Background

In de Tweede Kamer is op 17 februari 2011 motie 19 aangenomen. Deze motie betreft de herbeoordeling van bestrijdingsmiddelen op basis van neonicotinoïden voor het onderdeel (subletale) effecten op bijen. Dit document is een concept beoordeling van het risico voor bijen van momenteel in Nederland toegelaten middelen op basis van thiamethoxam. Deze concept beoordeling is geen standpunt van het College. Om de zorgvuldigheid van het herbeoordelingtraject te borgen, krijgt de toelatinghouder de gelegenheid om te reageren op de concept beoordeling. Mogelijk leidt dit tot wijziging van de voorlopige conclusies. De door Ctgb gesignaleerde vragen zijn paars gemarkeerd en de discussiepunten geel.

Gewasbeschermingsmiddelen op basis van thiamethoxam

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	toepassing	formulering	Toepassing(en)
12679	ACTARA	Syngenta Crop Protection B.V.	thiamethoxam 25%	Professioneel	Waterdispergeerbaar granulaat	Gewasbehandeling in aardappelen, bedekte teelt van knolenbolbloemgewassen, onbedekte en bedekte teelt van bloemisterij- en boomkwekerij gewassen en vaste planten; Grondbehandeling van aardappelen.
12913	CRUISER 350 FS	Syngenta Crop Protection B.V.	thiamethoxam 350G/L	Professioneel	Suspensieconcentraat voor zaadbehandeling	Zaadcoating in mais, erwten, peulen, kapucijners.
12863	CRUISER SB	Syngenta Crop Protection B.V.	thiamethoxam 600G/L	Professioneel	Suspensieconcentraat voor zaadbehandeling	Zaadcoating in bieten.
12852	CRUISER 70 WS	Syngenta Crop Protection B.V.	thiamethoxam 70%	Professioneel	Waterdispergeerbaar poeder voor vochtige zaadbehandeling	Zaadcoating in sla en andijvie.

Er zijn geen biociden toegelaten van Syngenta.

A. Plant protection products

Risk assessment is done in accordance with Chapter 2 of the RGB published in the Government Gazette (Staatscourant) 188 of 28 September 2007, including the update of 20 October 2009, which came into effect on 1 January 2010. The bee risk assessment is also

based on the most recent guidance document, which is EPPO 2010. This includes methodology to assess the risk from systemic substances.

A.1.1 Professional uses of plant protection products: spray treatments

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	toepassing	formulering	Toepassing(en)
12679	ACTARA	Syngenta Crop Protection B.V.	thiamethoxam 25%	Professioneel	Water dispergeerbaar granulaat	Gewasbehandeling in aardappelen, bedekte teelt van knol-en bolbloemgewassen, onbedekte en bedekte teelt van bloemisterij- en boomkwekerij gewassen en vaste planten; Grondbehandeling van aardappelen.

List of Endpoints Ecotoxicology

Thiamethoxam is placed on Annex I of 91/414/EEG since 02/2007 (2007/6/EC). In Commission Directive 2010/21/EU, the Inclusion Directive of thiamethoxam was amended with additional provisions to avoid accidents with seed treatments. The provisions relevant for honeybees are now as follows:

> "PART A
>
> Only uses as insecticide may be authorised.
>
> For the protection of non-target organisms, in particular honey bees, for use as seed treatment:
>
> - the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised,
>
> - adequate seed drilling equipment shall be used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.
>
> Member States shall ensure that:
>
> - the label of the treated seed includes the indication that the seeds were treated with thiamethoxam and sets out the risk mitigation measures provided for in the authorisation,
>
> - the conditions of the authorisation, in particular for spray applications, include, where appropriate, risk mitigation measures to protect honey bees,
>
> - monitoring programmes are initiated to verify the real exposure of honey bees to thiamethoxam in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.";

After inclusion in Annex I, the List of Endpoints was changed by the RMS, so that the most recent version is that of November 2007. However, no changes were made in the ecotox section. Therefore, the final List of Endpoints of thiamethoxam is used. Only the part relevant for the spray treatments is presented in this section. In the List of Endpoints in cursive text additional information and studies are included by Ctgb.

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

Acute oral toxicity	Technical a.s LD50 oral = 0.005 µg a.s/bee (*Apis mellifera*) Formulation (WG 25%) LD50 oral = 0.02 µg formulation/bee (*bombus terrestris*) CGA 322704: LD50 oral = 0.0168 µg/bee (*Apis mellifera*)

Acute contact toxicity	Technical a.s LD50 contact = 0.024 ug/bee (*Apis mellifera*) Formulation (WG 25%) LD50 contact = 0.11 μg formulation/bee (*bombus terrestris*) CGA 322704: LD50 oral = 0.0275 μg/bee

Field or semi-field tests
Toxicity in bees at proposed application rates; the toxicity is low at lower application rates.
Kleiner (1997): Toxicity of Actara 25 WG (0.8 and 0.2 kg formulation/ha, = *200 and 50 g a.s./ha*) to *Apis mellifera* under semi-field conditions. Application when bees were actively foraging *on flowering Phacelia*. High mortality in both treatments;secondary effects and reduction of foraging activity. *Observation for 10 and 7 days, respectively.*
Nengel (1998a): Semi-field test with Actara 25 WG on *Apis mellifera.* 1 and 5 g ai/ha. Application during bee flight and in the evening, *on flowering Phacelia*. Slight increase in mortality at 5 g ai/ha in both application times.Slight decrease of the flight intensity at all doses during the following application day. Symptoms of poisoning at 5 g ai/ha. No effects on the brood development *(last check 27 DAT)*.
Nengel (1997): Field test of Actara 25 WG (100 g ai/ha) on *Apis mellifera.* Application in a prebloom stage of the orchard. *The high volume of flowering plants on the ground ensured exposure of the bees was highly likely.* Application at the morning *when bees were actively foraging*. Symptoms of poisoning 25 minutes after application. *Mortality was increased with peaks on day 3, 4, 6 and 7 after application (checked for up to 19 days after application).* From 3-days post-application onwards, newly emerged workers were found dead *which indicates that contaminated pollen was brought to the hives and killed new emerging workers*. No effects on the colonies strength and the bee brood development (*checked for 34 days*). *During the observation time, flight activity in the blooming groundcover was low (lower than in the blooming crops on adjacent fields).*
Nengel (1997b): Field test of Actara 25 WG (100 g ai/ha) on *Apis mellifera.* Application after flowering of the apple trees and when bees are actively foraging. Groundcover was mulched. No acute intoxication of adult bees. No abnormal decrease of the colonies strength and bee brood.
Mayer (1998): Field investigations of mitigation methods for Actara 25 WG in apple orchards. Application at the pre-pink *(seven days before first bloom)* and the pink stage *(four days before first bloom)* at 60 g ai/ha. Groundcover was mulched. *Bees were introduced in the orchards seven to eleven hours after application.* No abnormal mortality. The application of Actara did not reduce both the number of foraging or the hive strength. *All parameters were checked for 18 days, until first petal fall.*
Nengel (1998 b): Field test to assess the side effects of Actara on *Apis mellifera* in applications after flowering. Application rate 75 g ai/ha. Morning application. No mulching groundcover. No effects of intoxication (*checked for 14 days after application)* or effects in colonies strength and bee brood development *(checked for 31 days after application)*. Thus, Actara applied to apple orchards after blooming with flowering groundcover at 75 g ai/ha was found to be not hazardous to bees.
Nengel (1998 c): Field test to assess the side effects of Actara on *Apis mellifera* after application on broad beans.100 g ai/ha applied in the morning during full flowering. No control included. Mortality slightly higher than before treatment but within a normal range *(checked up to 7 days after application)*. No alterations in behaviour, colonies strength or bee brood *(checked up to 26 days after application)*. Pollen collected indicated that the bees visited different flowers in the surrounding of the area. *The number of bees observed visiting the flowers of the broad beans very low during the whole evaluation period.*
Barth (2000): Field study to assess the side effects of Actara on honeybee in pome fruits orchards after application during bee-flight. 2 X 400 g formulation/ha; 7-days interval between application. *Weeds were mulched. Flight intensity in the treated plots was low. Mortality and behaviour checked for 21 days after application.* No behavioral impacts. Number of dead bees slightly higher compared to the control *but these* differences were

observed before and after application of test substance. No effects on brood development (*checked for 8 weeks after application)*.

Summary of additional, non-guideline studies
Additional studies were conducted in order to further evaluate the effect of oral exposure to thiamethoxam and the metabolite CGA 322704 on the behaviour of honey bees.

Tests to determine the return flight ability of honey bees
Thiamethoxam, fed to hungry forager bees at 50 µg/kg sucrose solution (mean consumed dose of 5.6 ng ai/bee) and 100 µg/kg sucrose solution (mean consumed dose of 13.6 ng ai/bee), affected the ability of bees to return to their hives (von der Ohe, 2001a). The highest concentration tested that did not significantly affect return flight ability was 25 µg/kg sucrose solution (equivalent to 3.0 ng thiamethoxam/bee).
Since the no effect dose is very close to the oral LD50 from the acute toxicity study (5 ng/bee, test duration 48 h), it is assumed that the ingested syrup has not been digested before the bees return to the hive after a 500 m flight for 1 hour. In the field, foragers would consume approximately 150 µL nectar at 40% sugar for a 5 hours flight. Therefore, at 25 µg as/kg, the ingested dose of 100 µL 50% sucrose solution would be digested after a 3 hours flight. It is expected that the no effect dose will depend on the distance to hive and the consumption of nectar during the flight. For distances up to 500 m, the no effect dose is 3 ng as/bee of which 1/3 might have been consumed during flight.

The ability of forager honey bees to return to their hives was affected following oral exposure to metabolite CGA 322704 at concentrations of 50 µg/kg sucrose solution (equivalent to 1.7 ng CGA322704/bee) and 100 µg/kg sucrose solution (3.1 ng/bee) (von der Ohe, 2001b). The highest concentration that did not significantly influence flight ability was 25 µg/kg sucrose solution (mean consumed dose 0.8 ng/bee).
The no effect dose is significantly below the oral LD50 (16.8 ng/bee). However, it is assumed that this ingested dose is not completely consumed after a 500 m flight distance (see study with parent).

Tests to determine feed consumption and trophalactic interactions of bees
Thiamethoxam was provided in feed in laboratory studies at up to 100 µg/kg sucrose solution (mean consumed dose of 5.0 ng ai/bee). After 4 hours, no lethal effects were noted. No effects were observed on feed consumption or feed exchange between fed and hungry bees (von der Ohe, 2001a). Since the no effect dose in this study is equal to the oral LD50 from the acute toxicity study (also 5 ng/bee, test duration 48 h), it is assumed that the ingested syrup has not been completely digested during this test.
Consumption of the metabolite CGA 322704 by adult honey bees at concentrations of up to 100 µg/kg sucrose solution (mean consumed dose of 2.8 ng/bee) did not affect their survival, feed consumption or feed exchange with unfed bees (von der Ohe, 2001b). The no effect dose is significantly below the oral LD50 (16.8 ng/bee). However, it is assumed that this ingested dose is not completely consumed during the test (see study with parent).

Chronic exposure in the laboratory
In a laboratory test, bees were provided with food containing thiamethoxam or the metabolite CGA 322704 at concentrations up to 10 µg/L for 10 hours each day for 10 days. Treatments did not affect the survival of the bees at any concentration tested (Belzunces, 2002). The maximum cumulative doses, which did not affect bee survival, were 1.845 ng thiamethoxam/bee and 1.892 ng CGA 322704/bee.

Chronic toxicity to Apis mellifera larvae
A laboratory study on bee larvae was performed with thiamethoxam technical a.s. according to

the method under development of Aupinel et al. (2005). Larvae were fed for six days. Test duration included subsequent pupation and emergence. Mortality was checked on day 7/8 (larvae mortality) and day 22 (pupae mortality). Results: NOEL 12.5 ppb, LOEL 25 ppb (Giffard, 2009). NB this study was evaluated by Anses, France for the Cruiser 350 dossier.

Actara is used in a number of crops:

I. Gewasbehandeling

a. in de teelt van consumptie-, zetmeel- en pootaardappelen
b. in de bedekte teelt van bloembol-, knol- en bolbloemgewassen
c. in de onbedekte teelt van bloemisterijgewassen, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei
d. in de bedekte teelt van bloemisterijgewassen
e. in de onbedekte teelt van boomkwekerijgewassen en vaste planten, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei
f. in de bedekte teelt van boomkwekerijgewassen en vaste planten

II. Grondbehandeling

a. ten behoeve van de teelt van consumptie-, zetmeel- en pootaardappelen

The application of Actara in outdoor grown ornamentals against white fly (high dose rate) is withdrawn by the applicant. This application will be included in the Actara label extension (20100903 UG).

7.4 Effects on bees

Direct exposure via spray

1) In-field risk

The risk assessment for bees is based on the ratio between the highest single application rate and toxicity endpoint (LD_{50} value). An overview of the risk of thiamethoxam at the proposed uses is given in Table E.1.

Table E.1 Risk for bees of thiamethoxam in-field

Use (Field/Glasshouse)	Application rate a.s. [g/ha]	LD_{50} [µg/bee]	HQ [Rate/LD_{50}]	Trigger value
Potatoes (ware, starch and seed) *(against aphids and Colorado beetle)* (F)	20	0.005	**4000**	50
Floriculture, tree nursery and perennials (G) *(against aphids)*	25	0.005	**5000**	50
Floriculture, tree nursery and perennials (G) *(against whitefly)*	100	0.005	**20000**	50
Floriculture, tree nursery and perennials (F) *(against aphids)*	25	0.005	**5000**	50
~~Floriculture, tree nursery and perennials (F) *(against whitefly)*~~	~~100~~	~~0.005~~	~~**20000**~~	~~50~~
Potato (seed) (F)	25	0.005	**5000**	50
Bulb flowers and flower bulbs (G)	25	0.005	**5000**	50

Table E.1 shows that since the ratio rate/LD_{50} is above 50, there is a potential high risk for bees for all uses.

To protect bees in glasshouses, restrictions should be included. Exposure to both introduced bees and bees flying into greenhouse from the outside should be avoided. With the appropiate restriction sentences (see below), the risk is considered to be acceptable for the glasshouse uses.

To refine the in-field risk for the field uses, the available semi-field and field studies at relevant dose rates will be considered.

In a cage test, application to Phacelia when bees were actively foraging caused high mortality, behavioural effects and highly reduced foraging activity at 50 and 200 g a.s./ha.

Five field tests were performed in apple orchards. There were variations in application timing (before, during or after flowering of the apple trees) and in presence of flowering weeds. Colony strength and brood development were never affected (tested for ca. 3-5 wks).
Two tests were done when the apple trees were in the pre-flowering stage. Application during bee flight but in the presence of flowering weeds at 100 g a.s./ha leads to increased mortality. When flowering weeds were removed and bees were not present in the orchard until seven to eleven hours after treatment, application of 60 g a.s./ha seven or four days before flowering of the apple trees did not cause abnormal mortality of reduction of foraging activity before and during subsequent flowering of the trees.
In a field trial during bee flight but designed for low attraction of the treated area, by applying 100 g a.s./ha after flowering of the crop and mulching flowering weeds, no adverse effects on mortality and foraging effects were seen. The same was found in a post-flowering trial in which flowering weeds were still present. Treatment rate was 75 g a.s./ha and application was done in the morning, so during bee flight, but it was not checked whether the bees were actually foraging on the flowering weeds in the treated orchard.
Lastly, a post-flowering trial at 2x 100 g a.s./ha (interval 7 days) was done without flowering weeds. This did not cause adverse effects.

One field trial was performed in a bean field. Application (100 g a.s./ha) was done at full flowering of the beans and during bee flight. No effects were found but foraging activity on the beans was very low during the whole evaluation period. The cause of this is unknown (e.g. low attractivity of the beans or presence of more attractive flowers nearby).

This assessment shows that the short-term risk of Actara to bees is acceptable for application rates up to 60 g a.s./ha, as long as application on flowering crops ánd flowering weeds is avoided and application is done at least 4 days before flowering. Spraying when bees are actively flying on a crop to collect honeydew should also be avoided. Therefore, the in-field risk of the field spray uses is acceptable, provided that risk mitigation measures are prescribed.

The following sentences must be included in the Statutory Instructions for Use:

Dit middel is gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn. Verwijder onkruid voordat het bloeit. Gebruik is wel toegestaan op bloeiende planten in de kas mits er geen bijen of hommels in de kas actief naar voedsel zoeken. Voorkom dat bijen en andere bestuivende insecten de kas binnenkomen door bijvoorbeeld alle openingen met insectengaas af te sluiten.

Also, crop-specific restrictions in application timing should be included:

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel als
I. Gewasbehandeling
- in de onbedekte teelt van bloemisterijgewassen, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei
- in de onbedekte teelt van boomkwekerijgewassen en vaste planten, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei

With these restrictions, it is expected that there the period between application and flowering is at least 4 days, which is the period tested to be safe at 60 g a.s./ha. Therefore, these provisions cover the risk of the low dose in ~~in~~ tree nursery and floristry crops (25 g a.s./ha, against aphids) and potatoes (20 g a.s./ha). ~~but not the high dose (100 g a.s./ha, against whitefly). For the field use in floriculture, tree nursery and perennials against whitefly, the applicant is requested to provide more information to show that the proposed restrictions in application timing will indeed not lead to a risk to bees, e.g. by providing support for the extrapolation of the field trial at 60 g a.s./ha to the proposed dose rate at 100 g a.s./ha.~~

2) Off-field risk
Considering the toxicity of the a.s., also an off-field risk assessment is performed. The drift rate used is the same as for the evaluation of non-target arthropods. This is 10% for field uses and maximally 6.3% for high tree nursery crops. Glasshouse uses and soil treatments do not cause drift exposure to off-field. See Table E.2.

Table E.2 Risk for bees of thiamethoxam off-field

Use (Field / Glasshouse)	Application rate a.s. [g/ha]	Drift %	Exposure [g/ha]	LD_{50} [µg/bee]	HQ [Rate/LD_{50}]	Trigger value
Potatoes (ware, starch and seed) *(against aphids and Colorado beetle)*	20	10%	2	0.005	**400**	50
Floriculture, tree nursery and perennials (G) *(against aphids)*	25	n.a.	0	0.005	n.a.	n.a.
Floriculture, tree nursery and perennials (G) *(against whitefly)*	100	n.a.	0	0.005	n.a.	n.a.
Floriculture, tree nursery and perennials (F) *(against aphids)*	25	10%	2.5	0.005	**500**	50
tree nursery: high trees (F) *(against aphids)*	25	6.3%	1.6	0.005	**315**	50
tree nursery: high trees (F) *(against whitefly)*	100	6.3%	6.3	0.005	**1260**	50
Potato (seed) soil treatment (F)	25	n.a.	0	0.005	n.a.	n.a.
Bulb flowers and flower bulbs (G)	25	n.a.	0	0.005	n.a.	n.a.

Table E.2 shows that there is a potential off-field risk for the field uses, except for the soil treatment of potatoes.

To refine the off-field risk for the field uses, the available higher tier studies will be discussed below to see if there is a dose rate at which no effects are expected. Note that the restriction sentences prescribed above are not targeted at protecting the off-field.

There is one cage test in which effects of low dose rates (1 and 5 g a.s./ha) were checked. At 5 g a.s./ha, mortality was slightly increased on the first day after application only (checked for 7 days), both when applied during and after bee flight. Also, behavioural effects and reduced foraging activity were seen. At 1 g a.s./ha, the only effect seen was a slight decrease of foraging activity on the first day after application. No effects on brood development and colony strength were found at both dose rates (checked until 27 days after treatment).

Based on the above, a dose rate of 1 g a.s./ha is considered to be an acceptable rate for spray drift. This rate can be achieved with drift reduction (based on reference 3 of Chapter 7 of the Evaluation Manual. Version 1.0, January 2010). See Table E.3 for the options for risk mitigation for the different uses. For all crops, the evaluation zone is 50-150 cm. Only the measures which are implemented in practice on a reasonable scale are proposed.
For high tree nursery crops, no default drift mitigation measures have been laid down in the Evaluation Manual. However, after consultation with PRI in April 2011 it was determined that the following measure can be used in high tree nursery to achieve a drift level below the required level of 1%: a 5 m spray free zone in the crop in combination with a 5 m zone outside the crop on which no flowering plants may be present. The 5 m spray free zone is based on Regeling the Lozingenbesluit Open Teelt en Veehouderij (LOTV). The 5 m flower free zone is based on calculations of PRI.

Table E.3 Required drift measures to reach acceptable risk for bees of thiamethoxam off-field

Use	Appl. rate [g/ha]	Maximum acceptable concen-tration [g/ha]	Required drift rate %	Available drift reducing measure
Potatoes (ware, starch and seed) *(against aphids and Colorado beetle)*	20	1	5%	Lage spuitboomhoogte (30 cm boven de top van het gewas) + driftarme spuitdop + kantdop; of Lage spuitboomhoogte (30 cm boven de top van het gewas) + driftarme Venturidop + kantdop; of Driftarme spuitdop + kantdop + luchtondersteuning
Floriculture, tree nursery and perennials (F) *(against aphids)* Except high trees	25	1	4%	Lage spuitboomhoogte (30 cm boven de top van het gewas) + driftarme spuitdop + kantdop; of Lage spuitboomhoogte (30 cm boven de top van het gewas) + driftarme Venturidop + kantdop; of Driftarme spuitdop + kantdop + luchtondersteuning
~~Floriculture, tree nursery and perennials (F) *(against whitefly)* Except high trees~~	~~100~~	~~1~~	~~1%~~	~~Lage spuitboomhoogte (30 cm boven de top van het gewas) + driftarme Venturidop + kantdop + luchtondersteuning.~~

Tree nursery (lane trees) *against aphids*	25	1	4%	5 m spray free zone in the crop in combination with a 5 m zone outside the crop on which no flowering plants may be present.
~~Tree nursery (lane trees) *(against whitefly)*~~	~~100~~	~~1~~	~~1%~~	~~5 m spray free zone in the crop in combination with a 5 m zone outside the crop on which no flowering plants may be present.~~

Table E.3 shows that for all uses, there are options available to reduce the exposure off-field to a level at which no effects are expected.

The following sentences should be added to the Statutory Instructions for use of Actara:

Om bijen te beschermen is toepassing van het middel uitsluitend toegestaan indien gebruik wordt gemaakt van één van de onderstaande driftreducerende maatregelen:

In aardappels:
- *conventionele spuitmachine met een lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met een driftarme spuitdop en een kantdop; of*
- *conventionele spuitmachine met een lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met een driftarme Venturidop en een kantdop; of*
- *conventionele spuitmachine met een driftarme spuitdop en een kantdop in combinatie met luchtondersteuning.*

In bloemisterijgewassen, boomkwekerijgewassen en vaste planten (tegen luis), met uitzondering van laanbomen:
- *conventionele spuitmachine met een lage spuitboomhoogte (30 cm boven de top van het gewas) in combinatie met een driftarme spuitdop en een kantdop; of*
- *conventionele spuitmachine met een lage spuitboomhoogte (30 cm boven de top van het gewas) en een driftarme Venturidop + kantdop; of*
- *conventionele spuitmachine met een driftarme spuitdop en een kantdop in combinatie met luchtondersteuning.*

~~*In bloemisterijgewassen, boomkwekerijgewassen en vaste planten (tegen witte vlieg), met uitzondering van laanbomen:*~~

~~*conventionele spuitmachine met een lage spuitboomhoogte (30 cm boven de top van het gewas) en een driftarme Venturidop + kantdop, in combinatie met luchtondersteuning.*~~

In boomkwekerijgewassen (laanbomen):

Het middel in de onbedekte teelt van hoge boomkwekerijgewassen niet toepassen in de buitenste 5 meter van het gewas; daarnaast dienen op een strook van 5 meter vanaf het midden van de laatste bomenrij geen bloeiende planten aanwezig te zijn.

With these restrictions, the risk to bees from direct exposure in the off-field area is expected to be acceptable.

Indirect exposure via systemic working mechanism

Nectar and pollen of the crop

Thiamethoxam is a systemic substance. It has many applications as seed treatment, where the substance and its metabolites are taken up by the plant and distributed to (among other plant parts) nectar and pollen. This may lead to a risk from flowering crops. It is not known how well the substance is taken up by the plant when it is sprayed. No residue data are available for spraying applications (in contrast to seed treatments), but due to the persistent nature of the a.s., it has to be investigated whether bees would still be at risk if they fly on crops which flower after spray application.
Spraying on crops in the pre-flowering stage was investigated in one of the field trials. This trial, in an apple orchard, showed that if spraying is done four days before the apple flowers open and bees are present in the following flowering period to forage on these open flowers, no direct adverse effects on bees occur. This was tested for an application rate of 60 g a.s./ha and effects were monitored up to 18 days after application.
For the other trial in which application was done pre-flowering, effects were seen, but no conclusions can be drawn from this since flowering weeds were present during spraying.

Based on this, no short-term adverse effects on adult bees are expected from the proposed field applications of Actara in floriculture, tree nursery and perennials against aphids, and in the spray treatment of potatoes with application rate below 60 g a s./ha. ~~The use against whitefly has a dose rate of 100 g a.s./ha and is not covered by the field trial. For the use in floriculture, tree nursery and perennials against whitefly, the applicant is requested to provide more information to show that the short-term risk via nectar and pollen of the crop is low.~~

Considering longer-term effects, laboratory studies are available for thiamethoxam which provide NOEC values for chronic mortality and behavioural effects. However, residue data in plant matrices relevant for the proposed uses of Actara are lacking, so these NOEC values cannot be compared with relevant exposure values for Actara.
In the spray field studies, colony effects were monitored for a period of at most eight weeks. Overwintering was not studied. For the seed treatment uses (see below), long-term effects have been studied for up to four years in monitoring trials. It is not known however, how relevant these trials are for the exposure level expected after the spray treatments of Actara.
The applicant proposes to restrict the application of Actara for outdoor uses to "after flowering only":

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel als
I. Gewasbehandeling
- in de teelt van consumptie-, zetmeel- en pootaardappelen, met dien verstande dat toepassing alleen is toegestaan na de bloei
- in de onbedekte teelt van bloemisterijgewassen, met dien verstande dat toepassing alleen is toegestaan na de bloei
- in de onbedekte teelt van boomkwekerijgewassen en vaste planten, met dien verstande dat toepassing alleen is toegestaan na de bloei

The applications that are withdrawn now will be included in the Actara label extension (20100903 UG).
~~Therefore, the applicant is requested to address the long-term effects of thiamethoxam for all field uses of Actara.~~

Potatoes flower during cultivation, but honeybees do not fly on potato flowers. Hence, the risk from this route of exposure is low for honeybees. There are however indications that bumblebees may fly on potato flowers to collect pollen (*pers.comm. bijen@wur)*.
Thiamethoxam is of the same toxicity to bumblebees and honeybees (see LoE). Since the dose rate in the potato uses are covered by the dose rate tested in the honeybee field studies, the risk to bumblebees is considered to be acceptable.

Nectar and pollen of weeds

It is stated on the label that application is not allowed when flowering weeds are present and that weeds should be removed before flowering:

Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn. Verwijder onkruid voordat het bloeit.

The exposure of bees to flowering weeds can therefore be excluded.
~~. Weeds may flower after application and then contain the a.s. or metabolites. This risk is considered to be covered for dose rates up to 60 g a.s./ha based on a spray field trial (see above). Flowering weeds are not expected to occur in large numbers in most crops, because this would be adverse to good and profitable agricultural practice. However, part of the tree nursery/floriculture/perennial crops may have a more permanent character and in such cases, flowering weeds may be more common. Therefore, for the use in floriculture, tree nursery and perennials against whitefly, the applicant is requested to provide more information to show that the risk via nectar and pollen of flowering weeds is low.~~

Nectar and pollen in succeeding crops
Thiamethoxam is persistent in soil. It has been shown that after use of the substance as seed treatment, residues of thiamethoxam and metabolite CGA322704 were found in nectar and pollen of succeeding crops. For the seed treatments, an additional question is asked to address the risk of succeeding crops (see below). This question is also relevant for Actara. It is noted that the French authorisation agency Anses have already evaluated this point for the use of Actara. They used the rotational crop studies in which thiamethoxam and 322 levels were measured in green parts of untreated crops following a bare soil application with 200 g/ha thiamethoxam (crops drilled 29, 104, 119 and 180 days after a soil application of the product). The concentrations in green parts can be considered as worst case compared to the concentrations that could be found in nectar and pollen (ICPBR, 2009). The mean concentrations of thiamethoxam (residue definition is thiamethoxam + CGA322704 expressed as thiamethoxam) are 0.0034, 0.0014 and 0.00017 mg/kg at 29, 104 and 119 days after treatment (the concentrations are recalculated for a dose rate of 38 g/ha which is considered to be the maximum dose rate reaching the soil after interception of the crop). These concentrations were compared to the LD50 of 5 ng/be and the subchronic 10-days NOEL of 0.2 ng/bee/day. The concentrations in the plant do not exceed the concentrations that are needed to reach the LD50. At day 29 the concentrations in the plants succeeded the concentrations needed to reach the NOEL. At day 104, 119 and 180 only a single exceedance was seen for pollinators consuming extreme high amounts of nectar. This will not affect the development of a bee colony because of the large size of the bee colonies. It was therefore proposed to add the following warning to the label: Do not sow a for bee attractive culture less that 3,5 month after a culture that was treated with thiamethoxam.

The concentrations in the soil 3 months after application with Actara are shown in the attached table. These concentrations correspond with the concentrations found in the seed treatment studies (see the assessment for seed treatment below). This confirms that a 3,5 months period as proposed by ANSES is acceptable to reduce the risk for bees.

It is proposed to add the following warning to the label:

In verband met het risico voor bijen mogen binnen 3,5 maand na toepassing van Actara geen voor bijen aantrekkelijke gewassen worden gezaaid.

~~prohibitied attractive succeeding crops for 3.5 months after use of Actara, but it is unclear how this value was derived.~~
~~The applicant is requested to address the risk of bee-attractive succeeding crops of the field uses of Actara.~~

Honeydew
Bees may forage on honeydew, which is produced by aphids. Spray exposure of bees actively foraging on honeydew is excluded by the restriction sentence. Aphids may take up thiamethoxam and metabolites from the plant also after spraying due to the systemic properties. According to the EPPO scheme, exposure to contaminated honeydew is not considered relevant in the case of soil and seed treatments, unless the compound is highly selective towards non-aphid insects (see note 4 EPPO scheme; it is assumed that in most cases aphids will be killed by the a.s. (i.e. honey dew exposure can be excluded)). The relative sensitivity of aphids compared to bees for thiamethoxam is not known so this expectation cannot be confirmed. However, since the label of Actara indicates that treatment should be done as soon as the first aphids are seen, occurrence of aphids is expected to be low in these crops. Hence, this risk is considered to be low.

Guttation
For thiamethoxam, a trial in maize and oilseed rape indicated that although guttation does occur after seed treatment, the risk to bees via this route is expected to be low. These findings were confirmed in studies with other active substances. Furthermore, due to dangers (e.g. presence of predators) bees are not keen on foraging on plants unless there is a considerable reward (pollen, nectar). Therefore, drinking droplets from plants is not likely to occur in the field (personal communication from a professional beekeeper, 5.1.2.e .
Lastly, it is good beekeeping practice to provide honeybees with sufficient water.
Taking all the available information into account Ctgb expects a low risk to honeybees from guttation.

A.1.2 Professional uses of plant protection products: seed treatments

List of Endpoints Ecotoxicology
After inclusion in Annex I, the List of Endpoints was changed by the RMS, so that the most recent version is that of November 2007. However, no changes were made in the ecotox section. Therefore, the final List of Endpoints of thiamethoxam is used. Only the part relevant for the seed treatments is presented in this section. In the List of Endpoints in cursive text additional information and studies are included by Ctgb.

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

Acute oral toxicity	Technical a.s LD50 oral = 0.005 µg a.s/bee (*Apis mellife* Formulation (WG 25%) LD50 oral = 0.02 µg formulation/ CGA 322704: LD50 oral = 0.0168 µg/bee (*Apis mellifera*
Acute contact toxicity	Technical a.s LD50 contact = 0.024 ug/bee (*Apis mellif* Formulation (WG 25%) LD50 contact = 0.11 µg formulat CGA 322704: LD50 oral = 0.0275 µg/bee

Field or semi-field tests
Nengel (1998): Semi-field test with Cruiser 70 WS on *Apis mellifera.* 350 g/100 kg seed. N differences in mortality, flight activity, duration of the bees visits to flowers between control and exposed field. No abnormal behaviour of the bees. *Addition Ctgb: This study considered a seed treatment of oilseed rape and was performed during flowering. Dose ra in this study is calculated as follows: 1200 ml/100 kg = 840 g/100 kg seed, 14.5 kg seed/ha yields 122 g a.s./ha.*

Risk to honeybees – additional studies aimed at seed treatment

In the DAR, the assessment was focussed on the spray treatment of thiamethoxam. Therefore, the LoE mainly contains (semi-)field studies with the spray formulation Actara. However, Syngenta also performed studies relevant for the applications as seed treatment. A large package with additional studies was submitted to Ctgb in 2003 (Ctgb report C-M-01). The studies are discussed below.

Cage tests

Summary of cage tests conducted with thiamethoxam seed treatment formulations.

Formulation	*Crop*	*Equivalent field rates (g ai/ha)*	*Reference*
CRUISER 70 WS	*Oilseed rape*	*33.6 to 268.8*	***Schur (2001a)***
CRUISER 350 FS	*Oilseed rape*	*60.9*	***Nengel (1998)***

In the cage test by Nengel (1998), honey bees were exposed to flowering oilseed rape grown from seeds dressed with CRUISER 350 FS (A-9700 B) at 1.2 L/100 kg seed (420 g ai/100 kg seed) and sown at a rate of 14.5 kg seed/ha (equivalent to 60.9 g ai/ha). Observation period was 7 days (28 d for brood). This treatment did not have any effect on mortality, flight activity or foraging behaviour. Furthermore, treatment did not affect the duration of bee visits to flowers, the egg-laying rate of the queen or bee brood development. Plants were not sampled for residue analysis in this study.

In a second cage test, bees were exposed to spring oilseed rape grown from seed dressed with CRUISER 70 WS (A-9567 B) at rates equivalent to 33.6, 67.2, 100.8, 134.4, 201.6 and 268.8 g ai/ha when sown at a rate of 8 kg seeds/ha (Schur, 2001a). Observation period was 12 days (3 weeks for brood, last assessment made 1 week after hives were removed from the cages). Exposure to plants grown from CRUISER-treated seed did not have any effect on mortality, behaviour or brood development. Foraging activity was reduced following exposure to OSR treated with 268.8 g ai/ha but was not affected or was slightly stimulated by exposure to rates up to and including 210.6 g ai/ha.

Tunnel tests

Summary of tunnel tests conducted with thiamethoxam seed treatment formulations.

Formulation	*Crop*	*Equivalent field rates (g ai/ha)*	*Reference*
CRUISER 70 WS	*Sunflowers*	*26.25 and 52.5*	***Barnavon (1999)***
	Sunflowers	*25.9*	***Barnavon (2001)***
	Sunflowers	*26.25*	***Schur (2001b)***

In a tunnel test by Barnavon (1999), honey bees were exposed to flowering sunflowers grown from seeds treated with CRUISER 70 WS at 350 g and 700 g ai/100 kg seed (equivalent to 26.25 g and 52.5 g ai/ha). Exposure to CRUISER-treated sunflowers did not have any significant effect on mortality, foraging activity in treated or refuge zones, flight intensity or behaviour relative to the control. Similarly, there were no adverse effects reported following exposure to the reference product 'Gaucho' applied at 1050 g ai/100 kg seed (NB this study was also evaluated in the DAR, but for unknown reasons not included in the LoE).

In a second tunnel test by Barnavon (2001), honey bees were exposed to flowering sunflowers grown from seeds dressed with CRUISER 70 WS applied at 0.5 kg product/100 kg seed (350 g ai/100 kg seed) and sown at 7.4 kg seed/ha (equivalent to 25.9 g ai/ha). Observation period 11 days. Exposure to CRUISER-treated sunflowers did not affect mortality, foraging activity, duration of flower visits, behaviour or colony condition. It was noted that there was a high level of base mortality in all treatments and controls.

In a tunnel test conducted in Spain, honey bees were exposed to flowering sunflowers, grown from seeds dressed with CRUISER 70 WS at 0.5 kg product/100 kg seed (350 g ai/100 kg seed) and sown at 7.5 kg seed/ha (equivalent to 26.25 g ai/ha) (Schur, 2001b). Observation period was 7 days (12 d for brood). The mean bee mortality was significantly higher 3 days after exposure to the test item than in the control, but still low (maximum of 18.7 bees/colony/day compared to 8 in the control). On the following days treatment mortality was lower than or equal to control mortality. Brood development and bee behaviour were not influenced by exposure to thiamethoxam.

Field tests

Summary of field studies conducted with thiamethoxam seed treatment formulations.

Formulation	*Crop*	*Equivalent field rates (g ai/ha)*	*Reference*
CRUISER 70 WS	*Oilseed rape*	*25.0*	***Schuld (2001a)***
	Oilseed rape	*29.4*	***Schuld (2001b)***
	Sunflower	*26.25*	***Balluff (2001)***
	Sunflower	*22.8*	***Schur (2001c)***
CRUISER 350 FS	*Sunflower*	*18.7*	***Szentes (2001a)***
	Sunflower	*17.0*	***Szentes (2001b)***
CRUISER OSR	*Oilseed rape*	*34.0*	***Barth (2001)***
	Oilseed rape	*18.0*	***Schur (2001d)***
	Oilseed rape	*17.0*	***Schur (2001e)***
'HELIX' 289 FS	*Oilseed rape*	*29.4*	***Purdy (2000)***

1. *In two field trials conducted by Schuld (2001a, b), honey bee colonies were exposed to flowering oilseed rape grown from seeds dressed with CRUISER 70 WS at 420 g ai/100 kg seeds with sowing rates of 5.94 kg and 7.0 kg seeds/ha (equivalent to 25.0 and 29.4 g ai /ha). Observation period was 9 days (ca. 40 d for brood). These trials indicated no treatment-related increases in honey bee mortality, with mortality in the treatment areas being similar to that in the control treatment. The only increase in mortality was observed on days 5 and 6 in one of these studies and was believed to be due to robbery by outside bees in one of the test item colonies (Schuld, 2001a). There were no effects on bee foraging activity, behaviour of the bees, colony strength, egg laying of the queen or bee brood development. However, it should be noted that due to the different test schedules of the control and test item treatments in one of these studies (Schuld, 2001b), direct comparisons between the treatment groups are not possible.*

2. *Balluff (2001) carried out a field trial in which honey bee colonies were exposed for 16 days in a flowering sunflower field. The sunflowers were grown from seeds dressed with CRUISER 70 WS at 0.5 kg product/100 kg seeds (nominally 350 g thiamethoxam/100 kg seeds) with a sowing rate of 7.5 kg seeds/ha (equivalent to 26.25 g ai/ha). Observation period was 16 days (48 d for brood). The level of bee mortality was generally low and within the range found in the control field (average mortality 8.1, 2.8 and 2.1 dead bees/colony/d in the treatment group, control and reference item (Gaucho), respectively). A higher number of dead bees in the dead bee traps and in front of the hives were observed in the thiamethoxam treatment group between days 5 and 7 after hive introductions. However, this was believed to be a consequence of higher foraging activity in this treatment group on these days. On the other days of the exposure period only negligible differences were observed in the foraging activity between the different treatments (the foraging rates were low, with 0.6 bees/m^2 in the treated field and 0.4 bees/m^2 in the control field). No test item related effects were observed during the study on the behaviour of the bees, the strengths of the colonies, egg laying of the queen or bee brood development. The pollen analysis showed that there were 10 times as many exposed*

experimental bees in treated colonies than in control ones.

3. *In another trial by Schur (2001c), honey bee colonies were exposed to flowering sunflowers grown from seeds dressed with CRUISER 70 WS at 0.5 kg/100 kg seeds (nominally 350 g thiamethoxam/100 kg seeds) with a sowing rate of 6.52 kg seeds/ha (equivalent to 22.8 g ai/ha). Observation period was 8 days (39 d for brood). No treatment-related differences in the number of dead bees in and around the hives were observed between 3 and 6 days after initiation of exposure. On days 7 and 8, higher numbers of dead bees were found in the dead bee traps and in front of hives in the thiamethoxam treatment group than in the controls (62.7 vs. 5.7 dead bees/colony on day 7). Only negligible differences were observed between the test item and control treatment with regard to the flight intensity of the bees over the crop (12 bees/25 plants in treated fields, 9 bees/25 plants in control fields). This cannot explain the increased mortality in the treatment group on day 7. Mortality decreased after day 8, but treatment mortality remained slightly higher than control mortality (18.7 vs. 9 dead bees/colony. Average mortality over the 8-d observation period was comparable in treatment and control (16.9 vs 15.3 dead bees/colony/d). Considering the overall low mortality and the fact that the average mortality over the test period was not increased, mortality is not considered to be treatment related.*
   No treatment-related effects were noted on the behaviour of the bees, colony strength or bee brood development. The exposure of bees assessed by pollen analysis showed that 22% of bees foraged in the treated field compared to 17% in the control field.

4. *In two field trials by Szentes (2001a, b), honey bee colonies were exposed to sunflowers grown from seed treated with CRUISER 350 FS at rate of 0.120 L product/150,000 sunflower seeds (equivalent to 368 and 339 g ai/100 kg seeds) and a sowing rate of 66 667 and 63 200 seeds/ha, respectively (giving 18.7 and 17.0 g ai/ha). Observation period was 11/10 days (14/12 d for brood, which is not long enough for adequate evaluation). The treatment was found to be harmless to the bees regarding foraging activity and behaviour. Bee colonies and nectar collection were also unaffected. In one trial (Szentes 2001a), mortality was higher in the treatment group (147.8 dead bees/colony/d in the treatment vs. 27.8 in the control). This was caused by a high level of mortality of worker bees (in this study considered to be >100 dead bees/colony/d) in two of the six test hives on day 7. This was considered to be not treatment-related by the author, but a result of an insect-control treatment on one of the melon fields nearby. At other days those two hives, in the other four hives in this trial and at all days in all hives during the other trial (Szentes 2001b), mortality was low and not different between treatment and control. Therefore, the explanation is accepted and the observed mortality is not attributed to the treatment. Though exposure of bees by microscopic pollen analysis was not done, it was estimated that 20%of the bees collected pollens from the treated field, 16 and 40% from the control fields.*

5. *In a field study conducted by Barth (2001), honey bee colonies were exposed for 21 or 22 days to flowering oilseed rape, grown from seeds dressed with CRUISER OSR at a rate equivalent to 34 g thiamethoxam/ha (the product also contains fludioxonil and metalaxyl-M). Observation period was 17 days (49 d for brood). No test-item related effects were noted on bee survival, foraging, pollen collection, brood development or hive weights.*

6. *In a field study by Schur (2001d), honey bee colonies were exposed for 13 days to winter oilseed rape grown from seed treated with CRUISER OSR at a rate equivalent to 18 g thiamethoxam/ha (the product also contains fludioxonil and metalaxyl-M). Observation period was 8 days (49 d for brood). Low mortality was observed in and around hives within the CRUISER-treated field, but it was higher than that observed in the control treatment (13.3-35.7 vs. 1.7-8.3 dead bees/colony/d). However, flight activity was also markedly higher in the field treated with CRUISER OSR. Thus, increased mortality may be a consequence of increased foraging activity. Exposure to the treatment did not affect colony strength, egg*

laying of the queen or bee brood development.

7. *In a further field study by Schur (2001e), bees were exposed for 31 days to a flowering rape crop grown from seeds treated with CRUISER OSR at 1.5 L/100 kg seeds and sown at 4.0 kg seeds/ha (equivalent to 17 g thiamethoxam/ha, the product also contains fludioxonil and metalaxyl-M). Observation period was 31 d for mortality, 20 d for flight intensity and behaviour and 22 d for brood. No increases in bee mortality related to the test item were observed. On some days an increase in the mean mortality was observed in the control as well as the test item. However, the dead bees appeared to have succumbed to a fungal infection. Exposure to CRUISER-treated rape flowers did not affect foraging activity, behaviour, colony strengths, egg laying of the queen, bee brood development, nectar collection or hive weight. No samples were taken for residue measurements.*

8. *In a field trial by Purdy (2000), honey bee colonies were exposed for 15 or 17 days to oilseed rape grown from seeds dressed with 'HELIX' 289 FS at 1.5 L/100 kg seeds (403.5 g thiamethoxam/100 kg seed; the product also contains difeconazole, fludioxonil and metalaxyl-M) with a sowing rate of 6.5-7.28 kg seeds/ha (equivalent to 26.2 and 29.4 g ai/ha). Observation period was 21 days for all parameters. Thiamethoxam treatment did not cause any adverse effects on bee survival, foraging, brood development or hive weights. Bees did not show signs of repellence from the treated crop.*

Summary of additional, non-guideline studies

Additional studies were conducted in order to further evaluate the effect of oral exposure to thiamethoxam and the metabolite CGA 322704 on the behaviour of honey bees.

Tests to determine the return flight ability of honey bees
Thiamethoxam, fed to hungry forager bees at 50 µg/kg sucrose solution (mean consumed dose of 5.6 ng ai/bee) and 100 µg/kg sucrose solution (mean consumed dose of 13.6 ng ai/bee), affected the ability of bees to return to their hives (von der Ohe, 2001a). The highest concentration tested that did not significantly affect return flight ability was 25 µg/kg sucrose solution (equivalent to 3.0 ng thiamethoxam/bee).
Since tthe no effect dose is very close to the oral LD50 from the acute toxicity study (5 ng/bee, test duration 48 h), it is assumed that the ingested syrup has not been digested before the bees return to the hive after a 500 m flight for 1 hour. In the field, foragers would consume approximately 150 µL nectar at 40% sugar for a 5 hours flight. Therefore, at 25 µg as/kg, the ingested dose of 100 µL 50% sucrose solution would be digested after a 3 hours flight. It is expected that the no effect dose will depend on the distance to hive and the consumption of nectar during the flight. For distances up to 500 m, the no effect dose is 3 ng as/bee of which 1/3 might have been consumed during flight.

The ability of forager honey bees to return to their hives was affected following oral exposure to metabolite CGA 322704 at concentrations of 50 µg/kg sucrose solution (equivalent to 1.7 ng CGA322704/bee) and 100 µg/kg sucrose solution (3.1 ng/bee) (von der Ohe, 2001b). The highest concentration that did not significantly influence flight ability was 25 µg/kg sucrose solution (mean consumed dose 0.8 ng/bee).
The no effect dose is significantly below the oral LD50 (16.8 ng/bee). However, it is assumed that this ingested dose is not completely consumed after a 500 m flight distance (see study with parent).

Tests to determine feed consumption and trophalactic interactions of bees
Thiamethoxam was provided in feed in laboratory studies at up to 100 µg/kg sucrose solution (mean consumed dose of 5.0 ng ai/bee). After 4 hours, no lethal effects were noted. No effects were observed on feed consumption or feed exchange between fed and hungry bees (von der

Ohe, 2001a). Since the no effect dose in this study is equal to the oral LD50 from the acute toxicity study (also 5 ng/bee, test duration 48 h), it is assumed that the ingested syrup has not been completely digested during this test.
Consumption of the metabolite CGA 322704 by adult honey bees at concentrations of up to 100 µg/kg sucrose solution (mean consumed dose of 2.8 ng/bee) did not affect their survival, feed consumption or feed exchange with unfed bees (von der Ohe, 2001b). The no effect dose is significantly below the oral LD50 (16.8 ng/bee). However, it is assumed that this ingested dose is not completely consumed during the test (see study with parent).

Chronic exposure in the laboratory
In a laboratory test, bees were provided with food containing thiamethoxam or the metabolite CGA 322704 at concentrations up to 10 µg/L for 10 hours each day for 10 days. Treatments did not affect the survival of the bees at any concentration tested (Belzunces, 2002). The maximum cumulative doses, which did not affect bee survival, were 1.845 ng thiamethoxam/bee and 1.892 ng CGA 322704/bee.

Chronic toxicity to Apis mellifera larvae
A laboratory study on bee larvae was performed with thiamethoxam technical a.s. according to the method under development of Aupinel et al. (2005). Larvae were fed for six days. Test duration included subsequent pupation and emergence. Mortality was checked on day 7/8 (larvae mortality) and day 22 (pupae mortality). Results: NOEL 12.5 ppb, LOEL 25 ppb (Giffard, 2009). NB this study was evaluated by Anses, France for the Cruiser 350 dossier.

Observations on foraging activity in the field
In a field test by Mühlen (1999), foraging activity was measured using a BeeSCAN monitoring device (a precision scanner at the hive entrance which measures flight activity) following exposure to flowering oilseed rape grown from seeds treated with CRUISER 70 WS at 4.32 g ai/kg and sown at 5.94 kg seed/ha (equivalent to 25.66 g ai/ha). Observation period was 7 days (28 d for brood). Treatment did not have any adverse effect on mortality, flight activity, behaviour or colony size. The short stay of forager bees on flowers in control and treated fields, combined with the hive weight data, suggested a relatively low nectar flow on both fields. All colonies at both the control and CRUISER 70 WS fields developed normally, consistent with the seasonal patterns, and contained all stages of brood. It should be noted that the BeeSCAN monitoring device has not been submitted to a thorough experimental validation. In particular there is no scientific results supporting its accuracy within a large range of flight activity.

Summary of the analysis for residues of thiamethoxam and the metabolite CGA 322704 in plant, honey, pollen and nectar samples

Plants samples were collected from the cage, tunnel and field tests described above for analysis of thiamethoxam and CGA 322704 concentrations. Residue concentrations are summarised in the following tables.

Summary of residues found in cage, tunnel and field studies with CRUISER 70 WS

Reference	Crop	Field rate (g ai/ha)	Residue analysis results (ng/g) – (in brackets is the number of sampling dates on which residues were above the LOD/the total number of sampling dates).						
			Monitored residue	Flowers / heads	Pollen on bees	Honey	Honey stomach	Pollen	Leaves
Schur (2001a)	Oilseed rape	33.6	thiamethoxam	1.8 (1/1)	-	-	-	-	1.0 (1/1)
			CGA 322704	<1.0 (0/1)	-	-	-	-	3.0 (1/1)

		67.2	thiamethoxam	3.9 (1/1)	-	-	-	-	1.7 (1/1)
			CGA 322704	1.3 (1/1)	-	-	-	-	5.7 (1/1)
		100.8	thiamethoxam	2.3 (1/1)	-	-	-	-	1.9 (1/1)
			CGA 322704	< 1.0 (0/1)	-	-	-	-	8.2 (1/1)
		134.4	thiamethoxam	13 (1/1)	-	-	-	-	1.7 (1/1)
			CGA 322704	4.2 (1/1)	-	-	-	-	6.3 (1/1)
		201.6	thiamethoxam	14 (1/1)	-	-	-	-	4.2 (1/1)
			CGA 322704	4.9 (1/1)	-	-	-	-	14 (1/1)
		268.8	thiamethoxam	27 (1/1)	-	-	-	-	5.2 (1/1)
			CGA 322704	10 (1/1)	-	-	-	-	12 (1/1)
Schur (2001b)	Sunflower	26.25	thiamethoxam	< 1.0 (0/1)	-	-	-	-	< 1.0 (0/1)
			CGA 322704	< 1.0 (0/1)	-	-	-	-	< 1.0 (0/1)
Barnavon (1999)	Sunflower	26.25	thiamethoxam	1.0 (1/1)	-	< 1.0 (0/1)	-	-	-
			CGA 322704	< 1.0 (0/1)	-	< 1.0 (0/1)	-	-	-
		52.5	thiamethoxam	1.0 (1/1)	-	< 1.0 (0/1)	-	-	-
			CGA 322704	< 1.0 (0/1)	-	< 1.0 (0/1)	-	-	-
Barnavon (2001)	Sunflower	25.9	thiamethoxam	< 1.0 (0/1)	< 1.0 (0/3)	< 1.0 (0/1)	-	-	-
			CGA 322704	< 1.0 (0/1)	< 1.0 (0/3)	< 1.0 (0/1)	-	-	-
Schuld (2001a)	Oilseed rape	25.0	thiamethoxam	3.1–4.2 (3/3)	2.5-4.2 (4/4)	1.0-< 1.0 (1/3)	1.0-2.1 (4/4)	2.8 (1/1)	-
			CGA 322704	< 1.0 (0/3)	< 1.0 (0/4)	< 1.0 (0/3)	< 1.0 (0/4)	< 1.0 (0/1)	-
Schuld (2001b)	Oilseed rape	29.4	thiamethoxam	<1.0-4.6 (1/2)	< 1.0 (0/3)	< 1.0 (0/2)	-	-	-
			CGA 322704	<1.0-1.0 (1/2)	< 1.0 (0/3)	< 1.0 (0/2)	-	-	-
Balluff (2001)	Sunflower	26.25	thiamethoxam	3.0 (1/1)	< 1.0-1.1 (4/7)	< 1.0-1.0 (2/3)	< 1.0 (0/6)	-	30.0 (1/1)
			CGA 322704	1.0 (1/1)	< 1.0 (0/7)	< 1.0 (0/3)	< 1.0 (0/6)	-	5.8 (1/1)
Schur (2001c)	Sunflower	22.8	thiamethoxam	< 1.0 (0/1)	< 1.0-3.2 (2/3)	< 1.0 (0/2)	-	-	1.9 (1/1)

			CGA 322704	< 1.0 (0/1)	< 1.0 (0/3)	< 1.0 (0/2)	-	-	< 1.0 (0/1)

Summary of residues from field studies with CRUISER 350 FS (A-9700 B)

Reference	Crop	Field rate (g ai/ha)	Residue analysis results (ng/g) – (in brackets is the number of sampling dates on which residues were above the LOD/the total number of sampling dates).					
			Monitored residue	Flower heads	Flowers	Fresh honey	Fresh nectar	Pollen loads
Szentes (2001a)	Sunflower	18.67	Thiamethoxam	2.0 (1/1)	1.0 (1/1)	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0 (0/2)
			CGA 322704	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0 (0/2)
Szentes (2001b)	Sunflower	17.7	Thiamethoxam	1.0 (1/1)	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0 (0/2)
			CGA 322704	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0 (0/2)

Summary of residues from oilseed rape field studies with CRUISER OSR (A-9807 C) and HELIX 289 FS (A-11642 A)

Author	Formulation	Field rate (g ai/ha)	Residue analysis results (ng/g) – (in brackets is the number of sampling dates on which residues were above the LOD/the total number of sampling dates).					
			Monitored residue	Flowers	Leaves	Fresh honey	Honey stomach	Pollen loads
Schur (2001d)	CRUISER OSR	18.0	thiamethoxam	1.0 (1/1)	1.4 (1/1)	< 1.0 (0/3)	< 1.0 (0/2)	< 1.0 (0/1)
			CGA 322704	< 1.0 (0/1)	4.1 (1/1)	< 1.0 (0/3)	1.0-< 1.0 (1/2)	< 1.0 (0/1)
Barth (2001)	CRUISER OSR	34.0	thiamethoxam	3.6 (1/1)	-	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0-3.6 (4/5)
			CGA 322704	< 1.0 (0/1)	-	< 1.0 (0/1)	< 1.0 (0/1)	1.0-< 1.0 (1/5)
Purdy (2000)	HELIX 289 FS	29.4	thiamethoxam	7.55 - < 0.4 (2/4)	-	(0.94) [a] - < 0.1 (2/4)	(0.053) [a] - < 0.02 (7/8) [c]	(0.66) [a] - < 0.2 (4/4)
			CGA 322704 [a]	(0.95) [b] < 0.4 (1/4)	-	< 0.1 (0/4)	(0.034) [a] - < 0.02 (3/8) [b]	(0.24) [a] - < 0.2 (1/4)

[a] *values in brackets are trace amounts detected below levels that can be quantified*
[b] *Values given are for residue analysis on macerated returning forager bees and not bee honey stomachs*

Summary of further trials to estimate residue levels

All evaluations in this section were done by Anses, France.

Residue analysis in pollens and wax when bees are exposed to treated maize

Reference	***Kühne-Thu (2001). Residue study with thiamethoxam in or on maize in France, SAM N°1402, Report N° 4000/00***
Method	*Residue analysis in maize (whole plant, pollen) after sowing seed treated with thiamethoxam as formulated product WS 70 (A-9767 C).* *Seed loading: 315 g as/q (nominal), 324.2 g as/q (actual)* *LOQ: 0.001 mg/kg (thiamethoxam and CGA 322704)*
Results	*Whole plant (78 d after sowing): 0.005 mg/kg (thiamethoxam), 0.003 mg/kg (CGA 322704)* *Pollen (78 d after sowing): 0.002 mg/kg (thiamethoxam), 0.002 mg/kg (CGA 322704)*

Reference	***Kühne-Thu (2001). Residue study with thiamethoxam in or on maize in France, SAM N°1401, Report N° 4001/00***
Method	*Residue analysis in maize (whole plant, pollen) after sowing seed treated with thiamethoxam as formulated product WS 70 (A-9767 C).* *Seed loading: 315 g as/q (nominal), 340.4 g as/q (actual)* *LOQ: 0.001 mg/kg (thiamethoxam and CGA 322704)*
Results	*Whole plant (64 d after sowing): 0.006 mg/kg (thiamethoxam), 0.003 mg/kg (CGA 322704)* *Pollen (64 d after sowing): 0.001 mg/kg (thiamethoxam), 0.001 mg/kg (CGA 322704)*

Reference	***Simon (2002). Determination of residues of thiamethoxam and CGA 322704 n maize plants and maize pollen after seed dressing with A9567C, study gr 64200/NAD 41001I***
Method	*Residue analysis in maize (whole plant, pollen) after sowing seed treated with thiamethoxam as formulated product WS 70 (A-9767 C) in Germany.* *Seed loading: 315 g as/q (nominal), 285.3 g as/q (actual)* *LOQ: 0.001 mg/kg (thiamethoxam and CGA 322704)*
Results	*Whole plant (93 d after sowing): 0.009 mg/kg (thiamethoxam), 0.005 mg/kg (CGA 322704)* *Pollen (85-93 d after sowing): 0.003 mg/kg (thiamethoxam), 0.003 mg/kg (CGA 322704)*

References	***Hecht-Rost S. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A 10590C treated maize seed, investigating residues in crop, soil and honeybee products in Alsace, France. Final Report No 20051149/F1-BZEU.***
	Hecht-Rost S. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A10590C treated maize seed, investigating residues in crop, soil and honeybee products in Southern France. Final Report No 20051149/F2-BZEU.
	Haergreaves N.J. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A10590C treated maize seed, investigating residues in crop, soil and honeybee products in Northern France. Final Report No T003256-05-REG.
Method	*On three locations, semi-field trials were conducted with the aim to determine the residue levels of thiamethoxam and CGA 322704 in pollens collected by bees as well as in pollen stores and wax. The trials were conducted two successive years (2005 and 2006) on the same plots to account for possible residues in soil.* *Large tunnels were used (36 x 5 m^2). The seeds were treated with an FS formulation A-10590C (420 g thiamethoxam + 3.33 g fludioxonil and 1.33 g metalaxyl-M/L) and the nominal seed concentration was 3150 mg thiamethoxam/kg seed (identical to the treatment with CRUISER 350) . The bees were exposed during flowering from BBCH*

		63 (start of pollen emission) to BBCH 69 (end of flowering) of the maize grown from treated seeds or untreated seeds (control). Exposure duration ranged from 3 to 9 days. At the end of flowering the hives were moved to a remote site. Development of bee brood was followed but for a too short period (ca. 1 week) to draw conclusions from. *Thiamethoxam: LOQ = 0.0005 mg/kg (wax and 0.001 mg/kg (pollens)* *CGA 322704: LOQ = 0.001 mg/kg (all matrices)*
	Results	*<u>Actual seeding rates (thiamethoxam):</u>* *Alsace: 89.27 g as/ha (2005) and 85.77 g as/ha (2006)* *Southern France: 90.36 g as/ha (2005) and 84.64 g as/ha (2006)* *Northern France: 87.31 g as/ha (2005) and 89.32 g as/ha (2006)* *<u>Residue levels in leaves:</u>* *Alsace: Residue levels in whole plants were 0.01-0.018 mg thiamethoxam/kg and 0.01-0.016 mg CGA322704/kg in 2005, and 0.003-0.012 mg thiamethoxam/kg and 0.002-0.008 mg CGA322704/kg in 2006.* *Southern France: Residue levels in whole plants were 0.009-0.020 mg thiamethoxam/kg and 0.004-0.008 mg CGA322704/kg in 2005, and 0.017-0.050 mg thiamethoxam/kg and 0.006-0.012 mg CGA322704/kg in 2006.* *Northern France: Residue levels in whole plants were 0.003-0.006 mg thiamethoxam/kg and 0.002-0.005 mg CGA322704/kg in 2005, and 0.002-0.004 mg thiamethoxam/kg and 0.002-0.004 mg CGA322704/kg in 2006.* *<u>Residue levels in soil cores (0-30 cm) before drilling in 2006:</u>* *Alsace: < 0.001 mg/kg (thiamethoxam and CGA 322704)* *Southern France: < 0.001 mg/kg (thiamethoxam), 0.001 mg/kg (CGA 322704)* *Northern France: 0.002 mg/kg (thiamethoxam and CGA 322704)* *<u>Residue levels in pollen loads:</u>*

Mean concentrations of thiamethoxam and CGA322704 in pollens collected by foraging bees

Site	Year	Thiamethoxam (ppb ou ng/g)	CGA322704 (ppb ou ng/g)
Alsace	2005	7.17	4.48
	2006	1.17	1.33
South	2005	4.70	1.37
	2006	3.43	1.64
North	2005	2.56	2.11
	2006	1.67	1.15
Mean of the 3 sites	2005	**4.81**	**2.65**
	2006	**2.09**	**1.37**
Overall mean	**2005 et 2006**	**3.45**	**2.01**

No increase of residue levels in pollen loads were observed the second year.

<u>Residue levels in hive pollens (2005 and 2006):</u>
Alsace: < 0.001 mg/kg (thiamethoxam and CGA 322704)
Southern France: < 0.001-0.002 mg/kg (thiamethoxam), <0.001-0.001 mg/kg (CGA 322704)
Northern France: < 0.001-0.002 mg/kg (thiamethoxam), <0.001-0.003 mg/kg (CGA 322704)

	Residue levels in wax (2005 and 2006): *Alsace: < 0.0005 mg/kg (thiamethoxam), < 0.001 mg/kg (CGA 322704)* *Southern France: < 0.0005-0.0009 mg/kg (thiamethoxam), < 0.001 mg/kg (CGA 322704)* *Northern France: < 0.0005-0.0014 mg/kg (thiamethoxam), < 0.001 mg/kg (CGA 322704)*
Comment	*Since confined bees are forced to feed on maize pollens, the residue levels determined in these trials are expected to cover any residue levels from field situations. The overall means of residue in pollen loads are used in the risk assessment, 3.45 ng thiamethoxam and 2.01 ng CGA 322704/g pollen load.*

Residue analysis in nectar, honey, royal jelly and wax when bees are exposed to treated oilseed rape

References	***Hecht-Rost S. (2007): Thiamethoxam (CGA293343) and its Metabolite (CGA322704). A Residue Study with A9807C Treated Winter oil-seed rape Seed, investigating Residues in Crop and Honeybee Products in Northern France : Analytical Phase Report. Final Report No 20051041/F2-BZEU.***
	Hecht-Rost S. (2007): Thiamethoxam (CGA293343) and its Metabolite (CGA322704). A Residue Study with A9807C Treated Winter oil-seed rape Seed, investigating Residues in Crop and Honeybee Products in Alsace (France). Final Report No 20051041/F1-BZEU.
	Hecht-Rost S. (2007): Thiamethoxam (CGA293343) and its Metabolite (CGA322704). A Residue Study with A9807C Treated Winter oil-seed rape Seed, investigating Residues in Crop and Honeybee Products in Southern France. Final Report No 20051041/F3-BZEU.
Method	*On three locations, semi-field trials were conducted with the aim to determine the residue levels of thiamethoxam and CGA 322704 in nectar collected by bees as well as in nectar and honey stores, royal jelly and wax. The trials were conducted on winter oilseed rape sown in 2004 and the bees were exposed in 2005 during flowering:* *Northern France: sowing 08/09/2004, exposure: 26/04/2005-06/05/2005* *Alsace: sowing 13/09/2004,exposure 29/04/2005-12/05/2005* *Southern France: sowing 10/09/2004,exposure 08/04/2005-17/04/2005* *Large tunnels were used (40 x 5 m^2). The seeds were treated with CRUISER OSR (FS formulation 280 g thiamethoxam + 8 g fludioxonil and 32.3 g mefenoxam/L). The bees were exposed from BBCH 60-62 (start of flowering) of the oilseed rape grown from treated seeds (3 treated tunnels) or thiram treated seeds (1 control tunnel). Exposure duration ranged from 9 to 13 days. At the end of flowering the hives were moved to a remote site. Some bee paramaters were checked (strength of the colony, presence of a healthy queen, visual assessment of pollen and nectar storage and bee brood), but for a too short period (9-13 days) to draw conclusions from.* *Samples were collected up to 20/09/2005 (Alsace and Northen France), 15/09/2005 (Southern France).* *Thiamethoxam: LOQ = 0.0005 mg/kg (hive honey, nectar, royal, jelly, wax), 0.001 mg/kg (hive pollen, whole plant)* *CGA 322704: LOQ = 0.001 mg/kg (all matrices)*
Results	*Actual seeding rates (thiamethoxam):* *Northern France: 12.6 g as/ha (nominal)* *Alsace: 12.6 g as/ha (nominal)* *Southern France: 12.6 g as/ha (nominal)* *Residue levels in whole plants:* *Northern France: <LOQ (thiamethoxam and CGA 322704)* *Alsace: <LOQ-0.007 mg/kg (thiamethoxam), <LOQ-0.002 (CGA 322704)* *Southern France: 0.001-0.005 mg/kg (thiamethoxam), <LOQ-0.001 (CGA 322704)* *Residue levels in bee pollen:*

	Northern France: *thiamethoxam: <LOQ-0.001 mg/kg (2nd and 5th day of exposure), <LOQ (9th day of exposures)* *CGA 322704: <LOQ (all samples)* *Alsace:* *thiamethoxam: 0.002-0.004 mg/kg* *CGA 322704: <LOQ* *Southern France:* *thiamethoxam: 0.001-0.004 mg/kg* *CGA 322704: <LOQ* *<u>Residue levels in hive pollen:</u>* *Northern France:* *thiamethoxam: <LOQ-0.001 mg/kg (during exposure, only one detection at 0.001 mg/kg the 5th day), <LOQ (post-exposure)* *CGA 322704: <LOQ* *Alsace:* *thiamethoxam: <LOQ-0.003 mg/kg (during exposure), <LOQ (post-exposure)* *CGA 322704: <LOQ* *Southern France:* *thiamethoxam: 0.001-0.002 mg/kg (during exposure), <LOQ (post-exposure)* *CGA 322704: <LOQ* *<u>Residue levels in nectar and honey:</u>* *Northern France:* *thiamethoxam: mean 0.00076 (0.0006-0.0014) mg/kg (bee nectar), <LOQ (hive nectar and honey)* *CGA 322704: <LOQ (all samples)* *Alsace:* *thiamethoxam: mean 0.0026 mg/kg (0.002-0.004 mg/kg) (bee nectar), <LOQ (hive nectar and honey)* *CGA 322704: <LOQ (all samples)* *Southern France:* *thiamethoxam: mean 0.0022 (0.001-0.004) mg/kg (bee nectar), <LOQ-0.009 (hive nectar, 2 detections in one tunnel the 9th day of exposure at 0.006 and 0.009 mg/kg), <LOQ (hive honey)* *CGA 322704: <LOQ (all samples)* *<u>Residue levels in royal jelly:</u>* *Alsace: <LOQ (thiamethoxam and CGA 322704)* *<u>Residue levels in wax:</u>* *Northern France: < LOQ (thiamethoxam and CGA 322704)* *Alsace: < LOQ (thiamethoxam and CGA 322704)* *Southern France: < LOQ (thiamethoxam and CGA 322704)* *<u>In-hive observations</u>* *Northern France (25/04/2005-06/05/2005): no obvious differences in the strength of the colonies and the brood status.* *Alsace (28/04/2005-12/05/2005): no obvious differences in the strength of the colonies and the brood status.* *Southern France (07/04/2005-17/04/2005): no obvious differences in the strength of the colonies and the brood status.*
Comment	*Since confined bees are forced to feed on oilseed rape pollens and nectars, the residue levels determined in these trials are expected to cover any residue levels from field situations. The highest levels of thiamethoxam were 0.004 mg/kg (bee pollen), 0.003 mg/kg (hive pollen during exposure), 0.004 (bee nectar) and 0.009 mg/kg (hive nectar during exposure. There was no residue of thiamethoxam above the LOQ in hive products after exposure. There was no residue of CGA 322704 above the LOQ in*

	all samples either during exposure or after exposure.

References	***Hecht-Rost S. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A9700B treated spring barley seed followed by A9807C treated winter oilseed rape seed, investigating residues in crop, soil and honeybee products in Northern France. Final Report No T003253-05-REG.***
	Hecht-Rost S. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A9700B treated spring barley seed followed by A9807C treated winter oilseed rape seed, investigating residues in crop and honeybee products in Northern France. Final Report No 20051040/F4-BZEU.
	Hecht-Rost S. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A9700B treated spring barley seed followed by A9807C treated winter oilseed rape seed, investigating residues in crop, soil and honeybee products in Southern France. Final Report No 20051040/F2-BZEU.
Method	*On three locations, semi-field trials were conducted with the aim to determine the residue levels of thiamethoxam and CGA 322704 in nectar collected by bees as well as in nectar and honey stores, royal jelly and wax. The trials were conducted on winter oilseed rape sown in 2005 after a treated spring barley and the bees were exposed in 2006 during flowering:* *Northern France 1:* *sowing: spring barley 18/03/2005, winter oilseed rape 31/08/2005* *exposure: 03/05/2006-12/05/2006* *Northern France 2:* *sowing: spring barley 17/03/2005, winter oilseed rape 06/09/2005* *exposure: 02/05/2006-14/05/2006* *Southern France:* *sowing: spring barley 08/03/2005, winter oilseed rape 19/09/2005* *exposure: 07/04/2006-17/04/2006* *Large tunnels were used (40 x 5 m^2). The seeds were treated with CRUISER OSR (FS formulation 280 g thiamethoxam + 8 g fludioxonil and 32.3 g mefenoxam/L). The bees were exposed from BBCH 60-62 (start of flowering) of the oilseed rape grown from treated seeds (3 treated tunnels) or fludioxonil+mefenoxam treated seeds (1 control tunnel). Exposure duration ranged from 9 to 10 days. At the end of flowering the hives were moved to a remote site. Strength of the colony and development of bee brood was followed but for a too short period (ca. 10 days) to draw conclusions from.* *Samples were collected up to 18/09/2006 (Northern trials), 28/09/2006 (Southern France)* *Thiamethoxam: LOQ = 0.0005 mg/kg (all matrices except soil), 0.001 mg/kg (soil)* *CGA 322704: LOQ = 0.001 mg/kg (all matrices)*
Results	*<u>Nominal seeding rates (thiamethoxam):</u>* *Northern France 1: 77 g as/ha (barley), 12.6 g as/ha (oilseed rape)* *Northern France 2: 77 g as/ha (barley), 12.6 g as/ha (oilseed rape)* *Southern France: 77 g as/ha (barley), 12.6 g as/ha (oilseed rape)* *<u>Residue levels in soil at sowing oilseed rape:</u>* *Northern France 1: 0.0035 mg thiamethoxam/kg soil, 0.0020 mg CGA 322704/kg soil* *Northern France 2: 0.0030 mg thiamethoxam/kg soil, 0.0020 mg CGA 322704/kg soil* *Southern France: 0.1027 mg thiamethoxam/kg soil, 0.0316 mg CGA 322704/kg soil* *<u>Residue levels in whole plants:</u>* *Northern France 1: <LOQ-0.002 (thiamethoxam), <LOQ-0.001 mg/kg (CGA 322704)* *Northern France 2: <LOQ (thiamethoxam), <LOQ-0.001 mg/kg (CGA 322704)* *Southern France: <LOQ-0.005 (thiamethoxam), 0.001-0.003 mg/kg (CGA 322704)* *<u>Residue levels in bee pollen:</u>* *Northern France 1: thiamethoxam: <LOQ-0.003 mg/kg; CGA 322704: <LOQ* *Northern France 2: thiamethoxam: <LOQ; CGA 322704: <LOQ*

	Southern France: thiamethoxam: 0.001-0.006 mg/kg; CGA 322704: <LOQ-0.002 mg/kg *<u>Residue levels in hive pollen:</u>* *Northern France:* *thiamethoxam: <LOQ-0.001 mg/kg (during exposure, only one detection at 0.001 mg/kg the 5th day), <LOQ (post-exposure)* *CGA 322704: <LOQ* *Northern France 2:* *thiamethoxam: <LOQ-0.001 mg/kg (during exposure), <LOQ (post-exposure)* *CGA 322704: <LOQ-0.004 (during exposure), <LOQ (post-exposure)* *Southern France:* *thiamethoxam: <LOQ-0.003 mg/kg (during exposure), <LOQ (post-exposure)* *CGA 322704: <LOQ* *<u>Residue levels in nectar and honey:</u>* *Northern France 1:* *thiamethoxam: mean 0.0011 (<LOQ-0.0024) mg/kg (bee nectar), <LOQ (hive nectar and honey)* *CGA 322704: <LOQ-0.001 mg/kg (bee nectar, detection in only one sample), <LOQ-0.001 mg/kg (hive nectar and honey, detection in only one sample of hive nectar)* *Northern France 2:* *thiamethoxam: mean 0.0013 (<LOQ-0.0022) mg/kg (bee nectar), <LOQ (hive nectar and honey)* *CGA 322704: <LOQ (all samples)* *Southern France:* *thiamethoxam: mean 0.0027 (0.0009-0.0046) mg/kg (bee nectar), <LOQ-0.0025 mg/kg (hive nectar), <LOQ-0.0008 (honey)* *CGA 322704: <LOQ (all samples)* *<u>Residue levels in royal jelly:</u>* *Northern France 2: <LOQ (thiamethoxam and CGA 322704)* *<u>Residue levels in wax:</u>* *Northern France 1: <LOQ (thiamethoxam and CGA 322704)* *Northern France 2: <LOQ (thiamethoxam and CGA 322704)* *Southern France: <LOQ-0.0009 mg/kg (thiamethoxam), <LOQ (CGA 322704)*
Comment	*Since confined bees are forced to feed on oilseed rape pollens and nectars, the residue levels determined in these trials are expected to cover any residue levels from field situations.*

Overall summary of residues in bee nectar:

Trial	***Thiamethoxam (ng/g)***
Oilseed rape North	*0.76*
Oilseed rape Alsace	*2.59*
Oilseed rape South	*2.19*
Overall mean	*1.85*
Barley/Oilseed rape North 1	*1.14*
Barley/Oilseed rape North 2	*1.29*
Barley/Oilseed rape South	*2.67*
Overall mean	*1.70*

Dust deposition

Syngenta performed several trials to study dust drift from treated maize seeds <u>Tummon 2006</u>, <u>Tummon & Jones 2007</u>, <u>Solé 2008</u>). The summary/evaluation was made by PRI (WUR, The Netherlands) in 2009.

In the study of Tummon, 2006 it was demonstrated that the peak of 0.55% of applied dose was found at 5 m distance (in average and in two out of 3 measurements 0.49%-0.62%).

In the study of Tummon & Jones, 2007 it was demonstrated that for the conventional sowing machine the highest dust drift deposition of dust of 0.81 % (0.80%-0.82%) occurs at 5 m distance. For the maize sowing machine using deflectors on the air exhaust pipe redirecting the air towards the seed hoppers it was demonstrated that the highest dust deposition is 0.037% (0.019%-0.24%) and occurs at 10 m distance but is still lower than the value at 50 m distance for the conventional sowing machine without air deflectors. Dust deposition decreases with increasing distance to a level of 0.004% at 50 m distance.

In the study of Solé, 2008 it was demonstrated that for the conventional sowing machine the dust drift deposition values for the two replications the highest deposition of dust of 0.99 % (0.87%-1.12%) occurs at 5 m distance.
For the maize sowing machine using dual tube deflectors on the air exhaust pipe redirecting the air towards the soil surface it was demonstrated that the highest dust drift deposition is 0.299% (0.30%-0.569%) occurs at 10 m distance.

Another applicant, Bayer, also studied drift from maize sowing. Dust drift from treated seeds is not considered to be dependent on active substance so these studies were also considered, to get a overall picture of dust drift from maize seeds. The overall conclusion is that the highest drift value from maize sowing with deflectors is 0.55% of the applied dose. This value will be used in the risk assessment.

Dust toxicity

Studies evaluated by Ctgb (March 2011)

Kling A 2009. Thiamethoxam (A9700B, A9584C) – Oral and Contact Toxicity of Maize Dust containing A9700B and Actara (A9594C) to the Honey Bee Apis mellifera L. RepOli Number: S09-02683 Syngenta file no. A9700B_10904.
The 48-hour oral LD50 value for dust from A9700B treated maize seed is 9.36 ng a.i./bee. For the formulation Actara the oral LD50 is 6.31 ng a.i./bee.
The 72-hour contact LD50 value for dust from A9700B treated maize seed is 13.26 g a.i./ha..For the formulation Actara the contact LD50 is 5.55 g a.i./ha.

Sigrun Bocksch 2010. Thiamethoxam (A9700B, A9584C) - A Semi-field Study with Dust from treated Maize Seeds to Evaluate Effects on the honeybee Apis mellifera L. (Hymenoptera, Apidae) in Phacelia tanacetifolia in Germany 2009. Report no. S09-02400. Syngenta file no.A9700B_10908
The objective of the study was to determine the effect of thiamethoxam applied as treated dust (1 and 5 g a.s./ha) and as spray treatment (5 g a.s./ha) on the honeybee, Apis mellifera L, in tunnel tests. 12 tunnels were set up on a field with flowering Phacelia tanacetifolia and one small bee colony was placed in each tunnel early in the morning, 4 days before the applications. Mortality, behaviour and foraging activity were assessed daily over seven days during the time of exposure in the tunnels. Colonies were then moved to a monitoring site. Furthermore, the mortality in the dead bee traps only was assessed until DAA+21. The condition of the colonies and the development of the bee brood were assessed once before application and four times after application (last evaluation after 27 days). Pollen samples from combs were collected for residue analysis during the brood evaluations on DAA+7 and on DAA+27. The pollen samples were analysed for residues of thiamethoxam and CGA322704.

The following endpoints were derived:

	dust		***spray***	
	NOEC	***NOAEC***		***NOAEC***
Mortality and behaviour	*<1 g a.s./ha*		*< 5 g a.s./ha*	
Flight intensity	*1 g a.s./ha*		*<5 g a.s./ha*	
Food resources	*<1 g a.s./ha*		*5 g a.s./ha*	
Colony strength (no. of bees)	*<1 g a.s./ha*	*5 g a.s./ha*	*<1 g a.s./ha*	*5 g a.s./ha*
Brood development	*5 g a.s./ha*		*5 g a.s./ha*	

Increased mortality was seen for 3 days after treatment at 1 g dust/ha and for 14 days after treatment at 5 g as./ha. Test item related effects on behaviour were observed until 2 days after treatment.
Residues of thiamethoxam ranging from < 0.001 (T1) to 0.016 (T2) mg/kg were found in the test item samples of DAA+7. In the samples of DAA+27 residues of thiamethoxam ranging from 0.012 to 0.028 mg/kg were detected in the test item treatment groups. No residues of CGA322704 were found in any of

the test item or reference item samples except of 0.003 mg/kg in the pollen samples of test item 2 (A9584C; treatment group T3) on DAA+7.

Long-term monitoring studies: maize

Evaluation by Ctgb (March 2011) based on an evaluation of these studies for the first three years of the trial from ANSES, France.

Hecht-Rost S. 2010a, b, c. Report N° 20061138/F1-BFEU, 20061138/F2-BFEU, 20061138/F3-BFEU. (interim reports of these studies of previous years are also available).

Three long-term over-wintering studies were conducted in maize in Lorraine, Alsace and Southern France. The trials begin in 2006 and end in 2010.

Six bee colonies per trial were exposed to Cruiser-treated maize fields (2 ha per field) during four years (2006-2009).
Dose rate was 350g a.s./100 kg seed (ca. 0.8 mg a.s./seed; 80-100 g a.s./ha) in the first three years and 32 g a.s./50.000 seeds (ca. 0.65 mg a.s./seed; 55-70 g a.s./ha) in the last year. Seeds were also treated with metalaxyl-M and fludioxonil.

Colonies were exposed to the flowering fields for as long as flowering lasted and kept at a monitoring location for the rest of the year. In 2009, the flowering and thereby the exposure period was extended by drilling two different varieties on two different dates in the same fields.
Exposure duration was:
Alsace: Exposure lasted 5 days (2006), 8 days (2007), 6 days (2008) and 24 days (2009).
Lorraine: Exposure lasted 5 days (2006), 8 days (2007), 7 days (2008) and 19 days (2009)
S-France: Exposure lasted 6 days (2006), 6 days (2007), 6 days (2008) and 23 days (2009)

Residues were measured in maize plants and pollen in each of the years of exposure (control and treated). Residues of thiamethoxam were always found in the plants and on some occasions residues of CGA322704 (maximum residues – 0.024 mg thiamethoxam/kg and 0.010 mg CGA322704/kg). Levels in pollen were always lower than those found in the plants (maximum residues – 0.002 mg/kg for both analytes).

The long-term studies were conducted in three regions in France with colonies exposed during the flowering of maize for four successive summers (2006, 2007, 2008, 2009) and observed up to spring 2010 that includes four over-wintering periods. The following parameters were studied in each trial: mortality and behaviour, foraging activity, colony strength, disease, brood (percentage of eggs, larvae and pupae), hive weights and over-wintering success. No significant differences or trends between hives exposed in thiamethoxam treated fields and the controls.
The overall health of bee colonies, placed in contact with a CRUISER treated crop, and forced to forage on this crop (by carefully selecting a site remote from any other flowering and attractive crop) is not affected.

It should be noted that the studies address the long-term effects of exposure via pollen lasting about one week or, in the last year, three weeks.

long-term monitoring studies: oilseed rape

Evaluation by Ctgb (March 2011) based on an evaluation of these studies from ANSES, France. ANSES stated that the trials will be fully assessed for the use of Cruiser OSR for the treatment of oilseed rape.

Hecht-Rost S. 2009a, b. Report N° 20051041/F1-BFEU, 20051041/F2-BFEU.

Two long-term over-wintering studies were conducted in the Picardie and Alsace regions of France. There were originally three oil-seed rape studies but the trial in the south was lost due to AFB (American Foulbrood) which occurred in both the thiamethoxam treatment and the control.
Data from four years including four over-wintering periods (trials commenced in 2005).

Six bee colonies per field were exposed to treated oil-seed rape fields (2 ha per field) in each of the four

years (2005-2008). Dose rate was 4200 mg a.s./kg seed (ca. 0.02 mg a.s./seed; 13-21 g a.s./ha). Seeds were also treated with metalaxyl-M and fludioxonil.
Colonies were exposed to the flowering fields for as long as flowering lasted. This was:
Alsace: Exposure lasted 19 days (2005, 2006), 13 days (2007) and 22 days (2008).
N-France (Picardie): Exposure lasted 21 days (2005 and 2008), 18 days (2006) and 12 days (2007). .

Residues were measured in oilseed rape plants, nectar and pollen in 2006, 2007 and 2008 (control and treated).
Maximum residues over the years: Plants: 0.002 mg thiamethoxam/kg and 0.001 mg CGA322704/kg). Pollen: 0.001 mg thiamethoxam/kg and <0.001 (LOQ) mg CGA322704/kg). Nectar: 0.003 mg thiamethoxam/kg and <0.001 (LOQ) mg CGA322704/kg).

The following parameters were studied in each trial: mortality and behaviour, foraging activity, colony strength, disease, brood (percentage of eggs, larvae and pupae), hive weights and over-wintering success. No significant differences or trends between hives exposed in thiamethoxam treated fields and the controls. The overall health of bee colonies, placed in contact with a CRUISER treated crop, and forced to forage on this crop (by carefully selecting a site remote from any other flowering and attractive crop) is not affected.

It should be noted that the studies address the long-term effects of exposure via nectar and pollen lasting about three weeks.

Residues in succeeding flowering crops
Studies evaluated by Ctgb (March 2011)

Dr. Silvio Knäbe 2010. Thiamethoxam Thiamethoxam (CGA293343) - A semi-field study with A9700B + A9638A treated maize seed, followed by untreated flowering crop(s), investigating residues in crop(s), soil and honeybee products in Alsace (France), in 2009 Final Report Report number: S08-01279
Syngenta file no A9700B_10915
Maize pre-treated with thiamethoxam was sown in a field plot in Alsace, France in spring 2008. The rate of thiamethoxam applied was 75.07 g/ha. The maize was followed by a seeding of winter barley treated with A9700B sown in the same field plot in autumn 2008. The rate of thiamethoxam applied with the seed dressing was 72.27 g/ha. The treated field plots were matched with a similar size control field plot sown with untreated seed. In spring 2009, untreated flowering crops (alfalfa, oilseed rape and Phacelia) were planted in both the treated and control field plots. Prior to the onset of flowering, three tunnels were set-up on each flowering crop in the treated field plot and one tunnel on each flowering crop in the control field plot.
In each tunnel one bee colony was placed during the flowering phase. Samples of forager bees (nectar and pollen) and whole plants of all three flowering crop species (oilseed rape / alfalfa / Phacelia tanacetifolia) were collected on three days in the flowering period (on day 1/4, 2/3/5, 5/6). Soil samples were collected (those presented are only those taken before seeding of the flowering crop). Samples were analysed for residues of thiamethoxam and its metabolite CGA322704.
Results:

	Thiamethoxam (mg/kg)	*CGA322704 (mg/kg)*
Soil	*0.008-0.011*	*0.003-0.004*
Alfalfa plant	*0.001-0.004*	*0.002-0.005*
Phacelia plant	*<0.001*	*0.002-0.003*
OSR plant	*0.001-0.003*	*0.002-0.004*
Alfalfa nectar	*<0.0005-0.0006*	*<0.001*
Phacelia nectar	*<0.0005*	*<0.001-0.001*
OSR nectar	*<0.0005-0.0022*	*<0.001*
Alfalfa pollen	*0.051 (1 sample)*	*0.002 (1 sample)*
Phacelia pollen	*<0.001-0.039*	*<0.001-0.002*
OSR pollen	*<0.001-0.001*	*<0.001-0.003*

The condition of the colonies and the development of the bee brood were assessed before introduction to the tunnel and once colonies were moved out of the tunnels (after ca. 1 week). According to the study author, results were according to expectations for standard bee tunnel tests. Evaluation period is too short to draw conclusions about effects on bees.

Dr. Silvio Knäbe 2010. Thiamethoxam Thiamethoxam (CGA293343) - A semi-field study with A9700B + A9638A treated maize seed, followed by untreated flowering crop(s), investigating residues in crop(s), soil and honeybee products in Picardie (France), in 2009 Final Report Report number: S08-01284 Syngenta file no A9700B_10914

Maize pre-treated with thiamethoxam was sown in a field plot in the region Picardie, France in spring 2008. The rate of thiamethoxam applied was 76.80 g/ha. The maize was followed by a seeding of winter barley treated with A9700B sown in the same field plot in autumn 2008. The rate of thiamethoxam applied with the seed dressing was 71.78 g/ha. The treated field plots were matched with a similar size control field plot sown with untreated seeds. In spring 2009, untreated flowering crops (alfalfa, oilseed rape and Phacelia tanacetifolia) were planted in both the treated and control field plots. Prior to the onset of flowering, three tunnels were set-up on each flowering crop in the treated field plot and one tunnel on each flowering crop in the control field plot.

In each tunnel one bee colony was placed during the flowering phase. Samples of forager bees (nectar and pollen) and whole plants of all three flowering crop species (oilseed rape / Phacelia / alfalfa) were collected on three days in the flowering period (on day 1/2, 2/3, 5/8). Soil samples were collected (those presented are only those taken before seeding of the flowering crop). Samples were analysed for residues of thiamethoxam and its metabolite CGA322704.

Results:

	Thiamethoxam (mg/kg)	*CGA322704 (mg/kg)*
Soil	*0.009-0.024*	*0.003-0.005*
Alfalfa plant	*0.002-0.005*	*0.001-0.005*
Phacelia plant	*0.001-0.006*	*0.005-0.012*
OSR plant	*0.003-0.012*	*0.004-0.011*
Alfalfa nectar	*<0.0005-0.0005*	*<0.001*
Phacelia nectar	*0.0005-0.0014*	*<0.001*
OSR nectar	*<0.0005-0.0052*	*<0.001-0.0023*
Alfalfa pollen	*<0.001 (1 sample)*	*<0.001 (1 sample)*
Phacelia pollen	*<0.001-0.001*	*<0.001-0.003*
OSR pollen	*0.003-0.008*	*0.001-0.003*

The condition of the colonies and the development of the bee brood were assessed before introduction to the tunnel and once colonies were moved out of the tunnels (after ca. 1 week). According to the study author, results were according to expectations for standard bee tunnel tests. Evaluation period is too short to draw conclusions about effects on bees.

Dr. Silvio Knäbe 2010. Thiamethoxam Thiamethoxam (CGA293343) - A semi-field study with A9700B + A9638A treated maize seed, followed by untreated flowering crop(s), investigating residues in crop(s), soil and honeybee products in Burgundy (France), in 2009 Final Report Report number: S08-01285 Syngenta file no A9700B_10916

Maize pre-treated with thiamethoxam was sown in a field plot in the region Burgundy, France in spring 2008. The rate of thiamethoxam applied was 60.03 g/ha. The maize was followed by a seeding of winter barley treated with A9700B sown in the same field plot in autumn 2008. The rate of thiamethoxam applied with the seed dressing was 83.37 g/ha. The treated field plots were matched with a similar size control field plot sown with untreated seed. In spring 2009, untreated flowering crops (alfalfa, oilseed rape and Phacelia tanacetifolia) were planted in both the treated and control field plots. Prior to the onset of flowering, three tunnels were set-up on each flowering crop in the treated field plot and one tunnel on each flowering crop in the control field plot.

In each tunnel one bee colony was placed during the flowering phase. Samples of forager bees (nectar and pollen) and whole plants of all three flowering crop species (oilseed rape / Phacelia / alfalfa) were collected on three days in the flowering period (on day 1/2, 2/5, 5/6; OSR only on day 3). Soil samples were collected (those presented are only those taken before seeding of the flowering crop). Samples were analysed for residues of thiamethoxam and its metabolite CGA322704. Planned analysis of oilseed rape nectar and pollen could not be done because OSR flowers were destroyed by pollen beetle. Planned analysis of alfalfa pollen was not done because the total amount of pollen sampled by forager bees was too low.

Results:

	Thiamethoxam (mg/kg)	*CGA322704 (mg/kg)*
Soil	*0.004-0.009*	*0.002-0.004*
Alfalfa plant	*<0.001-0.005*	*0.002-0.005*
Phacelia plant	*<0.001*	*0.002-0.006*
OSR plant	*0.007 (1 sample)*	*0.004 (1 sample)*

Alfalfa nectar	*<0.0005-0.0022*	*<0.001-0.0011*
Phacelia nectar	*<0.0005*	*<0.001-0.0021*
Phacelia pollen	*<0.001*	*<0.001-0.003*

The condition of the colonies and the development of the bee brood were assessed before introduction to the tunnel and once colonies were moved out of the tunnels (after ca. 1 week). According to the study author, results were according to expectations for standard bee tunnel tests. Evaluation period is too short to draw conclusions about effects on bees.

guttation field trial in maize

Evaluation by Ctgb (March 2011) based on an evaluation of an interim report of this study from ANSES, France.

Knäbe (2010) Thiamethoxam FS (A9700B) – A field study with treated maize seeds, investigating the effects of residues from dust during seeding and residues in guttation liquid, on honeybee colonies in Alsace (France), in 2009. Study N° : S09-01639.

In this trial 6 honeybee hives were placed 5-10 m from a maize crop treated with CRUISER 350 at an application rate of 69 g thiamethoxam/ha, and 6 hives placed 5-10 m from an untreated control maize crop. The control and treated plots were separated by 2.05 km. Hives were set up in the trial locations approx. 4 days before drilling of the maize crops (6th May 2009, Monosem seed driller with a deflector) and were left in situ for up to 41 days (worst case exposure period for guttation as reported by Prof. Girolami's trials) after maize emergence. The winter oilseed rape crop adjacent to the control and treated maize plots was flowering during drilling, but had finished flowering prior to the start of the guttation phase. Mortality, foraging activity of the bees and the condition of the colonies were assessed during the period of seeding and subsequent guttation. Thereafter hives were moved to a remote site without extensive agriculture until the end of the honeybee season. Total monitoring duration of the colonies lasted four months.
No artificial water source was provided for the honeybees during the trials, as a small natural farm pond was located approx 100 m from hives of the treated plot and a ditch passed by close to the hives of the untreated plot.

Dust was measured in the neighbouring oilseed rape field with Petri-dishes. The highest amount measured was 0.0038% of the applied, at a distance of 5 m. However, during drilling, wind direction was nearly parallel to the edge of the neighbouring oilseed rape field. Since the wind direction deviated more than 30% from the desired direction perpendicular to the measurement area (criterion used by Plant Research International for drift measurements), the dust drift measurements are not considered acceptable.

Residues were measured in dead bees and guttation liquid (and also in oilseed rape flower heads exposed via dust drift, but these measurements are not accepted for risk assessment).

Guttation was observed on 36 of the 40 assessment days. During the entire 40 day guttation period very low flight intensity was observed within the treated field and during this period, no honeybees were seen foraging on the guttation droplets. Residues in guttation droplets were very high at the start of the study with nearly 28 mg thiamethoxam/L and 1.9 mg CGA322704/L. Residues declined very fast and were below 1 mg/L 9 days after guttation started. The lowest values were measured at the last sampling with 0.028 mg thiamethoxam /L and 0.012 mg CGA322704/L guttation liquid. During the guttation exposure none of the dead bee samples contained thiamethoxam and two samples contained CGA322704.

It was considered that there was no treatment related mortality or effects on colony strength.

toelatingnr	**middelnaam**	**toelatinghouder**	**werkzame stoffen**	**dosering**	**formulering**	**Toepassing(en)**
12913	CRUISER 350 FS	Syngenta Crop Protection B.V.	thiamethoxam 350G/L	mais: 63 g a.s./ha erwt: 104-110 g	Suspensie concentraat voor zaadbehan	Zaadcoating in mais, erwten, peulen, kapucijners. Stofdriftrestricties op WG.

				a.s./ha	deling	
12863	CRUISE R SB	Syngenta Crop Protection B.V.	thiamethoxam 600G/L	60 g a.s./ha	Suspensie concentraat voor zaadbehandeling	Zaadcoating in bieten.
12852	CRUISE R 70 WS	Syngenta Crop Protection B.V.	thiamethoxam 70%	107 g a.s./ha	Water dispergeerbaar poeder voor vochtige zaadbehandeling	Zaadcoating in sla en andijvie.

Risk assessment for bees

Direct exposure

1) In-field

Direct in-field exposure is not expected, because it concerns a seed treatment and because bees will not be present in-field when the seeds are sown or when the plants are transplanted into the field.

2) Off-field - dust from treated seed

Dust drift from seed is not a relevant exposure route for the uses in lettuce and endive, because sowing takes place indoors. Maize, peas and beets are sown outside, however. The risk that dust from the seed coating reaches neighbouring crops or other flowering plants and in that way exposes bees to the a.s., depends on the type of coating in combination with the type of sowing. This assessment is based on the dust drift matrix available at www.ctgb.nl.

Sowing of beets is done mechanically and seeds have a film coating. No dust drift is expected. The risk is acceptable.

Maize seeds are coated with a normal/basic coating, so dust formation cannot be excluded. Whether this dust can be expelled outside the field depends on the type of machinery. The sowing of maize is done with pneumatic machines. The pneumatic machines used for maize sowing have been adapted since 01/2010 to ensure that the air flow is sent downwards, towards the maize field and not upwards. Furthermore, the dust level of maize seeds is kept to a minimum and sowing is not done under windy weather conditions. If those conditions are met, no exposure is expected outside the field where flowering plants may be present. Incidents with maize sowing causing acute mortality of bees foraging on neighbouring areas (in 2008 in Germany, Slovenia and Italy; probably also in 2011 in Slovenia, this incident is still under investigation) show that it is very important that these conditions are met. In the Netherlands, increased mortality after maize sowing has never been reported so far.

Studies were performed to determine the off-field dust level from treated maize seeds when sown with high quality seed and adapted sowing machines (with deflectors). The relevant drift rate for the risk assessment is 0.55% of the applied dose.

Since the application rate for maize is 63 g a.s./ha, the expected off-field dose is 0.0055*63 = 0.35 g a.s./ha. A dust toxicity study showed that the NOEC for dust exposure is < 1 g a.s./ha, but that effects do not last. The study author set the NOAEC at 5 g a.s./ha. However, at this rate increased mortality was seen for two weeks after application. At 1 g a.s./ha, effects only lasted three days. Therefore, Ctgb considers that 1 g a.s./ha can be used as endpoint for the risk assessment. Since the off-field rate for maize is a factor of 3 below this endpoint, the risk from dust exposure from maize sowing is considered to be acceptable, provided that the

following restrictions are mentioned on the label for maize:

Behandeld zaad mag bij het opzakken geen hoger stofgehalte hebben dan 0,75 g stof per 100.000 zaden (volgens de Heubach-methode).

Om de bijen te beschermen moet blootstelling via stofdrift geminimaliseerd worden. Om dit te bereiken dienen bij het uitzaaien van het behandelde zaad specifieke instructies gevolgd te worden die vermeld staan op de zakken behandeld zaad.

Het volgende moet worden vermeld op de zakken met behandeld zaad:

Voor het zaaien
Breng bij het vullen het eventueel aanwezige stof onderin de zaaizaadzak niet over in de zaaimachine.

Bij het zaaien
Zaai geen behandeld zaad bij sterke wind en zaai de aanbevolen hoeveelheid zaaizaad. Wanneer een pneumatische zaaimachine wordt gebruikt, moet de luchtstroom met eventueel daarin aanwezig stof van behandeld zaad naar het grondoppervlak of in de grond worden gericht via zogenaamde deflectoren.

Peas are coated with a normal/basic coating, so dust formation cannot be excluded. However, the sowing of peas is done with mechanical or pneumatic machines. No air is involved in mechanical sowing, so this method has no dust drift risk. The pneumatic machines used for pea sowing send the air flow downwards, towards the pea field and not upwards. Therefore, no exposure is expected outside the field where flowering plants may be present, as long as sowing is not done under windy weather conditions. However, there are no general agricultural regulations on wind conditions at sowing and it questionable if labelling of seed packages is currently feasible for pea seed bags. Therefore, the seed quality should be as high as possible to prevent off-field exposure.

No information is available on the amount of a.s. in the dust. Investigations from the JKI in Germany show that the level of a.s. in dust does not directly depend on the concentration of a.s. in the seed treatment product, but can be variable. Therefore, in a worst case approach it is assumed that the amount of dust is equal to the amount of a.s.

A dust toxicity study showed that the NOEC for dust exposure is < 1 g a.s./ha, but that effects do not last and a NOAEC may be set at 1 g a.s./ha.
Currently, a dust drift level of 0.1 g dust per 100 kg seeds is prescribed on the label for peas. At this level, the risk would be acceptable. The seed rate is 90-210 kg/ha, which would lead to a maximum off-field exposure of 0.21 g a.s./ha off-field, which is below the NOAEC of 1 g a.s./ha.

Thus, the risk from dust exposure from pea sowing is considered to be acceptable, provided that the following restriction is mentioned on the label for peas (this is a restriction for the coating facility):

Voor erwt: Behandeld zaad mag bij het opzakken geen hoger stofgehalte hebben dan 0,1 g stof per 100 kg zaden (volgens de Heubach-methode).

The applicant has recently submitted a request for change of the Statutory Instructions for Use (they now propose a dust drift level of 0.075 g dust/100.000 seeds and a revised dose rate of 30 mL product/100.000 seeds). This request is still under evaluation. The restriction

sentence may be revised in the near future after assessment of the request for change.

Indirect exposure via systemic working mechanism
Due to its systemic nature, the a.s. can be taken up by plants. If this plant carries flowers, bees may be exposed to thiamethoxam or its metabolites via nectar and/or pollen. This route may be relevant for the crop itself, weeds and succeeding crops. Guttation droplets may contain the active substance and/or metabolites. Also, the risk via honeydew from aphids must be assessed.

Lettuce, endive and beets are not supposed to flower during cultivation. Therefore, no exposure via nectar or pollen from the treated crops themselves will take place. The other routes are relevant.
Maize and peas will flower. Bees can collect pollen from maize, and pollen and nectar from peas. For these crops, all routes must be considered.

Laboratory studies
The new EPPO scheme (EPPO 2010) indicates that when risks from systemic substances are expected, a chronic (10-d) toxicity study should be performed. For thiamethoxam and its metabolite CGA 322704 (= clothianidin), these studies were done. The 10-d NOEL was 10 µg/L for both substances (8.4 µg/kg based on sucrose solution density of 1.19 kg/L), which corresponds to values of 1.845 ng thiamethoxam/bee and 1.892 ng CGA 322704/bee (cumulative doses over 10 days).
Also, a test on honeybee larvae was performed. The NOEC for larvae development was determined at 12.5 µg/kg.

Furthermore, tests were performed to determine effects on sublethal parameters in the laboratory. No adverse effects on return flight ability are expected at concentrations of 25 µg/kg for thiamethoxam (3 ng/bee) and 25 µg/kg for CGA 322704 (0.8 ng/bee). No adverse effects on feed consumption and trophalactic interactions are expected at concentrations of 100 µg/kg for thiamethoxam (5.0 ng/bee) and 100 µg/kg for CGA 322704 (2.8 ng/bee).
For thiamethoxam, the NOEC values determined in these studies are close to the oral LC50 value. This was explained by looking at the exposure duration. In the acute oral toxicity study, mortality is checked after 24 and 48 hours. In the current studies however, the test duration was much shorter. Therefore it is expected that the tested doses were not fully consumed in the sublethal toxicity studies. It was estimated by Anses (France) that about one third of the dose could have been consumed during the return flight ability test.

Based on the above laboratory studies, the level at which no adverse effects are expected is ca. 10 µg/kg. This is an indicative value since it is unclear if the NOEC values for return flight ability, feed consumption and tropholactic interactions would be lower than 25 and 100 µg/kg, respectively, if those studies would have had a longer duration.

Because no clear endpoint could be derived from the above mentioned laboratory studies, the NOEL of 10 µg/L from the chronic (10-d) toxicity study should be used for evaluation. The applicant is requested to address this issue.

(Semi-) field studies
A further evaluation of the lethal and sublethal effects of thiamethoxam and metabolites is done by looking at the (semi-) field studies. In these studies, the longer-term effects on colonies from exposure to flowering crops grown from treated seeds is checked. These studies are more realistic and therefore more relevant for the risk assessment than the laboratory studies. Usually, at least the following parameters are checked: mortality, foraging activity, colony strength and brood development.

Cage studies

No significant effects on mortality, foraging activity, behaviour or colony strength were observed in two cage tests in which bees were confined over flowering oilseed rape grown from seeds dressed with thiamethoxam, at rates up to the equivalent of 201.6 g ai/ha. At a rate equivalent to 268.8 g ai/ha, there were no effects on mortality but foraging activity was reduced. Observation duration was 3-4 weeks.

Tunnel studies
No significant effects on mortality, foraging activity, behaviour or colony strength were observed in three tunnel tests, in which bees were confined over flowering sunflowers grown from seeds dressed with thiamethoxam, at rates up to the equivalent of 52.5 g ai/ha. Observation duration was about 2 weeks.

Field studies
Ten field studies have been conducted with thiamethoxam seed treatments, including 6 studies in oilseed rape and 4 studies in sunflowers, at rates up to the equivalent of 34 g ai/ha. Colonies were exposed during flowering of the crop, which lasted ca. 2-4 weeks. Total observation duration of the colonies (during and after exposure) was ca. 4-7 weeks. No adverse effects were observed on foraging activity and ability, colony strength or bee brood. Generally no effects on mortality were observed. Where higher mortalities were reported in the thiamethoxam treatments, the mortality levels were either low (within normally expected numbers), or marginally higher due to bee robberies or increased foraging activities.

Monitoring studies
Finally, long-term effects have been studied in monitoring programmes in France lasting four years. In these studies, colonies were exposed every year to a flowering maize field or to a flowering oilseed rape field of which the seeds had been treated with thiamethoxam. After flowering, the colonies were transferred to a monitoring site (where they were not exposed to thiamethoxam). The following parameters were studied in each trial: mortality and behaviour, foraging activity, colony strength, disease, brood (percentage of eggs, larvae and pupae), hive weights and over-wintering success. No significant differences or trends were found between hives exposed in thiamethoxam treated fields and the controls. It should be noted that the duration of exposure in these trials was limited (up to at most three weeks). These studies therefore only address long-term effects of up to three weeks of exposure per year.

Residues
Residue measurements were done in a large number of studies.

In the cage, tunnel and field tests of 1999-2001, residue data were measured in plant tissues relevant for honeybee exposure (pollen and nectar, (as indication) flower heads, fresh honey, honey stomachs, pollen loads). Residues in leaves were also measured but these are considered less relevant for honey bees.
Results for oilseed rape at dose rates of up to 100.8 g a.s./ha: maximum 7.55 µg/kg thiamethoxam and 1.3 µg/kg CGA322704.
Results for sunflower at dose rates up to 52.5 g a.s./ha: maximum 3.0 µg/kg thiamethoxam and 1.0 µg/kg CGA322704.

Also trials in maize from 2007 are available in which treated maize was sown for two years in the same field. For bee exposure, the measurements in pollen (done both in pollen taken from the plants and in hive pollen collected by bees) are relevant. The residue level is always < 10 ug/kg (maximum 7.17 µg/kg thiamethoxam, 4.48 µg/kg CGA322704). No increase of residue levels in pollen loads were observed the second year.

Residue measurements were done in three trials (2007) with treated oilseed rape (12.6 g a.s./ha). Maximum residues:
Whole oilseed rape plants: 7 µg/kg thiamethoxam; 2 µg/kg CGA322704.

Bee pollen: 4 µg/kg thiamethoxam; CGA322704 < LOQ.
Hive pollen: 3 µg/kg thiamethoxam; CGA322704 <LOQ.
Nectar and honey: 9 µg/kg thiamethoxam; <LOQ.

Furthermore, residue measurements were done in three trials (2007) with treated oilseed rape (12.6 g a.s./ha) which was sown as a succeeding crop after treated barley (77 g a.s./ha).
Maximum residues:
Whole oilseed rape plants: 5 µg/kg thiamethoxam; 3 µg/kg CGA322704.
Bee pollen: 6 µg/kg thiamethoxam; 2 µg/kg CGA322704.
Hive pollen: 3 µg/kg thiamethoxam; CGA322704 <LOQ.
Nectar and honey: 4.6 µg/kg thiamethoxam; 1 µg/kg CGA322704.

Residues were also measured in the four-year monitoring trials (2010) in maize and oilseed rape in three or two French regions. Treated maize and oilseed rape were sown for four years on the same field.
Maximum residues over the years for maize:
Plants: 2.4 µg/kg thiamethoxam and 10 µg/kg CGA322704.
Pollen: always lower than those found in the plants, maximum residues 2 µg/kg for both analytes.
Maximum residues over the years for oilseed rape:
Plants: 2 µg/kg thiamethoxam and 1 µg/kg CGA322704).
Pollen: 1 µg/kg thiamethoxam and <1 (LOQ) µg/kg CGA322704).
Nectar: 3 µg/kg thiamethoxam and <1 (LOQ) µg/kg CGA322704).

Exposure via flowering crops
Based on the semi-field, field and monitoring studies, it can be concluded that exposure of up to three weeks to the tested flowering crops grown from thiamethoxam-treated seed does not have adverse long-term effects on honey bee colonies. The dose rate and the exposure period tested in the maize studies are relevant for the currently proposed dose rate in maize in the Netherlands.
In most of the residue trials, levels of thiamethoxam and metabolite were low and below 10 µg/kg. At 10 µg/kg, no mortality effects are expected on adult bees after 10-d exposure. At 12.5 µg/kg no effects are expected on larvae development. Thus, no effects are expected on these parameters from flowering treated crops. The NOEC values for return flight ability and feed consumption are uncertain. However, based on the long-term monitoring studies in which colony survival and condition was not affected, no adverse lethal and sublethal effects are expected from exposure via pollen of treated maize.
The dose rate in peas (104 g a.s./ha) is comparable with dose rates in the maize monitoring studies (79 -103 g/ha) with short exposure period (5-8 days), but higher than in the maize monitoring studies (55-70 g/ha) with long exposure period (20-24 days) and the oilseed rape monitoring studies (12-16 g/ha) with 12-22 days exposure time. However detectable residues in pollen and nectar are not related to dose rate per ha (occasionally present in maize pollen both at low and high rate and almost always in oilseed rape pollen and nectar at low dose rate). The residue concentrations are summarised in the attached table.
Based on the long term monitoring studies in both maize and oilseed rape with long exposure time in which colony survival and condition was not affected, no adverse lethal and sublethal effects are expected in peas. ~~The period of flowering for peas is considered to be covered by the exposure period tested in the monitoring studies (up to three weeks). The dose rate in peas (104 g a.s./ha) is however higher than in the monitoring studies (ca. 80 g a.s./ha).~~ ~~Therefore, for the uses in peas the applicant is requested to provide further information about the long-term effects on honeybees.~~

Flowering weeds

In all proposed crops, flowering weeds may occur in the field, but exposure via this route is not expected to be high for the proposed uses since a large amount of flowering weeds in fields is adverse to good and profitable agriculture.

Succeeding crops
Three trials (2010) were done in which residues were measured in untreated bee-attractive crops, alfalfa, Phacelia and OSR) which were sown in spring in soil in which in the previous year first treated maize (spring-summer) and then treated barley (autumn-winter) were grown. It was shown that the untreated succeeding crops contained thiamethoxam and metabolite CGA322704.
~~Maximum residues over all three trials:~~
~~Whole plants: 12 µg/kg thiamethoxam; 12 µg/kg CGA322704.~~
~~Nectar: 5.2 µg/kg thiamethoxam; 2.3 µg/kg CGA322704.~~
~~Pollen: 51 µg/kg thiamethoxam; 3 µg/kg CGA322704.~~
~~Exposure may thus occur via flowering succeeding crops. The flowering period of these may be variable. Long-term effects of exposure for a longer period than three weeks have not been studied. Furthermore, although most of the residue trials indicate that residues in pollen and nectar always stay below the provisional NOEC of 10 µg/kg, residues in nectar and pollen taken from bees foraging in untreated succeeding crops which followed two subsequent treated crops were occasionally above 10 µg/kg. Furthermore, the NOEC of 10 µg/kg is a provisional value and should be confirmed.~~
Residues over all three trials (summary in attached table):

Soil: range 4-24 µg/kg thiamethoxam; 2-5 µg/kg CGA322704

Whole plants:
- Alfalfa: range < 1-5 µg/kg thiamethoxam; 2-5 µg/kg µg/kg CGA322704
- Phacelia: range < 1-6 µg/kg thiamethoxam; 2-12 µg/kg µg/kg CGA322704
- Oilseed rape range 1-12 µg/kg thiamethoxam; 2-11 µg/kg µg/kg CGA322704

Nectar:
195 samples: range < 0.5 – 5.2 µg/kg thiamethoxam
131 samples: < LOQ thiamethoxam
195 samples: < 10 µg/kg thiamethoxam
190 samples: < LOQ CGA322704
Average is 0.75 µg/kg for thiamethoxam and at about LOQ for CGA322704

Pollen:
117 samples: range < 0.5 – 51 µg/kg thiamethoxam
69 samples: < LOQ thiamethoxam
115 samples: < 10 µg/kg thiamethoxam
27 samples: < LOQ CGA322704
Average is 3.0 µg/kg for thiamethoxam and 1.7 µg/kg for CGA322704

Exposure may occur via flowering succeeding crops. The flowering period of these may be variable, but exceptionally exceed the period of 3 weeks. Consequently the study is representative for flowering succeeding crops. Furthermore almost all of the residue trials indicate that residues in pollen and nectar stay below the NOEC of 10 µg/kg. In succeeding crops trial only two samples were above 10 µg/kg: however the average is far below 10 µg/kg. It can be concluded that the risk for bees via flowering succeeding crops is acceptable.

The residues in soil calculated for the registered uses of Actara and Cruiser are shown in the attached table. These residues correspond with the residues found in the above mentioned trials. Therefore these trials are representative for the uses of Actara and Cruiser.

For Actara residue levels are 5.8 – 9 µg/kg 90days after last application; this confirms the earlier proposed warning sentence on the label.

For Cruiser SB (600 FS) use in sugarbeets residue levels are 16,8 µg/kg after 90 days and 11.5 µg/kg after 180 days. The cultivation period of sugarbeets is about 6 months and sugarbeets are normally grown in rotation with other arable crops in next year. The risk for flowering succeeding crops is acceptable since in the exceptional cases flowering crops are grown after a sugarbeet crop the residue levels in soils are already at an acceptable level after 3 months.

For Cruiser 350 FS use in maize residue levels are 14,5 µg/kg after 90 days and 10.2 µg/kg after 180 days. The cultivation period of maize is about 5 - 6 months and maize is normally grown in rotation with maize, other arable crops or grassland in next year. The risk for flowering succeeding crops is acceptable since in the exceptional cases flowering crops are grown after a maize crop the residue levels in soils are already at an acceptable level after 3 months.

For Cruiser 350 FS use in peas residue levels are 25,5 µg/kg after 90 days, 22,5 µg/kg after 120 days and 17,8 µg/kg after 180 days. The cultivation period of peas is about 4 - 5 months and peas are normally grown in rotation other arable crops in next year. The risk for flowering succeeding crops is acceptable since in the exceptional cases flowering crops are grown after a pea crop the residue levels in soils are already at an acceptable level after 4 months.

For Cruiser 70 WS use in cabbage residue levels are 22,8 µg/kg after 90 days and 15,8 µg/kg after 180 days. These cases are worst case since no degradation from sowing to transplanting is taken into account. The cultivation period of cabbage is about 3 - 5 months after transplanting. The risk for flowering succeeding crops is acceptable since in the cases flowering crops are grown after a cabbage crop the residue levels in soils are already at an acceptable level after 3 months.

For Cruiser 70 WS use in leetuce/endive residue levels are 42 µg/kg after 90 days and 29,2 µg/kg after 180 days after 2 succeeding cultures. After a single residue levels are respectively 24,8 ug/kg and 17.3 ug/kg.These cases are worst case since no degradation from sowing to transplanting is taken into account. The cultivation period of lettuce is about 2 – 3 months after transplanting adn 1 month before transplanting. The risk for flowering succeeding crops is acceptable since in the cases flowering crops are grown after a single cultivation of a lettuce/endive crop the residue levels in soils are already at an acceptable level after 3 months. However a risk can not be excluded in case of 2 succeeding cultures per year.
It is proposed to add the following warning to the label:

In verband met het risico voor bijen mogen in hetzelfde kalenderjaar geen voor bijen aantrekkelijke gewassen worden gezaaid na meerdere teelten van met Cruiser behandelde gewassen.

~~The long-term effects from flowering succeeding crops should be further addressed by the applicant.~~

Guttation

It is known that guttation can occur in maize and to a lesser extent in sugarbeet. For peas, lettuce and endive, the relevance of guttation is unknown.
A trial in maize and oilseed rape (in which alternative water sources were available for the bees) indicated that although guttation does occur, the risk to bees via this route is expected to be low. Furthermore, due to dangers (e.g. presence of predators) bees are not keen on foraging on plants unless there is a considerable reward (pollen, nectar). Therefore, drinking droplets from plants is not likely to occur in the field (personal communication from a professional beekeeper, 5.1.2.e .
To reduce possible risks, it is recommended that beekeepers provide their colonies with sufficient water, but this is good beekeeping practice already. Therefore, the risk to bees from guttation is expected to be low.

Honeydew
Lastly, the risk from exposure via honeydew from aphids should be assessed.
According to the EPPO scheme, exposure to contaminated honeydew is not considered relevant in the case of soil and seed treatments, unless the compound is highly selective towards non-aphid insects (see note 4 EPPO scheme; it is assumed that in most cases aphids will be killed by the a.s. (i.e. honey dew exposure can be excluded)).
The relative sensitivity of aphids compared to bees for thiamethoxam is not known. Therefore the assumption of the EPPO scheme, that exposure via honeydew is not relevant due to immobilization of the aphids at concentrations below effect levels for bees, cannot be confirmed.
In lettuce, endive, ~~and~~ peas and sugar beets, Cruiser is intended to control (a.o.) aphid pests and the seed treatment will keep the crop free of aphids for about six weeks. It is indicated on the label that spray treatments against aphids may be necessary to keep the crop free of aphids when the infection pressure is high or in case of late infection (peas) or in the last weeks before harvest (lettuce). For sugar beets this needs also to be indicated on the label. The applicant submitted a new label proposal for Cruiser SB. Growers will strive to keep the crop free of aphids as much as possible. Therefore, the chance of honeydew formation in significant amounts is considered to be low and the risk to bees via this route is acceptable.
For maize aphid control is not on the Dutch label, but in general it can be assumed that thiamethoxam also controls aphids. In some countries were aphids can be a problem in maize (for instance France), thiamethoxam is registered for aphid control. In the Netherlands aphids is not considered to be a problem in maize. Therefore, the chance of honeydew formation in significant amounts is considered to be low and the risk to bees via this route is acceptable.

~~For maize and sugar beets, the product is also expected to control aphids, but this has not been addressed by the applicant up till now. The applicant is requested to confirm that the risk from honeydew in maize and sugar beets is acceptable.~~

A.2 Non-professional plant protection uses
None.

B. Biocides

B.1 Professional biocidal uses
None.

B.2 Non-professional biocidal uses
None.

Public literature:
Below, the preliminary results of a public literature survey are presented (see addendum).

Wu (2011) measured thiamethoxam in brood combs in the USA. The substance was found in 1 of the 13 samples, at a level of 38 ppb. The combs were contaminated with many other substances. Most frequently detected were a number of miticides used by beekeepers against Varroa. Delayed development was observed in bees reared in contaminated combs in a cage set-up. However, it is difficult to correlate this effect specifically to thiamethoxam because combs were contaminated with a cocktail of substances and may have contained also more pathogens than control combs. Also, this study does not include the implications for colony survival in the longer term.

Several large-scale monitoring studies were performed in which pesticide residues in bee hives were measured.

In a broad survey of pesticide residues, which was conducted on samples from migratory and other beekeepers across 23 USA states, one Canadian province and several agricultural cropping systems during the 2007–08 growing seasons, Mullin et al (2010) found thiamethoxam in only 0.3% (1 sample) of 350 pollen samples (at a level of 53.3 ppb). They also found 98 other pesticides and metabolites in mixtures up to 214 ppm in bee pollen alone, which according to them represents a remarkably high level for toxicants in the brood and adult food of this primary pollinator. They conclude that the effects of these materials in combinations and their direct association with CCD or declining bee health remains to be determined.

In a large study in Germany (Genersch et al., 2010), many pesticides (including miticides) were found in honeybee colonies. Thiamethoxam was not detected but it is unclear if it was included in the analysis. In this study, factors which significantly influenced overwintering succes were 1) high varroa infestiation level; 2) infection with deformed wing virus (DWV) and acute bee paralysis virus (ABPV) in autumn; 3) queen age; 4) weakness of the colonies in autumn. No effects could be observed for Nosema spp. or pesticides. The authors however consider that further investigations and controlled experiments are necessary to clarify the relation between pesticides and honeybee colony health in the long-term.

In a study in France (Chauzat et al, 2009), honeybee colony health was studied in relation to pesticide residues found in colonies. Thiamethoxam was not included in the analysis but other substances were found. No signficant relationship was found between the presence of pesticide residues and the abundance of brood and adults, nor between colony mortality and pesticide residues. The authors conclude that more work is needed to determine the role these residues play in affecting colony health.

The (thiamethoxam and other) residues reported in these publications cannot be linked to a certain (type of) use. Thus, from the public literature the only conclusion that can be drawn with certainty is that in some countries thiamethoxam is found in different bee matrices in the field. In these matrices usually a mixture is present of many pesticidal substances. So far, no statistical correlation has been found between the presence of pesticide residues in colonies and honeybee health in the long-term. Other factors than pesticides háve been shown to be linked to overwintering succes, though.

In the Netherlands, relatively high bee losses have been seen in recent years (increased mortality after winter). These losses have mainly been attributed to beekeeping practice with regard to pests and diseases, especially the *Varroa* mite, since it has been found that

adequate and timely Varroa treatment reduces winter mortality (personal communication bijen@wur and professional beekeepers; Van der Zee & Pisa 2011). Also, reduction of forage is likely to play a role. The relationship between pesticides and bee mortality has not been studied in the Netherlands so far.

A recent United Nations report (UNEP 2011) considers the status of honeybees and other pollinators worldwide. In Europe, North-America and Asia, increased bee losses have been reported. However, the symptoms seen are diverse. From Africa, reports of losses have only come from Egypt. In Australia, no increased honey bee losses have been reported (it is noted that the Varroa mite has not yet been introduced to this continent, except in New Zealand).

The UNEP report names many possible threats to pollinators:

- Habitat deterioration, with reduction of food sources (and habitat, for certain wild pollinators).
- Increased pathologies.
- Invasive species (the parasitic mite *Varroa destructor* is named as the most serious threat to apiculture globally).
- Pesticide use (chronic herbicide use and spray drift from broad spectrum insecticides; possible effects of chronic sublethal exposure to systemic insecticides, however this still needs to be proven in the field).
- Beekeeping activities.
- Climate change.

The conclusion of the UNEP report shows the complexity of the bee decline issue and is presented here in full:
Currently available global data and knowledge on the decline of pollinators are not sufficiently conclusive to demonstrate that there is a worldwide pollinator and related crop production crisis. Although honey bee hives have globally increased close to 45% during the last 50 years, declines have been reported in several locations, largely in Europe and Northern America. This apparent data discrepancy may be due to interpretations of local declines which may be masked by aggregated regional or global data. During the same 50-year period, agricultural production that is independent from animal pollination has doubled, while agricultural production requiring animal pollination has increased four-fold (reaching 6.1% in 2006). This appears to indicate that global agriculture has become increasingly pollinator dependant over the last 50 years. However, human activities and their environmental impacts may be detrimental to some species but beneficial to others, with sometimes subtle and counter-intuitive causal linkages. Pollination is not just a free service but one that requires investment and stewardship to protect and sustain it. There should be a renewed focus on the study, conservation and even management of native pollinating species to complement the managed colony tradition. Economic assessments of agricultural productivity should include the costs of sustaining wild and managed pollinator populations.

Many research networks and policy programmes have been created worldwide to study and counter pollinator decline (see the UNEP report for an overview).

Based on the available information it cannot be concluded that there is a link between thiamethoxam and the relatively high winter mortality in honeybee colonies observed in the Netherlands in recent years. Clearly, bee decline is caused by (an interaction of) a number of factors. Therefore, there is currently not enough evidence to justify a ban of thiamethoxam or other neonicotinoid products based on public literature. It should be noted that other (European and elsewhere) countries have not taken such steps either (with some exceptions where clear acute bee poisoning due to suboptimal sowing circumstances was observed; this has not been the case in the Netherlands).

Ctgb is considering to request a monitoring programme to further investigate the role that neonicotinoid substances play in bee decline. As this is suggested in the 'Inclusion Directive'. A decision on this matter will be taken at the end of the re-evaluation.

Cresswell (2011) has recently published a paper which questions the statistical power of honeybee field tests to show sublethal effects. This issue pertains to all pesticide risk assessments, not only to neonicotinoids, and will be considered by a European working group which has not started yet. The Netherlands will participate actively in this working group. As the impact of this paper as of yet is unclear, Ctgb will assess using the European harmonized methodologies.