly over a prolonged period in this unappealing habitat. Consequently, long-term exposure would be greatly reduced.

Conclusion

The refined risk assessment presented here follows Guidance of EFSA "Risk Assessment for Birds and Mammals" (2009). This document states in chapter 5.2: "*Tier 1 assumes that granivorous birds and mammals feed entirely on readily available, freshly treated seeds. The failure rate of pesticides used as seed treatments to meet the standard EU triggers for acute and reproductive risks under such a scenario is likely to be high…… The outcome of a refined assessment would, in most cases, take the form of a weight-of-evidence approach, rather than a quantitative assessment (e.g. TER)….* ".
Evidence is presented in this refined risk assessment that birds would have to graze a relatively large area over a prolonged period to exceed the "acceptable daily dose" and freshly drilled maize fields are not attractive for birds. Furthermore, exposure to treated seeds is very limited in time because the seeds germinate. Therefore it is deemed unlikely that a whole bird population would feed there regularly over a prolonged period.
As a result the risk of unacceptable effects on bird populations is regarded to be low.

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Seedlings emerged from treated seeds

Potential exposure is calculated based on the measured residue levels over time in young maize seedlings (starting from BBCH growth stage 12). For this purpose a starting concentration of 18 mg/kg fresh weight, a half-life of 3 days, and a default averaging period of 21 days is used. Accordingly, a time weighted average concentration of 3.68 mg/kg fresh weight in seedlings is calculated. Since the Skylark feeds on a mixed diet containing only 25% of seedlings, its FIR/bw for this item in the diet was calculated as 0.11. The other dietary items are considered as uncontaminated and therefore disregarded in the exposure calculation.
Dietary assumptions for the generic focal species are the same as in the acute risk assessment, i.e. 198 g seedling shoots at a body weight of 490 g, resulting in a FIR/bw of 0.40 (related to fresh weight) for the Woodpigeon and 4.4 g seedlings in the mixed diet for a 40 g Skylark (FIR/bw 0.11). At the time-weighted average concentration of 3.68 mg/kg fresh weight, a 490 g herbivorous bird would ingest a daily dose of 1.04 mg/kg bw and a 40 g omnivorous bird would ingest a daily dose of 0.48 mg/kg bw.

Table CP 10.1.1- 16: Calculation of the daily dietary dose

	bw (g)	daily food intake (g fresh weight)	time-weighted average concentration in diet (mg/kg fresh weight)	Dose in the daily food intake (mg/bird)	Daily dose (mg/kg bw/d)
Woodpigeon	490	198	3.68	0.73	1.49
Skylark	40	4.4		0.016	0.40

Toxicity Exposure Ratios

Taking the NOAEL of 11 mg a.s./kg bw from the duck reproduction study as toxicity endpoint, and comparing these to the daily doses calculated for the two generic focal species, the TER_{LT}s depicted in the table below are calculated.

Table CP 10.1.1- 17: TER calculations

	Woodpigeon	Skylark
Long-term toxicity endpoint (mg a.s./kg bw)	11	
Daily Dietary Dose (mg a.s./kg bw/d)	1.49	0.40
TER_{LT}	**7.4**	**27.2**

Comparison with a NOEL of 11 mg/kg bw/d resulted in a Tier-1 TER_{LT} of 7.4 for the Woodpigeon and 27.2 for the Skylark. Both values are well above the threshold of 5 for an acceptable long-term risk.

The appropriateness of this TER_{LT} calculation is further supported by the following lines of evidence:

- no bird species is known that would exclusively or even predominantly feed on maize seedlings over a prolonged period.
- Field observation data ([redacted] 2005, KCP 10.1.1.2/8) confirm that exposure of larks to maize shootings is very significantly lower than the default assumptions (PT = 1)

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Table CP 10.1.1- 18: Summary of parameters for risk assessment

Focal species	**Woodpigeon** (EFSA GD (2009), Appendix A)	**Skylark** (EFSA GD (2009), Appendix A, Woodlark mentioned, but never observed in maize field, therefore adapted to focal lark species)
body weight (g)	**490** (EFSA GD (2009), Appendix A)	**40** (Bird Bible (Buxton et al., 1998)[7]
Diet	**100% leaves** (as seedlings) (EFSA GD (2009), Appendix A)	**mixed diet** (25% crop leaves (seedlings), 25% weed seeds, and 50% arthropods) (EFSA GD (2009), Appendix A)
Daily feed intake	**0.40** calculated using parameters given for "grass and cereal shoots" (EFSA GD (2009), Appendix G)	FIR/bw **0.11** for crop leaf part of Skylark mixed diet (CRD calculator)
Exposure concentration in diet	**18 mg/kg fresh weight** (highest measured value in seedlings, [redacted]; 2009, KCP 10.1.1.2/5)	
Decline of exposure concentration	**f_{TWA} = 0.204** based on DT_{50} of 3 days in seedlings ([redacted], 2010; KCP 10.1.1.2/6) and default time window of 21 days (EFSA, 2009)	
Dietary dose (mg/kg bw)	**1.49** calculated with parameters above	**0.40** calculated with parameters above
Toxicity endpoint	**11 mg/kg bw/d** (lowest NOAEL from avian reproduction study)	
TER_A	**7.4**	**27.2**

All these lines of evidence are supported by the field studies in maize, which show that neither maize seeds nor seedlings are a relevant dietary component for birds.
So overall, all the evidence presented above provides sufficient confirmation that the risk to birds from maize seeds treated with Thiacloprid FS 400 and seedlings emerging from these seeds should be considered to be low and hence acceptable.

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[7] Buxton, J.M., Crocker, D.R. & Pascual, J.A. 1998. Birds and farming: information for risk assessment ("Bird Bible"). Report to Pesticides Safety Directorate, Contract PN0919. Central Science Laboratory, UK.

AMOUNT OF ACTIVE INGREDIENT IN OR ON EACH ITEM

The thousand grain weight (TGW) of maize ranges from 200 to 450 g[8]. Therefore, the following calculations are based on the worst-case assumptions of a TGW of 200 g.

Table CP 10.1.1- 19: Calculation of the maximum amount of active substance on one dressed seed

Crop	Max. dressing rate of the seed treatment product [A] [L/dt [B] seeds]	Content of active substances within the dressing product [g a.s./L product]	Nominal seed treatment rate [mg a.s./kg seeds]	Maximum amount of a.s. on one individual dressed seed [µg a.s./seed]
Thiacloprid				
Maize	1.25	400	5000	1000

[A] assuming a thousand grain weight (TGW) of 200 g
[B] dt = deciton; 1 dt = 100 kg

PROPORTION OF ACTIVE INGREDIENT LD_{50} PER 100 ITEMS AND PER GRAM OF ITEMS

Table CP 10.1.1- 20: Calculation of the proportion of the LD_{50} for the a.s. in 100 particles / gram particles

Crop	Maximum amount of a.s. on one individual dressed seed [A] [µg a.s./seed]	Content of active substance on 100 seeds [mg a.s.]	Amount of active substance on 100 seeds/LD_{50}	Content of active substance on 5 seeds = 1 g [mg a.s.]	Amount of active substance on 1 g seeds/LD_{50}
Thiacloprid					
Maize	1000	100	2.86	0.005	1.4 x10^{-4}

[A] Assuming a thousand grain weight (TGW) of 200 g

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for birds if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log K_{OW} > 3 is used to trigger an in-depth evaluation of the potential for bioaccumulation. Thiacloprid, however, has a log K_{OW} of 1.4 indicating a very low risk of bioaccumulation and, hence, secondary poisoning. A risk assessment is not deemed necessary.

CP 10.1.1.1 Acute oral toxicity

Toxicity of the formulated product

For animal welfare reasons, no acute oral toxicity study with the preparation was performed. Such a study is not deemed necessary, given the fact that birds have no access to the formulated product.

CP 10.1.1.2 Higher tier data on birds

The following studies are used for refining the risk assessment for birds.

[8] Faustzahlen für die Landwirtschaft (2005), published by Kuratorium für Technik und Bauwesen in der Landwirtschaft, Darmstadt, 13th edition, ISBN 3-7843-2194-1

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Report:	[redacted]2;[redacted]; 2001; M-031252-01-1
Title:	Attractiveness of freshly drilled maize fields for large seed eating birds
Report No.:	BAR/FS 005
Document No.:	M-031252-01-1
Guidelines:	**no specific guideline available; not applicable**
GLP/GEP:	**yes**

Objective:

The current study aimed to analyse the importance of maize fields as food source for birds. This study was designed as a reference study allowing assessment of the exposure of seeds on freshly drilled fields and the relevance of these seeds for wild birds. Therefore bird activities on maize fields were observed after drilling. On some fields a „worst case" exposure was artificially generated by scattering seeds on defined areas. This allows evaluation whether an exposure exceeding normal rates would increase the attractiveness to birds.

Study site:

The field study was performed in the Lower Rhineland in Germany on ten study fields, situated between the cities of [redacted] and [redacted], District of Kleve.

Material and Methods:

Two types of fields were examined, drilled fields and so-called 'reference fields'. On the drilled fields the sowing of commercial maize seeds was performed by the local farmers with their equipment. The maize seed was provided by the farmers. On the reference fields untreated maize was dispersed by technicians of the study team to generate an artificially high exposure rate on harrowed fields. Exposure of maize seeds after drilling was measured on day 0 by counting all visible seeds within areas of 2500 m^2 situated in the midfield and end row area. On three of the drilled and on three reference fields bird observations were carried out. The observed bird species, the number of individuals and the behaviour were recorded by means of „Scansampling" (one observation interval every five minutes). Simultaneously feeding rates and type of food which was ingested by the birds were determined. Observations were performed after dispersing/drilling of seed on day 0 until dusk and on the following day for the whole daylight period.

Results:

Only large seed eating birds were observed eating maize: Carrion Crow (570 g b.w.), Pheasant (950 – 1320 g b.w.), Wood Pigeon (490 g b.w.) (mean weights according to CSL 1996). Small seed eating birds only exceptionally frequented the fields. In no case a consumption of maize was observed. There was no evidence that maize seed remaining on the soil after drilling or the dispersed maize seed of the reference fields were of special attractiveness for seed eating birds.

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Table CP 10.1.1.2- 1: Availability and attractiveness of maize seeds for different bird species

Test substance	**Commercial maize seed dressed with different formulations**
Test object	**Natural bird community on three drilled and three reference fields**
Maize seeds on the soil surface immediately after drilling	midfield area: mean 0.007 seeds/m² (=0.1%) max.: 0.024 seeds/m² (= 0.3%) min.: 0; 0 seeds/m² end row area: mean 0.042 seeds/m² (=0.5%) max.: 0.11 seeds/m² (=1.3%) min.: 0.003 seeds/m² (=0.035%)
Results from behaviour observations	• reference fields: no special attractiveness of reference fields as feeding place, only slight uptake of maize seeds • drilled fields: low bird abundance on drilled fields, only slight uptake of maize seeds

Report: [redacted]; [redacted]; 2006; M-291204-01-1
Title: Utilisation of freshly drilled sunflower and maize fields in southern France by birds
Report No.: RA06-050-1
Document No.: M-291204-01-1
Guidelines: **The test was especially designed for the purpose of this study.; none**
GLP/GEP: **no**

Report: [redacted]; [redacted]; [redacted]; 2007; M-306215-01-1
Title: Letter of access for generic behavioural ecology data: Study report BASF DocID 2006/1039471; Grouping: Maize, pre-emergence (seed treatments) and early post-emergence
Report No.: M-306215-01-1
Document No.: M-306215-01-1
Guidelines: **not specified; not specified**
GLP/GEP: **no**

Report: [redacted]; [redacted]; [redacted]; 2007; M-306240-01-1
Title: Letter of access for generic behavioural ecology data - Study report BASF DocID 2006/1039471 - Grouping: Sunflower, pre-emergence (seed treatments)
Report No.: M-306240-01-1
Document No.: M-306240-01-1
Guidelines: **not specified; not specified**
GLP/GEP: **no**

Objective:

The current study aimed to determine the qualitative and quantitative occurrence of birds in freshly drilled sunflower and maize fields in southern France.

Study site and study plots:

The study fields (10 freshly drilled maize and 19 freshly drilled sunflower fields) were located in a representative sunflower and maize growing area around Toulouse, in southern France. The monitored study plots were chosen in such a way as to provide a readily surveyable sub-area of at least 2 ha of the field in question. However, the whole field was used if it could be readily viewed in its entirety.

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Each study plot was chosen to comprise representative parts of both headland and mainland areas and was further characterised by the adjacent (directly bordering) habitats (other arable fields, hedges/shrubs or woodland).

Material and Methods:

Scan sampling (i.e. uniformly surveying a defined area visually at regular intervals in order to record [qualify] and census [quantify] bird species and behaviour in the instant of observation) was carried out at 5-minute intervals for two consecutive hours per study plot. Each study plot was scan-sampled twice (once within 24 hours after sowing and the second time three to five days after sowing) from a car, using a binocular and a spotting scope. Each bird observed was directly allocated to one of the behaviour categories ‘foraging’, ‘non-foraging’ and ‘possibly foraging’ at the moment of visible contact.
To supplement the data obtained in this way, additional transect counts were performed after each scan sampling session by slowly walking along the borderline between headland and mainland parts of the study plot.
All data recorded were analysed using a standard spreadsheet application. Data processing was done on the basis of bird species observations on the study plot during a specific scan sampling interval. Each of the scanning intervals of both scanning surveys for each study plot (within 24 hours after sowing and three to five days after sowing) was considered to be an independent unit.

Results:

A total of 2105 individual bird contacts were recorded, comprising 30 different bird species (17 granivorous or omnivorous, 13 non-granivorous species). Based on the registration of 1797 observations of potentially grain-feeding birds on 29 freshly drilled fields (sunflower and maize) with a total study plot area of 163.5 ha during two scan sampling surveys an overall bird abundance of 26.3 ± 6.4 (SE) individuals/100 ha was calculated.
Bird abundance values for maize fields (914 observed individuals on 68.5 ha) were 6.2 ± 7.8 ind./100 ha. In maize highest abundance values were shown for the carrion crow (7.4 ± 2.6 ind./100 ha), followed by the magpie (6.8 ± 5.3 ind./100 ha), yellow-legged gull (4.9 ± 4.9 ind./100 ha) and starling (3.9 ± 2.1 ind./100 ha).
The most dominant species for maize fields was the carrion crow (34%) followed by the yellow-legged gull (23.2%), starling (21.0%) and magpie (15.8%).
The species-specific abundance and dominance values are presented in the table below.
The highest FO across all maize fields was recorded for the carrion crow (80.0%), followed by magpie and starling (40.0% each).

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Table CP 10.1.1.2- 1: Absolute numbers, abundance and dominance of potentially granivorous birds recorded on 29 maize (n = 10) fields in southern France ordered by the total abundance values (maximum values per column are in bold)

Species	Number of bird recordings	Abundance [ind./100 ha] ± SE	Dominance [%]
Magpie (*Pica pica*)	144	6.8 ± 5.3	15.8
Carrion crow (*Corvus corone*)	311	7.4 ± 2.6	34.0
Red-legged partridge (*Alectoris rufa*)	10	0.9 ± 0.9	1.1
Starling (*Sturnus vulgaris*)	192	3.9 ± 2.1	21.0
Yellow-legged gull (*Larus michahellis*)	212	4.9 ± 4.9	23.2
Crested lark (*Galerida cristata*)	17	0.8 ± 0.5	1.9
Wood pigeon (*Columba palumbus)*	7	0.2 ± 0.1	0.8
Blackbird (*Turdus merula*)	0	-	-
Feral pigeon (*Columba livia f. domestica*)	4	0.3 ± 0.3	0.4
Jay (*Garrulus glandarius*)	7	0.6 ± 0.5	0.8
Rook (*Corvus frugilegus*)	8	0.4 ± 0.3	0.9
Skylark (*Alauda arvensis*)	0	-	-
Fieldfare (*Turdus pilaris*)	0	-	-
Pheasant (*Phasianus colchicus)*	1	0.1 ± 0.1	0.1
Greylag goose (*Anser anser*)	0	-	-
Mallard (*Anas platyrhynchos*)	0	-	-
Jackdaw (*Corvus monedula*)	1	<0.1 ± 0.1	0.1
Total	914	26.2 ± 7.8	100

The headland areas of all investigated fields showed markedly higher bird abundances than the corresponding mainland areas (77.3 ± 25.2 ind./100 ha for headlands and 22.0 ± 5.6 ind./100 ha for mainlands), although this difference is statistically not significant.

Fields surrounded by hedges and shrubs revealed highest abundances (36.7 ± 16.6 ind./100 ha), followed by fields surrounded by other arable fields (23.0 ± 9.1 ind./100 ha) and fields with predominating woodlands as adjacent habitat (18.9 ± 7.9 ind./100 ha). These differences, however, are as well statistically not significant.

The data obtained on bird abundances were supported by values received for frequency of occurrence and dominance. The species, which were recorded as being most frequent and at the same time showing high dominance values overlapped with the species, which were recorded as being most abundant.
Among all bird recordings, the proportion of observations of foraging birds was 91.1%.

Conclusion:

The magpie, red-legged partridge, carrion crow and starling are the most common bird species found in freshly drilled sunflower fields in southern France. The most common bird species in freshly drilled maize fields are carrion crow, magpie, yellow-legged gull and starling. They are characterised by the largest figures for abundance, frequency of occurrence and dominance.
Fields adjacent to shrubs and hedges showed higher, but not significantly different abundances than fields bordered by other habitat types. Also, bird densities on headland parts of sunflower and maize fields were higher than on mainland areas, although this difference cannot be verified statistically.

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The results calculated separately for maize and sunflower fields are similar regarding the common bird species. Hence, it seems also justifiable to consider this type of habitat (freshly drilled plain surface) as comparable across the two crops, in terms of the use by birds.
Foraging was the most prevalent type of behaviour. 91.1% of all birds observed were foraging at the instant of observation. However, no information can be given about the type of food taken from drilled fields (e.g. seeds, arthropods and other invertebrates, weeds, harvest remains etc.).

Report:	[redacted]q;[redacted]; 2010; M-359454-02-1
Title:	Residues of thiacloprid and its metabolite KKO 2254 in maize seedlings, emerged from seeds treated with Thiacloprid FS 400 (nominally 1.00 mg thiacloprid/seed)
Report No.:	MR-09/66
Document No.:	M-359454-02-1
Guidelines:	**91/414/EEC of July 15, 1991; not specified**
GLP/GEP:	**yes**

Objective:

The aim of the study was to determine the residue levels of thiacloprid and its metabolite KKO 2254 in seedlings from maize plants which had been grown from seeds dressed with Thiacloprid FS 400 (a.s. thiacloprid; nominally 1.00 mg a.s./seed). Seedlings were sampled from maize plants.

Material and Methods:

Two field trials with maize plants were conducted in Germany with Thiacloprid FS 400 seed dressing. The seed dressing contained 1.0 mg thiacloprid per seed. Samples of seedlings were taken for analysis of residues of thiacloprid and its metabolite between 16 and 37 days after drilling in the field. Residues of thiacloprid and its metabolite KKO 2254 in/on maize seedlings were determined. Thiacloprid and YRC 2894-amide were extracted from maize seedlings using a mixture of acetonitrile/water (4/1, v/v). After filtration an aliquot of this solution was evaporated to the aqueous remainder and cleaned-up on a Chromabond® XTR cartridge. After elution of the residues with cyclohexane/ethyl acetate (1/1, v/v) the extract was evaporated to dryness and re-dissolved in an internal standard solution of YRC 2894-d2. The residues were quantified by reversed phase HPLC with electrospray and MS/MS-detection.

Results:

The individual recovery values for thiacloprid for green material ranged from 80 to 112% with an overall recovery of 96% and with a relative standard deviation (RSD) of 11.2% (n = 8). For KKO 2254 the individual recovery values ranged from 79 to 100% with an overall recovery of 85% and with a RSD of 8.1% (n = 8). All results of the method validation were in accordance with the general requirements for residue analytical methods, therefore the method was validated successfully.

Residues of thiacloprid on the day of first sampling were between 17 and 18 mg/kg seedlings and declined after approx. 18 to 20 days to values of 0.33 and 0.72 mg/kg seedlings. The metabolite KKO 2254 in maize seedlings, grown from Thiacloprid FS 400 dressed seeds (nominally 1.00 mg thiacloprid/seed) in Germany on the day of first sampling were between 0.42 and 1.5 mg/kg seedlings and declined after approx. 18 to 20 days to values of 0.05 and 0.25 mg/kg seedlings.

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Table CP 10.1.1.2- 2: Maize seedling samples from Germany.

Sample ID	Sample Name	Treatment	Date of sampling	Residue Thiacloprid [mg/kg]	Residue YRC 2894-amide [mg/kg]
8-001	Seedlings	Treated T	2009-05-11	18	0.42
8-002	Seedlings	Treated T	2009-05-14	10	0.23
8-003	Seedlings	Treated T	2009-05-18	2.3	0.49
8-004	Seedlings	Treated T	2009-05-25	0.27	0.12
8-005	Seedlings	Treated T	2009-05-31	0.33	0.05
5-001	Seedlings	Treated T	2009-05-13	17	1.5
5-002	Seedlings	Treated T	2009-05-16	5.6	1.1
5-003	Seedlings	Treated T	2009-05-20	4.3	0.89
5-004	Seedlings	Treated T	2009-05-31	0.72	0.25

Remark: LOQ = 0.001 mg/kg, LOD = 0.0001 mg/kg

Report: [redacted]; [redacted]; 2010; M-370085-01-1
Title: Statement on residues of thiacloprid in maize seedlings emerged from seeds treated with FS400 formulation: kinetic evaluation
Report No.: MEF-10/336
Document No.: M-370085-01-1
Guidelines: **not applicable; not applicable**
GLP/GEP: **no**

Objective:

This statement provides kinetic evaluation of the residues of thiacloprid as reported in the study report of ([redacted], 2009, M-359454-02-1, KCP 10.1.1.2/4) to determine a DT_{50} in seedlings.

Material and Methods:

Two data sets reported by [redacted], 2009, KCP 10.1.1.2/3 for residues in maize seedlings emerged from Thiacloprid FS400 treated seeds were evaluated using the following kinetic models: Single First-Order (SFO), Gustafson-Holden, First-Order Multiple-Compartment (FOMC), Dual First Order in Parallel (DFOP) and Hockey-stick (HS; DFOS).
The best fitting values of the kinetic parameters in the equations discussed above were determined by a numerical optimization process. Using non-linear least square fitting algorithms the parameter values leading to the smallest deviations between observed and calculated residues were determined. Apart from the kinetic rates k also the initial amount was fitted. Degradation half-lives (DT_{50}) were calculated from the degradation rates k, as $DT_{50} = \ln(2) / k$
The model fit was evaluated by visual inspection. A statistical measure of the quality of a fit was given by a χ^2–test. A t-test was employed to identify the probability that a parameter is not significantly different from zero

Results:

Visually acceptable fit was obtained for residues from Set 1, with scaled error value (ε) below 10%, indicating very good agreement between the fit and the original data. The t-test clearly showed that the derived rate constant is significantly different from zero.

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For Set 2, the quality of the SFO fit was questionable and also the scaled error was rather large. Attempted use of biphasic models (FOMC and DFOP) did not provide any better half-lives - in the case of FOMC, the estimated parameters failed the relevance t-test. The low number of sampling points (only 4) did not allow for assessing the quality of the DFOP fit since the number of deg[redacted] of freedom is zero. The resulting kinetic parameters (DT_{50}) were 2.9 days for Set 1 and 2.5 days for Set 2.

Report:	[redacted]v; [redacted]; [redacted]; 2010; M-371180-01-1
Title:	Field effect study on seed-eating birds potentially feeding on freshly drilled maize seeds treated with Thiacloprid in Germany
Report No.:	R09-089
Document No.:	M-371180-01-1
Guidelines:	**No official test guideline(s) available at present; not specified**
GLP/GEP:	**yes**

Objective:

The current study aimed to investigate the impact of Thiacloprid FS 400 G-treated maize seeds on birds feeding on freshly drilled maize fields from BBCH stage 0 until approximately BBCH stage 15-16 supported by radio-telemetry.

Study site:

The study area was located between [redacted], [redacted] am [redacted] and [redacted], Bavaria, Germany. For the purpose of the proposed methods nine fields ranging in size from 0.1 to 5.1 ha served as study fields. The selected test organisms are known to occur in this area and a high proportion of farmland is used for maize cultivation.

Material and Methods:

The study fields were precision drilled with a 'Monosem planter'. Within 24h after drilling exposure assessments were carried out on each field in order to quantify the number of seeds present on the study fields. Counts were conducted both in headland and midfield of the study fields.
Five bird species known to forage on freshly drilled maize seeds or maize seedlings after germination (the magpie, woodpigeon, pheasant, grey partridge and carrion crow) were considered as candidate focal species. Since carrion crows turned out to be extremely rare on the study fields the focus of the study was on the remaining four candidate focal species and the other species naturally occurring on the study fields. In order to follow individuals of the focal species, the radio tracking approach was applied. Focal species individuals present in the surroundings of the study fields were trapped and radio tagged. The locations and activity status of the tagged birds were checked using radio telemetric methods. Telemetric checks were undertaken routinely from one day prior to drilling of the first field until the crop had reached BBCH stage 15/16 on the last of the drilled fields. During the checks, telemetric searches for tagged birds were conducted on the study fields and the wider area. It was therefore possible to assess to what extent the tagged individuals used the study fields or other maize fields. On average 9.0 fixes per bird and day were recorded. The fate of individual tagged birds was determined throughout the study period.
In order to quantify the abundance and to characterise the behaviour of birds in general on the freshly drilled study fields, bird activity was observed by scan sampling. Typically scan sampling was conducted five times over six hours per study field (one time the day after drilling, twice before BBCH

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stage 10 and twice from BBCH stage 10 to 13 respectively). Every 15 minutes the visible part of each study field was scanned, all species present were recorded and their behaviour, including any unusual incidents, noted.
Each study field was thoroughly searched for dead birds on three different days following the drilling operations. In order to quantify potential exposure to Thiacloprid FS 400 G-treated maize seeds (as potential food items) the number of drilled seeds on the surface of the study fields was estimated from sample counts the day after drilling.

Results:

A total of 26 birds (14 grey partridges, seven magpies, four woodpigeons and one pheasant) were trapped and radio tagged either on the study fields or in their vicinity. Out of these 26 birds, 21 were proved to be alive until the end of the study. One magpie lost its tag and four grey partridges were found predated.
Four grey partridges, three magpies and one pheasant were located at least once on a study field. However, the study fields were not intensively used by the monitored birds. The pheasant no. 1 and the magpie no. 17 used the study fields most frequently with only 1.9% and 1.8%, respectively, of the localisation inside the study fields.
None of these individuals were observed to exhibit any signs or symptoms to suggest any deleterious effects resulting from the ingestion of Thiacloprid FS 400 G-treated maize seeds.
A total of 22 bird species were observed during scan sampling in the freshly drilled maize fields. The white wagtail, the skylark, the yellow wagtail and the starling were the most abundant species. Of those species more likely to feed on treated seeds, the woodpigeon and the magpie were most prominent in the scan sampling observations. No indication of any impacts on any bird was detected.
The exposure assessment revealed that low numbers of treated seeds were available on some study fields. Some small spills of treated seeds were detected on the fields but did not seem to attract feeding birds.
The following three species were observed once feeding on Thiacloprid FS 400 G-treated maize seeds: pheasant, woodpigeon and magpie. Only the magpies were observed feeding on freshly drilled maize seeds or seedlings, however on other maize fields than the study fields. However, the proportion of the diet was low. No bird carcasses were found on the study fields.

Radio tracking results are summarised in the table below.

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Table CP 10.1.1.2- 3: Radio tracking results

Radio tracking		
No. of tagged birds per species	**No. of 'user' and 'non-user' of treated fields between drilling and BBCH 15/16**	**Fate until BBCH 15/16**
7 magpies total no. of fixes: 2,107 mean no. of fixes/day: 9.4	3 user (0.31 – 1.79% of fixes inside treated fields)	3 alive and present
	4 non-user	3 alive and present 1 lost tag
14 grey partridges total no. of fixes: 3,013 mean no. of fixes/day: 8.7	4 user (0.63 - 1.02% of fixes inside treated fields)	4 alive and present
	10 non-user	6 alive and present 4 killed by predator (1 gizzard sampled for residue analysis)
4 woodpigeons total no. of fixes: 1,103 mean no. of fixes/day: 9.5	4 non-user	4 alive and present
1 pheasant total no. of fixes: 316 mean no. of fixes/day: 8.3	1 user (1.90% of fixes inside treated fields)	1 alive and present

Study fields										
Study field no.	1	2	3	4	5	6	7	8	9	Total
Area [ha]	5.1	2.1	2.8	3.4	2.0	1.7	2.7	1.9	0.1	21.8
Scan sampling										
Scan area [ha]	5.1	1.5	2.7	1.8	2.0	1.0	0.7	0.5	-	15.1
No. of scans	125	25	75	125	75	125	100	125	-	775
No. of bird contacts	102	23	64	392	41	132	41	10	-	805
No. of species	6	3	8	11	10	7	6	4	-	22
Bird incidents	0	0	0	0	0	0	0	0	-	0
Exposure assessment Additional recording and monitoring of seed spills on three study fields.										
Area [m²]	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	5.0	85.0
Seeds midfield/ headland [mean no./m²]	0/	0/	0/	0/	0/	0/	0/	0.2/.2	0/-	0.02
Carcass search										
Man hours of search per field [hh:mm]	13:04	06:04	08:45	10:01	07:46	05:33	09:06	09:45	05:44	75:48
Search area[1,2] [ha]	5.1	2.1	2.8	3.4	2.0	1.7	2.7	1.9	0.1	21.8

[1] plus a strip of five metres of the surroundings
[2] searched three times after application

Conclusion:

The various methods applied in the current study provided a reasonably robust approach to assessing the impact of Thiacloprid FS 400 G-treated maize seeds on birds feeding on freshly drilled maize fields. The combined results show that the availability and attractivity of seeds treated with Thiacloprid FS 400 G was low. Neither the monitored individuals nor other individuals of the local bird population were adversely affected.

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Report: [redacted]$;[redacted]; 2005; M-242960-01-1
Title: Generic field monitoring of birds and mammals on maize and beet fields in Austria
Report No.: WFC/FS 017
Document No.: M-242960-01-1
Guidelines: **The test was especially designed for the purpose of this study; none**
GLP/GEP: **yes**

Objective:

The current study aimed to find out how Skylarks and mammal species (mainly Wood mouse) use maize and beet fields within their daily movements and how much time per day they spend on those fields. Furthermore, the feeding behaviour on maize and beet fields was investigated (portion of time spent foraging). The study aimed to reveal behavioural information for these species.

Study site and study plots:

The study was conducted in and around 5 maize and 5 sugar beet fields in the '[redacted]' to the west of Vienna in Austria. This region is a typical area of maize and sugar beet cultivation in Europe.

Material and Methods:

The study started some weeks before drilling of maize and sugar beet and was completed when the BBCH-code 14 of maize and 16 of sugar beet was reached.

Birds

To appraise the relevance of maize and sugar beet fields as well as adjacent cultivation for birds, census counts were carried out along 5 different transects, representing typical agrarian habitats within the region. The 5 transects areas covered 65.4 ha in total and were monitored 10 times during the whole study period. For each crop type monitored the abundance of birds was calculated.
Additionally in 3 maize and in 3 sugar beet fields the scan sampling approach was carried out. Each field was scanned every 10 minutes for at least 3 days from dawn till dusk to register all present bird species using the field (51 sessions). Before drilling the same fields were 'scan sampled' to monitor the species composition on plain fields. This method offers very detailed information of the bird community using these crops as well as the species specific abundance.
From former studies it was known that Skylarks (*Alauda arvensis*) occasionally use sugar beet fields as foraging habitats. To quantify the actual relevance of sugar beet and also maize fields 16 Skylarks were trapped, tagged with radio transmitters and tracked for one to four daylight periods respectively. During each session a Skylark was tracked continuously so that the location, habitat and behaviour could be recorded to get information of the home range, habitat selection and time budget of individuals living in areas characterised by the occurrence of maize and sugar beet cultivation.
To get information about the food items selected by Skylarks and other bird species, faeces were gathered in maize and sugar beet fields and analysed quantitatively for composition (portion of animal and plant matter).

Mammals

The relevance of maize and sugar beet fields as well as the adjacent surrounding for small mammals was investigated. The presence of small mammal species and their abundance in different habitats was determined by live trapping (capture-mark-recapture method). On 6 investigated plots 45 life traps

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each were set in the field and the adjacent surrounding. Furthermore, individuals of different species were radio tracked continuously for 24 h and the location, habitat, and behaviour was recorded. From the telemetry data the potential foraging time, the habitat preference (Jacobs' index) and the home range were calculated.

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Table CP 10.1.1.2- 4: Results for Birds

PORTION OF TIME potentially foraging (PT) per habitat used by radio tracked Skylarks					
		Mean		90%ile	N
potential foraging time [1] 16 skylarks spent per habitat; [mean of sessions], (90%ile, N: no. of tracking sessions considered)	plain fields	19.9	%	(59.3)	15
	drilled maize fields	4.1	%	(14.1)	7
	germinated maize fields	42.1	%	(95.4)	10
	drilled sugar beet fields	8.1	%	(21.2)	9
	germinated sugar beet fields	19.7	%	(58.7)	14

HABITAT PREFERENCE of Skylarks according to radio tracking		
preference of crop types as a feeding habitat (Jacobs' index [D], Range: –1 to +1; MCP [100%])	plain fields	-0.47
	drilled maize fields	-0.83
	germinated maize fields	0.06
	drilled sugar beet fields	-0.73
	germinated sugar beet fields	-0.29

DIET of Skylarks in maize and sugar beet fields			
	food item	PD [%]	Frequency [%] [2]
mean portion of diet after the analysis of faeces gathered in sugar beet (63) and maize (6) fields	maize seeds	0	0
	maize seedlings	0	0
	sugar beet seeds[3]	< 0.7	3.2
	sugar beet seedlings[3]	< 3.6	23.8
	potentially sugar beet seeds[4]	< 2.1	17.5
	potentially sugar beet seedlings[4]	< 10.2	36.5

HABITAT of birds according to transect counts (based on population)			
	field status	Skylark	sum of other species
abundance of Skylarks and other species after 10 transect counts covering 65.4 ha respectively [individuals/ha]	plain fields	0.34	0.41
	drilled maize	0.41	0.86
	germinated maize	0.25	1.63
	drilled sugar beet	0.32	0.36
	germinated sugar beet	0.31	1.1
	all other fields	0.59	1.1

BIRD ABUNDANCE against crop type and stage according to scan sampling			
Densities of the 3 most abundant bird species in different crop types and stages [ind./ha/scan]	plain field (28 sessions)	Skylark	0.12
		Pied Wagtail	0.07
		Black Redstart	0.03
	drilled maize field (3 sessions)	Skylark	0.07
		Common Pheasant	0.03
		Pied Wagtail	0.03
	germinated maize fields (6 sessions)	Grey Partridge	0.02
		Barn Swallow	0.02
		Common Pheasant	0.02
	drilled sugar beet fields (4 sessions)	Skylark	0.14
		Common Pheasant	0.05
		Grey Partridge	0.01
	germinated sugar beet fields (10 sessions)	Skylark	0.21
		Whinchat	0.05
		Common Pheasant	0.04

[1] Sum of behaviour categories "foraging"+"potentially foraging"+"unknown"
[2] Portion of faeces with remains of the appropriate food item
[3] based on identified food items
[4] Sum of sugar beet and unspecified seeds or rather seedlings, as a conservative worst case approach

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Table CP 10.1.1.2- 5: Results for Mammals

small mammals					
trapping (based on population)					
relevant species in the field	*Apodemus sylvaticus* (90% of all field trappings)				
habitats	effort [trap nights]		result [trappings/1000 trap nights]		trappings in the field [%]
	field	surrounding	field	surrounding	
all fields / surrounding	4395	2198	9	31	22
plain field / surrounding	1440	720	10	7	60
sugar beet / surrounding	1395	698	11	53	18
maize field / surrounding	1560	780	4	32	12

radio tracking (based on individual Woodmice)						
habitat	no. of tracking sessions	no. of individuals tracked	PT [%] mean of sessions	PT [%] 90%ile of sessions	% of home range	preference [Jacob's Index (D)] (range: –1 to +1)
all fields	15	8	53	100	84	-0.5
plain field	4	4	17	34	45	-0.3
sugar beet drilled	3	3	38	81	54	-0.2
sugar beet germinated	8	5	32	93	38	-0.6
sugar beet total	11	5	33	98	42	-0.5
maize drilled	2	1	0	0	8.7	-1
maize germinated	3	2	2	4	28.3	-0.9
maize total	5	3	1.4	4	20	-0.9

Table CP 10.1.1.2- 6: Birds and mammals

potential grazing damage of vertebrates[1] (% of biomass)				
habitat	BBCH 12	BBCH 13	BBCH 14	BBCH 16
sugar beet	1.0	not stated	2.8	4.7
maize	0.3	1.5	0.8	not stated

[1]sum of unknown and vertebrate grazing damage

Conclusion:

Birds

Radio tracking of 16 individual Skylarks (each for a minimum of 24 and a maximum of 96 hours) in an agrarian landscape with a high portion of maize and sugar beet fields to the west of Vienna (Austria) showed that this field types were used as feeding habitats by these birds. Despite the fact, that it was normally not possible to identify the small items ingested by the tracked Skylarks, sugar beet and maize seedlings could mostly be excluded. Sugar beet fields were on average selected to a lower portion for foraging as to be derived from the available portion in the birds' home ranges (Jacobs' index [D]). In terms of habitat selection that means that they avoid this habitat type for foraging (Jacobs' index [D]: -0.29). The Skylarks neither preferred nor avoided germinated maize fields as a foraging habitat as it was used in conformity with the portion in their home range.
The results of the census counts support the findings of the tracking data that the surrounding fields were generally more attractive to Skylarks than the maize and sugar beet fields. The abundance of Skylarks in all other habitats was notably higher than in maize and sugar beet. However, the pre-selection of the Skylark as the species of concern in maize and sugar beet fields was confirmed by the finding, that it was generally the most abundant species in these crops. The dominance of the Skylark was due to a moderate bird abundance as a whole and not caused by comparatively high numbers of Skylarks.

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For risk assessment purposes a value for portion of time spent foraging in drilled as well as germinated maize and sugar beet fields (PT) can be derived for Skylarks from the study results: Skylarks settling in or in close vicinity to maize and sugar beet fields spent their potential foraging time on average 4.1% (90th percentile 14.1%) in drilled and 42.1 (90th percentile 95.4%) in germinated maize fields as well as 8.1% (90th percentile 21.2%) in drilled and 19.7% (90th percentile 58.7%) in germinated sugar beet fields.
From the analyses of Skylark faeces (n = 63) gathered in sugar beet fields can be concluded that the portion of diet (PD) was less than 0.7% for sugar beet seeds and less than 3.6% for sugar beet seedlings. To cover the worst case that all unspecified seeds or seedlings actually originated from sugar beet the portion of diet was less than 2.1% for the 'potentially sugar beet seeds' and less than 10.2% for the 'potentially sugar beet seedlings' respectively. No indication of the ingesting of maize was found from those faeces (n = 6) gathered from maize fields.

<u>Mammals</u>
According to the results of trapping and radio tracking the wood mouse has been the species of concern. The population densities were low due to the fact that the reproductive period starts in spring and the populations reached their low point after the non-reproductive winter. The live trapping revealed that the uncultivated plain field was most attractive, which was due to the leavings of the previous crops on the surface. These leavings were an easy food source. After the field cultivation began and the leavings were eroded in the soil, the attractiveness of sugar beet and of maize decreased. The average potential foraging time (PT) based on radio tracked wood mouse increased in sugar beet (33%) compared to plain field (17%). Maize (1.4%) was scarcely part of the PT. This indicated that maize was less attractive than plain field or sugar beet. The wood mouse showed a light avoidance for all habitats of concern. The food availability in spring is low so the plain field was a highly attractive food source. During telemetry no indication was found that mammals dug out seeds of maize and sugar beet seeds.
According to the transect counts Hares were most abundant in plain fields (0.14 ind./ha) followed by drilled maize fields (0.13 ind./ha), germinated maize (0.12 ind./ha) and sugar beet fields (0.03 ind./ha). Roe Deer were only observed in plain fields and other crops than maize and sugar beet during the transect counts. Hares were observed feeding on sugar beet seedling during scan sampling only in four cases. The incidence of feeding on maize seedlings was not detected. Roe Deer neither fed on maize nor sugar beet seedlings.
The cause for missing parts of the germinating maize and sugar beet seedlings could mostly not be assigned. Hence grazing damage caused by birds or mammals could not be excluded in these cases. However, the amount of missing biomass was negligible.
Thus neither maize nor sugar beet seeds nor seedlings provided a relevant food source for birds and mammals during the course of this study.

Report:	[redacted]; [redacted]; 2010; M-370696-01-1
Title:	Frequence of occurence of birds in arable fields in spring in Austria - A re-evaluation of the study : [redacted], Ch. (2005): Generic field monitoring of birds and mammals on maize and beet fields in Austria (E 308 2692-0, WFC/FS017)
Report No.:	M-370696-01-1
Document No.:	M-370696-01-1
Guidelines:	**The test was especially designed for the purpose of this study; none**
GLP/GEP:	**no**

Objective:

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This paper aims to re-evaluate the bird observation data of the transect counts (obtained by [redacted] 2005) in order make them more compatible for current risk assessment purposes.

Material and methods
The data of all single fields were aggregated into 10 "sessions". For each session it was determined how many fields could be assigned to a defined **crop/stage** (plain field; drilled maize field, germinated maize field; drilled sugar beet field, germinated sugar beet field and winter cereal fields) at the time of the census.

Afterwards, FO_{survey} (%) and FO_{flied}(%) were calculated as described in the following:

FO_{survey} (%) = number of surveys per crop/stage during which a certain species is observed * 100 / Ns (=number of surveys) per crop/stage

FO_{field} (%) = number of fields per crop/stage on which a certain species is observed * 100 / Nf (=number of fields) per crop/stage

Results
The calculated FO_{survey} and FO_{field} values in all defined crops/stages are presented in the following. Only values >20% were displayed.

Table CP 10.1.1.2- 9: FO_{survey} [%] and FO_{field} [%] values (only values > 20% were displayed)

Crop/Stage	Species	Latin Name	FO_{survey} [%]	FO_{field} (%)
Plain field	Eurasian Sky Lark	*Alauda arvensis*	-	55.10
	Carrion Crow	*Corvus corone*	-	28.57
Drilled maize field	Eurasian Sky Lark	*Alauda arvensis*	-	27.78
Drilled Sugar beet field	Eurasian Sky Lark	*Alauda arvensis*	-	30.00
Germinated maize field	Eurasian Sky Lark	*Alauda arvensis*	-	24.32
Germinated sugar beet	Eurasian Sky Lark	*Alauda arvensis*	-	30.00
Winter cereals	Eurasian Sky Lark	*Alauda arvensis*	26.60	65.63
	White Wagtail	*Motacilla alba*	-	21.88

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Report:	KCP 10.1.1.2/10[redacted]>; 2007; M-286951-01-1
Title:	Exposure of birds in different crops to Mesurol RB4 slug pellets in France in spring - attractiveness of those fields, species of concern and impacts
Report No.:	RA06-003
Document No.:	M-286951-01-1
Guidelines:	**Not applicable; the test was especially designed for the purpose of this study.; none**
GLP/GEP:	**yes**

Justification:

This study concerns a product that is not subject of this dossier. However, since it contains data on maize seeds potentially exposed on the soil surface after drilling and these data are used in the refined risk assessment for the product dealt with in this document, the study is presented here.
Only data on maize are considered relevant in the context of this document, therefore only data on maize is summarised.

Objective:

The aim of this study was to investigate the potential impact of Mesurol RB4 application in freshly treated maize, sugar beet and sunflower fields on the natural bird community. For this the species and abundance of birds were considered and the occurrence of bird incidents in Mesurol RB4 treated fields assessed.

Study site:

The study was conducted in maize fields in the department Tarn (Midi-Pyrénées region) in south-western France, typical cultivation areas for the crop.

Material and Methods:

In order to gain information on the occurrence of birds, bird activity was observed by scan sampling once in each field over an entire daylight period. Every ten minutes a defined section of the study field was scanned, records being taken of species, behaviour and any incidents. Each field was completely searched for dead birds. Predator removal tests and carcass search efficiency tests were conducted to evaluate the actual carcass detection rate. In order to quantify the exposure of Mesurol RB4 slug pellets and potential food items (seeds, earthworms, slugs) sample counts were carried out in each field.

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Results / Conclusions:

Table CP 10.1.1.2-7: Overview of the results in maize

	MAIZE
BIRD OBSERVATION	
Worked fields	15
Mean observed area [ha]	1.49
Mean no. of scans	88.5
Observed species per field	2 to 15
Total number of species	35
Frequency of occurrence of foraging birds [%] (top five species; given is the mean of the results for each field)	Magpie (4.18) Carrion Crow (2.93) Red-legged Partridge (2.88) Turtle Dove (2.33) Feral Pigeon (2.13)
Abundance of foraging birds [ind./ha/scan] (top five species; given is the mean of the results for each field)	Feral Pigeon (0.056) Red-legged Partridge (0.045) Carrion Crow (0.045) Magpie (0.034) Turtle Dove (0.026)
Relative Risk Index (top five species; given is the mean of the results for each field; the index varies from 0 (no risk) to 1 (high risk))	Magpie (0.026) Red-legged Partridge (0.023) Carrion Crow (0.022) Wood Pigeon (0.014) Turtle Dove (0.014)
Bird incidents	none
EXPOSURE ASSESSMENT (headlands / midfield)	
Worked fields	15
Area per field [m^2]	5 / 5
Mesurol RB4 [pellets/m^2] (mean of single results)	15.8 / 13.5
Slugs [no./m^2] (mean of single results)	<0.1 / 0.1
Earthworms [no./m^2] (mean of single results)	0.1 / <0.1
Seeds [no./m^2] (mean of single results)	0.2 / 0.1
CARCASS SEARCH	
Worked fields	15
Mean area searched [ha]	6.11
Total area searched [ha]	91.6
Carcasses found	one mallard chick (residues below LOQ[1])
Search efficiency [% of placed carcasses found]	100
Removal [% of placed carcasses removed by scavengers within 12 / 24 hrs.]	50.0 / 58.3

1) LOQ = 0.04 mg/kg for Methiocarb, Methiocarb-sulfone and Methiocarb-sulfoxide

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Table CP 10.1.1.2- 8: Quantity of Mesurol RB4 pellets and potential food items in maize fields

items	[numbers / m^2]											
	headland						midfield					
	minimum	maximum	mean	SD	50 %-quantile (median)	90 %-quantile	minimum	maximum	mean	SD	50 %-quantile (median)	90 %-quantile
Mesurol RB4 pellets	3.0	62.0	15.8	15.2	9.6	27.3	2.2	32.0	13.5	9.5	11.0	27.8
slugs	0	0.4	<0.1	0.1	0	0.1	0	0.6	0.1	0.2	0	0.2
earthworms	0	1.4	0.1	0.4	0	0	0	0.2	<0.1	0.1	0	0.2
maize seeds	0	1.0	0.2	0.3	0	0.4	0	1.0	0.1	0.3	0.	0,1

Report: KCP 10.1.1.2/11 [redacted] O. [redacted]; 2010; M-369149-01-1
Title: Exposure of mammals in maize fields in France - Attractiveness of maize fields and relevant species
Report No.: R09-012-2
Document No.: M-369149-01-1
Guidelines: **No official test guideline(s) available at present. The study was conducted under consideration of the Scientific Opinion of the Panel on Plant protection products and their residues on risk assessment for birds and mammals Anonymous 2008).; none**
GLP/GEP: **yes**

Report: KCP 10.1.1.2/12 [redacted].; 2010; M-369666-01-1
Title: Letter of access for generic behavioural ecology data - Study report: RIFCon report No. R09012-2, Syngenta study no. TK0003853 - Crop grouping: Maize, pre-emergence (seed treatments) and post-emergence: Exposure of mammals in maize fields in France - Attractiveness of maize fields and relevant species
Report No.: M-369666-01-1
Document No.: M-369666-01-1
Guidelines:
GLP/GEP: **no**

Objective:

This study aimed at obtaining information about the occurrence of wild mammals in maize fields in Southern Europe in order to define the focal species in this crop between drilling and BBCH growth stage 16.

Study site:

The study was conducted in Southern France in a typical maize growing region south of Toulouse in the departments Haute-Garonne and Ariege (region Midi-Pyrenees).

Material and Methods:

The study was conducted in spring 2009. The occurrence of mammals in drilled maize fields was assessed by small mammal live trapping and scan sampling.

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The live trapping of small mammals was carried out according to a 'Capture-Mark-Recapture (CMR)' design and was used to generate a list of small mammal species and their abundance in freshly drilled maize fields. This implicated individual marking of the captured animals with a passive integrated transponder (PIT). Data derived using this methodology enabled the abundance of mammals on the study fields to be estimated according to the 'Minimum Number Alive' (MNA) approach described by Krebs (1989). Trapping was carried out from 27 April until 27 May 2009 on four different maize fields with a trapping effort of 1,488 trapnights[9] per field, with 25% of the traps set up in the adjacent off-crop habitat.
In order to identify and quantify the occurrence of nocturnal mammals in maize fields 'thermographic scan sampling' observations were carried out in four fields, using a thermographic camera (InfraTec VarioCam, 4x zoom) which is suitable for the detection of nocturnal mammals (Boonstra et al. 1994, Focardi et al. 2001).
To quantify the abundance and to characterise the behaviour of diurnal mammals on drilled maize fields, ten study fields were observed by scan sampling for mammal activity.
With the purpose to obtain more detailed information about the foraging behaviour of mammals on maize fields (period: after drilling until BBCH 16), individual mammals with a focus on medium-sized herbivores (hares) were visually observed.
Live trapping, thermographic scan sampling, diurnal scan sampling and monitoring of foraging behaviour was done at three different times according to crop stages of the maize plants: shortly after drilling (BBCH 0), after emergence of maize seedlings (BBCH 10-11) and after emergence of leaves (BBCH 12-16).
In order to record any foraging damage to the maize crop potentially caused by mammals, a sample of maize seedlings was inspected twice after emergence of the crop. The first inspection was carried out shortly after the emergence of the seedlings and the second in the period of BBCH growth stages 12-16.
For the purpose of quantifying the exposure of maize seeds on the soil surface, counts were carried out within 24 hours after drilling was finished. This exposure assessment was conducted on ten maize fields.

Results:

Small mammal species in maize fields and their surroundings:
The most abundant small mammal species found was the wood mouse (*Apodemus sylvaticus*). Besides the wood mouse, the common vole (*Microtus arvalis*) and the greater white-toothed shrew (*Crocidura russula*) were captured. A comparison of trapping efficiencies for field and surrounding habitat evidently showed that small mammals were chiefly captured in the off-crop habitat.

Monitoring of diurnal and nocturnal mammal behaviour and activity:
Besides the wood mouse, the European brown hare (*Lepus europaeus*) and the European rabbit (*Oryctolagus cuniculus*) were the relevant species monitored as potentially foraging during thermographic scan sampling sessions. The hare was the only mammal species observed during daylight scan sampling. overall mammals showed low abundances.

[9] The parameter 'trapnights' is a measure of trapping effort taking the number of traps set and the number of checks into account: 1 trapnight = 1 trap set for 1 night

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Monitoring of individual mammals foraging on maize seeds or seedlings:
The European brown hare was the only mammal species being observed during feeding observations. In rare observations, hares fed occasionally on maize plants. Although the sample size was small, a feeding rate for maize leaves was calculated.

Damage assessment:
Due to ambiguous damage patterns no useful results were derived from this approach.

Exposure assessment:
The number of seeds found on the soil surface of maize fields was low.
The following table gives an overview of the key results.

Table CP 10.1.1.2- 10: Overview of key results

Small mammal trapping			
Species	Mean trapping efficiency [captures/100 trapnights]		
	Field (based on 1,116 trapnights)	Off-crop (based on 372 trapnights)	Captures in the field [% of total captures]
Wood mouse (*Apodemus sylvaticus*)	0.35	15.40	6.56
Greater white-toothed shrew (*Crocidura russula*)	0.00	6.60	0.00
Common vole (*Microtus arvalis*)	0.00	1.04	0.00

Diurnal and nocturnal mammal monitoring				
Thermographic scan sampling				
Species	Abundance [ind./ha]	Foraging Individuals [%]		FOfield [%]
Wood mouse (Apodemus sylvaticus)	0.31	57.14	3.43	100
European brown hare (Lepus europaeus)	0.04	45.83	9.80	75
European rabbit (Oryctolagus cuniculus)	0.02	46.15	5.39	50
Diurnal scan sampling				
European brown hare (Lepus europaeus)	0.004	61.11	2.63	40

Exposure assessment		
	Mean density of exposed seeds [seeds/m2] (SD)	Average number of seeds per ha
headland	0.16 (0.21)	1600
midfield	0.06 (0.10)	600

Conclusion:

Three small mammal species occurred in off-crop habitats adjacent to maize fields: the wood mouse (*Apodemus sylvaticus*), the common vole (*Microtus arvalis*) and the greater white-toothed shrew (*Crocidura russula*). Only the wood mouse was found inside maize fields and then only in very small numbers after emergence of maize.

· In addition to the wood mouse, the European brown hare (*Lepus europaeus*) and the European rabbit (*Oryctolagus cuniculus*) were also observed in maize fields.

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CP 10.1.2 Effects on terrestrial vertebrates other than birds

Table CP 10.1.2- 1: Endpoints used in risk assessment

Test substance	Test species	EU agreed endpoints		Endpoints used in risk assessment	
Thiacloprid	Rat acute, oral	LD_{50}	444 mg a.s./kg bw	**LD_{50}**	**315 mg a.s./kg bw (f)** 451 mg a.s./kg bw (m)
	Rat reproduction	NOEC **NO(A)ED**	100 mg a.s./kg diet 7.3 mg a.s./kg bw/d	NOEC NO(A)ED	300 mg a.s./kg diet **21 mg a.s./kg bw/d**

Table CP 10.1.2- 2: Relevant generic focal species feeding on seeds for Tier 1 risk assessment

Type of seeds	Generic focal species	FIR/bw
'Large seeds' (maize, beans or peas)	Small omnivorous mammal	0.24
'Small seeds' (not maize, beans or peas)	Small omnivorous mammal	0.24

Table CP 10.1.2- 3: Relevant generic focal species feeding on seedlings for Tier 1 risk assessment

Generic focal species	Short-cut value (SV) for acute risk*
Small omnivorous mammal	0.24 x NAR/5

* For the reproductive assessment, these shortcut values should be combined with appropriate time windows and default degradation/dissipation rates for residues

Toxicity of the formulated product

An acute study on rats was conducted with a Thiacloprid FS 400 formulation ([redacted]A; 2009; M-347604-01-1, Section 7, KCP 7.1.1/1). The formulation studies were performed with the formulated product Thiacloprid FS 400, specification no. 102000021815 the composition of this formulated product differs slightly from the final product (Thiacloprid FS 400, specification no. 102000022825), however the differences would not be expected to have any impact on the ecotoxicological profile. The results of the studies are therefore regarded as valid for the current specification.

This study, however, was carried out according to the toxic class method to satisfy classification and labelling requirements. As such, the spacing of the doses was very broad and only 2 doses were tested, the higher one with only 3 animals. Therefore, this figure is much less robust than the one determined for the active substance and it will not be used for the risk assessment.

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Table CP 10.1.2- 4: Mammalian toxicity data of the formulated product Thiacloprid FS 400

Test species	Test design	Ecotoxicological endpoint	Reference
Rat	acute, oral	$LD_{50\ cut\ off}$ 500 mg prod./kg bw 175 mg a.s./kg bw *	[redacted] (2009) M-347604-01-1 KCP 7.1.1/1

* considering a measured content of 414.4 g/L thiacloprid and a product density of 1.184 mg/mL

ACUTE DIETARY RISK ASSESSMENT

Table CP 10.1.2- 5: Tier 1 acute TER calculation for mammals feeding on seed treatment

Compound	Indicator species	Toxicity [mg/kg bw]	Exposure		TER_A	Trigger
			FIR/bw	NAR [mg a.s./kg seeds][1]		
Thiacloprid	Small omnivorous mammal	315	0.24	2222 - 5000	**0.26 – 0.59**	10

[1]Assuming a thousand grain weight of the seeds of 200-450 g [10]

Table CP 10.1.2- 6: Tier 1 acute TER calculation for mammals feeding on crop seedlings

Compound	Indicator species	Toxicity [mg/kg bw]	Exposure		TER_A	Trigger
			FIR/bw	NAR/5 [mg a.s./kg][1]		
Thiacloprid	Small omnivorous mammal	315	0.24	444 - 1000	**1.31 - 2.95**	10

The TER_A values calculated in the acute risk assessment on Tier 1 level do not exceed the a-priori-acceptability trigger of 10 for all evaluated scenarios. Thus, a refined risk assessment for these scenarios is presented below.

Refined risk assessment

The refined risk assessment presented here follows Guidance of EFSA "Risk Assessment for Birds and Mammals" (2009), this document states in chapter 5.2: "*Tier 1 assumes that granivorous birds and mammals feed entirely on readily available, freshly treated seeds. The failure rate of pesticides used as seed treatments to meet the standard EU triggers for acute and reproductive risks under such a scenario is likely to be high. Therefore, many cases will require refined assessment. At present, it is not possible to recommend standardized approaches for refined assessment. Therefore, a range of options for refinement are presented.*

The outcome of a refined assessment would, in most cases, take the form of a weight-of-evidence approach, rather than a quantitative assessment (e.g. TER). Risk managers will have to decide on whether the evidence provided is sufficient to allow for a decision whether the intended level of protection is reached. Guidance is provided on the method for such a weight-of-evidence approach."

[10] Faustzahlen für die Landwirtschaft (2005), published by Kuratorium für Technik und Bauwesen in der Landwirtschaft, Darmstadt, 13th edition, ISBN 3-7843-2194-1

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Treated seeds

Generic focal species and Focal species (FS)

The Generic focal species for large seeds like maize, beans and peas is a small omnivorous mammal with a FIR/bw of 0.24.
A field study was conducted in and around 5 maize and 5 sugar beet fields in the [redacted] to the west of Vienna in Austria ([redacted], C.; 2005; M-242960-01-1, KCP 10.1.1.2/8). This region is a typical area of maize and sugar beet cultivation in Europe. The study started some weeks before drilling of maize and sugar beet and was completed when the BBCH-code 14 of maize and 16 of sugar beet was reached.
The relevance of maize and sugar beet fields as well as the adjacent surrounding for small mammals was investigated. The presence of small mammal species and their abundance in different habitats was determined by live trapping (capture - mark - recapture method). On 6 investigated plots 45 life traps each were set in the field and the adjacent surrounding. Furthermore, individuals of different species were radio tracked continuously for 24 h and the location, habitat, and behaviour was recorded. From the telemetry data the potential foraging time, the habitat preference (Jacobs' index) and the home range were calculated.
According to the results of trapping and radio tracking the wood mouse has been the species of concern. The population densities were low due to the fact that the reproductive period starts in spring and the populations reached their low point after the non-reproductive winter. The live trapping revealed that the uncultivated plain field was most attractive, which was due to the leavings of the previous crops on the surface. These leavings were an easy food source. After the field cultivation began and the leavings were eroded in the soil, the attractiveness of sugar beet and of maize decreased. The average potential foraging time (PT) based on radio tracked Woodmouse was 0.33 in sugar beet (33%) and 0.17 in plain field (17%). Maize (1.4%) was scarcely part of the PT. The Woodmice clearly showed a preference for the off-crop area. This may also relate to the low number of Woodmice at this time of season and the resulting availability of sufficient preferred habitat and food in the proximity of the fields.
During telemetry no indication was found that mammals dug out seeds of maize seeds.
According to the transect counts Brown Hares were most abundant in plain fields (0.14 ind./ha) followed by drilled maize fields (0.13 ind./ha) and germinated maize (0.12 ind./ha). No incidence of feeding on maize seedlings was detected.
The author concluded that neither freshly sown maize seeds nor seedlings provided a relevant food source for mammals.

In a generic field study in Germany ([redacted],; [redacted]; [redacted]; 2013; M-486987-01-1, KCP 10.1.2.2/2), live trapping was conducted on four maize fields at six trapping sessions (each session comprised two trapping events) once per month from June until November 2011.
No wood mice were found in maize fields at the early growth stage (BBCH 19) at the trapping session in June. First wood mice were recorded in Maize at BBCH stages 51-61 (July).

In a further generic field study in France ([redacted]; [redacted]; 2010; M-371180-01-1 KCP 10.1.1.2/7) addressing the attractiveness of maize fields for mammals, again the Woodmouse and the Brown Hare as well as the European Rabbit were identified as the main species. In this study, however, no PT was determined for the three focal species. Hares were observed feeding on emerged seedlings and a feeding rate was calculated based on 7 observations. Durations for feeding activities

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ranged from one to 10 minutes with estimated ingestions of 0.25 to 15.54 g plant material at an average rate of 1.28 g/min (range 0.15 – 3.11 g/min).
In conclusion, the information gained from the field studies of [redacted],; 2005; M-242960-01-1, KCP 10.1.1.2/8) and [redacted]; [redacted]; 2010; M-369149-01-1, KCP 10.1.1.2/11) point at the **Woodmouse** and the **Brown Hare** as focal species in / on maize fields shortly after emergence. On freshly sown maize fields only the **Woodmouse** was found as focal species. None of these species, however, used maize fields as a significant source for feeding.

Dehusking

For granivorous mammals such as rodents, dehusking or cracking of seed or fruit shells is often a part of their typical behaviour. Two studies to quantify the extent of dehusking of maize by Woodmice were conducted ([redacted] et al., 2007[11], [redacted] et al. 2010[12]). Using different approaches, both authors came to a conclusive result: Woodmice dehusked sunflower seeds almost completely (≥90%) whereas dehusking efficiency in maize reduced potential exposure by more than half (59 to 62%).
According to these results, a dehusking factor of 0.41 (corresponding to 59% dehusking efficiency) can conservatively be assumed for maize.
To factor this mitigating aspect into the risk assessment, the nominal loading rate of maize seeds (1 mg a.s./kernel) is multiplied with the dehusking factor (0.41). Thus, the potential exposure of Woodmice is 0.41 mg a.s./maize seed.

Table CP 10.1.2- 7: Refined tier 1 acute TER calculation for mammals feeding on seed treatment

Indicator species	Toxicity [mg/kg bw]	Exposure			TER_A	Trigger
		FIR/bw	NAR [mg a.s./kg seeds]	dehusking factor		
Small omnivorous	315	0.24	2222 - 5000	0.41	**0.64 - 1.44**	10

Toxicity endpoint

An acceptable acute risk for all mammalian species is assumed, if a TER_A greater or equal 10 is demonstrated, i.e. exposure (i.e. intake over the relevant period) is no more than one tenth the LD_{50} of the species tested. In other words, intake of a dose equivalent to tenth the LD_{50} over an "acute" time period is considered a (regulatory) acceptable dose. As such, the regulatory margins of safety needed to extrapolate from the LD_{50} in the laboratory test species to a safe exposure level for species in the field are already included in the (regulatory) acceptable dose and do not need to be applied afterwards in a "classical TER calculation".
Accordingly the toxicity endpoint (LD_{50}) is divided by (the TER_A of) 10 to calculate the regulatory "acceptable dose". This allows a direct comparison of the "acceptable dose", expressed as number of treated maize seeds to achieve the 1/10 of the LD_{50} with the daily intake of maize seeds for that species. Such an approach makes particularly sense in cases where exposure is via distinct "portions"

[11] [redacted], J. et al. 2007, Comparison of dehusking experiments of laboratory mice and wild Apodemus spec. mice, SETAC Europe, 17th Annual Meeting, May 2007, Porto

[12] [redacted], C. et al., Exposure reduction of seed treatments through dehusking behaviour of the wood mouse (Apodemus sylvaticus), in press in Environmental Science and Pollution Research 2010

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(e.g. treated seeds, granules, bait particles) rather than via a concentration more or less evenly distributed in the diet (e.g. after spraying).
With the LD_{50} in female rats of 315 mg a.s./kg bw the regulatory acceptable dose would be calculated as 31.5 mg a.s./kg bw.
A risk clearly can be excluded if a granivorous mammal would need to ingest more maize seeds to exceed the "acceptable dose" (one tenth of the LD_{50}) than required to satisfy its daily energy needs when feeding exclusively on treated maize.

Table CP 10.1.2- 8: Number of seeds to achieve the regulatory acceptable dose (one tenth of LD_{50})

Species	body weight	"acceptable dose" [mg a.s./animal] (= 31.5 mg a.s./kg bw)	no. seeds to achieve the "acceptable dose"
Woodmouse	21.7	0.68	0.68

From this calculation it can be seen that a Woodmouse could ingest the regulatory acceptable dose with one treated maize seed. This is a worst case figure since no exposure mitigating factors like dehusking are considered.

Exposure density

Exposure densities measured in field studies are described in more detail in chapter 10.1 (Refined risk assessment for birds). Here, only the table with the results from the five studies mentioned is repeated.

Table CP 10.1.2- 9: Number of maize seeds exposed on the soil surface after drilling (seeds/m²)

midfield mean	midfield 90th%ile	end row mean	end row 90th%ile	Reference
0.02	0.02	0.02	0.02	[redacted] & [redacted], 2010 M-371180-01-1, KCP 10.1.1.2/7
0.06	0.10	0.16	0.42	[redacted] & [redacted], 2010 M-369149-01-1, KCP 10.1.1.2/11
0.1	0.0	0.1	0.3	[redacted], 2007 M-286951-01-1, KCP 10.1.1.2/9
0.007	0.016	0.042	0.095	[redacted], 2001 M-031252-01-1, KCP 10.1.1.2/1
0.02	0.05 [a]	0.08 [b]	0.20 [b]	[redacted] et al., 1995
0.028	**0.036**	0.064	**0.137**	**geomean**

a) value calculated based on mean and SD given by de [redacted] et al, 1995
b) value estimated based on midfield values and 4x higher number of seeds exposed on headland vs. midfield as presented in de [redacted] et al., 1995

The data show that exposure to treated maize seeds after sowing is very low. This is attributed to the sowing technique (precision drilling) utilized in maize cultivation. Spills may occasionally occur, but the number of seeds exposed on the soil surface is usually low.

Foraging area

In a further weight of evidence approach for the acute risk assessment, the number of seeds a Woodmouse has to ingest to achieve the regulatory "acceptable dose", was related to the area a

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Woodmouse had to forage assuming the mean 90[th]%ile values for midfield and end row exposed seeds.

Table CP 10.1.2- 10: Foraging area required to achieve the regulatory acceptable dose (one tenth of LD_{50})

Species	no. seeds to achieve "acceptable dose" (LD_{50}/10)	foraging area (m²) to achieve "acceptable dose"	
		midfield area	end row area
Woodmouse	0.68	19	5

From this table it can be seen, that under the worst-case assumption that the number of exposed seeds is the mean of the 90[th]%ile from the five studies cited above, a Woodmouse would have to search an area of 19 m² in the centre of the field or on an area of 5 m² in the end row area to find an exposed maize seed.

Dehusking

Including a dehusking factor of 0.41 as described above reduces the potential exposure of Woodmice is 0.41 mg a.s./maize seed and increases the foraging areas as depicted in the table below.

Table CP 10.1.2- 11: Number of seeds to achieve the regulatory acceptable dose (one tenth of LD_{50}) with dehusking

Species	body weight (g)	"acceptable dose" (mg a.s./animal) (= 31.5 mg a.s./kg bw)	no. seeds to achieve the "acceptable dose"	foraging area (m²) to achieve "acceptable dose"	
				midfield area	end row area
Woodmouse	21.7	0.68	1.7	46	12

Portion of Diet (PD)

No "portion of diet" data are available presently for the Woodmouse. Therefore this refinement option is not included in exposure calculation. Nevertheless, the Woodmouse is an opportunistic omnivore and therefore (even on drilled maize fields) the PD for maize seeds can be expected to be considerably lower than 1. This is supported by [redacted] (2005, KCP 10.1.1.2/8), who concluded from a study conducted in Austrian maize fields that maize seeds and seedlings were not a relevant food source for mammals.

Portion of time (PT)

The "portion of time" for the focal species Woodmouse (*Apodemus sylvaticus*) in freshly sown and germinating maize fields was determined by [redacted] (2005, KCP 10.1.1.2/8) in a study conducted in Austria. The mammals spent 1.4% (PT = 0.014) of their potential foraging time in freshly sown or germinating maize fields. A very low exposure at population level is also suggested by the low percentage of trappings in the maize field compared to the surroundings (12% in [redacted] 2005, KCP 10.1.1.2/8, 6.6% in [redacted] & [redacted] 2010, KCP 10.1.1.2/11, 0% in [redacted]-[redacted] et al. 2013, KCP 10.1.2.2/2).

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The PT value is not used in the refined risk assessment. Thus, single individuals might be exposed to a higher extent, however, this low PT and the trapping results clearly show that at the population level, at most only a small portion of the population would be exposed to a notable degree.

Conclusion for mammals exposed to treated seeds

As an overall conclusion, the acute risk for mammals feeding on maize seeds is deemed acceptable. Freshly drilled maize fields are not the primary habitat for any small mammalian species. Exposure to treated seeds, the number of animals utilizing the field as well as the time they may spend there are extremely low, rendering the overall risk for the population correspondingly low.
This conclusion is supported by field studies conducted in Austria ([redacted], 2005, KCP 10.1.1.2/8) and in France ([redacted] & [redacted], 2010, KCP 10.1.1.2/11, which included the period from sowing to BBCH stages 15-16. The different assessment and observation methods applied consistently showed that freshly drilled maize fields are very unattractive to small mammals. Only few individuals spent time foraging on these fields. Therefore, even if these individuals would be affected, an effect on the population can be deemed insignificant.

Seedlings emerged from treated seeds

Focal species

For the scenario of seedlings emerged from treated seeds EFSA (2009) proposes as relevant indicator species large herbivorous birds and mammals and small omnivorous birds and mammals. Two generic field studies conducted by [redacted] (2005, KCP 10.1.1.2/8) and [redacted] & [redacted] (2010, KCP 10.1.1.2/11) point at the **Woodmouse** and the **Brown Hare** as best candidates for focal species in / on maize fields shortly after emergence. These two species agree with the proposal of EFSA (2009).

Diet of the focal species

As worst-case scenario it will be assumed that the Hare will ingest its daily dietary demand exclusively from maize seedling shoots containing residues of thiacloprid at the maximum level found in samples from a field study. For the Woodmouse, a mixed diet (according to EFSA (2009, A, Mammals scenario 130) consisting of 25% weeds, 50% weed seeds, and 25% arthropods will be assumed, where the weed part is replaced by seedling shoots.

Toxicity endpoint

For the toxicity endpoint the same applies as outlined above in the section on treated seeds, i.e. the LD_{50} derived from the study with the active substance in female rats **(315 mg a.s./kg bw)** will be used in the Tier-1 risk assessment.

Portion of time (PT)

The "portion of time" for woodmice in germinating maize fields was determined by [redacted] (2005, KCP 10.1.1.2/8) in a study conducted in Austria. The mammals spent 1.4% (PT = 0.014) of their potential foraging time in freshly sown or germinating maize fields. A very low exposure at population level is also suggested by the low percentage of trappings in the maize field compared to the surroundings (12% in [redacted] 2005, KCP 10.1.1.2/8, 6.6% in [redacted] & [redacted], 2010, KCP 10.1.1.2/11, 0% in [redacted] et al. 2013, KCP 10.1.2.2/2).

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The PT value is not used in the refined risk assessment. Thus, single individuals might be exposed to a higher extent, however, this low PT clearly shows that at the population level, at most only a small portion of the population would be exposed to a notable degree.

Portion of Diet (PD)

[redacted] (2005, KCP 10.1.1.2/8 concluded from a study conducted in Austrian maize fields that maize seeds and seedlings were not a relevant food source for birds and mammals.
The PD value is not used quantitatively in the refined risk assessment. The low number however illustrates that there are significant additional margins of safety that remain unexploited.

Actual residue concentrations

A study was to determine the residue levels of thiacloprid in seedlings from maize plants which had been grown from seeds dressed with Thiacloprid FS 400 ([redacted], 2009, KCP 10.1.1.2/5). Samples of seedlings were taken for analysis of residues of Thiacloprid and its metabolite between 16 (BBCH 12) and 37 days (BBCH 17) after drilling in the field.
Residue levels were highest at the first sampling occasion (BBCH 12, 16/17 days after sowing) with 17 to 18 mg/kg fresh weight. Thereafter the concentrations declined rapidly with a half-life of less than 3 days.

Food intake of focal species (Woodmouse, Hare)

The estimates of food intake for woodmouse and hare are based on means of daily energy expenditure for free-ranging animals, energy and moisture content and assimilation efficiencies. The FIR is calculated following EFSA (2009, G) as:

$$FIR = \left(\frac{DEE}{FE * \left(1 - \frac{MC}{100}\right) * \left(\frac{AE}{100}\right)} \right) \quad \text{[g fresh weight/d]}$$

In which:
DEE = Daily energy expenditure of the species [kJ/d], FE = Food energy [kJ/dry g]
MC = Moisture content [%], AE = Assimilation efficiency [%]

Daily energy expenditure
Data for the DEE are derived from a research project carried out for DEFRA (Anonymous, 2007). Relationship between body weight (bw in g) and daily energy expenditure (DEE in kJ) in mammals can be described by the equation:

$$\log DEE = \log 0.814 + 0.715 \times \log bw$$

According to this formula, a 3800 g hare would require 2363 kJ/day and a 21.7 g woodmouse 58.83 kJ/day.

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Energy content of food
Cereal seeds and seedling shoots have been studied with respect to their energy and moisture content and their assimilation efficiency. The data are used in the table below to calculate the usable energy from these feed sources.

Table CP 10.1.2- 12: Data of seedling shoots to calculate usable energy

	moisture%	energy content dry (kJ/g)	energy content wet (kJ/g)	ass. eff.% mammals	usable energy content wet (kJ/g)
Seedling shoots	76.4	17.6	4.2	47	2.0

Daily food intake

A Brown Hare weighing 3800 g and requiring 2363 kJ/day would need to ingest 1211 g seedling shoots corresponding to a FIR/bw of 0.32.
The dietary requirements for the woodmouse were calculated using the CRD calculator for mixed diets. Based on a DEE of 58.83 kJ/day a 21.7 g Woodmouse would have to ingest 7.69 g of a mixed diet. Of these 7.69 g 1.92 g (= 25%) are assumed to be seedling shoots containing residues of (initially) 18 mg thiacloprid/kg fresh weight. The rest of the diet is considered free of residues since the other feed items like weed seeds or insects are unlikely to come into contact with the active substance to a great extent.

Table CP 10.1.2- 13: Daily Consumption and Energy Expenditure for 21.7g Mammals

Species:	Mammals			
Body Weight (g):	**21.7**			
Proportion of diet based on	**Wet**			
Food	% in diet WET wt	KJ/g Wet weight	Assimilation efficiency	Wt (g) fresh food consumed
Grasses and cereal shoots	25	4.15	0.46	1.92
Weed seeds	25	19.55	0.83	1.92
Arthropods	50	7.08	0.88	3.84
Sum	100			7.69
Daily Energy Expenditure for 21.7g Mammals	58.83	KJ/animal		

Exposure calculation, Maize seedling shoots

Mean maximum residue concentrations of Thiacloprid in freshly emerged seedling shoots (BBCH 12) were 18 mg/kg fresh weight.
A 3800 g Hare feeding exclusively on such maize seedling shoots could ingest with 1211 g seedlings a total dose of 21.8 mg which is equivalent to a dose of 5.7 mg/kg bw.
For the Woodmouse of 21.7 g bw and an intake of 1.92 g seedlings per day, the ingested total dose would be 0.035 mg which is equivalent to a dose of 1.6 mg/kg bw based on a measured concentration of 18 mg/kg fresh weight in the seedling part of its diet.

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Table CP 10.1.2- 14: Calculation of the daily dietary dose

	bw (g)	daily food intake (g fresh weight)	concentration in diet (mg/kg fresh weight)	Dose in the daily food intake (mg/animal)	Daily dose (mg/kg bw/d)
Brown Hare	3800	1211	18	21.8	5.7
Woodmouse	21.7	1.92 (seedlings)	18	0.035	1.6

Toxicity Exposure Ratios

Taking the LD50 for female rats of 315 mg a.s./kg bw as acute toxicity endpoint, and comparing these to the daily doses calculated for the two generic focal species, the TER_As depicted in the table below are calculated

Table CP 10.1.2- 15: TER calculations

	Brown Hare	Woodmouse
Acute oral toxicity endpoint (mg a.s./kg bw)	315	
Daily Dietary Dose (mg a.s./kg bw/d)	5.7	1.6
TER_A	**55**	**197**

An unacceptable acute risk to small omnivorous or large herbivorous mammals foraging on emerged maize seedlings can be excluded since TER_A exceeds the threshold of 10 for an acceptable risk. Taking into account the large TER for the omnivorous mammal, an acceptable risk would still result in the unlikely case that the arthropod part of the diet would contain residues at the same level as the seedlings.

Every additional factor, e.g. lower sensitivity, declining seedling residue concentrations due to growth, seedlings from untreated fields in the diet etc. will reduce the risk for mammals still further.

A summary of the parameters used in the risk assessment together with reasoning and/or their sources is provided in the following table.

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Table CP 10.1.2- 16: Summary of parameters for risk assessment

Focal species	**Brown Hare** (EFSA GD (2009), Appendix A #72)	**Woodmouse** (EFSA GD (2009), Appendix A)
body weight (g)	**3800** (EFSA GD (2009), Appendix A)	**21.7** (EFSA GD (2009), Appendix A)
Diet	**100% leaves** (as seedlings) (EFSA GD (2009), Appendix A)	**mixed diet** (25% weeds (seedlings), 50% weed seeds, and 25% arthropods) (EFSA GD (2009), Appendix A)
Daily Energy Expenditure	calculated according to formula for mammals (EFSA GD (2009), Appendix G)	calculated according to formula for mammals (EFSA GD (2009), Appendix G)
Daily feed intake	**1211 g seedling shoots** (FIR/bw 0.32) calculated using parameters given for "grass and cereal shoots" (EFSA GD (2009), Appendix G)	7.69 g mixed diet of which are **1.92 g seedling shoots** calculated using CRD calculator for mixed diet
Exposure concentration in diet	**18 mg/kg fresh weight** (highest measured value in seedlings, [redacted], 2009, KCP 10.1.1.2/5)	
Daily dietary dose (mg/kg bw/d)	**5.7** calculated based on parameters above)	**1.6** calculated with parameters above)
Toxicity endpoint	**315 mg/kg bw** (lowest LD_{50}, in female rats)	
TER_A	**55**	**197**

As an overall conclusion, the acute risk for mammals feeding on maize seedlings is deemed acceptable. This conclusion is supported by field studies conducted in Austria ([redacted], 2005, KCP 10.1.1.2/8) and in France ([redacted] & [redacted], 2010, KCP 10.1.1.2/11), which included the period from sowing to BBCH stages 15-16. The different assessment and observation methods applied consistently showed that freshly drilled maize fields are very unattractive to small mammals. Only few individuals spent time foraging on these fields. Therefore, even if these individuals would be affected, an effect on the population can be deemed insignificant.

Tier 1 risk assessment for mammals drinking contaminated water

EFSA (2009, chapter 5.2.1) proposes to focus the risk assessment for birds and mammals on the dietary route of exposure. An assessment of the risk potentially posed by consumption of contaminated drinking water after the use of a pesticide as seed treatment is not required since this route seems unlikely to be a critical one or to lead to TER greater than direct dietary consumption.

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LONG-TERM REPRODUCTIVE ASSESSMENT

Table CP 10.1.2- 17: Tier 1 long-term TER calculation for mammals feeding on seed treatment

Compound	Indicator species	Toxicity [mg/kg bw/d]	Exposure			TER_{LT}	Trigger
			FIR/bw	NAR [mg a.s./kg seeds][1]	f_{twa}		
Thiacloprid	Small omnivorous	21	0.24	2222 - 5000	0.53	**0.03 - 0.07**	5

[1]Assuming a thousand grain weight of the seeds of 200-450 g [13]

Table CP 10.1.2- 18: Tier 1 long-term TER calculation for mammals feeding on crop seedlings

Compound	Indicator species	Toxicity [mg/kg bw/d]	Exposure			TER_{LT}	Trigger
			FIR/bw	NAR/5 [mg a.s./kg seeds][1]	f_{twa}		
Thiacloprid	Small omnivorous	21	0.24	444 - 1000	0.53	**0.17 - 0.37**	5

The TER_{LT} values calculated in the reproductive risk assessment on Tier 1 level do not exceed the a-priori-acceptability trigger of 5 for all evaluated scenarios. Thus, a refined risk assessment for these scenarios is presented below.

Refined risk assessment

The protection goal of clearly establishing that there will be no visible mortality was dealt with in the acute risk assessment. Therefore the risk assessment for long-term exposure will address only the protection goal of clearly establishing that there will be no long-term repercussions for abundance and diversity.

Based on the sowing rate of 2.2 units per hectare (equivalent to 2.2 x 50000 seeds) one would expect 10 seedlings per m² whereas the number of seeds exposed on the soil surface would be 0.036/m². Therefore it is much less likely that the animals find seeds than seedlings to get a daily exposure over a prolonged period of time. Accordingly the reproductive risk assessment will focus on mammals feeding on maize seedlings emerged from treated seeds. Nevertheless a reproductive risk assessment for granivorous mammals is presented here.

Treated seeds

Dividing the long-term endpoint of 21 mg/kg bw/d by a factor of 5 (long-term TER trigger value) results in an "acceptable dose" of 4.2 mg/kg bw/d or 0.091 mg/wood mouse/d. Considering an initial loading of 1 mg thiacloprid/maize kernel and a default 21d-f_{TWA} of 0.53 gives a long-term loading of 0.53 mg thiacloprid/maize kernel.

Daily food intake

The dietary requirements for the woodmouse were calculated using the CRD calculator for mixed diets. In this calculation the "small seeds" part of the diet was replaced by maize seeds. Based on a

[13] Faustzahlen für die Landwirtschaft (2005), published by Kuratorium für Technik und Bauwesen in der Landwirtschaft, Darmstadt, 13th edition, ISBN 3-7843-2194-1

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DEE of 58.83 kJ/day a 21.7 g woodmouse would have to ingest 8.59 g of a mixed diet. Of these 8.59 g 2.15 g (= 25%) are assumed to be treated maize seeds containing residues of (initially) 2222 to 5000 mg Thiacloprid/kg. The rest of the diet is considered free of residues since the other feed items like weeds or insects are unlikely to come into contact with the active substance to a great extent.

Risk assessment for omnivorous mammals feeding on treated seeds: foraging area
Based on (mean) exposure of maize seeds on the soil surface after drilling as outlined in section 10.1.1 and in particular in Table CP 10.1.1- 7, and a long-term loading of 0.53 mg thiacloprid/maize kernel, the minimum area omnivorous mammal would have to forage daily over a prolonged period to exceed the "acceptable daily dose" is given in the table below.

Table CP 10.1.2- 19: Calculation of the minimum daily foraging area (m²)

Focal species	body weight [g]	"acceptable dose" (mg a.s./animal) (= 4.2 mg a.s./kg bw/d)	no. seeds per day to achieve the "acceptable dose"	minimum daily foraging area (m²) to achieve "acceptable daily dose"	
				midfield area	end row area
Wood mouse	21.7	0.091	0.17	**4.8**	1.3

While for acute situations the end row area is the realistic worst case, in a chronic/long-term situation the midfield area is more relevant because the endrow area is generally much smaller than the midfield area. This makes it very unlikely that a whole population would feed exclusively in the endrow area for a prolonged period.
Furthermore, the entire field studies presented in this document showed that freshly drilled maize fields are not attractive for small mammals. This adds further evidence to the notion that a whole small mammal population would unlikely feed regularly over a prolonged period in this unappealing habitat. Consequently, long-term exposure would be greatly reduced.

Dehusking

As described in the chapter on refined acute risk assessment, small mammals dehusk seeds and thereby reduce their potential exposure to the seed treatment. Applying a dehusking factor of 0.41 to the exposure calculation reduces the 21d time weighted average exposure on one seed to 0.22 mg/seed. The daily acceptable dose is 0.091 mg/animal/d. Accordingly the number of seeds an animal could ingest per day without exceeding the acceptable dose would be 0.42 seeds.

Table CP 10.1.2- 20: Number of seeds to achieve the regulatory acceptable dose (one fifth of NOAED) with dehusking

Species	body weight (g)	"acceptable dose" (mg a.s./animal) (= 3.7 mg a.s./kg bw/d)	no. seeds per day to achieve the "acceptable dose"	minimum daily foraging area (m²) to achieve "acceptable daily dose"	
				midfield area	end row area
Woodmouse	21.7	0.091	0.42	11.7	3.1

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Portion of time (PT)

The "portion of time" for the focal species Woodmouse (*Apodemus sylvaticus*) in freshly sown and germinating maize fields was determined by [redacted] (2005, KCP 10.1.1.2/8) in a study conducted in Austria. The mammals spent 1.4% (PT = 0.014) of their potential foraging time in freshly sown or germinating maize fields.
The PT value is not used in the refined risk assessment. Thus, single individuals might be exposed to a higher extent, however, this low PT clearly shows that at the population level, at most only a small portion of the population would be exposed to a notable degree.

Population modelling

Given the extremely low tier-1 TER and the limited options for refinement a demonstration of an acceptable risk for granivorous mammals based on a TER is impossible. Already in the GD it is stated that "*The failure rate of pesticides used as seed treatments to meet the standard EU triggers for acute and reproductive risks under such a scenario is likely to be high….*". Therefore the risk assessment for long-term exposure of granivorous mammals is addressed using a population modelling approach. Based on the fact that small mammals avoid as much as possible open landscapes devoid of cover or shelter and the low number of treated maize seeds on the soil surface after precision drilling it can be assumed that effects on a population inhabiting a landscape will be minimal at most. To substantiate this assumption, potential effects on a local population of woodmice from the exposure to seeds treated with the nominal application rate (NAR) of thiacloprid, as well as a 5- and a 10-fold overdose were modelled over a period of 20 years using an individual-based model ([redacted], 2014, M-470315-01-1, KCP 10.1.2.2/1).
A worst-case landscape was selected covering woodland and maize fields. This landscape has previously been extracted based on a geo-information system analysis (GIS) with the aim to identify relevant worst-case landscape scenarios for use in population-level risk assessment ([redacted] and [redacted], 2013[14]). To further shift the scenario towards a worst case it was supposed that the modelled population represented a closed island population in a landscape without immigration. Predicted effects at the population level were considered as adverse if their magnitude at the end of the season exceeded 5%.
Simulations with the population model showed that for an application rate of up to 5 times the intended application rate no effects were visible. For an application rate which was ten times the intended rate, only very small temporary effects were visible, which always disappeared until the end of the year. Also when conducting long-term simulations over 20 years no effects were visible, confirming long-term sustainability of the local population.
The outcome of this population simulation supports the hypothesis that due to very low exposure and high reproductive capacity, wood mouse populations will not be affected by maize seeds treated with thiacloprid.

Conclusion

The refined risk assessment presented here follows Guidance of EFSA "Risk Assessment for Birds and Mammals" (2009). This document states in chapter 5.2: "*Tier 1 assumes that granivorous birds*

[14] [redacted], M. and [redacted], R. 2013. Development of landscape scenarios for population-level risk assessment. Poster presentation at the 23rd Annual Meeting of Setac Europe, Glasgow.

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and mammals feed entirely on readily available, freshly treated seeds. The failure rate of pesticides used as seed treatments to meet the standard EU triggers for acute and reproductive risks under such a scenario is likely to be high…... The outcome of a refined assessment would, in most cases, take the form of a weight-of-evidence approach, rather than a quantitative assessment (e.g. TER)…. "

Evidence is presented in this refined risk assessment that small mammals would have to graze a relatively large area over a prolonged period to exceed the "acceptable daily dose" and freshly drilled maize fields are not attractive for small mammals because the offer no shelter and only little feed. Furthermore, exposure to treated seeds is very limited in time because the seeds germinate. Therefore it is deemed unlikely that a whole small mammal population would feed there regularly over a prolonged period.
As a result the risk of unacceptable effects on small mammal populations is regarded to be low. This view is supported by the outcome of a population modelling exercise.

Seedlings emerged from treated seeds

Potential exposure is calculated based on the measured residue levels over time in young maize seedlings (starting from BBCH growth stage 12). For this purpose a starting concentration of 18 mg/kg fresh weight, a half-life of 3 days, and a default averaging period of 21 days is used. Accordingly, a time weighted average concentration of 3.68 mg/kg fresh weight in seedlings is calculated. Since the woodmouse feeds on a mixed diet containing only 25% of seedlings, this (seedling) concentration is multiplied by a factor of 0.25 to get the concentration in the diet of woodmouse (i.e. 0.92 mg/kg fresh weight).

Dietary assumptions for the generic focal species are the same as in the acute risk assessment, i.e. 1211 g seedling shoots at a body weight of 3800 g, resulting in a FIR of 0.32 (related to fresh weight) for the brown hare and 8.59 g mixed diet for a 21.7 g woodmouse. At the time-weighted average concentration of 3.68 mg/kg fresh weight, a 3800 g herbivorous mammal would ingest a daily dose of 1.17 mg/kg bw. and a 21.7 g omnivorous mammal would ingest a daily dose of 0.33 mg/kg bw.

Table CP 10.1.2- 21: Calculation of the daily dietary dose

	bw (g)	daily food intake (g fresh weight)	concentration in diet (mg/kg fresh weight)	Dose in the daily food intake (mg/animal)	Daily dose (mg/kg bw/d)
Brown Hare	3800	1211	3.68	4.46	1.17
Woodmouse	21.7	1.92 (seedlings)	3.68	0.00791	0.33

Toxicity Exposure Ratios

Taking the NOAEL of 21 mg a.s./kg bw from the rat reproduction study as toxicity endpoint, and comparing these to the daily doses calculated for the two generic focal species, the TER_{LT}s depicted in the table below are calculated.

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Table CP 10.1.2- 22: TER calculations

	Brown Hare	**Woodmouse**
Long-term toxicity endpoint (mg a.s./kg bw)	21	
Daily Dietary Dose (mg a.s./kg bw/d)	1.17	0.33
TER_{LT}	**17.3**	**64**

Comparison with a NOAEL of 21 mg/kg bw/d reveals a Tier-1 TER_{LT} of 17.3 for the hare and 64 for the woodmouse. Both values are well above the threshold of 5 for an acceptable long-term risk. Taking into account the large TER for the omnivorous mammal, an acceptable risk would still result in the unlikely case that the arthropod part of the diet would contain residues at the same level as the seedlings.

Table CP 10.1.2- 23: Summary of parameters for risk assessment

Focal species	Brown Hare (EFSA GD (2009), Appendix A #72)	Woodmouse (EFSA GD (2009), Appendix A)
body weight (g)	3800 (EFSA GD (2009), Appendix A)	21.7 (EFSA GD (2009), Appendix A)
Diet	100% leaves (as seedlings) (EFSA GD (2009), Appendix A)	mixed diet (25% weeds (seedlings), 50% weed seeds, and 25% arthropods) (EFSA GD (2009), Appendix A, #130)
Daily Energy Expenditure	calculated according to formula for mammals (EFSA GD (2009), Appendix G)	calculated according to formula for mammals (EFSA GD (2009), Appendix G)
Daily feed intake	**1211 g seedling shoots** (FIR/bw 0.32) calculated using parameters given for "grass and cereal shoots" (EFSA GD (2009), Appendix G)	7.69 g mixed diet of which are **1.92 g seedling shoots** calculated using CRD calculator for mixed diet
Exposure concentration in diet	**18 mg/kg fresh weight** (highest measured value in seedlings, [redacted], 2009, KCP 10.1.1.2/3)	
Decline of exposure concentration	**f_{TWA} = 0.204** based on DT_{50} of 3 days in seedlings ([redacted], 2010, KCP 10.1.1.2/4) and default time window of 21 days (EFSA, 2009)	
Daily dietary dose (mg/kg bw/d)	**1.17** (calculated based on parameters above)	**0.33** (calculated with parameters above)
Toxicity endpoint	**21 mg/kg bw/d** (NOAEL from reproduction study in rats)	
TER_A	**17.3**	**64**

Conclusion

All these lines of evidence are supported by the field studies in maize, which show that neither maize seeds nor seedlings are a relevant dietary component for mammals. Furthermore, the field studies show that maize fields are no attractive habitats for mammals and the surrounding areas are strongly preferred. This explains the low trapping rate on the fields and substantiates the conclusion that only a small portion of individuals, irrelevant for the sustainability of the population, actually inhabits the field at that time of the year.

So overall, all the evidence presented above provides sufficient confirmation that the risk to mammals from maize seeds treated with Thiacloprid FS 400 and seedlings emerged thereof should be considered to be low and hence acceptable.

Long-term risk assessment for mammals drinking contaminated water

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EFSA (2009, chapter 5.2.1) proposes to focus the risk assessment for birds and mammals on the dietary route of exposure. An assessment of the risk potentially posed by consumption of contaminated drinking water after the use of a pesticide as seed treatment is not required since this route seems unlikely to be a critical one or to lead to TER greater than direct dietary consumption.

RISK ASSESSMENT OF SECONDARY POISONING

Substances with a high bioaccumulation potential could theoretically bear a risk of secondary poisoning for mammals if feeding on contaminated prey like fish or earthworms. For organic chemicals, a log $P_{OW} > 3$ is used to trigger an in-depth evaluation of the potential for bioaccumulation. Thiacloprid, however, has a log P_{OW} of 1.4 indicating a very low risk of bioaccumulation and, hence, secondary poisoning. A risk assessment is not deemed necessary.

CP 10.1.2.1 Acute oral toxicity to mammals

No additional studies were performed.

CP 10.1.2.2 Higher tier data on mammals

The following higher tier data has been used for the higher tier risk assessment.

Report:	[redacted]i; [redacted]; 2013; M-470315-01-1
Title:	Sonido: Population-level risk assessment for the wood mouse (Apodemus sylvaticus) - Use in maize
Report No.:	13038-BCS
Document No.:	M-470315-01-1
Guidelines:	**not applicable; not applicable**
GLP/GEP:	**no**

Objective:

The aim of this study was to conduct a population-level risk assessment for the substance thiacloprid, applied as a seed dressing for maize at a NAR of 2222 to 5000 mg a.s./kg seeds. The population-level risk assessment addresses acute and chronic effects in wood mice (*Apodemus sylvaticus*). Expected effects were calculated based on dietary intake according to appendix G of the EFSA guidance (2009). To evaluate how these effects may have an impact on the population development a population model was used.

Material and methods:

Simulations were conducted with the population model for the wood mouse (*Apodemus sylvaticus*) implemented in the software POLARIS (software version 1.3, wood mouse model version 1.0, WSC Scientific GmbH). This model is described in detail in [redacted] (2013)[15], which includes a detailed model description following the ODD protocol together with a description on the calibration and validation process as well as sensitivity analyses.

[15] [redacted], M. 2013. POLARIS - Wood mouse population model description, model version 1.0. Unpublished report 12026-WSC-2, WSC Scientific GmbH

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Effects were based on available studies with thiacloprid in rats. Dose response curves regarding acute effects were used in the model to calculate mortality in animals being located in maize fields. Chronic effects (still births) were implemented in the model by reducing litter size. The exposure was calculated according to the risk assessment for seed treatments and according to appendix G of the EFSA (2009) guidance for birds and mammals. A residue decline with a DT_{50} of 10 days was assumed Based on dehusking experiments in laboratory a dehusking factor of 0.41 (corresponding to 59% dehusking efficiency) was proposed for estimating the reduced intake of active ingredients due to dehusking of the maize seeds and used in the risk assessment.
For the simulations, a worst-case landscape was used, covering woodland, maize fields and a small hedge. Regarding crop growth of simulated maize fields it was assumed that plants emerge after five days as a worst case[16]. However, in the risk assessment it is assumed that seeds are available until eight days as a conservative value (higher exposure than when assuming only five day seed availability). A small amount of food was assumed to be present before sowing and after harvest. This amount corresponded to the default settings for arable fields of the model. No cover was assumed to be present before sowing and after harvest.
One-year and 20-year simulations were conducted. In 20-year simulations sowing of treated seeds was considered to take place from year 6 to year 15. This approach made it possible to observe long-term effects and allowed populations to stabilise for five years after the last application.
The number of simulations was based on a parametric power analysis, with the aim to reveal effects of 5% magnitude with a confidence of 95% (conducted in R). For this analysis, the typical variation of population density after 1 year was measured based on 20 one-year simulations. The density had a standard variation of 7.9%. The power analysis revealed that for detecting effects of 5% with a confidence of 95% 105 simulations are necessary. Therefore, 105 simulations were conducted in the present risk assessment.
As a simulation end-point population density on 1st of January was used to compare control populations and treatment populations. Simulations were conducted assuming 1 x, 5 x and 10 x the normal NAR.

Results:

Population development for one year
The results show that after the end of the year no differences in population density were observed. For 10 x the intended NAR temporary effects were apparent after sowing, but these differences disappeared until the end of the year. Therefore, no long-term effects are expected.

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[16] This corresponds to a worst case regarding crop growth, since wood mice prefer areas with vegetation cover and will therefore be more abundant in maize fields if plant growth starts at 5 days already instead of 8 days. Regarding exposure, however, emergence at 8 days is more conservative, since then exposure is longer, therefore for the calculation of exposure 8 days are assumed.

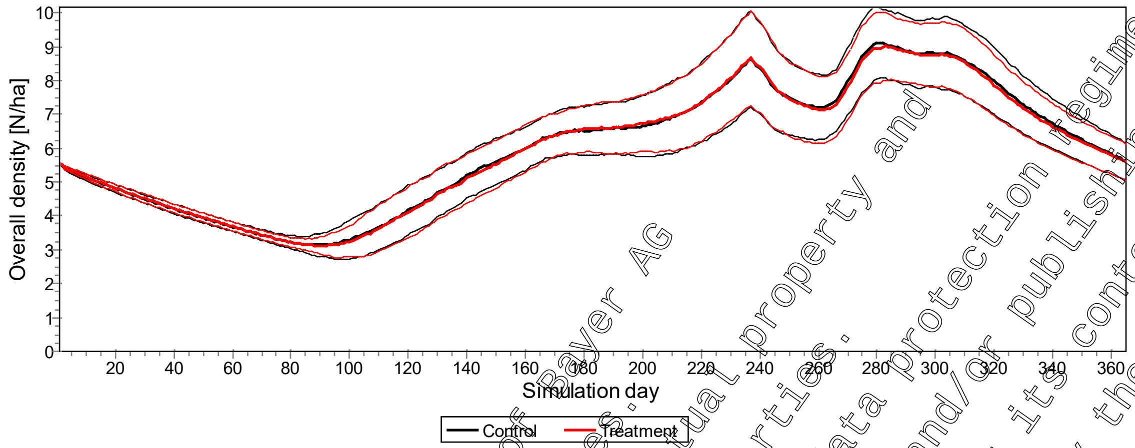

Figure CP 10.2.2.1- 1: Population development over 1 year, 1 x NAR. The middle lines show the mean population density of the treatment (red) and the control (black, mostly behind the red line), upper and lower lines the standard deviations.

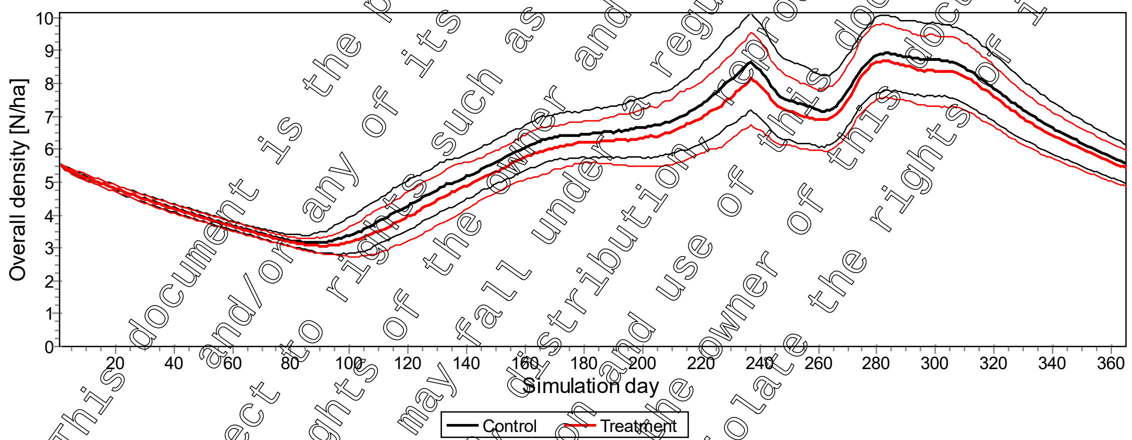

Figure CP 10.2.2.1- 2: Population development over 1 year, 10 x NAR. The middle lines show the mean population density of the treatment (red) and the control (black, mostly behind the red line), upper and lower lines the standard deviations.

Table CP 10.2.2.1- 1: Mean population density (N/ha) after one year (31st Dec) calculated from 105 simulations for each the control and the treatment.

	1 x NAR	5 x NAR	10 x NAR
Control simulations	5.58	5.42	5.43
Treatment simulations	5.61	5.47	5.56

Population development over 20 years

20-year simulations were conducted assuming sowing of Sonido treated seeds from year 6 to year 15. In no case did the intended NAR affect population density on 1st of January. Differences were below 5% in all cases. The highest effects observed during these 20 years, i.e. the maximal reductions of the population density in the treatment on 1st of January, are summarised below.

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Table CP 10.2.2.1- 2: Maximal effect (difference of population density in control vs. treatment simulations) observed for different application rates.

1 x NAR	5 x NAR	10 x NAR
2.6%	3.7%	2.4%

Conclusion:

Simulations with the population model showed that even for a NAR 10 x higher than the intended application rate no long-term effects were visible. Temporary effects were only apparent with 10 x the intended NAR. For 1 x or 5 x the NAR no effects (not even temporary ones) were apparent. Based on these results no effects are expected with up to 5 x the intended NAR in real population when a worst case field situation is considered. For 10 x the NAR only very small temporary effects may be present (probably smaller than measurable in the field), which do not cause long-term effects. Therefore, considering the protection goals defined by EFSA (2009) even an application rate of 10 x the NAR does not cause unacceptable effects.

Report: [redacted]; 2013; M-486987-01-1
Title: Habitat use of wood mice (Apodemus sylvaticus) in maize in Germany - Summary and evaluation of BASF Study 403749 (BASF DocID: 2011/1140611)
Report No.: M-486987-01-1
Document No.: M-486987-01-1
Guidelines: **not applicable; not applicable**
GLP/GEP: **no**

Report: [redacted]; 2014; M-487372-01-1
Title: Letter of access for generic behavioural ecology data - BASF docID 2013/1298445
Report No.: M-487372-01-1
Document No.: M-487372-01-1
Guidelines: **not specified; not specified**
GLP/GEP: **no**

Material and Methods

The following report represents an extract from the BASF Study ID: 403749 (BASF DocID: 2011/1140611) which was conducted in an agricultural landscape in Thuringia, Germany, in the administrative district of Gotha around the municipality Großfahner (coordinates: 32 U 628048/5657643 (UTM coordinate system)) from June to November 2011. Within the scope of this study small mammal trapping was conducted in eight different habitats (i.e. cereals, oilseed rape, maize, orchards, grassland/meadows, fallow land, hedgerows and forest) within a rectangle of 6 x 3 km. A total of 29 study fields were selected to set up ‘Ugglan’ multiple-capture traps. Live trapping of small mammals was carried out following a ‘Capture-Mark-Recapture’ (CMR) design. This involved individual marking of the captured animals with a Passive Integrated Transponder (PIT).

Trapping was carried out once per month from June until November 2011, thus a total of six trapping sessions per study field were conducted. A total of 580 traps were set up per trapping session.

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In each trapping session, a total of 20 traps was set up per study field either in a trapping grid or in trapping lines; the traps were distributed in a square of five by four traps. Spacing between traps was 10 m. In each study field the trapping grid or trapping line(s) covered 0.2 ha.

In this report special attention was given to the data concerning wood mouse captures in maize and the following abundance measurements:

- Trapping success (number of captured animals and individuals)
- Trapping efficiency (captures/100 trap nights)

Results

During the Field Phase of BASF Study ID: 403749 (BASF DocID: 2011/1140611), wood mice in maize fields were predominantly found during July and August, at high BBCH growth stages 51 – 75.

- Trapping success in maize: No wood mouse was recorded during the first trapping session in June 2011. The highest trapping success was found in July (13 captures of 11 individuals) at BBCH stages 51 – 61.
- Trapping efficiency in maize: The highest trapping efficiency was recorded in July as well with 8.1 wood mice per 100 trapping nights (5.6 in August).

Conclusion

Live trapping was conducted at six trapping sessions (each session comprised two trapping events) once per month from June until November 2011.

No wood mice were found in maize fields at the early growth stage (BBCH 19 at the only trapping session in June). First wood mice were recorded in Maize at BBCH stages 51-61 (July). The highest trapping efficiencies were found from BBCH 51-61 (July) until BBCH stages 73-75 (August), i.e. when maize plants reached their maximum height.

The abundance of wood mice decreased again in September after harvest, presumably due to habitat destructions and soil tillage.

CP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

No additional studies were performed.

CP 10.2 Effects on aquatic organisms

The risk assessment has been performed according to "Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC" (Sanco/3268/2001 rev.4 (final) 17 October 2002).

Ecotoxicological endpoints used in risk assessment

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Table CP 10.2- 1: Endpoints relevant for risk assessment

Test substance	Test species	Endpoint		Reference
Thiacloprid	Marine fish, acute *Cyprinodon variegatus* (sheepshead minnow)	LC_{50}	19.7 mg a.s./L	[redacted] (1998) M-001198-01-1 KCA 8.2.1/2
	Fish, chronic *Pimephales promelas* (fathead minnow)	NOEC	0.17 mg a.s./L	[redacted] (1999) M-009649-01-1 KCA 8.2.2.1/1
	Invertebrate, acute *Daphnia magna* (cladoceran)	EC_{50}	≥ 85.1 mg a.s./L	[redacted] (1995) M-000738-01-1 KCA 8.2.4.1/1
	Invertebrate, acute *Ecdyonurus* sp. Larvae (mayfly)	EC_{50}	0.0077 mg a.s./L	[redacted] 2002) M-059087-01-1 KCA 8.2.4.2/6
	Sediment dweller, acute *Chironomus riparius* (chironomid)	EC_{50}	0.00108 mg a.s./L	[redacted] (2014) M-491257-01-1 KCA 8.2.4.2/7
	Invertebrate, chronic *Daphnia magna* (cladoceran)	NOEC	0.58 mg a.s./L	[redacted] (1996) M-000652-01-2 KCA 8.2.5.1/1
	Sediment dweller, chronic *Chironomus riparius* (chironomid)	NOEC	0.00056 mg a.s./L	[redacted] (2014) M-493340-01-1 KCA 8.2.5.3/1
	Desmodesmus subspicatus (*Scenedesmus subspicatus*, green algae)	E_bC_{50} E_rC_{50}	44.7 mg a.s./L 96.7 mg a.s./L	[redacted] (1995) M-000731-01-1 KCA 8.2.6.1/1
Thiacloprid-amide	Fish, acute, *Lepomis macrochirus* (bluegill sunfish)	LC_{50}	> 78.6 mg p.m./L	[redacted] (1997) M-003825-01-1 KCA 8.2.1 /3
	Invertebrate, acute *Daphnia magna* (cladoceran)	EC_{50}	> 103 mg p.m./L	[redacted] (1998) M-002382-01-1 KCA 8.2.4.1/2
	Invertebrate, acute *Hyalella azteca* (amphipod)	LC_{50}	47.6 mg p.m./L	[redacted] (1997) M-000997-02-1 KCA 8.2.4.2/8
	Sediment dweller, chronic *Chironomus riparius* (chironomid)	EC_{15}	≥ 0.1 mg p.m./L	[redacted] (1997) M-000999-01-1 KCA 8.2.5.3/3
	Pseudokirchneriella subcapitata (green algae)	E_bC_{50} E_rC_{50}	> 100 mg p.m./L > 100 mg p.m./L	[redacted] (1998) M-004001-01-1 KCA 8.2.6.1/2
Thiacloprid sulfonic acid	Fish, acute *Oncorhynchus mykiss* (rainbow trout)	LC_{50}	> 90.1 mg p.m./L	[redacted] (1995) M-001013-01-1 KCA 8.2.1/4
	Invertebrate, acute *Daphnia magna* (cladoceran)	EC_{50}	> 96.1 mg p.m./L	[redacted] (1995) M-001002-01-1 KCA 8.2.4.1/3
	Sediment dweller, chronic *Chironomus riparius* (chironomid)	EC_{15}	> 100 mg p.m./L	[redacted] & [redacted] (2002) M-051861-01-1 KCA 8.2.5.3/4
	Desmodesmus subspicatus (*Scenedesmus subspicatus*, green algae	E_bC_{50} E_rC_{50}	> 100 mg p.m./L > 100 mg p.m./L	[redacted] (1996) M-001011-01-1 KCA 8.2.6.1/3

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Test substance	Test species	Endpoint		Reference
Thiacloprid-descyano	Sediment dweller, chronic *Chironomus riparius* (chironomid)	NOEC	0.00625 mg p.m./L	[redacted] (2011) M-419277-01-1 KCA 8.2.5.3/5
Thiacloprid FS 400	Sediment dweller, chronic Chironomus riparius (chironomid)	EC15	0.00448 mg prod/L (~0.00157 mg a.s./L)	[redacted] (2009) M-361244-01-1 KCP 10.2.2/1

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Predicted environmental concentrations used in risk assessment

Table CP 10.2- 2: Initial max PEC_{sw} values – FOCUS Step 1, 2

Compound	FOCUS Scenario	Maize, 1 × 110 g a.s./ha $PEC_{sw, max}$ [µg/L]
Thiacloprid	STEP 1	20.15
	STEP 2 - North	2.411
	STEP 2 - South	**4.823**
Thiacloprid-amide	STEP 1	24.49
	STEP 2 - North	4.580
	STEP 2 - South	**9.159**
Thiacloprid sulfonic acid	STEP 1	9.375
	STEP 2 - North	1.570
	STEP 2 - South	**3.139**
Thiacloprid-descyano	STEP 1	7.339
	STEP 2 - North	1.439
	STEP 2 - South	**2.878**

Bold – values considered in risk assessment

Table CP 10.2- 3: Initial max PEC_{sw} values – FOCUS Step 3

Compound	FOCUS Scenario	Maize, 1 × 110 g a.s./ha $PEC_{sw, max}$ [µg/L]
Thiacloprid	D3 (ditch)	< 0.001
	D4 (pond)	< 0.001
	D4 (stream)	< 0.001
	D5 (pond)	< 0.001
	D5 (stream)	< 0.001
	D6 (ditch)	< 0.001
	R1 (pond)	< 0.001
	R1 (stream)	< 0.001
	R2 (stream)	< 0.001
	R3 (stream)	< 0.001
	R4 (stream	< 0.001
Thiacloprid-descyano	D3 (ditch)	< 0.001
	D4 (pond)	< 0.001
	D4 (stream)	0.003
	D5 (pond)	< 0.001
	D5 (stream)	< 0.001
	D6 (ditch)	< 0.001
	R1 (pond)	< 0.001
	R1 (stream)	< 0.001
	R2 (stream)	< 0.001
	R3 (stream)	< 0.001
	R4 (stream	< 0.001

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ACUTE RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table CP 10.2- 4: TER_A calculations based on FOCUS Step 2

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	TER_A	Trigger
Maize					
Thiacloprid	Fish, acute *Cyprinodon variegatus*	LC_{50} 19 700	4.823	4085	100
	Invertebrate, acute *Daphnia magna*	EC_{50} ≥ 85 100	4.823	≥ 17 645	100
	Invertebrate, acute *Ecdyonurus* sp.	EC_{50} 7.7	4.823	**1.60**	100
	Sediment dweller, acute *Chironomus riparius*	EC_{50} 10.8	4.823	**2.24**	100
Thiacloprid-amide	Fish, acute *Lepomis macrochirus*	LC_{50} > 78 600	9.159	> 8582	100
	Invertebrate, acute *Daphnia magna*	EC_{50} > 103 000	9.159	> 11 245	100
	Invertebrate, acute *Hyalella azteca*	EC_{50} 47 600	9.159	5197	100
Thiacloprid sulfonic acid	Fish, acute *Oncorhynchus mykiss*	LC_{50} > 90 100	3.139	> 28 703	100
	Invertebrate, acute *Daphnia magna*	EC_{50} > 96 100	3.139	> 30 615	100

Bold values do not meet the trigger

For the metabolites the trigger was met for all organisms. For thiacloprid the trigger was met for all organisms except aquatic invertebrates, for these organisms a refined risk assessment considering the more realistic Step 3 FOCUS surface water exposure profiles is considered,

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Table CP 10.2- 5: TER_A calculations based on FOCUS Step 3

Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_A	Trigger
Thiacloprid, maize						
Invertebrate, acute *Ecdyonurus* sp.	EC_{50}	7.7	D3 (ditch)	< 0.001	> 7700	100
			D4 (pond)	< 0.001	> 7700	100
			D4 (stream)	< 0.001	> 7700	100
			D5 (pond)	< 0.001	> 7700	100
			D5 (stream)	< 0.001	> 7700	100
			D6 (ditch)	< 0.001	> 7700	100
			R1 (pond)	< 0.001	> 7700	100
			R1 (stream)	< 0.001	> 7700	100
			R2 (stream)	< 0.001	> 7700	100
			R3 (stream)	< 0.001	> 7700	100
			R4 (stream	< 0.001	> 7700	100
			D3 (ditch)	< 0.001	> 7700	100
Sediment dweller, acute *Chironomus riparius*	EC_{50}	10.8	D3 (ditch)	< 0.001	> 10800	100
			D4 (pond)	< 0.001	> 10800	100
			D4 (stream)	< 0.001	> 10800	100
			D5 (pond)	< 0.001	> 10800	100
			D5 (stream)	< 0.001	> 10800	100
			D6 (ditch)	< 0.001	> 10800	100
			R1 (pond)	< 0.001	> 10800	100
			R1 (stream)	< 0.001	> 10800	100
			R2 (stream)	< 0.001	> 10800	100
			R3 (stream)	< 0.001	> 10800	100
			R4 (stream	< 0.001	> 10800	100
			D3 (ditch)	< 0.001	> 10800	100

Considering the Step 3 FOCUS surface water values the trigger is met for all scenarios.

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CHRONIC RISK ASSESSMENT FOR AQUATIC ORGANISMS

Table CP 10.2- 6: TER_{LT} calculations based on FOCUS Step 2

Compound	Species	Endpoint [µg/L]	$PEC_{sw,max}$ [µg/L]	TER_{LT}	Trigger
Maize					
Thiacloprid	Fish, chronic	NOEC 170	4.823	35	10
	Invertebrate, chronic	NOEC 580	4.823	120	10
	Sediment dweller, chronic	NOEC 0.56	4.823	**0.12**	10
	Green algae, chronic	E_bC_{50} 44 700	4.823	9268	10
Thiacloprid-amide	Sediment dweller, chronic	EC_{15} > 100	9.159	11	10
	Green algae, chronic	E_bC_{50} > 100 000 E_rC_{50} > 100 000	9.159	10918	10
Thiacloprid sulfonic acid	Sediment dweller, chronic	EC_{15} > 100 000	3.139	31857	10
	Green algae, chronic	E_bC_{50} > 100 000 E_rC_{50} > 100 000	3.139	31857	10
Thiacloprid-descyano	Sediment dweller, chronic	NOEC 6.25	2.878	**2.17**	10

For the metabolites thiacloprid – amide and thiacloprid sulfonic acid the trigger was met for all organisms. For thiacloprid and the soil metabolite thiacloprid-descyano the TER trigger was not met for aquatic invertebrates, for these organisms a refined risk assessment considering the more realistic Step 3 FOCUS surface water exposure concentrations is considered,

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Table CP 10.2- 7: TER_{LT} calculations based on FOCUS Step 3

Species	Endpoint [µg/L]		$PEC_{sw,max}$ [µg/L]	FOCUS scenario	TER_{LT}	Trigger
Thiacloprid, maize						
Sediment dweller, chronic	NOEC	0.56	D3 (ditch)	< 0.001	> 560	10
			D4 (pond)	< 0.001	> 560	10
			D4 (stream)	< 0.001	> 560	10
			D5 (pond)	< 0.001	> 560	10
			D5 (stream)	< 0.001	> 560	10
			D6 (ditch)	< 0.001	> 560	10
			R1 (pond)	< 0.001	> 560	10
			R1 (stream)	< 0.001	> 560	10
			R2 (stream)	< 0.001	> 560	10
			R3 (stream)	< 0.001	> 560	10
			R4 (stream	< 0.001	> 560	10
Thiacloprid-descyano, maize						
Sediment dweller, chronic	NOEC	6.25	D3 (ditch)	< 0.001	> 6250	10
			D4 (pond)	< 0.001	> 6250	10
			D4 (stream)	0.003	2083	10
			D5 (pond)	< 0.001	> 6250	10
			D5 (stream)	< 0.001	> 6250	10
			D6 (ditch)	< 0.001	> 6250	10
			R1 (pond)	< 0.001	> 6250	10
			R1 (stream)	< 0.001	> 6250	10
			R2 (stream)	< 0.001	> 6250	10
			R3 (stream)	< 0.001	> 6250	10
			R4 (stream	< 0.001	> 6250	10

Considering the Step 3 FOCUS surface water values the trigger is met for all scenarios for both thiacloprid and thiacloprid-descyano.

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CP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

No additional acute aquatic studies have been performed with the formulation. Due to the use of the formulation as a seed treatment there will be no direct exposure to the formulation, additionally as the chronic chironomids provided the most sensitive end-point for the risk assessment a chronic study was performed for the formulation and is reported below.

CP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

Report:	[redacted]; [redacted]; 2009; M-361244-01-1
Title:	Chironomus riparius 28-day chronic toxicity test with thiacloprid FS 400 G in a water-sediment system using spiked water
Report No.:	EBYRL024
Document No.:	M-361244-01-1
Guidelines:	**OECD guideline 219: Sediment-water chironomid toxicity test using spiked water" (adopted 13 April 2004); none deviation**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid FS 400 G; Specification-no.: 102000021815; Density: 1.184 g/mL; Content of a.s.: 35.0% w/w (414.4 g/L).

First instar *of Chironomus riparius* larvae (4 beakers per test concentration and control with 20 animals each) were exposed in a static test system for 28 days to initial nominal concentrations in the overlying medium (spiked water application) of 0.91, 1.60, 2.86, 5.14, 9.14 and 16.0 µg form./L of a water-sediment system.
Dissolved oxygen concentrations ranged in the water phase from 7.2 to 8.5 mg O_2/L (7.7 mg O_2/L= 86.4% O_2 - saturation), the water pH-values ranged from 8.0 to 8.7 and the water temperature ranged from 20.5°C to 20.8°C measured from parallel beakers of each test concentration over the whole period of testing. Recoveries of active substance were measured three times during the study: 1 hour, 7 days and 28 days after application in one additional test container of each nominal initial test concentrations of 0.91, 1.60, 2.86, 5.14, 9.14 and 16.0 µg form./L and control of the overlying water and the pore water of the sediment.

Findings:

Analytical Findings:
Chemical analysis of overlying water and pore water over time reflect expected aquatic fate data. Due to the high recoveries of 86.4% to 92.8% (mean 88.8%) at the beginning of the exposure period in the overlying water of the test concentrations initial nominal concentrations were used for reporting and evaluation of the results. In the pore water of the sediment only low recoveries of 0.4 to 0.9% (averages) of nominal initial test concentrations were detected.

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Table CP 10.2.2- 1: Analytical results

	Analytical results of thiacloprid: Average% of nominal initial test concentrations		
	1 hour / day 0	day 7	day 28
Overlying water	88.8	30.3	12.2
Pore water	0.4	0.9	0.4

Biological findings:
Start of emergence was on day 13 to 14 for the control and test concentrations from 0.91 to 5.14 µg form./L. The start of emergence was postponed for one day at test concentration of 9.14 µg form./L and for 6 days at test concentration of 16.0 µg form./L.
97.5% of the inserted (n = 80) larvae maturated to adults in the control after 28 days, fulfilling the guideline requirements.

Table CP 10.2.2- 2: Influence on emergence and development rate after 28 days (based on initial mean measured concentrations of the test item in the overlying water)

Concentration		Number of emerged midges	Emergence of inserted larvae			Development rate [1 / d]
initial nominal [µg form./L]	initial mean measured [µg form./L]		total [%]	male [%]	female [%]	pooled sex
Control	0	78	97.50	48.75	48.75	0.061
0.91	0.32	75	93.75	36.25	57.50	0.062
1.60	0.56	66	82.50*	42.50	40.00	0.063
2.86	1.00	72	90.00	46.25	43.75	0.064
5.14	1.80	68	85.00*	37.50	47.50	0.063
9.14	3.20	63	78.75*	37.50	41.25	0.055*
16.0	5.60	3	3.75*	2.50	1.25	0.046*

*statistical significance (α = 0.05)

The Chi^2-Test indicates no statistically different distribution between sexes compared to the assumption of 50% females and 50% males. Therefore male and female results were pooled for further statistical analyses to increase the statistical power.
Statistical significance (α = 0.05) on emergence rate for male and female midges (pooled) was stated at test concentration of 5.14 µg form./L (= LOEC) and higher test concentrations, resulting in an NOEC of 2.86 µg form./L. In contrast to the results of the statistical evaluation, which stated the LOEC at initial nominal test concentration of 1.60 µg form./L, the LOEC was fixed at test concentration of 5.14 µg form./L, due to the absence of negative effects on larval growth and development at test level of 2.86 µg form./L.
For development rate of male and female midges (pooled) statistical significance was evaluated for initial nominal test concentration of 9.14 µg form./L (= LOEC) and higher test concentrations, resulting in an NOEC of 5.14 µg form./L.

Conclusions:

Test conditions met all validity criteria, given by the mentioned guideline.

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Table CP 10.2.2- 3: Results based on initial nominal concentrations in µg form./L of the test item in the overlying water

Endpoints	NOEC	LOEC	EC_{15}	EC_{50}
emergence rate (pooled sex) (95% confidence limits)	2.86	5.14	4.48 (n.d.)	9.80 (n.d.)
development rate (pooled sex) (95% confidence limits)	5.14	9.14	11.7 (11.0 – 12.4)	27.1 (24.2 – 31.5)

n.d. = not determined

Table CP 10.2.2- 4: Results displayed in µg a.s./L, corresponding to initial nominal concentrations of the formulation

Endpoints	NOEC	LOEC	EC_{15}	EC_{50}
emergence rate (pooled sex) (95% confidence limits)	1.00	1.80	1.57 (n.d.)	3.43 (n.d.)
development rate (pooled sex) (95% confidence limits)	1.80	3.20	4.10 (3.85 – 4.34)	7.59 (8.47 – 11.0)

CP 10.2.3 Further testing on aquatic organisms

No further testing of the Thiacloprid FS400 formulation has been performed, nor is it required.

CP 10.3 Effects on arthropods

CP 10.3.1 Effects on bees

Commission Regulations (EU) 283/2013 and 284/2013 require where bees are likely to be exposed, testing by both acute (oral and contact) and chronic toxicity, including sub-lethal effects, to be conducted. Consequently in addition to the standard toxicity studies performed with adult bees (OECD 213 and 214) the following additional studies are also provided:

- Acute oral and contact toxicity of thiacloprid-amide (metabolite of thiacloprid)
- Acute contact toxicity of thiacloprid to adult bumble bees (*Bombus terrestris*)
- Chronic 10 day toxicity to adult bees under laboratory conditions of thiacloprid
- Chronic 10 day toxicity to adult bees under laboratory conditions of thiacloprid-amide (metabolite of thiacloprid)
- Acute toxicity to larval bees under laboratory conditions of thiacloprid
- Tunnel test according to the guidance document EPPO 170. In this test honey bee colonies were exposed to maize plants grown from seeds treated with Thiacloprid FS 400 at a nominal rate of 1 mg a.s./seed.
- Field test with honey bee colonies exposed to maize plants grown from seeds treated with Thiacloprid FS 400 at a nominal rate of 1 mg a.s./seed. This test also included a measurement of residues in maize pollen.

Details of the honey bee testing with thiacloprid and ecotoxicological endpoints are presented in MCA, Section 8, Point 8.3.1, as well as within the existing Review Report for thiacloprid). Furthermore, data on the contact toxicity of Thiacloprid OD 240 included in the MCA document indicated that based on laboratory toxicity data there is no evidence to suggest that non-*Apis* bees were

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at greater risk can consequently the risk assessment for honey bees was considered to protect other bees.

The tests conducted with the formulation Thiacloprid FS 400 are presented in this MCP document.

A summary of the critical endpoints thiacloprid, thiacloprid-amide and formulated product Thiacloprid FS 400 are provided in the following tables. Endpoints shown in bold are considered relevant for risk assessment.

Table CP 10.3.1- 1: Critical endpoints for thiacloprid – acute toxicity to adult bees

Test substance	Test species	Endpoint		Reference
Thiacloprid	Honey Bee (oral 48 h)	LD$_{50}$	17.32 µg a.s./bee	[redacted] (1995) M-000856-01-1 KCA 8.3.1.1.1/1
	Honey Bee (contact 48 h)	LD$_{50}$	38.82 µg a.s./bee	
Thiacloprid-amide	Honey Bee (oral 48 h)	**LD$_{50}$**	**> 108.1 µg p.m./bee**	[redacted] (2009) M-360295-01-1 KCA 8.3.1.1.1/2
	Honey Bee (contact 48 h)	LD$_{50}$	> 100 µg p.m./bee	
Thiacloprid FS 400	Honey Bee (oral 48 h)	**LD$_{50}$**	**1.9 µg a.s./bee**	[redacted] (2010) M-361379-01-1 KCP 10.3.1.1.1/1
	Honey Bee (contact 72 h)	**LD$_{50}$**	**92.3 µg a.s./bee**	
Thiacloprid OD 240	Bumble bee (contact 48 h) (*Bombus terrestris*)	LD$_{50}$	> 100 µg a.s./bumblebee	[redacted] (2014) M-480628-01-1 KCA 8.3.1.1.2/1

Note: p.m. = pure metabolite

Table CP 10.3.1- 2: Critical endpoints for thiacloprid – chronic toxicity to adult bees

Test substance	Test species	Endpoint		Reference
Thiacloprid	Honey bee Laboratory chronic (10 d) (adults)	NOEC	8130 µg p.m./kg	[redacted] (2010) M-397536-01-1 KCA 8.3.1.2/1
Thiacloprid	Honey bee Laboratory chronic (10 d) (adults)	LC$_{50}$ NOEC LDD$_{50}$ NOED	50 900 µg a.s./kg 29 000 µg a.s./kg 3.0 µg a.s./bee/day 1.7 µg a.s./bee/day	[redacted] et al. (2013) M-475374-01-1 KCA 8.3.1.2/2
Thiacloprid-amide	Honey bee Laboratory chronic (10 d) (adults)	NOEC	8130 µg p.m./kg	[redacted] (2012) M-438963-01-1 KCA 8.3.1.2/3

Note: p.m. = pure metabolite; LDD$_{50}$ = median lethal dietary dose

Table CP 10.3.1- 3: Critical endpoints for thiacloprid – toxicity to larvae

Test substance	Test species	Endpoint	Reference
Thiacloprid	Honey bee Laboratory *in vitro*, single exposure test design (larvae)	LD$_{50}$ > 5.34 µg a.s./larva* NOED 1.78 µg a.s./larva	[redacted] et al. (2013) M-472283-01-1 KCA 8.3.1.3/1

*Highest dose tested and gave 17% mortality

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Table CP 10.3.1- 4: Critical endpoints for thiacloprid – forced exposure conditions (tunnel tests)

Test substance	Test species	Endpoint	Reference
Thiacloprid FS 400	Honey bee, semi-field study treated maize seeds exposed at pollen shedding (*Apis mellifera*)	No adverse effects at 1.00 mg a.s./seed	[redacted] (2010) M-385049-01-1 KCP 10.3.1.5/1

Table CP 10.3.1- 5: Critical endpoints for thiacloprid –field studies

Test substance	Test species	Endpoint	Reference
Thiacloprid FS 400	Honey bee, field study treated maize seeds exposed at pollen shedding (*Apis mellifera*)	No adverse effects at 1.00 mg a.s./seed Residues in pollen below LOQ for thiacloprid and thiacloprid-amide	[redacted] (2010) M-373436-01-1 KCP 10.3.1.6/1

LOQ = limit of quantification. LOQ thiacloprid = 0.0001 mg/kg LOQ thiacloprid-amide= 0.001 mg/kg

Risk assessment for bees

The risk assessment for bees is based on the maximum single application rate of thiacloprid applied as a seed treatment at 1 mg a.s./seed of 110 g a.s./ha for application in maize.

Hazard Quotients

The risk assessment is based on Hazard Quotient approach (Q_H) by calculating the ratio between the application rate (expressed in g a.s./ha or in g total substance/ha) and the laboratory contact and oral LD_{50} (expressed in µg a.s./bee or in µg total substance/bee).

Q_H values can be calculated using data from the studies performed with the active substance and with the formulation. Q_H values higher than 50 indicate the need of higher tiered activities to clarify the actual risk to honey bees.

Hazard Quotient, oral: $$Q_{HO} = \frac{\text{max. appl. rate}}{LD_{50}\ \text{oral}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or } \mu\text{g total substance/bee}]}$$

Hazard Quotient, contact: $$Q_{HC} = \frac{\text{max. appl. rate}}{LD_{50}\ \text{contact}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or } \mu\text{g total substance/bee}]}$$

Table CP 10.3.1- 6: Hazard quotients for bees – oral exposure

	Crop	LD_{50} [µg/bee]	Application rate [g/ha]	Hazard quotient Q_{HO}	Trigger
Thiacloprid FS 400	Maize	1.9	110	57.9	50
Thiacloprid	Maize	17.32	110	6.4	50
Thiacloprid-amide	Maize	> 108.1	110	1.0	50

The hazard quotient for oral exposure is just exceeded by the oral exposure route for the formulation but below the validated trigger value for higher tier testing (i.e. $Q_{HO} < 50$).

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Table CP 10.3.1- 7: Hazard quotients for bees – contact exposure

	Crop	LD_{50} [µg/bee]	Application rate [g/ha]	Hazard quotient Q_{HO}	Trigger
Thiacloprid FS 400	Maize	92.3	110	1.2	50
Thiacloprid	Maize	38.82	110	2.8	50
Thiacloprid-amide	Maize	> 100	110	1.1	50

The hazard quotient for contact exposure is below the validated trigger value for higher tier testing (i.e. $Q_{HC} < 50$).

The hazard quotient values based on this very simplistic approach indicated that there may be a risk to bees via exposure oral exposure to the formulated product. However, as the formulation is used exclusively for seed treatment the chances for bees to be exposed orally to the formulation are low.

As the risk assessment scheme for honeybees to be applied according to the Terrestrial Guidance Document (SANCO/ 10329/2002 rev 2) is recognized not to be fully sufficient to cover the specificities of soil-systemic pesticide uses, the risk assessment for the use of Thiacloprid FS 400 as a seed treatment in maize was conducted to EPPO PP 3/10 (3) 2010[17]. This is the currently valid and risk assessment scheme in force at the time of the submission of this dossier. However, this document does not specifically address exposure to dust, consequently product specific data on exposure are provided and the risk assessment used follows that of SANCO/ 10329/2002 rev 2 using the Hazard Quotient (HQ) approach using exposure levels estimated from a comprehensive data set of dust drift field trials. Furthermore, data on the contact toxicity of Thiacloprid OD 240 indicated that based on laboratory toxicity data there is no evidence to suggest that non-*Apis* bees were at greater risk can consequently the risk assessment for honey bees was considered to protect other bees.

For maize the use of plant systemic seed treatment applications may result in bees being exposed to test substance via the following routes of exposure (Alix and Miles 2012[18]; Fischer and Moriarty 2014[19])

- [redacted] emitted from seed drilling equipment at the time of sowing
- Guttation water during the early growth stage of the plants
- Consumption of residues in pollen

The relevance of each point will be discussed below and where necessary a risk assessment provided.

<u>Risk to bees due to exposure to dust emitted from seed drilling equipment at the time of sowing</u>

[17] EPPO 2010. Environmental risk assessment scheme for plant protection products. Chapter 10 Honey bees. OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 40, 1–9.

[18] Alix, A., Miles, M. (2012). Exposure of honey bees and other pollinating species to pesticides. 11th International Symposium of the ICP-BR Bee Protection Group, Wageningen (The Netherlands), November 2-4, 2011. Julius-Kühn-Archiv, 437, 2012 19.

[19] Fischer, D., Moriarty, T. (eds) 2014 Pesticide Risk Assessment for Pollinators: SETAC Pellston Workshop. Proceedings of the SETAC Pellston Workshop on Pesticide Risk Assessment for Pollinators 15–21 January 2011 Pensacola, Florida, USA

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During the drilling of maize seed treatment dust might be abraded and released in the environment. As the field is bare at the time of drilling any exposure will be due to the deposition of dust onto adjacent flowering areas.

Dust exposure assessment
To evaluate the exposure of honey bees to seed treatment dust in off-crop habitats 19 drift studies were conducted by several companies. These data have been independently evaluated by RLP AgroScience ([redacted], 2012; M-404875-02-1), by applying the same methodology as for the determination of the 90th percentile spray drift deposition values. This data compilation includes the evaluation of dust drift studies conducted for maize.

Based on the data as determined for the deflected, vacuum-pneumatic sowing operation of seed-treated maize seeds, characterized by a Heubach-value of < 0.75 g dust/100,000 seeds, the maximum downwind 90th percentile dust ground deposition in 1 m distance from the field is 0.125% of applied in-field rate.

A 3D-method trial has been conducted ([redacted], [redacted]; 2010; M-362242-01-1, KCP 10.3.1.6/3), to investigate the deposition of dust drift on vertically installed sampling devices. The outcome of this 3D-method trial revealed that vertically installed gauze netting can be considered to be the most appropriate surrogate sampling device for measuring vertical deposition in natural 3D off-crop structures. Currently, only a limited number of dust-drift studies have been conducted where concurrently ground dust-deposition (2D, Petri-dishes) and 3D dust deposition on vertically installed gauze netting has been measured. By analysing these available comparative 2D- and 3D-data, it was found that on average 4.9 times (median: 5.8 times) more active substance deposited on the 3D dust samplers (gauze netting) as compared to the Petri-dishes. In a data compilation by Kubiak *et al.* (2011[20]), as presented on an EU-Workshop on dust drift in Paris in May 2011, it was proposed to apply in the absence or only limited measured 3D dust drift-data the median extrapolation factor of 6 to the 90th percentile dust ground deposition to conservatively estimate the amount of dust being carried into high growing vegetation. Thus, a median extrapolation factor of 6 will be applied to the 90th percentile dust ground deposition value to estimate the 3D dust drift exposure. Furthermore it needs to be considered that the dust will only be transported in the down wind direction which will lead to a reduced average exposure in field margins. The address this reduction the drift value will be multiplied by a factor of 1/3.

Based on a 90th percentile ground deposition value of 0.125% for maize the 3D off-field exposure for honey bees can be calculated as follows: 0.125% × 6 × 1/3 = 0.25% of in-field application rate of the seed treatment product expressed as g a.s./ha. Considering the maximum in-field application rate of 110 g a.s./ha this corresponds to a 3D off-field dust exposure rate of **0.275 g a.s./ha**. This value is calculated under the consideration that the seed treatment quality of the treated seeds meets the minimum quality criterion of a Heubach value of < 0.75 g dust/100,000 seeds and that vacuum pneumatic drillers are equipped with an appropriate deflector.

The off-field exposure can be further reduced if the seed treatment quality is further increased. Bayer CropScience has developed a novel seed treatment concept for the use of maize seed treatment product Thiacloprid FS 400, based on the film-coating Impranil® DLN W 50 (from Bayer MaterialScience) in combination with Talcum Gloss® (from Cérès Seed Technology). Using this concept, a premium

20 [redacted], R.; [redacted], G.; [redacted], C.; [redacted], P.; "Non-target ground deposition of dust resulting from sowing pesticide treated seeds - Evaluation and analysis of current experimental datasets to establish dust deposition tables", M-412975-01-1, Presented at EU dust workshop May 10-11, 2011, Paris/France

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maize seed-coating quality can be achieved, which results under commercial agronomic use conditions in a high abrasion resistance of the treated maize seeds.

It is common commercial practice to perform a fungicide co-treatment when insecticides are used in seed-treatment, i.e. a routine fungicide is added when treating maize seeds. In order to perform our drift studies under realistic worst-case conditions, the employed maize seeds have been co-treated with Thiram SC 700 (from Bayer CropScience).

The dust drift of this premium seed treatment quality was assessed in 2 drift studies ([redacted], 2010, M-393034-01-1, KCP 10.3.1.6/4; [redacted], 2012, M-426528-01-1, KCP 10.3.1.6/5). The seeds for this drift studies were treated in commercial seed treatment plants. Based on the data from the first study ([redacted], 2010, M-393034-01-1), a 90th-percentile drift value of 0.033% (related to the in-field application rate) was derived for the ground deposition and a 90th-percentile tile drift value of 0.151% (related to the in-field application rate) was derived for the deposition on 3-dimensional structures (gauze netting). The drift rates form the second study ([redacted], 2012, M-426528-01-1) resulted in even lower drift values with a 90th-percentile drift value of 0.017% for the ground deposition and a 90th-percentile tile drift value of 0.017% for the deposition on 3-dimensional structures (gauze netting).

Using the higher 90th-percentile drift value of 0.151% from these 2 studies and the correction of 1/3 to address the reduced average exposure at the field margin under consideration of the wind direction this results in a 3D exposure value of 0.151% × 1/3 = 0.05% of in-field application rate. This translates for the maximum in-field application rate of 110 g a.s./ha to a corresponding a 3D off-field dust exposure rate of **0.055 g a.s./ha**. These data clearly indicate an increased seed treatment quality will further reduce the exposure of honey bees seed treatment dust in the off-crop vegetation.

Risk assessment for bees due to exposure to seed treatment dust
Two estimates are provided for exposure to seed treatment dust. A 90th-percentile worse case "normal" seed treatment value of 0.275 g a.s./ha and 0.055 g a.s./ha for a "premium" seed treatment. As seed treatment dust is not a source of food for bees the risk assessment is based upon acute toxicity values following the Hazard Quotient approach.

The risk assessment is based on Hazard Quotient approach (Q_H) by calculating the ratio between the seed treatment dust exposure level (expressed in g a.s./ha) and the laboratory contact and oral LD_{50} (expressed in µg a.s./bee or in µg total substance/bee).

Q_H values can be calculated using data from the studies performed with the active substance and with the formulation. Q_H values higher than 50 indicate the need of higher tiered activities to clarify the actual risk to honey bees.

Hazard Quotient, oral: $$Q_{HO} = \frac{\text{seed trt dust}}{LD_{50}\ \text{oral}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or }\mu\text{g total substance/bee}]}$$

Hazard Quotient, contact: $$Q_{HC} = \frac{\text{seed trt dust}}{LD_{50}\ \text{contact}} = \frac{[\text{g a.s./ha or g total substance/ha}]}{[\mu\text{g a.s./bee or }\mu\text{g total substance/bee}]}$$

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Table CP 10.3.1- 8: Hazard quotients for bees- oral exposure

	Crop	LD_{50} [µg/bee]	Exposure [g/ha]	Hazard quotient Q_{HO}	Trigger
"Standard" seed treatment quality					
Thiacloprid FS 400	Maize	1.9	0.275	0.14	50
Thiacloprid	Maize	17.32	0.275	0.016	50
Premium seed treatment quality					
ThiaclopridFS 400	Maize	1.9	0.055	0.03	50
Thiacloprid	Maize	17.32	0.055	0.003	50

The hazard quotient for oral exposure is below the validated trigger value for higher tier testing (i.e. Q_{HC} < 50).

Table CP 10.3.1- 9: Hazard quotients for bees- contact exposure

	Crop	LD_{50} [µg/bee]	Exposure [g/ha]	Hazard quotient Q_{HO}	Trigger
Normal seed treatment quality					
Thiacloprid FS 400	Maize	92.3	0.275	0.003	50
Thiacloprid	Maize	38.82	0.275	0.007	50
Premium seed treatment quality					
Thiacloprid FS 400	Maize	92.3	0.055	0.0006	50
Thiacloprid	Maize	38.82	0.055	0.0014	50

The hazard quotient for contact exposure is below the validated trigger value for higher tier testing (i.e. Q_{HC} < 50).

Risk to bees due to exposure to guttation water

Honey bees are specific in their requirement for water to cool the hive and also to dilute concentrated honey stores. Other bees do not require water for these purposes and get their water from their diet (nectar). The occurrence of guttation droplets is highly dependent upon systemic properties, soil and air humidity and the type of crop. A study to investigate the concentrations of Thiacloprid in guttation water from maize plants grown from treated seed (1 mg a.s./seed) is reported below (KCP 10.3.1.6/6; M-359919-01-1). Guttation was shown to occur from BBCH 10 to 17 with a marked decline in concentration from BBCH 13 onwards for periods of up to approximately 3 weeks (i.e. 12, 22 and 24 days respectively). A peak concentration (one occurrence, single field) of 50 mg a.s./L was observed for thiacloprid. However more typical residues were of the 5 mg a.s./L level. Thiacloprid-amide was found less often than the parent and at lower concentrations (peak residue measured of 16 mg a.s./L).

In tunnel and field tests where spray applications are made directly to bee attractive flowering crops during the period of bee activity applications were made at 72-73 g a.s./ha in 200 to 300 L/ha of water (see MCP Thiacloprid OD 240 section 10.3 effects on bees). The resulting spray solutions therefore ranged from between 244 and 360 mg a.s./L which is 5 – 7x more concentrated than the maximum concentrations of thiacloprid found in guttation water.

However, the exposure differs between spray application to bee foraging on pollen and nectar vs. water collection on maize but many more bees are likely to exposure following an application to a flowering crop and the spray solution is of far higher concentration. This information gives some supporting evidence that exposure to lower concentrations as guttation water and fewer bees is unlikely to adversely affect honey bee colonies.

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Consequently; although honey bees are observed to collect guttation water the due to the short period of time a guttation event may occur and the proportion of bees exposed means that this is not considered a significant route of exposure for the colony (however individual bees may be affected) and no risk assessment is necessary. It is good beekeeping practice to ensure an adequate supply of clean fresh water for colonies. Consequently no risk assessment is necessary[21][22].

Risk to bees due to consumption of residues in pollen

Thiacloprid and its soil residues are plant-systemic and maize crops can be attractive to foraging honey bees as a pollen source (but not as a nectar source). Honey bee colonies sited close to fields of maize may collect pollen and use for food.

Pollen exposure assessment
Information on the use and consumption of pollen as a food source by honey bees is provided by several authors (Simpson, 1955[23], Babendreier et al, 2004[24] and Rortais et al 2005[25]). Pollen is the only natural protein source available to honey bees and is used to feed larvae and is also consumed in the largest amounts by adult nurse bees that tend and fed the larvae in the colony. Forager bee pollen consumption levels are negligible. Consequently the risk to honey bees due to the consumption of pollen can be covered by considering the exposure to nurse bees and larvae. Pollen consumption levels for nurse bees and larvae are presented below:

Table CP 10.3.1- 10: Pollen consumption levels

Type of Honey bee	Location	Pollen consumption	Notes
Nurse bee	Within the colony	65 mg pollen / 10 days 6.5 mg pollen / day	May consume up to 12 mg pollen in one day
Larva (worker)	Within the colony	5.4 mg pollen total 1.3 mg on day 4 3.6 mg on day 5	On days 1-3 larvae are fed royal jelly. Pollen (and nectar) are fed on day 4 and 5 only

For an estimate of the worst case 95th percentile residue present in pollen (and nectar) irrespective of application or seed loading rate EPPO 2010 considers that a concentration of 1 mg a.s./kg (i.e.1 µg a.s./g) should be used for a screening level risk assessment. Based on this and pollen

[21] Frommberger M, Pistorius J, Joachimsmeier I, Schenke D, (2012) Guttation and the risk for honey bee colonies (Apis mellifera L.): a worst case semi-field scenario in maize with special consideration of impact on bee brood and brood development, ICPBR Wageningen, 11th Symposium Hazards of Pesticides to Bees, 2.-4.11.2011.

[22] Joachimsmeier,I, Pistorius J, Schenke, D, Kirchner, W. (2012) Guttation and risk for honey bee colonies (Apis mellifera L.): Use of guttation drops by honey bees after migration of colonies - a field study. , ICPBR Wageningen, 11th Symposium Hazards of Pesticides to Bees, 2.-4.11.2011

[23] Simpson, J. 1955. The significance of the presence of pollen in the food of worker larvae of the honey bee. Quarterly Journal of Microscopical Science, 96(1): 117-120.

24 Babendreier, D., Kalberer, N., Romeis, J., Fluri, P. and F. Bigler. 2004. Pollen consumption in honey bee larvae: a step forward in the risk assessment of transgenic plants. Apidologie, 35: 293-300.

[25] Rortais, A., Arnold, G., Halm, M.P., F. Touffet-Briens. 2005. Modes of honey bees exposure to systemic insecticides:estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie, 36: 71-83.

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consumption rates the following realistic worst case risk assessment scenarios which cover the risk to bees due to the use of Thiacloprid FS 400 as a seed treatment for maize cultivation are calculated.

Table CP 10.3.1- 11: Estimated worse case exposure levels

Type of honey bee	Pollen consumption (g)	Residue level	Dose (µg/bee)
Nurse bees (acute risk)	0.012 g	1 µg a.s./g	0.012 µg/bee
Nurse bees	0.0065 g /day		0.0065 µg/bee/day
Larva (worker)	0.0054g (on day 4 and 5)		0.0054 µg /bee

Risk assessment for bees due to exposure to pollen

Using the appropriate endpoints the risk to bees due to the consumption of pollen containing residues of thiacloprid is presented below. According to EPPO 2010 a Toxicity Exposure Ratio trigger of 10 is applied to acute endpoints (LD_{50}) and 1 to No Observed Effect Dose endpoints (NOED). As larvae are only fed on pollen for 2 days the endpoint from the acute test (KCA 8.3.1.3/1) is directly applicable.

Table CP 10.3.1- 12: Thiacloprid FS 400 seed treatment: Systemic risk to bees via pollen consumption

Type of honey bee	Risk	Endpoint	Exposure	Toxicity Exposure Ratio (TER)	EPPO (2010) Trigger
Nurse bee	Acute	LD_{50}: 17.32 µg a.s./bee	0.012 µg/bee	1443	10
	Chronic	LDD_{50}: 3.0 µg a.s./bee/day	0.0065 µg/bee/day	462	10
	Chronic	NOED: 1.7 µg a.s./bee/day	0.0065 µg/bee/day	261	1
Larva (worker)	Dietary	LD_{50}: > 5.34 µg a.s./larva*	0.0054 µg /bee	989	1
		NOED: 1.78 µg a.s./larva	0.0054 µg /bee	330	1

Note: Endpoints for technical material are used as exposure via pollen will not be to formulated product. Dose of 5.34 µg a.s./larva gave only 17% mortality.

The calculated TER values range from 261 to 1443 for nurse bees and 330 to 989 for larval bees. These margins of safety are high and exceed the EPPO 2010 triggers by several orders of magnitude. As thiacloprid-amide is of far lower toxicity than the parent no separate risk assessment (based on the default residue level of 1 mg a.s./kg) is considered necessary the calculate TER values would be at least two orders of magnitude higher.

Interpretation of calculated TER values

The TER values are clearly in excess of the trigger values of 10 and 1 for use with LD_{50} and NOED respectively. Where a NOED endpoint was used the TER can be used to indicate the margin of safety. For example for nurse and larval bees the worst-case exposure levels are 261 to 330 times lower than the observed NOED respectively. A remarkably similar level of safety is observed for both stages of bee.

Where a lethal (LD_{50} or LDD_{50}) endpoint is used these can be interpreted by understanding the slope of the dose response and estimating the chance of an individual effect at the given exposure level. This can be based on the following formula assuming a dose-response model based on a probit assumption (i.e. log normal distribution of individual sensitivity)

$$\log LD_k = \log LD_{50} + (z/b)$$

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where: z is the standard normal deviate and b equals slope.

The slope for acute endpoint of LD_{50} = 17.32 µg a.s./bee is not given in the report but can be estimated from the data to be approximately 2 (1.99). For the chronic endpoint of LDD_{50} = 3.0 µg a.s./bee/day a slope of 1.748 is reported. Consequently for the acute risk assessment the TER calculated of 1443 gives chance of an individual effect (i.e. one dead bee) of 1 in 7.16 x 109 (i.e. 1 dead bee out of 7 billion exposed to this dose). For the chronic risk assessment the TER calculated of 462 gives chance of an individual effect to be calculated of 1 in 8.39 x 105 (or 1 bee 0.839 million exposed to this dose). Consequently even using the worst case default exposure values of 1 mg a.s./kg in pollen the risk to bees is extremely low.

However, this risk assessment is still a large overestimate as the actual exposure level expected under conditions of use are far lower. In the effects field study (KCP 10.3.1.6/1 M-373436-01-1) and a residue field study (M-363263-01-1) the measured residue concentrations of thiacloprid and thiacloprid-amide in pollen taken from treated maize were below the limits of quantification (LOQ) of 0.0001 and 0.001 mg/kg respectively. Even if the LOQ values are taken as an estimate of field level concentrations in pollen the calculated doses would be 3 to 4 orders of magnitude lower than those used in this risk assessment. The resulting TER values would therefore be 3 to 4x orders of magnitude higher i.e. up to 2,610,000 to 14,430,000 for nurse bees and 3,300,000 to 9,890,000 for larval bees demonstrating a very extraordinarily high margin of safety and conservatism in the risk assessment presented.

In addition, the findings from the risk assessment for consumption of pollen from treated maize are supported by the results from two higher tier studies. These studies (one semi-field and one field) are presented and investigate the effects on honey bee colonies foraging on maize grown from seed either treated with Thiacloprid FS 400 or untreated seed (KCP 10.3.1.5/1, M-385049-01-1 and KCP 10.3.1.6/1, M-373436-01-1).

The semi-field study was conducted under confined, forced exposure conditions where bees and crop were held under gauze tunnels. In this study detailed and replicated observations of the mortality, foraging behaviour, colony strength, brood condition and food stores were made and no differences between the colonies exposed to treated maize compared to the control were noted. In a second study conducted under field conditions these finding were confirmed and in addition the health status and overwintering performance was also investigated. Overall the study revealed that honey bee colonies exposure to maize grown from seed treated with Thiacloprid FS 400 at 1.00 mg a.s./seed experienced no adverse effects on mortality, foraging, brood condition, food stores health status or over wintering performance compared to controls. In addition, pollen residues were measured and found to be below the LOQ of 0.0001 mg/kg indicating that the reason for the no effects can be explained due to the relatively low toxicity of thiacloprid (as an insecticide) to bees and the low exposure levels due to this method of application.

Overall conclusions for bees

The calculated Hazard Quotients based on the empirical exposure level of 110 g a.s./ha for technical thiacloprid are well below the validated trigger value which would indicate the need for a refined risk assessment; no adverse effects on honey bee mortality are to be expected. For the formulated product Thiacloprid FS 400 the trigger was slightly exceeded for an oral route of exposure but well below the trigger for a contact route of exposure. However, this risk assessment was considered too simplistic to

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fully cover all concerns such as exposure to dust emitted from seed drilling equipment at the time of sowing, exposure to guttation water and consumption of residues in pollen. Using experimentally derived data for dust exposure risk assessment and the risk assessment for systemic products provided in EPPO PP 3/10 (3) 2010 a detailed assessment of risk was conducted and indicated that there was no unacceptable risk to bees due to the use of Thiacloprid FS 400 as a seed treatment for maize. Furthermore this conclusion is confirmed by the results of tunnel and field studies.

Overall, it can be concluded that thiacloprid, when applied at the maximum application rate of 1 mg a.s./seed for maize, equivalent to 110 g a.s./ha does not pose an unacceptable risk to honey bees and honey bee colonies. Additionally there is no evidence to suggest that non-*Apis* bees were at greater risk.

CP 10.3.1.1 Acute toxicity to bees

CP 10.3.1.1.1 Acute oral toxicity to bees

Report:	[redacted]; [redacted]; 2010; M-361379-01-1
Title:	Effects of thiacloprid FS 400 G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory
Report No.:	52261035
Document No.:	M-361379-01-1
Guidelines:	**OECD 213 and 214 (1998); none**
GLP/GEP:	**yes**

Material and Methods:

Test item: Thiacloprid FS 400 G (active substance thiacloprid (YRC 2894)); Specification No.: 102000021815; Density: 1.184 g/mL; Content of a.s.: 35.0% w/w, 414.4 g/L.

Thirty worker bees per treatment were exposed for 72 hours to doses of 200.0, 100.0, 50.0, 25.0, 12.5 and 6.3 µg a.s. per bee for topical application (contact) and for 48 hours to doses of 2.5, 2.7, 1.4, 0.68, 0.35, 0.17 and 0.088 µg a.s. per bee for feeding (oral, value based on the actual intake of the test item). Due to increasing mortality between 24 and 48 hours the contact test was prolonged for further 24 hours up to 72 hours.

Results:

Contact test
Dose levels of 200.0, 100.0, 50.0, 25.0, 12.5 and 6.3 µg a.s. led to mortality of 66.7, 56.7, 13.3, 36.7, 0.0 and 3.3% at the end of the test (72 hours). 3.3% mortality occurred in the control group (water + 0.5% Adhaesit). During the first 4 hours behavioural abnormalities (e.g. movement coordination problems and/or apathy and cramps) were observed in all dose levels. 24 hours following the application a few bees were behaying abnormal in the 200.0 and 100.0 µg a.s./bee dose level. At the 48 and 72 hours assessments, no behavioural abnormalities were found any more.
Oral Test
In the oral test, the maximum nominal dose level of the test item (5 µg a.s./bee) could not be achieved, because the bees did not ingest the full volume of treated sugar solution even when offered over a period of 6 hours. Oral doses of 2.5, 2.7, 1.4, 0.68, 0.35 and 0.17 µg a.s./bee resulted in mortality ranging from 90.0% to 3.3% at the end of the test (48 hours after application). No mortality occurred in the 0.088 µg a.s./bee group. Control mortality was 0.0%. During the 4 hours assessment movement

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coordination problems and/or apathy were observed in all dose levels, except the 0.17 and 0.088 µg a.s./bee dose groups. After 24 hours one bee was apathetic in the highest dose level. These were the only irregularities within the oral test.

Table CP 10.3.1.1.1- 1: Toxicity to honey bees in a laboratory tests with Thiacloprid FS 400

Test Item	**Thiacloprid FS 400 G**	
Test object	***Apis mellifera***	
Application rate µg a.s./bee	**200.0, 100.0, 50.0, 25.0, 12.5 and 6.3**	**2.5, 2.7, 1.4, 0.68, 0.35, 0.17 and 0.088**
Exposure	**contact (solution in Adhaesit (0.5%)/water)**	**oral (sugar solution)**
LD_{50} µg a.s./bee	24 hours: 158.7; 48 hours: 92.3; 72 hours: 92.3	24 hours: 1.9; 48 hours: 1.9

Conclusion:

The toxicity of Thiacloprid FS 400 G was tested in both an acute contact and oral toxicity test on honey bees. The LD_{50} (24 h + 48 h) was 1.9 µg a.s./bee in the oral toxicity test.
The LD_{50} (24, 48 + 72 h) of Thiacloprid FS 400 G was determined to be 158.7, 92.3 and 92.3 µg a.s./bee in the contact toxicity test.

CP 10.3.1.1.2 Acute contact toxicity to bees

Report: [redacted]; 2010; M-361379-01-1
Title: Effects of thiacloprid FS 400 G (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory
Report No.: 52261035
Document No.: M-361379-01-1
Guidelines: **OECD 213 and 214 (1998); none**
GLP/GEP: **yes**

The study is summarised above as KCP 10.3.1.1.1/1, therefore only the conclusion is repeated here.

Conclusion:

The LD_{50} (24, 48 + 72 h) of Thiacloprid FS 400 G was determined to be 158.7, 92.3 and 92.3 µg a.s./bee in the contact toxicity test, respectively.

CP 10.3.1.2 Chronic toxicity to bees

A study with formulated product is not required. See Point CA 8.3.1.2 where studies on the chronic toxicity of technical thiacloprid and thiacloprid-amide are presented.

CP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A study with formulated product is not required. See Point CA 8.3.1.3 where a study on the toxicity of technical thiacloprid to honey bee larvae is presented.

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CP 10.3.1.4 Sub-lethal effects

There is no particular study design / test guideline to assess “sub-lethal effects” in honey bees. However, in each laboratory study as well as in any higher-tier study, sub-lethal effects, if occurring, are described and reported.

Two publications are summarized at Point CA 8.3.1.4 which describe the well know initial and short term repellence (foraging reduction) and influence on homing behaviour. In both cases these short term effects, (when they occur) are not biologically significant in terms of pollination or for the colony as demonstrated under GLP and test guideline semi-field and field conditions (see thiacloprid FS 400 KCP 10.3.1.5/1 and KCP 10.3.1.6/1; thiacloprid OD 240 KCP 10.3.1.5/1, KCP 10.3.1.5/2 , KCP 10.3.1.6/2 and KCP 10.3.1.6/3).

CP 10.3.1.5 Cage and tunnel tests

Report:	[redacted]x; [redacted]; 2010; M-385049-01-1
Title:	Thiacloprid FS 400: A semi-field study with Thiacloprid FS 400 treated maize seed, investigating potential effects to exposed honeybee colonies in Northern Germany
Report No.:	S09-02422
Document No.:	M-385049-01-1
Guidelines:	**OEPP/EPPO Guideline No. 170 (3) (2001), with adaptations; none**
GLP/GEP:	**yes**

Objective:

The purpose of the study was to determine potential effects of maize, seed-treated with Thiacloprid FS 400 on the honeybee, *Apis mellifera*, under semi-field conditions. The evaluation of the treatment effects focused on mortality, foraging activity of the bees, as well as condition of the colonies and the development of the bee brood within a period of 38 and 36 days after the beginning of exposure for the colonies of the first and second drilled plots, respectively.

Material and methods:

Test item: Thiacloprid FS 400 G; Batch ID: 2009-000903; Master recipe ID: 0099769-001; Material no.: 79722931; Specification no.: 102000021813; Content(s) of a.s. nominal: 1.00 mg a.s./kernel; Content(s) of a.s. analysed: 1.09 mg a.s./kernel. The maize seed-dressing was applied nominally at 50 g a.s./Unit (50000 seeds) with a drilling rate of 1.8 Units (90000 seeds/ha).

The study was carried out at Celle, Northern Germany. It was conducted on one field with maize grown from untreated seeds (control field) and on one other field with maize grown from seeds treated with Thiacloprid FS 400 (test item field; nominal seed-dressing rate: 1.0 mg thiacloprid/seed).

Maize seeds, dressed with the seed treatment Thiacloprid FS 400, were drilled in the spring 2009. The drillings were done under GLP with 1.8 units (90.000 seeds/ha). The treated field plot was matched with a control field plot drilled one day earlier with untreated maize seeds. The distance between the plots was approximately 12 km. For the drilling both field plots (treatment and control) were divided into two approximately equally-sized sub-plots which were drilled at two subsequent dates. Drillings took place on 29 April and 12 May 2009 (control) and on 30 April and 14 May 2009 (treatment).

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Each field was divided into two plots on which the maize had been drilled in an interval of approximately two weeks. Two tunnels were setup on each of the first drilled plots and one tunnel on each of the second drilled plots, respectively. Bee colonies were set up in the tunnels at the beginning of flowering and removed to a monitoring side at the end of flowering period. Consequently two tunnels per treatment were placed on the earlier drilled field and a third tunnel on those drilled two weeks later.

The evaluation of potential treatment-related effects focused on mortality, foraging activity of the bees as well as condition of the colonies and the development of the bee brood within a period of 38 and 36 days after the beginning of exposure for the colonies of the first and second drilled plots, respectively. The influence of the test item was evaluated by comparing the results in the tunnels of the test item treatments to those of the control. The following points were assessed:

- Number of dead bees before exposure at a monitoring site (dead bee traps) as well as during exposure in the tunnel tents (linen sheets and dead bee traps)
- Flight intensity (mean number of bees/30 plants/min)
- Behaviour of the bees in the crop and around the hive
- Condition of the colonies and development of the bee brood (number of bees (strength), mean abundances of the different brood stages per colony and assessment date).

Findings:

Honey bee mortality
The mean daily mortality (assessed with dead bee traps) of the control colonies before exposure (DAS-6 to -1) was 1.1 dead bees/day and 0.9 dead bees/day for the treatment group (T). During the confined exposure period the mean mortality values (mean sum of dead bees on linen sheets and dead bee traps) of the control colonies (C) was 59.4 dead bees/day and 79.4 dead bees/day for the test item colonies. The mean number of dead bees observed in the dead bee traps during exposure was 4.4 dead bees/day for the control group and 4.0 dead bees/day for the test item group. Most of the dead bees during the confined exposure period where found on the linen sheet on the opposite side of the hives (C: 55.0; T: 75.5). The increased mortality on the linen sheets may be caused by the extreme conditions especially in maize tunnels (lack of a nectar source, limited environment). The number of dead bees was higher (especially on the linen sheets) during the first three days after setup (DAA0 to 2) in both, treatment and control, which is due to the disturbance of the colonies caused by their relocation. Generally, the number of dead bees was significantly fluctuating in both, treatment and control, during the exposure period. Although overall mortality was slightly higher in the treatment than in the control group on most assessment days (which could be explained by the slightly higher number of bees and brood cells in the test item colonies at the beginning of the study, which entails a higher turnover of the colonies in terms of mortality rates as well as by the generally higher flight activities in the treatment tunnels), mortality in both, treatment and control was within the same range. As such, it can be concluded that the exposure of honey bees to flowering maize-plants, seed-treated with thiacloprid at a rate of nominally 1.0 mg a.s./seed did not have an adverse effect on mortality. See following figures for the first and second drilled plots respectively.

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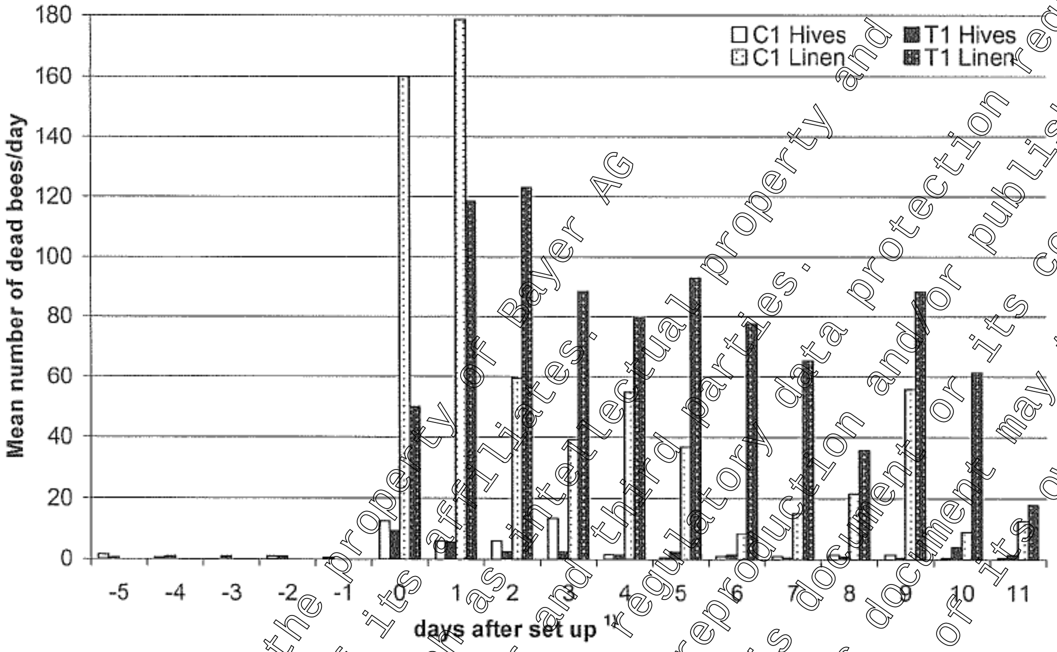
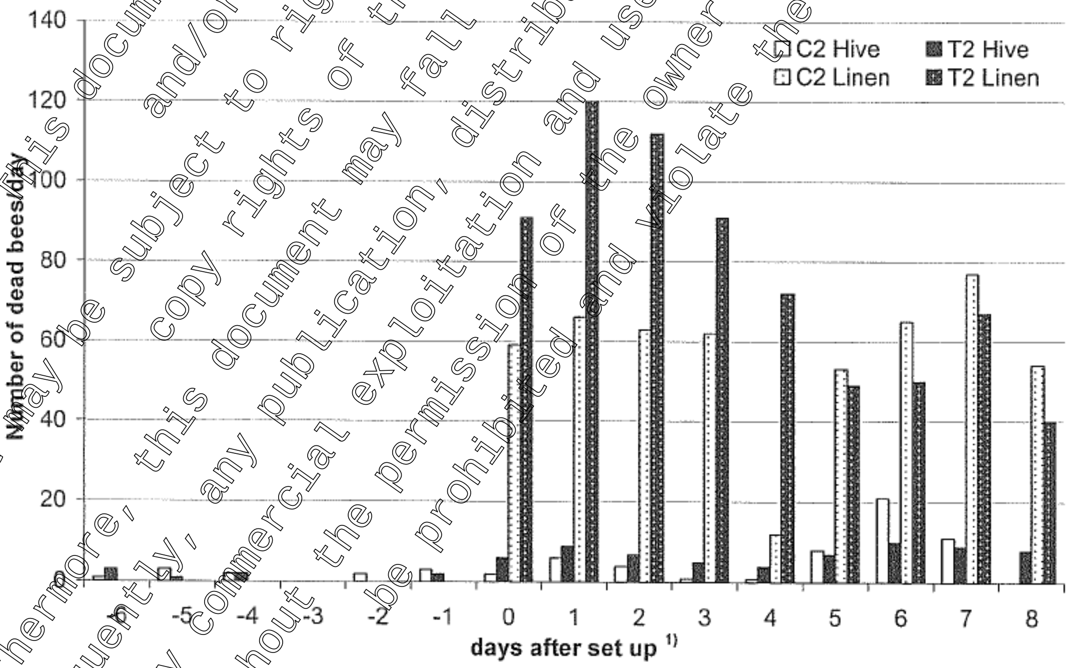


1) = no assessments on linen sheets on DAS -5 to -1

Figure CP 10.3.1.5.- 1: Mean mortality: Tunnels located on 1st drilled plots.



1) = no assessments on linen sheets on DAS -6 to -1

Figure CP 10.3.1.5.- 2: Mean mortality: Tunnels located on 2nd drilled plots.

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Honey bee flight intensity

On almost all assessment days, the mean daily flight intensity in the test item tunnels was higher than that recorded in the control tunnels. The mean daily flight activity (foraging bees and bees flying over the crop) during exposure was found to be 2.2 bees/30 plants/min in the control tunnels and 3.9 bees/30 plants/min in the test item tunnels. The daily mean flight activity in the control tunnels was fluctuating between 0.3 and 3.6 bees/30 plants/min, in the test item tunnels it was fluctuating between 0.4 and 7.0 bees/30 plants/min. No test-item related adverse effects on honey bee flight intensity were observed.

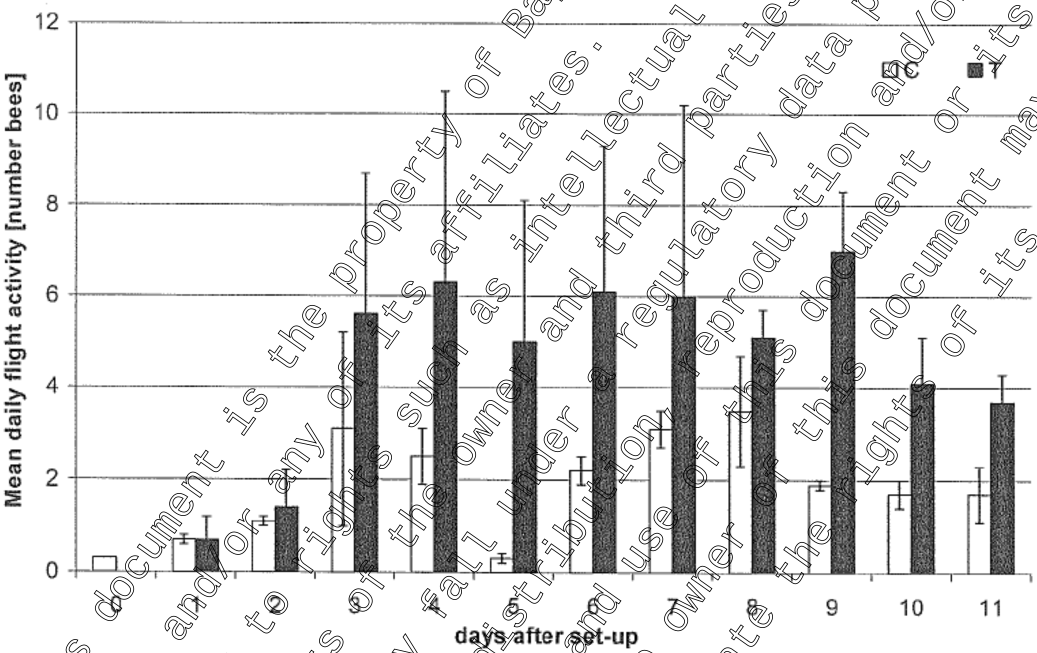

Figure CP 10.3.1.5.- 3: Foraging activity: Tunnels located on 1st drilled plots

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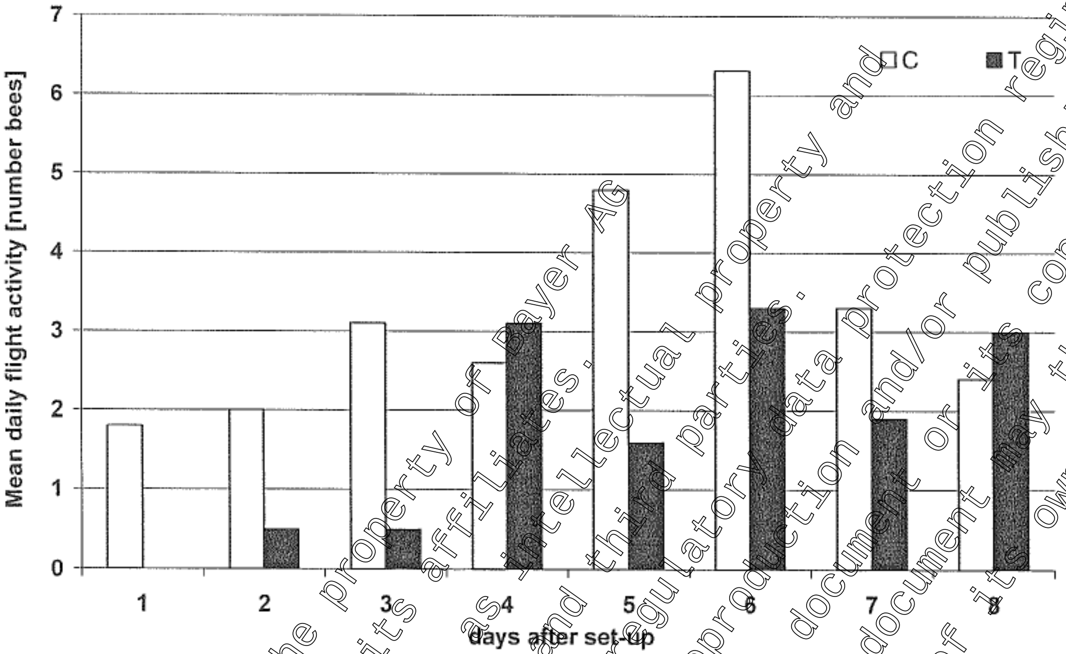

Figure CP 10.3.1.5.- 4: Foraging activity: Tunnels located on 2nd drilled plots

Strength of the colonies

The mean number of bees per hive, assessed before setup of the hives was slightly lower in the control (6246 bees/hive) than in the test item group hives (7033 bees/hive). At the second assessment (during exposure), the mean number of bees was slightly decreased in both C (5927 bees) and T (6527 bees). On the third assessment (after the end of confined exposure) the mean number of bees increased to its highest values during the study period in both, treatment and control (C: 7933 bees, T: 7070 bees). On the following two assessments the mean number of bees decreased to its lowest values at the 5th brood assessment (4th assessment: C: 6621 / T: 5608; 5th assessment: C: 5683, T: 4933). At the last brood assessment the mean number of bees was 7051 and 6171 bees for the control and test item group, respectively. The curve of development was comparable between C and T throughout the study period and showed the fluctuations which are typical of this endpoint. As such, no test-item related adverse effects on colony strength were observed.

Development of brood

The mean abundance of brood (sum of cells containing eggs, larvae, and pupae) of the colonies showed its highest value at the brood assessment before setup of the colonies in the tunnels (C: 16380 cells, T: 16260 cells). The number of brood cells decreased from the second assessment (C: 9300 cells, T: 7200 cells) towards the third assessment with the lowest values assessed during the study period (C: 6240 cells, T1: 4620 cells). The total amount of brood increased at the fourth brood assessment (C: 12300 cells, T: 8800) and reached its highest post-exposure values at the fifth brood assessment (C: 13680 cells, T: 13440 cells). At the last brood assessment the number of cells with brood was slightly decreased compared to the fifth assessment (C: 11280 cells, T: 11400 cells).
The curve of the brood development was comparable between the control and the test item colonies, differences were within the range of natural variation. No test-item related adverse effects on brood development were observed.

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Development of the food storage area

The extent of food stores in the colonies (both control and treatment) decreased at the second brood assessment compared to the first assessment. After the relocation of the colonies to the monitoring site a continuously increase of food stores took place with a maximum food storage at the last assessment. The observed decrease in food stores in both, treatment and control, during confinement as well as the subsequent increase can be considered as typical for this type of study. No test-item related adverse effects on the development of the food storage area were observed.

Honey bee behaviour

No abnormal behaviour was recorded in the control and the test item tunnels, respectively.

Table CP 10.3.1.5- 1: Toxicity to honey bees in a semi-field test with Thiacloprid FS 400

Test item	**Thiacloprid FS 400**	
Test object	***Apis mellifera***	
Exposure	T1: Thiacloprid FS 400 treated maize seeds, 1st drilling, 12 days exposure, 2 tunnels	
	T2: Thiacloprid FS 400 treated maize seeds 2nd drilling, 9 days exposure, 1 tunnel	
	C1: untreated maize seeds, 1st drilling, 12 days exposure, 2 tunnels	
	C2: untreated maize seeds, 2nd drilling, 9 days exposure, 1 tunnel	
	Control	**Treatment**
Application rate (seed-treatment)	-	1.00 mg a.s./kernel*
Mean mortality 1) (bee trap, pre-exposure) [dead bees/day]	1.1	0.9
Mean mortality 2) (linen / bee trap, during exposure) [dead bees/day]	55.0 / 4.4	75.5 / 4.0
Daily mean flight intensity during exposure 3) [bees/30 plants/min]	2.2	3.9

* nominal
1) = pre-exposure mortality was assessed only with dead bee traps
2) = post-exposure mortality was assessed on linen sheets with dead bee traps
3) = flight intensity was assessed on 30 plants within 1 minute

Conclusion:

Overall, it can be concluded that maize grown from seeds, seed-treated with Thiacloprid FS 400 at a nominal rate of 1.0 mg a.s./seed, has no adverse effects on mortality, flight intensity, brood and food development and behaviour of bees under forced exposure conditions

CP 10.3.1.6 Field tests with honeybees

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Report:	[redacted]y; [redacted]; 2010; M-373436-01-1
Title:	Assessment of side effects of maize grown from seeds treated with thiacloprid FS 400 on the honeybee (Apis mellifera L.) in a long-term field study in Northern Germany
Report No.:	S09-01654
Document No.:	M-373436-01-1
Guidelines:	**OEPP/EPPO Guideline No. 170 (3) (2001)** **EU 91/414/EEC (1997)** **IVA (1992), EU (1997); not specified**
GLP/GEP:	**yes**

Objective:

The long-term effects of exposure of honeybees (*Apis mellifera* L.) to maize, grown from seeds treated with Thiacloprid FS 400 were tested under field conditions.

Material and methods:

Test item: Thiacloprid FS 400 treated maize seeds; active ingredient in formulation: thiacloprid (400 g a.s./L, nominal); batch of formulation: 2009-000903.

Maize seeds, treated with the seed treatment product Thiacloprid FS 400 at a nominal rate of 1.00 mg a.s./kernel, were drilled on a field plot near Celle, in the region Lower Saxony, Germany, in spring 2009. This treated field plot was matched with a similar-sized control field plot drilled at the same time with untreated maize seeds. The size of the control field plot and of the Thiacloprid FS 400 treatment field plot was 5.5 ha. For drilling, both field plots (treatment and control) were divided into two approximately equal sized sub-plots. Drilling took place at two different drilling dates at the two sub-plots of each field. The first drilling was 14 days (treatment group) and 13 days (control group), respectively, before the second. The field plots were separated by approximately 11 km in order to exclude that bees from one treatment group visit the field of the control group and vice versa. The field plots have not been treated with neonicotinoid insecticides in the last two previous cropping seasons before use. Only one exception was documented in June 2008 on the test item plot where Biscaya (a.s.: thiacloprid) was used once.

The effects of honeybee exposure to flowering maize plants, seed-treated with the test item was examined on commercial bee colonies. Honeybees were maintained at the maize field plots during flowering of the crop (exposure phase) and thereafter at a monitoring site, without extensive agricultural crops attractive to bees (monitoring phase).

The experimental phase started with the first drilling of the Thiacloprid FS 400 treated and untreated maize seeds in spring 2009 and ended in spring 2010 after monitoring overwintering survival, colony strength and colony development.

In order to determine the pre-exposure level of mortality the number of dead bees in the dead bee traps were counted over a period of 5 days within the week before start of exposure. Shortly before the exposure period at the fields started an assessment of brood development was performed.

At the start of flowering of the maize plants at the 1st-drilled sub-plots (treatment and control) at BBCH 59–61, six bee colonies were placed at these 1st-drilled sub-plots (treatment and control); this location was in-between the 1st- and the 2nd- drilled sub-plots, allowing for foraging of the bees also to the 2nd- drilled sub-plot (treatment and control), which started flowering a couple of days later than the corresponding 1st-drilled sub-plots. Mortality, foraging activity and behaviour of the bees were assessed during the flowering periods on both sub-plots of the fields (treatment and control). Once

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during each period of flowering of both sub-plots of the fields maize pollen samples were taken directly from the plants.

Pollen from pollen traps was collected twice on each sub-plot of the field.

At the end of flowering (BBCH 67-69) on both sub-plots, i.e. after 15 days of continuous exposure to flowering maize (treatment and control), the bee colonies were relocated to a monitoring site without extensive agricultural crops attractive to bees (monitoring location) where colony health, colony strength as well as the brood development was assessed one day after set up of the colonies. Thereafter, and for the whole duration of the study, a time interval of 3 weeks was followed for further assessments. No assessments were carried out while colonies were overwintering (between 23 September 2009 and 14 April 2010) as well as during the exposure phase of the study.

The influence of the test item treatment was evaluated by comparing the data from the control field plot (i.e. maize grown from untreated seeds) with the data of the test item field plot (i.e. maize from seeds, treated with Thiacloprid FS 400 at a rate of nominally 1.00 mg a.s./kernel).

Findings:

Table CP 10.3.1.6- 1: Effects on honey bees during the exposure phase of the study

Test item (maize seed-treatment product)		**Thiacloprid FS 400**	
Study type		**Long-term field study in maize**	
Test object		***Apis mellifera* L.**	
Location		**Lower Saxony, near Celle, Germany**	
Treatment group		**Control (C)**	**Test item (T)**
Application rate (seed-treatment)		-	**1.00 mg a.s./kernel***
Mean mortality [dead bees/colony/day]	Pre-exposure [DAS-6 to -2]:	2.9	2.6
	Exposure period [DAS0 to 14]:	14.0	9.0
Daily mean flight intensity, sub-plot 1	Exposure period [DAS0 to 11]:	0.1	0.2
Daily mean flight intensity, sub-plot 2	Exposure period [DAS7 to 14]:	0.1	0.1

* based on the nominal content of a.s.
DAS = days after set-up
DAS0 = first day the bees are exposed to the crop

Adult Bee Mortality:
The mean mortality (dead pupae and adult worker bees) from DAS-6 to DAS-2 at the monitoring site, and from DAS0 to DAS5, DAS7 and DAS10 at the exposure site showed no effect of the test item treatment group. On these test days, except on DAS6, the mortality in the control group was slightly higher or on the same level compared to the test item treatment group. The daily mean number of dead pupae and adult worker bees in front of the hives (dead bee traps and linen sheet in front of the hives) during the time of exposure was 9.0 dead bees/hive in the test item treatment group and 14.0 dead bees/hive in the control group.

On the linen sheets spread out in the test fields (mortality within the crop area) no dead bees were found in the test item treatment and a mean of 0.1 bees/day was found in the control group during exposure.

Overall, the recorded mortality was on a low level for both, treatment and control and showed typical natural fluctuations. No test item-related increase of mortality compared to the control was observed during the whole exposure period (see the following figure for details).

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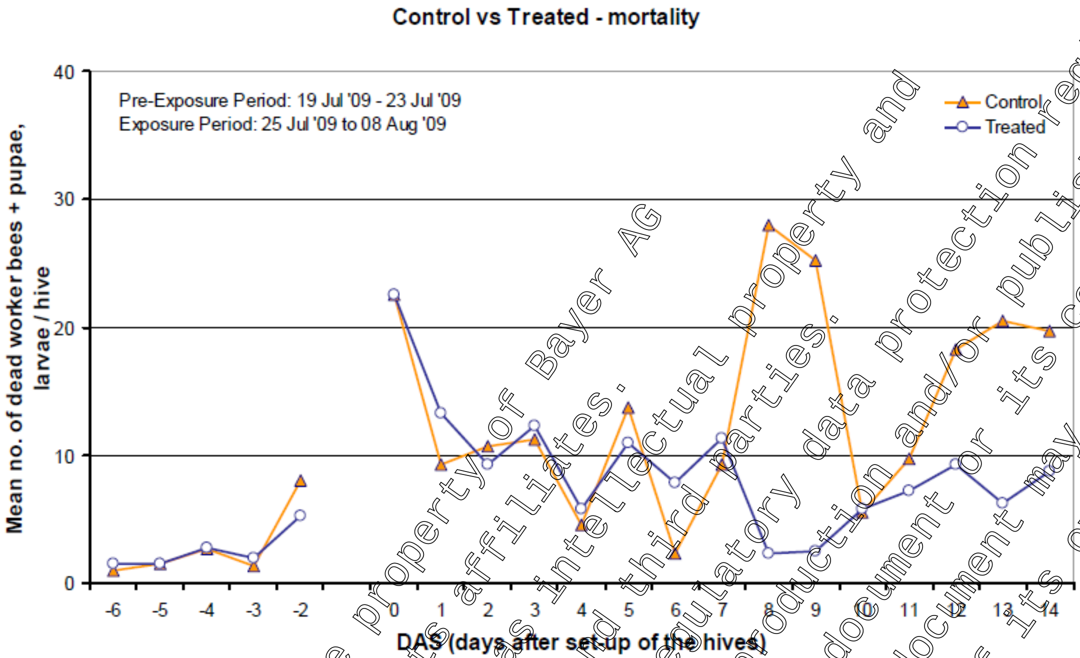

Figure CP 10.3.1.6- 1: Mortality: Mean number of dead worker bees and pupae, larvae/hive/day collected in the dead bee traps and on the linen sheet in front of the hives in the test item treatment and the control group before and during time of exposure.

Flight Intensity of the Bees:

1st drilled sub-plots, from DAS0 to DAS11:

The daily mean flight and foraging activity in the test item treatment group was throughout the entire observation period (DAS0 to DAS11), except for one day, on a slightly higher or at least on the same level compared to the one of the control group. The mean flight and foraging activity (expressed as mean of forager bees observed per 30 plant assessment area per one-minute assessment interval) in the 1st drilled sub-plots from DAS0 to DAS11 was 0.2 in the test item treatment group and 0.1 in the control group (see following figure for details).

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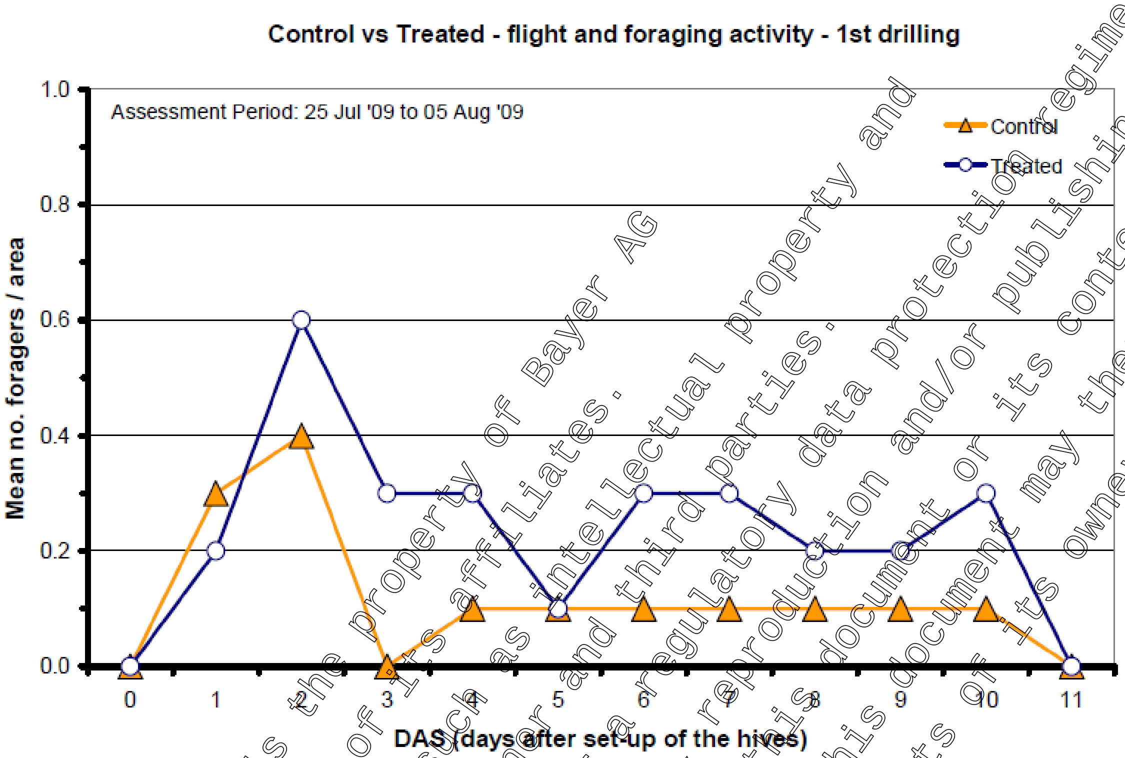

Figure CP 10.3.1.6- 2: Flight intensity (1st drilled sub-plot).

2nd drilled sub-plots, from DAS7 to DAS14:

On all but one test day during the exposure period the daily mean number of flight and foraging activity of the control group was slightly above or at least on the same level as the one of the test item treatment group, without much difference between treatment and control, as the mean flight and foraging activity (expressed as mean of forager bees observed per 30 plant assessment area per one-minute assessment interval) in the second drilled sub-plots from DAS7 to DAS14 was 0.1 in both test groups (test item treatment and control group). See following figure for details.

Overall, no test-item related adverse effects on flight intensity were observed.

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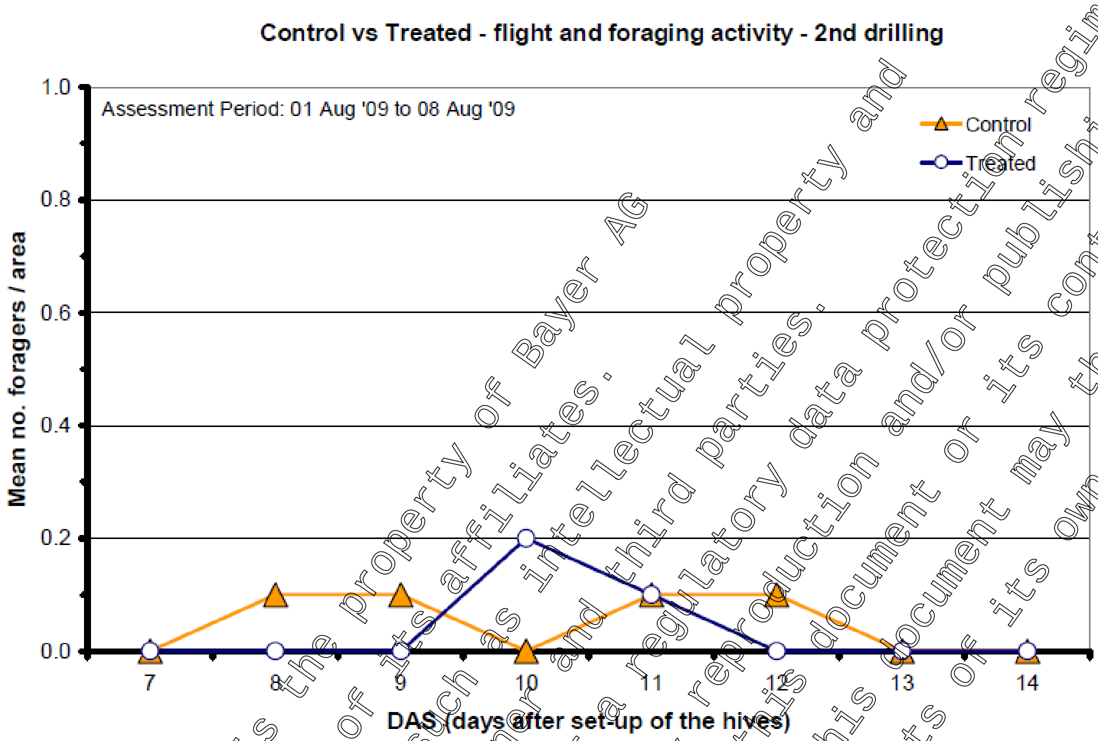

Figure CP 10.3.1.6- 3: Flight intensity (2nd drilled sub-plot).

Observation at the Entrance of the Hives:

At the entrances of the test item group hives on DAS1 one single bee with intensive cleaning behaviour was observed. On all other test days during the entire exposure period no behavioural anomalies of the bees were observed in the test item group compared to the bees in the control group. No test-item related adverse effects were observed.

Behaviour of the Bees in the Field:

In the marked assessment areas no behavioural differences of the bees in the test item treatment group compared to the bees in the control group were observed during the entire exposure period to the crop. No test-item related adverse effects on honeybee behaviour were observed.

Survey of Flowering Crops:

No flowering crops were present in the surrounding area of the test item field during exposure of the bees but some single flowering plants on adjacent meadows. No flowering crops were present in the surrounding area of the control field during exposure of the bees but some single flowering plants on an adjacent meadow.

Residue Analysis:

Residues of thiacloprid and its metabolite YRC 2894-amide in/on the maize pollen sampled from plants and from forager bees from the test item treatment group as well as from the control were always below the LOQ of 0.001 mg/kg (Table CP 10.3.1.6-2)

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Table CP 10.3.1.6- 2: Residue data of thiacloprid and thiacloprid-amide in maize pollen, either directly collected from flowering maize plants or from forager-bees

Sample ID	Origin of sample	Treatment	Date of sampling	Residue Thiacloprid [mg/kg]	Residue YRC 2894-amide* [mg/kg]
Maize variety "Dirigent", five maize pollen samples were collected from flowering maize plants on two study plots located around Celle in Lower Saxony (Germany), respectively, as well as from forager bees, which actively foraged in fields with the maize variety "Dirigent", seed-treated with Thiacloprid FS 400					
1-001	Pollen from plant	Treated T	2009-07-28	<LOQ	<LOD
1-002	Pollen from plant	Treated T	2009-07-28	<LOQ	<LOQ
1-003	Pollen from plant	Treated T	2009-07-28	<LOQ	<LOD
1-004	Pollen from plant	Treated T	2009-07-28	<LOQ	<LOD
1-005	Pollen from plant	Treated T	2009-07-28	<LOQ	<LOQ
2-001	Pollen from plant	Treated T	2009-08-02	<LOQ	<LOD
2-002	Pollen from plant	Treated T	2009-08-02	<LOQ	<LOD
2-003	Pollen from plant	Treated T	2009-08-02	<LOQ	<LOQ
2-004	Pollen from plant	Treated T	2009-08-02	<LOQ	<LOQ
2-005	Pollen from plant	Treated T	2009-08-02	<LOQ	<LOD
Sample A+B	Pollen from bees	Treated T	2009-08-02	<LOQ	<LOD
Sample A	Pollen from bees	Treated T	2009-07-28	<LOQ	<LOD
Sample B	Pollen from bees	Treated T	2009-07-28	<LOQ	<LOQ

* = Thiacloprid-amide = KKO 2254; LOQ = 0.001 mg/kg, LOD = 0.0001 mg/kg

<u>Pollen Source Identification:</u>

Pollen for pollen source identification was collected twice during exposure on each subplot using pollen traps. Samples were taken from each bee hive.

In subplot 1 of the treatment group, the percentage of maize pollen collected per hive was 2-13% on DAS2 and 5-10% on DAS4. In subplot 1 of the control, the percentage of maize pollen collected per hive was < 1-5% on DAS2 and 2-7% on DAS4.

In subplot 2 of the treatment group, the percentage of maize pollen collected per hive was 1-3% on DAS10 and < 1% on DAS12. In subplot 2 of the control, the percentage of maize pollen collected per hive was up to < 1-1% on DAS10 and < 1% on DAS12.

<u>Colony Health and Colony Strength:</u>

Number of bees per colony (colony strength):

The colony strength of all monitored bee colonies showed the same seasonal tendency in decrease from July 2009 to September 2009 and remained on approximately the same level from the beginning until the end of overwintering in April 2010. The mean estimated number of bees of test item treatment group was during the entire test period above the one of the control group. Over the entire observation period from July 2009 to April 2010, no test item-related differences in colony strength were noticed.

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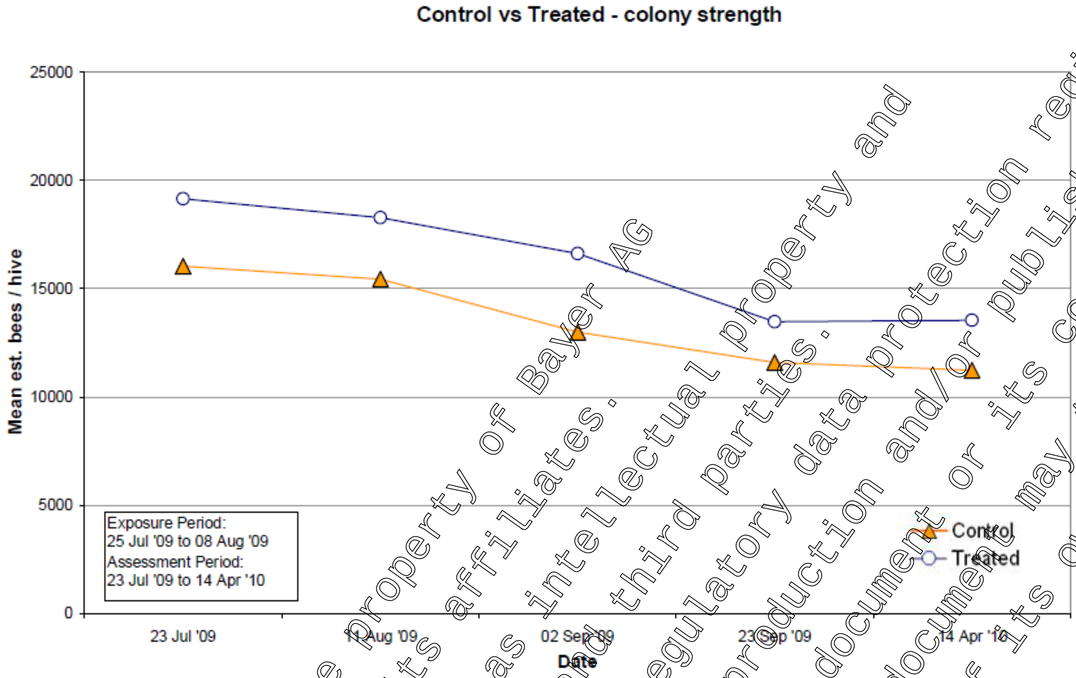

Figure CP 10.3.1.6- 4: Colony strength: Mean number of honey bees per hive.

Brood assessment:
The mean% comb coverage in the colonies showed the same development, i.e. the same increase and decrease of brood cells (eggs, larvae and pupae) and food stores (nectar and pollen), in the control and the test item treatment group in 2009 and 2010. No test-item related adverse effects on brood development were observed (see figures).

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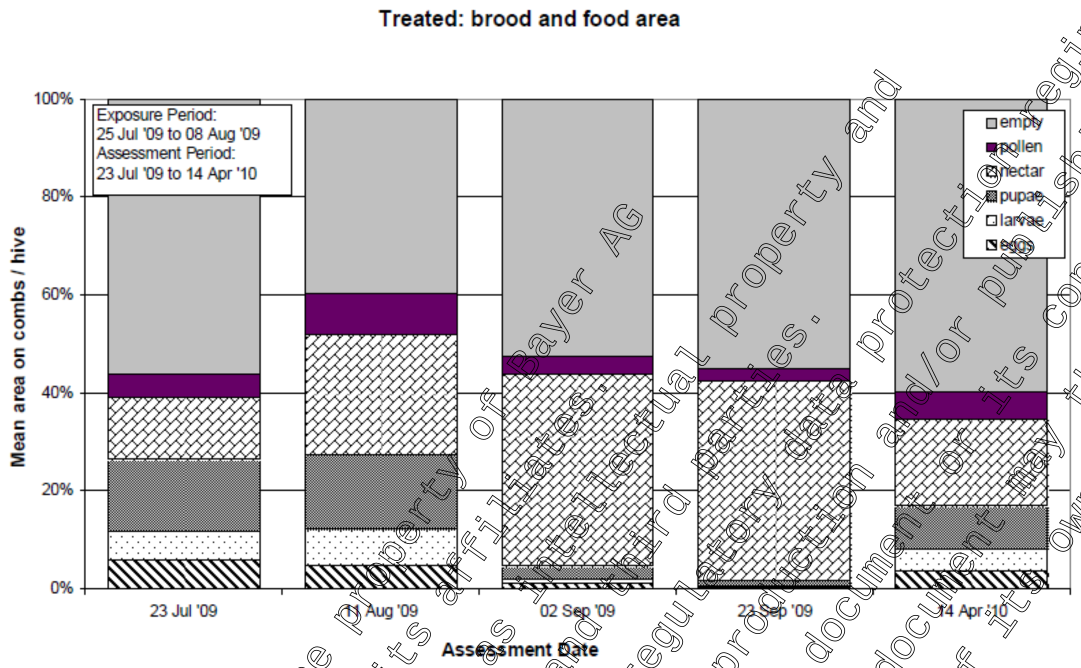

Figure CP 10.3.1.6- 5: Brood strength and food stores: Mean combs area per hive (%) occupied with brood cells (eggs, larvae and pupae) and with food stores (nectar and pollen).

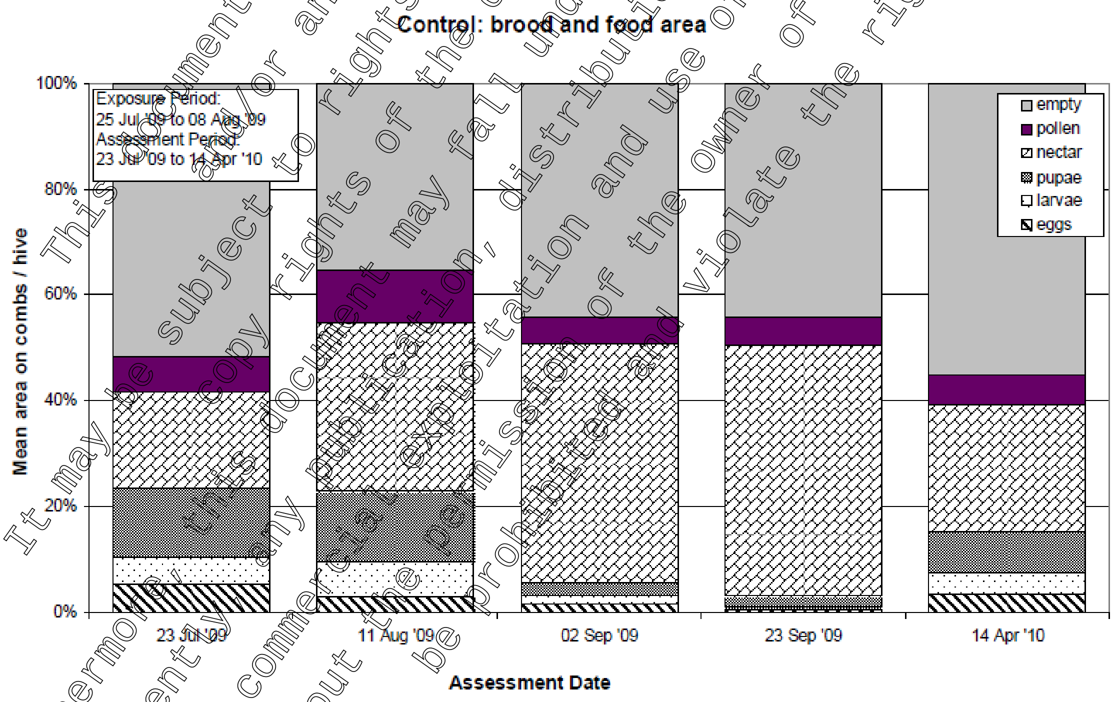

Figure CP 10.3.1.6- 6: Brood strength and food stores: Mean combs area per hive (%) occupied with brood cells (eggs, larvae and pupae) and with food stores (nectar and pollen).

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Colony health:
-Bee disease

The objective of the bee disease analysis phase was to determine the presence of different pathogens (*Nosema* sp., *Malphigamoeba mellificae*, *Varroa destructor*, *Paenibacillus larvae*) in bee samples taken at different time points during the observation period.

2009: No *Nosema* sp. spores were found in most of the bee samples taken from the control and from the test item treatment colonies before exposure, after exposure and before over-wintering (C1, C4, C5, C6, T1, T3, T4, and T6). Exceptions were one subsample of colony C2, one subsample of colony C3 and one subsample of colony T2 taken before exposure, each of them was infected with a low level of *Nosema* sp. spores. A medium infection level was found in two subsamples of colony T5 taken before and after exposure. In the subsamples of colony T5 taken before over-wintering, no *Nosema* sp. spores were found.

The results of the tests for *Malpighamoeba mellificae* were all negative.

No *Varroa* mites were found in 4 samples taken before exposure (C2, T1, T2 and T6) and in 1 sample taken after exposure (C5) and in 2 samples taken before over-wintering (C2 and T6). The Varroa infestation levels of the other samples ranged from 0.4% to 3.8% before exposure, from 0.8% to 7.1% after exposure and from 0.6% to 17.6% before over-wintering.

No spores of *Paenibacillus larvae* were found in any of the samples taken in 2009.

2010: After over-wintering *Nosema* sp. spores were only found in one subsample of colony T6 (low infection level).

The results of the tests for *Malpighamoeba mellificae* were all negative.

After over-wintering no Varroa mites were found in the bee samples of colonies C1, C2, C5, C6, T1 and T6. In the bee samples of colonies C4, T2, T3, T4 and T5 an infestation level from 0.4% to 1.7% was found.

No spores of *Paenibacillus larvae* were found in any of the samples taken in 2010.

-Viruses

The objective of the bee virus analysis was to determine the presence of different viruses (deformed wing virus, sac brood virus, acute bee paralysis virus, chronic bee paralysis virus) in bee samples taken at different time points during the observation period.

Acute bee paralysis virus and chronic bee paralysis virus were not detected in any of the samples. Sac brood virus was detected in sample C3 of the control group at the start of the exposure phase. Deformed wing virus was detected in sample C6 of the control group at the start of the exposure phase, and in two samples of the control group (C3, C6) at the start of overwintering.

Overall, the results of the disease and virus analysis revealed that the test item treated colonies were as healthy as the control colonies and as such, no test-item related adverse effects on colony health were observed.

<u>Overwintering assessment of the colonies:</u>

Overwintering survival was assessed during the brood assessment after overwintering in April 2010. In the test item treatment group, all colonies were alive after the overwintering period. In the control group, all except one colony (C3) were alive after overwintering. As such, no test-item related adverse effects on the overwintering performance of the exposed colonies were observed.

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Colony weight development

The weight development of the colonies with its increases and decreases, measured from July to September 2009 was very similar between the test item treatment and the control group. No test-item related adverse effects on colony weight development were observed (see figure).

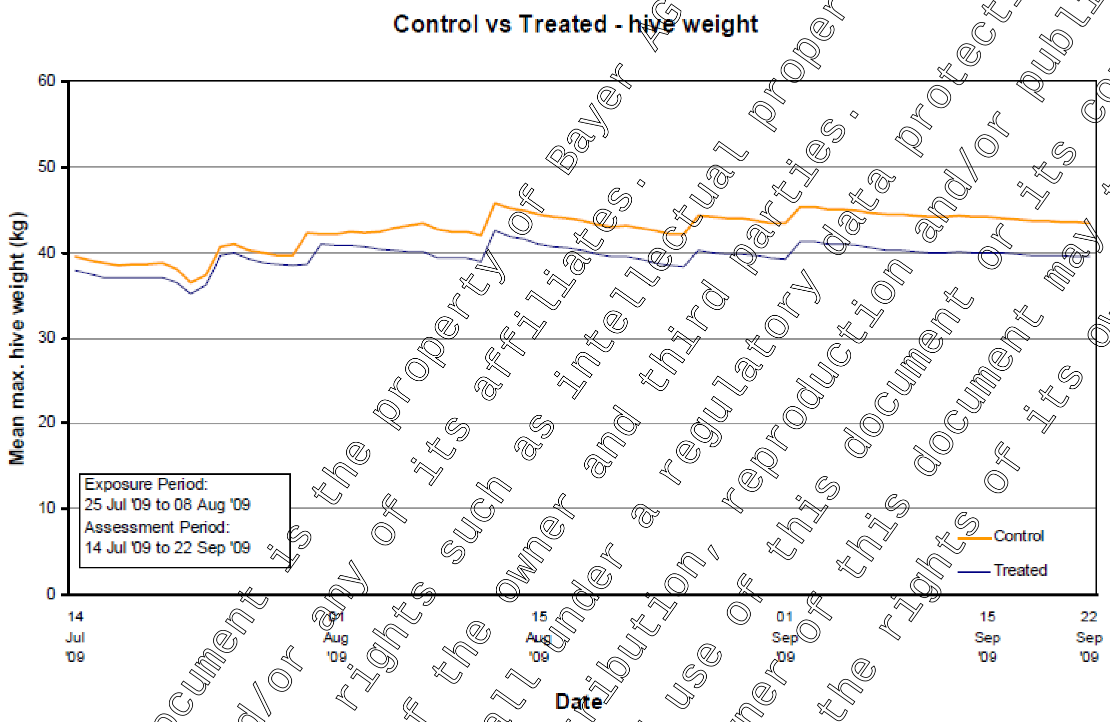

Figure CP 10.3.1.6- 7: Colony weight: Mean hive weight (kg).

Conclusions:

After exposure of honeybees (*Apis mellifera* L.) to flowering maize, grown from seeds, treated with Thiacloprid FS 400 at a nominal seed dressing rate of 1.00 mg a.s./kernel, no adverse effects on honeybee health and colony development (e.g. strength, health, brood and food development) during the exposure period and during the entire period until the end of over-wintering in spring 2010 could be observed. Furthermore, no test item-related difference between the test item treatment and the control group in mortality, flight and foraging intensity in the test fields and behaviour of the bees during exposure to the maize fields was observed.

Also overwintering success, colony health and colony strength of the treatment group colonies was not adversely affected by the exposure to Thiacloprid FS 400 seed-treated maize. The loss of the control colony C3 during overwintering can probably be explained by the presence of deformed wing virus and a relatively high *Varroa destructor* infestation level of 17.6% at the start of overwintering.

Overall, it can be concluded that exposure of honeybee colonies to flowering maize, grown from seeds, seed-treated with thiacloprid at a rate of 1.00 mg a.s./kernel, does neither cause acute, short-term nor long-term effects in exposed colonies, including colony health, colony vitality and overwintering performance.

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Report:	[redacted]*; [redacted]; 2012; M-404875-02-1
Title:	Non-target ground deposition of dust resulting from sowing pesticide treated seeds - evaluation and analysis of current experimental datasets to establish dust deposition tables
Report No.:	M-404875-02-1
Document No.:	M-404875-02-1
Guidelines:	**Special designed study protocol; none**
GLP/GEP:	**no**

Objective:

During the sowing of pesticide dressed seeds, mechanical abrasion of the dressed seeds occurs in sowing machines and abraded dust particles, containing amounts of active ingredients, are partially emitted into the environment, which might lead to aerial transport, dispersion, and deposition of active substances in adjacent off-crop areas. Depending on the extent of emission, weather conditions and the individual toxicity of the pesticide, effects on non-target species cannot be excluded.
The quality of seed coating and the sowing technique were identified as key factors affecting the amount of dust emitted into the environment during the sowing process.
The basis for the evaluation were experimental data from field studies carried out in the years 2005, 2006, 2008, and 2009 in Germany, Italy and France. The results of these studies were provided in 26 reports containing the results of in total 169 experiments. The studies were carried out on behalf of the Julius Kühn Institute (JKI), Bayer Crop Science (BCS), Syngenta Agro (SYN), Industrieverband Agrar e.V. (IVA) and the BASF SE.

Material and methods:

The same methodology as for the 90th percentile spray drift deposition values was used to determine the respective dust drift deposition. The results of the experiments and the corresponding experimental boundary conditions were consolidated and standardized in order to establish a comprehensive dataset with amounts of dust drift ground deposition (in % of applied active substance to the target area) as function of the downwind distance from the treated area. On the basis of the comprehensive dataset a statistical evaluation was carried out in order to provide crop specific (maize, oilseed rape, cereals and sugar beet) ground dust drift deposition tables. If sufficient data concerning sowing technique and seed treatment quality were available, attempts were made to establish individual dust drift tables for sowing technique and coating quality of the seeds.
The empirically derived dust deposition tables (on the basis of the 90th Percentile for each downwind distance) can be used to estimate ground deposition onto non-target areas after sowing pesticide containing coated seeds.

Findings/Conclusions:

Maize:
Under consideration of the proposed Heubach threshold value of < 0.75 g / 100,000 seeds and assuming that only dust drift reduced pneumatic sowing machines with deflection technique are used the following dust drift deposition tables for maize sowing was calculated (90th Percentile% of applied).

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Crop: **Maize**	Downwind distance from the seeded area [m]						
Sowing technique	1	3	5	10	20	30	50
Pneumatic deflected 90th Percentile% of applied	**0.125**	**0.112**	**0.093**	**0.094**	**0.054**	**0.026**	**0.018**
Number of Petri dishes	220	200	230	80	50	50	50
Number of experiments	20	20	21	8	5	5	5

Report: [redacted]*; [redacted]; [redacted]; 2010; M-362242-01-1
Title: Comparison of measurement methods to assess off-crop drift deposition patterns of seed treatment particles abraded from dressed maize seeds, emitted during sowing with a deflector modified pneumatic machine
Report No.: IVADUST1
Document No.: M-362242-01-1
Guidelines: **Special designed study protocol, considering recommendations of the BBA Drift Guideline Part VII, 2-1.1, 1992; none**
GLP/GEP: **no**

Objective

The aim of the study was to compare different methods to assess the off-crop drift deposition of seed treatment particles.

Material and methods:

Test item: maize seeds treated with a seed treatment formulation provided by BASF SE. For confidentiality reasons, the name of the seed treatment product and the contained active ingredient were not disclosed to the CWFG (Sponsor) and the other involved industry companies. Within this study report the seed treatment product and its active ingredient will be referred to as of "PRODUCT" and "COMPOUND", respectively. Seeds were intentionally treated twice without the use of a sticker to increase the potential dust release during drilling. The Heubach value at the time of drilling was 1.23 g/100,000 seeds.
The aim of the study was to gain experience with technical options to quantify aerial dust drift and deposition from the sowing of treated seeds in future drift trials. Therefore, the capture efficiency of several types of artificial, vertically oriented sampling devices and a semi-natural hedge were compared for the assessment of aerial dust drift occurring during sowing of PRODUCT treated maize seeds with a JKI (Julius Kühn-Institut, Germany) approved modified pneumatic drilling machine. Samplers were located downwind from the drilled area at different heights above the ground. In order to distinguish between direct, secondary and long-term drift, different sampling times were considered in the test design.

Discussion and Conclusion:

Dust deposition decreases with increasing height of sampling, indicating that the relevant sampling zone is less than 2 m above ground. In comparison to the primary drift the secondary drift was at least an order of magnitude lower.

Based on the vertical projection area the BSNE samplers, the gauze netting, and the pipe cleaners collected more dust than the glycerol/water treated semi-natural proxy hedge. Dust measurements with these samplers give therefore a conservative estimate for a projection area related exposure estimation of natural vegetation. It was concluded that gauze netting provides the largest sampling area of all

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artificial samplers, supporting the generation of robust data in circumstances of low exposure. It may also show an aerodynamic behaviour which, amongst the tested samplers, is closest to a natural hedge.

Additionally by analysing these available comparative 2D- and 3D-data, it was found that on average 4.9 times (median: 5.8 times) more active substance deposited on the 3D dust samplers (gauze netting) as compared to the Petri-dishes.

Report:	[redacted]l; [redacted]; [redacted]; 2010; M-393034-01-1
Title:	Measurement of drift deposition of seed treatment particles in the off-crop abraded from Thiacloprid FS 400 treated maize seeds, emitted during sowing with a vacuum-pneumatic machine
Report No.:	NNP-DUST-04
Document No.:	M-393034-01-1
Guidelines:	**Special designed study protocol; considering recommendations of the BBA Drift Guideline Part VII, 2-1.1, 1992; none**
GLP/GEP:	**yes**

Objective:

The aim of the study was to quantify drift of seed treatment dust and its deposit in the off-crop area (g a.s./ha) using passive collectors downwind from the drilled area during and after sowing of Thiacloprid FS 400 treated maize seeds with a vacuum-pneumatic sowing machine.

Material and methods:

Test item: Commercial maize seeds (Variety Ronaldinio, purchased from KWS Mais GmbH, Grimsehlstr. 31, D-37574 Einbeck, Germany) were treated with the seed treatment formulation Thiacloprid FS 400 (TOX-No. TOX09093-00), nominally 50 g thiacloprid/Unit, together with Thiram (TMTD) SC 700 at a rate of 43 mL/Unit, the film-coating product Impranil DLN W 50 at 15 mL/Unit and Talcum Gloss powder at 30 g/Unit (1 Unit = 50,000 seeds). The seed treatment operation was performed in the commercial seed treatment plant of [redacted] GmbH (D-[redacted], Germany). A total of 12 Units were treated with a commercial Satec Twin 50 batch treater. The analysed content of thiacloprid on the treated seeds was 51.44 g a.s./Unit (TOX-No. TOX09167-00).

The sowing machine used was a vacuum-pneumatic Kverneland, Accord Optima HD. Working width of the machine was 4.5 m. The dressed maize seeds were stored in bags, each containing one single Unit (= 50,000 seeds). The Heubach dust abrasion test indicated under the standardised laboratory test conditions a dust abrasion value of 0.04 g dust/100,000 seeds eight days after seed treatment and 0.07 g dust/100,000 seeds on the day after drilling.
Before drilling, the hoppers of the sowing machine were filled on the yard in front of the machine-hall of Bayer CropScience's Application Technology Unit, [redacted], D-[redacted], approximately 2.5 km away from the trial site (access to the trial site was via paved roads and field paths). For the drift experiment, each hopper of the sowing machine was filled with one complete seed bag. Particular care was taken to transfer the entire content of each seed bag into the hopper, including any dust from transport-related seed treatment abrasion.
The size of the drilling plot was 1.08 ha (200 m x 54 m). The actual drilling rate was 102.44 g a.s. thiacloprid/ha.

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An average wind speed of 2.2 m/s and a mean deviation from the wind direction perpendicular to the edge of the sowing area of 2.6° were the conditions during sowing and the following waiting period of 30 minutes.
The sampling systems were installed prior to the drilling procedure at distinct locations along the downwind long edge of the drilling area (base line). The distance to the first row of maize seeds (zero-line) was 3 m. Petri dishes of two different sampling types were placed in metal placeholders on the soil surface and filled with either a glycerol/water mixture (1/1, v/v) or quartz sand moistened with glycerol/water mixture (1/1, v/v). Gauze netting was installed to a construction fence (2 m high and 5 m wide) and wetted with a glycerol/water mixture (1/1, v/v) to enhance dust adhesion.
Sowing started at the zero-line. After drilling of 12 rows in alternating directions, there was a subsequent waiting period of 30 minutes to allow the settlement of all dust particles which had been dispersed during drilling. The uniquely labelled Petri dishes that contained the quartz sand were closed with their lids directly after the waiting period and were transported to the laboratory. There, the content was transferred into uniquely labelled polyethylene container. All other passive collectors were transferred in uniquely labelled polyethylene container on the field starting after expiration of the waiting period of 30 minutes.

From all collected dust samples thiacloprid was extracted and analysed. Further details concerning the analysis are documented in the GLP study report. All the samples (exception soil) were extracted in the original containers. Procedural fortification at adequate levels was processed concurrently with sample analysis for recoveries.

Findings:
The residue findings in the Petri dishes pre-filled with glycerol/water were between <LOD (< 0.0014 g a.s./ha) and 0.052 g a.s./ha. The mean value was below the LOQ (< 0.014 g a.s./ha) and the 90th-percentile value was 0.022 g a.s./ha.
The thiacloprid residues in the Petri dishes prepared with moistened quartz sand were between <LOQ (< 0.014 g a.s./ha) and 0.110 g a.s./ha. The mean values of this samples was 0.019 g a.s./ha and the 90th-%tile was 0.034 g a.s./ha. Relating the 90th-percentile of the ground deposition to the application rate in the field results in a drift rate of 0.033%.
The residue findings in the gauze netting ranged from 0.082 g a.s./ha to 0.162 g a.s./ha, with a mean value of 0.121 g a.s./ha and a 90th-percentile value of 0.155 g a.s./ha. Relating the 90th-percentile value to the actual application rate results in an aerial drift rate of 0.151%.

Conclusion:
The results indicate that dust drift (ground deposition and aerial drift) from maize seeds treated according to the above stated procedure was low. The maximum value of the 90th-percentile for ground deposition was 0.033% and the 90th-percentile for aerial drift was 0.151%.

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Report:	[redacted]l; [redacted]; 2012; M-426528-01-1
Title:	Thiacloprid FS 400 - Investigating the dust deposition during sowing of thiacloprid FS 400 treated maize seeds with modified (deflected) vacuum pneumatic sowing machinery
Report No.:	S10-03080
Document No.:	M-426528-01-1
Guidelines:	**Working document 1607/VI/97 rev. 1 with the part integration of the BBA Drift Guideline Part VII, 2-1.1 (1992); none**
GLP/GEP:	**yes**

Objective:

The purpose of the study was to determine the dust deposition of thiacloprid, released during the vacuum-pneumatic sowing operation of Thiacloprid FS 400 treated maize seeds with modified (deflected) vacuum-pneumatic sowing equipment under field conditions.

Material and methods:

Test item: A total of 12 Units (each Unit comprised 50,000 kernel) maize seeds were seed-treated on the 1 September 2010 in the commercial seed treatment plant of [redacted] GmbH & Co. KG, [redacted], Germany. The maize seeds were treated with Thiacloprid FS 400 (Tox. No. 09093-00, nominally 1.00 mg thiacloprid as/kernel), together with Thiram (TMTD) SC 700 at a rate of 43 mL/Unit, the film-coating product Impranil DLN W 50 at 15 mL/Unit and Talcum Gloss powder at 30 g/Unit. The seed treatment operation was performed with a commercial Niklas WN 5/100 batch treater.

The field study was conducted in Germany during autumn 2010. The purpose of the study was to establish the drift pattern of dust emitted from a vacuum-pneumatic drilling machine during sowing of Thiacloprid FS 400 treated maize seed.
The plot size was 200 m x 54 m and was drilled with maize with downwind collection of emitted dust. Thirty Petri dishes filled with glycerol/water (1/1, v/v) and 30 Petri dishes with sand wetted with glycerol/water (1/1, v/v) were placed at 3 m distance from the zero line (first driller row + ½ row) spacing together with three gauze netting of 5 m length and 2 m height. Petri dishes were placed horizontally on the ground. The gauze netting was attached to mobile building fences. The minimum distance between fence and the closest row of Petri dishes was 13 m. Both the gauze and the rows of Petri dishes were oriented parallel to the driving directions of sowing.
Soil samples from the upper 10 cm were taken for soil characterisation and for residue analysis. Soil samples from the upper 5 cm were taken for the determination of the water content.
Petri dishes and gauze netting samples respective samples were analysed for the residues of thiacloprid. Soil samples were not analysed for residues.
Maize, pre-treated with Thiacloprid FS 400 (provided by Bayer CropScience), was sown in the vicinity of [redacted] (Baden-Württemberg) on 11 October 2010. The plot size was 200 m x 54 m.
The dust from the mechanical abrasion of the dressed seed item which emitted during seeding with a modified (deflected) vacuum-pneumatic drilling machine was collected using Petri dishes and gauze netting.
The drilling rate was 93340 seeds/ha. A total area of 1.08 ha was drilled. This drilling rate of treated seeds was equivalent to an actual application rate of 93.88 g a.s./ha.
The average wind speed during drilling was 3.87 ± 0.60 m/s (1.69 m/s to 6.69 m/s) and the average deviation to the intended wind direction was -26.47° ± 8.53°.

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Findings:

Residues were found in all Petri dishes filled with a glycerol/water mixture with an overall average of 0.016 ± 0.023 g a.s./ha. The average amount of thiacloprid over the three areas was 0.017% of the actual field application rate. The 90th-percentile (0.021 g a.s./ha) was equivalent to 0.022% of the actual field application rate.

In Petri dishes filled with a glycerol/water/sand mixture, only 10 of the 30 Petri dishes contained residues above the LOD (0.004 g a.s./ha). Seven out of 10 residue values were below the LOQ (0.014 g a.s./ha). The average amount of thiacloprid over all three areas was 0.025 g a.s./ha which is equivalent to 0.026% of the actual field rate. This value was heavily influenced by one extreme value which was by a factor of more than 10 above the next lower value. Excluding this extreme value from the evaluation would lower the mean value from 0.025 g a.s./ha to 0.006 g a.s./ha.

The 90th-percentile (0.016 g a.s./ha) was equivalent to 0.017% of the actual field application rate.

For Gauze the highest amount of thiacloprid was 0.022 g a.s./ha. The mean amount over the three areas was 0.014 ± 0.003 g a.s./ha. The 90th-percentile (0.016 g a.s./ha) was equivalent to 0.017% of the actual field application rate.

Conclusion:

The drilling of Thiacloprid FS 400 treated maize on a 1.08 ha field resulted in dust containing residues of thiacloprid. The average amount of residues was 0.017% of the actual field rate for the glycerol/water and 0.026% of the actual field rate for the glycerol/water/sand mixture. The value for the glycerol/water/sand mixture was heavily influenced by one extreme value which was by a factor of more than 10 above the next lower value. Excluding this value from the evaluation would lower the mean value from 0.025 g a.s./ha to 0.006 g a.s./ha. The 90th-percentile for the residues in gauze netting was equivalent to 0.017% of the actual field application rate.

Report:	[redacted]; [redacted]; 2009; M-359919-01-1
Title:	Determination of residue levels of thiacloprid and its metabolite KKO 2254 in guttation solutions collected from maize plants, grown from Thiacloprid FS 400 dressed seeds (nominally 1.00 mg thiacloprid/seed) in Germany
Report No.:	MR-09/68
Document No.:	M-359919-01-1
Guidelines:	**91/414/EEC of July 15, 1991; not specified**
GLP/GEP:	**yes**

Preface and study set-up

A series of in total 113 individual guttation samples have been collected under typical use conditions of Thiacloprid FS 400 treated maize plants under field conditions. The maize plants under investigation were grown from maize seeds, seed-treated with Thiacloprid FS 400 at the commercial target rate of nominally 1.00 mg thiacloprid a.s./kernel. On three different fields (Field ID-Code 3, 5, 8) maize seeds were sown at three different dates. With the onset of guttation after seedling emergence, guttation liquid was collected every morning if guttation droplets were visible. Depending on the amount of available guttation droplets present on the maize plants every morning, up to three samples of a volume of about 1 mL were collected manually by means of a pipette and stored in 2 mL Eppendorf caps. In case of no or little guttation, either no or only 1 or 2 samples were collected. The field collection of samples per field under investigation covered time periods of 1 ½ - 3 ½ weeks after onset of guttation as well as BBCH growth stages from 10 – 17. Once the samples were collected, they were placed in the field in a cooler to

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be transferred into a deep freezer within a few hours after collection. Thereafter, the samples were kept deep frozen until analysis.

Details are summarised in the table below.

Table CP 10.3.1.6- 3: Summary of sampling schedule for Study

Field ID-code	Date of maize sowing	First guttation liquid sampling		Last guttation liquid sampling		Duration of daily guttation collection 2	No. of field-collected samples
		Date	DAS 1	Date	DAS 1		
3	07 MAY 2009	20 MAY 2009	13	31 MAY 2009	24	12 days	15
5	27 APR 2009	10 MAY 2009	13	31 MAY 2009	34	22 days	43
8	24 APR 2009	08 MAY 2009	14	31 MAY 2009	37	24 days	55
Total							113
1 DAS = Days after sowing 2 In case guttation occurred							

Results / Conclusion

The analytical data revealed that the peak thiacloprid concentration in the guttation fluid of thiacloprid seed-treated maize plants occurs immediately after emergence, at about BBCH 10-12, followed by a rapid decline in concentration within the following few days (Figure CP 10.3.1.6-8 to CP 10.3.1.6-10). The maximum measured thiacloprid concentration in the guttation fluid was determined to be 50 ppm, on a single day.

The concentration of thiacloprid-amide remained at all t points in time below the concentration of parent thiacloprid, only occasionally - and then at the very early growth stages – did the concentration exceed 5 ppm. The maximum measured thiacloprid-amide concentration in the guttation fluid was determined to be 16 ppm, on a single day.

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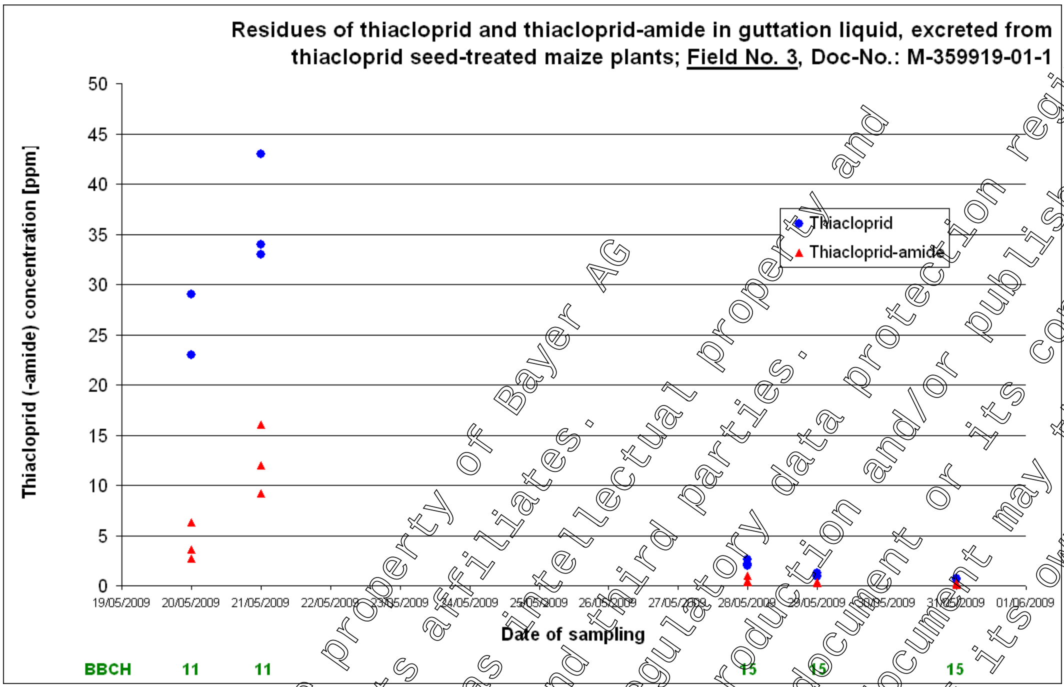

Figure CP 10.3.1.6- 8: Residues of thiacloprid and thiacloprid-amide in the guttation liquid collected on field 3

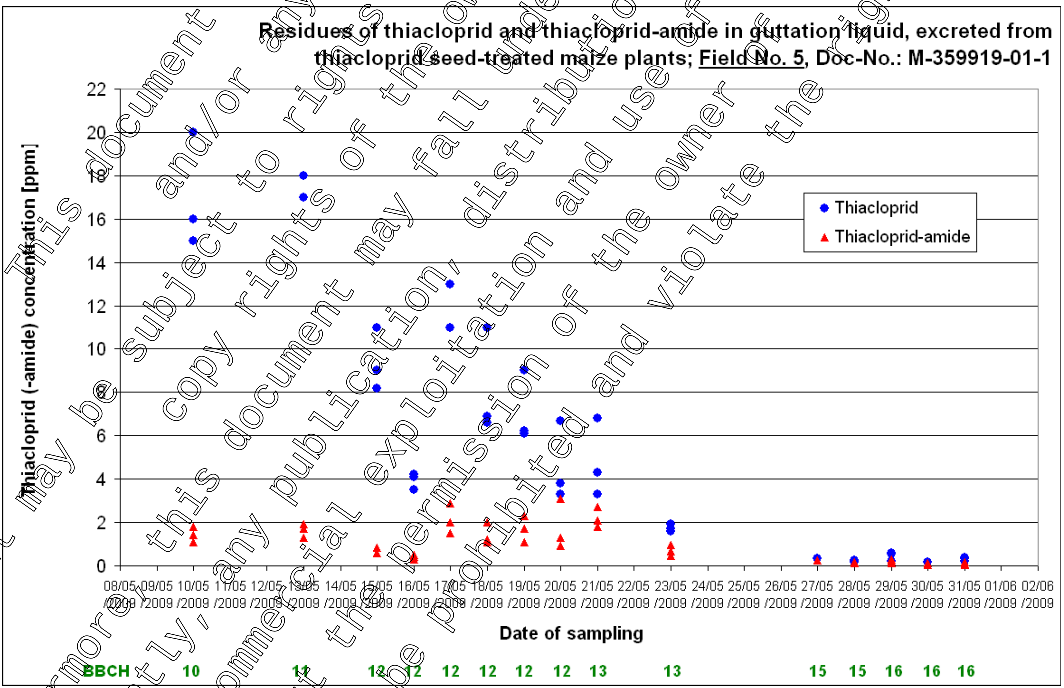

Figure CP 10.3.1.6- 9: Residues of thiacloprid and thiacloprid-amide in the guttation liquid collected on field 5

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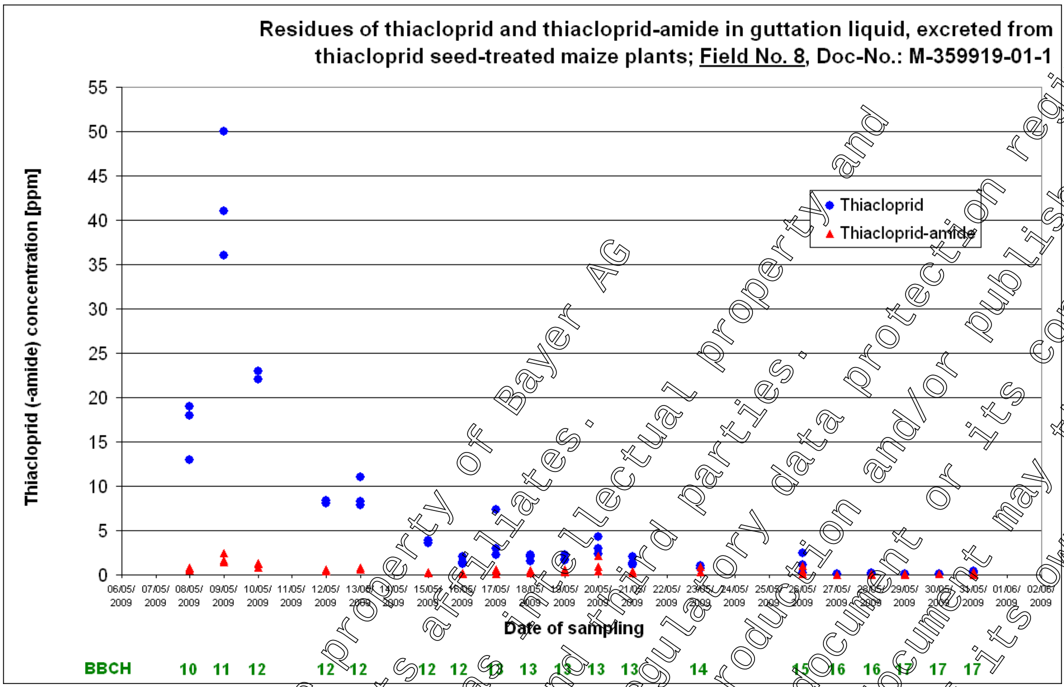

Figure CP 10.3.1.6- 10: Residues of thiacloprid and thiacloprid-amide in the guttation liquid collected on field 8

Report:	[redacted]; [redacted]; 2010; M-363263-01-1
Title:	Determination of residue levels of thiacloprid and its metabolite KKO 2254 in pollen, harvested from maize plants, grown from Thiacloprid FS 400 dressed seeds (nominally 1.00 mg thiacloprid/seed) in Germany
Report No.:	MR-09/94
Document No.:	M-363263-01-1
Guidelines:	**91/414/EEC; not specified**
GLP/GEP:	**yes**

Objective:

The purpose of the study was to determine the residues of thiacloprid and its metabolite KKO 2254 (= YRC 2894-amide) in pollen from maize plants after seed dressing with Thiacloprid FS 400 in the field. In total, six field trials were conducted in Germany. Pollen-samples were collected in the field between 76 and 84 days after drilling of the thiacloprid-dressed maize seed.

Material and methods:

Residues of thiacloprid and its metabolite KKO 2254 (= YRC 2894-amide) in/on maize pollen were determined according to validated method 01155. Thiacloprid and YRC 2894-amide were extracted from maize pollen using a mixture of acetonitrile/water (4/1, v/v). After filtration an aliquot of this solution was evaporated to the aqueous remainder and cleaned-up on a Chromabond® XTR cartridge. After elution of the residues with cyclohexane/ethyl acetate (1/1, v/v) the extract was evaporated to dryness and re-dissolved in an internal standard solution of YRC 2894-d2. The residues were quantified by reversed phase HPLC with electrospray and MS/MS-detection. The individual recovery values for thiacloprid with method 01155 for pollen ranged from 75 to 91% with an overall recovery of 84% and with a relative standard deviation (RSD) of 5.8% (n = 7). For KKO 2254 (= YRC 2894-

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amide) the individual recovery values ranged from 91 to 109% with an overall recovery of 97% and with a RSD of 6.4% (n = 7). All results of the method validation were in accordance with the general requirements for residue analytical methods, therefore the method was validated successfully. The Limit of Quantitation (LOQ) in/on pollen, defined as the lowest validated fortification level, was 0.001 mg/kg for thiacloprid and its metabolite KKO 2254, respectively.
Residues of thiacloprid and its metabolite KKO 2254 in field-collected pollen from maize plants, grown from maize seeds dressed with Thiacloprid FS 400 at a nominal rate of 1.0 mg a.s./seed, were always below the LOQ.

Results / Conclusion:

An overview of the results is given below:

Table CP 10.3.1.6- 4-: Residue data of thiacloprid and thiacloprid-amide in maize pollen, directly collected from flowering maize plants, seed-treated with Thiacloprid FS 400 at a nominal rate of 1.0 mg a.s./kernel

Sample ID	Origin of sample	Treatment	Date of sampling	Residue Thiacloprid [mg/kg]	Residue YRC 2894-amide* [mg/kg]
Maize variety "Atletico", five maize pollen samples were collected from six study fields located around Schwarzenau in Bavaria (Germany) from flowering maize plants, seed-treated with Thiacloprid FS 400					
1-001	Pollen from plants	Treated T	2009-07-22	< LOQ	< LOQ
1-002	Pollen from plants	Treated T	2009-07-22	< LOQ	< LOQ
1-003	Pollen from plants	Treated T	2009-07-22	< LOQ	< LOQ
1-004	Pollen from plants	Treated T	2009-07-22	< LOQ	< LOD
1-005	Pollen from plants	Treated T	2009-07-22	< LOQ	< LOQ
2-001	Pollen from plants	Treated T	2009-07-24	< LOQ	< LOD
2-002	Pollen from plants	Treated T	2009-07-24	< LOQ	< LOQ
2-003	Pollen from plants	Treated T	2009-07-24	< LOQ	< LOD
2-004	Pollen from plants	Treated T	2009-07-24	< LOQ	< LOD
2-005	Pollen from plants	Treated T	2009-07-24	< LOQ	< LOQ
3-001	Pollen from plants	Treated T	2009-07-22	< LOQ	< LOD
3-002	Pollen from plants	Treated T	2009-07-22	< LOQ	< LOD
3-003	Pollen from plants	Treated T	2009-07-22	< LOQ	< LOD
3-004	Pollen from plants	Treated T	2009-07-22	< LOQ	< LOD
3-005	Pollen from plants	Treated T	2009-07-22	< LOQ	< LOD
6-001	Pollen from plants	Treated T	2009-07-17	< LOQ	< LOQ
6-002	Pollen from plants	Treated T	2009-07-17	< LOQ	< LOD
6-003	Pollen from plants	Treated T	2009-07-17	< LOQ	< LOD
6-004	Pollen from plants	Treated T	2009-07-17	< LOQ	< LOD
6-005	Pollen from plants	Treated T	2009-07-17	< LOQ	< LOD
7-001	Pollen from plants	Treated T	2009-07-17	< LOQ	< LOQ
7-002	Pollen from plants	Treated T	2009-07-17	< LOQ	< LOD
7-003	Pollen from plants	Treated T	2009-07-17	< LOQ	< LOQ
7-004	Pollen from plants	Treated T	2009-07-17	< LOQ	< LOQ
7-005	Pollen from plants	Treated T	2009-07-17	< LOQ	< LOQ
8-001	Pollen from plants	Treated T	2009-07-13	< LOQ	< LOD
8-002	Pollen from plants	Treated T	2009-07-13	< LOQ	< LOD
8-003	Pollen from plants	Treated T	2009-07-13	< LOQ	< LOD
8-004	Pollen from plants	Treated T	2009-07-13	< LOQ	< LOD
8-005	Pollen from plants	Treated T	2009-07-13	< LOQ	< LOD

* = Thiacloprid-amide = KKO 2254; LOQ = 0.001 mg/kg, LOD = 0.0001 mg/kg

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CP 10.3.2 Effects on non-target arthropods other than bees

Thiacloprid FS 400 is a seed dressing product that is applied on maize. The maximum recommended rate is 0.25 L product/ha which corresponds to 110 g thiacloprid/ha. In the case of a seed treatment the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002-final) recommends that the risk assessment for non-target arthropods should be covered with studies and the corresponding risk assessment for soil macro-invertebrates *Hypoaspis aculeifer* and/or *Folsomia candida.* Data for *H. aculeifer and F. candida* and the corresponding risk assessment are presented in chapter CP 10.4.2.

The study results for the corresponding spray formulation Thiacloprid OD 240 (see MCP for Thiacloprid OD240) indicate that *A. rhopalosiphi* is the most sensitive species. Extended laboratory studies were conducted with *A. rhopalosiphi and Coccinella septempunctata to* compare the toxicity of the seed treatment formulation Thiacloprid FS 400 to the spray formulation Thiacloprid OD 240. The results of these studies are summarised in the table below.

Table CP 10.3.2-1: Thiacloprid FS 400 g/L: Ecotoxicological endpoints for arthropods other than bees

Test species, Reference Dossier-file-No.	**Tested Formulation, study type, exposure**	**Ecotoxicological Endpoint**	
Aphidius rhopalosiphi	FS 400	LR_{50} 3.43 g a.s./ha	
[redacted] (2009)	Extended Lab., exposure on	ER_{50} < 1.24 g a.s./ha	
M-359663-01-1	detached bean leaves (2D)	Corr. Mortality [%]	Effect on Reproduction [%]
KCP 10.3.2.2/1	0.15 g a.s./ha	-7.1[A]	-38.7[B]
	0.30 g a.s./ha	0.0	-5.8[B]
	0.61 g a.s./ha	-7.1[A]	-25.7[B]
	1.24 g a.s./ha	7.1	37.2
	2.50 g a.s./ha	46.4	61.8
	0.25 g a.s./ha	-1.7[A]	34.7
	0.53 g a.s./ha	5.1	47.0
	1.12 g a.s./ha	-1.7[A]	32.6
	2.36 g a.s./ha	28.8	83.8
	5.00 g a.s./ha	74.6	n.a.
Coccinella septempunctata	FS 400	LR_{50} 14.1 g a.s./ha	
[redacted] (2009)	Extended Lab., exposure on	no impact on reproduction at 10.6 g a.s./ha	
M-360082-01-1	detached bean leaves	Corr. Mortality [%]	Fertile eggs/Female/Day
KCP 10.3.2.2/2	Control	-	7.9
	5.0 g a.s./ha	27.3	7.6
	10.6 g a.s./ha	18.2	6.5
	22.4 g a.s./ha	75.1	n.a.
	47.3 g a.s./ha	100.0	n.a.
	100.0 g a.s./ha	90.9	n.a.

[A]: A negative value indicates a lower mortality in the treatment than in the control
[B]: A negative value indicates a higher reproduction rate in the treatment than in the control.
n.a.: not assessed

Results for ground dwelling non-target arthropods are available for Thiacloprid SC480 the previous representative formulation for the Annex I inclusion. The study summaries are available in the DAR and the results are also provided in the table blow.

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Table CP 10.3.2-2: Thiacloprid SC 480: Ecotoxicological endpoints for soil dwelling arthropods other than bees

Test species, Reference Dossier-file-No.	Tested Formulation, study type, exposure	Ecotoxicological Endpoint
Aleochara bilineata [redacted] (1996) M-001036-01-1 (KCA 8.3.2)	Thiacloprid SC 480 Laboratory, spray deposits on quartz sand 187.5 g a.s./ha 375 g a.s./ha	Effect on Reproduction [%] 97.1 99.2
Aleochara bilineata Schmuck (1998) M-001610-01-1 (KCA 8.3.2)	Thiacloprid SC 480 Extended lab., spray deposits on soil 187.5 g a.s./ha 375 g a.s./ha	ER_{50} > 187.5 g a.s./ha. Effect on Reproduction [%] -5.2[A] -3.4[A]
Pardosa sp. Schmuck (1998) M-002261-01-1	Thiacloprid SC 480 Laboratory, spray deposits on quartz sand 187.5 g a.s./ha 375 g a.s./ha	Corr. Mortality [%] / Effect on feeding capacity [%] 19 / 31.5 63 / 63.0
Poecilus cupreus Schmuck (1998) M-003812-01-1	Thiacloprid SC 480 Laboratory, spray deposits on sand Control 100 g a.s./ha 216 g a.s./ha	ER_{50} > 216 g a.s./ha Corr. Mortality [%] / Effect on Feeding Rate [%] - / - 0 / 39 3 / 22
Poecilus cupreus Schmuck (1998) M-002262-01-1	Thiacloprid SC 480 Semi-field, natural soil, 2x 150 g a.s./ha (interval 7 days) Control 2x 150 g a.s./ha	Mortality [%] / Consumed pupae/beetle/day 3.3 / 0.02 2.5 / 0.01

The available data on ground dwelling arthropods indicate that under more realistic exposure conditions (extended laboratory or semi-field) no unacceptable adverse effects on soil dwelling non-target arthropods are to be expected from exposure rates even exceeding the maximum application rate of 110 g a.s./ha for Thiacloprid FS 400.

CP 10.3.2.1 Standard laboratory testing for non-target arthropods

No tier 1 standard laboratory studies were performed, extended laboratory studies are reported below.

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CP 10.3.2.2 Extended laboratory testing, aged residue studies with non-target arthropods

Report:	[redacted]u;[redacted]; 2009; M-359663-01-1
Title:	Toxicity to the parasitoid wasp Aphidius rhopalosiphi (DESTEPHANI-PEREZ) (Hymenoptera: Braconidae) using an extended laboratory test on Phaseolus vulgaris thiacloprid FS 400 g/L
Report No.:	CW09/56
Document No.:	M-359663-01-1
Guidelines:	**MEAD-BRIGGS ET AL. (2000) modified: Use of natural substrate (bean leaf) fixed in a glass cage; CANDOLFI ET AL. (2001); none**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid FS 400 g/L; Sample description: TOX08522-00; Specification no.: 102000021815; Batch ID: 2009-000968; Density: 1.184 g/ml; Analysed content: 35.0%w/w

The test item was applied at rates of 0.15, 0.3, 0.61, 1.24 and 2.5 g a.s./ha and the effects were compared to a water treated control. A toxic reference (a.s.: dimethoate) applied at 3 g a.s./ha was included to indicate the relative susceptibility of the test organisms and the test system.
The study had to be repeated because a LR_{50} value could not be determined because the highest rate in the first trial showed a corrected mortality of < 50%. In the second study trial the test item was applied at rates of 0.25, 0.53, 1.12, 2.36 and 5.0 g a.s./ha and a LR_{50} value could be calculated.
Mortality of 60 adults was assessed 2, 24 and 48 hours after exposure.
From the water control and all dose rates in the first trial and the dose rates of 0.25, 0.53, 1.12 and 2.36 g a.s./ha in the second trial, 15 impartially chosen females per treatment were each transferred to a cylinder containing untreated barley seedlings infested with *Rhopalosiphum padi* for a period of 24 hours. The number of mummies was assessed 10 days later in the first and 12 days later in the second trial.

Findings:

Mortality and reproduction in each of the treatments of both study trials are summarised below.

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Table CP 10.3.2.2- 1: Effects of Thiacloprid FS 400 on mortality and reproduction of *Aphidius rhopalosiphi* (trial 1)

Trial 1							
Test item		**Thiacloprid FS 400 g/L**					
Test organism		***Aphidius rhopalosiphi***					
Exposure on:		**Detached leaf of *Phaseolus vulgaris***					
		Mortality [%]			**Reproduction**		
Treatment	**g a.s./ha**	**Uncorr.**	**Corr.**	**P-Value(*)**	**Rate (mummies per female)**	**Red. rel. to Control [%]**	**P-Value(#)**
Control	0	6.7			12.7		
Test item	0.15	0	-7.1	1.000 n.sign.	17.7	-38.7	0.088 n.sign.
Test item	0.30	6.7	0	1.000 n.sign.	13.5	-5.8	0.708 n.sign.
Test item	0.61	0	-7.1	1.000 n.sign.	16.0	-25.7	0.608 n.sign.
Test item	1.24	13.3	7.1	0.724 n.sign.	8.0	37.2	0.039 sign.
Test item	2.50	50.0	46.4	<.001 sign.	4.9	61.8	<.001 sign.
Reference item	3.00	100	100		n.d.	n.d.	
ER_{50}: >1.24 g a.s./ha (estimated) * Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm, # Welch test n.d. not detected, n.sign. not significant, sign. significant							

Table CP 10.3.2.2- 2: Effects of Thiacloprid FS 400 on mortality and reproduction of *Aphidius rhopalosiphi* (trial 2)

Trial 2							
Test item		**Thiacloprid FS 400 g/L**					
Test organism		***Aphidius rhopalosiphi***					
Exposure on:		**Detached leaf of *Phaseolus vulgaris***					
		Mortality [%]			**Reproduction**		
Treatment	**g a.s./ha**	**Uncorr.**	**Corr.**	**P-Value(*)**	**Rate (mummies per female)**	**Red. rel. to Control [%]**	**P-Value(#)**
Control	0	1.7			32.1		
Test item	0.25	0	-1.7	1.000 n.sign.	20.9	34.7	0.095 n.sign.
Test item	0.53	6.7	5.1	0.547 n.sign.	17.0	47.0	0.067 n.sign.
Test item	1.12	0	-1.7	1.000 n.sign.	21.6	32.6	0.092 n.sign.
Test item	2.36	30.0	28.8	<.001 sign.	5.2	83.8	<.001 sign.
Test item	5.00	75.0	74.6	<.001 sign.	n.d.	n.d.	
Reference item	3.00	100	100		n.d.	n.d.	
LR_{50}: 3.43 g a.s./ha; 95% Confidence Interval: (2.84 - 4.23) (calculated with Probit analysis) ER_{50}: >1.12 g a.s./ha (estimated) * Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm # Wilcoxon test (one-sided), p-values are adjusted according to Bonferroni-Holm n.d. not detected, n.sign. not significant, sign. significant							

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Conclusions:

In this extended laboratory test the effects of residues of Thiacloprid FS 400 g/L on the survival and reproduction of *Aphidius rhopalosiphi* were determined. The LR_{50} was calculated to be 3.43 g a.s./ha. The ER_{50} was estimated to be >1.24 g a.s./ha.

Report:	[redacted] §; [redacted]; 2009; M-360082-01-1
Title:	Toxicity to the ladybird beetle Coccinella septempunctata L. (Coleoptera, Coccinellidae) using an extended laboratory test on Phaseolus vulgaris Thiacloprid FS 400 g/L
Report No.:	CW09/41
Document No.:	M-360082-01-1
Guidelines:	**SCHMUCK ET AL. (2000) modified: Use of natural substrate (bean leaves) instead of glass plate; CANDOLFI ET AL. (2001); none**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid FS 400 g/L; Sample description: TOX08522-00; Specification no.: 102000021815; Batch ID: 2009-000968; Density: 1.184 g/ml; Analysed content: 35.0% w/w.

The test item was applied to leaves of *Phaseolus vulgaris* at rates of 5.0, 10.6, 22.4, 47.3 and 100.0 g a.s./ha and the effects were compared to a water treated control. A toxic reference (a.s.: dimethoate) applied at 12.0 g a.s./ha was included to indicate the relative susceptibility of the test organisms and the test system.
The preimaginal mortality was monitored over the duration of the study. The fertility and fecundity of the surviving hatched adults were then evaluated over the period of 17 days.
Mortality and reproduction in each of the treatments are summarized below.

Findings:

Table CP 10.3.2.2- 3: Effects of Thiacloprid FS 400 on mortality and reproduction of *Coccinella septempunctata*

Test item		**Thiacloprid FS 400 g/L**				
Test organism		***Coccinella septempunctata***				
Exposure on:		**Bean leaves**				
		Mortality [%]			**Reproduction**	
Treatment	**g a.s./ha**	**Uncorr.**	**Corr.**	**P-Value(*)**	**Eggs per female and day**	**Fertility [hatching rate in%]**
Control	0	17.5			7.9	92.8
Test item	5.0	40.0	27.3	0.047 sign.	7.6	87.0
Test item	10.6	32.5	18.2	0.098 n.sign.	6.5	94.2
Test item	22.4	79.5	75.1	<.001 sign.	n.d.	n.d.
Test item	47.3	100	100	<.001 sign.	n.d.	n.d.
Test item	100.0	92.5	90.9	<.001 sign.	n.d.	n.d.
Reference item	12.0	97.5	97.0		n.d.	n.d.
LR_{50}: 14.1 g a.s./ha; 95% Confidence Interval: (-) (calculated with Probit analysis) * Fisher`s Exact test (one-sided), p-values are adjusted according to Bonferroni-Holm n.d. not detected, n.sign. not significant, sign. significant						

Reproduction was assessed at the two lowest rates of Thiacloprid FS 400 g/L, 5.0 and 10.6 g a.s./ha. The mean number of fertile eggs per female and day was 7.9 in the control and 7.6 and 6.5,

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respectively, in the 5.0 and 10.6 g a.s./ha rate. Because the reproductive performance was within the historical data base for control beetles (≥ 2 fertile eggs per female and day) this parameter is considered as not impacted by both test item rates.

Conclusions:

In this extended laboratory study the effects of the test item residues of Thiacloprid FS 400 g/L to larvae of the ladybird beetle *Coccinella septempunctata* were determined.
The LR_{50} was calculated to be 14.1 g a.s./ha and up to and including 10.6 g a.s./ha reproduction was not impacted.

CP 10.3.2.3 Semi-field studies with non-target arthropods

Semi-field studies are not required.

CP 10.3.2.4 Field studies with non-target arthropods

Additional field studies are not required for non-target arthropods.

CP 10.3.2.5 Other routes of exposure for non-target arthropods

The exposure of soil-dwelling non-target arthropod as assessed in chapter CP 10.3.2 is considered the main route of exposure for non-target arthropods.

CP 10.4 Effects on non-target soil meso- and macrofauna

The risk assessment procedure follows the requirements as given in the EU Regulation 1107/2009 and the Guidance Document on Terrestrial Ecotoxicology.

Predicted environmental concentrations used in risk assessment

Predicted environmental concentrations in soil (PEC_{soil}) values were calculated for the formulation, based on the standard assumptions of distribution in a soil layer of 5 cm with a bulk density of 1.5 g/cm³; a crop interception of 0% was taken into account.

The relevant PEC values considered for TER calculations are summarised in the tables below. Maximum values are used for risk assessments.

Table CP 10.4- 1: Initial max PEC_{soil} values

Compound	Maize		
	$PEC_{soil,ini}$ [mg/kg]	$PEC_{soil,\ accu}$ [mg/kg]	$PEC_{soil,\ max}$ [mg/kg]
Thiacloprid	0.147	-	**0.147**
Thiacloprid-amide	0.136	0.028	**0.165** a)
Thiacloprid sulfonic acid	0.039	-	**0.039** a)
Thiacloprid-descyano	0.044	0.029	**0.073** a)

a) PEC_{accu} (mixing depth 20 cm)
Bold values: worst case considered in risk assessment

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CP 10.4.1 Earthworms

Table CP 10.4.1- 1: Endpoints used in risk assessment

Test substance	Test species	Endpoint		Reference
Thiacloprid FS 400	Earthworm, reproduction	NOEC	≥ 654 g a.s./ha **≙ 0.872 mg a.s./kg dws** [a]	[redacted] (2009) M-357709-01-1 KCP 10.4.1.1/1
Thiacloprid-amide	Earthworm, reproduction	NOEC	**60 mg p.m. /kg dws**	[redacted] (2010) M-362816-01-1 KCA 8.4.1/1
Thiacloprid sulfonic acid	Earthworm, reproduction	NOEC	**≥ 9.49 mg p.m./kg dws**	[redacted] (2010) M-369557-01-1 KCA 8.4.1/2
Thiacloprid-descyano	Earthworm, reproduction	NOEC	**3.1 mg p.m./kg dws**	[redacted] (2013) M-446955-01-1 KCA 8.4.1/3

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite
Bold values: endpoints used for risk assessment
[a] calculated for a soil depth of 5 cm, a soil density of 1.5 g/cm³

Risk assessment for earthworms

Based on the endpoints in the table above the TER values are calculated using the following equations:

$TER_{LT} = NOEC / PEC_{soil}$

The risk is considered acceptable if the TER_{LT} is >5.

For lipophilic substances (log P_{OW} > 2) all results from the laboratory studies are corrected by a factor 2 even when the organic matter is less than 10%.
However, for none of the components $logP_{OW}$ exceeds this trigger (refer to Section 2 of the MCA document, CA 2.7), hence an additional assessment factor is not required.

Table CP 10.4.1-2: TER calculations for earthworms

Compound	Species	Endpoint [mg/kg]		$PEC_{soil,max}$ [mg/kg]	TER_{LT}	Trigger
Maize						
Thiacloprid FS 400	Earthworm, reproduction	NOEC	≥ 0.872	0.147	≥ 5.9	5
Thiacloprid-amide	Earthworm, reproduction	NOEC	60	0.165	364	5
Thiacloprid sulfonic acid	Earthworm, reproduction	NOEC	≥ 9.49	0.039	≥ 243	5
Thiacloprid-descyano	Earthworm, reproduction	NOEC	3.1	0.073	42.5	5

All TER values calculated with the worst case $PEC_{soil, max}$ values exceed the trigger value of 5 indicating that no unacceptable adverse effects on earthworms are to be expected from the intended use of the product.

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CP 10.4.1.1 Earthworms sub-lethal effects

Report:	[redacted],;[redacted]; 2009; M-357709-01-1
Title:	Thiacloprid FS 400 G: Effects on survival, growth and reproduction on the earthworm Eisenia fetida tested in artificial soil with 5 % peat
Report No.:	KRA-RG-R-1/9
Document No.:	M-357709-01-1
Guidelines:	**ISO 11268-2: 1998 (E) and OECD 222; April 13, 2004; For the control as well as for the treatment 40 adult earthworms were tested in a container with a surface of 4256 cm² containing 30 kg dry weight artificial soil**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid FS 400 G; Specification No.: 102000021815; Density: 1.176 g/mL; Analysed content: 389.3 g /L (33.1% w/w).
Dressed maize seeds with the test item (amount of thiacloprid (analysed) 54.48 g/Unit (one unit consists of 50 000 maize seeds).

Adult *Eisenia fetida* (7 to 8 months old, 1 x 40 animals for the control group and treatment group each) were exposed in an artificial soil (with 5% peat content) to the nominal test concentration of 600 000 seeds/ha and 1.00 g a.s./seed. Dressed maize seeds were sown in a single row in the test container at a depth of approximately 5 cm. After 28 days the number of surviving animals and their weight alteration was determined. They were then removed from the artificial soil. After further 28 days, the number of offspring was determined.

Results and Discussion:

Table CP 10.4.1.1-1: Effects on mortality and changes in body weight of the adults after an exposure period of 28 days and the number of offspring per test vessel after 56 days.

	Control	Treatment	% of Control
Mortality after 28 days			
No. of survived adults	40	39	97.5
Mortality [%]	0.0	2.5	
Changes in body weight after 28 days			
Total body wet weight of surviving adults [g]	18.02	16.26	90.2
Mean body wet weight per surviving adult [g]	0.45	0.42	93.3
Mean change in body weight [%]	21.02	17.28	82.2
Reproduction after 56 days			
Mean no. of juveniles per sample	29.2	27.9	95.7
Standard deviation	7.6	7.30	
Coefficient of variation	26.0	26.1	
Juveniles per surviving adult	33.5	32.1	95.8

Mortality
No mortality was observed after 28 days of exposure in the control vessel and a mortality of 2.5% was observed in the treatment vessel. This is not an adverse effect, since it is below the allowed maximum mortality of ≥ 10% for controls.

Effects on growth

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Total body wet weight of surviving adult worms, mean body wet weight and mean change in body weight of surviving adult worms in the treatment was slightly lower than in the control. But this is not considered to be an adverse effect, but rather caused by biological variability of the test system.

Effects on reproduction
No statistically significant different values for the number of juveniles per sample relative to the control were observed for the treatment.
Therefore, based on statistical significance:
NOEC related to reproduction: ≥ 600,000 dressed seeds/ha (≥ 654 g thiacloprid/ha)
LOEC related to reproduction: > 600,000 dressed seeds/ha (> 654 g thiacloprid/ha)

Conclusion:

Overall, based on the biological and statistical significance of the effects observed on growth and reproduction, it is concluded, that the NOEC for this study is ≥ 600,000 dressed seeds/ha (corresponding to 654 g thiacloprid/ha).

CP 10.4.1.2 Earthworms field studies

Not required as no risk to earthworms was identified.

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CP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Table CP 10.4.2- 1: Endpoints used in risk assessment

Test substance	Test species	Endpoint		Reference
Thiacloprid FS 400	*Folsomia candida*	NOEC	≥ 615.8 g a.s./ha ≙ ≥ **0.821 mg a.s./kg dws** [a)]	[redacted] (2010) M-362494-01-1 KCP 10.4.2.1/1
	Hypoaspis aculeifer	NOEC	≥ 5561.2 g a.s./ha ≙ ≥ **7.415 mg a.s./kg dws** [a)]	[redacted] (2010) M-362189-01-1 KCP 10.4.2.1/2
Thiacloprid-amide	*Folsomia candida*	NOEC	**10 mg p.m./kg dws**	[redacted] (2001) M-070983-01-1 KCA 8.4.2.1/1
	Hypoaspis aculeifer	NOEC	**≥ 10 mg p.m./kg dws**	[redacted] (2010) M-364270-01-1 KCA 8.4.2.1/3
Thiacloprid sulfonic acid	*Folsomia candida*	NOEC	**≥ 1000 mg p.m./kg dws**	[redacted] & [redacted] (2002) M-043981-01-1 KCA 8.4.2.1/4
	Hypoaspis aculeifer	NOEC	**≥ 100 mg p.m./kg dws**	[redacted] (2011) M-420081-01-1 KCA 8.4.2.1/5
Thiacloprid-descyano	*Folsomia candida*	NOEC	**10 mg/kg dws**	[redacted] (2012) M-432536-01-1 KCA 8.4.2.1/7
	Hypoaspis aculeifer	NOEC	**≥ 100 mg p.m./kg dws**	[redacted] (2011) M-419836-01-1 KCA 8.4.2.1/6

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite
Bold values: endpoints used for risk assessment
[a)] calculated for a soil depth of 5 cm and a soil density of 1.5 g/cm³

Risk assessment for other non-target soil meso- and macrofauna (other than earthworms)

Ecotoxicological endpoints and PEC_{soil} values used for TER calculations for soil non-target macro-organisms are summarised below. TER values were calculated using the equation:

$$TER = NOEC / PEC_{soil}$$

The risk is considered acceptable if the TER is >5.

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Table CP 10.4.2- 2: TER calculations for other non-target soil meso- and macrofauna

Compound	Species	Endpoint [mg/kg]		$PEC_{soil,max}$ [mg/kg]	TER_{LT}	Trigger
Maize						
Thiacloprid FS 400	*Folsomia candida*	NOEC	≥ 0.821	0.147	≥ 5.6	5
	Hypoaspis aculeifer	NOEC	≥ 7.415	0.147	≥ 50.4	5
Thiacloprid-amide	*Folsomia candida*	NOEC	10	0.165	60.6	5
	Hypoaspis aculeifer	NOEC	≥ 10	0.165	≥ 60.6	5
Thiacloprid sulfonic acid	*Folsomia candida*	NOEC	≥ 1000	0.039	≥ 25 641	5
	Hypoaspis aculeifer	NOEC	≥ 100	0.039	≥ 2564	5
Thiacloprid-descyano	*Folsomia candida*	NOEC	10	0.073	137	5
	Hypoaspis aculeifer	NOEC	≥ 100	0.073	≥ 1370	5

All TER values calculated with the worst case $PEC_{soil,max}$ values exceed the trigger value of 5 indicating that no unacceptable adverse effects on soil macro-organisms are to be expected from the intended use of the product.

CP 10.4.2.1 Species level testing

Report:	[redacted]; [redacted]; 2010; M-362494-01-1
Title:	Thiacloprid FS 400 G dressed maize seed (variety 'Dirigent'): Influence on the reproduction of the collembola species Folsomia candida tested in artificial soil with 5 % peat
Report No.:	FRM-COLL-77/10
Document No.:	M-362494-01-1
Guidelines:	**ISO 11267 (1999); To fulfil the recommendations of the new OECD 232 guideline 5 % peat instead of 10 % peat in the artificial soil was tested.**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid FS 400 G; Specification No.: 102000021815; Density: 1.176 g/mL; Analysed content a.s.: 389.3 g /L (33.1% w/w).
Dressed maize seeds with the test item (amount of thiacloprid (analysed) 54.48 g/Unit (one unit consists of 50 000 maize seeds); Degree of loading: 109.0%)

Thirty Collembola (11-12 days old) per replicate (5 replicates) were exposed to control (1 undressed maize seed/vessel) and 1 maize seed dressed with Thiacloprid FS 400 G/vessel (PET wide mouth bottles volume: 3 L, diameter: 15 cm, covered with perforated plastic lids, surface 177 cm2), corresponding to 564.972 kernel/ha (615.8 g a.s/ha).
Test conditions: artificial soil with 5% peat, 18 – 22°C, 400 – 800 [redacted], 16h light : 8h dark. During the study, they were fed with granulated dry yeast.
Mortality and reproduction were determined after 28 days.
The validity criteria of the test according to the guideline were fulfilled (mortality of the adults, mean rate of reproduction of juveniles and the coefficient of variation of reproduction in the control).

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Results:

In the control group 4.7% of the adult Collembola died which is within the tolerated range of ≤ 20% mortality recommended by the guideline. In the treatment group the mortality rate was 14%. Concerning the number of juveniles statistical analysis (Pairwise Mann-Whitney U-Test T-test, one sided-smaller, $\alpha = 0.05$) reveals no significant difference between the control and the treatment group.

Table CP 10.4.2.1- 1: Effects of Thiacloprid FS 400 on mortality and reproduction of *Folsomia candida*

Test item Test object Exposure	Thiacloprid FS 400 G dressed maize seeds (variety 'Dirigent') *Folsomia candida* Artificial Soil		
	Adult mortality (%)	**Mean number of juveniles±SD**	**Reproduction (% of control)**
Control	4.7	4636 ± 850	-
Treatment*	14	4401 ± 207	94.9 n.s.
$NOEC_{reproduction}$:	≥ 564.972 kernel/ha (615.8 g a.s./ha)		
$LOEC_{reproduction}$:	> 564.972 kernel/ha (615.8 g a.s./ha)		
The calculations were performed with unrounded values n.s. = statistically not significant (Pairwise Mann-Whitney U-Test T-test one-sided-smaller, $\alpha = 0.05$) * = 564.972 kernel/ha (615.8 g a.s./ha)			

Conclusions:

$NOEC_{reproduction}$: ≥ 564.972 kernel/ha (corresponding to 615.8 g a.s./ha).
$LOEC_{reproduction}$: > 564.972 kernel/ha (corresponding to 615.8 g a.s./ha).

Report:	[redacted] & [redacted] 2010; M-362189-01-1
Title:	Thiacloprid FS 400 G: Influence on mortality and reproduction on the soil mite species Hypoaspis aculeifer tested in artificial soil with 5 % peat
Report No.:	KRA-HR-22/9
Document No.:	M-362189-01-1
Guidelines:	**OECD 226 from October 03, 2008: OECD guideline for the Testing of Chemicals - Predatory mite (Hypoaspis (Geolaelaps) aculeifer) reproduction test in soil; yes, 40 g dry weight artificial soil per test vessel were used**
GLP/GEP:	**yes**

Material and methods:

Test item: Thiacloprid FS 400 G; Specification No.: 102000021815; Density: 1.176 g/mL; Analysed content: 389.3 g /L (33.1% w/w).
Dressed maize seeds with the test item (amount of thiacloprid (analysed) 50.61 g/Unit (one unit consists of 50,000 maize seeds); Degree of loading: 101.2%.

Ten adult, fertilized, female *Hypoaspis aculeifer* per replicate (8 control replicates and 8 treatment replicates) were exposed to control (untreated maize seeds) and treatment (dressed maize seeds). In each test vessel 20 g dry weight artificial soil were weighed in. One maize seed was put in the middle of each test vessel and covered with 20 g dry weight artificial soil. The soil surface covered an area of 19.6 cm². The *Hypoaspis aculeifer* were of a uniform age not differing more than three days (28 days after start of egg laying). During the test, they were fed with cheese mites bred on brewer's yeast. During the study a temperature of 20 ± 2 °C and light regime of 400 – 800 Lux, 16 h light : 8 h dark was applied. The artificial soil was prepared according to the guideline with the following constituents

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(percentage distribution on dry weight basis): 74.8% fine quartz sand, 5% Sphagnum peat, air dried and finely ground, 20% Kaolin clay and approximately 0.2% Calcium carbonate ($CaCO_3$).
After a period of 14 days, the surviving adults and the living juveniles were extracted by applying a temperature gradient using a MacFadyen-apparatus. Extracted mites were collected in a fixing solution (20% ethylene glycol, 80% deionised water; 2 g detergent/L fixing solution were added). All *Hypoaspis aculeifer* were counted under a binocular.

Results:

Mortality
In the control group 1.3% of the adult *Hypoaspis aculeifer* died which is below the allowed maximum of ≤ 20% mortality. A LC_{50} cannot be calculated and is considered to be > 5 102 041 dressed maize seeds/ha.

Reproduction
Concerning the number of juveniles statistical analysis (Student-t test, one-sided smaller, α = 0.05) revealed no significant difference between control and treatment.
Therefore the No-Observed-Effect-Concentration (NOEC) for reproduction is ≥ 5 102 041 dressed maize seeds/ha. The Lowest-Observed-Effect-Concentration (LOEC) for reproduction is > 5 102 041 dressed maize seeds/ha. An EC_{50} could not be calculated and is considered to be > 5 102 041 dressed maize seeds/ha.

Table CP 10.4.2.1- 2: Effects of Thiacloprid FS 400 on mortality and reproduction of *Hypoaspis aculeifer*

Test item Test object Exposure	**Thiacloprid FS 400 G *Hypoaspis aculeifer* Artificial Soil**		
	% mortality (Adults)	**Mean number of juveniles per test vessel ± standard dev.**	**Reproduction (% of control)**
Control	**1.3**	**366.0 ± 24.6**	**---**
Treatment	**2.5**	**387.1 ± 27.5**	**105.8**
			Reproduction
NOEC (dressed maize seeds/ha) LOEC (dressed maize seeds/ha)			≥ 5 102 041 > 5 102 041
No statistical significance (Student-t test one-sided smaller, α = 0.05)			

Conclusions:

NOEC: ≥ 5 102 041 dressed maize seeds/ha.
LOEC: > 5 102 041 dressed maize seeds/ha.
Considering an active substance content of 1.09 mg/seed 5 102 041 dressed maize seeds/ha correspond to 5561.2 g a.s./ha.

CP 10.4.2.2 Higher tier testing

No higher tier testing was performed or required.

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CP 10.5 Effects on soil nitrogen transformation

Table CP 10.5- 1: Endpoints used in risk assessment

Test substance	Test species	Endpoint		Reference
Thiacloprid FS 400	Nitrogen transformation, 28 d	No influence	≥ 2.13 mg prod./kg dws ≙ **≥ 0.74 mg a.s./kg dws**	[redacted] (2013) M-469324-01-1 KCP 10.5/1
Thiacloprid		No influence	**≥ 2.57 mg a.s./kg dws**	[redacted] (19[illegible]) M-001022-02-1 KCA 10.5/1
Thiacloprid-amide		No influence	**≥ 16 mg/kg dws**	[redacted] (2008) M-301378-01-1 KCA 10.5/2
Thiacloprid sulfonic acid (Na salt)		No influence	**≥ 4 mg/kg dws**	[redacted] (2008) M-301383-01-1 KCA 10.5/3
Thiacloprid-descyano		No influence	**≥ 5 mg/kg dws**	[redacted] (2012) M-422083-01-1 KCA 10.5/4

dws = dry weight soil; a.s. = active substance; p.m. = pure metabolite
Bold values: endpoints used for risk assessment

Risk assessment for Soil Nitrogen Transformation

Table CP 10.5- 2: Risk Assessment for soil micro-organisms

Compound	Species	Endpoint [mg/kg]	$PEC_{soil,max}$ [mg/kg]	Refinement required
Thiacloprid FS 400	Soil micro-organisms	≥ 0.74	0.147	No
Thiacloprid	Soil micro-organisms	≥ 2.57	0.147	No
Thiacloprid-amide	Soil micro-organisms	≥ 16	0.165	No
Thiacloprid sulfonic acid (Na salt)	Soil micro-organisms	≥ 4	0.039	No
Thiacloprid-descyano	Soil micro-organisms	≥ 5	0.073	No

According to current regulatory requirements the risk is considered acceptable if the effect on nitrogen mineralisation at the recommended application rate of a compound/product is ≤ 25% after 100 days.

Deviations from the control did not exceed the threshold level of 25% at 28 days after application. The tested concentrations by far exceeded the maximum predicted environmental concentrations in soil of the respective components. This indicates acceptable risk to soil micro-organisms for the intended uses.

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Report:	[redacted]_;[redacted]; 2013; M-469324-01-1
Title:	Thiacloprid FS 400 G: Effects on the activity of soil microflora (nitrogen transformation test)
Report No.:	13 10 48 054 N
Document No.:	M-469324-01-1
Guidelines:	**OECD 216; adopted January 21, 2000, OECD Guideline for the Testing of Chemicals, Soil Microorganisms: Nitrogen Transformation; none**
GLP/GEP:	**yes**

Objective:

The purpose of this study was to determine the effects of the test item on the activity of soil microflora with regard to nitrogen transformation in a laboratory test. The test was performed in accordance with OECD guideline 216 (2000) by measuring the nitrogen turnover.

Material and methods:

Test item: Thiacloprid FS 400 G; Batch ID: 2011-002173; BCS-code: BCS-AA56362; Specification No.: 102000022825 - 01; Material No.: 79858876; Density (20 °C): 1.184 g/mL, Purity: 34.6% w/w.

A loamy sand soil (DIN 4220) was exposed for 28 days to 0.43 and 2.13 mg test item/kg soil dry weight. Application rates were equivalent to 0.27 and 1.35 L test item/ha. The nitrogen transformation was determined in soil enriched with lucerne meal (concentration in soil 0.5%). NH_4-nitrogen, NO_3- and NO_2-nitrogen were determined by an Autoanalyzer at different sampling intervals (0, 7, 14 and 28 days after treatment).

Findings:

Validity criteria:
The coefficients of variation in the control (NO_3-N) were maximum 4.2% and thus fulfilled the demanded range (≤ 15%).

Reference test:
In a separate study the reference item Dinoterb caused a stimulation of nitrogen transformation of +33.7% and +42.6% at 16.00 mg and 27.00 mg Dinoterb per kg soil dry weight, respectively, determined 28 days after application.

Biological findings:
No adverse effects of thiacloprid FS 400 G on nitrogen transformation in soil could be observed at both test concentrations (0.43 mg/kg dry soil and 2.13 mg/kg dry soil) during the 28-day experiment. Differences from the control of +16.3% were measured for both test concentrations at the end of the 28-day incubation period (time interval 14-28).

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Table CP 10.5- 3: Effects on nitrogen transformation in soil after treatment with Thiacloprid FS 400 G

Time Interval (days)	Applications rates									
	Control			[Thiacloprid OD 240 G] 0.43 mg test item/kg soil dry weight equivalent to 0.27 L test item/ha				2.13 mg test item/kg soil dry weight equivalent to 1.35 L test item/ha			
	Nitrate-N[1]			Nitrate-N[1]			% difference to control	Nitrate-N[1]			% difference to control
0-7	3.91	±	0.26	3.80	±	0.13	**-2.9** n.s.	3.82	±	0.21	**-2.4** n.s.
7-14	1.48	±	0.24	1.60	±	0.34	**+8.0** n.s.	1.75	±	0.35	**+18.0** n.s.
14-28	0.69	±	0.16	0.80	±	0.06	**+16.3** n.s.	0.80	±	0.21	**+16.3** n.s.

The calculations were performed with unrounded values
[1] Rate: Nitrate-N in mg/kg soil dry weight/time interval/day, mean of 3 replicates and standard deviation
n.s. = No statistically significant difference to the control (Student's t-test for homogeneous variances, 2-sided, $p \leq 0.05$).

Conclusion:

Thiacloprid FS 400 G caused no adverse effects (difference to control < 25%, OECD 216) on the soil nitrogen transformation (measured as NO_3-N-production) at the end of the 28-day incubation period. The study was performed in a field soil at concentrations up to 2.13 mg test item/kg dry soil, which are equivalent to application rates up to 1.35 L test item/ha and equivalent to 0.74 mg a.s./kg dws.

CP 10.6 Effects on terrestrial non-target higher plants

Risk assessment for Terrestrial Non-Target Higher Plants

In the case of a seed treatment, exposure of non-target terrestrial plants to the product and its active ingredient(s) is not to be expected. Therefore, no risk assessment will be performed. However, a specific study is available in which the product was directly sprayed to plants (KCP 10.6.2/1).

CP 10.6.1 Summary of screening data

No screening data is available.

CP 10.6.2 Testing on non-target plants

Report: [redacted]; [redacted]; 2010; M-362853-01-1
Title: Thiacloprid FS 400 g/L - Effects on the vegetative vigour of ten species of non-target terrestrial plants (Tier 1)
Report No.: VV09/30
Document No.: M-362853-01-1
Guidelines: **OECD Guideline for the testing of Chemicals, Terrestrial Plant Test OECD 227: Vegetative Vigour Test, July 2006; none**
GLP/GEP: **no**

Objective:

The purpose of this specific study was to evaluate the effect of Thiacloprid FS 400 on the vegetative vigour of ten plant species representing a broad range of dicotyledonous and monocotyledonous plant families.

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Material and methods:

Test item: Thiacloprid FS 400; Sample description: TOX 08522-00; Master recipe ID: 0099769-001; Batch-ID: 2009-000968; Material No.: 79722931; Specification No.: 102000021815; Analysed content: 35.0% w/w (414.4 g/L).

A total of ten species were tested in this vegetative vigour study including seven dicotyledonous and three monocotyledonous species representing eight plant families. The following species were tested: *Beta vulgaris*, *Brassica napus*, *Cucumis sativus*, *Fagopyrum esculentum*, *Glycine max*, *Lactuca sativa*, *Lycopersicon esculentum*, *Allium cepa*, *Avena sativa* and *Zea mays*.
Plants were grown in pots and each pot (= replicate) contained 4 plants. There were 20 plants per test group, i.e. 5 replicates. At the 2-4 leaf stage plants were treated with the test item using a laboratory track sprayer. The test item was applied at a rate of 286 g product/ha (corresponding to 100 g a.s./ha nominal) and a volume rate of 200 L water/ha. Control pots were treated with deionised water only. Pots were grown and maintained under glasshouse conditions with a temperature control set at 23 ± 8°C during day and 18 ± 8°C at night with a 16 h photoperiod.
Survival and phytotoxicity were recorded 7, 14 and 21 days after application and assessments were made against the water treated controls. The study was terminated 21 days after application. Parameters measured were survival, visual phytotoxicity, plant growth stage and shoot dry weight. Statistical analysis of shoot dry weight data was performed by using the Pairwise Mann-Whitney-U-Test (one sided smaller; p ≤ 0.05).

Results:

This study can be considered valid as the validity criterion of 90% survival throughout the study period in the untreated controls was achieved for all species.
A summary of the findings from a single application of 286 g product/ha (corresponding to 100 g a.s./ha nominal) Thiacloprid FS 400 g/L to the 10 plant species tested is given in the following table:

Table CP 10.6- 1: Summary of effects on ten plant species after treatment with Thiacloprid FS 400

Species	Survival * (% inhibition)	Phytotoxicity**	Shoot Dry Weight *** (% inhibition)
Dicotyledonae			
Beta vulgaris	0	0	**11.0**
Brassica napus	0	0	(12.3)
Cucumis sativus	0	0	(5.1)
Fagopyrum esculentum	0	0 - A[f]	7.3
Glycine max	0	0	5.3
Lactuca sativa	0	0	(16.6)
Lycopersicon esculentum	0	0	6.9
Monocotyledonae			
Allium cepa	0	0	(21.9)
Avena sativa	0	0	17.0
Zea mays	0	0	(28.4)

* survival is a measure of treated plants that survived at the end of the study and is expressed as an inhibition compared to the untreated control
** see materials and methods for a description of the phytotoxicity rating
*** inhibition or reduction is expressed on a per plant basis
( ) figures in parentheses indicate that there was an increase when compared to the untreated control
Bold figures for shoot dry weight are statistically significant (Pairwise Mann-Whitney-U-test, one sided smaller; p ≤ 0.05)

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There was no effect of 286 g product/ha Thiacloprid FS 400 g/L on the survival of the ten species tested. No symptoms of phytotoxicity were observed at test end in any of the species tested, except *Fagopyrum esculentum* with slight stunting in one replicate pot. With regard to shoot dry weight, *Beta vulgaris* and *Avena sativa* were the most sensitive species exhibiting inhibitions of 11% and 17%, respectively. Only the reduction with *Beta vulgaris* was statistically significant.

Conclusion:

Following a foliar application of Thiacloprid FS 400 g/L applied at 286 g product/ha (corresponding to 100 g a.s./ha nominal) to ten terrestrial plant species at the 2 to 4 leaf stage, no adverse effects on survival and shoot dry weight reaching or exceeding the 50% effect level were obtained in this vegetative vigour study.

CP 10.6.3 Extended laboratory studies on non-target plants

No additional studies were performed.

CP 10.6.4 Semi-field and field tests on non-target plants

No additional studies were performed.

CP 10.7 Effects on other terrestrial organisms (flora and fauna)

Please refer to KCP 10.6.

CP 10.8 Monitoring data

No monitoring data are available.

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