Background

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

Gewasbeschermingsmiddelen op basis van imidacloprid

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	toepassing	formulering	Toepassing(en)
13178	ADMIRE	LTO Nederland	imidacloprid	Professioneel	Water dispergeerbaar granulaat	Traybehandeling (kort voor planten) of fytodrip (bij zaaien) in spruitkool, bloemkool en broccoli.
13321	MERIT TURF	Bayer CropScience B.V.	imidacloprid 0,5%	Professioneel	Granulaat	Strooien in openbare grasvegetatie en graszodenteelt.
13059	MONAMI	Bayer CropScience B.V.	imidacloprid 17,5G/L # pencycuron 250G/L	Professioneel	Suspensie concentraat	Aardappelen, grondbehandeling tijdens poten.
12942	ADMIRE O-TEQ	Bayer CropScience B.V.	imidacloprid 350G/L	Professioneel	Olie dispersie	Gewasbehandeling in appel en peer, vruchtgroenten onder glas, bloemisterijgewassen buiten en onder glas, bloembol- en bloemknol, boomkwekerij en vaste planten, hop, pennenteel van witlof.
11662	AMIGO FLEX	Bayer CropScience B.V.	imidacloprid 350G/L	Professioneel	Suspensie concentraat voor zaadbehandeling	Aardappelen, grondbehandeling tijdens poten.
11483 (parallel: 11547, 13363)	ADMIRE	Bayer CropScience B.V.	imidacloprid 70%	Professioneel	Water dispergeerbaar granulaat	Gewasbehandeling in appel en peer, vruchtgroenten onder glas, bloemisterijgewassen buiten en onder glas, bloembol- en bloemknol, boomkwekerij en vaste planten.
11455	GAUCHO	Bayer CropScience B.V.	imidacloprid 70%	Professioneel	Water dispergeerbaar poeder voor vochtige zaadbehandeling	Zaadcoating in suiker- en voederbieten.
11601	GAUCHO ROOD	Bayer CropScience B.V.	imidacloprid 70%	Professioneel	Water dispergeerbaar poeder voor vochtige zaadbehandeling	Zaadcoating in mais.
12341	GAUCHO TUINBOUW	Bayer CropScience B.V.	imidacloprid 70%	Professioneel	Water dispergeerbaar	Zaadcoating van sla, andijvie, kolen, prei.

					poeder voor vochtige zaadbehandeling	
11998 (afgeleide: 12219)	ADMIRE N PIN	Bayer CropScience B.V.	imidacloprid 2,5%	Niet-professioneel	Plantenstaafje	Sierplanten in potten en bakken.
12115 (afgeleides: 12945, 12919)	PROVADO GARDEN	Bayer CropScience B.V.	imidacloprid 5%	Niet-professioneel	Water dispergeerbaar granulaat	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.

List of Endpoints Ecotoxicology

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 the EFSA conclusion is used (Word-version d.d. 02/2008, endpoints are the same as for the published conclusion on 05/2009).

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. and metabolites. See the risk assessment for a discussion of these.

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).
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-Delegue 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 0.012 or 27 g a.s./ha. Foraging activity decreased with increasing imidacloprid

concentration. 4) Exposure to apple orchard with 10% of apple flowers open. Spraying was done before bee flight. No effect on mortality.
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. 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 unknown rate. 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.

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):

Nikolakis et al 2011 (Laacher Hof):
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.

Nikolakis et al 2011 (Hoefchen):
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 *<u>Tummon, 2006</u>* *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 *<u>Tummon & Jones, 2007</u>* *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 *<u>Solé, 2008</u>* *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

<u>Lueckmann, J. & Staedtler, T. 2009</u>
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 90^{th}%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.

<u>Nikolakis, A., Schoening, R. 2008</u>
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.

Risk assessment for bees
During EU review for inclusion of imidacloprid on Annex I of 91/414/EEG, the risks of seed treatment for sugar beet (0.117 kg 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. Then, the re-evaluation of all imidacloprid-containing products currently allowed in the Netherlands is performed based on the EU peer reviewed data and the newer data from the applicant.

<u>EFSA conclusion.</u>
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 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.

In general, 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.
The risk for bees via surface water is not considered to be relevant. Bees can drink 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 for hive climate regulation in warm weather. Exposure of bees to imidacloprid in surface water is expected to be very low.

A.1.1 Professional uses – spray application

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	dosering	formulering	Toepassing(en)
12942	ADMIRE O-TEQ	Bayer CropScience B.V.	imidacloprid 350G/L	70-105 g a.s./ha – see Table 1	Olie dispersie	Gewasbehandeling in appel en peer, vruchtgroenten onder glas, bloemisterijgewassen buiten en onder glas, bloembol- en bloemknol, boomkwekerij en vaste planten, hop, pennenteel van witlof.
11483 (parallel: 11547, 13363)	ADMIRE	Bayer CropScience B.V.	imidacloprid 70%	15.7-1960 g a.s./ha – see Table 2	Water dispergeerbaar granulaat	Gewasbehandeling in appel en peer, vruchtgroenten onder glas, bloemisterijgewassen buiten en onder glas, bloembol- en bloemknol, boomkwekerij en vaste planten.

Table 1: Intended uses ADMIRE O-TEQ

Uses	**Field / Glass-house**	**Dose a.s. (g a.s./ha)**	**No. of appl.**	**Int. betw. appl.**	**Application time (growth stage and season)**
Apple against common green capsid bug (*Lygus pabulinus*), European apple sawfly (*Hoplocampa testudinea*); met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	Young crop 0.07 Adult crop 0.105	2	7-14 days	April-July;
Apple against rosy apple aphid (*Dysaphis plantaginea*), apple aphid (*Aphis pomi*), rosy leaf-curling aphid (*Dysaphid devecta*, *Dysaphis anthrisci*), apple-grass aphid (*Rhopalosiphum insertum;* met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	Young crop 0.07 Adult crop 0.105	2	7-14 days	April-Sept;
Pear against common green capsid bug (*Lygus pabulinus*), pear sawfly (*Hoplocampa brevis*); met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	Young crop 0.07 Adult crop 0.084	2	7-14 days	April-July;
Pear against pear aphid (*Dysaphis pyri*), pear coltsfoot aphid (*Anuraphis farfarae*), *Melanaphis pyaria,* black bean aphid (*Aphis fabae*); met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	Young crop 0.07 Adult crop 0.084	2	7-14 days	April-Sept;
Aubergine, gherkins, courgettes, cucumber, tomato, red pepper, and sweet pepper on artificial substrate (protected culture) against glasshouse potato aphid (*Aulacorthum solani*), green and red peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean aphid (*Aphis fabae*)	G	2.45 g a.s./1000 plants	2	1 day	March-Nov
Aubergine, gherkins, courgettes, cucumber, tomato, red pepper, and sweet pepper on artificial substrate (protected culture) against greenhouse whitefly (*Trialeurodes vaporariorum*)	G	28 ml/1000 plants	2	1 day	March-Nov
Floriculture crops on artificial substrate (protected culture) against glasshouse potato aphid (*Aulacorthum solani*), green and red peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean aphid (*Aphis fabae*)	G	2.45 g a.s./1000 plants	2	1 day	March-Nov
Floriculture crops on artificial substrate (protected culture) against greenhouse whitefly (*Trialeurodes vaporariorum*)	G	9.8 g a.s /1000 plants	2	1 day	March-Nov
Floriculture crops in the open ground (protected culture) against glasshouse potato aphid (*Aulacorthum solani*), green and red peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean aphid (*Aphis fabae*)	G	0.084	2	7-10 days	Jan-Dec
Gerbera and chrysanthemum (protected culture) against glasshouse potato aphid (*Aulacorthum solani*), green and red peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean	G	0.084	2	7-10 days	Jan-Dec

aphid (*Aphis fabae*), greenhouse whitefly (*Trialeurodes vaporariorum*)					
Perennial floriculture crops in the open ground against glasshouse potato aphid (*Aulacorthum solani*), green and red peach aphid (*Myzus persicae*), black bean aphid (*Aphis fabae*), greenhouse whitefly (*Trialeurodes vaporariorum*); met dien verstande dat toepassing alleen is toegestaan voor de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei	F	0.084	2	7-10 days	Jan-Dec;
Flower bulb- and bulb flower crops (open field) against green peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean aphid (*Aphis fabae*); met dien verstande dat toepassing alleen is toegestaan voor de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei	F	0.07	2	7-10 days	March-Sept;
Flower bulb- and bulb flower crops (protected culture) against green peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean aphid (*Aphis fabae*)	G	0.07	2	7-10 days	March-Sept;
Flower bulb- and bulb flower crops (dip treatment) against green peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean aphid (*Aphis fabae*); met dien verstande dat bloei moet worden voorkomen;	F	0.08%	1	-	Jan-Dec,
Gladiolus against gladiolus thrips (*Taeniothrips simplex*)	F	0.07	3	7-10	May-Sept
Gladiolus against gladiolus thrips (*Taeniothrips simplex*)	F	0.07	3	7-10	Jan-Dec
Gladiolus (dip treatment) against gladiolus thrips (*Taeniothrips simplex*)	G	0.08%	1	-	Jan-Dec
Tree nursery crops and perennials (protected culture) against glasshouse potato aphid (*Aulacorthum solani*), green and red peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean aphid (*Aphis fabae*), rose aphid (*Macrosiphum rosae*), shallot aphid (*Myzus ascolonicus*), plum leaf-curling aphid (*Brachycaudys helichrysi*)	G	0.07	2	7-10 days	Jan-Dec
Tree nursery crops and perennials in the open ground against glasshouse potato aphid (*Aulacorthum solani*), green and red peach aphid (*Myzus persicae*), black bean aphid (*Aphis fabae*), rose aphid (*Macrosiphum rosae*), shallot aphid (*Myzus ascolonicus*), plum leaf-curling aphid (*Brachycaudys helichrysi*), potato aphid (*Macrosiphum euphorbiae*), black cherry aphid (*Myzus cerasi*), apple aphid (*Aphis pomi*), green spruce aphid (*Elatobium abietinum*), bird cherry aphid (*Rhopalosiphum padi*), woolly beech aphid (*Phyllaphis fagi*); met dien verstande dat toepassing alleen is toegestaan voor de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei	F	0.084	2	7-10 days	March-Sept,
Tree nursery crops and perennials in the open ground against Boxwood psyllids (*Psylla buxi*); met dien verstande dat toepassing alleen is toegestaan voor de bloei tot het zichtbaar worden	F	0.084	1	-	April-May,

van de eerste bloemknoppen alsmede na de bloei					
Hop against hop vine aphid (*Phorodon humuli*) (*aanstrijkbehandeling)*	F	0.032 g a.s./1000 shouts	1	-	May-June
Root growing culture of witloof chicory against lettuce root aphid (*Pemphigus bursarius*) (*spuitbehandeling in zaaivoor)*	F	0.0875	1	-	April-May

Tabel 1 Toepassingsoverzicht ADMIRE

Toepassing	Bijzonderheden	Field / Glass-house	Dosering w.s. [kg/ha]	Freq.	Interval [dag]	Tijdstip
appels, peren (jong gewas)	gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	0,0700	2	7	mei-juli
appels	gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	0,1050	2	7	mei-juli
peren	gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	0,0840	3	7	jan-dec
aubergine	substraatteelt, og	G	0,0314	2	50	jan-dec
tomaat	substraatteelt, og	G	0,0392	2	50	jan-dec
paprika	substraatteelt, og	G	0,0588	2	50	jan-dec
augurk	substraatteelt, og	G	0,0353	2	50	jan-dec
courgette	substraatteelt, og	G	0,0157	2	50	jan-dec
komkommer	substraatteelt, og	G	0,0255	2	50	jan-dec
aubergine	substraatteelt, og	G	0,1254	2	50	jan-dec
tomaat	substraatteelt, og	G	0,1568	2	50	jan-dec
paprika	substraatteelt, og	G	0,2352	2	50	jan-dec
augurk	substraatteelt, og	G	0,1411	2	50	jan-dec
courgette	substraatteelt, og	G	0,0627	2	50	jan-dec
komkommer	substraatteelt, og	G	0,1019	2	50	jan-dec
aubergine, tomaat, paprika (opkweek plantmateriaal)	gewasbehandeling, og	G	0,0700	1	0	jan-dec
bloembollen- en bolbloementeelt	gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan voor de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei	F	0,0700	2	7	april-sept
bloembollen- en bollenteelt)	gewasbehandeling og	G	0,0700	2	7	jan-dec
plantgoed bloem-	dompelbehandeling, met	F	0,3360	1	0	sep-okt

Toepassing	Bijzonderheden	Field / Glass-house	Dosering w.s. [kg/ha]	Freq.	Interval [dag]	Tijdstip
bollenteelt en bolbloementeelt)	dien verstande dat bloei moet worden voorkomen;					
bloemisterijgewassen overige (grondteelten)	gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan voor de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei	G	0,0700	2	7	jan-dec
Bloemisterijgewassen(roos; grondteelt)	gewasbehandeling, og	G	0,0840	2	7	jan-dec
bloemisterijgewassen	substraatteelt, og	G	0,4900	2	50	jan-dec
bloemisterijgewassen (overjarige teelt/ pot- en perkplanten, vaste-planten, snijbloemen	gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei	F	0,0700	2	7	jan-dec
bloemisterijgewassen	substraatteelt, og	G	1,9600	2	50	jan-dec
bloemisterijgewassen (roos)	gewasbehandeling og	G	0,0840	3	7	hele jaar
bloemisterijgewassen (overige)	gewasbehandeling og	G	0,0700	3	7	hele jaar
boomkwekerijgewassen en vaste planten	gewasbehandeling og	G	0,0700	3	7	hele jaar
boomkwekerijgewassen (laanbomen)	gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei	F	0,0840	3	7	april-sept
boomkwekerijgewassen (overige)	gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei	F	0,0840	3	7	april-sept
boomkwekerijgewassen (vaste planten)	gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei	F	0,0700	3	7	april-sept

Direct exposure via spray

1) In-field risk

The first tier risk assessment for bees is based on the ratio between the highest single application rate and toxicity endpoint (LD_{50} value). An overview of the risk of imidacloprid at the proposed uses is given in Table E.3.

Table E.3 Risk for bees of imidacloprid in-field

Use (Field and glasshouse)	Application rate a.s. [g/ha]	LD_{50} [µg/bee]	HQ (trigger 50) [Rate/LD_{50}]
Admire O-Teq all uses	70- 105	0.0037	**18919-28378**
Admire all uses	15.7-1960	0.0037	**4243-529730**

Table E.3 shows that since the ratio rate/LD_{50} is above 50, there is a potential high in-field risk for bees for all spray uses.

A part of these uses is in the glasshouse. To protect bees in glasshouses, restrictions can be included. Exposure to both introduced bees (for pollination service) and bees flying into greenhouses from the outside should be avoided. With the appropiate restriction sentences, the risk is considered to be acceptable for the glasshouse uses:

Dit middel is gevaarlijk voor bijen en hommels. Gebruik is wel toegestaan op bloeiende planten in de kas mits er geen bijen of hommels in de kas actief naar voedsel zoeken. Voorkom dat bijen en andere bestuivende insecten de kas binnenkomen door bijvoorbeeld alle openingen met insectengaas af te sluiten.

Note that the default restriction sentence only covers direct spray risk. Information to determine an appropiate waiting period in glasshouses for bees and bumblebees is not available. This should be addressed by the applicant.
Bijvoorbeeld een restrictiezin: ***Gebruik is wel toegestaan op bloeiende planten in de kas mits er geen bijen of hommels in de kas actief naar voedsel zoeken of na toepassing ingezet worden.***

For the field uses, direct exposure to bees should also be avoided. This can be achieved with the default restriction sentence (Annex V of 91/414/EG):

Dit middel is gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn. Verwijder onkruid voordat het bloeit.

In conclusion, to avoid the risk from direct exposure to bees, the following sentences must be included in the Statutory Instructions for Use:

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

2) Off-field risk

Considering the toxicity of the a.s., also a first-tier off-field risk assessment is performed. The drift rate used is the same as for the evaluation of non-target arthropods. This is 10% for field uses, 37.5% for orchards (before May 1st) and maximally 6.3% for high tree nursery crops. Glasshouse uses and soil treatments do not cause drift exposure to off-field. See Table E.4.

Table E.4 Risk for bees of imidacloprid off-field

Use	Application rate a.s.	Drift %	Exposure	LD_{50}	HQ	Trigger value
	[g/ha]		[g/ha]	[µg/bee]	[Rate/LD_{50}]	
Apple and pear	105	37.5%	39	0.0037	**10641**	50
Flower bulbs, bulb flowers	70	10%	7	0.0037	**1892**	50
Floriculture crops, tree nursery and perennials	84	10%	8.4	0.0037	**2270**	50
Tree nursery, high trees	84	6.7%	5.6	0.0037	**1521**	50

Table E.10b shows that there is a potential off-field risk from the field uses in the first tier. This risk was also highlighted in the EFSA conclusion: "*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".*

To refine the off-field risk for the field uses, higher tier studies will be considered to see if there is a dose rate at which no adverse effects are expected. Note that the standard restriction sentences for the in-field as prescribed above are not targeted at protecting the off-field area. A cage study with flowering *Phacelia tanacetifolia* (Bakker, 2001, cage study p in LoE) is available. It was demonstrated that when Imidacloprid SL 200 is applied during bee flight, rates of 0.6 and 1.2 g a.s./ha had no effects on mortality and foraging activity. At a rate of 2.0 g a.s./ha, 4.0 g a.s./ha and 9.0 g a.s./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. The reduction in foraging activity during a short period as observed in the test is not seen as an adverse effect, due to the short duration and the fact that it will reduce the exposure to imidacloprid (it is assumed that there are sufficient alternative foraging areas during the period of reduced foraging activity on the off-field area after an application with imidacloprid). Hence, 14 g a.s./ha is considered as an acceptable off-field dose rate.

Table E.5 presents the drift reduction measures which are available to reach a maximum off-field dose of 14 g a.s./ha (based on reference 3 of Chapter 7 of the Evaluation Manual. Version 1.0, January 2010).

Table E.5 Required drift measures to reach acceptable risk for bees of imidacloprid off-field

Use	Appl. rate	Maximum acceptable concen-tration	Required drift rate	Available drift reducing measure
	[g/ha]	[g/ha]	%	
Apple and pear, before May 1st	105	14	13.3%	Tunnel; Cross-flow + venturi nozzle + one-sided spraying outside row; Wanner cross-flow + reflection shield;

				Wanner cross-flow + reflection shield + venturi nozzle.
Apple and pear, from May 1st	105	14	13.3%	Cross-flow + reflection shield; Tunnel; Cross-flow + one-sided spraying outside row; Cross-flow + crop detection sensor; Cross-flow + venturi nozzle + one-sided spraying outside row; Wanner cross-flow + reflection shield; Wanner cross-flow + reflection shield + venturi nozzle.
High tree nursery	84	14	16.7%	Not necessary, since drift rate at normal spraying is 6.3%.
Other crops	70-84	14	20-16.7%	Not necessary, since drift rate at normal spraying is 10%.

Table E.5 shows that drift reduction measures to protect bees are only necessary for the uses in apple and pear.

In an earlier risk assessment of Admire and Admire O-Teq, mitigation measures for apple and pear were also prescribed to protect aquatic organisms. These are prescribed only for fields bordering water bodies. For reasons of clarity, all restriction sentences for both aquatic organisms and bees are given here.
The following must be stated in the statutory instructions for use:

Om in het water levende organismen en bijen te beschermen is toepassing in de teelt van appel en peer op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van één van de onderstaande driftreducerende maatregelen:

Vóór 1 mei (kaal)
- *Venturidop + éénzijdige bespuiting laatste bomenrij; ventilatorstand uit.*
- *Wannerspuit met reflectiescherm + venturidop.*

Vanaf 1 mei (volblad)
- *Tunnelspuit.*
- *Combinatie windhaag op de rand van het rijpad en éénzijdige bespuiting van de laatste bomenrij.*
- *Venturidop + éénzijdige bespuiting laatste bomenrij; ventilatorstand aan.*
- *Wannerspuit met reflectiescherm + venturidop.*

Om bijen te beschermen is toepassing in de teelt van appel en peer op percelen die niet grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van één van de onderstaande driftreducerende maatregelen:

Vóór 1 mei (kaal)
- *Tunnelspuit.*
- *Dwarsstroomspuit + venturidop + éénzijdige bespuiting laatste bomenrij.*
- *Wannerspuit met reflectiescherm.*

Vanaf 1 mei (volblad)
- *Tunnelspuit.*
- *Dwarsstroomspuit + éénzijdige bespuiting laatste bomenrij.*
- *Dwarsstroomspuit + reflectiescherm.*
- *Dwarsstroomspuit + sensorbesturing.*
- *Wannerspuit met reflectiescherm.*

With these restrictions, no direct adverse effects to bees from exposure in the off-field area are expected for all uses of Admire and Admire O-Teq.

Indirect exposure via systemic working mechanism

1) Nectar and pollen of the crop
Imidacloprid is a systemic substance. It has many applications as seed treatment, where the substance and its metabolites are taken up by the plant and distributed to plant parts. As stated in the EFSA conclusion, imidacloprid is preferentially translocated to leaves and shoots and to a much lower extent to the reproductive organs. However, if the substance ends up in nectar and pollen, this may lead to a risk from flowering crops.

As concluded above, spraying on flowering crops is not allowed. However, it is not known how well the substance is taken up by the plant when it is sprayed. Data from the residue section indicate that translocation after spraying is small in terms of percentages of sprayed dose, but small quantities may still cause effects on honeybees. Residues in pollen and nectar have not been measured after spray application (in contrast to seed treatments).

Effects on bees after spraying on crops in the pre-flowering stage was 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 these 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.

Based on the cage and field trials, no adverse short-term effects on adult bees are expected from the proposed field applications of Admire and Admire O-Teq 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. This is already included in the Statutory Instructions for Use.
It has not been studied whether the distribution of residues to flowers after spraying for the other field uses (floriculture, flower bulbs, tree nursery and perennials) is comparable to that in apple. Currently, for these uses application is only allowed before (until the first flower buds are visible) and after but not during flowering. However, the time between application and flowering may be shorter for these uses than has been tested in apple and pear (the time between the mouse-ear stage and full flowering is about 3-4 weeks) and if so, the tests performed in apple orchards may not be representative. Therefore, the applicant is requested to provide more information to show that the short-term risk via nectar and pollen of the field uses in floriculture, flower bulbs, tree nursery and perennials is low.

Considering longer-term effects, laboratory studies are available for imidacloprid which provide NOEC values for chronic mortality and behavioural effects. The lowest relevant NOEC was determined during EU peer review to be 20 ppb. However, residue data in nectar and pollen relevant for the proposed spray uses of Admire O-Teq and Admire (in flowers of crops which have been sprayed before flowering, as required on the label) are lacking, so these NOEC values cannot be compared with residue data for the spray uses. Furthermore, in the spray field studies, colony effects were monitored for a period of at most a couple of weeks. Overwintering was not studied.
Because the long-term effects of imidacloprid cannot be adequately addressed based on the available information, further data are required. Thus, the applicant is requested to address the long-term effects of imidacloprid for all field uses of Admire O-Teq and Admire, e.g. by providing data on residues in nectar and pollen after spray application of imidacloprid and/or by providing long-term studies.

For the dip treatment in flower bulbs, it is currently stated that flowering should be avoided altogether. It will be discussed with the nVWA whether this is a realistic restriction.

2) Nectar and pollen of weeds

It is stated on the label that application is not allowed when flowering weeds are present. However, weeds may flower after application and then still contain the a.s. or metabolites due to their systemic and persistent properties. This risk is not considered to be covered by the spray (semi-)field trials in apple orchards, because in these trials application was relatively long before flowering (at BBCH 10). Weeds may start flowering sooner than apple trees and may then contain higher residues than the apple flowers, potentially causing more effect. This has not been investigated (in the studies, no specific attention was given to the presence or absence of flowering weeds). In fruit orchards and tree nursery, flowering weeds can be expected in some amount. Therefore, the applicant is requested to provide more information to show that the risk via nectar and pollen of flowering weeds is low for the proposed field spray applications in orchards and in tree nursery crops.

In the other crops, the presence of a large amount of flowering weeds is not expected, since this is adverse to profitable agriculture. Therefore, the risk via exposure from flowering weeds in the other crops is expected to be low.

3) Nectar and pollen in succeeding crops

Imidacloprid is persistent in soil and therefore residues of imidacloprid may be expected in nectar and pollen of succeeding crops. As the EFSA conclusion states, since no major soil metabolites were detected in the soil degradation studies, bees would therefore only be exposed to imidacloprid residues in succeeding crops.

In the DAR, the risk of succeeding crops was discussed. "Specifically designed succeeding crop studies were conducted on different locations with significantly different soil characteristics, imidacloprid soil residue levels and climate. Residue levels of imidacloprid were found in soils of all treated fields. In contrast, no residues of imidacloprid and the imidacloprid metabolites monohydroxy- and olefine- were detected in nectar, pollen or honey from rape, clover or maize planted as succeeding crops. 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."

The conclusion drawn in the DAR is**:** " Succeeding crop plants do not exhibit residue levels of imidacloprid (including the monohydroxy- and olefine-metabolites) higher than 2 ppb in nectar or pollen." This conclusion is based on untreated crops grown in soils with imidacloprid residues of 0.0127-0.025 mg/kg. See for more information Table B.9.4-5 in the DAR. [It is unknown whether the soil levels in the DAR are measured or calculated; and if calculated, over 5 or 20 cm. It will be assumed that they were calculated over a 20 cm layer; this is worst case with respect to a calculation over 5 cm].

In addition, two new studies have recently been submitted to Ctgb. These studies, performed in Germany, confirm the above findings. On soils in which a plateau concentration of 126 g a.s./ha (analysed: 45.7 and 34.0 ug a.s./kg soil) was simulated, winter wheat seed treated at 126 g a.s./ha was sown in autumn 2007 and harvested in summer 2008. Then in late summer 2008 untreated winter OSR was sown. Directly before sowing of OSR, soil concentration had decreased to 18.8 and 15.2 ug a.s./kg soil. In April 2009, honeybees were confined over the flowering OSR crop in tunnels. Pollen and nectar were collected from foraging honeybees. Residues of imidacloprid in OSR-nectar collected on the imidacloprid treatment test plot were always below the LOD of 0.3 ppb. The imidacloprid concentration in pollen samples from the imidacloprid treatment test plot was determined to be at most 2 ppb. 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.

Based on all the above studies, it can be concluded that imidacloprid residues in nectar and pollen from succeeding crops are not expected to be higher than 2 ppb when these succeeding crops are untreated and sown in soils containing 13-25 µg a.s./kg soil

It has been calculated for the proposed field uses after how many days the concentration in soil (calculated over 20 cm; this is considered to be the relevant soil layer) reaches 25 ug/kg soil (0.025 mg/kg). Calculations are based on the maximum non-normalised field DT50 of 196 d (according to HTB 1.0/Evaluation Manual). See Table E.6.

Table E.6 Number of days to reach residue <0.025 mg/kg soil (20 cm)

Use	Substance	Rate [kg a.s./ha]	Frequency/ interval (days)	Fraction on soil	PECsoil 5 cm [mg a.s./kg]	Residue in soil < 0.025 mg/kg after … d (20 cm soil layer)
Apples and pears	imidacloprid	0.105	2/7	0.2	0.055	<0 d
Floriculture (field)	item	0.084	2/7	0.8	0.177	162 d
Flowerbulbs and bulbflowers, (field)	item	0.07	3/7	0.8	0.219	220 d
Flowerbulbs and bulbflowers (dipping)	item	0.210	1/-	1	0.280	290 d
Tree nursery and perennial (field)	item	0.084	2/7	0.8	0.177	162 d
Chicory (spray treatment in seed drill)	item	0.0875	1/-	1	0.117	45 d

The Table above shows that for apple and pear, succeeding crops are not a problem (furthermore, succeeding crops are not expected since orchards are permanent crops).
For the other crops, the time period is indicated after which it can be said with certainty that the residue level in nectar and pollen of an untreated flowering crop will be at or below a level that is harmless for bees. For all crops, this period is < 1 year.
The applicant is requested to address the risk of bee-attractive succeeding crops (imidacloprid-treated and - untreated) of the spray field uses in floriculture, flowerbulbs and bulb flowers, tree nursery and perennials and chicory of Admire O-Teq and Admire.

4) Honeydew
Risk from exposure to honeydew excreted by aphids and contaminated with residues (from systemic uptake after spraying) is not of concern according to the DAR because the oral LD_{50} of imidacloprid for aphids is much lower (0.000 000 5 µg as/aphid) than for bees (0.004 µg as/bee). Therefore it can be assumed that appreciable amounts of honeydew will only be present at residue concentrations that are not relevant for bees.
As was stated in the EFSA conclusion, the derivation of the LD50 value for aphids was unclear during the Praper meeting and the experts suggested a data gap for the applicant to clarify this point. The applicant has now submitted the study in which the LD50 was derived: *Elbert et al (1991), Imidacloprid – a new systemic insecticide.* This is an overview of efficacy studies with imidacloprid, demonstrating the toxicity to target organisms. Even though the method to derive

the LD50 may be questioned and the endpoint is only derived for one sensitive species, on the basis of this study it can be concluded that the LD50 for aphids will be some orders of magnitude lower than that for bees and thus the risk via honeydew will indeed be low. RMS Germany agrees with this.

5) Guttation
No studies considering guttation are available for imidacloprid. However, several studies are available in which the risk via guttation from clothianidin-seed-treated crops was considered. These studies are owned by Bayer.
The occurrence of guttation was recorded in twelve commercial sugar beet fields and its adjacent crops or habitats, in a typical German sugar beet growing area. Guttation was observed, but not often. In maize, guttation is a much more common phenomenon, which was shown in four trials in France (Liepold). In these trials, seedlings were inspected for guttation droplets from emergence till the occurrence of guttation had stopped for more than five days (24-53 days), several times per day from early in the morning until guttation had stopped for that day (between 11 and 13 h). Bee hives were present close to these fields. Guttation was observed to take place in the morning on the majority of observation days, and timing during the day partly overlapped with the period of high flight activity of the bees. Bees were never observed to collect guttation fluid, and seldom were they seen in contact with guttating plants.
A similar trial was performed in Austria: maize seedlings sown from treated seed were observed for guttation and for bees drinking from guttation droplets. Residues in guttation droplets were measured. This study demonstrated that honey bees do occasionally use guttation fluid as drinking supply, and guttation does contain considerable amounts of clothianidin, diminishing over time, but guttation is not a favoured water source, and mortality of adult bees measured at the hives was generally low, confirming that potential exposure to and/or optake of contaminated guttation fluid did not lead to noticeable increases of adult bee mortality measured at the hive.
These studies sufficiently demonstrated that exposure to and consumption of guttation fluid by foraging bees is unlikely to happen, or only at a very low rate. The studies are considered to be relevant for also for the proposed uses of Admire O-Teq and Admire.
Furthermore, due to dangers (e.g. presence of predators) bees are not keen on foraging on plants unless there is a considerable reward (pollen, nectar). Therefore, drinking droplets from plants is not likely to occur in the field (personal communication from a professional beekeeper, Dr. Johan Calis).
Further, it is also communicated by beekeeper-organisations that beekeepers should provide their bees with sufficient water.
Taking all the available information into account Ctgb expects a low risk to honeybees from guttation.

A.1.2 Professional uses – other than spray application

A.1.2.1 Soil treatments

toelatingnr	**middelnaam**	**toelating houder**	**werkzame stoffen**	**dosering**	**formulering**	**Toepassing(en)**
13178	ADMIRE	LTO Nederland	imidacloprid	**1 x 0.14 kg a.s./ha**	Water dispergeerbaar granulaat	Traybehandeling (kort voor planten) of fytodrip (bij zaaien) in spruitkool, bloemkool en broccoli.

Direct exposure

Direct exposure of bees is not relevant, since it concerns a tray treatment or phytodrip treatment, during which bees will not be present in the field and from which no drift to off-field areas is expected.

Indirect exposure

1) Nectar and pollen of flowering crops

The crops themselves, cabbages, cauliflower and broccoli, will not flower and therefore this risk is low.

2) Nectar and pollen of weeds

Weeds may flower and then contain the active substance or metabolites. For seed treatment uses, tests with respect to long-term effects on bees are available which indicate low risk. The maximum tested dose rate in these tests was 120 g a.s./ha, while the dose rate in the case of the Admire soil treatments is higher (140 g a.s./ha). However, flowering weeds are not expected to occur in large number in cabbage, cauliflower and broccoli fields, because this would be adverse to good and profitable agrcultural practice. This in combination with the low risk expected from the seed treatment trials, indicates that the risk via flowering weeds will be acceptable.

3) Nectar and pollen of succeeding crops

Succeeding crops may flower after application and then contain the active substance. Studies to determine residues in succeeding crops have shown that the residue level of imidacloprid is not expected to be higher than 2 ppb and that the metabolites are not of concern (see discussion above, field spray uses of Admire O-Teq and Admire). The dose rate used in these studies is slightly lower than the dose rate used in the soil treatment.

It has been calculated for the proposed field uses after how many days the concentration in soil (calculated over 20 cm; this is considered to be the relevant soil layer) reaches 25 ug/kg soil (0.025 mg/kg). Calculations are based on the maximum non-normalised field DT50 of 196 d (according to HTB 1.0/Evaluation Manual). See Table E.7.

Table E.7 Number of days to reach residue <0.025 mg/kg soil (20 cm)

Use	Rate [kg a.s./ha]	Frequency/ interval (days)	Fraction on soil	Residue in soil < 0.025 mg/kg after … d (20 cm soil layer)
Cabbages, tray treatment or phytodrip	0.140	1/-	1	176 d

The Table above shows that for the proposed uses in cabbages, after 176 d it can be said with certainty that the residue level in nectar and pollen an untreated flowering crop will be at or below a level that is harmless for bees.

The applicant is requested to address the risk of bee-attractive succeeding crops (imidacloprid-treated and untreated) of the soil treatment uses of Admire.

4) Honeydew

Risk from exposure to honeydew excreted by aphids and contaminated with residues (from systemic uptake after spraying) is not of concern according to the DAR because the oral LD_{50} of imidacloprid for aphids is much lower (0.000 000 5 µg as/aphid) than for bees (0.004 µg as/bee). Therefore it can be assumed that appreciable amounts of honeydew will only be present at residue concentrations that are not relevant for bees.

As was stated in the EFSA conclusion, the derivation of the LD50 value for aphids was unclear during the Praper meeting and the experts suggested a data gap for the applicant to clarify this point. The applicant has now submitted the study in which the LD50 was derived: *Elbert et al (1991), Imidacloprid – a new systemic insecticide.* This is an overview of efficacy studies with imidacloprid, demonstrating the toxicity to target organisms. Even though the method to derive the LD50 may be questioned and the endpoint is only derived for one sensitive species, on the basis of this study it can be expected that the LD50 for aphids will be some orders of magnitude lower than that for bees and thus the risk via honeydew will indeed be low.

5) Guttation

No studies considering guttation are available for imidacloprid. However, several studies are available in which the risk via guttation from clothianidin-seed-treated crops was considered. These studies are owned by Bayer.

The occurrence of guttation was recorded in twelve commercial sugar beet fields and its adjacent crops or habitats, in a typical German sugar beet growing area. Guttation was observed, but not often. In maize, guttation is a much more common phenomenon, which was shown in four trials in France (Liepold). In these trials, seedlings were inspected for guttation droplets from emergence till the occurrence of guttation had stopped for more than five days (24-53 days), several times per day from early in the morning until guttation had stopped for that day (between 11 and 13 h). Bee hives were present close to these fields. Guttation was observed to take place in the morning on the majority of observation days, and timing during the day partly overlapped with the period of high flight activity of the bees. Bees were never observed to collect guttation fluid, and seldom were they seen in contact with guttating plants.

A similar trial was performed in Austria: maize seedlings sown from treated seed were observed for guttation and for bees drinking from guttation droplets. Residues in guttation droplets were measured. This study demonstrated that honey bees do occasionally use guttation fluid as drinking supply, and guttation does contain considerable amounts of clothianidin, diminishing over time, but guttation is not a favoured water source, and mortality of adult bees measured at the hives was generally low, confirming that potential exposure to and/or optake of contaminated guttation fluid did not lead to noticeable increases of adult bee mortality measured at the hive.

These studies sufficiently demonstrated that exposure to and consumption of guttation fluid by foraging bees is unlikely to happen, or only at a very low rate. The studies are considered to be relevant for also for the proposed use in cabbages of Admire.

Furthermore, due to dangers (e.g. presence of predators) bees are not keen on foraging on plants unless there is a considerable reward (pollen, nectar). Therefore, drinking droplets from plants is not likely to occur in the field (personal communication from a professional beekeeper, Dr. Johan Calis).

Further, it is also communicated by beekeeper-organisations that beekeepers should provide their bees with sufficient water.

Taking all the available information into account Ctgb expects a low risk to honeybees from guttation.

toelatingnr	**middelnaam**	**toelatinghouder**	**werkzame stoffen**	**dosering**	**formulering**	**Toepassing(en)**
13321	**MERIT TURF**	**Bayer CropScience B.V.**	**imidacloprid 0,5%**	**1x 0.15 kg a.s./ha**	**Granulaat**	**Strooien in openbare grasvegetatie en graszodenteelt.**

Merit Turf is applied as a granule on grass fields and will only be applied on intensively managed fields like greens of golf courses and turf.

<u>*Direct exposure*</u>

From the granular application, direct exposure of bees is not expected. Bees will not be oversprayed and drift is not expected to occur because application is not done with pneumatic machines with high air flow output.

Indirect exposure

1) *Nectar and pollen of flowering crop*

The grass fields in which Merit Turf is applied, are not expected to flower. Therefore, the risk to bees via this route is acceptable.

2) *Nectar and pollen of flowering weeds*

In the proposed uses, flowering weeds are avoided as much as possible. Also a restriction sentence is applied: *Gevaarlijk voor bijen en hommels. Gebruik dit product niet in de buurt van in bloei staand onkruid. Verwijder onkruid voordat het bloeit.*Therefore, exposure via nectar and pollen is considered to be negligible.
As an extra precaution, the risk can be estimated by looking at the results from several field studies with treated seeds which are available in the DAR. In several cage tests on maize seeds, (1 mg imidacloprid/seed) no residues above the LOQ of 5 µg/kg were found. No effects were observed in the exposed bees. Also in tests on other crops (oilseed rape, summer rape, sunflower) no residues above the LOQ (5 µg/kg- 10 µg/kg) could be determined.
In the DAR a NOEC of 20 µg/kg based on chronic behavioural impacts was determined. This NOEC also covers acute and chronic lethal effects and effects on learning behaviour. The tested rate in the field studies with treated seeds is lower when expressed in kg/ha (tested rates at max 0.12 kg a.s./ha) than the proposed application (0.15 kg a.s./ha), but since the tests were preformed with dressed seeds, in which plant uptake is optimal, it can be assumed that residues in nectar and pollen will be higher than from granular application of Merit Turf. This in combination with expected negligible presence of flowering weeds means that an acceptable risk to bees is expected. It should be considered whether it is necessary to explicitly only allow Merit Turf for use on intensively managed fields: golf greens and turf.

3) Nectar and pollen in succeeding crops

Not relevant for the proposed uses since they are assumed to be permanent.

4) Honeydew

Risk from exposure to honeydew excreted by aphids and contaminated with residues (from systemic uptake after spraying) is not of concern according to the DAR because the oral LD_{50} of imidacloprid for aphids is much lower (0.000 000 5 µg as/aphid) than for bees (0.004 µg as/bee). Therefore it can be assumed that appreciable amounts of honeydew will only be present at residue concentrations that are not relevant for bees.
As was stated in the EFSA conclusion, the derivation of the LD50 value for aphids was unclear during the Praper meeting and the experts suggested a data gap for the applicant to clarify this point. The applicant has now submitted the study in which the LD50 was derived: *Elbert et al (1991), Imidacloprid – a new systemic insecticide.* This is an overview of efficacy studies with imidacloprid, demonstrating the toxicity to target organisms. Ctgb is of the opinion that even though the method to derive the LD50 may be questioned and the endpoint is only derived for one sensitive species, on the basis of this study it can be expected that the LD50 for aphids will be some orders of magnitude lower than that for bees and thus the risk via honeydew will indeed be low.

5) Guttation

No studies considering guttation are available for imidacloprid. However, several studies are available in which the risk via guttation from clothianidin-seed-treated crops was considered. These studies are owned by Bayer.
The occurrence of guttation was recorded in twelve commercial sugar beet fields and its adjacent crops or habitats, in a typical German sugar beet growing area. Guttation was

observed, but not often. In maize, guttation is a much more common phenomenon, which was shown in four trials in France (Liepold). In these trials, seedlings were inspected for guttation droplets from emergence till the occurrence of guttation had stopped for more than five days (24-53 days), several times per day from early in the morning until guttation had stopped for that day (between 11 and 13 h). Bee hives were present close to these fields. Guttation was observed to take place in the morning on the majority of observation days, and timing during the day partly overlapped with the period of high flight activity of the bees. Bees were never observed to collect guttation fluid, and seldom were they seen in contact with guttating plants.
A similar trial was performed in Austria: maize seedlings sown from treated seed were observed for guttation and for bees drinking from guttation droplets. Residues in guttation droplets were measured. This study demonstrated that honey bees do occasionally use guttation fluid as drinking supply, and guttation does contain considerable amounts of clothianidin, diminishing over time, but guttation is not a favoured water source, and mortality of adult bees measured at the hives was generally low, confirming that potential exposure to and/or optake of contaminated guttation fluid did not lead to noticeable increases of adult bee mortality measured at the hive.
These studies sufficiently demonstrated that exposure to and consumption of guttation fluid by foraging bees is unlikely to happen, or only at a very low rate.
Furthermore, due to dangers (e.g. presence of predators) bees are not keen on foraging on plants unless there is a considerable reward (pollen, nectar). Therefore, drinking droplets from plants is not likely to occur in the field (personal communication from a professional beekeeper, Dr. Johan Calis).
In terms of the exposure scenario, application of Merit Turf on grass or turf is comparable to a cereal seed treatment but the likelihood of beehives being exposed on or aside such treated areas is even lower if compared to the situation in agricultural landscapes.
Based on the above information and further because there will be, also by applying the restriction sentence, only small amounts of flowering plants in these vegetations will be present (thus, not attractive as foraging areas for bees), Ctgb expects a low risk for honeybees with respect to guttation.

toelatingnr	**middelnaam**	**toelatinghouder**	**werkzame stoffen**	**dosering**	**formulering**	**Toepassing(en)**
13059	**MONAMI**	**Bayer CropScience B.V.**	**imidacloprid 17,5G/L # pencycuron 250G/L**	**1 x 0.175 kg a.s./ha, March - May**	**Suspensie concentraat**	**Aardappelen, grondbehandeling tijdens poten.**
11662	**AMIGO FLEX**	**Bayer CropScience B.V.**	**imidacloprid 350G/L**	**1 x 0.175 kg a.s./ha**	**Suspensie concentraat**	**Aardappelen, grondbehandeling tijdens poten.**

<u>Direct exposure</u>

Since the application considers soil treatment during which bees will not be present on the field and from which drift is not expected off-field, direct exposure to bees will not occur.

<u>Indirect exposure</u>

Monami contains both imidacloprid and pencycuron, but since pencycuron is not systemic, only the risk of imidacloprid needs to be addressed.

1) Nectar and pollen of flowering crop

Potatoes flower during cultivation, but honeybees do not fly on potato flowers. Hence, the risk from this route of exposure is low for honeybees. There are however indications that bumblebees may fly on potato flowers to collect pollen (*pers.comm. bijen@wur)*. Imidacloprid is acutely not more toxic for bumblebees than for honeybees. However, it is difficult to estimate the potential risk, since the dose rates tested in the higher tier studies with honeybees are below the proposed dose rate of Monami and Amigo Flex of 175 g a.s./ha. Therefore, the applicant is requested to address the effects of imidacloprid to bumblebees from the soil treatment in potatoes.

2) Nectar and pollen of flowering weeds
Weeds may flower and then contain the active substance or metabolites. In the case of seed treatments tests with respect to long-term effects on bees are available which indicate low risk. The maximum tested dose rate in these tests was 120 g a.s./ha, while the dose rate in the case of the Monami and Amigo Flex soil treatment is higher (175 g a.s./ha). Extrapolation of measured residues in one species to other plant species is uncertain and should be interpreted with caution. However, flowering weeds are not expected to occur in large number in potato fields, because this would be adverse to good and profitable agrcultural practice. This in combination with the low risk expected from the seed treatment trials, indicates that the risk via flowering weeds will be acceptable.

3) Nectar and pollen of flowering succeeding crops
Succeeding crops may flower after application and then contain the active substance. Studies to determine residues in succeeding crops have shown that the residue level of imidacloprid is not expected to be higher than 2 ppb and that the metabolites are not of concern (see discussion above, field spray uses of Admire O-Teq and Admire). However, the dose rate used in these studies is lower than the dose rate of Monami and Amigo Flex.

It has been calculated for the proposed field uses after how many days the concentration in soil (calculated over 20 cm; this is considered to be the relevant soil layer) reaches 25 ug/kg soil (0.025 mg/kg). Calculations are based on the maximum non-normalised field DT50 of 196 d (according to HTB 1.0/Evaluation Manual). See Table E.8.

Table E.8 Number of days to reach residue <0.025 mg/kg soil (20 cm)

Use	Rate [kg a.s./ha]	Frequency/ interval (days)	Fraction on soil	Residue in soil < 0.025 mg/kg after … d (20 cm soil layer)
Potato, soil treatment	0.175	1/-	1	240 d

The Table above shows that for the proposed uses in potatoes, after 240 d it can be said with certainty that the residue level in nectar and pollen an untreated flowering crop will be at or below a level that is harmless for bees.
The applicant is requested to address the risk of bee-attractive succeeding crops (imidacloprid-treated and untreated) of the soil treatment uses of Monami and Amigo Flex.

4) Honeydew
Risk from exposure to honeydew excreted by aphids and contaminated with residues (from systemic uptake after spraying) is not of concern according to the DAR because the oral LD_{50} of imidacloprid for aphids is much lower (0.000 000 5 µg as/aphid) than for bees (0.004 µg as/bee). Therefore it can be assumed that appreciable amounts of honeydew will only be present at residue concentrations that are not relevant for bees.
As was stated in the EFSA conclusion, the derivation of the LD50 value for aphids was unclear during the Praper meeting and the experts suggested a data gap for the applicant to clarify this point. The applicant has now submitted the study in which the LD50 was derived: *Elbert et al (1991), Imidacloprid – a new systemic insecticide.* This is an overview of efficacy studies with imidacloprid, demonstrating the toxicity to target organisms. Even though the method to derive

the LD50 may be questioned and the endpoint is only derived for one sensitive species, on the basis of this study it can be expected that the LD50 for aphids will be some orders of magnitude lower than that for bees and thus the risk via honeydew will indeed be low.

5) Guttation
No studies considering guttation are available for imidacloprid. However, several studies are available in which the risk via guttation from clothianidin-seed-treated crops was considered. These studies are owned by Bayer.
The occurrence of guttation was recorded in twelve commercial sugar beet fields and its adjacent crops or habitats, in a typical German sugar beet growing area. Guttation was observed, but not often. In maize, guttation is a much more common phenomenon, which was shown in four trials in France (Liepold). In these trials, seedlings were inspected for guttation droplets from emergence till the occurrence of guttation had stopped for more than five days (24-53 days), several times per day from early in the morning until guttation had stopped for that day (between 11 and 13 h). Bee hives were present close to these fields. Guttation was observed to take place in the morning on the majority of observation days, and timing during the day partly overlapped with the period of high flight activity of the bees. Bees were never observed to collect guttation fluid, and seldom were they seen in contact with guttating plants.
A similar trial was performed in Austria: maize seedlings sown from treated seed were observed for guttation and for bees drinking from guttation droplets. Residues in guttation droplets were measured. This study demonstrated that honey bees do occasionally use guttation fluid as drinking supply, and guttation does contain considerable amounts of clothianidin, diminishing over time, but guttation is not a favoured water source, and mortality of adult bees measured at the hives was generally low, confirming that potential exposure to and/or optake of contaminated guttation fluid did not lead to noticeable increases of adult bee mortality measured at the hive.
These studies sufficiently demonstrated that exposure to and consumption of guttation fluid by foraging bees is unlikely to happen, or only at a very low rate. This conclusion is considered to be relevant also for the proposed use in cabbages of MonAmi and Amigo Flex.
Furthermore, due to dangers (e.g. presence of predators) bees are not keen on foraging on plants unless there is a considerable reward (pollen, nectar). Therefore, drinking droplets from plants is not likely to occur in the field (personal communication from a professional beekeeper, Dr. Johan Calis).
Further, it is also communicated by beekeeper-organisations that beekeepers should provide their bees with sufficient water.
Taking all the available information into account Ctgb expects a low risk to honeybees from guttation.

A.1.2.2 Seed treatments

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	Dosering	formulering	Toepassing(en)
11455	GAUCHO	Bayer CropScience B.V.	imidacloprid 70%	0.091 kg a.s./ha	Water dispergeerbaar poeder voor vochtige zaadbehandeling	Zaadcoating in suiker- en voederbieten.
11601	GAUCHO ROOD	Bayer CropScience B.V.	imidacloprid 70%	0.120 kg a.s./ha	Water dispergeerbaar poeder voor vochtige zaadbehandeling	Zaadcoating in mais.
12341	GAUCHO TUINBOUW	Bayer CropScience	imidacloprid 70%	0.089-0.120 kg a.s./ha	Water dispergeerbaar	Zaadcoating van sla, andijvie, kolen, prei.

		B.V.			poeder voor vochtige zaadbehandeling	

<u>*Direct exposure*</u>
1) In-field
Direct iIn-field exposure is not expected, because it concerns a seed treatment and because bees will not be present in-field when the seeds are sown or when the plants are transplanted into the field.

2) Off-field
Dust drift from treated seed is not a relevant exposure route for the uses in lettuce, endive and cabbages, because sowing takes place indoors (seedlings are later transplanted outdoors). Maize, leek and beets are sown outside, however. The risk that dust from the seed coating reaches neighbouring crops or other flowering plants and in that way exposes bees to the a.s., depends on the type of coating in combination with the type of sowing. This assessment is based on the dust drift matrix available at www.ctgb.nl (version of October 2010).

Sowing of beets is done mechanically and seeds are incorporated in a pill which has a film coating. No dust drift is expected. The risk is acceptable.

Sowing of leek is done with pneumatic sowing machines, but no dust drift is expected because seeds have an advanced filmcoating. The risk is acceptable.

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

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

Since the application rate for maize is 120 g a.s./ha, the expected off-field dose is 0.0055*120 = 0.66 g a.s./ha. This is a factor 20 below the NOAEC of 14 g a.s./ha which was found for spray exposure. At this level, no mortality was seen. There are indications that exposure via dust causes higher toxicity than via spray liquid. A dust toxicity endpoint for imidacloprid is not available. However, it is considered that there is sufficient margin of safety to expect that no direct adverse effects will occur at maize sowing, provided that the following restrictions are mentioned on the label for maize:

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

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

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

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

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

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

1) Nectar and pollen of the crop
Lettuce, endive, cabbages, leek and beets are not supposed to flower during cultivation. Therefore, no exposure via nectar or pollen from these crops themselves will take place. Maize, however, will flower and bees can collect pollen from maize.

During EU review, the risks of sugar beet seed treatment (0.117 kg a.s./ha) was assessed. A NOEC of 20 ppb was determined , which is expected to cover lethal, sublethal and brood effects.
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. The dose rate used in the maize trials was not reported in kg a.s./ha, but it is likely that the currently proposed dose rate for Gaucho Rood (120 g a.s./ha) is covered by those trials. Therefore, the residue levels in maize pollen from the use in Gaucho Rood are not expected to result in unacceptable effects on bees, also on the long-term, considering that the assessment is based on a NOEC value which covers both lethal and sublethal effects.

2) Nectar and pollen of weeds
Because the a.s. is systemic and persistent, it may occur in flowering weeds. This risk may be considered by looking at the seed treatment trials which show that residues are not expected to reach unacceptable levels at dose rates covering the proposed dose rates (see above). Extrapolation of measured residues in one species to other plant species is uncertain and should be interpreted with caution. However, flowering weeds are not expected to occur in large number in the proposed crops, because this would be adverse to good and profitable agricultural practice. This in combination with the low risk expected from the seed treatment trials, indicates that the risk via flowering weeds will be acceptable.

3) Nectar and pollen of succeeding crops
Succeeding crops may flower after application and then contain the active substance. Studies to determine residues in succeeding crops have shown that the residue level of imidacloprid is not expected to be higher than 2 ppb and that the metabolites are not of concern (see discussion above, field spray uses of Admire O-Teq and Admire). The dose rate used in these studies covers the dose rates of the seed treatmens.

Since the expected residue level will be at most a factor 10 below the NOEC of 20 ppb which covers both lethal and sublethal effects, the risk via untreated succeeding crops is expected to be low.
It is not known how high the residues would be in imidacloprid-treated succeeding crops. Accumulation in soil may cause increase in residue levels after several years of imidacloprid use. The applicant is requested to address this issue.

4) Honeydew
Risk from exposure to honeydew excreted by aphids and contaminated with residues (from systemic uptake after spraying) is not of concern according to the DAR because the oral LD_{50} of imidacloprid for aphids is much lower (0.000 000 5 µg as/aphid) than for bees (0.004 µg as/bee). Therefore it can be assumed that appreciable amounts of honeydew will only be present at residue concentrations that are not relevant for bees.
As was stated in the EFSA conclusion, the derivation of the LD50 value for aphids was unclear during the Praper meeting and the experts suggested a data gap for the applicant to clarify this point. The applicant has now submitted the study in which the LD50 was derived: *Elbert et al (1991), Imidacloprid – a new systemic insecticide.* This is an overview of efficacy studies with imidacloprid, demonstrating the toxicity to target organisms. Even though the method to derive the LD50 may be questioned and the endpoint is only derived for one sensitive species, on the basis of this study it can be expected that the LD50 for aphids will be some orders of magnitude lower than that for bees and thus the risk via honeydew will indeed be low.

5) Guttation
No studies considering guttation are available for imidacloprid. However, several studies are available in which the risk via guttation from clothianidin-seed-treated crops was considered. These studies are owned by Bayer.
The occurrence of guttation was recorded in twelve commercial sugar beet fields and its adjacent crops or habitats, in a typical German sugar beet growing area. Guttation was observed, but not often. In maize, guttation is a much more common phenomenon, which was shown in four trials in France (Liepold). In these trials, seedlings were inspected for guttation droplets from emergence till the occurrence of guttation had stopped for more than five days (24-53 days), several times per day from early in the morning until guttation had stopped for that day (between 11 and 13 h). Bee hives were present close to these fields. Guttation was observed to take place in the morning on the majority of observation days, and timing during the day partly overlapped with the period of high flight activity of the bees. Bees were never observed to collect guttation fluid, and seldom were they seen in contact with guttating plants.
A similar trial was performed in Austria: maize seedlings sown from treated seed were observed for guttation and for bees drinking from guttation droplets. Residues in guttation droplets were measured. This study demonstrated that honey bees do occasionally use guttation fluid as drinking supply, and guttation does contain considerable amounts of clothianidin, diminishing over time, but guttation is not a favoured water source, and mortality of adult bees measured at the hives was generally low, confirming that potential exposure to and/or optake of contaminated guttation fluid did not lead to noticeable increases of adult bee mortality measured at the hive.
These studies sufficiently demonstrated that exposure to and consumption of guttation fluid by foraging bees is unlikely to happen, or only at a very low rate.
Furthermore, due to dangers (e.g. presence of predators) bees are not keen on foraging on plants unless there is a considerable reward (pollen, nectar). Therefore, drinking droplets from plants is not likely to occur in the field (personal communication from a professional beekeeper, Dr. Johan Calis).
Further, it is also communicated by beekeeper-organisations that beekeepers should provide their bees with sufficient water.
Taking all the available information into account Ctgb expects a low risk to honeybees from guttation.

A.2 Non-professional uses

toelatingnr	middelnaam	toelating-houder	werkzame stoffen	formulering	Toepassing(en)
11998 (afgeleide: 12219)	ADMIRE N PIN	Bayer CropScience B.V.	imidacloprid 2,5%	Plantenstaafje	Sierplanten in potten en bakken.

Admire N Pin is a plant stick which is used in ornamentals in pots by non-professionals. The sticks are inserted into the soil and the a.s. is then taken up in the plant and may in that way reach the flowers also. At the request of the applicant, recently (April 2011) the use was explicitly restricted to indoor use because it was only used indoors anyway. Exposure of honeybees to flowering plants inside private houses is considered to be negligible. Therefore, the risk of Admire N Pin is acceptable, provided that the following sentence is mentioned on the label:

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel bij kamerplanten binnenshuis.

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

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
Since imidacloprid is very toxic to bees, exposure should be avoided. With this aim, the following restriction is indicated on the label (since April 2011):

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

This is a recently developed sentence which is specifically targeted at non-professional users, who have not had training in application of pesticides and in label-reading and who should therefore be informed of potential risks with a simple sentence. The sentence mentioned above is considered to fulfill this requirement. If the product is not sprayed or poured on or near flowering plants, bees will not be exposed directly.

Indirect exposure
Flowering crops
The risk via flowering crops is expected to be low for the professional uses in apple, pear and grass fields. The amount of imidacloprid used for non-professional use is very small compared to professional use (less than 1% of total imidacloprid use in the Netherlands is for non-professional use) and there will be a much more patchy distribution as compared to professional use. Therefore, the contribution of the non-professional use of imidacloprid to potential effects on honeybees on a regional/national scale is expected to be very small. However, effects may occur on a local scale.

The field studies in apple orchards showed that effects are acceptable when orchards are sprayed at the mouse-ear stage (about 3-4 weeks before full flowering). This can be communicated to professional users, but not to non-professional users.
For ornamentals, an additional question was asked for professional use and this is also relevant for the non-professional use.
The risk via this route is not considered to be high considering the patchy and relatively small application of the non-professional use as compared to the professional use. However, the applicant is requested to address this issue for the uses in ornamentals and orchards.

Flowering weeds
For the professional use in orchards, an additional question is asked regarding the risk of flowering weeds. This question is also relevant for Provado Garden.
For the professional uses in ornamentals and grassland, it is expected that weeds will be kept to a minimum. For non-professional gardens and lawns, this is less certain. If the product is sprayed or poured on weeds before they flower, they may still contain some residue when they flower. The risk via this route is not considered to be high considering the patchy and relatively small application of the non-professional use as compared to the professional use. However, the applicant is requested to address this issue for all uses.

Succeeding crops
Succeeding crops are 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).

B. Biocides
The final LoE of imidacloprid, taken from the revised Doc I from the final revised CAR (July 2010), indicates high toxicity of imidacloprid to honeybees.

Effects on honeybees (Annex IIIA, point XIII.3.1)

Acute oral toxicity	LD_{50} (48 h) = 0.0037 µg/bee
Acute contact toxicity	LD_{50} (48 h) = 0.081 µg/bee

B.1.1 Professional uses against flies

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	formulering	Toepassing(en)
13160 (afgeleide: 13173)	LURECTRON FLYBAIT	Denka Registrations B.V.	imidacloprid 0,5%	Granulaat	Tegen vliegen. Korrels die je moet oplossen en dan op de muur etc smeert. In dierverblijfplaatsen.
12665 (afgeleide: 13063)	QUICK BAYT	Bayer CropScience B.V.	imidacloprid 0,5%	Lokmiddel (klaar voor gebruik)	Tegen vliegen. Korrels die je moet oplossen en dan op de muur etc smeert. In dierverblijfplaatsen.
13116	QUICK BAYT	Bayer	imidacloprid	Water	Tegen vliegen. Middel

	SPRAY	CropScience B.V.	10%	dispergeerbaar granulaat	verspuiten op oppervlakten waar vliegen vaak zitten. Dierverblijfplaatsen en opslagplaatsen.

The risk assessment method for these products is taken from the CAR of imicloprid (Doc II, final). Since potential exposure of honeybees will be through exposure to residues in flowering crops/plants grown in fields which have received manure containing imidacloprid, field studies conducted for assessing risk from agricultural uses are also appropriate for the biocidal use risk assessment. In several field studies analysis of nectar and pollen of flowering crops grown on soils treated formerly with imidacloprid was performed. The results are summarised in the table below (taken from the CAR):

Table 4-35 Residue concentrations of imidacloprid and its metabolites in flowering crops

Aged soil residue µg/kg	Limit of quantification			Residue concentrations (mg/kg)				Reference
				imidacloprid		Metabolites		
	Parent	5-OH	Olefin	Nectar	Pollen	Nectar	Pollen	
Sunflower crops								
15.7	B	B	A	n.d.	n.d.	n.d.	n.d.	Schmuck et. al. (1999a)
12.7	B	B	A	n.d.	n.d.	n.d.	n.d.	
14.3	B	B	A	n.d.	n.d.	n.d.	n.d.	
Seed rate 52 g a.i./ha	B	B	A	n.d.	n.d.	n.d.	n.d.	
17.8	B	B	A	n.d.	n.d.	n.d.	n.d.	Schmuck et. al. (1999b)
<6	B	B	A	n.d.	n.d.	n.d.	n.d.	
Seed rate 45 g a.i./ha	B	B	A	n.d.	n.d.	n.d.	n.d.	
Rape crops								
15.7	B	B	A	n.d.	n.d.	n.d.	n.d.	Schmuck et. al. (1999d)
12.7	B	B	A	n.d.	<LOQ	n.d.	n.d.	
14.3	B	B	A	n.d.	<LOQ	n.d.	n.d.	
Seed rate 33.5 g/ha	B	B	A	<LOQ	n.d.	n.d.	n.d.	
17.8	B	B	A	n.d.	n.d.	n.d.	n.d.	Schmuck et. al. (1999c);
< 6	B	B	A	n.d.	n.d.	n.d.	n.d.	
Seed rate 72 g/ha	B	B	A	<LOQ	<LOQ	n.d.	n.d.	
Clover crops and nearby wildflowers (soil residue aging period approx. 28 months)								
25	C	C	C	n.d.	n.d.	n.d.	n.d.	Kemp, J. R.; Rogers, R. E. L. (2002)
14	C	C	C	n.d.	n.d.	n.d.	n.d.	
24	C	C	C	n.d.	n.d.	n.d.	n.d.	
17	C	C	C	n.d.	n.d.	n.d.	n.d.	

n.d.: below limit of detection (= typically 1/3 of LOQ); LOQ = limit of quantification

limit of quantification: A = 10 µg/kg; B = 5 µg/kg; C = 2 µg/kg

Neither in pollen nor in nectar of the plants grown in soils with residues in the range of 12.7 to 25 µg/kg imidacloprid, could imidacloprid or its metabolites be detected or quantified (LOQ in the range of 2 -10 ug/kg). In addition to residue measurements, each study included an assessment of honey bee colonies placed in the fields during flowering periods. The assessment criteria included mortality, behavioural anomalies, colony development and brood status. No treatment-related mortality or adverse impacts were noted in any study. These studies indicate the lack of adverse impact on honeybees foraging on flowering crops grown in soils containing residue levels of up to 25 ppb of imidacloprid. The proposed use of imidacloprid against flies in stables have an expected PECsoil of <25 ppb (calculated in the CAR).

The field studies referred to are taken from the PPP DAR. Effects on bees in these studies were only monitored for a couple of weeks. However, in the DAR a NOEC of 20 µg/kg based on chronic behavioural impacts was determined. This NOEC also covers acute and chronic lethal effects and effects on learning behaviour.
At the expected concentration in soil, the expected concentration in nectar and pollen is below the NOEC of 20 µg/kg. Based on this, the products Lurectron Flybait, Quick Bayt and Quick Bayt Spray have an acceptable risk to bees.

B.1.2 Professional uses against ants

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	toepassing	formulering	Toepassing(en)
13074	MAXFORCE QUANTUM	Bayer CropScience B.V.	imidacloprid 0,31G/KG	Professioneel	Lokmiddel (klaar voor gebruik)	Tegen mieren. Gel (visceuze druppels) die je met een pistool binnen of buiten, in nesten of op looppaden moet aanbrengen.

Maxforce Quantum is a gel which is used against ants, both indoors and outdoors. The gel contains a substance to attract ants. Whether this also attracts bees is unknown. Bees may take up the gel.
Exposure of bees is considered to be negligible from the indoor use of Maxforce Quantum, which thus has an acceptable risk to bees. However, since the attractivity to bees of the gel is unknown, some exposure to bees cannot be excluded from the outdoor use of Maxforce Quantum. The applicant is requested to address this risk.

B.1.2 Professional uses against cockroaches

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	toepassing	formulering	Toepassing(en)
13250	MAXFORCE PRIME	Bayer CropScience B.V.	imidacloprid 2,15%	Professioneel	Lokmiddel (klaar voor gebruik)	Bestrijding van kakkerlakken in gebouwen en transportmiddelen.
12094	MAXFORCE WHITE IC	Bayer CropScience B.V.	imidacloprid 2,15%	Professioneel	lokaas	Bestrijding van kakkerlakken in gebouwen en transportmiddelen.

Maxforce Prima and Maxforce White IC are used indoors against cockroaches. Since exposure to bees is considered to be negligible for indoor uses, the products have an acceptable risk to bees.

B.2 Non-professional uses

13055 (afgeleides : 13104, 13127, 13073, 13072, 13121,	PIRON MIERENLOKDOOS	Bayer CropScience B.V.	imidacloprid 0,03%	Professioneel & Niet-professioneel	Lokmiddel (klaar voor gebruik)	Mierenlokdoos. Zowel buiten als binnen.

13124)						
12952 (afgeleides : 13026, 12974, 13052, 12979, 12980, 12024)	BAYTHION MIERENMIDDEL N	Bayer CropScienc e B.V.	imidaclopri d 0,0500%	Professionee l & Niet-professioneel	Granulaat	Korrels die je bij mierennest moet strooien. Alleen buiten.
13280 (parallel: 13351_	VAPONA RAAMSTICKER	Sara Lee Household and Body Care NL B.V.	imidaclopri d 0,4890%	Niet-professioneel	Diversen	Sticker tegen vliegen. Binnenshuis.
13369	VLIEGENSTICKER	Bayer CropScienc e B.V.	imidaclopri d 5G/KG	Niet-professioneel	Diversen	Sticker tegen vliegen. Binnenshuis.

Exposure to bees is not considered relevant from the above products which are ant traps; granules against ants; or fly stickers for indoor use. Therefore, these products have an acceptable risk for bees.

Public literature:
Below, the preliminary results of a public literature survey are presented.

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.

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.

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 determined imidacloprid is unclear. 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. terestris 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).

Several large-scale monitoringstudies were performed in which imidacloprid 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 6-chloronicotinic acid was conducted on 81 samples (the same for) 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 an d1.2 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. The maximum residue concentration of imidacloprid and 6-chloronicotinic acid in pollen samples was 5.7 and 9.3 µg/kg, respectively.
Also, 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.

Higes et al (2010) estimated the prevalence of honey bee colony depopulation symptoms in Spain in a random selected sample (*n* = 61) and we 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 depopulated. This preliminary study of epidemiological factors suggests that *N. ceranae* 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.

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

In the Netherlands, relatively high bee losses have been seen in recent years (increased mortality after winter). These losses have mainly been attributed to beekeeping practice with regard to pests and diseases, especially the *Varroa* mite, since it has been found that adequate and timely Varroa treatment reduces winter mortality (personal communication bijen@wur and professional beekeeper; Van der Zee & Pisa 2011). 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.

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

The UNEP report names many possible threats to pollinators:

- Habitat deterioration, with reduction of food sources (and habitat, for certain wild pollinators).

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

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

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

Based on the available information it cannot be concluded that there is a link between 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. Therefore, there is currently not enough evidence to justify a ban of imidacloprid or of neonicotinoid products based on public literature. It should be noted that other (European and elsewhere) countries have not taken such steps either (with some exceptions where clear acute bee poisoning due to suboptimal sowing circumstances was observed; this has not been the case in the Netherlands).

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

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