Background
In de Tweede Kamer is op 17 februari 2011 motie 19 aangenomen. Deze motie betreft de herbeoordeling van bestrijdingsmiddelen op basis van neonicotinoïden voor het onderdeel (subletale) effecten op bijen. Dit document bevat de beoordeling van het risico voor bijen van momenteel in Nederland toegelaten middelen op basis van imidacloprid. Deze middelen zijn in onderstaande tabellen weergeven.
Wijzigingen ná C-vergadering 15 juni in geel.

Gewasbeschermingsmiddelen op basis van imidacloprid

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	toepassing	formulering	Toepassing(en)
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.
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.
13178	ADMIRE	LTO Nederland	imidacloprid	Professioneel	Water dispergeerbaar granulaat	Traybehandeling (kort voor planten) of fytodrip (bij zaaien) in spruitkool, bloemkool en broccoli.
13059	MONAMI	Bayer CropScience B.V.	imidacloprid 17,5G/L # pencycuron 250G/L	Professioneel	Suspensie concentraat	Aardappelen, grondbehandeling tijdens poten.
11662	AMIGO FLEX	Bayer CropScience B.V.	imidacloprid 350G/L	Professioneel	Suspensie concentraat voor zaadbehandeling	Aardappelen, grondbehandeling tijdens poten.
13321	MERIT TURF	Bayer CropScience B.V.	imidacloprid 0,5%	Professioneel	Granulaat	Strooien in grasvegetatie en graszodenteelt.
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 poeder voor vochtige zaadbehandeling	Zaadcoating van sla, andijvie, kolen, prei.

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.

Biociden op basis van imidacloprid

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	toepassing	formulering	Toepassing(en)
13160 (afgeleide: 13173)	LURECTRON FLYBAIT	Denka Registrations B.V.	imidacloprid 0,5%	Professioneel	Granulaat	Tegen vliegen. Korrels om op te lossen en dan op oppervlakten te smeren in dierverblijfplaatsen.
12665 (afgeleide: 13063)	QUICK BAYT	Bayer CropScience B.V.	imidacloprid 0,5%	Professioneel	Lokmiddel (klaar voor gebruik)	Tegen vliegen. Korrels om op te lossen en dan op oppervlakten te smeren in dierverblijfplaatsen.
13116	QUICK BAYT SPRAY	Bayer CropScience B.V.	imidacloprid 10%	Professioneel	Water dispergeerbaar granulaat	Tegen vliegen. Middel verspuiten op oppervlakten waar vliegen vaak zitten. Dierverblijfplaatsen en opslagplaatsen.
13074	MAXFORCE QUANTUM	Bayer CropScience B.V.	imidacloprid 0,31G/KG	Professioneel	Lokmiddel (klaar voor gebruik)	Tegen mieren. Gel (visceuze druppels), met een pistool binnen of buiten, in nesten of op looppaden aan te brengen.
13250	MAXFORCE PRIME	Bayer CropScience B.V.	imidacloprid 2,15%	Professioneel	Lokmiddel (klaar voor gebruik)	Bestrijding van kakkerlakken in gebouwen en transportmiddelen. Gel aanbrengen in kieren en spleten.
12094	MAXFORCE WHITE IC	Bayer CropScience B.V.	imidacloprid 2,15%	Professioneel	lokaas	Bestrijding van kakkerlakken in gebouwen en transportmiddelen. Gel aanbrengen in kieren en spleten.
13055 (afgeleides: 13104, 13127, 13073, 13072, 13121, 13124)	PIRON MIERENLOKDOOS	Bayer CropScience B.V.	imidacloprid 0,03%	Professioneel & Niet-professioneel	Lokmiddel (klaar voor gebruik)	Mierenlokdoos. Zowel buiten als binnen.
12952 (afgeleides: 13026, 12974,	BAYTHION MIERENMIDDEL N	Bayer CropScience B.V.	imidacloprid 0,0500%	Professioneel & Niet-professioneel	Granulaat	Korrels om bij mierennest te strooien. Alleen buiten.

13052, 12979, 12980, 12024)						
13280 (parallel: 13351)	VAPONA RAAMSTICKER	Sara Lee Household and Body Care NL B.V.	imidacloprid 0,4890%	Niet-professioneel	Diversen	Sticker tegen vliegen. Binnenshuis.
13369	VLIEGENSTICKER	Bayer CropScience B.V.	imidacloprid 5G/KG	Niet-professioneel	Diversen	Sticker tegen vliegen. Binnenshuis.

A. Plant protection products

Risk assessment is done in accordance with Chapter 2 of the RGB published in the Government Gazette (Staatscourant) 188 of 28 September 2007, including the update of 20 October 2009, which came into effect on 1 January 2010. The bee risk assessment is also based on the most recent guidance document, which is EPPO 2010. This includes methodology to assess the risk from systemic substances.

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

Part A: For the protection of non-target organisms, in particular honey bees and birds, for use as seed treatment:

- the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage and transport can be minimised,

- adequate seed drilling equipment shall be used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.

Member States shall ensure that:

- the label of treated seed includes the indication that the seeds were treated with imidacloprid and sets out the risk mitigation measures provided for in the authorisation,

- the conditions of the authorisation, in particular for spray applications, include, where appropriate, risk mitigation measures to protect honey bees,

- monitoring programmes are initiated to verify the real exposure of honey bees to imidacloprid in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.";

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

A.1 Professional uses of plant protection products

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

<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 PPP uses currently allowed in the Netherlands will be assessed. Due to the particular properties of imidacloprid, the following exposure routes will be considered for each product:
- Direct exposure, both in- and off-field
- Indirect exposure, from the crop itself, weeds, succeeding crops, honeydew and guttation.
- Special consideration for the risk of introduced pollinators in greenhouses.

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 E.1	Olie dispersie	See Table E.1
11483 (parallel: 11547, 13363)	ADMIRE	Bayer CropScience B.V.	imidacloprid 70%	15.7-1960 g a.s./ha – see Table E.2	Water dispergeerbaar granulaat	See Table E.2

Table E.1 and E.2 show the uses of Admire O-Teq and Admire as they are currently authorised.

Table E.1: Intended uses ADMIRE O-TEQ

Uses	Field / Glass-house	Dose a.s. (kg 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*);	F	Young crop 0.07 Adult crop	2	7-14 days	April-July;

met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;		0.105			
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 aphid (*Aphis fabae*), greenhouse whitefly (*Trialeurodes vaporariorum*)	G	0.084	2	7-10 days	Jan-Dec
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*);	F	0.084	2	7-10 days	Jan-Dec;

met dien verstande dat toepassing alleen is toegestaan voor de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei					
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 van de eerste bloemknoppen alsmede na de bloei	F	0.084	1	-	April-May,
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 E.2 Toepassingsoverzicht ADMIRE (*in Dutch*)

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-bollenteelt en bolbloementeelt)	dompelbehandeling, met dien verstande dat bloei moet worden voorkomen;	F	0,3360	1	0	sep-okt
bloemisterijgewassen overige (grondteelten)	gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan voor de bloei tot het zichtbaar	G	0,0700	2	7	jan-dec

Toepassing	Bijzonderheden	Field / Glass-house	Dosering w.s. [kg/ha]	Freq.	Interval [dag]	Tijdstip
	worden van de eerste bloemknoppen alsmede na de bloei					
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

For the spray uses, the first tier risk assessment for bees for direct exposure 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	Application	LD_{50}	HQ

glasshouse)	rate a.s. [g/ha]	[µg/bee]	(trigger 50) [Application 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 HQ is above 50, there is a potential high in-field risk for bees for all spray uses.

1a) Glasshouse uses
Part of the proposed 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 direct 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.*

Introduced pollinators in greenhouses should be considered specifically. If pollinators are affected, this can harm crop production. Note that for the soil treatments in the glasshouse, no direct exposure is expected but a residual effect may occur.
As highlighted in the EFSA conclusion, information to determine an appropiate waiting period in glasshouses for introduction of bees and bumblebees was not available at the time of the EU review. The applicant has now presented a statement regarding the appropiate waiting period:

"*Imidacloprid is used in/on various crops grown under protection in The Netherlands since many years (>10). These uses include spray and soil applications in/on plants not depending on pollination by bees (e.g. floriculture) and crops where particularly bumble bees are used as pollinators to increase and stabilize fruit production (e.g. solanaceous crops). These uses include imidacloprid soil applications to cucurbits of up to and including 141 g a.s./ha and solanaceous crops with soil applications of up to and including 235 g a.s./ha.*

In two crop pollination studies under confined conditions, considering imidacloprid soil drip/drench applications of up to 300 g a.s./ha (Doc. No.: M-030167-01-1;) and 267 g a.s./ha (Doc. No.: M-304435-01-2), it was concluded that the use of imidacloprid does not impair the pollination efficacy of confined bumble bees (for details of the studies see chapter 2.5).

Moreover, Bayer CropScience is not aware of complaints or claims of damages by vegetable growers who use both, imidacloprid for aphid and whitefly control and bumble bees for crop pollination. As such, due to several years of coexistence between imidacloprid uses in greenhouses and pollination services provided mainly by bumble bees, Bayer CropScience does not see the imminent need to define on short notice waiting periods in greenhouses to protect pollinators. Nonetheless, in light of the current discussions with Ctgb, Bayer CropScience will propose appropriate waiting periods for the entry of pollinators for those uses, where this is in line with common practice (i.e. tomato and bell pepper)."

One of the documents referred to, Doc. No.: M-030167-01-1, is a greenhouse trial by Bielza et al. (2000) which is included in the DAR (see LoE, section *Field or semi-field tests, other studies)*. According to the summary in the DAR, in this trial in SE Spain, no adverse effects on pollination (percentages of flowers pollinated, aborted, closed/non-marked and marked, as well as bumblebee flight frequencies) were detected after soil-application of 150 g imidacloprid/ha on flowering tomato.

The second document, Doc. No.: M-304435-01-2, Vacante (1997) was not included in the DAR but it was submitted to Ctgb for this assessment. In this greenhouse trial in Italy, the bumblebees were introduced to the tomato plants 7 days after treatment (soil-application of 178 or 267 g imidacloprid/ha) and no adverse on pollination were detected.
However, these studies were performed in Southern-European countries in which the environmental circumstances are different from the Netherlands and are therefore considered to be less relevant.

The applicant proposes a two-month waiting period for tomato and bell pepper. For the other crops in greenhouses in which pollinators may be used (courgette, gherkin, aubergine and pepper), no waiting period is necessary according to the applicant based on experience in practice.

However, consultation with pollinator-producing companies Koppert and Biobest and with IPM consultancy IPM Impact showed that side-effects on pollinators from imidacloprid may occur and the appropiate waiting period will depend on many variables such as the crop, the method of application (foliar spray/soil/substrate), the weather (temperature, sunlight), the crop stage *etc.*, and may vary from 14 days to 10 weeks to even longer. Therefore, it is not possible to give specific advice on the label about a waiting period. A generic warning should be indicated on the label:

> *Let op: dit middel kan schadelijk zijn voor bestuivers in kasteelten. Raadpleeg uw leverancier van bestuivers over het gebruik van dit middel in combinatie met het gebruik van bestuivers en over de in acht te nemen wachttijden.*

With this addition to the Statutory Instructions for Use, the risk to introduced pollinators in greenhouses is acceptable.

1b) Field uses
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.*

With this addition to the Statutory Instructions for Use, the risk is acceptable.

Conclusion In-field risk
In conclusion, to avoid the risk from direct exposure to bees and to highlight the possible risks to introduced pollinators in greenhouses, the following sentences must be included in the Statutory Instructions for Use:

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

Let op: dit middel kan schadelijk zijn voor bestuivers in kasteelten. Raadpleeg uw leverancier van bestuivers over het gebruik van dit middel in combinatie met het gebruik van bestuivers en over de in acht te nemen wachttijden.

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]**	**[Exposure/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	6.3%	5.6	0.0037	**1521**	50

Table E.4 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 do not protect bees in 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). Cage study q in the LoE shows that at 21-35 g a.s./ha, there were effects on mortality (twice as high as in the control). 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, risk to bees is acceptable from exposure in the off-field area for all uses of Admire and Admire O-Teq.

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 metabolite. Also, the risk via honeydew from aphids must be assessed.

The EPPO scheme (EPPO 2010) indicates that when risks from systemic substances can be expected based on acute toxicity of the substance, toxicity after longer-term exposure should be considered. Data on this are available and will be discussed below.

1) Nectar and pollen of the crop

1a) Foliar spray uses

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. If the substance ends up in nectar and pollen, this may lead to a risk from flowering crops. As stated in the EFSA conclusion, imidacloprid is preferentially translocated to leaves and shoots and to a much lower extent to the reproductive organs. 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 after seed treatments).

The applicant now presented a statement to address the risks to bees of translocation of imidacloprid and metabolites to flowering organs after spraying.

"*All outdoor foliar uses of imidacloprid in The Netherlands in flowering plants exclude the flowering period. As such, honey bees are not exposed to residues of imidacloprid in blossoms of (potentially) bee attractive target plants. This conclusion is also valid for the post-flowering uses. With regard to pre-flowering applications, the questions was asked whether there is a potential risk for foraging honey bees later on in the season when the (potentially) bee attractive flowering plant was sprayed before flowering. Bayer CropScience specifies the latest pre-flowering growth stage to be sprayed in floriculture for imidacloprid containing products – e.g. in recently submitted dossiers for Imidacloprid SC 350 – to be BBCH 49 (i.e. end of vegetative propagation, before inflorescence emergence [BBCH 50-59] and before beginning of flowering [BBCH 60]).*

Bayer CropScience has investigated the potential impacts of pre-flowering applications in a highly bee attractive crop. i.e. in flowering apple orchards. In total, five independent studies have been conducted:

- *One study in Germany, 1 × 105 g a.s./ha, application 24 days before exposure of honey bee colonies (Doc.-No.: M-084030-01-1* [Ctgb: this is Schur 2001, field study m from the LoE]*).*
- *Four studies in Italy, 1 × 120 - 1 × 160 g a.s./ha, 15 - 20 days before exposure of honey bee colonies (Doc.-No.: M-355844-01-1* [Ctgb: not previously submitted; see below] *and M-064758-02-1* [Ctgb: this is Cantoni et al 1998, field study n from LoE]*), at which in study with the highest application rate (160 g a.s./ha) there was the shortest interval to honey bee exposure (15 days, Verona, Doc.-No.: M-355844-01-1)*

In none of the studies any impact on foraging honey bees as well as on colony development has been recorded.
Moreover, the critical review of various translocation experiments after foliar application of imidacloprid (Doc.-No.: M-308631-01-1 [Ctgb: statement, not previously submitted]*) revealed that when imidacloprid is applied on leaf surfaces there is a good translocation to shoots and leaves (xylem mobility) but a poor translocation to sinks, like e.g. storage organs, roots, fruits (negligible phloem mobility). The studies investigated in Doc.-No.: M-308631-01-1 revealed a consistent distribution pattern with predominant acropetal* [towards the tips of leaves] *and only marginal basipetal* [towards the base of leaves] *transportation. The authors concluded that it is highly unlikely that a foliar application of imidacloprid will lead to any significant residues in nectar and pollen of plants treated in the pre-flowering stage. This conclusion is supported by the 5 studies conducted in highly bee attractive apple orchards. Moreover, it needs to be considered that the half live of total imidacloprid residues on plant surfaces is very low (< 1 up to max. 2.6 days; see DAR of imidacloprid).*

As concluded above, spraying on flowering crops is not allowed.

The following pictures illustrate the predominant acropetal and the only marginal basipetal distribution of ^{14}C-Imidacloprid by autoradiography; this predominant acropetal transport is also the reason of the empirical observations in commercial practice that new shoots are not protected from aphid infestations after imidacloprid spray applications (aphids are much more susceptible to imidacloprid than honey bees, LD_{50} = 0.54 pg/aphid; see Doc.-No.: M-110655-01-1 [Ctgb: see point 4 below]*).*

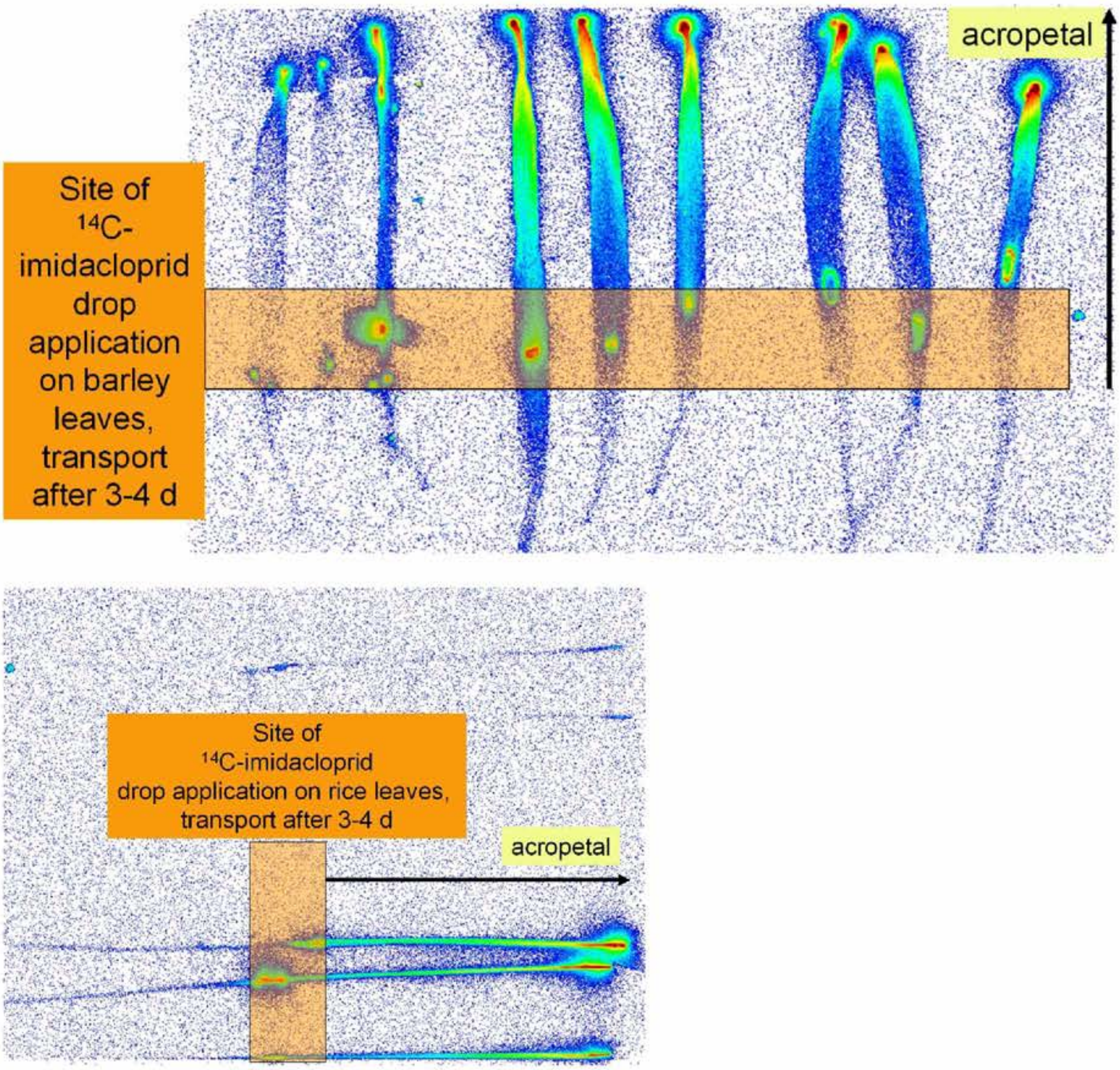

Figure 2.2.1: Illustration of the acropetal transport of imidacloprid after foliar application

Considering (i) the translocation behaviour of imidacloprid after foliar application, (ii) the short half-live of total imidacloprid residues of plant surfaces and (iii) no observable adverse effects on honey bees and honey bee colonies from a pre-flowering foliar application of up to 160 g a.s./ha, the weight of evidence suggests that pre-flowering applications of up to and including 70 g a.s./ha at the latest at BBCH 49 - still several days before onset of flowering - will not pose an unacceptable risk to honey bees. This conclusion is supported by the findings of Mayer and Lunden (1997; Doc.-No.: 110179-01-1 [Ctgb: field study I in LoE]*) who found no impact on honey bee mortality from an imidacloprid spray application of 112 g a.s./ha in an apple orchard with 10% open bloom and with on average 6 flowering dandelions per m^2 understorey.*

Regarding potential impacts of imidacloprid residues on hibernation, Faucon et al. (2005; Doc.-No.: 387723-01-1 [Ctgb: public literature]*) fed honey bee colonies during summer repeatedly with sugar syrup, fortified with 0.5 and 5 µg/L imidacloprid. The authors have not observed* *elevated acute mortality, or sub-lethal or delayed effects, or effects on brood, colony development or finally overwintering mortality. A systematic investigation of Aubert et al. (2008; Doc.-No.: 400335-01-1* [Ctgb: public literature]*), who investigated the effect of microbial and parasitic agents and pesticide residues on the evolution of domestic bee colonies under natural conditions revealed that the only parameters for which a statistically significant relationship to the mortality of the colonies could be found were the level of attention paid by the apiarist to preventive measures and the early detection and identification of Varroa disease. This conclusion is in line with the recent publication of the German Bee Monitoring (Genersch et al., 2010; Doc.-No.: M-408279-01-1 1* [Ctgb: public literature]*) - which has been systemically scrutinizing impacts on up to 1200 honey bee colonies in Germany for many years - where it was concluded that no correlation between plant protection products and overwintering losses have been found and that the principal factor of overwintering losses is an insufficient or improper Varroa control.*

Considering all the available information and applying the weight-of-evidence principle, it can be concluded with reasonable certainty that honey bee colonies and bee keeping practices will not be impaired from pre-flowering foliar applications in apple orchards when sprayed at the latest at the mouse ear stage or from pre-flowering foliar applications in flowering ornamentals (for flowering ornamentals, Bayer CropScience fixed the timing of application to BBCH 10 – 49 [end of vegetative propagation] and from BBCH 69 [end of flowering] onwards). However, for flowerbulbs and bulbflowers, spraying before the first flower buds are visible, is not a realistic option. As such, we propose to restrict the use in flowerbulbs and bulbflowers to post-flowering."

<u>Response Ctgb:</u>
The argumentation on the translocation behaviour of imidacloprid after spraying was discussed with a residue expert and accepted. Also, the short-half life of imidacloprid on leaves will reduce the possible exposure. Therefore it is likely that the residues in flowering organs from uptake after foliar spray will be very low as long as application on flowers is avoided. The risk will be considered further for the different uses.

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

Considering effects of longer-term exposure, laboratory studies are available for imidacloprid which provide NOEC values for chronic mortality and behavioural effects. The 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 are lacking, so these NOEC values cannot be compared directly to residue data for the spray uses. Therefore, effects seen in the field studies will be considered.
In the spray field studies, colony effects were monitored for a period of at most a couple of weeks. However, overwintering was studied in the Faucon study (field study j in LoE). In this study, bee colonies were fed with treated sirop (0.5 or 5 ppb) three times per week for one month during summer. This study shows that long-term effects of imidacloprid at concentrations of up to 5 ppb are not expected. The other two publications mentioned by the applicant (Aubert *et al.* and Genersch *et al.*) confirm this finding. Public literature will be discussed at the end of this evaluation report.

In conclusion, for apple and pear effects on honeybees are expected to be acceptable based on i) the low translocation to flowering organs after spray application, ii) the absence of adverse effects after foraging on orchards treated according to GAP, tested for several weeks and iii) the absence of adverse effects in the long-term, including overwintering succes, after realistic worst-case exposure. Application should be restricted to before flowering (up to the mouse-ear stage) and after flowering, as already indicated on the label (only relevant use shown):

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel:

in de teelt van appels en peren door middel van een gewasbehandeling met een maximum aantal behandelingen van totaal twee keer per seizoen, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;

Flowering ornamentals
The applicant proposes to restrict the use in flowering ornamentals to before flowering (up to BBCH 49) and after flowering (from BBCH 69).
It has not been studied whether the distribution of residues to flowers after spraying for the field uses in flowering ornamentals is comparable to that in apple. The time between application and flowering may be shorter for these uses than has been tested in orchards (the time between the mouse-ear stage and full flowering is about 3-4 weeks). The applicant refers to the study of Mayer and Lunden and most specifically to the presence of flowering dandelions during spraying to conclude that the risk from flowering ornamentals will be low. However, this study only tested the adverse effects for a short time after spraying: on foraging activity only on the day of spraying, for mortality only until two days after spraying. Effects on the colony were checked only five days after spraying. Furthermore, this study should be considered as additional information only since the raw data are not reported.
However, based on the studies in orchards and the translocation behaviour in the plant of the a.s. after spraying (see above), the substance will not occur in flowers when the flower buds have not been sprayed. Therefore, spraying in flowering ornamentals is only allowed before flower buds are visible and after flowering. The Statutory Instructions for Use should state (only relevant uses included):

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel:

In de onbedekte teelt van bloemisterijgewassen door middel van een gewasbehandeling, met dien verstande dat toepassing alleen is toegestaan vóór de bloemknoppen zichtbaar zijn alsmede na de bloei;
in de onbedekte teelt van en ten behoeve van de teelt van bloembol-, knol-, knolbloem- en bolbloemgewassen door middel van een gewasbehandeling, met dien verstande dat de toepassing uitsluitend plaatsvindt vóór de bloemknoppen zichtbaar zijn alsmede na de bloei of na het koppen

in de onbedekte teelt van boomkwekerijgewassen en vaste planten door middel van een gewasbehandeling, met dien verstande dat in gewassen die in bloei kunnen komen toepassing alleen is toegestaan vóór de bloemknoppen zichtbaar zijn alsmede na de bloei.

1b) Dipping applications

Dipping applications in bulbs are currently allowed both in field and protected use and both for bulb and flower production (in Dutch, *bloembol- en bloemknolgewassen* are for bulb production, *bolbloem- en knolbloemgewassen* are for flower production).

There are no measurements of residues in flowering organs of ornamental bulbs after dipping application. The uptake mechanism in the plant after bulb treatment is expected to be more comparable to seed treatment than to foliar spray. Seed treatment dose rates of imidacloprid are in the range of 0.9-1.2 mg/seed. As reported in the EFSA conclusion, at this dose rate, residues in nectar and pollen of the crops are expected to be at an acceptable level for bees.
The dose per bulb is not reported, as bulbs are usually planted per kg, not per number. The dose per bulb will depend on the planting density, which varies with crop and cultivar. The applicant has indicated that for tulips, the density is ca. 150 / m2, which, based on a dose rate of 200-210 g/ha, would lead to a dose per bulb of 0.13-0.14 mg/bulb. This indicates that the amount of a.s. per tulip bulb would be lower than per seed. Data are currently lacking to determine the relevant range of planting density for all different bulb crops.
It is not known if the uptake and dilution mechanism of the a.s. is indeed comparable between bulb and seed treatment. For bulbs, the growing period may be shorter, which would mean that during bulb development the amount of a.s. lost by dissipation will be lower than during seed development. Also, dilution by growth is expected to be lower for bulbs than for seed treatment.
Based on the above, it is not possible to conclude that the concentration in nectar and pollen of bulbs which have been dip treated will be at an acceptable level for bees. Thus, the risk is only acceptable when exposure can be excluded, as is already indicated on the label.

Exposure will depend on attractivity ánd on whether the bulbs will flower on the field.

A list is currently under development by PPO bollen and Bijen@WUR indicating the possibility of exposure for the different ornamental bulbs.

For none of the ornamental bulbs, it can be said with certainty that bees or bumblebees will not forage on the flowers. Even where flowers are not very attractive, bees may fly on them in situations where other forage is scarce. Therefore, there is potential exposure from all bulb crops.

The label currently states that *flowering has to be avoided* for bulbs in the field which have had a dip treatment. 'Bulbs' comprises a large range of crops. For all flower crops belonging to the 'bulb' category it was investigated whether it is possible in practice to avoid flowering (in consultation with nVWA and bulb experts).

For Hyacinth, Crocus and Narcis, flowers are never removed (not for bulb production nor for flower production) and exposure on the field to these flowers can therefore not be excluded. For the broad category of 'bijgoed', the same conclusion holds.
For Tulip bulb production, flowers will be removed some time after flowering so exposure cannot be excluded. For Dahlia, Lily and Gladiolus bulb production, in practice it is difficult to remove flowers and exposure cannot be excluded. When these bulbs are grown for flower production, flowering may occur on the field (at least for a short period, until the flowers are harvested to be sold).

For Allium, Hippeastrum (Amaryllis) and Iris, flowers are removed before flowering when the bulbs are grown for bulb production. However, when bulbs are grown for flower production, flowering may occur on the field (at least for a short period, until the flowers are harvested to be sold).

Thus, for bulbs growing outdoors, exposure can only be excluded for bulb production of Allium, Hippeastrum and Iris.

The Statutory Instructions for Use need not be revised as they already state (only bulb dipping uses included):

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel:

> ***in de bedekte teelt van en ten behoeve van de teelt van bloembol-, -knol, knolbloem- en bolbloemgewassen door middel van een dompelbehandeling, waarbij niet meer dompelvloeistof wordt gebruikt dan in de gebruiksaanwijzing is aangegeven,***
> ***in de onbedekte teelt van en ten behoeve van de teelt van bloembol-, -knol, knolbloem en bolbloemgewassen door middel van een dompelbehandeling, met dien verstande dat bloei moet worden voorkomen en niet meer dompelvloeistof wordt gebruikt dan in de gebruiksaanwijzing is aangegeven;***

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.
In fruit orchards and semi-permanent tree nursery, flowering weeds can be expected in some amount. 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, but it must be further considered for orchards.

The risk of flowering weeds 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 of the apple trees (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 most studies (no specific attention was given to the presence or absence of flowering weeds). Only in field study I in the LoE flowering dandelions were included in the study protocol. The applicant considers that "*the findings of [this study I] who applied imidacloprid at 112 g a.s./ha in an apple orchard with 10% open bloom and additionally with on average 6 flowering dandelions per m^2 understorey with no impact on honey bee mortality suggest that the relevance of emerging flowering and bee attractive weeds in the orchard understorey soon after an imidacloprid application in terms of associated risks for honey bees is acceptable. Nonetheless, in light of the recent discussion with Ctgb on this subject, Bayer CropScience suggests to state on the label that the understorey has to be cut in any case before applying imidacloprid to orchards and tree nursery crops and that potential weeds in the understorey have to be managed to prevent them from flowering for two weeks after application (e.g. by frequent mowing which is common practice for most growers anyway).*"

Ctgb agrees that the risk from flowering weeds will be sufficiently reduced when the understorey is mowed for at least two weeks after application. The following sentence will be added to the bee restriction sentence:

Na een spuittoepassing percelen nog minimaal twee weken vrijhouden van bloeiende

onkruiden.

3) Nectar and pollen in succeeding crops

Imidacloprid is persistent in soil (laboratory DT50,soil values from EFSA conclusion, normalised to FOCUS reference conditions: 99-129 days) 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

According to the DAR, 2 ppb is expected to be a safe concentration to bees, based on the NOEC of 20 ppb.

Now, the risk to adult bees foraging on nectar or pollen can also be estimated by using the daily intake data from Rortais et al. (2005), as indicated in EPPO 2010. This article presents the the daily food intake for different bee categories.

According to Rortais *et al.*, nurse bees are expected to consume the highest amount of pollen of all categories of bees: 65 mg/bee in 10 days, so 6.5 mg/d. The estimated highest residue value in pollen of 2 µg/kg leads to an possible intake of imidacloprid by nurse bees of (6.5 mg*2 pg/mg=) 0.013 ng/bee/day. This value can be compared to the acute LD50 for adult bees of 3.7

ng/bee/d, which leads to a TER of 285, indicating a low risk (the trigger is 10, according to EPPO 2010, so there is still a large margin of safety).
The worst-case exposure is expected for nectar foragers, which consume the highest amount of nectar of all categories of bees: 224-899 mg sugar/bee in 7 days, which translates into a level of 32 – 128 mg sugar/bee/day. How much nectar or honey intake is needed to reach this sugar intake, depends on the crop and environmental conditions. Rortais et al. give the example of sunflower: when a honeybee requires 1 mg of sugar, it will have to consume either 2.5 mg of fresh sunflower nectar or 1.25 mg of sunflower honey. Thus, a bee would need 80-321 mg sunflower nectar/day or 40-160 mg sunflower honey/day.
Taking therefore the residue level in nectar of a succeeding crop as 2 µg/kg, as explained above, the exposure can be calculated as 2 ng/g * (0.080 to 0.321 g/bee/day) = 0.16 to 0.642 ng/bee/day (taking the example of sunflower nectar). This value compared to the acute LD50 for adult bees of 3.7 ng/bee/day leads to a TER of 23 to 5.8. This shows that based on worst-case assumptions (highest nectar intake), the TER is (slightly) below 10, which is the trigger suggested by EPPO 2010 to cover chronic exposure. Based on the lowest value for nectar intake, no risk is indicated.
These calculations assume that all food that is taken in, is contaminated with imidacloprid, which is worst case. There is some uncertainty related to the fact that the calculations are based on sunflower nectar, while other flower species may have a lower sugar content and thus might lead to higher exposure. However, the example used is that given in the EPPO scheme 2010 as an adequate estimate.

This calculation of daily intake confirms the conclusion in the DAR that 2 ppb can be seen as a safe concentration to honeybees.

As said above, imidacloprid residues in nectar and pollen from succeeding crops are not expected to be higher than 2 ppb when these succeeding crops are sown in soils containing 13-25 µg a.s./kg soil.

Therefore, 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	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)	Required waiting period for succeeding crops which are foraged on by bees
Apples and pears	0.105	2/7	0.2	0.055	<0 d	0 d
Floriculture (field), before flowering	0.084	2/7	0.8	0.177	162 d	6 months
Floriculture (field), after flowering	0.084	2/7	0.5[1]	0.111	28 d	1 month
Flowerbulbs and bulbflowers,	0.07	1[2]/-	0.8	0.093	0 d	0 d

(field), before flowering						
Flowerbulbs and bulbflowers, (field), after flowering	0.07	3/7	0.4[3]	0.109	24 d	1 month
Flowerbulbs and bulbflowers (dipping)	0.210	1/-	1	0.280	290 d	10 months
Tree nursery and perennial (field), before flowering	0.084	2/7	0.8	0.177	162 d	6 months
Tree nursery and perennial (field), after flowering	0.084	2/7	0.5[4]	0.111	28 d	1 month
Chicory (spray treatment in seed drill)	0.0875	1/-	1	0.117	45 d	2 months

[1] Based on onion scenario (considered to be worst case; no scenario for floriculture is available).
[2] Before flowering, only one application will take place (this will be indicated on the label and is the realistic situation in practice)
[3] No scenario for bulbs is available, but an interception of 60% is considered realistic worst case based on the high density of flowerbulbs, comparison with vegetable crops and beets, and literature data on interception of flower bulbs.
[4] Based on conservative estimate (no scenario for tree nursery is available)

The above Table shows that for apple and pear and for the one-fold foliar spray in flower bulbs before flowering, the *initial* concentration is already below the acceptable level, so a waiting period is not necessary. 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 was 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. They provided the following statement:

"*Carry-over of soil residues and subsequent uptake by succeeding, bee-attractive flowering crops has been investigated in a range of studies. The maximum residues in bee relevant matrices like nectar and pollen that has been found was 2 µg imidacloprid/kg, originating from a soil-borne imidacloprid residue levels ranging from 13 - 25 µg imidacloprid/kg soil. Ctgb has now calculated on the basis of the max. non-normalised field DT_{50} of imidacloprid and the initial PEC_{SOIL} after soil or foliar use of imidacloprid the time period until when the soil borne residue level has declined in the upper 20 cm to 25 µg imidacloprid/kg soil. The calculated time period for all imidacloprid used in The Netherlands is < 1 year (max. ≈10 months), i.e. whatever the field use of imidacloprid in The Netherlands, a bee attractive flowering crop can be sown on a field which received its last imidacloprid application about 1 year before. Studies on the time dependent sorption of imidacloprid in mineral soils with an organic carbon content of 0.9 and 1.8% showed a constant increase of the K_{OC}-value of imidacloprid over time with increase*

factors of 3.2 and 3.8 after 100 days (Doc. No.: M-023945-01-) which translates into a steadily decreasing bioavailability of soil borne imidacloprid.
However, ***there are to date no studies with higher than 25 µg/kg soil residues available to experimentally prove that bee attractive crops can be planted with a shorter time interval than 10 months after the last imidacloprid application. Therefore, Bayer CropScience proposes to adjust the label with waiting periods before planting a bee attractive flowering crop that are in line with the suggestions made by Ctgb in their draft evaluation"****.*

In accordance with Table E.6, the required waiting periods should be prescribed on the label. See the attached revised WG/GA. With these restrictions, the risk from succeeding crops is acceptable.
The risks to bees in a crop failure scenario were not considered relevant, because crop failure almost never occurs in the crops in which Admire and Admire O-Teq are used.

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).
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.
Thus, a waiting period of 6 months is required before bee-attractive succeeding crops can be planted. This would also cover the risks to bees in crop failure scenario's (note that crop failure is not considered relevant for the proposed crops).
Since the authorisation of Admire ends at 01/08/2011, a new label proposal was not submitted by the applicant. The need for a label change will be discussed.

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).
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)**
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.**

Direct exposure
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.

Indirect exposure
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 metabolite. Also, the risk via honeydew from aphids must be assessed.

The EPPO scheme (2010) indicates that when risks from systemic substances can be expected based on acute toxicity of the substance, toxicity after longer-term exposure should be considered. Data on this are available and will be discussed below.

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 hardly fly on potato flowers. Hence, the risk from this route of exposure is low for honeybees. However, bumblebees may fly on potato flowers to collect pollen. Imidacloprid is acutely not more toxic for bumblebees than for honeybees. However, it is difficult to estimate the potential risk with the available honeybee studies, 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 was

requested to address the effects of imidacloprid to bumblebees from the soil treatment in potatoes.

The following statement was provided:
"Solanaceous crops are known to be a non-attractive feeding source for honey bees. Solanaceous crops do not provide nectar and release pollen only after the flowers are sonicated. Sonication is not performed by honey bees but bumble bees may obtain pollen from sonicated solanaceous crop-flowers. In The Netherlands, imidacloprid is used in potatoes after soil application of up to and including 175 g a.s./ha. No studies have been conducted specifically in potatoes after imidacloprid soil applications, but two studies are available where imidacloprid has been soil-applied in tomatoes – an other solanaceous crop. In one crop pollination study by the University of Cartagena in greenhouses in Spain (Doc. No.: M-030167-01-1), tomato plants received a soil drip/drench application corresponding to 10 mg a.s./plant (4 applications in a ten days interval, starting 4 days after the bumble bee colonies were introduced into the greenhouse). The plant density under investigation ranged from 1.5 - 3 plants/m^2 which corresponds to 15 - 30,000 plants/ha and in turn to 150 - 300 g a.s./ha. Bumble bees were used as crop pollinators. The authors concluded that there were no differences between control and the treatments and that the crop has been effectively pollinated by the foraging bumble bees. In a second study conducted by the department of plant protection of the University of Tuscia in Viterbo in Italy (Doc. No.: M-304435-01-2), tomato plants received a soil drip application of imidacloprid corresponding to 178 and 267 g a.s./ha. Bumble bee colonies were introduced into gauze netting enclosures 7 days after drip application. The author concluded that 7 days after drip application of imidacloprid to tomato plants bumble bee forage and pollinate imidacloprid treated tomato plants as effectively as untreated control plants.

Gels et al. 2002 (Doc. No.: M-210591-01-1) investigated the impact of imidacloprid soil applications in turf with 25 - 50% white clover coverage on bumble bees. The authors concluded that imidacloprid, when irrigated into the soil at rates corresponding to 336 g a.s./ha, cause no adverse effects on bumble bee colony vitality even when bumble bees are exposed to flowering white clover on the treated plots under confined conditions for up to 30 days. Moreover, available data on the sensitivity of bumble bees to imidacloprid as compared to honey bees show no distinct differences (DAR, imidacloprid).

Moreover, on the labels for Amigo and MonAmi, Bayer CropScience claims an efficacy against aphids for up to 8 -10 weeks. This is about the time potatoes need to develop flowers. Thus, when bumble bees are potentially exposed to potato pollen, imidacloprid levels in potato leaves are not longer sufficient to control aphids. Furthermore, considering the translocation information provided in chapter 2.2, it appears to be unlikely that the concentration in pollen will be higher than in the leaves. Moreover, it needs to be considered that there is a large difference in the imidacloprid-LD_{50} between bees and aphids (0.00000054 µg/aphid vs. 0.0037 µg/bee).

Considering (i) the findings of the two pollination studies with bumble bees in tomato plants, which received at least one soil application of imidacloprid >175 g a.s./ha with no impact on the pollination efficacy, which can be considered as an indirect parameter of the health status of the individual foraging bumble bees as well as the associated bumble bee colonies, (ii) the findings of Gels et al., where bumble bees were confined on plots with flowering white clover without adverse effects on colony vitality parameters after a soil application of 336 g a.s./ha, and (iii) the fact that aphids, which are much more sensitive than bees, are no longer controlled at the time of potato flowering, it is highly unlikely that an imidacloprid soil application to potatoes at the day of potato planting will pose an unacceptable risk to foraging bumble bees at the time of potato flowering, which occurs several weeks after planting."

Response Ctgb:

One of the documents referred to, Doc. No.: M-030167-01-1, is a greenhouse trial by Bielza et al. (2000) which is included in the DAR. According to the summary in the DAR, in this trial in SE Spain, no adverse on pollination (percentages of flowers pollinated, aborted, closed/non-marked and marked, as well as bumblebee flight frequencies) were detected after soil-application of 150 g imidacloprid/ha (0.75 L Confidor 200 LS/ha, according to the DAR).
The second document, Doc. No.: M-304435-01-2, Vacante (1997) was not included in the DAR but it was submitted to Ctgb for this assessment. In this greenhouse trial in Italy, the bumblebees were introduced to the tomato plants 7 days after treatment (soil-application of 178 or 267 g imidacloprid/ha) and no adverse effects on pollination were detected.
In the study by Gels et al. (2002) from the public literature, bumblebee colonies were caged for about one month on flowering white clover which had been soil-treated with granular imidacloprid and then irrigated. The authors did not find adverse effects on the colonies.
These studies can be used as supplemental information since the raw data are not presented in the study report. However, most important is the fact that aphids are no longer controlled at the time of potato flowering, which means that it is highly unlikely that bumblebees will at that time be adversely affected by imidacloprid in potato pollen.
In conclusion, the risk to bumblebees from the soil treatment of imidacloprid in potatoes is expected to be acceptable.

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 (8 months) it can be said with certainty that the residue level in nectar and pollen of an untreated bee-attractive crop will be at or below a level that is harmless for bees.

The applicant has agreed to a waiting period of 8 months. The label will state:

Toegestaan is uitsluitend het gebruik in de teelt van pootaardappelen, toegepast door middel van een grondbehandeling tijdens het poten, met dien verstande dat er binnen 8 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden.

With this restriction, the risk from succeeding crops is acceptable. The risks to bees in a crop failure scenario are not considered relevant for potatoes, because crop failure almost never occurs, but would be covered with the restriction sentence anyway.

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 acceptable.

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).
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 acceptable 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 grasvegetatie en graszodenteelt.**

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

Direct exposure
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 the tests were preformed with dressed seeds, in which plant uptake is optimal as compared to granules. This in combination with expected negligible presence of flowering weeds means that an risk to bees is acceptable.

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).
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.

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	Zaadcoating in suiker- en voederbieten.

					zaadbehandelin g	
11601	GAUCHO ROOD	Bayer CropScience B.V.	imidaclopri d 70%	0.120 kg a.s./ha	Water dispergeerbaar poeder voor vochtige zaadbehandelin g	Zaadcoating in mais.
12341	GAUCHO TUINBOUW	Bayer CropScience B.V.	imidaclopri d 70%	0.089-0.120 kg a.s./ha	Water dispergeerbaar poeder voor vochtige zaadbehandelin g	Zaadcoating van sla, andijvie, kolen, prei.

Direct exposure

1) In-field

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

2) Off-field

Dust 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 via this route is acceptable for the use in beets without additional measures.

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.

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 (cage study p in LoE, see risk assessment of Admire and Admire O-Teq). 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 level of dust drift is kept to a minimum.

To ensure this, and reduce exposure outside the field where flowering plants may be present as much as possible, the dust level of maize seeds should be as low as possible, deflectors should be used and sowing should not be done under windy weather conditions. Incidents with insecticide-treated 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 bee mortality after maize sowing has never been reported so far.

The following restrictions should be mentioned on the product label for maize (already prescribed since January 2010):

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.

With these restrictions, it is expected that the long-term effects on honeybee colonies after exposure to dust from maize sowing are acceptable.

<u>*Indirect exposure via systemic working mechanism*</u>
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.

The EPPO scheme (2010) indicates that when risks from systemic substances can be expected based on acute toxicity of the substance, toxicity after longer-term exposure should be considered. Data on this are available and will be discussed below.

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 or 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. It was concluded in the DAR therefore that 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.

Now, the risk to adult bees foraging on maize pollen can also be estimated by using the daily intake data from Rortais et al. (2005), as indicated in EPPO 2010. A residue level of 5 ppb will be used as exposure estimate in maize pollen. According to Rortais *et al.*, nurse bees are expected to consume the highest amount of pollen of all categories of bees: 65 mg/bee in 10 days, so 6.5 mg/d.
The estimated residue value in maize pollen of 5 µg/leads to an possible intake of imidacloprid by nurse bees of (6.5 mg*5 pg/mg=) 0.0325 ng/bee/day. This value can be compared to the acute LD50 for adult bees of 3.7 ng/bee/d, which leads to a TER of 114, indicating a low risk (the trigger is 10, according to EPPO 2010, so there is still a margin of safety). This calculation assumes that all pollen is taken from maize, which may be considered a worst case. E.g. the French Authority uses a maximum rate of 80% maize pollen in pollen intake based on an INRA survey on the collection of maize pollen by forager bees (information from the French risk assessment of Cruiser 350 dd. December 2009). Therefore, this calculation of daily intake confirms the conclusion in the DAR.

There are no long-term studies in which the effects on overwintering honeybee colonies after exposure to treated maize pollen are studied. However, one study did study effects on overwintering, but exposure was achieved by feeding the bees with a sugar solution, which can be seen as a reasonable approach to study effects via food exposure. In this study (field study j in LoE, Faucon 2004), colonies were fed for 3 times/week with sugar solution treated with 0.5 or 5 ug/kg imidacloprid. The total exposure duration was 1 month, the total observation duration was 8 months and included overwintering. No adverse effects on flight activity, mortality and brood development were seen. After the winter, treated and control colonies were of comparable status (tested parameters were brood, strength, weight and health of the colony).

It is noted that the same author published an article describing a similar experiment (Faucon *et al.* 2005). The study is discussed in more detail in the public literature section below, but the conclusion, that repeated feeding with syrup supplemented with imidacloprid did not provoke any immediate or any delayed mortality before, during or following the next winter, confirms the above.

Based on these observations, it is not expected that exposure to imidacloprid in maize pollen will cause adverse effects on honeybees, both in the short and the long term.

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.
The expected residue level will be at least a factor 10 below the NOEC of 20 ppb which covers both lethal and sublethal effects. To estimate the risk in another way, the method of Rortais *et al.* can be followed, as suggested by EPPO 2010. This article presents the daily food intake for different bee categories. The worst-case exposure is expected for nectar foragers, which consume the highest amount of nectar of all categories of bees: 224-899 mg sugar/bee in 7 days, which translates into a level of 32 – 128 mg sugar/bee/day. How much nectar or honey intake is needed to reach this sugar intake, depends on the crop and environmental conditions. Rortais et al. give the example of sunflower: when a honeybee requires 1 mg of sugar, it will have to consume either 2.5 mg of fresh sunflower nectar or 1.25 mg of sunflower honey. Thus, a bee would need 80-321 mg sunflower nectar/day or 40-160 mg sunflower honey/day.
As said above, according to the DAR residues in nectar and pollen in succeeding crops are not expected to exceed a residue concentration of 2 ppb. Taking therefore the residue level in nectar of a succeeding crop as 2 µg/kg, as explained above, the exposure can be calculated as 2 ng/g * (0.080 to 0.321 g/bee/day) = 0.16 to 0.642 ng/bee/day. This value compared to the acute LD50 for adult bees of 3.7 ng/bee/day leads to a TER of 23 to 5.8. This shows that based on worst-case assumptions (highest nectar intake), the TER is (slightly) below 10, which is the trigger suggested by EPPO 2010 to cover chronic exposure. Based on the lowest value for nectar intake, no risk is indicated. Furthermore, these calculations assume that all food that is taken in, is contaminated with (the highest residue value expected of) imidacloprid.
Thus, the risk via untreated succeeding crops is expected to be low.

However, residues in imidacloprid-treated succeeding crops may be higher, since theoretically, accumulation in soil may cause increase in residue levels after several years of imidacloprid use and this might lead to increased residue levels in nectar and/or pollen. The applicant was requested to address this issue and they provided the following statement:

"As indicated in chapter 2.4 above, studies on the time dependent sorption of imidacloprid in mineral soils with an organic carbon content of 0.9 and 1.8% showed a constant increase of the K_{OC}-value of imidacloprid over time with increase factors of 3.2 and 3.8 after 100 days (Doc. No.: M-023945-01-1) which translates into a steadily decreasing bioavailability of soil borne imidacloprid over time. A study with the neonicotinoid compound clothianidin in maize (Doc.-No.: M-256474-01-1 [Ctgb:) revealed no, or at best a non-significant marginal increase in the clothianidin residue level in maize pollen if seed-treated maize seeds are sown during springtime in clothianidin-treated soil compared to residue-free soil. In this study it needs to be considered that the soil was treated with clothianidin shortly before sowing, i.e. residues did not age in the soil matrix as typical for a "grown" soil background concentration. Therefore, the established soil background concentration of clothianidin in this study can be expected to be (nearly) fully bio-available due to the short aging period of only 55 and 42 days (see also chapter 3.3, below).

The findings and the conclusion made for the neonicotinoid compound clothianidin in maize (Doc.-No.: M-256474-01-1) are further supported by the findings in studies with imidacloprid, where either imidacloprid-seed-treated sunflowers, spring-OSR (oil seed rape) or maize was planted either in imidacloprid-treated (Doc. No.: M-016820-01-1, M-016827-01-1, M-016828-02-1, M-016830-01-1, M-016836-01-1 and M-016842-02-1) or in imidacloprid-free soil (e.g. Doc. No.: M-006815-01-1, M-006811-01-1, M-040023-01-1, M-018436-01-1, M-075630-01-1, M-052637-01-1 and M-052238-01-1; further reports can be found in the DAR of imidacloprid).

When comparing the results of these studies, it can be concluded that there is, if any, only a non-significant marginal increase in the imidacloprid residue level in pollen and nectar of imidacloprid-seed-treated crops when grown in imidacloprid-treated soil as compared to imidacloprid-seed-treated crops grown in imidacloprid-free soil.

Since (i) the comparison of a range of studies where imidacloprid-seed-treated crops were grown either in imidacloprid-treated or imidacloprid-free soil revealed, if any, only a non-significant marginal increase of the imidacloprid residue levels in bee relevant matrices, (ii) in none of all these studies any adverse effects on foraging honey bees have been observed when honey bee colonies were confined on flowering spring-OSR and sunflowers, grown from imidacloprid-treated seeds in imidacloprid-treated soil (Doc. No.: M-016820-01-1, M-016827-01-1, M-016828-02-1 and M-016842-02-1) or when honey bees were confined on flowering crops, grown from imidacloprid-treated seeds in imidacloprid-free soil, (iii) the measured imidacloprid residue levels in nectar and pollen were in any case and in every investigated crop - with and without an imidacloprid background concentration in soil - below the field-relevant NOEC of imidacloprid for honey bees (i.e. 20 µg imidacloprid/kg food matrix; Doc. No.: M-016832-01-1 and M-016845-01-1), (iv) also the study with clothianidin with fresh clothianidin residues showed no or only a marginal increase of residue levels in bee relevant matrices (max. 0.1 µg/kg; Doc.-No.: M-256474-01-1) and because (v) aged imidacloprid residues can be expected to be much less bio-available in terms of root uptake by succeeding crops than fresh imidacloprid soil residues (Doc. No.: M-023945-01-1), ***it can be concluded that imidacloprid-seed-treated crops grown in soils with an imidacloprid background concentration as a succeeding crop will not pose an unacceptable risk to honey bees and bee keeping practices****."*

Response Ctgb.
It should be noted that bioavailibility in soil is currently not taken into account in the risk assessment, because of uncertainties in extrapolation between different soil types and conditions, and because soil-bound residues may become available again (after an unknown period of time). Furthermore, it is not part of the current guidance on persistence.
The other parts of the argumentation can be considered.
The applicant refer in their argumentation to studies in the DAR as well as new studies. The new studies are five new trials on residues in succeeding crops, which were submitted for the active substance clothianidin (also from Bayer). They indicate that no elevated residue levels will occur in nectar or pollen after clothianidin application as seed treatment during several years, no matter whether the succeeding crops themselves are treated or non-treated. The residue studies with imidacloprid which are available in the DAR of imidacloprid, indicate the same. Furthermore, imidacloprid is less persistent than clothianidin.

As said above, 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 (see discussion above, field spray uses of Admire O-Teq and Admire). The applicant argues that there would be also no risk from treated succeeding crops, based on new studies with clothianidin. Until further support is submitted for the extrapolation of the clothianidin studies to imidacloprid, the required waiting period is calculated as was done for Admire and Admire O-Teq.

It has been calculated for the proposed seed treatment uses of Gaucho 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). For the use in lettuce and endive, two different calculations have been done, to account for the possibility of one and two crops per growing season. See Table E.9.

Table E.9 Number of days to reach residue <0.025 mg/kg soil (20 cm)

Use	Rate [g a.s./ha]	Frequency/ interval (days)	Fraction on soil	Residue in soil < 0.025 mg/kg after … d (20 cm soil layer)
Seed treatment in beets	91	1/-	1	55 d
Seed treatment in maize	120	1/-	1	134 d
Seed treatment in lettuce, endive, cabbages, leek	max. 120	1/-	1	134 d
Seed treatment in lettuce and endive (double crop scenario)	max. 120	2/ 90	1	287 d

For the use in sugarbeets the residue level is below 25 µg a.s./kg after 55 days (1.8 months). The cultivation period of sugarbeets is about 6 months and sugarbeets are normally grown in rotation with other arable crops in the next year. The risk for flowering succeeding crops is acceptable since in the exceptional cases that flowering crops are grown after a sugarbeet crop, the residue levels in soils are already at an acceptable level after 2 months. Therefore no restriction is necessary.

For the use in maize the residue level is below 25 µg/kg after 134 days (4.5 months). The cultivation period of maize is about 5 - 6 months and maize is normally grown in rotation with maize, other arable crops or grassland in next year. The risk for flowering succeeding crops is acceptable since in the exceptional cases that flowering crops are grown after a maize crop the residue levels in soils are already at an acceptable level after 4.5 months. Therefore no restriction is necessary.

For the use in cabbage, the residue level is below 25 µg/kg after 134 days (4.5 months). The cultivation period of cabbage is about 3 - 5 months after transplanting. The calculation is worst case since no degradation from sowing to transplanting is taken into account. Therefore no restriction is necessary.

For the single crop scenario of lettuce and endive, the residue level is below 25 µg/kg after 134 days (4.5 months) and for the double crop scenario in lettuce and endive, the residue level is below 25 µg/kg after 287 days (9.6 months). The cultivation period of lettuce is about 2 – 3 months after transplanting (1 month before transplanting). It is acknowledged that the calculations are worst case since no degradation from sowing to transplanting is taken into account, but no method for this is available. Therefore, it is considered that a restriction is necessary for the use in lettuce and endive:

> ***In verband met het risico voor bijen mogen binnen een periode van 10 maanden gerekend vanaf zaai of uitplanten op het veld geen voor bijen aantrekkelijke gewassen worden gezaaid of geplant.***

Based on the above, the risk from succeeding crops is acceptable.

The risks to bees in a crop failure scenario were also considered. Of the crops in which imidacloprid is used as seed treatment, only beets are relevant for crop failure since crop failure almost never occurs in the other crops. Furthermore, in the large majority of the cases in which crop failure occurs in beets, again beets are sown and these are not attractive to bees. Therefore, the chance that a bee-attractive crop is sown in replacement of a failed beet crop is very small in practice. The risk to bees in crop failure situations is considered to be acceptable without specific restrictions.

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 there is an acceptable risk via honeydew .

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).
Further, it is also communicated by beekeeper-organisations that beekeepers should provide their bees with sufficient water.
Taking all the available information into account there is an acceptable risk from guttation.

A.2 Non-professional uses

toelatingnr	middelnaam	toelating-	werkzame	formulering	Toepassing(en)

		houder	stoffen		
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.

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

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

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

With the restriction, the risk is acceptable.

<u>*Indirect exposure*</u>
Flowering crops and flowering weeds

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

"*Provado® Garden is authorised in The Netherlands for uses in pome fruit, ornamentals and lawns. Concerns were raised by Ctgb whether the restriction to pre-flowering applications in pome fruits, as established for the agronomic uses (i.e. BBCH 10, mouse-ear stage), will reliably be respected by non-professionals. In order to address this question, Bayer CropScience has prepared a document (*5.1.2.e *128; date: 04 MAR 2005), proposing a less and a* *more stringent wording as well as an illustration of the restriction to pre-flowering and post-flowering, i.e. when Provado® Garden can be used by non-professionals. Particularly the more stringent wording and illustration, as proposed in document* 5.1.2.e *128, is considered to enable every non-professional to identify the crop stage where application of Provado® Garden is possible, considering honey bees foraging on flowering apple or pear trees. As such, Bayer CropScience is convinced that with an appropriate label in combination with an intuitive and illustrative user manual (e.g. illustration of growth stages as proposed in document* 5.1.2.e *128 or illustration of situations where and when, respectively where and when not to apply), Provado® Garden can be used in pome fruit and ornamentals without adverse effects on honey bees. Moreover, it needs to be considered that potentially treated areas are small-scaled and as such deliver much less forage to bee colonies than e.g. commercial orchards, which require bee colonies to get hold of other pollen and nectar sources, which finally results in a dilution of potential residues at the hive level.*

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

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

When considering in addition the findings of Mayer and Lunden (1997; Doc.-No.: 110179-01-1) who applied imidacloprid at 112 g a.s./ha in an apple orchard with 10% open bloom and additionally with on average 6 flowering dandelions per m² understorey with no impact on honey bee mortality, in combination with the negligible phloem mobility of imidacloprid, ***it can be concluded that risk for bees in house gardens from the use of Provado® Garden in pome fruit, ornamentals and lawns can be effectively mitigated by appropriated label instructions."***

Response Ctgb

Residues in flowering crops
The risk via flowering crops is indeed expected to be low for the professional uses in apple, pear and grass fields.
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) or after flowering. To instruct non-professional users, the applicant has provided an instruction leaflet with pictures, indicating at which stages Provado Garden can be applied on apple and pear trees.

Considering the large variety in ornamentals, it is not practical to instruct the non-professional user with pictures on the correct application time before flower buds are visible. Therefore, these uses are restricted to post-flowering only. Thus, the label should be revised (only relevant use shown):

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel:

in siergewassen in de tuin, met dien verstande dat toepassing alleen is toegestaan na de bloei.

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

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

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

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

B. Biocides

The final LoE of imidacloprid, taken from the revised Doc I from the final revised CAR (July 2010), indicates high acute toxicity of imidacloprid to honeybees. Since the LoE is small, it is presented here and not added as an annex.

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 om op te lossen en dan op oppervlakten te smeren in dierverblijfplaatsen.
12665 (afgeleide: 13063)	QUICK BAYT	Bayer CropScience B.V.	imidacloprid 0,5%	Lokmiddel (klaar voor gebruik)	Tegen vliegen. Korrels om op te lossen en dan op oppervlakten te smeren in dierverblijfplaatsen.
13116	QUICK BAYT SPRAY	Bayer CropScience B.V.	imidacloprid 10%	Water dispergeerbaar granulaat	Tegen vliegen. Middel verspuiten op oppervlakten waar vliegen vaak zitten. Dierverblijfplaatsen en opslagplaatsen.

The risk assessment method for these products is taken from the CAR of imidacloprid (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), met een pistool binnen of buiten, in nesten of op looppaden aan te brengen.

Maxforce Quantum is a gel which is used against ants, currently 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 was requested to address this risk and they propose a label restriction which will exclude application of the gel on places accessible for bees. The Instructions for Use were adapted accordingly. With this restriction, exposure to bees can be excluded and the risk is acceptable.

B.1.3 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 Prime 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, 13124)	PIRON MIERENLOKDOOS	Bayer CropScience B.V.	imidacloprid 0,03%	Professioneel & Niet-professioneel	Lokmiddel (klaar voor gebruik)	Mierenlokdoos. Zowel buiten als binnen.
12952 (afgeleides: 13026, 12974, 13052, 12979, 12980,	BAYTHION MIERENMIDDEL N	Bayer CropScience B.V.	imidacloprid 0,0500%	Professioneel & Niet-professioneel	Granulaat	Korrels om bij mierennest te strooien. Alleen buiten.

12024)						
13280 (parallel: 13351)	VAPONA RAAMSTICKER	Sara Lee Household and Body Care NL B.V.	imidacloprid 0,4890%	Niet-professioneel	Diversen	Sticker tegen vliegen. Binnenshuis.
13369	VLIEGENSTICKER	Bayer CropScience B.V.	imidacloprid 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:
The above risk assessment, based on protected data from the applicant, indicates that the risks of the proposed uses of imidacloprid in general are acceptable, provided that restrictions are mentioned on the labels. In this section it will be considered whether studies available in the public literature domain confirm or contradict the risk assessment as shown above. A preliminary result of a public literature survey is used. The included public references are presented in Annex II.

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

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

Wu (2011) measured imidacloprid in brood combs in the USA. The substance was found in 1 of the 13 samples, at a level of 45 ppb. The combs were contaminated with many other substances. Most frequently detected were a number of miticides used by beekeepers against Varroa. Delayed development was observed in bees reared in contaminated combs in a cage set-up. However, it is difficult to correlate this effect specifically to imidacloprid because combs were contaminated with a cocktail of substances and may have contained also more pathogens than control combs. Also, this study does not include the implications for colony survival in the longer term. Therefore, this study does not contradict the above risk assessment.

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

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

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

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

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 and 1.2 ppb), respectively.
In another study in France (Chauzat et al, 2009), honeybee colony health was studied in relation to pesticide residues found in colonies. Imidacloprid metabolites were analysed in pollen, honey and honeybee samples.
The most frequent residue in pollen loads, honey, and honey bee matrices was imidacloprid or 6-chloronicotinic acid. Mean concentrations of imidacloprid residue, from those positive samples, were 1.2 µg/kg in honey bees, 0.9 µg/kg in pollen, and 0.7 µg/kg in honey. The concentration obtained for imidacloprid and 6-chloronicotinic acid in pollen loads was above the limits of detection (LOD) in 40 (75/185) and 33% (61/185) of the samples, respectively. When both were found together, the concentrations were above the LOD in 16% (30/185) of the samples. The maximum residue concentration of imidacloprid and 6-chloronicotinic acid in pollen samples was 5.7 and 9.3 µg/kg, respectively.

It is not known to which extent imidacloprid was used in the areas in which the bee samples of the studies of Chauzat et al. were taken. Apart from imidacloprid, many other pesticidal substances were found in the bee matrices.
No signficant relationship was found between the presence of pesticide residues and the abundance of brood and adults, nor between colony mortality and pesticide residues. The authors conclude that more work is needed to determine the role these residues play in affecting colony health.

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

Higes et al (2010) estimated the prevalence of honey bee colony depopulation symptoms in Spain in a random selected sample (*n* = 61) and 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.
In two other studies in Spain (Garcia-Chao et al 2010, Bernal et al. 2010), imidacloprid was not detected either.

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

In a broad survey of pesticide residues, which was conducted on samples from migratory and other beekeepers across 23 USA states, one Canadian province and several agricultural cropping systems during the 2007–08 growing seasons, Mullin et al (2010) found the following residue levels of imidacloprid: wax 2.4-13.6 ppb (detected in 1.0% of 208 samples, mean 8.0 ppb); pollen 6.2-206 ppb (detected in 2.9% of 350 samples, mean 39 ppb). They also found 98 other pesticides and metabolites in mixtures up to 214 ppm in bee pollen alone, which according to them represents a remarkably high level for toxicants in the brood and adult food of this primary pollinator. They conclude that the effects of these materials in combinations and their direct association with CCD 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. There is currently no evidence that imidacloprid or other neonicotinoid products significantly contribute to bee decline 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).

In the 'Inclusion Directive' of imidacloprid it is suggested that a monitoring programme may be required to further investigate the role that neonicotinoid substances play in bee decline. Recently, a study has been started by bijen@wur to investigate the long-term effects on honeybee colonies of chronic sublethal exposure to imidacloprid in relation to the vitality of honeybee colonies. Therefore, further monitoring is currently not required.

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 (EFSA mandate M-2011-0185). 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.

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

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

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

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

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

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

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

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

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

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

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

activity, behaviour, condition of the colonies and brood development. Exposure and observation duration: 7 days.
p) Bakker 2001. Colonies exposed to flowering Phacelia which was sprayed with 0.6 – 14 g a.s./ha during bee flight. When applied during bee flight, 0.6 g a.i./ha and 1.2 g a.i./ha of Confidor SL 200 had no effects on foraging activity and mortality of the honeybee Apis mellifera. At a rate of 2.0 g a.i./ha, 4.0 g a.i./ha and 9.0 g a.i./ha foraging activity was reduced on the day of application, but no effects on mortality were observed.
At the highest test rate (14.0 g a.i./ha) statistically significant reduction in foraging was found during the first two days, but no effects on mortality were observed. (Please note that the summary in the DAR states that mortality was significantly higher than control in dose rates 2.0-14.0 g a.s./ha; RMS Germany agrees that this has been a mistake).
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 50 or 112 g a.s./ha. Foraging bees were counted 0.5, 1 and 4 hours after spraying. Foraging activity decreased with increasing imidacloprid concentration. 4) Spraying of 112 g a.s./ha to apple orchard with 10% of apple flowers open and with on average 6 flowering dandelions per m2 understorey. Spraying was done before bee flight, at 8 am; foraging activity and mortality were checked on that same day (foraging activity between 11 and 14 h). No adverse effects.

spray treatment:

m) Schur 2001. Colonies exposed to full flowering apple orchards which had been sprayed during the mouse-ear stage (BBCH 10) at 0.105 kg a.s./L, in Germany. No effects on mortality, foraging activity, behaviour, condition of the colonies and brood development. Exposure and observation duration for 7 days (4 weeks for brood).

n) Cantoni 1998. Colonies exposed to full flowering apple orchards which had been sprayed during the mouse-ear stage (BBCH 10) at 150 g a.s./ha (based on 1500 L spray liquid/ha containing 50 mL/hL Confidor SL 200; info from report amendment dd 17/09/2009). Study performed in Italy. No adverse effects on foraging activity, colony weight, honey yield and number of returning bees. Exposure and observation duration: 11 days.

See also field study g) above.

other studies:

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

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

Further studies in greenhouse

Not included in the DAR. Submitted to Ctgb in June 2011.

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

Residues in succeeding crops

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

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

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

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

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

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

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

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

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

Dust deposition sugarbeet
Summarised/evaluated by Ctgb, May 2011

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

The 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.

Nikolakis, A., Schoening, R. 2008

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

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

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

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

Literature

Alaux C, Brunet J-L, Dussaubat C, Mondet F, Tchamitchan S, Cousin M, Brillard J, Baldy A, Belzunces LP & LeConte Y, 2010. Interactions between Nosema microspores and a neonicotinoid weaken honeybees (Apis mellifera). Environm. Microbiology 12(3),774-782.
Alaux C, F Ducloz, D Crauser & Y Le Conte 2010. Diet effects on honeybee immunocompetence. Biology Letters online doi: 10.1098/rsbl.2009.0986
Aliouane Y, Adessalam K, El Hassani AK, Gary V, Armengaud C, Lambin M, Gauthier M. 2009. Subchronic exposure of honeybees to sublethal doses of pesticides: effect on behavior. Environ Toxicol Chem 28: 113-122.
Bacandritsos N, Granato A, Budge G, Papanastasiou I, Roinioti E, Caldon M, Falcaro C, Gallina A, Mutinelli F. 2010. Sudden deaths and colony population decline in Greek honey bee colonies. Journal of Invertebrate Pathology 105:335-340.
Bailey J, Scott-Dupree C, Harris R, Tolman J, Haris B. 2005. Contact and oral toxicity to honey bees (Apis mellifera) of agents registered for use for sweet corn insect control in Ontario, Canada. Apidologie 36: 623-633.
Bernadou A, Démares F, Couret-Fauvel T, Sandoz JC, Gauthier M. 2009. Effect of fipronil on side-specific antennal tactile learning in the honeybee. J Insect Physiol: 1099-1106.
Bernal J, Garrido-Bailon E, del Nozal MJ, Gonzalez-Porto AV, Martin-Hernandez R, Diego JC, Jimenez JJ, Bernal JL, Higes M. 2010. Overview of pesticide residues in stored pollen and their potential effect on bee colony (*Apis mellifera*) losses in Spain. Journal of Economic Entomology 103:1964-1971.
Bernal J, Martin-hernadez R, Diego JC, Nozal MJ, Gozalez-Porto AV, Bernal JL & Higes M, 2011. An exposure study to assess the potential impact of fipronil in treated sunflower seeds on honey bee colony losses in Spain. Pest Manag Sci on line, DOI10.1002/ps.2188
Bonmatin JM, Moineau I, Charvet R, Fleche C, Colin ME, Bengsch ER. 2003. A LC/APCI-MS/MS method for analysis of imidacloprid in soils, in plants, and in pollens. Analytical Chemistry 75:2027-2033.
Bonmatin JM, PA Marchand, R Charvet, I Moineau, ER Bengsch & ME Colin 2005. Quantification of imidacloprid uptake in maize crops. J. Agric Food Chem 53, 5336-41
Bortolotti, L, Montanari R, Marcelino J, Medrzycki P, Maini S & Porrini C 2003. Effects of sub-lethal imidacloprid doses on the homing rate and foraging activity of honey bees. Bulletin of Insectology 56, 63-67
Brunet JL, Badiou A, Belzunces LP. 2005. In vivo metabolic fate of [C-14]-acetamiprid in six biological compartments of the honeybee, *Apis mellifera* L. Pest Management Science 61:742-748.
Charvet R, Katouzian-Safadi M, Colin ME, Marchand PA, Bonmatin JM. 2004. Systemic insecticides: New risk for pollinator insects. Annales Pharmaceutiques Francaises 62:29-35.
Chaton PF, Ravanel P, Meyran JC, Tissut M. 2001. The toxicological effects and bioaccumulation of fipronil in larvae of the mosquito *Aedes aegypti* in aqueous medium. Pesticide Biochemistry and Physiology 69:183-188.
Chauzat MP, Carpentier P, Martel AC, Bougeard S, Cougoule N, Porta P, Lachaize J, Madec F, Aubert M, Faucon JP. 2009. Influence of pesticide residues on honey bee (Hymenoptera: Apidae) colony health in France. Environmental Entomology 38:514-523.
Chauzat MP, Faucon JP, Martel AC, Lachaize J, Cougoule N, Aubert M. 2006. A survey of pesticide residues in pollen loads collected by honey bees in France. Journal of Economic Entomology 99:253-262.
Chauzat MP, Martel AC, Cougoule N, Porta P, Lachaize J, Zeggane S, Aubert M, Carpentier P, Faucon JP. 2011. An assessment of honeybee colony matrices, *Apis mellifera* (Hymenoptera Apidae) to monitor pesticide presences in continental France. Environmental Toxicology and Chemistry 30:103-111.
Chauzat, M. P., J. P. Faucon, A. C. Martel, J. Lachaize, N. Cougoule, and M. Aubert. 2006. A survey on pesticide residues in pollen loads collected by honey-bees (*Apis mellifera*) in France. J. Econ. Entomol. 99: 253-262.
Chauzat, MP, Carpentier P, Martel AM, Bougeard S, Cougoule N, Porta P, LaChaize J, Madec F, Aubert M & Faucon JP 2009. Influence of Pesticide Residues on Honey Bee (Hymenoptera: Apidae) Colony Health in France. Environ. Entomol. 38(3): 514-523

Choudhary A, Sharma DC. 2008. Dynamics of pesticide residues in nectar and pollen of mustard (*Brassica juncea* (L.) Czern.) grown in Himachal Pradesh (India). Environmental Monitoring and Assessment 144:143-150.

Comité Scientifique et Technique de l'Etude Multifactorielle des Troubles des abeilles (CST), 2003. Imidaclopride utilisé en enrobage de semences (Gaucho®) et troubles des abeilles. Rapport final. 106 pp.

Cresswell JE (1999) The influence of nectar and pollen availability on pollen transfer by individual flowers of oil-seed rape (*Brassica napus*) when pollinated by bumblebees (Bombus lapidarius). J Ecol 87:670–677

Cresswell JE. 2011. A meta-analysis of experiments testing the effects of neonicotinoid insecticide (imidacloprid) on honey bees. Ecotoxicology 20: 149-157.

Cutler GC & Scott-Dupree CD, 2007. Exposure to Clothianidin seed treated canola has no long-term impact on honey bees. J. Econ. Entomol 100, 765-772

Cutler GC, Scott-Dupree CD. 2007. Exposure to clothianidin seed-treated canola has no long-term impact on honey bees. Journal of Economic Entomology 100:765-772.

De la Rúa P., R. Jaffé, R. Dall'Olio, I. Muñoz & J. Serrano 2009. Biodiversity, conservation and current threats to European honeybees. Review. Apidologie 40, 263-284

Decourtye A & Devillers J 2010. Ecotoxicity of neonicotinoid insecticides to bees. *In:* ST Thany (ed.) "Insect nicotinic acetylcholine receptors" Landes Bioscience and Springer Science + Business media. pp. 85-95.

Decourtye A, Armengaud C, Renou M, Devillers J, Cluzeau S, Gauthier M, Pham-Delègue M-H. 2004b. Imidacloprid impairs memory and brain metabolism in the honeybee (*Apis mellifera* L.). Pestic Biochem Physiol 78: 83-92.

Decourtye A, Devillers J, Aupinel P, Brun F, Bagnis C, Fourrier J, Gauthier M. 2011. Honeybee tracking with microchips: a new methodology to measure the effects of pesticides. Ecotoxicology 20: 429-437.

Decourtye A, Devillers J, Cluzeau S et al. 2004a. Effects of imidacloprid and deltamethrin on associative learning in honeybees under semi-field and laboratory conditions. Ecotoxicol Environ Saf 57: 410-419.

Decourtye A, Devillers J, Genecque E, Le Menach K, Budzinski H, Cluzeau S, Pham-Delegue MH. 2005. Comparative sublethal toxicity of nine pesticides on olfactory learning performances of the honeybee *Apis mellifera*. Arch Environ Contam Toxicol 48: 242-250.

Decourtye A, Lacassie E, Pham-Delegue MH. 2003. Learning performances of honeybees (*Apis mellifera* L.) are differentially affected by imidacloprid according to the season. Pest Manag Sci 59: 269-278.

Decourtye A, Le Metayer M, Pottiau H, Tisseur M, Odoux JF, Pham-Delegue MH. 2001. Impairment of olfactory learning performances in the honey bee after long term ingestion of imidacloprid. Hazard of Pesticides to Bees, 113-117.

Decourtye A, Mader E, Desneux N, 2010 Landscape enhancement of floral resources for honey bees in agro-ecosystems. Apidologie 41, 264–277

Durham EW, Siegfried BD, Scharf ME. 2002. In vivo and in vitro metabolism of fipronil by larvae of the European corn borer *Ostrinia nubilalis*. Pest Management Science 58:799-804.

El Hassani AK, Dacher M, Garry V et al. 2008. Effects of sublethal doses of acetamiprid and thiamethoxam on the behavior of the honeybee (*Apis mellifera*). Arch Environ Contam Toxicol 54: 653-661.

El Hassani AK, Dacher M, Gauthier M, Armengaud C. 2005. Effects of sublethal doses of fipronil on the behavior of the honeybee (*Apis mellifera*). Pharmacol Biochem Behav 82: 30-39.

El Hassani AK, Dupuis JP, Gauthier M, Armengaud C. 2009. Glutamatergic and GABAergic effects of fipronil on olfactory learning and memory in the honeybee. Invert Neurosci 9: 91-100.

Elbert C, Erdelen C, Kuehnhold J, Nauen R, Schmidt HW, Hattori Y. 2000. Thiacloprid: a novel neonicotinoids insecticide for foliar application. Brighton Crop Protection Conference, Brighton, UK. Pest and Diseases 2(a): 21-26.

Fang Q, Huang CH, Ye GY, Yao HW, Cheng JA, Akhtar ZR. 2008. Differential fipronil susceptibility and metabolism in two rice stem borers from China. Journal of Economic Entomology 101:1415-1420.
Faucon J-P, Aurières C, Drajnudel P, Mathieu L, Ribière M, Martel A-C, Zeggane S, Chauzat M-P, Aubert MFA. 2005. Experimental study on the toxicity of imidacloprid given in syrup to honey bee (*Apis mellifera*) colonies. Pest Manag Sci 61: 111-125.
Faucon, J. P., C. Aurières, P. Drajnudel, L. Mathieu, M.Ribière, A. C. Martel, S. Zeggane, M. P. Chauzat, and M.Aubert. 2005. Experimental study on the toxicity of imidacloprid given in syrup to honey bee (*Apis mellifera*) colonies. Pest Manag. Sci. 61: 111-125
Garcia-Chao M, Jesus Agruna M, Flores Calvete G, Sakkas V, Llompart M, Dagnac T. 2010. Validation of an off line solid phase extraction liquid chromatography-tandem mass spectrometry method for the determination of systemic insecticide residues in honey and pollen samples collected in apiaries from NW Spain. Analytica Chimica Acta 672(1-2, Sp. Iss. SI).
Genersch E, 2010. Honey bee pathology: current threats to honey bees and beekeeping. Appl Microbiol Biotechnol 87, 87-97
Genersch E, Von der Ohe W, Kaatz H, Schroeder A, Otten C, Büchler R, Berg S,Ritter W, Mühlen W, Gisder S, Meixner M, Liebig G, Rosenkranz P 2010. The German bee monitoring project: a long term study to understand periodically high winter losses of honey bee colonies. Apidologie 41, 332–352
Girolami V, Mazzon L, Squartini A, Mori N, Marzaro M, Di Bernardo A, Greatti M, Giorio C, Tapparo A. 2009. Translocation of Neonicotinoid insecticides from coated seeds to seedling guttation drops: a novel way of intoxication for bees. Journal of Economic Entomology 102:1808-1815.
Guez D, Suchail S, Gauthier M, Maleszka R, Belzunces LP (2001) Contrasting effects of imidacloprid on habituation in 7- and 8-day-old honeybees (*Apis mellifera*). Neurobiol Learn Mem 76: 183-191.
Halm MP, Rortais A, Arnold G, Tasei JN, Rault S. 2006. New risk assessment approach for systemic insecticides: The case of honey bees and imidacloprid (Gaucho). Environmental Science & Technology 40:2448-2454.
Higes M, Martin-Hernandez R, Martinez-Salvador A, Garrido-Bailon E, Gonzalez-Porto AV, Meana A, Bernal JL, del Nozal MJ, Bernal J. 2010. A preliminary study of the epidemiological factors related to honey bee colony loss in Spain. Environmental Microbiology Reports 2:243-250.
Iwasa T, Motoyama N, Ambrose JT et al (2004) Mechanism for the differential toxicity of neonicotinoid insecticides in the honey bee, *Apis mellifera*. Crop Prot 23: 371-378.
Johnson RM, Ellis MD, Mullin CA & Frazier M 2010. Pesticides and honey bee toxicity – USA. Apidologie 41, 312-331
Kadar A, Faucon JP. 2006. Determination of traces of fipronil and its metabolites in pollen by liquid chromatography with electrospray ionization-tandem mass spectrometry. Journal of Agricultural and Food Chemistry 54:9741-9746.
Kluser S, Neumann P, Chauzat M-P & Pettis JS 2011. UNEP Emerging Issues: Global Honey Bee Colony Disorder and Other Threats to Insect Pollinators. www.unep.org; 12 pages
Krischik VA, Landmark AL, Heimpel GE. 2007. Soil-applied imidacloprid is translocated to nectar and kills nectar-feeding *Anagyrus pseudococci* (Girault) (Hymenoptera : Encyrtidae). Environmental Entomology 36:1238-1245.
Lambin M, Armengaud C, Raymond S, Gauthier M (2001) Imidacloprid-induced facilitation of the proboscis extension reflex habituation in the honeybee. Arch Insect Biochem Physiol 48: 129-134.
Laurent FM, Rathahao E. 2003. Distribution of [C-14]imidacloprid in sunflowers (*Helianthus annuus* L.) following seed treatment. Journal of Agricultural and Food Chemistry 51:8005-8010.
Li X, Bao C, Yang D, Zheng M, Li X, Tao S 2010. Toxicities of fipronil enantiomers to the honeybee Apis mellifera L and enantiomeric compositions of fipronil in honey plant flowers. Environ Toxicol Chem 29: 127-132.

Maini S, Medrzycki P & Porrini C, 2010. The puzzle of honey bee losses: a brief review. Bull of Insectology 63, 153-160
Maxim L & Van der Sluis JP 2007. Uncertainty: cause or effect of stakeholders' debates? Analysis of a case study: the risk for honeybees of the insecticide Gaucho®. Science of the Total Environment 376, 1-17
Mayer DF, Lunden JD. 1999. Field and laboratory tests of the effects of fipronil on adult female bees of *Apis mellifera*, *Megachile rotundata* and *Nomia melanderi*. J Apicult Res 38: 191-197.
Morandin LA & Winston ML 2003. Effects of novel pesticides on bumble bee (Hymenoptera: Apidae) colony health and foraging ability. Environ Entomol 32, 555-63
Mullin CA, Frazier M, Frazier JL, Ashcraft S, Simonds R, vanEngelsdorp D, Pettis JS. 2010. High Levels of miticides and agrochemicals in North American apiaries: implications for honey bee health. Plos One 5(3).
Mullin CA, Frazier M, Frazier JL, Ashcroft S, Simonds R, vanEngelsdorp, D & Pettis JS 2010. High levels of miticides and agrochemicals in North American apiaries: implications for honey bee health. PlosOne 5(3), e9754. doi:10.1371
Nauen R, Ebbinghaus-Kintscher U, Schmuck R. 2001. Toxicity and nicotinic acetylcholine receptor interaction of imidacloprid and its metabolites in *Apis mellifera* (Hymenoptera: Apidae). Pest Manag Sci 57: 577-586.
Neumann P & Carreck NL 2010. Honey bee colony losses. Journal of Apicultural Research 49, 1-6
Nguyen BK, Saegerman C, Pirard C, Mignon J, Widart J, Thirionet B, Verheggen FJ, Berkvens D, De Pauw E & Haubruge E. 2009. Does Imidacloprid Seed-Treated Maize Have an Impact on Honey Bee Mortality? J. Econ. Entomol. 102(2): 616-623
Nguyen BK, Saegerman C, Pirard C, Mignon J, Widart J, Tuirionet B, Verheggen FJ, Berkvens D, De Pauw E, Haubruge E. 2009. Does imidacloprid seed-treated maize have an impact on honey bee mortality? Journal of Economic Entomology 102:616-623.
Pirard C, Widart J, Nguyen BK, Deleuze C, Heudt L, Haubruge E, De Pauw E, Focant JF. 2007. Development and validation of a multi-residue method for pesticide determination in honey using on-column liquid-liquid extraction and liquid chromatography-tandem mass spectrometry. Journal of Chromatography A 1152:116-123.
Ramirez-Romero R, Chaufaux J, Pham-Delegue MH (2005) Effects of Cry1Ab protoxin, deltamethrin and imidacloprid on the foraging activity and the learning performances of the honeybee *Apis mellifera*, a comparative approach. Apidologie 36: 601-611.
Rortais A, Arnold G, Halm MP, Touffet-Briens, F 2005. Modes of Honeybees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie 36, 71-83
Rortais A, Arnold G, Halm MP, Touffet-Briens F. 2005. Modes of honeybees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie 36:71-83.
Scharf ME, Siegfried BD, Meinke LJ, Chandler LD. 2000. Fipronil metabolism, oxidative sulfone formation and toxicity among organophosphate- and carbamate-resistant and susceptible western corn rootworm populations. Pest Management Science 56:757-766.
Schmuck R (1999) No causal relationship between Gaucho seed dressing in sunflowers and the French bee syndrome. Pflanzenschutz Nachrichten Bayer 52: 257-299.
Schmuck R, Schoning R, Stork A, Schramel O et al (2001) Risk posed to honeybees (*Apis mellifera* L. Hymenoptera) by an imidacloprid seed dressing of sunflowers. Pest Manag Sci 57: 225-238.
Schmuck R, Schoning R, Stork A, Schramel O. 2001. Risk posed to honeybees (*Apis mellifera* L. Hymenoptera) by an imidacloprid seed dressing of sunflowers. Pest Management Science 57:225-238.
Scott-Dupree CD, Conroy L & Harris CR 2009. Impact of currently used or potentially useful insecticides for canola agroecosystems on *Bombus impatiens*, *Megachile rotundata* and *Osmia lignaria*. J Econ Entomol. 102, 177-182

Smodis Skerl MI, Velikonja Bolta S, Basa Cesnik H, Gregorc A. 2009. Residues of Pesticides in honeybee (*Apis mellifera carnica*) bee bread and in pollen loads from treated apple orchards. Bulletin of Environmental Contamination and Toxicology 83:374-377.

Stark JD, Jepson PC, Mayer DF. 1995. Limitation to the use of topical toxicity data for prediction of pesticide side-effect in the field. J Econ Entomol: 1081-1088.

Suchail S, De Sousa G, Rahmani R, Belzunces LP. 2004a. In vivo distribution and metabolisation of C-14-imidacloprid in different compartments of *Apis mellifera* L. Pest Management Science 60:1056-1062.

Suchail S, Debrauwer L, Belzunces LP. 2004b. Metabolism of imidacloprid in *Apis mellifera*. Pest Management Science 60:291-296.

Suchail S, Guez D and Belzunces LP. 2001. Discrepancy between acute and chronic toxicity induced by imidacloprid and its metabolites in Apis mellifera. Environ Toxicol Chem 20: 2482-2486.

Suchail S, Guez D, Belzunces LP. 2000. Characteristics of imidacloprid toxicity in two Apis mellifera subspecies. Environmental Toxicology and Chemistry 19: 1901-1905.

Tasei JN, Lerin J & Ripault G 2000. Sub-lethal effects of imidacloprid on bumblebees, *Bombus terrestris* (Hymenoptera: Apidae), during a laboratory feeding test. Pest Manag Sci 56, 784-788

Tasei JN, Ripault G & Rivault E 2001. Hazards of imidacloprid seed coating to *Bombus terrestris* (Hymenoptera: Apidae) when applied to sunflower. J Econ Entomol 94, 623-627

Thompson HM. 2010. Risk assessment for honey bees and pesticides—recent developments and ‘new issues’. Pest Management Science 66:1157-1162.

Visser, A 2009. Subletale effecten van neonicotinen. Bijennieuws 12, juli 2009. Electronische Nieuwsbrief bijen@wur

Visser, A 2010 Invloed van imidaclopridresiduen in oppervlaktewater op bijensterfte in Nederland. Rapport CAH Dronten opleiding Dier- en gezondheidszorg. 61 pagina’s

Von Der Ohe, W & Janke M 2009 Bienen im Stress. Schäden entstehen wenn verschiedene Faktoren zusammen kommen. Algemeine Deutsche ImkerZeitung 2009/4, 10-11.

Wu JY, Anelli CM & Sheppard WS, 2011. Sub-lethal effects of pesticide residues in brood comb on worker honey bee (*Apis mellifera*) development and longevity. PlosOne 6 (2), e14720.

Yang EC, Chuang YC, Chen YL & Chang LH 2008. Abnormal foraging behavior induced by sublethal dosage of imidacloprid in the honey bee (Hymenoptera: Apidae). J Econ Entomol 101, 1743-48

Yang EC, Chuang YC, Cheng YL et al. 2008. Abnormal foraging behavior induced by sublethal dosage of imidacloprid in the honey bee (Hymenoptera: Apidae). J Econ Entomol 101: 1743-1748.

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

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

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