ctgb

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 WIJZIGING TOELATING

Gelet op het verzoek d.d. 1 juni 2011 (20110607 WGGAG) van

Bayer CropScience B.V.
Energieweg 1
3641 RT MIJDRECHT

tot wijziging van de toelating als bedoeld in artikel 28, eerste lid, Wet gewasbeschermingsmiddelen en biociden van het gewasbeschermingsmiddel, op basis van de werkzame stof imidacloprid

Provado Garden

gelet op artikel 121, eerste lid, jo. artikel 41, tweede lid, Wet gewasbeschermingsmiddelen en biociden,

BESLUIT HET COLLEGE als volgt:

1.1 Wijziging toelating

Het middel Provado Garden is laatstelijk bij besluit d.d. 19 juni 2009 verlengd tot 31 januari 2014. Voorts is naar aanleiding van het herbeoordelingsprogramma van neonicotinoïden de toelating (het wg/ga) op 20 april 2011 op verzoek van de toelatinghouder gewijzigd. Vervolgens is de toelating bij besluit van 31 mei 2011 geschorst door de Staatssecretaris van Economische Zaken, Landbouw en Innovatie. Deze schorsing is op datum van bekendmaking van het onderhavige besluit door de Staatssecretaris van Economische Zaken, Landbouw en Innovatie weer opgeheven.
De toelating van het middel Provado Garden wordt gewijzigd en is met ingang van datum dezes toegelaten voor de in bijlage I genoemde toepassingen. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.

1.2 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.3 Gebruik
Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage I onder A bij dit besluit is voorgeschreven.

1.4 Classificatie en etikettering

Gelet op artikel 29, eerste lid, sub d, Wet gewasbeschermingsmiddelen en biociden,

1. De aanduidingen, welke ingevolge artikelen 9.2.3.1 en 9.2.3.2 van de Wet milieubeheer en artikelen 14, 15a, 15b, 15c en 15e van de Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten op de verpakking moeten worden vermeld, worden hierbij vastgesteld als volgt:

   aard van het preparaat: Water dispergeerbaar granulaat

werkzame stof:	*gehalte:*
imidacloprid	5 %

   op verpakkingen die (mede) bestemd zijn voor huishoudelijk gebruik: het kca-logo (het kca-logo is het logo voor klein chemisch afval bestaande uit een afvalbak met een kruis erdoor als opgenomen in bijlage III bij de genoemde Nadere regels)

<u>letterlijk en zonder enige aanvulling:</u>

andere zeer giftige, giftige, bijtende of schadelijke stof(fen):
-

gevaarsymbool:	*aanduiding:*
-	-

Waarschuwingszinnen:

-

Veiligheidsaanbevelingen:

S21 -Niet roken tijdens gebruik.

Specifieke vermeldingen:

DPD01 -Volg de gebruiksaanwijzing om gevaar voor mens en milieu te voorkomen.

2. Behalve de onder 1. bedoelde en de overige bij de Wet Milieugevaarlijke Stoffen en Nadere regels verpakking en aanduiding milieugevaarlijke stoffen en preparaten voorgeschreven aanduidingen en vermeldingen moeten op de verpakking voorkomen:

- letterlijk en zonder enige aanvulling:
  het wettelijk gebruiksvoorschrift
  De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I, onder A.

- hetzij letterlijk, hetzij naar zakelijke inhoud:
  de gebruiksaanwijzing
  De tekst van de gebruiksaanwijzing is opgenomen in Bijlage I, onder B.
  De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.

- bij het toelatingsnummer een cirkel met daarin de aanduiding W_{part}.5.

1.5 Aflever- en opgebruiktermijn

Op grond van artikel 41, vijfde lid, Wet gewasbeschermingsmiddelen en biociden en het Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007, mag het middel Provado Garden voor vorige etiketten:

1. voor de periode van 8 juli 2011 tot 8 september 2011 nog worden gebruikt en in voorraad of voorhanden worden gehouden;
2. voor de periode van 8 juli 2011 tot 8 september 2011 nog op de markt worden gebracht.

De onderbouwing van de termijnen is opgenomen in Hoofdstuk 4 van dit besluit.

2 DETAILS VAN HET VERZOEK EN DE TOELATING

2.1 Verzoek

Het betreft een verzoek tot wijziging van de toelating van het middel Provado Garden (12115 N), een middel op basis van de werkzame stof imidacloprid.

De gevraagde wijzigingen betreffen:

In siergewassen wordt een inperking van het gebruik gevraagd. Alleen gebruik ná de bloei tot de winterrust is nu toegestaan.

In appel en peer wordt de toegestane toepassingsperiode verduidelijkt met een bijsluiter met illustraties.

Gezien de aard van het wijzigingsverzoek omvat de risicobeoordeling voor ecotoxicologie enkel het aspect 'risico voor bijen'.

3 RISICOBEOORDELINGEN

Het gebruikte toetsingskader voor de beoordeling van deze aanvraag is weergegeven in de RGB.

3.1 Fysische en chemische eigenschappen

Gelet op de aard van het verzoek is dit aspect niet beoordeeld. De fysische en chemische eigenschappen wijzigen niet (zie Hoofdstuk 2, Physical and Chemical Properties, in Bijlage II bij dit besluit).

3.2 Analysemethoden

Gelet op de aard van het verzoek is dit aspect niet beoordeeld (zie Hoofdstuk 3, Methods of Analysis, in Bijlage II bij dit besluit).

3.3 Risico voor de mens

Gelet op de aard van het verzoek is dit aspect niet beoordeeld (zie Hoofdstuk 5, Residues in bijlage II behorende bij dit besluit.

3.4 Risico voor het milieu
Het middel voldoet aan de voorwaarde dat het, rekening houdend met alle normale omstandigheden waaronder het middel kan worden gebruikt en de gevolgen van het gebruik, voor bijen geen onaanvaardbaar effect heeft.
Gelet op de aard van het verzoek is het aspect Environmental Fate and Behaviour niet beoordeeld (zie Hoofdstuk 6, Environmental Fate and Behaviour). De beoordeling van het aspect Ecotoxicology staat vermeld in Bijlage II, Hoofdstuk 7 bij dit besluit.

3.5 Werkzaamheid
Gelet op de aard van het verzoek is dit aspect niet beoordeeld (zie Hoofdstuk 8, Efficacy, in Bijlage II bij dit besluit.

3.6 Eindconclusie
Bij gebruik volgens het gewijzigde Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel Provado Garden op basis van de werkzame stof imidacloprid voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu (artikel 28, Wet gewasbeschermingsmiddelen en biociden).

4 AFLEVER- EN/OF OPGEBRUIKTERMIJN

Uit oogpunt van bestuurlijke zorgvuldigheid is het van eminent belang dat de toelatinghouder, de distributeurs (waaronder detailhandel) en de gebruikers reëel in staat moeten worden gesteld om de nodige maatregelen te nemen zonder direct in overtreding te zijn. Dit belang is afgewogen tegen het milieubelang (met name van bijen) en de mate waarin effecten mogelijk optreden.
Het College besluit de opgebruik- en aflevertermijn op 2 maanden te stellen.

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 119, eerste lid, Wet gewasbeschermingsmiddelen en biociden en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 8 juli 2011

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN
BIOCIDEN,

i.o.

dr. D. K. J. Tommel
voorzitter

Dit middel is uitsluitend bestemd voor niet-professioneel gebruik

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I bij het besluit d.d. 8 juli 2011 tot wijziging van de toelating van het middel Provado Garden, toelatingnummer 12115 N

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel:

a. in siergewassen in de tuin, met dien verstande dat toepassing alleen is toegestaan na de bloei tot aan de winterrust.
b. in appels en peren in de tuin of particuliere boomgaard, door middel van een gewasbehandeling met een maximum aantal behandelingen van totaal twee keer per seizoen, met uitzondering van de periode dat de bloemknoppen zichtbaar zijn (zie bijsluiter).
c. in het gazon, door middel van een aangietbehandeling met dien verstande dat het middel maximaal één keer per jaar wordt toegepast.

Gevaarlijk voor bijen en hommels. Niet gebruiken op of in de buurt van bloeiende planten en bloeiende onkruiden.

Om in het water levende organismen te beschermen is de toepassing in percelen (gazons) die grenzen aan oppervlaktewater uitsluitend toegestaan indien niet gegoten wordt op de strook van 1 meter breed grenzend aan het oppervlaktewater (sloot / vijver/etc.)

Veiligheidstermijn:
De termijn tussen de laatste toepassing en de oogst mag niet korter zijn dan:
2 weken voor appels en peren.

Het middel is uitsluitend bestemd voor niet-professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Algemeen

Provado Garden werkt tegen de meeste op sierplanten in huis en tuin voorkomende zuigende insecten zoals bladluis, wolluis, buxusbladvlo en witte vlieg. Het middel is op appel en peer in te zetten tegen diverse luizen en tegen de appel- en perenzaagwesp. Voor deze toepassingen geldt dat het middel moet worden aangebracht door middel van een gewasbehandeling. Het gazon kan worden behandeld door middel van aangieten ter bestrijding van zowel engerlingen (o.a. larve van de meikever) als emelten (larven van de langpootmug). Door preventief aanbrengen van het middel op het gazon wordt vergeling of zelfs het plaatselijk afsterven van het gazon voorkomen.
Maai het gazon de dag voor de toepassing of vlak voor de toepassing. Breng het middel aan op een windstille, droge dag als de aarde een beetje vochtig is. Pas het middel niet toe bij helder, zonnig weer. Pas het middel tevens niet toe op een drijfnat of juist zeer droog gazon, aangezien de effectiviteit van het middel onder deze omstandigheden vermindert. Het meest geschikte moment om het middel aan te brengen is aan het begin van de avond. Nadat het

middel is aangebracht, dient het gazon onmiddellijk te worden beregend (5 tot 15 liter water per m^2. Dit beregenen is nodig om het middel door de gras/bodem laag heen te transporteren. Voorkom dat meer dan 15 l/m^2 wordt aangebracht.

Attentie:
Bijen kunnen actief vliegen op niet-bloeiende planten, bijvoorbeeld om door luizen afgescheiden honingdauw te verzamelen.

Toepassingen

Niet bloeiende sierplanten of sierplanten na de bloei tot aan de winterrust, ter bestrijding van bladluis, wolluis en witte vlieg. Zodra aantasting wordt waargenomen een gewasbehandeling uitvoeren.

Niet bloeiende sierplanten of sierplanten na de bloei tot aan de winterrust, ter bestrijding van de buxusbladvlo. Een gewasbehandeling uitvoeren zodra de larven uit de wintereieren komen.

Attentie
Langdurig gebruik van een en het zelfde middel moet voorkomen worden omdat dit de kans op resistentieontwikkeling kan verhogen. Het middel mag maximaal 2 keer per seizoen worden toegepast.

Appel, ter bestrijding van diverse luizen (roze appelluis, groene appeltakluis, fluitekruidluis, bloedvlekkenluis, appel-grasluis). Bij aanwezigheid van de luis een gewasbehandeling uitvoeren.

Appel, ter bestrijding van de appelzaagwesp.
Bij het vinden van de prikken van de appelzaagwesp gedurende de bloei van appel, direct na de bloei een gewasbehandeling uitvoeren.

Peer, ter bestrijding van diverse luizen (roze perenluis, vouwgalluis, zwarte perenluis, zwarte bonenluis). Bij aanwezigheid van de luis een gewasbehandeling uitvoeren.

Peer, ter bestrijding van de perenzaagwesp.
Bij het vinden van de prikken van de perenzaagwesp gedurende de bloei van peer, direct na de bloei een gewasbehandeling uitvoeren.

Appel en peer, ter bestrijding van de groene appelwants. Bij aanwezigheid van larven van de groene appelwants een gewasbehandeling uitvoeren.

Gewasbehandeling

Dosering: 0,15%, per liter water 1,5 gram Provado Garden gebruiken.

De planten zodanig bespuiten dat zowel de boven- als de onderzijde van de bladeren goed wordt geraakt. Het kan nodig zijn de behandeling te herhalen, wanneer er opnieuw aantasting optreedt. Maximaal 150 ml per vierkante meter toepassen.

Aanmaken van de oplossing:

Neem de gewenste hoeveelheid water en voeg daar de benodigde hoeveelheid Provado Garden aan toe. Gebruik geen ijskoud water. Roer dit goed door en laat de oplossing enkele minuten staan. Roer vervolgens nog een keer goed. De oplossing is nu klaar voor gebruik.

Behandeling van het gazon
Gazon, ter bestrijding van engerlingen (larven van de meikever), zodra aantasting wordt waargenomen of wanneer aanwezigheid van engerlingen is geconstateerd. Voor een optimale behandeling wordt het middel aangebracht in mei of juni wanneer volwassen meikevers gesignaleerd worden (tijdens de legperiode) .
Dosering: 3 gram per 9 liter water voor 10 m2. Het middel gelijkmatig over het gazon verdelen met behulp van een gieter, voorzien van een hiervoor geschikte verdeler.

Gazon, ter bestrijding van emelten (larven van de langpoot mug), zodra langpoot muggen worden waargenomen boven of op het gras. Dit is meestal rondom half augustus tot september (tijdens de legperiode).
Dosering: 3 gram per 9 liter water voor 10 m2. Het middel gelijkmatig over het gazon verdelen met behulp van een gieter, voorzien van een hiervoor geschikte verdeler.

Bijsluiter: Ontwikkelstadia bij appel en peer.

Zoals omschreven in het wettelijk gebruiksvoorschrift is toepassing op appel of peer alleen toegestaan in de periode dat de bloemknoppen niet zichtbaar zijn. Om te verduidelijken wanneer het middel wel en niet kan worden toegepast, volgt hier een overzicht van verschillende ontwikkelstadia.

1. Het groene blad knop stadium.
Moment waarop de appel of perenboom na de winter uit de vegetatie rust komt. Op dit moment kan Provado Garden worden ingezet.

2. Het muizenoorstadium.
Twee blaadjes zijn al iets verder uitgegroeid. Dit is het laatste stadium voor de bloei waarop Provado Garden kan worden ingezet.

3. Stadium waarop bloemknopjes zichtbaar worden. In dit stadium Provado Garden niet toepassen.

4. Einde van de bloei. Alle bloemblaadjes zijn eraf gevallen. Na dit stadium mag het middel weer worden ingezet.

5. Periode na de bloei. De ontwikkeling van de vrucht is ingezet. De nu nog kleine vruchtbeginsels zullen ontwikkelen tot appels of peren. Provado Garden kan worden ingezet.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 8 juli 2011 tot wijziging van de toelating van het middel Provado Garden, toelatingnummer 12115 N

1. Identity of the plant protection product

1.1 Applicant

Bayer CropScience B.V.
Energieweg 1
3641 RT MIJDRECHT

1.2 Identity of the active substance

The identity of the active substance does not change.

1.3 Identity of the plant protection product

The identity of the active substance does not change.

1.4 Function

Insecticide.

1.5 Uses applied for

The field of uses does not change.

1.6 Background to the application

It is an application for label change concerning the safety for bees.

1.7 Packaging details

Packaging details do not change.

2. Physical and chemical properties

The physical and chemical properties of the plant production product remain unchanged.

3. Methods of analysis

n.a.

4. Mammalian toxicology

n.a.

5. Residues

n.a.

6. Environmental fate and behaviour

n.a.

7. Ecotoxicology

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 bevat de beoordeling van het risico voor bijen van het middel Provado Garden op basis van imidacloprid. Zie onderstaande tabel.

Gewasbeschermingsmiddel Provado Garden op basis van imidacloprid

toelatingnr	middelnaam	toelating-houder	werkzame stoffen	formulering	Toepassing(en)
12115 (afgeleides: 12945, 12919)	PROVADO GARDEN	Bayer CropScience B.V.	imidacloprid 5%	Water dispergeerbaar granulaat	Niet-professioneel. Gewasbehandeling in siergewassen en appels en peren of particuliere boomgaard, en aangietbehandeling in gazon.

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.

Imidacloprid is placed on Annex I of 91/414/EEG since 08/2009 (2008/116/EC). In Commission Directive 2010/21/EU, the Inclusion Directive of imidacloprid was amended with additional provisions to avoid accidents with seed treatments. The provisions relevant for honeybees are now as follows:

Part A: For the protection of non-target organisms, in particular honey bees and birds, 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 treated seed includes the indication that the seeds were treated with imidacloprid 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 imidacloprid in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.";

For the risk assessment the final LoEP of 05/2009 is used and additional data from the applicant (presented in Appendix I). Also, information from the public literature is taken into account (presented in Appendix II). Abbreviations are explained in Appendix III.

During EU review for inclusion of imidacloprid on Annex I of 91/414/EEG, the risks of seed treatment for sugar beet (117 g a..s/ha) and of foliar spray for apples (70 – 105 g a.s./ha) and tomatoes (2x 100-150 g a.s./ha) were assessed. The EFSA has summarised the peer reviewed assessment in the EFSA conclusion, which is shown below.

EFSA conclusion.

A large number of studies with bees including tunnel tests, field and semi-field tests were submitted by the applicant. Imidacloprid is acutely very toxic to bees. The observed LD50 values ranged from 3.7 to >70.3 ng/bee for the acute oral toxicity and from 42.2 to 129 ng/bee for the acute contact toxicity. The acute toxicity of the main plant metabolites was also investigated. The metabolites olefine-imidacloprid and hydroxyl-imidacloprid are very toxic to honey-bees.

In addition to the standard acute toxicity tests also chronic tests and studies to investigate sublethal effects (bee behaviour) were conducted. The NOEC values for the dietary exposure were determined as 46 ppb (acute oral toxicity), 50 ppb sublethal effects (learning behaviour), 24 ppb chronic lethal effects and 20 ppb behavioural impacts including bee hive development. It was questioned during the peer-review whether effects on bee-brood are sufficiently addressed. No effects on bee-brood were observed in a number of field tests. The experts agreed that the available studies provide sufficient information to conclude on the representative uses evaluated.

The HQ values for oral and contact exposure were far in excess of the HQ trigger value of 50 indicating a high risk to bees from the use as a spray application in orchards and tomatoes.

Imidacloprid has a distinct systemic mode of action. Therefore the uptake in plants from soil/seed treatment applications was investigated in different crops (maize, cotton, egg-plant, potato and rice). The plants absorbed up to 20% (maize) of the amount of imidacloprid applied as seed dressing. Imidacloprid is preferentially translocated to leaves and shoots and to a much lower extend to the reproductive organs. The concentrations of imidacloprid and its main plant metabolites were investigated in the nectar and pollen of sunflower where the seeds were treated with 0.7 mg radiolabelled imidacloprid/seed. Only imidacloprid was found in the study but no plant metabolites (limit of detection was 0.1 ppb). Imidacloprid concentrations measured in pollen and nectar of different crops from different locations in Europe suggest that it is likely that residue levels in nectar of pollen will not exceed 5 ppb for the seed dressing uses currently registered in Europe. It was noted by the experts that extrapolation of measured residues to other crops is uncertain and should be interpreted with caution. No major soil metabolites were detected in the soil degradation studies. Bees would therefore only be exposed to imidacloprid residues in succeeding crops.

In order to assess the risk from application as a seed treatment the RMS calculated TER values on the basis of NOEC values from the available studies for the acute oral toxicity, sublethal effects (learning behaviour), chronic lethal effects and chronic behavioural impacts including bee hive development as 46, 50, 24 and 20 ppb. These NOECs were compared to residue levels in nectar and/or pollen of <5 ppb resulting in TER values of >9.2, >10, >4.8 and >4 indicating a low risk to bees from the representative use as a seed treatment. These findings were confirmed by the field tests where no adverse effects were observed where bees were exposed to flowering sunflowers, rape and maize treated as seeds with imidacloprid. Furthermore sugar beet is harvested before flowering hence no risk to bees is anticipated from the use as a seed treatment in sugar beet.

In the expert meeting it was discussed whether adverse long-term effects to bees are sufficiently covered by the risk assessment since the duration of most of the studies was 4-6 weeks. Two studies with a longer duration were available and one study also investigated winter bees. No sublethal effects were observed in the studies below a concentration of 5 ppb. The experts considered the information on long-term effects as sufficient to conclude on the risk from the representative uses evaluated.

The risk from exposure to honeydew excreted from aphids was considered as low. The acute oral LD50 for aphids is several orders of magnitude lower than for bees. Therefore it was suggested that it is highly unlikely that aphids would survive exposure to imidacloprid at concentrations in sap which could lead to the excretion of honeydew which is toxic to bees. Therefore it was assumed that appreciable amounts of honeydew will only be present at residue concentrations which are not hazardous for bees. The line of argumentation was agreed by the experts but it was not clear how the toxicity value for aphids was derived and the experts suggested a data gap for the applicant to clarify this point.

Overall it is concluded that the spray applications of imidacloprid pose a high risk to bees. Risk mitigation is required for the use in orchards. The risk to bees is considered to be low if the product is not applied during flowering and if flowering weeds are removed/mown before the product is applied. However it should be noted that bees potentially foraging in the off-crop area would still be exposed via spray drift and hence not be protected by the suggested risk mitigation measure.

Flowering tomato plants are visited by honey-bees and other pollinators. The risk mitigation suggested for orchards is not an option for the use in tomato since the tomato plants flower almost continuously. The RMS informed in a comment that it may be possible to apply risk mitigation measures in tomato e.g. restrict the application to the time before tomatoes start flowering. It was further noted that bumblebees are used in glasshouses to pollinate tomatoes. An appropriate waiting period should be kept before bumblebees are released after treatment. However no data are available for bumblebees to determine the waiting period.

As stated, the above EFSA conclusion focussus on the EU uses (foliar spray in apple and tomato, and sugar beet seed treatment). Below, the PPP uses currently allowed in the Netherlands will be assessed. Due to the particular properties of imidacloprid, the following exposure routes will be considered for each product:
- Direct exposure, both in- and off-field
- Indirect exposure, from the crop itself, weeds, succeeding crops, honeydew and guttation.
- Special consideration for the risk of introduced pollinators in greenhouses.

Surface water is not considered to be a relevant source of neonicotinoid exposure to honeybees (according to bee experts among which bijen@wur). Bees can take water from larger surface water like ditches, but only occasionally in dry periods in situations with low forage (nectar) availability. Surface water will in most cases be used by the bees for hive climate regulation in warm weather. Exposure of bees to imidacloprid in surface water is expected to be very low.

The risk to other bee species (e.g. bumblebees) is expected to be covered by the risk assessment for honeybees, as is the assumption of the current guidance document. However, in some cases this may not be a valid assumption and then the risk to those other species is separately discussed.

Provado Garden is used by non-professionals as a spray in ornamentals and apple and pear orchards and as a pouring use in lawns.

Direct exposure
In cases of direct exposure, imidacloprid is very toxic to bees. Therefore direct exposure should be avoided. If the product is not sprayed or poured on or near flowering plants, bees will not be exposed directly.

To prevent direct exposure, in the current label the following restriction sentence is indicated on the label:

> *Gevaarlijk voor bijen en hommels. Niet gebruiken op of in de buurt van bloeiende planten en bloeiende onkruiden.*

With the restriction, the risk is acceptable.

Indirect exposure
Flowering crops and flowering weeds

The applicant provided the following statement regarding the risks from non-professional use of imidacloprid:

"Provado® Garden is authorised in The Netherlands for uses in pome fruit, ornamentals and lawns. Concerns were raised by Ctgb whether the restriction to pre-flowering applications in pome fruits, as established for the agronomic uses (i.e. BBCH 10, mouse-ear stage), will reliably be respected by non-professionals. In order to address this question, Bayer CropScience has prepared a document (EPK 128; date: 04 MAR 2005), proposing a less and a more stringent wording as well as an illustration of the restriction to pre-flowering and post-flowering, i.e. when Provado® Garden can be used by non-professionals. Particularly the more stringent wording and illustration, as proposed in document EPK 128, is considered to enable every non-professional to identify the crop stage where application of Provado® Garden is possible, considering honey bees foraging on flowering apple or pear trees. As such, Bayer CropScience is convinced that with an appropriate label in combination with an intuitive and illustrative user manual (e.g. illustration of growth stages as proposed in document EPK 128 or illustration of situations where and when, respectively where and when not to apply), Provado® Garden can be used in pome fruit and ornamentals without adverse effects on honey bees. Moreover, it needs to be considered that potentially treated areas are small-scaled and as such deliver much less forage to bee colonies than e.g. commercial orchards, which require bee colonies to get hold of other pollen and nectar sources, which finally results in a dilution of potential residues at the hive level.

This holds also true for the question raised by Ctgb with regard to potentially flowering weeds around treated areas in house gardens.

Concerns were also raised with regard to the application of Provado® Garden to lawns. Bayer CropScience is convinced that also this use does not pose an unacceptable risk to bees, based on the risk assessment of Merit® Turf and the knowledge that the lawn use is commercialized as a specific product, which is mainly bought by consumers who will take proper care of their lawn. Furthermore, the use on private lawns is considered small scale in comparison to the Merit® Turf application.

When considering in addition the findings of Mayer and Lunden (1997; Doc.-No.: 110179-01-1) who applied imidacloprid at 112 g a.s./ha in an apple orchard with 10% open bloom and additionally with on average 6 flowering dandelions per m^2 understorey with no impact on honey bee mortality, in combination with the negligible phloem mobility of imidacloprid, ***it can be concluded that risk for bees in house gardens from the use of Provado® Garden in***

pome fruit, ornamentals and lawns can be effectively mitigated by appropriated label instructions."

Response Ctgb

Residues in flowering crops

For orchards, studies are available. In the EU dossier, effects on bees after spraying on crops in the pre-flowering stage were investigated in one cage (study o) and two field (studies m & n) trials. These trials, in apple orchards, showed that if spraying is done at the mouse-ear stage (BBCH 10) and bees are present in the following flowering period to forage on the open flowers, no adverse effects on bees occur. This was tested for an application rate of 105 g a.s./ha and bees were monitored for up to four weeks. The applicant recently also submitted a paper by Cantoni *et al.* published in the Bayer Pflanzenschutz-Nachrichten (54/2001). This paper describes the Italian field trial presented in the DAR (field study n from LoE) but also three similar field trials, performed in Italy in 1995. Tested rate was 120, 130 or 160 g a.s./ha, applied at the mouse-ear stage. Bees were introduced 19, 20 or 15 days after application, respectively. No adverse effects on foraging bees or colony development occurred. The observation period was 16 days. This paper can only be considered as additional information since the raw data are not available. Admire and Admire O-Teq can be applied twice per season, but there will be only one application before flowering. Therefore the tests are relevant for the proposed use in orchards.

Based on the cage and field trials, no adverse short-term effects on adult bees are expected from the proposed application of Provado Garden in apple and pear orchards by indirect exposure via nectar and pollen of the crop, provided that application is only allowed before flowering up to and including the mouse ear stage, and after flowering. To instruct non-professional users, the applicant has provided an instruction leaflet with pictures, indicating at which stages Provado Garden can be applied on apple and pear trees.

Based on the translocation behaviour of imidacloprid when applied as foliar spray, the substance will not occur in flowers when the flowerbuds are not sprayed. For apple and pear trees, the correct application stages can be explained with pictures. However, considering the large variety in ornamentals, it is not practical to instruct the non-professional user with pictures on the correct application time before flower buds are visible. Therefore, these uses are restricted to post-flowering only.

Thus, the label should be revised (only relevant use shown):

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel:

in siergewassen in de tuin, met dien verstande dat toepassing alleen is toegestaan na de bloei.
in appels en peren in de tuin of particuliere boomgaard, door middel van een gewasbehandeling met een maximum aantal behandelingen van totaal twee keer per seizoen, met uitzondering van de periode dat de bloemknoppen zichtbaar zijn (zie bijsluiter).

Grass plants in lawns will not produce much pollen due to frequent mowing so the risk via flowering grass is low.

Residues in flowering weeds

The exposure route is considered negligible for non-professional uses, as the use has a much more patchy distribution than professional use. This route poses no risk to the bee population.

Succeeding crops

The risk from succeeding crops is not considered to be relevant for non-professional use.

Honeydew
The risk via honeydew is considered to be low based on the much higher sensitivity of aphids as compared to bees (see professional uses for more explanation).

Guttation
The risk via guttation is considered to be low based on the low attractivity of guttation droplets to honeybees (see professional uses for more explanation).

Public literature:
The above risk assessment, based on protected data from the applicant, indicates that the risks of the proposed uses of imidacloprid in general are acceptable for bees, provided that restrictions are mentioned on the labels. In this section it will be considered whether studies available in the public literature domain confirm or contradict the risk assessment as shown above. A preliminary search on public literature has been carried out recently. The included references are presented in Annex II and the main results are summarised below. The text refers to the assessment of all imidacloprid uses, not only to Provado Garden.

Acute and chronic toxicity in laboratory studies
Acute toxicity reported in public literature is equal to or lower than the acute toxicity endpoint used in the risk assessment as shown above. The chronic mortality and sublethal effect studies were already considered in the DAR of imidacloprid. Therefore, these laboratory studies do not give rise to concerns that the risk assessment as shown above is not sufficiently conservative.

Residues in nectar and pollen
The residue data in nectar and pollen reported in the public literature survey are in agreement with the levels used in the risk assessment.

Sublethal/indirect effects
Wu (2011) measured imidacloprid in brood combs in the USA. The substance was found in 1 of the 13 samples, at a level of 45 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 imidacloprid 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. Therefore, this study does not contradict the above risk assessment.

Faucon et al (2005) fed two groups of eight honey bee colonies with two different concentrations of imidacloprid in saccharose syrup during summer (each colony was given 1 litre of saccharose syrup containing 0.5 µg/L or 5 µg/L of imidacloprid on 13 occasions). Their development and survival were followed in parallel with control hives (unfed or fed with saccharose syrup) until the end of the following winter. The parameters followed were: adult bee activity (number of bees entering the hive and pollen carrying activity), adult bee population level, capped brood area, frequency of parasitic and other diseases, mortality, number of frames with brood after wintering and a global score of colonies after wintering. The only parameters linked to feeding with imidacloprid-supplemented saccharose syrup when compared with feeding with non-supplemented syrup were: a statistically non-significant higher activity index of adult bees, a significantly higher frequency of pollen carrying during the feeding period and a larger number of capped brood cells. When imidacloprid was no longer applied, activity and pollen carrying were re-established at a similar level for all groups. Repeated feeding with syrup supplemented with imidacloprid did not provoke any immediate or any delayed mortality before, during or following the next winter. This confirms the expectation made in the risk assessment that exposure to a residue level of 5 ppb does not lead to adverse long-term effects.

Nguyen et al. (2009) studied the connection between imidacloprid seed-treated maize and winter bee mortality in Belgian apiaries. Imidacloprid was measured in bee matrices: bees and bee wax: 0 out of 48 positive; honey: mean 0.275 ppb (between LOD and LOQ) in 4 out of 48 samples. The origin (floral resource) of the measured imidacloprid in honey is unclear, since maize does not produce nectar. No correlation of mortality was found with imidacloprid. Winter mortality had a negative correlation with the surface of maize in the surroundings.

In a study of the effects of imidacloprid sunflower seed coating to *Bombus terrestris* (Tasei *et al.,* 2001) the authors concluded that applying imidacloprid at the registered dose, as a seed coating of sunflowers cultivated in greenhouse or in the field, did not significantly affect the foraging and homing behavior of *B. terrestris* and its colony development.

Morandin & Winston (2003) subjected bumblebee colonies to 7 or 30 ppb imidacloprid in pollen. There were no effects on pollen consumption, bumble bee worker weights, colony size, amount of brood, or the number of queens and males produced. No lethal, sublethal colony, or individual foraging effects were found at residue levels found in the field (7 ppb), suggesting that bumble bee colonies will not be harmed by proper use of these pesticides. Effects on foraging speed were detected at 30 ppb (a higher concentration than found in the field).

Girolami et al (2009) measured residue levels in guttation droplets from plants grown from treated seeds and found high concentrations, which had a significant effect on honey bees. However, as indicated by Thompson (2010), these findings should be treated with caution as the data were generated by feeding collected droplets directly to bees, and in many cases sucrose was added to ensure that the honey bees consumed the dose. Furthermore, from studies in the protected dossiers on the relevance of guttation in the field it is concluded that guttation does not lead to risks in practice.

It is important to realize that some of the studies used in the risk assessment above have been subjected to a meta-analysis recently published in a paper by Cresswell (2011). The analysis comprised 14 published studies of the effects of imidacloprid on honey bees under laboratory and semi-field conditions that included measurements on 7073 adult individuals and 36 colonies. The resulting fitted dose-response relationships estimate that trace dietary imidacloprid at field-realistic levels in nectar will have no lethal effects, but will reduce expected performance in honey bees by between 6 and 20%. Statistical power analysis showed that published field trials that have reported no effects on honey bees from neonicotinoids were incapable of detecting these predicted sublethal effects with conventionally accepted levels of certainty.
This issue pertains to all pesticide bee risk assessments, not only to neonicotinoids, and will be considered by a European working group which has not started yet (EFSA mandate M-2011-0185). The Netherlands will participate in this working group. Ctgb will assess using the European harmonized methodologies until the impact of this paper has been clarified in the European framework.

Monitoring studies
Several large-scale monitoringstudies were performed in which bee health was studied and pesticide residues in bee hives were measured.

In a large study in Germany (Genersch et al., 2010), many pesticides (including miticides) were found in honeybee colonies. Imidacloprid was detected in one of the 215 samples of beebrood. 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 on French apiaries in France (Chauzat et al. 2006), pesticide residues were analysed in pollen loads. Search of imidacloprid and 6-chloronicotinic acid was conducted on 81 samples of pollen loads. Residues of imidacloprid were found in 40 samples. The most frequent residues were imidacloprid (49.4% of samples), 6-chloronicotinic acid (44.4%) and fipronil (12.4%). The proportion of samples with either imidacloprid, 6-chloronicotinic acid, or both was 69.1%. Maximum imidacloprid and 6-chloronicotinic acid concentration found in these positive samples was 5.7 and 9.3 µg/kg (mean: 1.2 and 1.2 ppb), respectively.
In another study in France (Chauzat et al, 2009), honeybee colony health was studied in relation to pesticide residues found in colonies. Imidacloprid metabolites were analysed in pollen, honey and honeybee samples. The most frequent residue in pollen loads, honey, and honey bee matrices was imidacloprid or 6-chloronicotinic acid. Mean concentrations of imidacloprid residue, from those positive samples, were 1.2 µg/kg in honey bees, 0.9 µg/kg in pollen, and 0.7 µg/kg in honey. The concentration obtained for imidacloprid and 6-chloronicotinic acid in pollen loads was above the limits of detection (LOD) in 40% (75/185) and 33% (61/185) of the samples, respectively. When both were found together, the concentrations were above the LOD in 16% (30/185) of the samples.
It is not known to which extent imidacloprid was used in the areas in which the bee samples of the studies of Chauzat et al. were taken. Apart from imidacloprid, many other pesticidal substances were found in the bee matrices.
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.

In a study of Belgian apiaries comparable to the above trials, imidacloprid was found in 5 of the 109 samples in amounts <0.084 ppb (Pirard et al 2007).

Higes et al (2010) estimated the prevalence of honey bee colony depopulation symptoms in Spain in a random selected sample (n = 61) and explored the implication of different pathogens, pesticides and the flora visited in the area under study. Imidacloprid was not detected in any sample. Acaricides like fluvalinate, and chlorfenvinphos used to control *Varroa* mite were the most predominant residues in the stored pollen, probably as a result of their application in homemade formulae. None of the pesticides identified were statistically associated to colony depopulation. This preliminary study of epidemiological factors suggests that *Nosema Ceranae*, a unicellular parasite, is a key factor in the colony losses detected over recent years in Spain. However, more detailed studies that permit subgroup analyses will be necessary to contrast these findings.
In two other studies in Spain (Garcia-Chao et al 2010, Bernal et al. 2010), imidacloprid was not detected either.

Schmuck (2001) found imidacloprid residue levels in greenhouse grown sunflower pollen and nectar grown in greenhouses of 3.9 and 1.9 ppb, respectively. He found no detectable residues under field growing conditions, nor in succeeding crops.

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 the following residue levels of imidacloprid: wax 2.4-13.6 ppb (detected in 1.0% of 208 samples, mean 8.0 ppb); pollen 6.2-206 ppb (detected in 2.9% of 350 samples, mean 39 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 (colony collapse disorder) or declining bee health remains to be determined.

The residues reported in these publications cannot be linked to a certain (type of) use. imidacloprid is an insecticide used in agriculture, horticulture, animal health, house protection/household markets and locust control, thus a number of different sources can contribute to bee exposure.

Thus, from the public literature the only conclusion that can be drawn with certainty is that in many countries imidacloprid is found in different bee matrices in the field. More research is needed to determine causal relationships with bee colony health.

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 hâve been shown to be linked to overwintering succes, though.

Bee colony losses in the Netherlands

In the Netherlands, relatively high bee losses have been reported in recent years (increased mortality after winter).

A scientific report on bee mortality and bee surveillance in Europe, submitted to EFSA (Hendrikx *et al.* 2009), reported the results regarding The Netherlands and Belgium as shown in the table below.

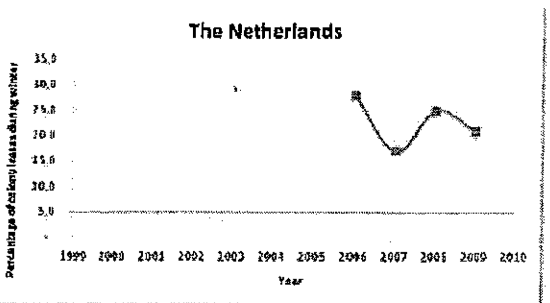

Figure 47. **Percentage of winter colony losses in the Netherlands from 2000 to 2009**

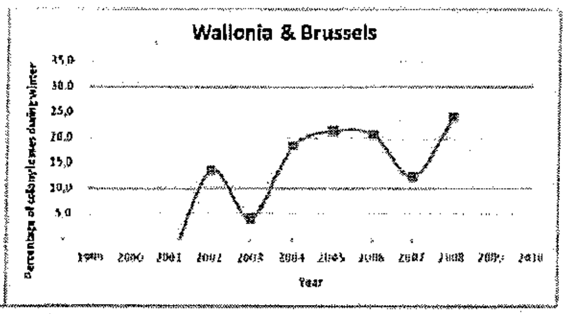

Figure 48. **Percentage of winter colony losses in Wallonia & Brussels from 2000 to 2009**

The yearly NCB (Dutch monitor on honeybee colony losses) established a mortality rate of 23% during winter 2007/2008 and 26% during winter 2005/2006. Colony loss in 2009-2010 was 23.1 (after adjusting for inappropriate winter feeding (Ambrosius Fructo-Bee)) (Van der Zee, 2010; Van der Zee & Pisa, 2011).

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 (Van der Zee & Pisa 2011; personal communication bees@wur and professional beekeeper). Also, reduction of forage is likely to play a role. The relationship between pesticides and bee decline has not been studied in the Netherlands so far.

Europe

A report submitted to EFSA on bee mortality and bee surveillance in Europe (Hendrikx *et al.* 2009), concluded on results derived from surveillance systems in 27 European countries and a thorough literature search of the existing databases, as well as relevant grey literature about causes of colony losses:

• General weakness of most of the surveillance systems in the 24 countries investigated;

• Lack of representative data at country level and comparable data at EU level for colony losses;

• General lack of standardisation and harmonisation at EU level (systems, case definitions and data collected);

• Consensus of the scientific community about the multifactorial origin of colony losses in Europe and in the United States and insufficient knowledge of causative and risk factors for colony losses.

International observations

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 information as shown above, it cannot be concluded that there is a link between imidacloprid 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. There is currently no evidence that imidacloprid or other neonicotinoid products significantly contribute to bee decline based on the referred public literature. It should be noted that other (European and elsewhere) countries have not withdrawn these substances from the market 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).
Finding associations between bee decline and all possible environmental factors is a complex issue that has to be established the coming years in a scientific way. It seems rational that the possible association of imidacloprid (and other neonicotinoids) on high winter mortality in honeybee colonies observed in the Netherlands is part of these investigations. In the 'Inclusion Directive' of imidacloprid it is suggested that a monitoring programme may be required to further investigate the role that neonicotinoid substances play in bee decline. Recently, a study has been started by bijen@wur to investigate the long-term effects on honeybee colonies of chronic sublethal exposure to imidacloprid in relation to the vitality of honeybee colonies. Awaiting the results of this study, more extensive monitoring programmes targeted at the effects of imidacloprid on honeybees are currently not required.

Appendix I. List of Endpoints Ecotoxicology
Final LoE imidacloprid for inclusion in Annex I of 91/414/EEC.

For the risk assessment the final LoE of the EFSA conclusion is used (Word-version d.d. 02/2008, endpoints are the same as for the published conclusion on 05/2009) and additional data from the applicant (summarised and evaluated by Ctgb, May 2011). Additions to and clarifications of the LoE are shown in italics.

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

Acute oral toxicity	LD_{50} = 0.0037 µg as/bee (active substance) LD_{50} = 0.0056 µg as/bee (formulation)
Acute contact toxicity	LD_{50} = 0.081 µg as/bee (active substance) LD_{50} = 0.042 µg as/bee (formulation)

The LoE contains only the lowest endpoints for the a.s. and the formulation. More acute toxicity tests were done with the a.s.. Table B.9.4-1 in the DAR presents the results from these tests (ranges: oral LD50 >21->70.3 ng a.s./bee, oral NOEL 1.5-9.0 ng/bee; contact LD50 42.9-129 ng/bee, contact NOEL <40 ng/bee).

In addition, acute toxicity tests with metabolites were done. Of the 7 imidacloprid plant metabolites only the olefine- and the monohydroxymetabolites are considered relevant for evaluating the risk to honeybees from a crop seed treatment with imidacloprid. These metabolites also have high acute toxicity to bees, but significantly lower subacute toxicity than the parent .

Also, in the DAR the sensitivity of other hymenopterans (Bombus terrestris, Nomia melanderi, Megachile rotundata and Bombus occidentalis) to imidacloprid compared to honey bees was performed. Based on that reviewed data it can not be concluded that imidacloprid poses a higher risk to wild than to domestic bees.

Furthermore, several chronic tests and studies to investigate sublethal effects (bee behaviour) on honeybees were conducted with the a.s. The chronic lethal and sublethal toxicitywas extensively discussed in the DAR and summarised in the EFSA conclusion on imidacloprid, which has been copied in the beginning of the risk assessment for plant protection products above. In the DAR, NOEC values from the available studies for the acute oral toxicity, sublethal effects (learning behaviour), chronic lethal effects and chronic behavioural impacts including bee hive development were set at 46, 50, 24 and 20 ppb. The 20 ppb is derived from semi-field and field studies; the DAR concludes that the laboratory NOLEC would not be lower than 10 ppb.

Field or semi-field tests Because of the high toxicity of the active substance all spray applications have to be classified as hazardous for bees. Because of the distinct systemical mode of action in combination with the high toxicity a large number of practical tests have been performed regarding effects on bees by seed treatment. In total 14 cage tests and 11 field tests have been regarded for the evaluation. By all results the seed treatment with imidacloprid containing products has been proved as not hazardous for bees. *A summary from the (semi-) field tests presented in the DAR (with additional information in addendum 4) is added here by Ctgb. Residues were taken from bee-relevant matrices in most of the studies (these are discussed in the risk assessment). The validation of the analytical methods for residue analysis is presented in addendum 2 of the DAR. Addendum 4 contains a list of studies which were not considered relevant for the risk assessment of*

bees by the RMS. These studies have not been included below.

Cage tests.
seed treatment:
a) Maus 2002. Colonies were fed with pollen from seed-treated maize (1 g a.s./1000 seeds). No effects on foraging activity, behaviour, egg laying activity, breeding succes, pollen and honey stores, colony strength and weight. Exposure and observation duration: 52 days.
b) Maus & Schoening 2001. Colonies were fed with pollen from seed-treated maize (49 g a.s./unit'). No effects on mortality, foraging activity, behaviour, egg laying activity, pollen and honey stores, colony strength. Exposure and observation duration: 38 days.
c) Schmuck & Schoening 1999. Colonies were exposed to flowering rape seed treated with 1 kg a.s./dt'. No effects on mortality and behaviour. Exposure and observation duration: 3 days. France.
d) Schmuck & Schoening 1999. Colonies were exposed to flowering rape seed treated with 1 kg a.s./dt'. No effects on mortality and behaviour. Exposure and observation duration: 3 days. Sweden.
e) Schmuck & Schoening 1999. Colonies were exposed to flowering rape seed treated with 1 kg a.s./dt'. No effects on mortality and behaviour. Exposure and observation duration: 3 days. UK.
f) Schmuck & Schoening 1999. Colonies were fed with sunflower honey treated with imidacloprid (up to 20 ug/kg) and untreated pollen. No effects on mortality, foraging activity, behaviour, food consumption, storage behaviour, egg laying activity, breeding succes, comb cell production, colony strength and weight. Exposure and observation duration: 39 days.
g) Schmuck & Schoening 1999. Colonies were fed with maize pollen treated with imidacloprid (up to 20 ug/kg) and untreated sunflower honey. No effects on mortality, foraging activity, behaviour, food consumption, storage behaviour, egg laying activity, breeding succes, comb cell production, colony strength and weight. Exposure and observation duration: 39 days.
h) Schmuck et al. 1999. Exposure to flowering sunflowers, which was either seed-treated (52 g a.s./ha) or sown as untreated succeeding crop after imidacloprid use. No effects on mortality and behaviour. Exposure and observation duration: 8 days.
i) Schmuck et al. 1999. Exposure to flowering sunflower, which was either seed-treated (45 g a.s./ha) or sown as untreated succeeding crop after imidacloprid use. No effects on mortality and behaviour. Exposure and observation duration: not reported, but likely 8 days as in similar trial above.
j) Schmuck et al. 1999. Exposure to flowering summer rape, which was either seed-treated (72 g a.s./ha) or sown as untreated succeeding crop after imidacloprid use. No effects on mortality and behaviour. Exposure and observation duration: 8 days.
k) Schmuck et al. 1999. Exposure to flowering summer rape, which was either seed-treated (72 g a.s./ha) or sown as untreated succeeding crop after imidacloprid use. No effects on mortality and behaviour. Exposure and observation duration: 8 days.
l) Wallner 1999. Exposure to flowering Phacelia, seed-treated (50 g a.s./ha). No effects on mortality, disorientation, foraging activity and honey yield. Exposure and observation duration: not reported in DAR.
m) Harris 1999. Exposure to flowering canola (OSR), seed-treated (51 g a.s./ha; 800 g/100 kg seed). No effects on mortality, foraging activity, brood development, colony strength. Exposure and observation duration: 43 days.
n) Brasse 1999. Exposure to flowering summer rape, seed-treated (63 g a.s./ha; 10.5 g/kg seed). No effects on mortality, foraging activity, brood development, colony strength. Exposure and observation duration: 21 days. It is mentioned that both colonies overwintered as full colonies.
r) Colin & Bonmartin 2000 and s) Colin 2003. Not considered valid by RMS.
spray treatment:
o) Schur 2001. Colonies exposed to full flowering apple orchards which had been sprayed during the mouse-ear stage (BBCH 10) at 0.105 kg a.s./L. No effects on mortality, foraging

activity, behaviour, condition of the colonies and brood development. Exposure and observation duration: 7 days.
p) Bakker 2001. Colonies exposed to flowering Phacelia which was sprayed with 0.6 – 14 g a.s./ha during bee flight. When applied during bee flight, 0.6 g a.i./ha and 1.2 g a.i./ha of Confidor SL 200 had no effects on foraging activity and mortality of the honeybee Apis mellifera. At a rate of 2.0 g a.i./ha, 4.0 g a.i./ha and 9.0 g a.i./ha foraging activity was reduced on the day of application, but no effects on mortality were observed.
At the highest test rate (14.0 g a.i./ha) statistically significant reduction in foraging was found during the first two days, but no effects on mortality were observed. (Please note that the summary in the DAR states that mortality was significantly higher than control in dose rates 2.0-14.0 g a.s./ha; RMS Germany agrees that this has been a mistake and that in fact no mortality occurred in the study).
q) Bakker 2003. Colonies exposed to flowering Phacelia which had been sprayed with 21 or 35 g a.s./ha 24, 48 and 96 h before exposure. Foraging activity significantly reduced in all treatments. Mortality twice as high as in control.

Field tests.
seed treatment
a) Schmidt et al. 1998. Exposure to flowering sunflowers, seed-treated with 59 g a.s./ha (0.7 mg a.s./seed). No effects on mortality, behaviour, hive weight, foraging, flight and pollen collection activity. Exposure and observation duration: 14 days
b) Schuld 2002. Exposure to flowering oilseed rape, seed-treated with 1051 g a.s./100 kg seed = 31.4 g a.s./ha. No effects on mortality, behaviour, brood development, flight intensity and colony strength. Exposure and observation duration: 15 days. After flowering all colonies were transferred to the bee research institute and developed normally up to the end of the season.
c) Schulz 2000. Exposure to flowering sunflower, seed-treated with imidacloprid (dose not reported, but assumed to be equivalent to the intended use in sunflower, i.e. ca. 60 g a.s./ha). No effects on mortality, foraging behaviour, colony development, flight activity. Exposure and observation duration: 17 days.
d) Scott-Dupree 2001. Exposure to flowering oilseed rape, seed-treated with 1000 g a.s./100 kg seed (seed dressing rate 6-7 lbs/acre) or 600 g /100 kg seed. No effects on mortality, behaviour, foraging activity, brood development, honey yield and colony strength. Exposure and observation duration: 1 month.
e) Stadler 2000. Exposure to flowering sunflowers, seed-treated with 0.2458 mg a.s./seed. No adverse effects on mortality, flight and foraging activity, brood development,honey and pollen stores and colony strength. Exposure and observation duration: 24 days.
f) Szentes 1999. Exposure to flowering sunflowers, seed-treated with 38 g a.s./ha. No adverse effects on mortality, foraging activity, behaviour, input of nectar and pollen, egg laying activity, brood development and colony strength. Exposure and observation duration: 15 days.
g) Kemp & Rogers 2002. Exposure to flowering clover fields which had been sprayed with imidacloprid (presumably before introduction of bees since no effects were seen; dose unknown) and which were sown on fields on which two years earlier imidacloprid had been applied as soil treatment (potato in-furrow application, 204 g a.s./ha), one year earlier grain had been sown (according to the DAR treated with 204 or 312 g a.s/ha; according to addendum 4 not treated), and earlier in the same season also a clover crop had been sprayed (dose unknown). All colonies placed in the treated clover fields developed normally and did not show any impact of the test product on colony strength, brood status, honey storage and behaviour. Few colonies showed symptoms of chalkbrood, Varroa and European foulbrood. Exposure and observation duration:8 weeks. However, results for bee effects are not considered useful due to missing data on dose rate and introduction time.
h) Kirchner 1998. Effects of sublethal doses on foraging behaviour and orientation ability, both in the lab (groups of individual bees) and in the field (whole colonies). Bees were fed with sucrose solution containing 10 to 100 ppb. In concentrations of 20 ppb and more

imidacloprid has a significant impact on the behaviour on foraging honeybees: The frequency of trembling dances is increased, the number of visits at the contaminated food is decreasing, corresponding to increase of concentration and time the frequency of waggeling dances is decreasing and also the precision in the informations (regarding distance and direction) given by the waggeling bees is decreasing. The combination of these changings in the behaviour of the bees at concentrations of 20 ppb and more may lead to a total suspension of foraging, but it is not likely to cause a damage in honeybee colonies
i) Kirchner 2000. Effects of sublethal doses on the behaviour (trembling, waggling dances, learning behaviour (PER), both in the lab and in the field, of imidacloprid, dihydroxy-imidacloprid and olefine-imidacloprid. A short-term effect of imidacloprid on the learning process was only recorded at concentrations > 100 ppb. Olefine-imidacloprid did not have effects <100 ppb, learning behaviour was significantly reduced at 500 ppb. Dihydroxy-imidacloprid had no effect at 100 ppb, learning behaviour was significantly reduced at 2 ppm.
j) Faucon 2004. Colonies fed for 1 month 3 times/week with sugar solution treated with 0.5 or 5 ug/kg imidacloprid. Total exposure duration 1 month, total observation duration 8 months (including overwintering). No adverse effects on flight activity, mortality , brood development. After the winter, treated and control colonies were of comparable status (brood, strength, weight, health).
k) Pham-Deleque and Cluzeau 1999. Test programme to investigate bee losses in France. Colonies exposed to seed-treated flowering sunflowers). No adverse effects on mortality, flight activity, health status, brood development, colony strength and yield of honey and pollen (dose rate and test duration not reported in DAR). No adverse effect on the number of returning foragers. No adverse effects on bumblebees. Also lab and cage studies were done A concentration related change in the behaviour of the bees was observed when foraging on contaminated food. No impact on honeybees was observed when imidacloprid was used in combination with fungicides for seed dressing. No impact on bumblebees was observed when imidacloprid was used in sunflowers for seed treatment. A concentration related effect of imidacloprid on social behaviour and food consumption was observed for honeybees. It was observed that imidacloprid offered in sublethal doses on the oral and the contact way has concentration related effects on the learning ability of honeybees. It is assumed that imidacloprid is rapidly metabolised in the bee body and it may be concluded that the active substance therefore can not be detected in dead bees after intoxication..
l) Mayer & Lunden 1997. 1) Cage study where honeybees, alkali bees and leafcutting bees were exposed to 2 or 8 h field-aged residues on sprayed alfalfa (0.028 – 0.28 kg/ha). Honeybees were a little bit more sensitive than the other species. Mortality increased with dose. 2) Colonies were given the choice between untreated and treated (2-500 ppm) syrup. Visits decreased with increasing imidacloprid concentration. 3) Flowering dandelion was sprayed with 50 or 112 g a.s./ha. Foraging bees were counted 0.5, 1 and 4 hours after spraying. Foraging activity decreased with increasing imidacloprid concentration. 4) Spraying of 112 g a.s./ha to apple orchard with 10% of apple flowers open and with on average 6 flowering dandelions per m2 understorey. Spraying was done before bee flight, at 8 am; foraging activity and mortality were checked on that same day (foraging activity between 11 and 14 h). No adverse effects.
spray treatment:
m) Schur 2001. Colonies exposed to full flowering apple orchards which had been sprayed during the mouse-ear stage (BBCH 10) at 0.105 kg a.s./L, in Germany. No effects on mortality, foraging activity, behaviour, condition of the colonies and brood development. Exposure and observation duration for 7 days (4 weeks for brood).
n) Cantoni 1998. Colonies exposed to full flowering apple orchards which had been sprayed during the mouse-ear stage (BBCH 10) at 150 g a.s./ha (based on 1500 L spray liquid/ha containing 50 mL/hL Confidor SL 200; info from report amendment dd 17/09/2009). Study performed in Italy. No adverse effects on foraging activity, colony weight, honey yield and number of returning bees. Exposure and observation duration: 11 days.
See also field study g) above.
other studies:

o) Belzunces et al 1998. *Marked foragers from small honeybee colonies were followed while foraging on feeders containing sucrese solution (0.1 and 1 mg/L i.e. 100 ppb and 1 ppm). Bees which had ingested the 1 ppm sucrose solution shortly did not return to the feeder and showed symptoms of poisoning while bees which had ingested uncontaminated solution returned frequently to the control feeder. The poisoned bees could not be found in the hives any more. No difference could be observed between bees which had ingested the 100 ppb sucrose solution and control bees. At this concentration the number of marked bees observed at both the treated and the control feeder was comparable and variability, respectively, was on the level. No symptoms of poisoning could be observed in the test colonies at 100 ppb. Also a laboratory test was performed to investigate metabolism of imidacloprid in honeybees, but information on this part of the study was not reported and thus cannot be used.*

Bielza 2000. *This study is presented in section 10.5 (non-target arthropods) of the DAR but is included here because it gives information on effects on bumblebees. Greenhouse trial in SE Spain. Soil-application of 150 g imidacloprid/ha (0.75 L Confidor 200 LS/ha on flowering tomato 38, 48, 58 and 68 days after transplanting of tomato plants. Assessments of pollinating activities were performed 38, 44, 52, 59, 66, 73 and 80 days after transplant. No adverse on pollination (percentages of flowers pollinated, aborted, closed/non-marked and marked, as well as bumblebee flight frequencies) were detected. After laboratory evaluation of hives at the end of the experiment, no significant differences were detected between treatments for any of the parameters studied.*

Further studies in greenhouse
Not included in the DAR. Submitted to Ctgb in June 2011.
Vacante (1997). *In this greenhouse trial in Italy (Sicily), bumblebees were introduced to tomato plants 7 days after treatment (soil-application of 178 or 267 g imidacloprid/ha) for pollination purpose. Effects on bumblees were not studied, but no adverse on pollination (number of fruits set; fruit weight) were detected. The authors conclude that a waiting period of 7 days between treatment and introduction of Bombus terrestris is sufficient to record no reduction in impollination.*

Residues in succeeding crops
Seven studies which measured residues in succeeding crops are available in the DAR. The summary below is added by Ctgb based on the DAR (some of these studies are also mentioned above).

Schmuck et al 1999 *BIE2003-221, BIE2003-220, BIE2003-219, BIE2003-218; Residues measured in sunflower nectar and pollen, maize pollen and rape nectar and pollen; these untreated crops were sown in soils with imidacloprid residue 0.0127-0.0178 mg/kg. No residues of imidacloprid (LOQ 5 ppb) and the imidacloprid metabolites monohydroxy- (LOQ 5 ppb) and olefine- (LOQ 10 ppb) were detected in nectar, pollen or honey from rape, clover or maize planted as succeeding crops (all residues < LOD; LOD typically 1/3 of LOQ).*

Lagarde 2001, BIE2003-189; *In sunflower crops, Lagarde (2001) reported detectable residues in 1 of 4 nectar (1.6 ppb) and in 1 of 14 pollen (1.5 – 2 ppb) samples but it is unclear from the study report whether the positive results were obtained from seed-treated or untreated crop plants. From a comparative measurement in sunflower seedlings, Lagarde (2001) recorded a 40-fold higher imidacloprid adsorption rate in seed-treated sunflower crops compared to sunflower plants grown as succeeding crops.*

Kemp and Rogers 2002, *BIE2003-181: Residues were measured in nectar and pollen of clover crops, sown in soil with approximately 28 months ageing period which after ageing had* *residues of 14-25 ppb. All clover flowers, wildflowers pollen, nectar and uncapped honey did not have any detectable levels of imidacloprid or its hydroxy and olefine metabolites (all residues < LOD; LOD typically 1/3 of LOQ; LOQ 2 ppb for a.s. and metabolites).*

Furthermore, two new studies were submitted by Bayer (28/04/2011, CD no. 5172) and summarised and evaluated by Ctgb (RES, 02/05/2011):

<u>Nikolakis et al 2011a (Laacher Hof):</u>
In autumn 2007 a mixture of imidacloprid, fuberidazol, imazalil and triadimenol was applied and incorporated down to 20 cm soil depth (Laacher Hof, Germany). The rate corresponded to 126 g imidacloprid/ha and the application was performed to represent a long-term soil plateau concentration of imidacloprid simulating the consecutive use of imidacloprid on the same plot over several years. On the same day, imidacloprid-treated winter wheat seeds were sown at a nominal sowing rate of 180 kg seeds/ha (corresponding to 126 g imidacloprid/ha). The winter wheat was harvested at 30 July 2008 and imidacloprid-free oil-seed rape seeds were sown on 18 August 2008. No further crops was sown during the intervening period after harvesting of winter wheat and sowing of the oil-seed rape seeds. During the flowering period of the oil-seed rape a gauze tunnel was set up and a honeybee colony (Apis mellifera carnica) was installed inside the tunnel. Nectar- and pollen foraging honeybees were manually collected inside the tunnel (on 3 different sampling days) and stored deep frozen (-17 to -21 °C). Afterwards, the frozen honeybees were worked up by separating pollen loads from the legs of the bees an by extracting nectar by puncturing the honey bulbs in the bees with an ultra-fine syringe.
Results:
Directly after spray application and incorporation, mean measured concentration of imidacloprid was 45.7 µg/kg dry soil. Directly before sowing of the OSR, mean measured concentration of imidacloprid was 18.8 µg/kg dry soil.
Residues of imidacloprid in oil-seed rape nectar collected on the imidacloprid treatment test plot were always below the LOD of 0.3 ppb. The imidacloprid concentration in the three pollen samples from the imidacloprid treatment test plot was determined to be 0.002 mg a.s./kg, respectively. The imidacloprid-monohydroxy and imidacloprid-olefine concentration of all pollen and nectar samples from the treatment test plot was always below the LOD of 0.3 ppb.

<u>Nikolakis et al 2011b (Hoefchen):</u>
In autumn 2007 a mixture of imidacloprid, fuberidazol, imazalil and triadimenol was applied and incorporated down to 20 cm soil depth (Höfchen, Germany). The rate corresponded to 126 g imidacloprid/ha and the application was performed to represent a long-term soil plateau concentration of imidacloprid simulating the consecutive use of imidacloprid on the same plot over several years. On the same day, imidacloprid-treated winter wheat seeds were sown at a nominal sowing rate of 180 kg seeds/ha (corresponding to 126 g imidacloprid/ha). The winter wheat was harvested at 1 August 2008 and imidacloprid-free oil-seed rape seeds were sown on 21 August 2008. No further crops was sown during the intervening period after harvesting of winter wheat and sowing of the oil-seed rape seeds. During the flowering period of the oil-seed rape a gauze tunnel was set up and a honeybee colony (Apis mellifera carnica) was installed inside the tunnel. Nectar- and pollen foraging honeybees were manually collected inside the tunnel (on 4 different sampling days) and stored deep frozen (-17 to -21 °C). Afterwards, the frozen honeybees were worked up by separating pollen loads from the legs of the bees an by extracting nectar by puncturing the honey bulbs in the bees with an ultra-fine syringe.
Results:
Directly after spray application and incorporation, mean measured concentration of imidacloprid was 34.0 µg/kg dry soil. Directly before sowing of the OSR, mean measured concentration of imidacloprid was 15.2 µg/kg dry soil.
Residues of imidacloprid in oil-seed rape nectar collected on the imidacloprid treatment test plot were always below the LOD of 0.3 ppb. The imidacloprid concentration in two of the four

pollen samples from the imidacloprid treatment test plot matched the limit of detection (LOD) of 0.0003 mg a.s./kg, and in the other two pollen samples from the treatment test plot the imidacloprid concentration was <LOD. The imidacloprid-monohydroxy and imidacloprid-olefine concentration of all pollen and nectar samples from the treatment test plot was always below the LOD of 0.3 ppb. The residue finding of imidacloprid-monohydroxy in one of the pollen samples collected on the control test plot ("Pollen C2") is suspected to result from a contamination in the analytical laboratory, as neither parent imidacloprid nor imidacloprid-olefine was detected in this particular sample.

Dust deposition maize

Nikolakis, A.; Casadebaig, J.; Appert, C.; Schoening, R. 2009 Summarised/evaluated by Ctgb, May 2011
Monitoring of dust drift deposits during the sowing of maize seeds, treated with Poncho® (Clothianidin FS 600) on bee health study plots in France with Poncho® (Clothianidin FS 600) treated maize seeds. The analytical verified content of clothianidin per individual maize seed was 0.50-0.51 mg a.s/maize seed.
All fields were sown with commercial vacuum-pneumatic single-kernel maize sowing machine which were modified with deflectors. Overall, four different machines with identical modification principle were used on the fields under investigation. Sowing rate was 100,000 seeds/ha. On each site of the field in 1 m distance to the sowing area, an array of 10 polystyrene Petri-dishes with an intra-row spacing of 1 m had been arranged horizontally on metal bearings at a height of approx. 1.5 to 2 cm above the soil surface or at the height of the vegetation surface, depending on the actual field boundary morphology. The actual placement of the Petri-dishes on the 4 field edges followed the actual wind direction, in order to collect as much dust as possible. Sowing parameters and environmental conditions were presented.

The maximum 90th%ile ground deposition value as determined along the four borders of each plot, respectively, was 0.092 g clothianidin a.s./ha.
Considering all plots, despite the high wind speed of plot Champagne 2 and despite a > 30 degrees wind angle, the arithmetic mean of the 90^{th}%ile values is 0.0522 g a.s./ha. In this calculation the < LOQ value of Aquitaine plot was set to 0.014 g a.s./ha. No reference (technique) was used in the study. Only a distance of 1 m to the sowing area has been performed in the monitoring study.

In other studies (from Syngenta) evaluated by The Netherlands, the highest deposition of dust occurs at a larger distance than 1 m (see below). The downwind ground deposition is not considered a maximum conservative value for all plots because no < LOD/LOQ was measured in the Alsace and Champagne 2 plots. Therefore it is considered that a determination of a drift reduction percentage from this study cannot be performed adequately. A comparison with the other available and evaluated studies is also not possible because the distance and/or the height of the measurements is/are different. Therefore this study is not used in the risk assessment.

Nikolakis & Schoening 2008. Summary/evaluation by PRI (WUR, The Netherlands) in 2009.
Drift deposition pattern of seed treatment particles abraded from Clothianidin FS 600 dressed maize seeds and emitted by different modified and un-modified pneumatic and mechanical sowing machines.
Dust emission was studied from different maize sowing machines (vacuum pneumatic; pos/neg pressure; mechanical; with/without deflectors) and for different seed coating types. Dust drift can significantly be reduced by means of adaptations to the machine like deflectors, redirecting air towards the fertilizer bins, and redirecting exhaust air towards soil surface. Mechanical and positive air pressure maize sowing machines produce less dust drift than the standard negative pressure sowing machines. Dust drift deposit on soil surface is lower than of airborne dust drift at 1 m height at the same distance.

Other studies on dust deposition from maize sowing
The studies presented below are owned by Syngenta and were not performed with clothianidin. However, dust drift from treated seeds is not considered to be dependent on active substance.Therefore, the studies are presented below to give a overall picture of dust drift from maize seeds. 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%) and occurs at 10 m distance.

In conclusion, the highest drift value from maize sowing with deflectors as measured in the above studies is 0.55% of the applied dose. This value will be used in the risk assessment.

Dust deposition sugarbeet
Summarised/evaluated by Ctgb, May 2011

Lueckmann, J. & Staedtler, T. 2009
Monitoring of dust drift deposits during and after the sowing of sugar beet pills, treated with Poncho® Beta or Poncho® Beta Plus in Germany with commercially dressed sugar beet pills (nominally 0.60 mg clothianidin & 0.08 mg beta-Cyfluthrin (+ 0.30 mg imidacloprid) per individual sugar beet pill.
All 20 fields were sown with mechanical sowing machines. The test field sizes varied between 1.5 and 21.0 ha. Shortly before sowing, the wind direction was determined and ten Petri-dishes were placed in groups of two at a distance of 1, 3 and 5 m (in total 30 Petri-dishes) at the down-wind border of the field. To monitor a potential dust drift during a 24h-period after sowing ten new Petri-dishes were placed in pairs at the approximate middle of each field side at a distance of 1 m to the field borders. Weather conditions were presented.

The 90th%ile residue levels during the sowing operation and the 24h-sampling were all below the limit of determination (LOD 0.004 g a.s./ha). These results indicate that the dust drift produced during and after the sowing of Poncho® Beta Plus treated sugar beet pills is very limited. From these results it can be concluded that standard mechanical sowing of sugar beet pills lead to low off-crop deposition values when sown with commercial sowing equipment. This is in line with the current matrix 'Relevance of dust for pesticide treated seeds'.
The conclusion in the matrix that dust formation is not relevant for sugar beet can be used for risk assessment.

Nikolakis, A., Schoening, R. 2008
Drift deposition pattern of seed treatment particles abraded from Poncho® Beta Plus treated

sugar beet pills and emitted by a typical mechanical sowing machine in Germany with commercially treated sugar beet pills, treated with Poncho® Beta Plus, which contains the neonicotinoid active substances clothianidin and imidacloprid (analysed neonicotinoid seed loading: 0.589 mg clothianidin a.s./pill, 0.325 mg imidacloprid a.s./pill). The actual machine tested was a Kverneland Accord Monopill SE, a 12-row mechanical precision sugar beet planter (12 hoppers). The size of each drilling plot was about 1.0 ha with an orientation of the sampling devices 180° ± 30° to the prevailing wind direction. An average wind speed of 2 - 5 m/s and a deviation of wind direction of maximum ± 30° to the perpendicular wind direction (i.e., 180° to the sampling devices) were the target conditions during drilling.
All clothianidin-containing dust and abrasion particles which deposited at 1, 3, 5, 10, 20, 30 and 50 metres distance from the drilling area during sugar beet sowing ("primary drift") were sampled in polystyrene Petri-dishes (Ø 13.7 cm, 147.41 cm²), filled with an acetonitrile-water mixture (2/8, v/v). For each sampling distance, three arrays of 10 Petri-dishes each were installed with a distance of 1 metre between the dishes and 50 m between the arrays.
Passive dust-drift collectors were installed at 1 m, 2 m, 3 m, 4 m and 5 m above the soil surface. The dust collectors were made of a polypropylene fabric mesh, built up of filaments with a 0.80 × 0.18 mm cross-section. This type of collector has a slightly oval shape with a length of ≈ 85 mm and a diameter of ≈ 65 mm; at its poles, the diameter is ≈ 50 mm. The polypropylene fabric mesh collectors were pinned on each end of horizontal metal rods, which in turn were mounted at the respective height on a vertical tripod-pylon (height ≈ 6 m), giving in total 10 collectors per pylon (2 at each height). In all arrays, a pylon was installed at 5 and 30 m distance from the drilling area, respectively, resulting in 6 collectors per height per distance.
Weather conditions were presented.

All 90th%ile values for ground deposition ("primary" and "secondary" drift, respectively) were at least below the limit of quantification (i.e. = LOQ = 0.014 g a.s./ha).
Considering atmospheric drift, clothianidin was measured in 75% of the passive polypropylene-mesh-collectors which were set up in different heights at 5 and 30 m distance from the sowing area. However, in contrast to ground deposition data, which are direct, area-related exposure figures [g a.s./ha], the airborne residues determined in passive samplers of an unknown collection efficiency only allow for a derivation of qualitative conclusions.
The consistent overall lack of quantifiable deposition within the off-field area suggests that airborne particles, trapped by passive polypropylene-mesh-collectors in the same area, are mainly subject to further dispersion and dilution.

These results indicate that the dust drift produced during and after the sowing of Poncho® Beta Plus treated sugar beet pills is very limited.From these results it can be concluded that standard mechanical sowing of sugar beet pills lead to low off-crop deposition values when sown with commercial sowing equipment.This is in line with the current matrix 'Relevance of dust for pesticide treated seeds'.The conclusion in the matrix that dust formation is not relevant for sugar beet can be used for risk assessment.

Reference list

This appendix serves only to give an indication of which data have been used for decision making; as a result of concurring applications for authorisations, the data mentioned here may have been used for an earlier decisions as well. Therefore, no rights can be derived from this overview.

Reference list of protected studies:

Reference	Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Data protection claimed Y/N	Owner
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-8.3.1.1; AIIIA-10.4	Cole, J.H.	1994	The acute oral and contact toxicity to Honey bees of compound NTN 33893 technical. BAY 158/901384 ! MO-99-002223 GLP, unpublished BIE2003-138	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-8.3.1.1	Faucon, J-P. et al.	2004	Etude experimentale de la toxicite de l' imidaclopride distribue dans le sirop de nourrisseurs a des colonies d' abeilles (*Apis mellifera*). open, published BIE2004-141	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-8.3.1.1; AIIIA-10.4	de Ruijter, A.	1999	Honey bee (*Apis mellifera* L.) oral toxicity study in the laboratory with imidacloprid techn. AH99.4.22.4 ! MO-99-015617 GLP, unpublished BIE2003-140	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-8.3.1.1; AIIIA-10.4	de Ruijter, A.	1999	Honey bee (*Apis mellifera* L.) contact toxicity study in the laboratory with imidacloprid techn. AH99.4.22.3 ! MO-99-016047 GLP, unpublished BIE2003-139	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-8.3.1.1; AIIIA-10.4	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD_{50}) of NTN 33893 on Honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae). 6400036 ! MO-99-015831 GLP, unpublished BIE2003-141	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-8.6 AIIIA-10.4	de Ruijter, A.	1999	Bumblebee (*Bombus terrestris* L.) oral toxicity study in the laboratory with imidacloprid techn. AH99.4.22.2 GLP, unpublished PFL2003-211	Y	BAY

Reference	Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Data protection claimed Y/N	Owner
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-8.6; AIIIA-10.4	de Ruijter, A.	1999	Bumblebee (*Bombus terrestris* L.) contact toxicity study in the laboratory with imidacloprid techn. AH99.4.22.1 GLP, unpublished PFL2003-210 BIE2003-142	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4;	Mayer, D.F. and Lunden, J.D.	1997	Effects of imidacloprid insecticide on three bee polinators. Journ: Horticultural science, 29, 1997, 93-97 Lit. 7876 not GLP, published AVS2004-245	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	III A, 10.4.	Anonymous	1991	Council directive of 15 July 1991 concerning the placing of plant protection products on the market Report No.: 91/414/EEC, Edition Number: M-110333-01-1 Non GLP, unpublished BIE2003-169	Yes	BCS
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	III A, 10.4.	Bai, D.; Lummis, S.C.R.; Leicht, W.; Breer, H.; Sattelle, D.B.	1991	Actions of imidacloprid and a related nitromethylene on cholinergic receptors of an identified insect motor neurone Publisher:SCI, Location:Great Britain, Pestic Science, Volume:33, Pages:197-204, Report No.: MO-03-011632, Edition Number: M-110734-01-1 Non GLP, published BIE2003-159	No	--
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Barth, M.	2000	Acute oral toxicity of substance B to the honeybee *Apis mellifera* L. under laboratory conditions prolonged for 10 days. 00 10 48 0502b not GLP, unpublished BIE2003-161	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Barth, M.	2000	Acute toxicity of substance A to the honeybee *Apis mellifera* L. under laboratory conditions. 00 10 48 0501 not GLP, unpublished BIE2003-160	Y	BAY

Reference	Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Data protection claimed Y/N	Owner
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Barth, M.	2000	Acute oral toxicity of substance C to the honeybee *Apis mellifera* L. under laboratory conditions prolonged for 10 days. 00 10 48 0502c not GLP, unpublished BIE2003-162	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4; AIIIA-10.4.1	Barth, M.	2001	Acute toxicity of Imidacloprid SL 200 to the honeybee *Apis mellifera* L. under laboratory conditions. 011048048 GLP, unpublished BIE2003-149	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Belzunces, L.P., Guez, D. and Suchail, S.	1998	Effets de l'imidaclopride chez l'abeille *Apis mellifera*. MO-03-011446 not GLP, published BIE2003-163	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Bitterman, M.E., Menzel, R., Fietz, A. and Schäfer, S.	1983	Classical conditioning of proboscis extension in honeybees (*Apis mellifera*). Lit. 7688 not GLP, published BIE2003-164	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Brasse, D.	1999	Preliminary report on a tunnel test with imidacloprid-treated summper rape. MO-03-011517 not GLP, unpublished BIE2003-165	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Briggs, G.G., Bromilow, R.H. and Evans, A.A.	1982	Relationships between lipophilicity and root uptake and translocation of non-ionised chemicals by barley. MO-03-011634 not GLP, published BIE2003-166	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Bromilow, R.H. and Chamberlain, K.	1989	Designing molecules for systemicity. MO-03-011894 not GLP, published BIE2003-167	N	-

Reference	Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Data protection claimed Y/N	Owner
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Bruhnke, C.	2000	Repeat Test: Substance C: Feeding test on the honeybee *Apis mellifera* L. (Hymenoptera, Apidae), non-GLP. IBA7242N not GLP, unpublished BIE2003-168	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Decourtye, A., Lacassie, E. and Pham-Delègue, M.-H.	2002	Learning performances of honeybees (*Apis mellifera* L.) are differentially affected by imidacloprid according to the season. MO-03-011573 not GLP, published BIE2003-174	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-10.4	Decourtye, A.	2000	Impact de l'imidaclopride et de ses principaux metabolites sur l'abeille domestique *Apis mellifera* L: effects d'expositions chroniques sur la mortalite et l'apprentissage. Engl. translation: Impact of Imidacloprid and its Main Metabolites on the honeybee *Apis mellifera* L.: Effects of Chronic Exposure on Mortality and Learning. I.N.R.A. National Institute of Agricultural Research, Bur-sur-Yvette. MO-03-011479 not GLP, unpublished BIE2003-173	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Drescher, W.	1990	Examination of the bee toxicity for registration purposes - Laboratory testing. 900240 not GLP, unpublished BIE2003-248	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Drescher, W.	1990	Examination of the bee toxicity for registration purposes, laboratory testing. 900239 not GLP, unpublished BIE2003-247	Y	BAY

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dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Ebadi, R., Gary, N.E. and Lorenzen, K.	1980	Effects of carbon dioxide and low temperature narcosis on honey bees, *Apis mellifera*. MO-03-011881 not GLP, published BIE2003-175	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA, 10.4.	Elbert, A.; Becker, B.; Hartwig, J.; Erdelen, C.	1991	Imidacloprid - a new systemic insecticide Publisher:Bayer AG, Location:Leverkusen, Journal:Pflanzenschutz-Nachrichten, Volume:44, Issue:2, Pages:113-136, Report No.: Lit. 8666, Edition Number: M-110655-01-1 Non GLP, published BIE2003-177	No	--
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Guez, D., Suchail, S., Gauthier, M., Maleszka, R. and Belzunces, L.P.	2001	Contrasting effects of imidacloprid on habituation in 7- and 8-day-old honeybees (*Apis mellifera*). MO-03-011619 not GLP, published BIE2003-178	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Harris, L.	1999	1999 Evaluation of: Gaucho seed dressing applied to canola on the honey bee (*Apis mellifera* Linnaeus) at indian head, Saskatchewan (indian head research station site). MO-03-000723 not GLP, unpublished BIE2003-179	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	*AIIIA, 10.4.*	*Ishii, Y.; Kobori, I.; Araki, Y.; Kurogochi, S.; Iwaya, K.; Kagabu, S.*	*1994*	*HPLC Determination of the new insecticide Imidacloprid and its behaviour in rice and cucumber* *Publisher:American Chemical Society,* *Location:USA,* *Journal:Journal of Agricultural and Food Chemistry, Volume:42, Pages:2917-2921,* *Report No.: MO-03-011544,* *Edition Number: M-110488-01-1* *Non GLP, published* *BIE2003-180*	*No*	--

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dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Kemp, J.R. and Rogers, R.E.L.	2002	Imidacloprid (Admire) residue levels following in-furrow application in potato fields in Prince Edward Island and New Brunswick. MO-02-006773 not GLP, unpublished BIE2003-181	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Kirchner, W.H.	1998	The effects of sublethal doses of imidacloprid on the foraging behaviour and orientation ability of honeybees. MO-03-000206 not GLP, unpublished BIE2003-182	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Kirchner, W.H.	2003	The effects of sublethal doses of imidacloprid, dihydroxy-imidacloprid and olefine-imidacloprid on the behaviour of honeybees. MO-03-000205 not GLP, unpublished BIE2003-183	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Kling, A.	2000	Substance B: Assessment of side effects in a ten days feeding test on the honey bee, *Apis mellifera* L. in the laboratory - hive bees (< 5 days). 20001148/01-BLEU 2. not GLP, unpublished BIE2003-185	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Kling, A.	2000	Substance C: Assessment of side effects in a ten days feeding test on the honey bee, *Apis mellifera* L. in the laborators - hive bees (< 5 days). 20001149/01-BLEU not GLP, unpublished BIE2003-187	Y	BAY

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dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Kling, A.	2000	Substance C: Assessment of side effects in a ten days feeding test on the honey bee, *Apis mellifera* L. in the laboratory - foraging bees (= 22 - 32 days). 20001149/01-BLEU 2. not GLP, unpublished BIE2003-186	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Kling, A.	2000	Substance B: Assessment of side effects in a ten days feeding test on the honey bee, *Apis mellifera* L. in the laboratory - foraging bees (= 22 - 32 days). 20001148/01-BLEU not GLP, unpublished BIE2003-184	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA, 10.4.	Knaust, H.-J.; Poehling, H.-M.	1992	Studies of the action of imidacloprid on grain aphids and their efficiency to transmit BYD-virus Journal:Pflanzenschutznachrichten, Volume:45, Issue:3, Pages:1992, Report No.: MO-03-011631, Edition Number: M-110727-01-1 Non GLP, published BIE2003-188	No	--
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Kurogochi, S., Maruyama, M. and Araki, Y.	1988	Absorption and translocation of [^{14}C]-NTN 33893 in eggplants and rice plants. NR1273 not GLP, unpublished BIE2003-131	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Lagarde, F.	2001	Sunflower and Gaucho: CETIOM results. MO-03-011654 not GLP, published BIE2003-189	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA, 10.4.	Leicht, W.	1993	Imidacloprid - a chloronicotinyl insecticide Pesticide Outlook, Volume:4 (3), Pages:17-21, Report No.: MO-03-011386, Edition Number: M-109880-01-1 Non GLP, published BIE2003-190	No	--

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dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA, 10.4.	Liu, M. Y.; Casida, J. E	1993	High affinity binding of [3H]Imidacloprid in the insect acetylcholine receptor Pesticide Biochemistry and Physiology, Report No.: MO-00-006412, Edition Number: M-030113-01-1 Non GLP, published BIE2003-191	No	–
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Maus, C.	2002	Evaluation of the effects of residues of Imidacloprid FS 600 in maize pollen from dressed seeds on honeybees (*Apis mellifera*) in the semifield. MAUS/AM 018 GLP, unpublished BIE2003-192	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Maus, C. and Schoening, R.	2001	Effects of residues of imidacloprid in maize pollen from dressed seeds on honey bees (*Apis mellifera*). MAUS/AM 012 GLP, unpublished BIE2003-193	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Mayer, D.F., Lunden, J.D. and Husfloen, M.R.	1991	Integrated pest and pollinators investigations 1991 (including hony bee toxicity of NTN 33893). 103815 not GLP, unpublished BIE2003-194	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Mayer, D.F., Patten, K.D., Macfarlane, R.P. and Shanks, C.H.	1994	Differences between susceptibility of four pollinator species (Hymenoptera. Apoidea) to field weathered insecticide residues. Lit. 8135 not GLP, published BIE2003-195	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA, 10.4.	Methfessel, C.	1992	Die Wirkung von Imidacloprid am nikotinergen Acetylcholin-Rezeptor des Rattenmuskels Journal:Pflanzenschutznachrichten, Volume:45, Issue:3, Pages:369-380, Report No.: MO-03-011633, Edition Number: M-110744-01-1 Non GLP, published BIE2003-196	No	–

Reference	Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Data protection claimed Y/N	Owner
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Nauen, R., Ebbinghaus-Kintscher, U. and Schmuck, R.	2001	Toxicity and nicotinic acetylcholine receptor interaction of imidacloprid and its metabolites in *Apis mellifera* (Hymenoptera: Apidae). Lit. 7882 not GLP, published BIE2003-197	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Pham-Delegue, M.-H. and Cluzeau, S.	1999	Effects of crop protection products on bees, effects of GAUCHO seed dressing on losses of foraging bees with comments on the summary report from Gaelle Curé and Bernard Ambolet, 16.11.1998. MO-03-011487 not GLP, unpublished BIE2003-198	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Ray, S. and Ferneyhough, B.	1998	Behavioural development and olfactory learning in the honeybee (*Apis mellifera*). MO-03-012018 not GLP, published BIE2003-199	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	de Ruijter, A.	1999	Bumblebee (*Bombus terrestris* L.) oral toxicity study in the laboratory with imidacloprid techn. AH99.4.22.2 GLP, unpublished BIE2003-143	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-6.1; AIIIA-10.4	Sakamoto, H.	1991	Metabolism of [pyridinyl-^{14}C-methyl]-NTN 33893 in rice plants (nursery box application). NR1284 GLP, unpublished BIE2003-132 RIP2003-1689	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmidt, H.W., Schmuck, R. and Schoening, R.	1998	The impact of Gaucho 70 WS seed treated sunflower seeds on honey bees. BF 1/98 not GLP, unpublished BIE2003-201	Y	BAY

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dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmitzer, S.	1995	Laboratory testing for toxicity (acute contact and oral LD_{50}) of Confidor WG 70 to honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae). 780036 ! MO-00-007456 GLP, unpublished BIE2003-203	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmitzer, S.	1995	Laboratory testing for toxicity (acute contact and oral LD_{50}) of Confidor SC 200 to honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae). 790036 GLP, unpublished BIE2003-202	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD_{50}) of WAK 4103 on honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae). 6340036 GLP, unpublished BIE2003-204	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD_{50}) of WAK 3772 on honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae). 6330036 GLP, unpublished BIE2003-206	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD_{50}) of WAK 3839 on honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae) - limit test. 6390036 GLP, unpublished BIE2003-208	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD_{50}) of BNF 5119B on honey *bees (Apis mellifera* L.) (Hymenoptera, Apidae) - limit test -. 6380036 GLP, unpublished BIE2003-209	Y	BAY

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dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmitzer, S.	2000	Laboratory testing for toxicity (acute oral LD_{50}) of WAK 5074 on honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae) - limit test. 7150036 GLP, unpublished BIE2003-210	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD_{50}) of WAK 4168 on honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae) - limit test -. 6370036 GLP, unpublished BIE2003-211	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD_{50}) of WAK 4140 on honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae) - limit test -. 6360036 GLP, unpublished BIE2003-207	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD_{50}) of WAK 3745 on honey bees (*Apis mellifera* L.) (Hymenoptera, Apidae). 6320036 GLP, unpublished BIE2003-205	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4; AIIIA-10.4.1	Schmitzer, S.	2001	Effects of Imidacloprid SL 200 (acute contact and oral LD_{50}) on honey bees (*Apis mellifera* L.) in the laboratory. 9981036 ! MO-01-020753 GLP, unpublished BIE2003-148	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R. and Schoening, R.	1999	Residues of imidacloprid and imidacloprid metabolites in nectar, blossoms, pollen and honey bees sampled from a british summer rape field and effects of these residues on foraging honeybees. SXR/AM 003 GLP, unpublished BIE2003-215	Y	BAY

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dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R. and Schoening, R.	1999	Residues of imidacloprid and imidacloprid metabolites in nectar, blossoms, pollen and honey bees sampled from a summer rape field in Sweden and effects of these residues on foraging honeybees. SXR/AM 002 GLP, unpublished BIE2003-214	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R. and Schoening, R.	1999	Effects of imidacloprid residues in sunflower honey on the development of small bee colonies under field exposure conditions. SXR/AM 004 GLP, unpublished BIE2003-216	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R. and Schoening, R.	1999	Effects of imidacloprid residues in maize pollen on the development of small bee colonies under field exposure conditions. SXR/AM 005 GLP, unpublished BIE2003-217	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R. and Schoening, R.	1999	Residue levels of imidacloprid and imidacloprid metabolites in honeybees orally dosed with imidacloprid in standardised toxicity tests (EPPO 170). SXR/AM 013 GLP, unpublished BIE2003-224	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R. and Schoening, R.	1999	Residues of imidacloprid and imidacloprid metabolites in nectar, blossoms, pollen and honey bees sampled from a French summer rape field and effects of these residues on foraging honeybees. SXR/AM 001 GLP, unpublished BIE2003-213	Y	BAY

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dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R., Schoening, R. and Schramel, O.	1999	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of sunflowers cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. 'Hoefchen' 1999. SXR/AM 006 GLP, unpublished BIE2003-219	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R., Schoening, R. and Schramel, O.	1999	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. Laacher Hof 1999. SXR/AM 008 GLP, unpublished BIE2003-222	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R., Schoening, R. and Schramel, O.	1999	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effects of these residue on foraging honeybees. 'Hoefchen' 1999. SXR/AM 010 GLP, unpublished BIE2003-223	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R., Schoening, R. and Schramel, O.	1999	Residue levels of imidacloprid and imidacloprid metabolites in pollen of maize plants cultivated on soils with different imidacloprid residue levels Test location: Farmland 'Hoefchen' - 1999. SXR/AM 011 GLP, unpublished BIE2003-221	Y	BAY

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dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R., Schoening, R. and Schramel, O.	1999	Residue levels of imidacloprid and imidacloprid metabolites in pollen of maize plants cultivated on soils with different imidacloprid residue levels. Test location: Farmland 'Laacher Hof' - 1999. SXR/AM 009 GLP, unpublished BIE2003-220	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schmuck, R., Schoening, R. and Schramel, O.	1999	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of sunflowers cultivated on soils with different imidacloprid residue levels and effects on these residues on foraging honeybees. 'Laacher Hof' 199. SXR/AM 007 GLP, unpublished BIE2003-218	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schoening, R.	2002	Determination of residues of imidacloprid and relevant metabolites in nectar, pollen and honey of winter rape. MR-147/01 GLP, unpublished BIE2003-245	N	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schoening, R.	2003	Residue levels of imidacloprid and imidacloprid metabolites in sunflower pollen, sunflower honey and bees from Gaucho treated sunflowers in the field. MR-710/99 GLP, unpublished BIE2003-244	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schuld, M.	2002	Field test: Side effects of oil-seed rape grown from seeds dressed with imidacloprid and beta-Cyfluthrin FS 500 on the honey bee (*Apis mellifera* L.). 99398/01-BFEU GLP, unpublished BIE2003-226	Y	BAY

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dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Schulz, A.	2000	Field trials with Gaucho in sunflowers - experiences from the region of Rheinhessen in 1999. MO-03-011595 not GLP, published BIE2003-227	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4; AIIIA-10.4.4	Scott-Dupree, C.D., Spivak, M.S., Bruns, G., Blenskinsop, C. and Nelson, S.	2001	The impact of Gaucho and TI-435 seed-treated Canola on honey bees, *Apis mellifera* L. 110403 not GLP, unpublished BIE2003-228	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Stadler, T.	2000	Field evaluation in Argentina of possible risk for honey bees from the product Gaucho on sunflowes. LPE-41/00 not GLP, unpublished BIE2003-229	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Stork, A.	1999	Residues of [^{14}C]-NTN 33893 (imidacloprid) in blossoms of sunflower (*Helianthus annuus*) after seed dressing. MR-550/99 GLP, unpublished BIE2003-230	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Szentes, C.	1999	Field test of Gaucho 350 FS seeddressed sunflowers on honeybee colonies. 3103/99 GLP, unpublished BIE2003-234	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Tasei, J.N.	2003	Impact of agrochemicals on non-Apis bees. MO-03-011866 not GLP, unpublished BIE2003-235	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Thompson, H.M.	2000	Substance B: Feeding study with honey bees (*Apis mellifera*). HT0400c not GLP, unpublished BIE2003-239	Y	BAY

Reference	Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Data protection claimed Y/N	Owner
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Thompson, H.M.	2000	Substance A - Acute oral toxicity to honey bee *Apis mellifera*. HT0400b not GLP, unpublished BIE2003-238	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Thompson, H.M.	2000	Substance C: Feeding study with honey bees (*Apis mellifera*). HT0400d not GLP, unpublished BIE2003-240	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Thompson, H.M.	2000	Substance A - Acute contact toxicity to honey bees (*Apis mellifera*). HT0400a not GLP, unpublished BIE2003-237	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-6.1; AIIIA-10.4	Vogeler, K. and Brauner, A.	1993	Metabolism of NTN 33893 in cotton after seed treatment. PF3675 GLP, unpublished BIE2003-126 RIP2003-1679	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-6.1; AIIIA-10.4	Vogeler, K., Clark, T. and Brauner, A.	1992	Metabolism of [^{14}C]-NTN 33893 in apples. PF3676 GLP, unpublished BIE2003-124 RIP2003-1677	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-6.1; AIIIA-10.4	Vogeler, K., Draeger, G. and Brauner, A.	1992	Investigation of the metabolism of NTN 33893 in potatoes following granular application. PF3628 GLP, unpublished BIE2003-129 RIP2003-1683	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Wallner, K.	1999	Tests regarding the danger of the seed disinfectant, Gaucho, for bees. MO-03-011452 not GLP, published BIE2003-241	N	-

Reference	Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not *BVL registration number*	Data protection claimed Y/N	Owner
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Wilhelmy, H.	2000	Substance A - Acute effects on the honeybee *Apis mellifera* (Hymenoptera, Apidae). IBA7240N not GLP, unpublished BIE2003-242	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4	Wolf, T.J., Ellington, C.P. and Begley, L.S.	1998	Foraging costs in bumblebees: Field conditions cause large individual differences. MO-03-011646 not GLP, published BIE2003-246	N	-
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIA-6.1; AIIIA-10.4	Yoshida, H.	1991	Metabolism of NTN 33893 in eggplant by planting hole application. NR1290 GLP, unpublished BIE2003-127 RIP2003-1680	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4.3	Bakker, F.M.	2003	A multiple-rate cage test to study effects of Confidor SL 200 on honeybee (*Apis mellifera* L.) when applied to flowering *Phacelia tanacetifolia* 24, 48 and 96 hours before bee exposure. B075AMS ! MO-03-005575 GLP, unpublished BIE2003-153	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4.3	Bakker, F.M.	2001	Confidor SL 200: a multiple rate cage study to determine effects on honeybees, *Apis mellifera* L, when applied to flowering *Phacelia tanacetifolia*. B074AMS ! MO-01-022345 GLP, unpublished BIE2003-152	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4.3	Hancock, G.A., Fischer, D.L., Mayer, D.F. and Grace, T.J.	1992	NTN 33893: Toxicity to honey bees on alfalfa treated foliage. 103938 ! MO-99-009814 GLP, unpublished BIE2003-137	Y	BAY

Reference	Annex point/ reference number	Author(s)	Year	Title Source (where different from company) Report no. GLP or GEP status (where relevant) Published or not BVL registration number	Data protection claimed Y/N	Owner
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4.4	Cantoni, A.	1998	Side effects of Confidor SL 200 on bees following one application to apple trees at the mouse-ear stage. ITA-98-901 not GLP, unpublished BIE2003-151	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4.4	Schur, A.	2001	Assessment of side effectsc of Confidor SL 200 on the honey bee (*Apis mellifera* L.) in apple orchard following application before flowering (mouse-ear stage) of the crop. 20011099/01-BFEU ! MO-01-021827 GLP, unpublished BIE2003-150	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.4.5	Schur, A.	2001	Tunnel test: Assessment of side effects of Confidor SL 200 on the honey bee (*Apis mellifera* L.) in apple orchard following application before flowering (mouse-ear stage) of the crop. 20011099/01-BZEU ! MO-01-020736 GLP, unpublished BIE2003-154	Y	BAY
dossier PPP (DAR), from List of studies relied upon_version4_Final November 2008	AIIIA-10.5.1	Bielza, P., Contreras, J., Guerrero, M.M., Izquierdo, J., Lacasa, A. and Mansanet, V.	2000	Effects of Confidor 20 LS and Nemacur CS on bumblebees pollinating greenhouse tomatoes. IOBC/wprs Bulletin Vol. 24(4) 2001, Working Group "Pesticides and Beneficial Organisms", Proceedings of the meeting at Castelló de la Plana (Spain), 18-20 October, 2000. Edited by: H. Vogt, E. Vinuela & J. Jacas. ISBN 92-9067-133-5 MO-00-016382 not GLP, published ANA2003-426	N	-

Reference	Ref	Author(s)	Year	Title, Source, Company Name, Owner, Date	Data protecti	Owner

	no.			Report-No., Document-No., published or not	on claimed Y/N	
Submitted to Ctgb in 2011 (CD 5167).	1	Schmuck	2003	R Schmuck _ pollinating bees - imidacloprid seed treatment.doc	Y	BCS
Submitted to Ctgb in 2011 (CD 5167).	3	Keppler, J.	2010	CRD Guttation 2010 01 21.ppt	Y	BCS
Submitted to Ctgb in 2011 (CD 5167).	4	Keppler, J.	2010	CTD & Dust.ppt	Y	BCS
Submitted to Ctgb in 2011 (CD 5167).	21	Nikolakis, A., Schoening, R.	2008	Drift deposition pattern of seed treatment particles abraded from Poncho® Beta Plus treated sugar beet pills and emitted by a typical mechanical sowing machine Generated by: Bayer CropScience AG, Monheim, Germany Owner: Bayer CropScience Date: November 14, 2008 Amended: March 20, 2009 Document-No.: M-309580-02-1 Unpublished	Y	BCS
Submitted to Ctgb in 2011 (CD 5167).	22	Nikolakis, A.	2009	Relevance of guttation as a potential water source for honey bees in neonicotinoid seed-treated sugar beet Generated by: Bayer CropScience AG, Monheim, Germany Owner: Bayer CropScience Date: September 04, 2009 Document-No.: M-355012-01-1 Unpublished	Y	BCS
Submitted to Ctgb in 2011 (CD 5167).	25	Faucon *et. al.*	2005	Experimental study on the toxicity of imidacloprid given in syrup to honey bee (Apis mellifera) colonies Pest Manag Sci 61:111–125 (2005)	Y	BCS
Submitted to Ctgb in 2011 (CD 5167).	26	Gobin *et. al.*	2008	Sublethal effects of crop protection onhoney bee pollination: foraging behaviour flower visits. Comm. Appl. Biol. Sci. Ghent University, 73/3, 2008	Y	BCS
Submitted to Ctgb in 2011 (CD 5167).	27	Nguyen *et. al.*	2009	Does Imidacloprid Seed-Treated Maize Have an Impact on Honey Bee Mortality? J. Econ. Entomol. 102(2): 616Ð623 (2009)	Y	BCS
Submitted to Ctgb in 2011 (CD 5167).	28	Tasei *et. al.*	2000	Sub-lethal effects of imidacloprid on bumblebees, Bombus terrestris (Hymenoptera: Apidae), during a laboratory feeding test Pest Manag Sci 56:784±788 (2000)	Y	BCS
Submitted to Ctgb in 2011 (CD 5167).	29	Tasei *et. al.*	2001	Hazards of Imidacloprid Seed Coating to Bombus terrestris (Hymenoptera: Apidae) when Applied to Sunflower J. Ecol. Entomol. 94(3):623-627 (2001)	Y	BCS
Submitted to Ctgb in 2011 (CD 5167).	30	Visser *et. al.*	2010	Survival rate of honeybee (Apis mellifera) workers after exposure to sublethal concentrations of imidacloprid PROC. NETH. ENTOMOL. SOC. MEET. - VOLUME 21 - 2010	Y	BCS
Submitted	31	Wehling	20	Intoxication of honeybees – Interactions of plant	Y	BCS

to Ctgb in 2011 (CD 5167).		*et. al.*	06	protections products and other factors Proceedings of the second European conference of apidology EurBee, Prague, Czech republic, 10-16 sept. 2006.		
Submitted to Ctgb in 2009. Report no. 6840.	n. a.	A. Nikolakis R. Schoening	2008	Drift deposition pattern of seed treatment particles abraded from Clothianidin FS 600 dressed maize seeds and emitted by different modified and un-modified pneumatic and mechanical sowing machines. NAX/SP03-2008, 2008-10-20.	Y	BCS

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A 7.5.4.1. /01	Cole, J. H.	1990	The acute oral and contact toxicity to honey bees of compound NTN 33893 technical Huntingdon Research Centre Ltd., Huntingdon, Great Britain Bayer CropScience AG, Report No.: BAY 158/901384, Edition Number: M-006940-02-1 Date: 28.12.1990, Amended: 06.01.1994 GLP, unpublished	Yes	BCS
A 7.5.4.1. /02	Schmitzer, S.	1999	Laboratory testing for toxicity (acute oral LD50) of NTN 33893 on honey bees (Apis mellifera L.) (Hymenoptera, Apidae) IBACON GmbH, Rossdorf, Germany Bayer CropScience AG, Report No.: 6400036, Edition Number: M-016942-01-1 Date: 30.09.1999 GLP, unpublished	Yes	BCS

A 7.5.4.1. /03	Kemp, J. R.; Rogers, R. E. L.	2002	Imidacloprid (Admire) residue levels following in-furrow application in potato fields in Prince Edward Island and New Brunswick University Prince Edward Island, Wildwood Labs., Canada Bayer CropScience AG, Report No.: MO-02-006773, Edition Number: M-061850-01-1 Date: 02.05.2002 Non GLP, unpublished	Yes	BCS
A 7.5.4.1. /04	Schmuck, R.; Schoening, R.; Schramel, O.	1999a	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of sunflowers cultivated on soils with different imidacloprid residue levels and effects on these residues on foraging honeybees. 'Laacher Hof' 1999 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SXR/AM 007, Edition Number: M-016827-01-1 Date: 28.09.1999 GLP, unpublished	Yes	BCS
A 7.5.4.1. /05	Schmuck, R.; Schoening, R.; Schramel, O.	1999b	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of sunflowers cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. 'Hoefchen' 1999 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SXR/AM 006, Edition Number: M-016820-01-1 Date: 27.09.1999 GLP, unpublished	Yes	BCS
A 7.5.4.1. /06	Schmuck, R.; Schoening, R.; Schramel, O.	1999c	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effects of these residue on foraging honeybees. 'Hoefchen' 1999 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SXR/AM 010, Edition Number: M-016842-01-1 Date: 28.09.1999 GLP, unpublished	Yes	BCS
A 7.5.4.1. /07	Schmuck, R.; Schoening, R.; Schramel, O.	1999d	Residue levels of imidacloprid and imidacloprid metabolites in nectar, blossoms and pollen of summer rape cultivated on soils with different imidacloprid residue levels and effects of these residues on foraging honeybees. Laacher Hof 1999 Bayer AG, Leverkusen, Germany Bayer CropScience AG, Report No.: SXR/AM 008, Edition Number: M-016828-01-1 Date: 28.09.1999 GLP, unpublished	Yes	BCS

Reference	Annex point / reference number	Author(s)	Year	Title Source *(where different from company)* Company name, Report No., Date, GLP status *(where relevant)*, published or not	Data protection claimed Y/N	Owner
Submitted to Ctgb on 28/04/2011 (CD 5172).	April - /08	Nikolakis, A.; Przygoda, D.; Freitag, Th.; Schoening, R.	2011	Determination of residue levels of imidacloprid, imidacloprid-monohydroxy and imidacloprid-olefine in bee relevant matrices of winter rape in a cereal succeeding crop scenario at Bayer CropScience AG experimental farm Laacher Hof, Germany Bayer CropScience, Report No.: E 319 3388-5, Edition Number: M-406075-01-1 Date: 2011-04-27 GLP, unpublished	Y	BCS
Submitted to Ctgb on 28/04/2011 (CD 5172).	April - /09	Nikolakis, A.; Przygoda, D.; Freitag, Th.; Schoening, R.	2011	Determination of residue levels of imidacloprid, imidacloprid-monohydroxy and imidacloprid-olefine in bee relevant matrices of winter rape in a cereal succeeding crop scenario at Bayer CropScience AG experimental farm Höfchen, Germany Bayer CropScience, Report No.: E 319 3387-4, Edition Number: M-406083-01-1 Date: 2011-04-27 GLP, unpublished	Y	BCS
Reference	Annex point / reference number	Author(s)	Year	Title Source *(where different from company)* Company name, Report No., Date, GLP status *(where relevant)*, published or not	Y	BCS
Submitted to Ctgb on 26/05/2011 (CD 5182).	May - /10	Cantoni, A.	1998	Side effects of Confidor SL 200 on bees following one application to apple	Y	BCS

				trees at the mouse-ear stage Bayer S. P. A., Milano *Viale Certosa, Italy* Bayer CropScience, Report No.: ITA-98-901, Edition Number: M-064758-02-1 Date: 1998-10-06 **...Amended: 2009-09-16** Non GLP, *unpublished*		
Submitted to Ctgb on 26/05/2011 (CD 5182).	May - /11	Cantoni, A.; Schmidt, H.-W.; Gilli, J.	2001	Bee-friendly use of Confidor + oliocin in apple cultivation in Italy Publisher:Bayer CropScience AG, Location:Leverkusen, Germany, *Journal:Pflanzenschutz-*Nachrichten Bayer, Volume:54, Issue:3, Pages:353-368, Year:2001, Report No.: Lit. 9209, Edition Number: M-355844-01-1 Non GLP, published	Y	BCS
Submitted to Ctgb on 01/06//2011 (by e-mail).	n.a.	Nauen, R. and Kwiatkowski.	2008	Imidacloprid residue movement in plants following foliar applications and the implications for potential bee exposure. *Bayer CropScience,* Edition Number: M-308631-01-1 Date: 2008-10-08	Y	BCS
Submitted to Ctgb on 01/06/2011 (by e-mail).	n.a.	Vacante, V.	1997	The influence of Imidacloprid on the impollination of the *tomato with Bombus terrestris* Generated by: University of Tuscia, Viterbo, Italy Owner: Bayer CropScience Date: Year 1997 *Document No.:* M-304435-01-2 Non-GLP, published	Y	BCS

Appendix II. Public literature

A public literature survey on the effects of neonicotinoids and fipronil on bee mortality and decline is in development under the authority of the Ministry of Economy, Agriculture and Innovation (EL&I). The preliminary results of this survey have been used for this risk assessment. Literature consulted is shown below.

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APPENDIX III – ABBREVIATIONS USED IN THE LIST OF ENDPOINTS AND RISK ASSESSMENT

ANSES	l'Agence nationale de sécurité sanitaire de l'Alimentation de l'Environnement et du Travail
a.s.	active substance
CAR	Competent Authority Report
d	day
DAR	draft assessment report
DT_{50}	period required for 50 percent dissipation (define method of estimation)
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC_{50}	effective concentration
EEC	European Economic Community
EFSA	European Food Safety Authority
EPPO	European and Mediterranean Plant Protection Organization
ER50	emergence rate, median
ESD	Emission Scenario Document
EU	European Union
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
GAP	good agricultural practice
GS	growth stage
h	hour(s)
ha	hectare
HQ	hazard quotient
L	litre
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LoE	List of Endpoints
LOQ	limit of quantification (determination)
m	meter
µg	microgram
ng	nanogram
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OSR	oilseed rape
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water

ppm	parts per million (10^{-6})
ppb	parts per billion (10^{-9})
ppp	plant protection product
PRI	Plant Research International, Wageningen UR
RGB	Regeling gewasbeschermingsmiddelen en biociden
TER	toxicity exposure ratio
WHO	World Health Organisation
WG	water dispersible granule
yr	year

8. Efficacy

n.a.

9. Conclusion

The product complies with the Uniform Principles.

The evaluation is in accordance with the Uniform Principles laid down in appendix VI of Directive 91/414/EEC. The evaluation has been carried out on basis of a dossier that meets the criteria of appendix III of the Directive.

10. Classification and labelling

Classification and labeling does not change.

Reference List

See chapter 7