Herbeoordeling neonicotinoïde houdende bestrijdingsmiddelen

afdeling:
verschijningsdatum: 24 juni 2011

Vertrouwelijk: ☐ ja ☒ nee

Status: ☒ concept ☐ definitief

Opsteller / auteur:
Janine van Gelder
Lars Hogendoorn
Martine Lans
Jacoba Wassenberg

Opdrachtgever(s)
5.1.2.e (EL&I)

Verspreiding: ☐ intern ☒ extern

Versiebeheer

versie	datum	auteur	opmerkingen
0.1	17 juni 2011	5.1.2.e	Eerste concept
0.2	22 juni 2011	5.1.2.e	Tweede concept inclusief opmerkingen College
0.3	24 juni 2011	5.1.2.e 5.1.2.e	Derde concept, losse bijdragen
0.4	24 juni 2011	5.1.2.e 5.1.2.e 5.1.2.e	Vierde concept

Recensiehistorie

versie	datum	recensent	opmerkingen

Inhoudsopgave

Voorwoord

Sinds midden jaren 90 zijn bestrijdingsmiddelen op basis van neonicotinoïden toegelaten in Nederland. Neonicotinoïden bestrijden insecten door werking op het zenuwstelsel van insecten.

Na enkele ongelukken in het buitenland waarbij stof van met neonicotinoïden behandeld zaad in de omgeving van behandelde percelen is terecht gekomen en ~~massale bijensterfte is opgetreden~~grote schade aan bijenvolken veroorzaakte, is de maatschappelijke en wetenschappelijke belangstelling voor deze bestrijdingsmiddelen toegenomen. Verschillende wetenschappers brengen deze middelen ~~ook –~~ in meer of mindere mate - in verband met de hoge sterfte onder bijenvolken die over de hele wereld waargenomen wordt. Ook in Nederland wordt achteruitgang van de bijenstand waargenomen en zijn er zorgen over het mogelijke verband tussen het gebruik van neonicotinoïden in bestrijdingsmiddelen en de achteruitgang van de bijenstand. Deze zorg is voor de Tweede Kamer een reden geweest om de regering te verzoeken alle bestrijdingsmiddelen op basis van neonicotinoïden opnieuw te toetsen op de effecten op de gezondheid van bijen. De herbeoordeling is door het Ctgb ter hand genomen. Deze rapportage geeft de resultaten weer van deze herbeoordeling.

Commented [illegible]: Om verwarring te voorkomen met de term bijensterfte die we verder voor de achteruitgang van de bijen gebruiken (gemeten als toenemende wintersterfte). Bij deze incidenten ging het om directe en acute schade en dat is iets anders.

1 Inleiding

1.1 Neonicotinoiden en bijensterfte

Sinds midden jaren 90 zijn bestrijdingsmiddelen op basis van neonicotinoïden toegelaten in Nederland. Neonicotinoiden worden gebruikt in gewasbeschermingsmiddelen en biociden. Neonicotinoïden bestrijden insecten door werking op het zenuwstelsel van insecten.
In 2008 leidde de combinatie van slecht gecoat maïszaad, ongunstige weersomstandigheden en het zaaien met pneumatische zaaimachines in het buitenland tot het verwaaien van stof (stofdrift) met daarin hoge concentraties neonicotinoiden.
Hierdoor werden bijen in de omgeving blootgesteld aan dusdanig hoge concentraties dat ~~massale sterfte~~grote schade aan ~~onder~~ bijenvolken opgetreden~~ is~~. Om dergelijke incidenten in Nederland te voorkomen, heeft het Ctgb per januari 2010 risicobeperkende maatregelen ingesteld voor de behandeling van zaad, de pneumatische zaaimachines en zaaiomstandigheden. In maart 2010 heeft de Europese Commissie in dezelfde lijn plaatsingsrichtlijnen (Annex I van 91/414/EEG) (zie Bijlage xx) van een aantal voor bijen zeer toxische stoffen aangepast met 'additional provisions to protect honeybees'.

Wereldwijd is er bezorgdheid over ~~het verdwijnende~~ achteruitgang van bijen~~volken~~. In Nederland wordt melding gemaakt van een jaarlijkse sterfte van 23% in 2010. Een onlangs verschenen UNEP rapport concludeert dat er een veelheid van factoren ten grondslag ligt aan deze afname, zoals achteruitgang van de leefomgeving, toename van ziekten, toename van plagen, gebruik van bestrijdingsmiddelen, bijenverzorging en klimaatverandering.
Door verschillende onderzoekers worden neonicotinoïden ~~ook~~ -in meer of mindere mate- in verband gebracht met de bijensterfte, die wordt waargenomen over de hele wereld.

Commented [illegible]: 'verdwijnziekte' is vooral een amerikaans fenomeen

1.2 Toelating van neonicotinoïde houdende middelen in Nederland.

Het Ctgb toetst voor de toelating van gewasbeschermingsmiddelen en biociden de aangevraagde toepassing aan de wettelijk vastgelegde voorwaarden. Zo worden ook neonicotinoïde houdende middelen getoetst aan deze voorwaarden. Een toelating wordt doorgaans verleend voor een periode van 10 jaar, of tot het moment van herregistratie bepaald door de plaatsing van de werkzame stof op de Europese plaatsingsrichtlijn.
De algemene werkwijze van het Ctgb is dat het zich op de hoogte houdt van de wetenschappelijke inzichten aangaande de risico's van het gebruik van toegelaten gewasbeschermingsmiddelen en biociden. Indien het op basis van deze inzichten aannemelijk wordt dat er bijzondere nog niet eerder onderkende en onaanvaardbare risico's van het toegestane gebruik optreden, kan ingegrepen worden door het opleggen van additionele gebruiksvoorschriften of het intrekken van de toelating. Indien er geen aannemelijk verband is tussen het waargenomen effect en het toegelaten gebruik, wordt niet ingegrepen in de verleende toelating en wordt het middel herbeoordeeld tijdens de herregistratie.

Aangezien er een aannemelijk verband is tussen de directe blootstelling van bijen door stofdrift van behandeld zaaizaad en ~~de waargenomen~~ bijensterfte, heeft het Ctgb reeds eerder risicobeperkende maatregelen ingesteld. Voor een relatie tussen de achteruitgang van de bijenstand en het toegestane gebruik van neonicotinoïden ontbreken wetenschappelijke onderbouwde aanwijzingen.

Daardoor was er voor het Ctgb tot op heden geen reden om in te grijpen in de lopende toelatingen als reactie op de achteruitgang van de bijenstand. Bij de verplichte herregistratie van de toegelaten middelen, die afhankelijk van de gebruikte werkzame stof in de periode 2011 - 2018, plaats zal vinden, zou de toelatinghouder opnieuw aan moeten tonen dat het aangevraagde gebruik voldoet aan alle in de wet gestelde voorwaarden.

De maatschappelijke bezorgdheid over de bijensterfte is groot. Ook in de Tweede Kamer is de bijensterfte onderwerp van discussie en wordt de zorg uitgesproken over een eventueel verband tussen neonicotinoïden en de waargenomen bijensterfte. In het kamerdebat over de wijziging van de Wet gewasbeschermingsmiddelen en biociden op 17 februari 2011 wordt de regering door de Tweede Kamer verzocht 'de reeds toegelaten bestrijdingsmiddelen die behoren tot de klasse neonicotinoïden opnieuw te toetsen op de effecten op de gezondheid van bijen, en hierbij ook expliciet eventuele sublethale effecten mee te nemen' (motie Ouwehand; kamernr II 2009/10 nr 32372 nr 19; zie Bijlage I). De Staatssecretaris van Economische Zaken, Landbouw en Innovatie (EL&I) heeft de herbeoordeling van de neonicotinoïden toegezegd aan de Tweede Kamer en het Ctgb verzocht deze uit te voeren.

1.3 Afbakening

In Nederland (evenals in Europa) zijn middelen toegelaten op basis van zeven werkzame stoffen die tot de chemische klasse van de neonicotinoïden behoren. Slechts 3 van deze stoffen zijn acuut zeer toxisch voor honingbijen: clothianidin, imidacloprid en thiamethoxam. Daarnaast zijn er middelen toegelaten op basis van fipronil, een stof die geen neonicotinoïde is, maar wel een grote toxiciteit voor honingbijen heeft en persistent is. In Europa is in de context van het risico voor bijen in 2010 de plaatsingsrichtlijn aangepast voor clothianidin, imidacloprid, thiamethoxam en fipronil. In navolging hiervan is de nationale herbeoordeling van het risico voor bijen gericht op deze vier stoffen.

Er zijn in totaal 55 middelen, op basis van clothianidin, imidacloprid, thiamethoxam en fipronil, op de markt in Nederland (dd. 18 februari 2011):

	Gewasbeschermingsmiddel	Biocide	Totaal
Professioneel	18 (+ 2 afgeleide)	12 (+ 4 afgeleide)	36
Niet-professioneel	4 (+ 3 afgeleide)	4 (+ 11 afgeleide)	22
Totaal	22 (+ 5 afgeleide) = 27	14 (+ 14 afgeleide) = 28*	55*

*3 middelen hebben zowel professionele als niet-professionele toepassing.

Voor deze 55 middelen is het risico voor bijen herbeoordeeld. Op grond van de laatste stand van de wetenschap en het van toepassing zijnde toetsingskader is geoordeeld over de risico's van het toegestane gebruik en de te nemen maatregelen om eventuele risico's te beperken. Binnen de herbeoordeling is het risico voor bijen getoetst aan toelatingsvoorwaarden vastgelegd in artikel 28 of 49 van de Wet gewasbeschermingsmiddelen en biociden (Wgb).

Zoals afgesproken levert het Ctgb op basis van de herbeoordeling de volgende resultaten op:

- beslissingen van het College om op dat moment niet ambtshalve in te grijpen in de toelating;
- besluiten op aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 28 of 49 van de Wgb;
- voorgenomen besluiten tot ambtshalve wijziging van de toelating op basis van artikel 41 of 68 van de Wgb;
- besluit tot tijdelijk verbod of tijdelijke inperking van het gebruik en het voorhanden hebben van het middel op basis van artikel 40 of 67 van de Wgb;

Voor 3 van de betrokken 55 middelen is door de Staatssecretaris van EL&I op 6 juli 2011 het besluit genomen tot schorsing van de toelating. Dit besluit is door de Staatssecretaris genomen op grond van zijn aanhoudende ernstige twijfel over de risico's voor bijen bij gebruik van de 3 middelen totdat uit nader onderzoek blijkt dat deze middelen veilig te gebruiken zijn. Op basis van de resultaten van de herbeoordeling van deze 3 middelen zal het Ctgb de Staatssecretaris opnieuw adviseren over de toelaatbaarheid van deze drie middelen.

2 Beoordelings- en besluitvormingskader

De herbeoordeling van de 55 middelen is uitgevoerd conform Europees afgestemde beoordelingsmethodiek. De beoordeling is gebaseerd op de definitieve Europees vastgestelde eindpuntenlijst. In de eindpunten-lijst zijn de voor de stof beschikbare studies opgenomen. Daarnaast zijn nieuwe, door de toelatinghouder aangedragen studies en een analyse van de openbare literatuur betrokken bij de herbeoordeling.

2.1 Beoordelingsmethodiek

Het Ctgb beoordeelt de risico's voor bijen op basis van het 'Guidance document on terrestrial ecotoxicology' in de context van Directive 91/414/EEC, Sanco/10392/2002,rev 2 final (2002) (zie Bijlage IV waarin het voor bijen relevant hoofdstuk 4 is opgenomen). Dit Guidance document is door de ministeries van EL&I en I&M aangereikt aan het Ctgb door opname in de Regeling gewasbeschermingsmiddelen en Biociden in 'Bijlage XV. Beoordelingsmethodieken uit richtsnoeren en andere beoordelingsmethodieken'.
Het nationale toetsingskader voor de beoordeling van het risico voor bijen is hiermee gelijk aan het Europese toetsingskader. Bij de toelating van de 55 middelen die onderwerp zijn van de herbeoordeling zijn door het Ctgb destijds ook de toen bekende sublethale effecten betrokken in de risicobeoordeling voor bijen. Dit betreft de effecten op gedrag, vlucht-en/of foerageeractiviteit, broedontwikkeling, stuifmeel- en nectaropslag, en op het gewicht van het volk.

In de Europese beoordeling voor de plaatsing van fipronil, imidacloprid, thiamethoxam en ~~imidacloprid~~ clothianidin op Annex I van 91/414/EEG is in aanvulling op het standaard toetsingskader extra aandacht besteed aan het kwantificeren van risico's voor bijen als gevolg van subletale effecten en aan de met de systemische werking samenhangende blootstellingroutes.

In 2010 is binnen Europa een nieuw toetsingskader vastgesteld voor de beoordeling van het risico voor bijen. Dit toetsingskader richt zich expliciet op de beoordeling van systemische stoffen, zoals neonicotinoïden, omdat deze via indirecte routes beschikbaar kunnen komen voor bijen. In de in 2010 door EPPO vastgestelde richtlijn (EPPO 170, 10), staat beschreven hoe het risico van systemisch werkende stoffen moet worden beoordeeld (gepubliceerd in EPPO Bulletin 40(3) december 2010). Deze richtlijn is gebruikt bij de herbeoordeling. Een uitvoerige beschrijving van de besluitvorming rondom deze Eppo richtlijnen is ter informatie toegevoegd in Bijlage IV.

Volgens het bijbehorende Guidance Document moeten ook residugegevens in pollen en nectar in de beoordeling betrokken worden en indien nodig hogere tier studies uitgevoerd ~~moeten~~ worden met realistische blootstelling. Deze gegevens zijn voor de vier te herbeoordelen stoffen aanwezig en zijn dus waar relevant gebruikt in de onderhavige herbeoordeling voor de risico voor bijen volgens bovengenoemd kader.

Gebruik openbare literatuur

Openbare wetenschappelijke literatuur is door het Ctgb betrokken bij de herbeoordeling. Dit is dezelfde openbare literatuur over de effecten van neonicotinoïden en fipronil op bijensterfte die momenteel door de Wageningen Universiteit en Research centre wordt geanalyseerd voor een review rapport in opdracht van het ministerie van EL&I . Bij de herbeoordeling is gebruik gemaakt van de voorlopige literatuurlijst voor deze review.

Commented [illegible]: Worden de biociden ook getoetst o/v de gewasbeschermings guidance? Goed om daar enige uitleg over te geven!

Commented [illegible]: ??

Commented [illegible]:

Commented [illegible]: Wordt die dan ook nu (voor het eerst?) gebruikt? Neem de lezer mee waarom je dit hier beschrijft en waarom het hier relevant is!

Commented [illegible]: Zoiets?

Commented [illegible]: Waarom de besluitvorming? Is het resultaat niet informatiever?

Commented [illegible]: Het risico van bijen is dat ze je steken...

De conclusies van de risicobeoordeling uitgevoerd op basis van het beschermde dossier zijn getoetst aan de nieuwste wetenschappelijke gegevens.

In 2000 heeft de Nederlandse Gezondheidsraad een advies uitgebracht over de statistische onderbouwing van effecten in veldonderzoek[1]. De aanbevelingen van de gezondheidsraad worden gebruikt bij de beoordeling van de toelaatbaarheid van gewasbeschermingsmiddelen. Het statistisch onderscheidingsvermogen van veldproeven vormt een belangrijk aandachtspunt bij het interpreteren van de resultaten. Het Ctgb volgt waar mogelijk de internationale richtlijnen voor het omgaan met resultaten van veldonderzoek (Europees geharmoniseerd).

Verschillende van de in de risicobeoordeling gebruikte studies over één van de neonicotinoïden zijn gebruikt in een meta-analyse die recent is gepubliceerd in een artikel van Cresswell (2011). In dit artikel wordt de statistische power van honingbij-semi-veldtesten om subletale effecten aan te tonen in twijfel getrokken. Dit geldt niet alleen voor de neonicotinoïden, maar heeft betrekking opvoor alle bestrijdingsmiddelen waar (semi-)veldtesten gebruikt zijn in de risicobeoordeling voor bijen.

Commented [[redacted]]: ?? uit de herbeoordeelde groep?

Commented [[redacted]]: Nee, geldt voor alle stoffen.

Specifiek voor het veldonderzoek voor bijen zal op korte termijn een wetenschappelijk panel van de EFSA (EFSA mandaat M-2011-0185; nog niet gestart) de problemen met de statistische power van bijenveldonderzoek in kaart brengen en aanbevelingen doen op dit gebied. Nederland zal participeren in dit panel. Het Ctgb zal in de toekomst de resultaten die voortkomen uit dit panel bij de beoordeling van de toelaatbaarheid van gewasbeschermingsmiddelen betrekken.

Commented [[redacted]]: Dat kan dus nog niet gebeurd zijn

Commented [[redacted]]: Nee dat klopt, dat gaan we doen als de werkgroep klaar is. Of als de resultaten van de werkgroep in Europees toetsingskader zijn verwerkt.

2.2 Besluitvormingskader gewasbeschermingsmiddelen en biociden

pmDe herbeoordeling van het risico voor bijen is gestart in februari 2011. Het juridisch kader voor de herbeoordeling wordt gevormd door de Wgb, zowel voor de gewasbeschermingsmiddelen als de biociden. De nieuwe Gewasbeschermingsverordening 1107/2009/EG is niet van toepassing.

Binnen de herbeoordeling wordt het risico voor bijen getoetst aan toelatingsvoorwaarden vastgelegd in artikel 28 of 49 van de Wgb. Deze herbeoordeling leidt tot verschillende resultaten:

- beslissingen van het College om op dat moment niet ambtshalve in te grijpen in de toelating;

In de risicobeoordeling is geen risico geconstateerd. Het Ctgb zal in dit geval beslissen om op dat moment niet ambtshalve in te grijpen in de toelating.

- besluiten op aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 28 of 49 van de Wgb;

In de risicobeoordeling is een risico geconstateerd en vastgesteld dat dit risico door het wijziging van de toelating, bijvoorbeeld risico mitigerende maatregelen, kan worden weggenomen. De toelatinghouder heeft het Ctgb het verzoek gedaan tot het overeenkomstig wijzigen van de toelating. Het Ctgb zal in dit geval besluiten op aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 41 of 68 van de Wgb.

[1] Health Council of the Netherlands: Committee on pesticides and field research. Field research for the authorisation of pesticides. The Hague: Health Council of the Netherlands, 2000; publication no: 2000/07E

- voorgenomen besluiten tot ambtshalve wijziging van de toelating op basis van artikel 41 of 68 van de Wgb;

In de risicobeoordeling is een risico geconstateerd en vastgesteld dat dit risico door het wijziging van de toelating, bijvoorbeeld risico mitigerende maatregelen, kan worden weggenomen. De toelatinghouder heeft het Ctgb niet het verzoek gedaan tot het overeenkomstig wijzigen van de toelating. Het Ctgb zal in dit geval voorgenomen besluit nemen tot ambtshalve wijziging van de toelating op basis van artikel 41 of 68 van de Wgb.

- besluit tot tijdelijk verbod of tijdelijke inperking van het gebruik en het voorhanden hebben van het middel op basis van artikel 40 of 67 van de Wgb;

In de risicobeoordeling is een risico geconstateerd en vastgesteld dat dit risico door het wijziging van de toelating, bijvoorbeeld risico mitigerende maatregelen, kan worden weggenomen. De toelatinghouder heeft het Ctgb niet het verzoek gedaan tot het overeenkomstig wijzigen van de toelating. In het geval dat de geconstateerde risico's dermate groot zijn, dat niet gewacht kan worden tot het eerder genoemde voorgenomen besluit inwerking treedt, zal het Ctgb een besluit nemen tot tijdelijk verbod of tijdelijke inperking van het gebruik en het voorhanden hebben van het middel op basis van artikel 40 of 67 van de Wgb. Dit besluit wordt tegelijk met het voorgenomen besluit tot ambtshalve wijziging van de toelating genomen.

- advies van het College over de middelen, die tijdelijk zijn verboden, bij besluit Schorsing niet-professioneel gebruik insectenmiddelen (publicatiedatum 6 juni 2011)

Voor 3 van de betrokken 55 middelen is door de Staatssecretaris van EL&I op 6 juni 2011 het besluit genomen tot schorsing van de toelating. Dit besluit is door de Staatssecretaris genomen op grond van zijn aanhoudende ernstige twijfel over de risico's voor bijen bij gebruik van de 3 middelen totdat uit nader onderzoek blijkt dat deze middelen veilig te gebruiken zijn. Op basis van de resultaten van de herbeoordeling van deze 3 middelen zal het Ctgb de Staatssecretaris opnieuw adviseren over de toelaatbaarheid van deze drie middelen.

Onder de Wgb is het mogelijk een opgebruik- en aflevertermijn af te geven op grond van artikel 41, lid 5 alsmede artikel 68, lid 5 Wgb. Uit oogpunt van bestuurlijke zorgvuldigheid is het wenselijk dat de toelatinghouder, de distributeurs (waaronder detailhandel) en de gebruikers reëel in staat moet worden gesteld om de nodige maatregelen te nemen zonder direct in overtreding te zijn. In de besluitvorming zal het Ctgb een termijn vaststellen. Het is de bedoeling dat tot binnen deze termijn voorraden worden opgemaakt en maatregelen worden genomen om overeenkomstig voornoemd besluit te handelen.

3 Resultaten Herbeoordeling

3.1 Literatuur review

Op basis van de informatie uit de momenteel bij het Ctgb bekende openbare literatuur kan worden geconcludeerd dat niet is aangetoond dat neonicotinoïden en fipronil significant bijdragen aan de achteruitgang van de bijen.

De algemene bevindingen die naar voren komen op basis van de openbare literatuur over de effecten van neonicotinoïden en fipronil op bijen zijn de volgende:

- In monitoringsonderzoeken waarbij residuen in bijenvolken zijn gemeten, zijn de neonicotinoïden en fipronil aangetroffen in verschillende matrices in bijenvolken. Deze residuen van de neonicotinoïden en fipronil die gevonden zijn in bijenvolken kunnen meestal niet worden gerelateerd aan een bekend (type van) gebruik. De stoffen kennen veel verschillende gebruiken en zodoende zijn er verschillende bronnen die kunnen bijdragen aan de blootstelling van bijen aan deze stoffen.
- In de bijenvolken is gewoonlijk een mix van een aantal bestrijdingsmiddelen aanwezig. Tot nu toe is geen statistische correlatie gevonden tussen de aanwezigheid van residuen van specifieke bestrijdingsmiddelen of de totale hoeveelheid in bijenvolken en de gezondheid van bijenvolken op de lange termijn.
- Andere factoren dan bestrijdingsmiddelen, zoals bijvoorbeeld bestrijding van de Varroa mijt of kwaliteit en aanwezigheid van voedselbronnen, kunnen wel worden gerelateerd aan het overwinteringsucces van bijenvolken.
- In Nederland lijkt de wintersterfte onder bijen de laatste jaren toe te nemen-. Deze sterfte wordt met name toegerekend aan de niet afdoende bestrijding van plagen en ziekten die in bijenvolken kunnen voorkomen, speciaal de Varroa mijt. Adequate en tijdige bestrijding van de Varroa mijt reduceert de wintersterfte onder bijen aanzienlijk. Daarnaast lijkt ook de reductie van voedselbronnen voor de bijen een rol te spelen. De relatie tussen bestrijdingsmiddelen en de achteruitgang van bijenvolken is tot nu toe niet duidelijk bestudeerd in Nederland.
- In een recent rapport van de Verenigde Naties (UNEP 2011) wordt geconcludeerd dat een veelheid aan oorzaken ten grondslag ligt aan de bijensterfte in Europa, de Verenigde Staten en Azië, en dat er momenteel onvoldoende kennis bestaat over de causale verbanden en risicofactoren die kunnen leiden tot bijensterfte.

3.2 Clothianidin

Clothiadinin wordt toegepast in twee middelen voor professioneel gebruik met een toepassing als zaadcoating (zie tabel).

toelating nr	Middelnaam	toelatinghouder	werkzame stoffen	Prof / Niet-prof	formulering	Toepassing(en)
13044	PONCHO BETA	Bayer CropScience B.V.	clothianidine 400G/L beta-cyfluthrin 53,3G/L	Prof	Suspensie concentraat voor zaadbehandeling	zaadcoating in bieten
13276	PONCHO ROOD	Bayer CropScience B.V.	clothianidine 600G/L	Prof	Suspensie concentraat voor zaadbehandeling	zaadcoating in snij- en korrelmais

De toegelaten toepassingen zijn beoordeeld op de risico's voor bijen middels directe en indirecte blootstelling. Bij directe blootstelling komt het insecticide tijdens of na de toepassing rechtstreeks bij bijen terecht. Bij indirecte blootstelling wordt clothianidin als systemisch werkend insecticide opgenomen door de plant en komt via deze route bij de bij terecht.

Bij bepaling van de directe blootstelling is gelet op de risico's tijdens en vlak na het zaaien voor bijen aanwezig in het veld en op de risico's voor bijen buiten het veld door blootstelling via verwaaid stof van behandeld zaad. In beide omstandigheden treden er bij het toegestane gebruik geen onaanvaardbare risico's op.

Bij bepaling van de indirecte risico's voor bijen is onderzocht wat de blootstelling is middels residuen in nectar en pollen van de behandelde gewassen, middels bloeiende onkruiden of vervolggewassen die in de bodem aanwezige resten clothiadinin opnemen, middels guttatie en de blootstelling via door bladluizen geproduceerde honingdauw. In alle gevallen treden er bij het toegestane gebruik geen onaanvaardbare risico's op.
De uitgebreide risicobeoordeling van de middelen op basis van clothiadinin is opgenomen in bijlage xxx.

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met clothiadinin oordeelt het ~~college~~College dat Poncho Beta (toelatingnr. 13044) en Poncho Rood (toelatingnr. 13276) voor dit aspect voldoen aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 40 en 41 van de Wgb.

3.3 Thiamethoxam

Thiamethoxam wordt toegepast in zes gewasbeschermingsmiddelen en één biocide (zie tabel).

Gewasbeschermingsmiddelen op basis van thiamethoxam

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	Prof / Niet-prof	formulering	Toepassing
12679	ACTARA	Syngenta Crop Protection B.V.	thiamethoxam 25%	Prof	Water dispergeerbaar granulaat	Gewasbehandeling in aardappelen, bedekte teelt van knol-en-bolbloemgewassen, onbedekte en bedekte teelt van bloemisterij- en boomkwekerij gewassen en vaste planten; Grondbehandeling van aardappelen.
12913	CRUISER 350 FS	Syngenta Crop Protection B.V.	thiamethoxam 350G/L	Prof	Suspensie concentraat voor zaadbehandeling	Zaadcoating in mais, erwten, peulen, kapucijners.
12863	CRUISER SB	Syngenta Crop Protection B.V.	thiamethoxam 600G/L	Prof	Suspensie concentraat voor zaadbehandeli	Zaadcoating in bieten.

					ng	
12852	CRUISER 70 WS	Syngenta Crop Protection B.V.	thiamethoxam 70%	Prof	Water dispergeerbaar poeder voor vochtige zaadbehandeling	Zaadcoating in sla en andijvie.
13215	AXORIS QUICK-GRAN	Compo Benelux N.V.	thiamethoxam 12,00G/KG	Niet-prof	Granulaat	Granulaat voor in potten en bakken van sierplanten binnenshuis.
13216	AXORIS QUICK-STICKS	Compo Benelux N.V.	thiamethoxam 12,00G/KG	Niet-prof	Planten-staafje	Pin voor in potten en bakken van sierplanten binnenshuis.

Biociden op basis van thiamethoxam

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	Prof/Niet-prof	formulering	Toepassing
13399	AGITA 10 WG	Novartis Consumer Health B.V.	thiamethoxam 10%	Prof	Water dispergeerbaar granulaat	Tegen vliegen. Korrels om op te lossen en dan op oppervlakten te smeren in dierverblijf-plaatsen.

De toegelaten toepassingen zijn beoordeeld op de risico's voor bijen middels directe en indirecte blootstelling. Bij directe blootstelling komt het insecticide tijdens of na de toepassing rechtstreeks bij bijen terecht. Bij indirecte blootstelling wordt thiamethoxam als systemisch werkend insecticide opgenomen door de plant en komt via deze route bij de bij terecht.

Commented [[illegible]]: Het biocide heeft wellicht een andere route

Bij bepaling van de directe blootstelling is gelet op de risico's tijdens en vlak na het spuiten of het zaaien voor bijen aanwezig in het veld en op de risico's voor bijen buiten het veld door blootstelling via de spuitnevel of verwaaid stof van behandeld zaad. Bij bepaling van de indirecte risico's voor bijen is onderzocht wat de blootstelling is middels residuen in nectar en pollen van de behandelde gewassen, middels bloeiende onkruiden of vervolggewassen die in de bodem aanwezige resten thiamethoxam opnemen, middels guttatie en de blootstelling via door bladluizen geproduceerde honingdauw.

De uitgebreide risicobeoordeling van de middelen op basis van thiamethoxam is opgenomen in bijlage xxx-. In de hiernavolgende paragrafen worden de belangrijkste resultaten van de beoordeling weergegeven.

3.3.1 Cruiser SB, Axoris Quick Gran, Axoris Quick sticks, Agita 10WG

Bij het toegestane gebruik van de gewasbeschermingsmiddelen Cruiser SB (toelatingnr 1285263), Axoris Quick Gran (toelatingnr 13215) en Axoris Quick Sticks (toelatingnr. 13216) en het biocide Agita 10WG (toelatingnr 13399) treden geen onaanvaardbare risico's voor bijen op door blootstelling middels de hierboven beschreven routes.

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met thiamethoxam oordeelt het collegeCollege dat Cruiser SB, Axoris Quick Gran, en Axoris Quick Sticks en Agita 10WGvoor dit aspect voldoen aan de toelatingsvoorwaarden vastgelegd in artikel 28 of 49 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van van artikel 40 of 67 en 41 of 68 van de Wgb.

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met thiamethoxam oordeelt het collegeCollege dat Agita 10WG voor dit aspect voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 49 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van van artikel 67 en 68 van de Wgb.

3.3.2 Actara

Het momenteel toegestane gebruik van Actara (toelatingnr 12679) laat een verhoogd risico zien voor bijen door verwaaiing van het gewasbeschermingsmiddel bij het toepassen door spuiten (spray drift). Dit risico kan afdoende gereduceerd worden door de volgende extra driftreducerende maatregelen:

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

In aardappels (gewasbehandeling):

- *spuitboomverlaging (30 cm boven de top van het gewas) in combinatie met driftarme spuitdoppen (dopafstand 25 cm) en een kantdop; of*
- *conventionele spuitmachine met een driftarme spuitdop en een kantdop in combinatie met luchtondersteuning.*

In bloemisterijgewassen, boomkwekerijgewassen en vaste planten (tegen luis), neerwaartse bespuiting:

- *spuitboomverlaging (30 cm boven de top van het gewas) in combinatie met driftarme spuitdoppen (dopafstand 25 cm) en een kantdop; of*
- *conventionele spuitmachine met een driftarme spuitdop en een kantdop in combinatie met luchtondersteuning.*

In boomkwekerijgewassen (laanbomen) (tegen luis), opwaartse bespuiting:

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

Om de risico's voor bijen in te schatten middels blootstelling aan door de plant in het systeem opgenomen thiamethoxam dat via nectar en pollen bij foeragerende bijen terecht komt, zijn momenteel onvoldoende gegevens beschikbaar. De volgende gebruiksbeperkingen kunnen voorkomen dat er risico's voor bijen optreden door deze blootstellingsroute (alleen de toepassingen waarvan de tekst is gewijzigd zijn weergegeven):

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

Tenslotte blijkt dat blootstelling van bijen bij het toegestane gebruik van Actara niet uitgesloten kan worden doordat resten thiamethoxam en metaboliet CGA322704 in de bodem opgenomen kunnen worden door vervolggewassen en vervolgens via de nectar en pollen van deze vervolggewassen doorgegeven worden aan bijen. Deze risico's kunnen gereduceerd worden met de volgende gebruiksbeperking:

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

De overige blootstellingsroutes laten voor het momenteel toegestane gebruik van Actara volgens het huidige wettelijk gebruiksvoorschrift geen onaanvaardbare risico's zien.

Commented [[redacted]]: Ik vraag me toch af of de nadruk nu niet alleen maar ligt op de nieuwe restricties. Het huidige etiket bevat ook al bijenrestrictiezinnen en die zie je nu alleen als je naar de bijlage gaat. Het is voor de goede lezer wel te vinden maar de pers zal het misschien verkeerd lezen. Maar ik weet niet of mijn toevoeging dat oplost.

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met thiamethoxam oordeelt het ~~college~~College dat voor dit aspect het toegestane gebruik van Actara (toelatingnr 12679) voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb onder voorwaarde van het opnemen van extra gebruiksrestricties.

In overeenstemming met bovenstaande voorwaarden is door de toelatinghouder een aanvraag tot wijziging van het WGGA ingediend. Het ~~college~~College oordeelt dat het gebruik volgens het gewijzigde WGGA voor het aspect risico's voor bijen voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb en heeft besloten de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 41 van de Wgb te honoreren.

3.3.3 Cruiser 350FS, Cruiser 70 WS

Bij blootstelling van bijen bij het toegestane gebruik van Cruiser 350FS (toelatingnr.12913) (in erwt) en Cruiser 70 WS (toelatingnr. 12852) (in alle gewassen) kan niet uitgesloten worden dat resten thiamethoxam en metaboliet CGA322704 in de bodem achterblijven en opgenomen worden door vervolggewassen. Via de nectar en pollen van deze vervolggewassen kan ~~thiamethoxam~~ de stof doorgegeven worden aan bijen. Deze risico's kunnen gereduceerd worden met de volgende gebruiksbeperking, die geldt voor het gebruik van Cruiser 350FS in landbouwerwten, doperwten, peulen, asperge-erwten, kapucijners en suikererwten en voor alle gewassen van Cruiser 70 WS :

> *In verband met het risico voor bijen mogen binnen een periode van een jaar (365 d) gerekend vanaf zaai of uitplanten op het veld geen voor bijen aantrekkelijke gewassen worden gezaaid of geplant.*

De overige blootstellingsroutes laten voor het toegestane gebruik van Cruiser 350FS en Cruiser 70 WS geen onaanvaardbare risico's zien.

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met thiamethoxam oordeelt het ~~college~~College dat voor dit aspect het toegestane gebruik van Cruiser 350FS (toelatingnr.12913)(in erwt) en Cruiser 70 WS (toelatingnr. 12852) (in alle gewassen) voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb onder voorwaarde van het opnemen van extra gebruiksrestricties.

In overeenstemming met bovenstaande voorwaarden is door de toelatinghouder een aanvraag tot wijziging van het WGGA ingediend. Het ~~college~~College oordeelt dat het gebruik volgens het gewijzigde WGGA voor het aspect risico's voor bijen voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb en heeft besloten de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 41 van de Wgb te honoreren.

3.4 Imidacloprid

Imidacloprid wordt toegepast in elf gewasbeschermingsmiddelen voor professioneel gebruik, vijf gewasbeschermingsmiddelen voor niet-professioneel gebruik, tien biociden voor professioneel gebruik, twaalf biociden voor niet-professioneel gebruik en vijf biociden voor zowel professioneel als niet-professioneel gebruik (zie tabel).

Gewasbeschermingsmiddelen

toelating nr	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	imidacloprid 350G/L	Professioneel	Suspensie concentraat	Aardappelen, grondbehandeling

		B.V.			voor zaadbehandeling	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 maïs.
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

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	Bestrijding van kakkerlakken in gebouwen en transportmiddelen. Gel aanbrengen in kieren en

					gebruik)	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, 13052, 12979, 12980, 12024)	BAYTHION MIEREN MIDDELN	Bayer CropScience B.V.	imidacloprid 0,0500 %	Professioneel & Niet-professioneel	Granulaat	Korrels om bij mierennest te strooien. Alleen buiten.
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.

De toegelaten toepassingen zijn beoordeeld op de risico's voor bijen middels directe en indirecte blootstelling. Bij directe blootstelling komt het insecticide tijdens of na de toepassing rechtstreeks bij bijen terecht. Bij indirecte blootstelling wordt imidacloprid als systemisch werkend insecticide opgenomen door de plant en komt via deze route bij de bij terecht.

Commented [5.1.2.e]: Biociden???

Bij bepaling van de directe blootstelling is gelet op de risico's tijdens en vlak na het zaaien of spuiten voor bijen aanwezig in het veld en en op de risico's voor bijen buiten het veld door blootstelling via de spuitnevel of verwaaid stof van behandeld zaad. Bij bepaling van de indirecte risico's voor bijen is onderzocht wat de blootstelling is middels residuen in nectar en pollen van de behandelde gewassen, middels bloeiende onkruiden of vervolggewassen die in de bodem aanwezige resten imidacloprid opnemen, middels guttatie en de blootstelling via door bladluizen geproduceerde honingdauw.

Commented [5.1.2.e]: Ex de 10 biociden?

De uitgebreide risicobeoordeling van de middelen op basis van imidacloprid is opgenomen in bijlage xxx. In de hiernavolgende paragrafen worden de belangrijkste resultaten van de beoordeling weergegeven. Omdat de hoeveelheid middelen die imidacloprid bevatten omvangrijk is, is gekozen voor overzichtsparagraaf (4.4.1) waarin de middelen opgesomd staan die voor het aspect risico voor bijen voldoen aan artikel 28 en 49 van de Wgb. Vervolgens zijn middelen per paragraaf opgenomen waarbij wel een mogelijk risico voor bijen is geconstateerd en waar wijzigingen in de WG/GAs worden voorgesteld.

43.4.1 Middelen o.b.v. imidacloprid die voldoen aan artikel 28 Wgb

Bij het toegestane gebruik van onderstaande gewasbeschermingsmiddelen en biociden treden geen onaanvaardbare risico's voor bijen op door blootstelling middels de hierboven beschreven routes.

Gewasbeschermingsmiddelen

13321 MERIT TURF
11455 GAUCHO
11601 GAUCHO ROOD
11998 ADMIRE N PIN (afgeleide: 12219 POKON PLANTSTICK)

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met imidacloprid oordeelt het collegeCollege dat bovengenoemde middelen voor dit aspect voldoen aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van van artikel 40 en 41 van de Wgb.

Biociden

13160 LURECTRON FLYBAIT (afgeleide: 13173 MS VB-08)
12665 QUICK BAYT (afgeleide: 13063 AMOS FLY FINISH)
13116 QUICK BAYT SPRAY
13250 MAXFORCE PRIME
12094 MAXFORCE WHITE IC
13055 PIRON MIERENLOKDOOS (afgeleides: 13104 FINION MIERENLOKDOOS; 13127 HGX MIERENLOKDOOS; 13073 MAXFORCE LN MIERENLOKDOOS; 13072 PIRON MIERENLOKDOOS; 13121 POKON MIEREN STOP LOKDOOS; 13124 ROXASECT MIERENLOKDOOS)
12952 BAYTHION MIERENMIDDEL N (afgeleides: 13026 HGX KORRELS TEGEN MIEREN; 12974 MAXFORCE LN; 13052 MIERENSTOP; 12979 PIRON MIERENMIDDEL; 12980 POKON MIEREN; 13024 ROXASECT TEGEN TUINMIEREN
13280 VAPONA RAAMSTICKER (parallel: 13351 ROXASECT RAAMSTICKER)
13369 VLIEGENSTICKER

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met imidacloprid oordeelt het collegeCollege dat bovengenoemde middelen voor dit aspect voldoen aan de toelatingsvoorwaarden vastgelegd in artikel 49 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van van artikel 67 en 68 van de Wgb.

43.4.21 Admire (11483) en Admire O-Teq (12942)

Het momenteel toegestane gebruik van Admire (toelatingnr. 1143) en parallelle toelatingen Imex-imidacloprid (toelatingnr. 11547) en Kohinor 70 WG (toelatingnr. 13363) en Admire O-Teq (toelatingnr. 12942) in kassen laat een risico zien voor wilde bestuivers. Dit risico kan afdoende gereduceerd worden door de volgende extra restrictie:

> *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.*

Verder moeten telers erop geattendeerd worden dat ingezette bestuivers schadelijke effecten kunnen ondervinden. Dit wordt bereikt met de volgende zin:

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.

Het momenteel toegestane gebruik in het veld laat een verhoogd risico zien voor bijen door verwaaiing van het gewasbeschermingsmiddel bij het toepassen door spuiten (spray drift) in appel- en peerboomgaarden. Dit risico kan afdoende gereduceerd worden door de volgende extra driftreducerende maatregelen:

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.*

De risico's voor bijen middels blootstelling aan door de plant in het systeem opgenomen imidacloprid dat via nectar en pollen bij foeragerende bijen terecht komt, zijn acceptabel mits bespuiting van de bloemknoppen wordt voorkomen. Dit wordt voor het gewas zelf bereikt met de volgende gebruiksbeperkingen (alleen de toepassingen waarvan de tekst is gewijzigd zijn weergegeven):

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.

Voor onkruid is deze route acceptabel met de volgende restrictie:

Na een spuittoepassing percelen nog minimaal twee weken vrijhouden van bloeiende onkruiden.

Tenslotte blijkt dat blootstelling van bijen bij het toegestane gebruik van Admire en Admire O-Teq niet uitgesloten kan worden doordat resten imidacloprid in de bodem opgenomen kunnen worden door vervolggewassen en vervolgens via de nectar en pollen van deze vervolggewassen doorgegeven worden aan bijen. Deze risico's kunnen gereduceerd worden met de volgende gebruiksbeperkingen (alleen de toepassingen waarvan de tekst is gewijzigd zijn weergegeven):

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel:

In de onbedekte teelt van bloemisterijgewassen

- *door middel van een gewasbehandeling vóór de bloemknoppen zichtbaar zijn, met dien verstande dat er binnen 6 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;*
- *door middel van een gewasbehandeling na de bloei, met dien verstande dat er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;*

in de onbedekte teelt van en ten behoeve van de teelt van bloembol-, knol-, knolbloem- en bolbloemgewassen

- *door middel van een éénmalige gewasbehandeling vóór de bloemknoppen zichtbaar zijn;*
- *door middel van een gewasbehandeling na de bloei of na het koppen, met dien verstande dat toepassing alleen is toegestaan indien er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;*

in de onbedekte teelt van en ten behoeve van de onbedekte teelt van bloembol-, knol-, knolbloem- en bolbloemgewassen met uitzondering van grofbollige narcissen 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, en er binnen 10 maanden na planten geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;

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 is toegestaan vóór de bloemknoppen zichtbaar zijn en indien er binnen 6 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;*
- *door middel van een gewasbehandeling, met dien verstande dat in gewassen die in bloei kunnen komen toepassing is toegestaan na de bloei en indien er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;*

In de pennenteelt van witlof door middel van een behandeling in de zaaivoor, met dien verstande dat er binnen 2 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden.

In de onbedekte teelt van bloemisterijgewassen door middel van een gewasbehandeling vóór de bloemknoppen zichtbaar zijn alsmede na de bloei, waarbij toepassing voor de bloemknoppen zichtbaar zijn alleen is toegestaan indien er binnen 6 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden, en toepassing na de bloei alleen is toegestaan indien er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden.

in de onbedekte teelt van en ten behoeve van de onbedekte teelt van bloembol-, knol-, knolbloem- en bolbloemgewassen door middel van een éénmalige gewasbehandeling vóór de bloemknoppen zichtbaar zijn alsmede na de bloei of na het koppen, met dien verstande dat toepassing na de bloei of na het koppen alleen is toegestaan indien er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden.;

in de onbedekte teelt van en ten behoeve van de onbedekte teelt van bloembol-, knol-, knolbloem- en bolbloemgewassen met uitzondering van grofbollige narcissen 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, en er binnen 10 maanden na planten geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden.

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; waarbij toepassing vóór de bloemknoppen zichtbaar zijn alleen is toegestaan indien er binnen 6 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden, en toepassing ná de bloei alleen is toegestaan indien er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden.

In de pennenteelt van witlof door middel van een behandeling in de zaaivoor, met dien verstande dat er binnen 2 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden.

De overige blootstellingsroutes laten voor het toegestane gebruik van Admire en Admire O-Teq volgens het huidige wettelijk gebruiksvoorschrift geen onaanvaardbare risico's zien.

Commented [...]: Idem als bij Actara

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met imidacloprid oordeelt het collegeCollege dat voor dit aspect het toegestane gebruik van Admire (toelatingnr. 1143) en parallelle toelatingen Imex-imidacloprid (toelatingnr. 11547) en Kohinor 70 WG (toelatingnr. 13363) en Admire O-Teq (toelatingnr. 12942) voldoetn aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb onder voorwaarde van het opnemen van extra gebruiksrestricties.

In overeenstemming met bovenstaande voorwaarden is door de toelatinghouder een aanvraag tot wijziging van het WGGA ingediend. Het collegeCollege oordeelt dat het gebruik volgens het gewijzigde WGGA voor het aspect risico's voor bijen voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb en heeft besloten de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 41 van de Wgb te honoreren.

43.4.23 Admire

Uit de herbeoordeling blijkt dat blootstelling van bijen bij het toegestane gebruik van Admire (toelatingnr. 13178) als traybehandeling of fytodrip in kolen niet uitgesloten kan worden doordat resten imidacloprid in de bodem opgenomen kunnen worden door vervolggewassen en vervolgens via de nectar en pollen van deze vervolggewassen doorgegeven worden aan bijen. Deze risico's kunnen gereduceerd worden met de volgende gebruiksbeperkingen:

> *Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel met maximaal 1 toepassing per teelt, met dien verstande dat er binnen 6 maanden na planten geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden.*

De overige blootstellingsroutes laten voor het toegestane gebruik geen onaanvaardbare risico's zien.

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met imidacloprid oordeelt het collegeCollege dat voor dit aspect het toegestane gebruik van Admire (toelatingnr. 13178) voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb onder voorwaarde van het opnemen van extra gebruiksrestricties.

In overeenstemming met bovenstaande voorwaarden is door de toelatinghouder een aanvraag tot wijziging van het WGGA ingediend. Het collegeCollege oordeelt dat het gebruik volgens het gewijzigde WGGA voor het aspect risico's voor bijen voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb en heeft besloten de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 41 van de Wgb te honoreren.

43.4.35 Monami (13059) en Amigo Flex (11662)

Uit de herbeoordeling blijkt dat blootstelling van bijen bij het toegestane gebruik van Monami en Amigo Flex niet uitgesloten kan worden doordat resten imidacloprid in de bodem opgenomen kunnen worden door vervolggewassen en vervolgens via de nectar en pollen van deze vervolggewassen doorgegeven worden aan bijen. Deze risico's kunnen gereduceerd worden met de volgende gebruiksbeperkingen:

> *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.*

De overige blootstellingsroutes laten voor het toegestane gebruik geen onaanvaardbare risico's zien.

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met imidacloprid oordeelt het collegeCollege dat voor dit aspect het toegestane gebruik van Monami (toelatingnr. 13059) en Amigo Flex (toelatingnr. 11662) voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb onder voorwaarde van het opnemen van extra gebruiksrestricties.

In overeenstemming met bovenstaande voorwaarden is door de toelatinghouder een aanvraag tot wijziging van het WGGA ingediend. Het collegeCollege oordeelt dat het gebruik volgens het gewijzigde WGGA voor het aspect risico's voor bijen voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb en heeft besloten de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 41 van de Wgb te honoreren.

43.4.46 Gaucho Tuinbouw (12341)

Uit de herbeoordeling blijkt dat blootstelling van bijen bij het toegestane gebruik van Gaucho Tuinbouw in sla en andijvie niet uitgesloten kan worden doordat resten imidacloprid in de bodem opgenomen kunnen worden door vervolggewassen en vervolgens via de nectar en pollen van deze vervolggewassen doorgegeven worden aan bijen. Deze risico's kunnen gereduceerd worden met de volgende gebruiksbeperking (alleen de toepassingen waarvan de tekst is gewijzigd zijn weergegeven):

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel voor de behandeling van zaden, (zaadcoating of dummy-pil techniek en voor toepassing a en b ook de phytodriptechniek) voor de

a) opkweek ten behoeve van de onbedekte teelt van sla (met uitzondering van veldsla), Radicchio rosso, groenlof en andijvie, met dien verstande dat maximaal 100.000 planten per hectare worden uitgeplant indien de hoge dosering wordt toegepast en dat binnen een periode van 10 maanden gerekend vanaf uitplanten op het veld geen voor bijen aantrekkelijke gewassen worden gezaaid of geplant;

De overige blootstellingsroutes laten voor het toegestane gebruik geen onaanvaardbare risico's zien.

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met imidacloprid oordeelt het collegeCollege dat voor dit aspect het toegestane gebruik van Gaucho Tuinbouw (toelatingnr. 12341) voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb onder voorwaarde van het opnemen van extra gebruiksrestricties.

In overeenstemming met bovenstaande voorwaarden is door de toelatinghouder een aanvraag tot wijziging van het WGGA ingediend. Het collegeCollege oordeelt dat het gebruik volgens het gewijzigde WGGA voor het aspect risico's voor bijen voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb en heeft besloten de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 41 van de Wgb te honoreren.

43.4.57 Provado Garden, Admire N en Gazon-insect

De risico's voor bijen middels blootstelling aan door de plant in het systeem opgenomen imidacloprid dat via nectar en pollen bij foeragerende bijen terecht komt, zijn acceptabel mits bespuiting van de bloemknoppen wordt voorkomen. Dit kan voor appel- en

peerboomgaarden aan de niet-professionele gebruiker duidelijk worden gemaakt met een bijsluiter bij het WG met daarin plaatjes die de juiste toepassingsstadia laten zien.
Voor siergewassen dient de toepassing vóór de bloei uitgesloten te worden, omdat het voor de vele verschillende siergewassen momenteel niet mogelijk is met plaatjes het juiste toepassingsstadium aan te geven.
Een acceptabel risico wordt bereikt met de volgende gebruiksbeperkingen (alleen de toepassingen waarvan de tekst is gewijzigd zijn weergegeven):

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel;

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

- in appels en peren in de tuin of particuliere boomgaard, door middel van een gewasbehandeling met een maximum aantal behandelingen van totaal twee keer per seizoen, met uitzondering van de periode dat de bloemknoppen zichtbaar zijn (zie bijsluiter).

De overige blootstellingsroutes laten voor het toegestane gebruik geen onaanvaardbare risico's zien.

En de afgeleide toelatingen Admire N (toelatingnr. 12945); Gazon-insect (toelatingnr. 12919)

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met imidacloprid oordeelt het collegeCollege dat voor dit aspect het toegestane gebruik van Provado Garden (toelatingnr. 12115) en de afgeleide toelatingen Admire N (toelatingnr. 12945); Gazon-insect (toelatingnr. 12919) voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb onder voorwaarde van het opnemen van extra gebruiksrestricties.

In overeenstemming met bovenstaande voorwaarden is door de toelatinghouder een aanvraag tot wijziging van het WGGA ingediend. Het collegeCollege oordeelt dat het gebruik volgens het gewijzigde WGGA voor het aspect risico's voor bijen voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb en heeft besloten de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 41 van de Wgb te honoreren.

Advies : Het College stelt vast dat het middel Provado GardenROVADO GARDEN (toelatingnr. 12115) en afgeleide toegelaten middelen -Admire N (toelatingnr. 12945); Gazon-insect (toelatingnr. 12919) voldoen aan de toelatingsvoorwaarden voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit, onder voorwaarde dat deze toelatingsbesluiten niet worden vernietigd door het ministerie van EL&I, de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 41 van de Wgb te honoreren

43.4.66 Maxforce Quantum

De herbeoordeling laat zien dat er een mogelijk risico is voor bijen als de gel ter bestrijding van mieren wordt aangebracht op plekken die toegankelijk zijn voor bijen. Met de volgende aanpassingen in het WG wordt blootstelling van bijen voorkomen en is het risico acceptabel:

Bij gebruik buiten mag het middel uitsluitend worden aangebracht in de nestingangen van mierennesten.

Commented [ ]: Wie weet later met smartphones?

~~Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met imidacloprid oordeelt het college dat voor dit aspect het toegestane gebruik van Maxforce Quantum (toelatingnr. 13074) voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb onder voorwaarde van het opnemen van extra gebruiksrestricties.~~

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met imidacloprid ~~thiamethoxam~~ oordeelt het ~~college~~College dat voor dit aspect het toegestane gebruik van Maxforce Quantum (toelatingnr. 13074) voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 49 van de Wgb onder voorwaarde van het opnemen van extra gebruiksrestricties.

In overeenstemming met bovenstaande voorwaarden is door de toelatinghouder een aanvraag tot wijziging van het WGGA ingediend. Het ~~college~~College oordeelt dat het gebruik volgens het gewijzigde WGGA voor het aspect risico's voor bijen voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 49 van de Wgb en heeft besloten de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 68 van de Wgb te honoreren.

3.5 Fipronil

Fipronil wordt toegepast in drie gewasbeschermingsmiddelen voor professioneel gebruik met een toepassing als zaadcoating en in twee biociden voor professioneel gebruik voor de bestrijding van kakkerlakken (zie tabel).

Gewasbeschermingsmiddelen

toelatingnr	Middel-naam	Toelatinghouder	werkzame stoffen	dosering	Prof/ Niet-prof	Formulering	Toepassin
12802	MUNDIAL	BASF Nederland B.V.	fipronil 500G/L	1x 5-20 g a.s./ha	Prof	Suspensie concentraat voor zaadbehandeling	zaadcoating in bloemkool, boerenkool, broccoli, rodekool, savooienkool spitskool, spruitkool en witte kool.
12977	MUNDIAL	LTO Nederland (LTO coördinator middelenpakket vollegrondsgroenten)	fipronil 500G/L	1x 5-15 g a.s./ha	Prof	Suspensie concentraat voor zaadbehandeling	zaadcoating in Chinese kool, Oosterse bladkolen en koolrabi.
13384	MUNDIAL	Productschap Akkerbouw	fipronil 500G/L	1x 100 g a.s./ha	Prof	Suspensie concentraat voor zaadbehandeling	zaadcoating in uien en sjalotten

Biociden

toelatingnr	middelnaam	Toelating houder	werkzame stoffen	Prof/ Niet-prof	formulering	Toepassing
12119	GOLIATH AASSTATIONS	BASF Nederland	fipronil 0,05%	Prof	lokaas	Bestrijding van kakkerlakken in

		B.V.				gebouwen.
12120	GOLIATH GEL	BASF Nederland B.V.	fipronil 0,05%	Prof	lokaas	Bestrijding van kakkerlakken in gebouwen.

De toegelaten toepassingen zijn beoordeeld op de risico's voor bijen middels directe en indirecte blootstelling. Bij directe blootstelling komt het insecticide tijdens of na de toepassing rechtstreeks bij bijen terecht. Bij indirecte blootstelling wordt fipronil als systemisch werkend insecticide opgenomen door de plant en komt via deze route bij de bij terecht.

Commented [5.1.2.e]: Biociden?

Commented [illegible]: Er is gekeken of de route relevant is. Voor de goliaths is dat niet zo. Daar heb je alleen een mogelijk risico via directe blootstelling, maar omdat ze binnen gebruikt worden valt dat ook weg.

Bij bepaling van de directe blootstelling is gelet op de risico's tijdens of vlak na het zaaien voor bijen aanwezig in het veld en en op de risico's voor bijen buiten het veld door blootstelling via verwaaid stof van behandeld zaad. Bij bepaling van de indirecte risico's voor bijen is onderzocht wat de blootstelling is middels residuen in nectar en pollen van de behandelde gewassen, middels bloeiende onkruiden of vervolggewassen die in de bodem aanwezige resten fipronil opnemen, middels guttatie en de blootstelling via door bladluizen geproduceerde honingdauw.

Commented [5.1.2.e]: Biociden?

Bij de bepaling van de risico's van de biocidentoepassingen is gekeken of de middelen zodanig worden toegepast dat ze toegankelijk zijn voor bijen.

De uitgebreide risicobeoordeling van de middelen op basis van fipronil is opgenomen in bijlage xxx~~.~~. In de hiernavolgende paragrafen worden de belangrijkste resultaten van de beoordeling weergegeven.

3.5.1 Goliath Aasstations, Goliath Gel, Mundial (13384)

Bij het toegestane gebruik van de ~~gewasbeschermingsmiddelen~~ biociden Goliath aasstations (toelatingnr 12119), Goliath Gel (toelatingnr 12120) en het gewasbeschermingsmiddel Mundial (toelatingnr. 13384) treden geen onaanvaardbare risico's voor bijen op door blootstelling middels de hierboven beschreven routes.

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met ~~thiamethoxam~~ fipronil oordeelt het ~~college~~College dat Goliath aasstations (toelatingnr 12119), Goliath Gel (toelatingnr 12120) en Mundial (toelatingnr. 13384) voor dit aspect voldoen aan de toelatingsvoorwaarden vastgelegd in artikel 49 resp. artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van ~~van~~ artikel 67 en 68 resp. 40 en 41 van de Wgb.

3.5.2 Mundial (12802), Mundial (12977)

Bij blootstelling van bijen bij het toegestane gebruik van Mundial (toelatingnrs. 12802 en 12977) kan niet uitgesloten worden dat fipronil via door bladluizen geprod~~u~~uceerde honingdauw bij bijen terechtkomt. Dit risico kan gereduceerd worden met de volgende gebruiksbeperking:

> *De toepasser dient de afnemer van zaden en/of planten er schriftelijk van op de hoogte te stellen dat bladluizen zodanig bestreden moeten worden dat er geen honingdauw wordt gevormd waar bijen op af kunnen komen.*

De overige blootstellingsroutes laten voor het toegestane gebruik van Mundial (toelatingnrs. 12802 en 12977) geen onaanvaardbare risico's zien.

Op basis van de resultaten van de beoordeling van de risico's voor bijen van de middelen met ~~imidacloprid~~ fipronil oordeelt het ~~college~~College dat voor dit aspect het toegestane gebruik van Mundial (toelatingnrs. 12802 en 12977) voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb onder voorwaarde van het opnemen van extra gebruiksrestricties.

In overeenstemming met bovenstaande voorwaarden is door de toelatinghouder een aanvraag tot wijziging van het WGGA ingediend. Het ~~college~~College oordeelt dat het gebruik volgens het gewijzigde WGGA voor het aspect risico's voor bijen voldoet aan de toelatingsvoorwaarden vastgelegd in artikel 28 van de Wgb en heeft besloten de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 41 van de Wgb te honoreren.

4 Conclusie en signaleringen

Het College voor de Toelating van Gewasbeschermingsmiddelen en Biociden heeft 55 gewasbeschermingsmiddelen en biociden op basis van de actieve stoffen clothadinin, thiamethoxam, imidacloprid of fipronil opnieuw individueel beoordeeld met betrekking tot de effecten op de gezondheid van bijen. Op basis van de resultaten van deze herbeoordeling aan de hand van het meest actuele toetsingskader, concludeert het College dat voor 38 middelen de toelatingen voor dit aspect voldoen aan de toelatingscriteria zoals gesteld in art 28 en 49 Wgb en op dit moment voor die middelen geen reden is om in te grijpen in de toelating.

Aanvullende gebruiksrestricties
Voor 14 middelen concludeert het ~~college~~College dat het toegelaten gebruik bij toepassing van het meest actuele toetsingskader niet meer voldoet aan ~~het meest recente toetsingskader~~de toelatingscriteria. Met aanvullende gebruiksrestricties voldoen deze toepassingen wel aan de meest recente eisen met betrekking tot het vermijden van risico's op effecten op de gezondheid van bijen. In al deze gevallen is door de toelatinghouder een wijziging aangevraagd van het wettelijk gebruiksvoorschift en gebruiksaanwijzing (WGGA) op basis van art 41, lid 2 Wgb of artikel 68, lid 2. Het College honoreert deze aanvragen tot wijziging waarmee ~~Met deze wijziging wordt~~ het gebruik in overeenstemming wordt gebracht met de actuele eisen die de wet conform art 28 en 49 Wgb aan een toelating stelt.

Een ingrijpen door het College op basis van art. 41, lid 3 Wgb of art. 68, lid 3 Wgb, waarbij een besluit genomen wordt tot ambtshalve wijziging van de toelating of tot een tijdelijk verbod of tijdelijke inperking van het gebruik en het voorhanden hebben van het middel, is voor geen van de 55 bestrijdingsmiddelen die herbeoordeeld zijn aan de orde.

Geschorste toelatingen
Voor drie middelen voor particulier gebruik, Provado Garden, Gazon Insect en Admire N, heeft de staatsecretaris van Economische zaken, Landbouw en Innovatie op 31 mei j.l. de toelating geschrorst totdat nader onderzoek heeft uitgewezen dat de desbetreffende middelen daadwerkelijk geen onaanvaardbare effecten hebben op bijen. Deze drie middelen zijn eveneens in de herbeoordeling betrokken en de risico's van het gebruik van deze middelen op effecten op de gezondheid van bijen zijn beoordeeld. Op grond van de resultaten van deze beoordeling concludeert het College dat voor deze toepassing van deze middelen ~~er~~ met een aanvullende gebruiksrestrictie geen onaanvaardbare effecten op bijen te verwachten zijn.

Verband tussen neonicotinoïden en bijensterfte
In een recent rapport van de Verenigde Naties (UNEP 2011) worden achteruitgang van de leefomgeving, toename van ziekten, toename van plagen, gebruik van bestrijdingsmiddelen, bijenverzorging en klimaatverandering genoemd als mogelijke oorzaken van de wereldwijd waargenomen bijensterfte genoemd.
Op grond van een analyse van de momenteel beschikbare ~~gegevens~~wetenschappelijke literatuur is echter niet de conclusie te trekken dat neonicotinoïden of fipronil significant bijdragen aan de achteruitgang van de bijenstand.

Signaleringen
Het College signaleert verder de volgende punten, die met deze herbeoordeling naar voren zijn gekomen:

~~D~~de gangbare werkwijze van het College bij tussentijds beschikbaar komen van informatie die betrekking heeft op de risico's van een lopende toelating.

Commented [5.1.2.e]: Het moet zijn: het vermijden van risico' voor bijen óf: het vermijden van effecten op de gezondheid van bijen, maar niet deze verhaspeling

Commented [5.1.2.e]: Het moet zijn: en de risico' van het gebruik voor bijen zijn beoordeeld óf: en de effecten op de gezondheid van bijen zijn beoordeeld, maar niet deze verhaspeling

Commented [5.1.2.e]: Het gaat over openbare literatuur, is dat nu duidelijker?

Commented [5.1.2.e]: 5.2.1 zijn bij het huidige gebruik voor 14 middelen mogelijke risico's gevonden. Die risico' worden nu ingeperkt en daarmee een eventuele bijdrage van gewasbeschermingsmiddelen en biociden beperkt. Bovendien zijn alleen individuele middelen beoordeeld en is helemaal niets gezegd over cumulatieve effecten, laat staan mogelijke synergistische effecten.

De gangbare werkwijze van het Ctgb is dat het zich op de hoogte houdt van de maatschappelijke ontwikkelingen en wetenschappelijke inzichten aangaande de risico's van het gebruik van toegelaten gewasbeschermingsmiddelen en biociden.

Indien deze ontwikkelingen of inzichten aanleiding geven om te veronderstellen dat er bijzondere nog niet eerder onderkende en onaanvaardbare risico's van het toegestane gebruik optreden maakt het College deze middelen onderwerp van nader onderzoek. In het verleden is dat bijvoorbeeld gebeurd na het incident met een neonicotinoide in Duitsland. Dit heeft ertoe geleid dat het Ctgb extra risicoreducerende maatregelen heeft voorgeschreven ~~heeft~~ voor de toepassing van deze middelen.

Tussentijdse toetsing aan de criteria van de wet zoals vastgelegd in art 28 en 49 Wgb gebeurt dus enkel als er bijzondere aanwijzingen zijn dat het toegelaten gebruik onaanvaardbare risico's met zich meebrengt. In alle andere gevallen vindt een integrale herbeoordeling van de risico's plaats op het moment dat de termijn van de toelating vervalt en opnieuw een registratie wordt aangevraagd. Deze termijn is voor een reguliere toelating gesteld op 10 jaar, of korter afhankelijk van vereisten voortkomend uit de plaatsing van een werkzame stof op Annex 1 van de plaatsingsrichtlijn. Voor de middelen die onderwerp zijn van de onderhavige herbeoordeling zal deze wettelijk voorgeschreven herregistratie, plaatsvinden in de periode 30-9-2011 tot 1-11-2018. Een en ander afhankelijk van de datum van plaatsing van de werkzame stof op de plaatsingsrichtlijn. Bij deze herregistratie zullen voor alle 55 middelen uit deze herbeoordeling alle aspecten opnieuw beoordeeld worden.

Handhaving van professioneel gebruik
In kader van deze herbeoordeling heeft overleg plaatsgevonden met toelatinghouders en de nVWA. In afstemming met hen zijn voor het professioneel gebruik uitvoerbare, naleefbare, en handhaafbare risico mitigerende maatregelen geformuleerd voor opname in het WG/GA. Deze maatregelen worden voorgeschreven ten einde het risico voor bijen weg te nemen. Handhaving op deze voorschriften speelt een belangrijke rol bij de daadwerkelijke naleving van de opgelegde mitigerende maatregelen. Het College vraagt hier extra aandacht voor, met name bij met neonicotinoiden behandelde bloembollen die niet tot bloei mogen komen om blootstelling van bijen te voorkomen.

Mitigerende maatregelen voor non-professioneel gebruik
Recent zijn gebruiksrestricties voor niet professioneel gebruik onderwerp van discussie geworden. Het College constateert dat het zinvol is om op dit terrein beleid te ontwikkelen dat (internationaal) duidelijkheid moet scheppen ten aanzien van het voorschrijven van risico mitigerende maatregelen bij niet-professioneel gebruik. Hierbij speelt een rol dat niet-professionele gebruikers, in tegenstelling tot professionele gebruikers, niet geschoold zijn in het toepassen van bestrijdingsmiddelen en de mogelijkheid bestaat dat complexe mitigerende maatregelen niet of niet volledig worden opgevolgd. Niet-professionele gebruikers vallen niet onder de controle van handhavende instanties.

In de *Central Zone Steering Committee*, waarin wordt gesproken met de andere Europese toelatingsinstanties voor gewasbeschermingsmiddelen, blijkt dat ook hier de behoefte bestaat aan beleid ten aanzien van risicomitigerende maatregelen bij niet-professioneel gebruik. Het Ctgb is graag bereid u van advies te voorzien over de praktische invulling van voorgenomen beleid.

Overschrijding oppervlakte water
De afgelopen jaren zijn overschrijdingen van het MTR door de gemeten concentratie imidacloprid in het oppervlakte water geconstateerd. Deze overschrijding heeft geen gevolgen in het kader van deze herbeoordeling aangezien de blootstelling van bijen via oppervlakte water niet relevant is. Dit blijkt uit de beoordelingen opgenomen in Bijlage II. Deze overschrijdingen kunnen wel relevant zijn binnen de beoordeling van het risico voor waterorganismen.

Commented [5.1.2e]: Ik begrijp niet waarom dit stuk hier is opgenomen. Wat wil je hiermee signaleren? Het lijkt mij geen signaal maar een beschrijving van de gebruikelijke werkwijze die wellicht in paragraaf 1.2 past

Commented [5.1.2e]: Anders formuleren! Hier staat in feite dat er wel risico's zijn en even hierboven beweer je dat die er niet zijn...

Commented [5.1.2e]: Plotseling duikt hier een "U" op. Hou de tekst neutraal, dat is die overal!

Commented [5.1.2e]: Afkorting verklaren!

Op dit moment wordt, in opdracht van de ministeries van EL&I en I&M, toetsingskader ontwikkeld hoe om te gaan met dit type overschrijdingen gedurende de looptijd van een toelating. Op basis van deze ontwikkelingen zal het College de eventueel verdere nooodzakelijke risicobeperkende maatregelen treffen.

Communicatie

Om de effectiviteit van de opgelegde gebruiksbeperkingen te vergoten is het van belang de resultaten van de herbeoordeling en het belang van een juist gebruik van de middelen te communiceren naar telers, gebruikers en voorlichters.
Om eventuele risico's te beperken dient de meest recente informatie verwerkt te worden in een lijst van gewassen die aantrekkelijk zijn voor bijen. Deze lijst kan geraadpleegdt worden door telers bij toepassing van het middel.

Commented [5.1.2.e]: Dit anders omschrijven, waarom hier spreken over eventuele risico's?? Ik denk dat het hier gaat om **verkeerd gebruik**. Beperk het gebruik van het woord 'risico' tot de risico's die getoetst worden en die voortkomen uit het toegestane gebruik!

5.1.2.e **groot gemis vind ik dat er helemaal niets in staat over cumulatieve effecten. Individuele stoffen en producten worden beoordeeld. Voor individuele producten worden mogelijke risico' gevonden. Is het dan niet zeer aannemelijk dat er grote kans bestaat dat de combinatie van al die middelen aanleiding geeft tot risico's?**

5.2.1 [redacted]

5.1.2.e Bij beoordelingsmethodiek of signalering zou zoiets kunnen:

De effecten van combinaties van bestrijdingsmiddelen op organismen worden momenteel alleen beoordeeld als gecombineerde toepassing specifiek op het etiket staat.

Maar ik denk dat daar allang heel vaak ook in communicatieberichten stukjes over gemaakt zijn die beter zijn?!

Bijlagen

Bijlage I Motie Ouwehand
Bijlage II Beoordelingen
Bijlage III Aangepaste WGGA 's
Bijlage IV Europees en EPPO kader
Bijlage V Lijst met voor bijen aantrekkelijke gewassen
Bijlage VI Lijst met afkortingen
Bijlage VII Collegebesluiten

Bijlage I motie Ouwehand; kamernr II 2009/10 nr 32372 nr 19

'Motie 19' van Mevr. Ouwehand (Partij voor de Dieren) is op 17 februari 2011 door de Tweede Kamer aangenomen. De motie luidt:
De Kamer,
gehoord de beraadslaging,
constaterende dat wetenschappers een verband zien tussen bestrijdingsmiddelen die behoren tot de klasse neonicotinoïden en de voortgaande bijensterfte;
constaterende dat bij de toelating van bestrijdingsmiddelen onvoldoende rekening is gehouden met de (cumulatieve) effecten van deze middelen op de gezondheid van de bijenpopulatie;
overwegende dat de regering aangeeft dat er meer onderzoek nodig is om dit verband inderdaad vast te stellen;
verzoekt de regering, de reeds toegelaten bestrijdingsmiddelen die behoren tot de klasse neonicotinoïden opnieuw te toetsen op de effecten op de gezondheid van bijen, en hierbij ook expliciet eventuele sublethale effecten mee te nemen,
en gaat over tot de orde van de dag.

Bijlage xxx Aanpassing plaatsingsrichtlijn

Clothianidin is placed on Annex I of 91/414/EEG since 08/01/2006 (2006/41/EC).
In Commission Directive 2010/21/EU, the Inclusion Directive of clothianidin was amended with additional provisions to avoid accidents with seed treatments. The provisions relevant for honeybees are now as follows:

Only uses as insecticide may be authorised.
For the protection of non-target organisms, in particular honey bees, for use as seed treatment:
- the seed coating shall only be performed in professional seed treatment facilities. Those facilities must apply the best available techniques in order to ensure that the release of dust during application to the seed, storage, and transport can be minimised,
- adequate seed drilling equipment shall be used to ensure a high degree of incorporation in soil, minimisation of spillage and minimisation of dust emission.
Member States shall ensure that:
- the label of the treated seed includes the indication that the seeds were treated with clothianidin 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 clothianidin in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.";

Bijlage II Beoordelingen

Bijlage II-1 clothianidin

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 clothianidin. Deze middelen zijn in onderstaande tabel weergeven.

Gewasbeschermingsmiddelen op basis van clothianidin

toelating nr	middelnaam	toelatinghouder	werkzame stoffen	toepassing	formulering	Toepassing(en)
13044	PONCHO BETA	Bayer CropScience B.V.	clothianidine 400G/L # beta-cyfluthrin 53,3G/L	Professioneel	Suspensie concentraat voor zaadbehandeling	zaadcoating in bieten
13276	PONCHO ROOD	Bayer CropScience B.V.	clothianidine 600G/L	Professioneel	Suspensie concentraat voor zaadbehandeling	zaadcoating in snij- en korrelmaïs

Er zijn geen biociden en geen niet-professionele middelen toegelaten op basis van clothianidin.

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

Clothianidin is placed on Annex I of 91/414/EEG since 08/01/2006 (2006/41/EC).
In Commission Directive 2010/21/EU, the Inclusion Directive of clothianidin was amended with additional provisions to avoid accidents with seed treatments. The provisions relevant for honeybees are now as follows:

"PART A

Only uses as insecticide may be authorised.

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

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

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

Member States shall ensure that:

- the label of the treated seed includes the indication that the seeds were treated with clothianidin 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 clothianidin in areas extensively used by bees for foraging or by beekeepers, where and as appropriate.";

The risk assessment is based on the final LoE of October 2005 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 - seed treatments

toelating nr	middelnaam	toelatinghouder	werkzame stoffen	dosering	formulering	Toepassing(en)
13044	PONCHO BETA	Bayer CropScience B.V.	clothianidine 400G/L & beta-cyfluthrin 53.3G/L	1× 60 g a.s./ha (clothianidin)	Suspensie concentraat voor zaadbehandeling	zaadcoating in bieten
13275	PONCHO ROOD	Bayer CropScience B.V.	clothianidine 600G/L	1× 50 g a.s./ha	Suspensie concentraat voor zaadbehandeling	zaadcoating in snij- en kuilmais

Risk assessment for bees

Exposure to honeybees may occur via several routes, which will be discussed separately below.

Direct exposure
Direct exposure to clothianidin should be avoided because of its high acute toxicity to bees (LD_{50} = 0.00379 and 0.04426 μg a.s./bee (oral and contact, respectively) according to the LoE. It is noted that on May 29th 2011, the applicant submitted a new acute toxicity study to honeybees which showed slightly lower values: 0.0025 and 0.0399 μg a.s./bee for oral and contact toxicity, respectively. This new study (Schmitzer 2008) was submitted too late for full evaluation and is not essential for the risk assessment as the EU-agreed endpoint is in the same range (indicating the high toxicity of the active substance). Therefore, the new study is not included in the current risk assessment.

1) In-field
In-field exposure during sowing is not expected for the proposed uses, because they are seed treatment uses.

2) Off-field - dust from treated seed

Dust drift from seed is a relevant exposure route for the use in beets and maize, because the seeds are sown outside. The risk that dust from the seed coating reaches neighbouring crops or other flowering plants and in that way exposes bees to the a.s., depends on the type of coating in combination with the type of sowing. This assessment is based on the dust drift matrix available at www.ctgb.nl.

Sowing of beets is done mechanically and seeds have a film coating. No dust drift is expected. The recently submitted studies on dust drift from sugar beet sowing (see LoE, section *dust deposition sugarbeet*) confirm this expectation. 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.

The worst case value for drift outside the field when maize sowing is done according to these restrictions is 0.55% of applied dose (at 5 m from the field, see LoE section *dust deposition maize*). This leads to an off-field dose of 0.55% of 50 = 0.28 g a.s./ha.

The NOER for mortality of dust exposure to clothianidin was set at <0.50 g a.s./ha in a cage study (Bakker 2010, LoE section *dust toxicity*). Thus, for the use in maize mortality of honeybees which are exposed to dust from sowing cannot be excluded based on this value and further work (e.g. higher tier studies) is necessary. However, this cage study also showed that mortality returned to normal levels immediately after moving the hives to an uncontaminated area and that no effects of the treatments on colony condition were observed.

Effects from exposure to dust from maize sowing were also studied in a field test (Garrido 2010, LoE section *dust toxicity*). In this study, the application rate was higher than proposed for Poncho Rood (132.9 vs. 50 g a.s./ha). As explained in the study summary in the LoE, it is expected that no adverse long term effects are induced by exposure to low levels of abraded dust from clothianidine dressed maize seeds, released during sowing. This study is still running and the final report, scheduled for summer 2011, will include an assessment of the overwintering performance of the colonies.

In addition to the semi-field and field studies, long-term monitoring studies were performed which studied the effects on honeybee colonies after exposure to dust from maize sowing.

In Germany, monitoring was set up after the dust drift incident with clothianidin-treated maize in 2008 (Liebig 2008 and 2009, LoE section *bee monitoring*). The study authors concluded that even if exposure of dust during sowing of maize seeds has adverse effects on bee colonies, they can recover and succesfully overwinter. This conclusion is probably correct, but the evaluator noted some shortcomings which should be addressed by the applicant (see below).

In four studies (Liepold, 2010 a-d, see LoE section *guttation and dust exposure*) on isolated field plots in France, honey bee colonies were exposed during sowing of maize seeds, seed-treated with clothianidin at a rate of nominally 0.5 mg clothianidin a.s./kernel (50 g a.s./ha) and during the subsequent period when guttation was regularly observed on the maize seedlings . The study author concluded that in none of the studies adverse effects on honey bees and honey bee colonies have been observed, neither during the sowing operation of the clothianidin-treated maize seeds nor during the subsequent growing period of the maize seedlings when guttation occurred. The evaluator accepted this conclusion for guttation and also accepted the conclusion that maize seed drilling (and subsequent guttation of seedlings) had no short term effects on bee colony development during the exposure period (24 days) for one of the four studies (Champagne area). In the other three areas, it was considered not likely that exposure to dust during and shortly after drilling has had considerable effects on bee mortality or colony development during the exposure phase, but there were some shortcomings in the analysis of the data..

The study evaluator remarked that interpretation of most of the long-term studies in France and Germany would be improved by statistical hypothesis testing (e.g. a pre-post repeated measures design). However, statistical analysis of bee field studies is not commonly performed in the current European risk assessment framework; instead, the results are interpreted by expert judgment. Based on expert judgment (of Ctgb and the study evaluator) of the wealth of available data for clothianidin, it is concluded that the long-term effects on honeybee colonies after exposure to dust from maize sowing are acceptable. It is therefore concluded that the risk from dust drift of Poncho Rood is acceptable, 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 (strong wind as defined for spray applications as ≥ 5 m/s). Incidents with maize sowing causing acute mortality of bees foraging on neighbouring areas (in 2008 in Germany, Slovenia and Italy; probably also in 2011 in Slovenia, this incident is still under investigation) show that it is very important that these conditions are met. In the Netherlands, increased 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.'

Thus, with these restrictions and based on the available data for clothianidin, it is concluded that the long-term effects on honeybee colonies after exposure to dust from maize sowing are acceptable.

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 clothianidin 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 risk of the metabolites is considered to be covered by that of the parent, as the metabolites are less or much less toxic than the parent (metabolite TZNG is of moderate toxicity to bees: acute LD_{50} = 3.9 µg TZNG/bee; all other metabolites are not toxic to bees, as indicated in the DAR) and in all residue studies the analysed concentrations of TZMU and TZNG in nectar and pollen were below the limit of detection of 0.3 µg/kg. Therefore, only the parent substance clothianidin is considered.

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. For clothianidin, a chronic (10-d) toxicity study with adult bees was done. The 10-d NOEL was 10 µg/L and since the density of the sucrose solution was ca. 1.18 g/cm^3, this corresponds to a value of 8.5 µg/kg. The study author calculated that at this concentration, the cumulative dose over 10 days was 3.8 ng/bee.
Furthermore, a larvae toxicity study indicates that the NOEC for adverse effects on larvae development should be set at 20 µg a.s./kg diet.

Based on these two laboratory studies, the level at which no adverse effects are expected from clothianidin is 8.5 µg/kg.

The applicant also submitted two further laboratory studies (Simoens & Jacobs 2005 a+b). One study aimed at demonstrating whether clothianidin, brought into the bee hive via contaminated pollen, will be transferred to the next generation of honey bees (larvae) via larval food (royal jelly) provided by nurse bees. In the other study, the effect of clothianidin in bee bread (mixture of pollen and honey consumed by nurse bees to produce royal jelly) on food gland development has been determined. According to the applicant, the residue analysis of all royal jelly samples revealed that there is no transfer of clothianidin from the food of nurse bees (bee bread contaminated with 10 µg/kg of clothianidin) to the royal jelly provided to the larvae when the nurse bees are exclusively fed with clothianidin-contaminated bee bread. Moreover, no impact on the development of the brood food glands of nurse bees was found when nurse bees exclusively fed on bee bread, contaminated with 10 µg/kg of clothianidin. These studies were submitted too late (May 26th 2011) to enable a full evaluation. Based on the summary of the applicant, they do not give concerns about the relevant long-term laboratory endpoint, which is now determined for adult bee mortality at 8.5 ppb and for larval development at 20 ppb. The studies are also not required according to the risk assessment scheme. For these reasons, they are not included in the LoE and the current risk assessment but will be evaluated for future risk assessment of clothianidin.

1) Residues in nectar and pollen of the treated crops
Beets are not supposed to flower during cultivation. Therefore, no exposure via nectar or pollen from the treated crop itself will take place.

Maize, however, will flower and bees can collect the pollen from maize. Therefore, the exposure route via maize pollen must be considered.

Several residue studies in maize are available in the DAR (LoE, section *Field or semi-field studies - residue studies)* in which the seeds were treated at the intended use rate. In none of these studies residues of the metabolites TZMU or TZNG in pollen was found (residue usually <0.3 µg a.s./kg (LOD), once < 1 µg a.s./kg (LOQ)). The retrieved residues of clothianidin in maize pollen ranged from 2.1-6.2 µg a.s./kg pollen (mean value not calculated; from here on, 'ppb' will be used instead of µg a.s./kg).
The applicant now submitted an additional residue study in maize (LoE, section *Residues*).
Residue measurements in maize pollen at a worst case dose rate (1.25 mg a.s./seed, as opposed to the proposed 0.5 mg a.s./seed) showed that the mean values of clothianidin in pollen are 3.4 ppb in pollen from plants and 1.1 ppb in pollen taken from bees. Only very exceptionally is a value above the NOEC of 8.5 ppb found.

The risk to adult bees foraging on maize pollen can be estimated by using the data from Rortais et al. (2005), as indicated in EPPO 2010. Nurse bees are expected to consume the highest amount of pollen of all categories of bees: 65 mg/bee in 10 days.

For the chronic risk assessment, mean residue values are appropiate (see EPPO 2010, note 10). The mean residue value in pollen of 3.4 µg/kg (taken from the study with worst-case seed treatment rate of 1.25 mg a.s./seed) leads to a possible intake of clothianidin by nurse bees of (65 mg*3.4 pg/mg=) 0.221 ng/bee in 10 days. This value can be compared to the chronic NOEL for adult bees of 3.8 ng/bee in 10 days, which leads to a TER of 17, indicating a low risk. 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).

Furthermore, since the residues in maize pollen are always below the NOEC for larvae development of 20 ppb, even at a seed treatment rate wich is more than twice as high as the proposed rate, the risk to larvae fed with pollen from treated maize is expected to be low.

Thus, based on the residue levels in pollen and the laboratory endpoints for chronic adult mortality and larvae development, the risk to honeybees from foraging on maize which has been treated with clothianidin is expected to be low. This expectation can be checked by looking at the higher tier studies.

In the DAR of clothianidin, several higher tier studies are presented (see LoE, section *Field or semi-field tests*). Semi-field and field studies are available in which colonies were foraging on seed-treated flowering crops (sunflower and oilseed rape) or fed with treated pollen or honey. No adverse effects on bees were found. However, in all studies in the DAR, the observation period was short, only up to a couple of weeks. This means that less than one full brood cycle was covered during these trials. It was concluded in the DAR that the risk to bees from the uses in maize (53.8 g a.s./ha) and sugar beet (78 g a.s./ha) is acceptable based on the higher tier studies in the DAR. These uses in principle cover the proposed uses in the Netherlands. However, only the risk of exposure via the crop itself was considered and effects on bees were not studied for longer than two weeks. Ctgb considers that the risk of this persistent, systemic substance should be more thouroughly investigated than was done in the DAR.

Studies of longer duration are now available to assess the possible long-term effects of exposure to clothianidin in maize pollen. In France, on three locations long-term exposure studies on honey bees are running (Hecht-Rost and others, LoE section *long-term studies after exposure to flowering maize*), which include overwintering success.

In these studies the same honey colonies are exposed for three years in succession to flowering maize on isolated field plots, which have been grown from maize seeds, seed-treated with clothianidin at a rate of nominally 0.5 mg clothianidin a.s./kernel (nominal dose rate: 50 g a.s./ha; no exposure during sowing, only from foraging on pollen). Exposure lasts for 10-12 days per year, the period of flowering, after which the colonies are transferred to a monitoring site. Residues in maize pollen are low (reported as 1, 3 and 5 µg/kg in the three studies).

The study authors conclude that on the basis of available data in the interim reports, no long-term adverse effects on honey bees and honey bee colonies are induced from exposure to flowering maize grown from clothianidin dressed maize seeds. As indicated in the LoE, one of the three studies was not accepted in its current state (re-analysis of the data is considered necessary). The other two studies however indicate that there are no long term effects induced by exposure to flowering maize grown from clothianidin dressed maize seeds.
The evaluator remarked that interpretation of these long-term studies would be improved by statistical hypothesis testing. However, statistical analysis of bee field studies is not commonly performed in the current European risk assessment framework; instead, the results are interpreted by expert judgment.
Based on the above risk assessment using laboratory data, higher tier studies including multi-year trials, and measured residue data, long-term adverse effects on honeybee colonies when exposed to flowering maize treated with Poncho Rood at the proposed rate are not expected, so the risk is acceptable.

2) Flowering weeds
In the proposed crops, flowering weeds may occur in the field, but exposure via this route is not expected to be very high since a large amount of flowering weeds in fields is adverse to profitable agriculture. Therefore, exposure via this route is expected to be low.

3) Succeeding crops
Based on the persistent nature of clothianidin (in the final LoE, the following values are given for clothiaindin for the $DT_{50,soil}$ (laboratory, 20°C, aerobic): 143-1001 days), it may occur in succeeding crops. This route was not assessed in the DAR. To assess the risk from exposure via succeeding crops, the higher tier studies with flowering crops (sunflower and oilseed rape) available in the DAR will first be considered. In these studies, seeds were directly treated, so they may be seen as worst case for exposure from untreated succeeding crops.

Several studies were done with oilseed rape. During the cage tests, treated rape seed was tested in Sweden, France and Great Britain at the intended use rate. In all these studies no increased mortality or behavioral impacts were observed. Residue analyses were conducted which resulted in maximum 8.6 µg a.s./kg rape nectar sampled by bees and maximum 1.7 µg a.s./kg rape pollen sampled by bees. In addition there is a field study (in Ontario and Minnesota) with an application rate slightly lower than the intended use for oil seed rape. No treatment related effects were observed during this field study. Also two tunnel tests are available, established in summer rape fields in Germany at the intended use seed dressing rate. In both studies no treatment related effect on behavior and mortality could be observed. Analyzed residues : maximum 5.4 µg a.s./kg rape nectar and max. 2.5 µg a.s./kg rape pollen. A study on the residue levels of clothianidin and its relevant metabolites in nectar and pollen of winter rape was conducted. In this study the seeds were treated slightly below the intended use rate. The nectar and pollen contained no residues of clothianidin (below the LOD of 0.3 µg /kg), nor of its metabolites TZMU and TZNG.

Studies were also done with sunflower: There are two tunnel tests available established in sunflower fields in Germany, slightly above the intended use rate. During both tests no effects on behavior were observed. On day 3, high mortality was observed in one test.
This was probably due to an escape trial of a bee swarm. This high mortality on day 3 is not regarded as treatment related. Analyzed residues : maximum 3.1 µg a.s./kg sunflower pollen and < 0.3 µg a.s./kg sunflower nectar (below the limit of detection).
A test was conducted to investigate the effect of treated sunflower honey on the development of small bee colonies. During the test the behavior was not affected. The honey deposition area and the proportion of the comb area occupied by adults were not affected by the treatment. There was no treatment related effect observed on population growth, queen egg laying activity, larval and pupae abundance. The number of dead bees found at the tent edges in the treatment group was slightly higher than in the control but no dose relationship was observed. On day 22 an abnormal high number of dead bees was found in front of the beehive of the 10 µg/kg group. This effect was not dose-response related and arrived just on one single day. Besides these crop dependent studies two more studies were performed.
A field study investigated the effects of treated sugar solution. No treatment related effects on the behaviour could be observed. A raised mortality was observed for the highest test concentration. Therefore the NOEC of this study is established at 20 µg/kg sugar solution. The second test investigated the effects of treated pollen on the development of small bee colonies. The behavior was not affected. The honey deposition area and the proportion of the comb area occupied by adults were not affected by the treatment. There was no treatment related effect observed on the population growth, queen egg laying activity, larval and pupae abundance at 20 µg/kg. No effect on mortality was observed.

The available higher tier trials show that no short-term adverse effects are expected on honeybee colonies when exposed to flowering oilseed rape and sunflower at 50 and 25 g a.s./ha, respectively. It is considered that these studies are relevant to assess the risk of succeeding bee-attractive crops for the proposed uses, even if the use in beets has a slightly higher dose rate. As already noted above, the studies in the DAR are of short duration and do not assess possible long-term effects on bees. They are however useful for their residue measurements. Using the residue measurements, the risk to bees foraging on pollen or nectar can be estimated by using the data on daily intake from Rortais et al. (2005), as indicated in EPPO 2010. For the chronic risk assessment, mean residue values are appropiate (see EPPO 2010, note 10).

The worst-case mean residue value in maize pollen of 3.4 µg/kg (taken from the study with worst-case seed treatment rate of 1.25 mg a.s./seed) is used here (it is noted that this is higher than all residues measured in sunflower and OSR pollen). As already calculated above, at this level a low risk is indicated to bees feeding on pollen. Also, the residues in nectar and pollen of directly treated crops are always below the NOEC for larvae development of 20 ppb. Therefore, the risk to larvae fed with forage from succeeding crops is expected to be low.

Considering nectar, nectar foragers are expected to 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.
Measured residues in sunflower nectar are <0.3 µg/kg (for honey, no measurements are available). The exposure can be calculated as <0.3 ng/g * 0.321 g/bee/day = <0.0963 ng/bee/day. This value compared to the chronic NOEL for adult bees of 0.38 ng/bee/day (calculated from 3.8 ng/bee in 10 days) leads to a TER of >4.

Thus, the expected exposure from foraging on treated sunflower is lower than the NOEL for adults (it is noted that the EPPO scheme does not give a trigger value to compare the TER with). This calculation is based on the worst case intake level for nectar foragers and on a <-value for nectar concentration.
Residue levels in rape nectar indicate a higher level: a maximum level of 8.6 µg/kg was found. Sugar content in rape nectar and rape honey is unknown, but assuming comparable content as sunflower, it is clear that with these levels the TER may be above 1. However, it is also clear that it is a very worst case approach to use measured residue values from directly treated crops for untreated succeeding crops.

Therefore, the applicant has now submitted studies (Neuman *et al.* 2005a,b,c; Przygoda *et al.* 2007a,b) in which the residue levels in nectar and pollen of succeeding crops collected by bees have been investigated. In the studies, a background soil level of clothianidin was applied by spraying 90 g ai/ha which was incorporated 15-20 cm deep.

In two trials succeeding crop maize with or without clothianidin seed treatment were planted 42 to 52 days after the spray application. The plot with both spray application and seed treatment resulted in residue levels of 0.0013 and 0.0019 mg clothianidin/ kg pollen and no TZNG and TZMU was found. A seed treatment-only-scenario resulted in 0.0012 and 0.0018 mg clothianidin / kg pollen and no TZNG and TZMU was found. No residues were found in the trial with only a soil spray application.

In one trial, a crop failure scenario was simulated. Oilseed rape without clothianidin seed treatment was planted 22 days after the spray application. An average of 0.0035 mg clothianidin / kg was found in pollen and 0.00215 mg clothianidin / kg was found in nectar.
No TZNG and TZMU was found in pollen and nectar.

In two trials, a realistic succeeding crop scenario was simulated. Seed treated barley was sown directly after the spray application. After harvest of the barley (11 months after the spray application) untreated seeds of oilseed rape were sown. Up to 0.001 mg /kg clothianidin was found in OSR pollen, no TZNG and no TZMU was found in OSR pollen (<LOQ of 0.001 mg/kg). No clothianidin, TZNG and TZMU was found in OSR nectar (<LOQ of 0.001 mg/kg).

The succeeding crop studies indicate that the residues in pollen are not expected to be higher in treated succeeding crops than in untreated succeeding crops.

The maximum residue level in pollen, 3.5 µg/kg, was found in the crop failure scenario. This value is almost equal to the value of 3.4 µg/kg which has already been shown to be acceptable.

Considering nectar, nectar foragers are expected to 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.
In the crop failure situation, measured residues in oilseed rape nectar are 2.15 µg/kg (for honey, no measurements are available). The exposure can be calculated as 2.15 ng/g * (0.080 - 0.321 g/bee/day) = 0.172 - 0.690 ng/bee/day. This value compared to the chronic NOEL for adult bees of 0.38 ng/bee/day (calculated from 3.8 ng/bee in 10 days) leads to a TER of 2.2 - **0.55**. Thus, the expected exposure from foraging on treated sunflower nectar after a crop failure situation is at the level of the NOEL for adults (it is noted that the EPPO scheme does not give a trigger value to compare the TER with).

In the trials simulating regular succeeding crop scenario's, the maximum level in nectar found was <1 µg/kg. The exposure can be calculated as <1 ng/g * (0.080 - 0.321 g/bee/day) = <0.08 - 0.321 ng/bee/day. This value compared to the chronic NOEL for adult bees of 0.38 ng/bee/day (calculated from 3.8 ng/bee in 10 days) leads to a TER of >4.8 - > 1.2. Thus, in normal crop rotation situations, the risk is acceptable.

Based on these trials, it can be concluded that residues in **pollen** in succeeding crops are at an acceptable level when these crops are sown in soils containing up to 20 µg a.s./kg soil. However, residues in **nectar** in succeeding crops are at an acceptable level only when these crops are sown in soils containing up to 13 µg a.s./kg soil.

It has been calculated for the proposed seed treatment uses after how many days the concentration in soil (calculated over 20 cm; this is considered to be the relevant soil layer) reaches 13 ug/kg soil (0.013 mg/kg). Calculations are based on the maximum non-normalised field DT50 of 305 d (according to HTB 1.0/Evaluation Manual). See the Table below.

Table Number of days to reach residue <0.013 mg/kg soil (20 cm)

Use	Rate [g a.s./ha]	Frequency/ interval (days)	Fraction on soil	Residue in soil < 0.013 mg/kg after ... d (20 cm soil layer)
Seed treatment in beets	60	1/-	1	190 d
Seed treatment in maize	50	1/-	1	110 d

For the use in sugarbeets the residue level is below 13 µg a.s./kg after 190 days (6.3 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 residue levels in soils are almost at an acceptable level after 6 months based on a worst-case calculation (maximum field DT50). Therefore, the risk for flowering succeeding crops is considered acceptable without restriction.

For the use in maize the residue level is below 16 µg/kg after 110 days (3.7 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 cases that flowering crops are grown after a maize crop the residue levels in soils are already at an acceptable level after 4 months. Therefore no restriction is necessary.

The residue trial in which crop failure was simulated indicates that the residue level may be too high in a crop failure situation, and the resowing or replanting period after crop failure would clearly be shorter than 110 or 190 days. However, of the crops in which clothianidin is used, 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 acceptable without specific restrictions.

4) Guttation
Several studies are available in which the risk via guttation from clothianidin-seed-treated crops was considered:
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 (see LoE, section *guttation in sugarbeet*).

In maize, guttation is a much more common phenomenon, which was shown in four trials in France (see LoE, section *guttation and dust exposure in maize*, Liepold 2010 studies).
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 (see LoE, section *guttation and dust exposure in maize*, Lueckmann *et al.* 2010): 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). Therefore, the risk of guttation is acceptable.

<u>*5) Honeydew*</u>
According to the new EPPO scheme (2010), exposure to contaminated honeydew is not considered relevant in the case of soil and seed treatments, unless the compound is highly selective towards non-aphid insects (see note 4 EPPO 2010 scheme). Section B.6.1.6 of the DAR of clothianidin describes the effects achieved and the mode of action on target organisms. It is concluded there that "the biological efficacy of clothianidin against the sucking pests tested is roughly comparable to that of imidacloprid and thiacloprid". Based on this, the applicant states: "*As such, when comparing the above mentioned data on clothianidin and imidacloprid, it can be concluded that clothianidin exhibits a similar intrinsic affinity to nAChR-binding sites than imidacloprid at a similar to even higher efficacy against aphids. Thus it can be concluded that the sensitivity difference between pest aphids and honey bees is even larger for clothianidin as it is for imidacloprid.*".
Based on the above, Ctgb agrees that the risk via honeydew from the proposed uses of clothianidin is acceptable.

Public literature:
The above risk assessment, based on protected data from the applicant, indicates that the risks of the proposed uses of clothianidin are expected to be 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 this risk assessment.
This assesement is based on the preliminary results of a public literature survey which is presented in Appendix II.

Laboratory and (semi-)field studies
Bailey *et al.* (2005) confirm the high acute toxicity of clothianidin.

Girolami et al. (2009) showed that high residue levels can occur in guttation droplets from maize plants grown from treated seeds. However, the field studies in the industry dossier show that the risk to honeybees from actual foraging on these droplets is very low.

In a field study, Cutler and Scott-Dupree (2007) found no effects on brood and colony development (including overwintering) after foraging on treated oilseed rape (residue levels up to 2.59 ppb, in pollen). This study does not contradict the expectation of low risk from exposure to clothianidin.

Wu (2011) measured clothianidin in brood combs in the USA. The substance was found in 1 of the 13 samples, at a level of 35 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 clothianidin because combs were contaminated with a cocktail of substances and may have contained also more pathogens than control combs, and because no information is available on how clothianidin contamination could have occurred (relation with agricultural use is therefore unclear). 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.

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

Cresswell (2011) performed a meta-analysis of imidacloprid laboratory and semi-field studies, which result questions the statistical power of honeybee semi-field tests to show sublethal effects. This issue pertains to all pesticide risk assessements, not only to neonicotinoids, and will be considered by a European working group which has not started yet (EFSA mandate M-2011-0185). The Netherlands will participate in this working group. Ctgb will assess using the European harmonized methodologies until the impact of this paper has been clarified in the European framework.

Monitoring studies
Furthermore, several large-scale monitoring studies were published in which bee health was studied and pesticide residues in bee hives were measured.

In a broad survey of pesticide residues, which was conducted on samples from migratory and other beekeepers across 23 USA states, one Canadian province and several agricultural cropping systems during the 2007–08 growing seasons, Mullin et al (2010) found no clothianidin (although it was included in the analysis). However, they did find 98 other pesticides and metabolites in mixtures up to 214 ppm in bee pollen alone, which according to them represents a remarkably high level for toxicants in the brood and adult food of this primary pollinator. They conclude that the effects of these materials in combinations and their direct association with CCD (colony collapse disorder) or declining bee health remains to be determined.

In a large study in Germany (Genersch et al., 2010), many pesticides (including miticides) were found in honeybee colonies. Clothianidin was not detected but it is unclear if it was included in the analysis. In this study, factors which significantly influenced overwintering succes were
1) high varroa infestation 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. (unicellular parasites) or pesticides.

The authors however consider that further investigations and controlled experiments are necessary to clarify the relation between pesticides and honeybee colony health in the long-term.

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

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

Bee colony losses in the Netherlands

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

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

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

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

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

These losses have mainly been attributed to beekeeping practice with regard to pests and diseases, especially the *Varroa* mite, since it has been found that adequate and timely Varroa treatment reduces winter mortality (Van der Zee & Pisa 2011; personal communication bijen@wur and professional beekeeper). Also, reduction of forage is likely to play a role. The relationship between pesticides and bee decline has not been studied in the Netherlands so far.

Europe
A report submitted to EFSA on bee mortality and bee surveillance in Europe (Hendrikx *et al.* 2009), concluded on results derived from surveillance systems in 27 European countries and a thorough literature search of the existing databases, as well as relevant grey literature about causes of colony losses:
• General weakness of most of the surveillance systems in the 24 countries investigated;
• Lack of representative data at country level and comparable data at EU level for colony losses;
• General lack of standardisation and harmonisation at EU level (systems, case definitions and data collected);
• Consensus of the scientific community about the multifactorial origin of colony losses in Europe and in the United States and insufficient knowledge of causative and risk factors for colony losses.

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

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

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

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

Based on the information as shown above it cannot be concluded that there is a link between clothianidin 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 clothianidin or other neonicotinoid products significantly contribute to bee decline based on the referred public literature.
It should be noted that other (European and elsewhere) countries have not withdrawn these substances from the market either (with some exceptions where clear acute bee poisoning due to suboptimal sowing circumstances was observed; this has not been the case in the Netherlands).
Finding associations between bee decline and all possible environmental factors is a complex issue that has to be established the coming years in a scientific way.
Long-term monitoring studies investigating the effects of yearly repeated exposure on honeybee colonies to clothianidin-treated maize are still running and indicate acceptable risks. Final reports are expected in 2011. When these are available, Ctgb will re-assess the risk from the clothianidin products. If necessary, further monitoring may then be requested to investigate the role that clothianidin plays in bee decline, as is suggested in the 'Inclusion Directive'. At the moment, monitoring other than already ongoing is not considered necessary for clothianidin.

Appendix I. List of Endpoints Ecotoxicology

Final LoE clothianidin for inclusion in Annex I of 91/414/EEC.

For the risk assessment the final LoE of October 2005 is used and additional data from the applicant (summarised and evaluated by Bioresearch & Promotion, Report May 2011; and by Ctgb, May and June 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} = 0.00379 µg a.s./bee LD_{50} = 3.9 µg TZNG/bee *(metabolite)* *Metabolites TMG, MNG and TZMU: LD50 oral >100 µg /bee (endpoints from DAR)*
Acute contact toxicity	LD_{50} = 0.04426 µg a.s./bee

On May 26[th] 2011, the applicant submitted a new acute toxicity study to honeybees which showed slightly lower values: 0.0025 and 0.0389 µg a.s./bee for oral and contact toxicity, respectively. This new study (Schmitzer 2008) was submitted too late for full evaluation and is not essential for the risk assessment as the EU-agreed endpoint is in the same range (indicating the high toxicity of the active substance). Therefore, the new study is not included in the current risk assessment.

Further laboratory tests
Chronic adult toxicity
Summarised/evaluated by Ctgb, June 2011
Kling, 2005
Acceptable: Yes
NOEC: 10 µg a.s./L sugar solution (10 d feeding).
The chronic effect of clothianidin on the honey bee, Apis mellifera L., was determined in a 10 days continuous feeding test in the laboratory. Bees (30 groups of 10 bees per test concentration and 60 groups of 10 bees in the control) were exposed to 50 % sugar solution containing four different concentrations of clothianidin by continuous and ad libitum feeding over a period of 10 days (240 hours). Mortality was observed every day. After 10 days, corrected mortality was 0.74, 14.06, 43.72 and 87.45% at 10, 20, 50 and 100 µg a.s./L, respectively. Mortality in the control was 12.35%, which was below the validity criterion of 15% set by the authors. The total intake of test item per bee accumulated over the entire test period was 0.0038 ug a.i./bee (10 ug a.i./L treatment), 0.0084 ug a.i./bee (20 ug a.i./L treatment), 0.0202 ug a.i./bee (50 ug a.i./L treatment) and 0.0485 ug a.i./bee (100 ug a.i./L treatment).
No official guideline is available for this test. EPPO 2010 says that the test should be performed according to the method described in Decourtye et al. 2005. The current test is sufficiently in accordance with this method, including control mortality (Decourtye et al tested nine pesticides and found control mortality of 4-18%).
Effects on honeybee larvae
Summarised/evaluated by Bioresearch & Promotion, Report May 2011

Maus 2009
Acceptable: Yes.
NOEC: 20 µg a.s./kg diet.
Guideline: Aupinel et al (2009; draft).
Honeybee (Apis mellifera carnica) larvae were fed on an artificial diet with Clothianidin Tech. between day 4 and 6. Test rates ranged from 5 to 40 µg/kg. Mortality was determined on day +5, +6, +7, +8, +11, +13, +15 and +22.
Based on the statistical significance of the effects observed on the mortality until day +22 in three valid test runs, the study author concluded that the NOEC for this study is between 20 and 40 µg a.s./kg diet. However, differences may not be statistically significant in all runs at 40 µg a.s./kg diet, but based on graphical presentation of mean values obtained from the three valid runs there is clearly a dose related response. Also, mean mortality in the 40 µg/kg is above 30% and tests would be rejected if this

had been the control mortality. Therefore it is considered that the NOEC should be set at 20 µg a.s./kg diet. The LOEC is determined to be ≥ 40 µg a.s./kg diet.
On May 26th 2011, the applicant submitted two further laboratory studies (Simoens & Jacobs 2005 a+b), on transfer of clothianidin via contaminated pollen via nurse bees to larvae and on the effect of clothianidin in bee bread to food gland development. Since these studies are not required according to the risk assessment scheme, were submitted very late in the process (May 26th 2011) and do not give concerns about the relevant long-term laboratory endpoint, these studies are not included in the current risk assessment.

Field or semi-field tests
Several crop-dependent studies were established for maize, oilseed rape (OSR) and sunflower. Besides these studies 2 crop-independent field studies are available in which no adverse effects were observed.

As sugar beet and fodder beet do not flower under good agricultural practice and are not favored by honeybees, no risk calculation or studies are considered necessary for this crop.

The higher tier studies mentioned above were presented in the DAR. A short summary has been added below by Ctgb. In most of these studies, residues were measured in bee-relevant matrices (honeybees, nectar, pollen). Results are given in tables copied from the DAR.

Cage tests
Maus 2002d: Bees fed with pollen from dressed maize seeds (1 g a.s./1000 seeds) resulting in pollen containing 0.8 ug/kg. Observation period: 2 weeks. No mortality, brood and behavioural impacts related to treatment.
Schmuck & Schöning 2000a: OSR 50 g a.s./ha. Observation period: 4 days. No mortality and behavioural impacts. Residue levels in µg a.s./kg: honeybees 14; rape nectar sampled by bees: 5.6; rape nectar sampled from flowers: 1.2-7.2; rape blossoms: 4.1.
Schmuck & Schöning 2000b: OSR 50 g a.s./ha. Observation period: 4 days. No mortality and behavioural impacts. Exposure to cage in which treated and untreated plants were present. Residue levels in µg a.s./kg: honeybees <0.3; rape blossoms: 3.3.
Schmuck & Schöning 2000c: OSR 50 g a.s./ha. Observation period: 4 days. No mortality and behavioural impacts. Residue levels in µg a.s./kg: honeybees <0.3; rape nectar sampled by bees: < 10 (LOQ); rape nectar sampled from flowers: < 10 (LOQ); rape pollen sampled by bees: 1.7.

Tunnel tests

Maus & Schöning 2001b: OSR 27 g a.s./ha. Observation period: 15 days. No mortality and behavioural impacts. 0

Table 9.4.7-01 Summary of the analytical findings :

	Residues of TI-435 (µg/kg)	Residues of TZMU (µg/kg)	Residues of TZNG (µg/kg)
Control rape nectar A	n.d.	n.d.	n.d.
Control rape nectar B	n.d.	n.d.	n.d.
Treated rape nectar A	2.8	< LOQ	n.d.
Treated rape nectar B	3.0	n.d.	n.d.

n.d. : residues below the limit of detection (= 0.3 µg/kg for TI-435, TZMU and TZNG)
LOQ = 1µg/kg for TI-435, TZMU and TZNG

Maus & Schöning 2001c: OSR 27 g a.s./ha. Observation period: 3 weeks. No mortality and behavioural impacts.

Table 9.4.7-02 Summary of the analytical findings :

	Residues of TI-435 (µg/kg)	Residues of TZMU (µg/kg)	Residues of TZNG (µg/kg)
Control rape nectar A (capillary)	n.d.	n.d.	n.d.
Control rape nectar B (capillary)	n.d.	n.d.	n.d.
Control rape nectar C (honey comb)	n.d.	n.d.	n.d.
Treated rape nectar A (capillary)	5.4	< LOQ	n.d.
Treated rape nectar B (capillary)	1.0	n.d.	n.d.
Treated rape nectar C (honey comb)	n.d.	n.d.	n.d.
Control rape pollen A	n.d.	n.d.	n.d.
Treated rape pollen A	1.9/2.5*	n.d.	n.d.

n.d. : residues below the limit of detection (= 0.3 µg/kg for TI-435, TZMU and TZNG)
LOQ = 1µg/kg for TI-435, TZMU and TZNG
* repetition of first analysis

Maus 2002g: OSR. Residues measured at ca. 50 g a.s./ha. Effects on bees not studied.

Table 9.4.7-07 Summary of the analytical findings :

	Residues of TI-435 (µg/kg)	Residues of TZMU (µg/kg)	Residues of TZNG (µg/kg)
Control Nectar (rape blossoms)	n.d.	n.d.	n.d.
Control Nectar (honey comb)	n.d.	n.d.	n.d.
Control Pollen (honey comb)	n.d.	n.d.	n.d.
Control Leaves of Rape Blossoms	n.d.	n.d.	n.d.
Control Bees	n.d.	n.d.	n.d.
Treatment Nectar (rape blossoms)	LOQ	n.d.	n.d.
Treatment Nectar (honey comb)	LOQ	n.d.	n.d.
Treatment Pollen (honey comb)	< LOQ	n.d.	n.d.
Treatment Leaves of Rape Blossoms	< LOQ	n.d.	n.d.
Treatment Bees	< LOQ	n.d.	n.d.

n.d. : residues below the limit of detection (= 0.3 µg/kg for TI-435, TZMU and TZNG)
LOQ = 1µg/kg for TI-435, TZMU and TZNG

Maus & Schöning 2001d: Sunflower 25 g a.s./ha. Observation period: 2 weeks. No behavioural impacts. No mortality effects attributed to treatment.

Table 9.4.7-03 Summary of the analytical findings :

	Residues of TI-435 (µg/kg)	Residues of TZMU (µg/kg)	Residues of TZNG (µg/kg)
Control Sunflower Nectar A (honey comb)	n.d.	n.d.	n.d.
Treated Sunflower Nectar A (honey comb)	n.d.	n.d.	n.d.
Control Sunflower Pollen A (direct from the head)	n.d.	n.d.	n.d.
Control Sunflower Pollen B (honey comb)	n.d.	n.d.	n.d.
Treated Sunflower Pollen A (direct from the head)	2.4/3.1*	<LOQ/<LOQ*	<LOQ/n.d.*
Treated Sunflower Pollen B (honey comb)	1.2/1.3*	n.d./n.d.*	n.d./n.d.*

n.d. : residues below the limit of detection (= 0.3 µg/kg for TI-435, TZMU and TZNG)
LOQ = 1µg/kg for TI-435, TZMU and TZNG
* repetition of first analysis

Maus & Schöning 2001e: Sunflower 25 g a.s./ha. Observation period: 2 weeks. No mortality and behavioural impacts.

Table 9.4.7-04 Summary of the analytical findings :

	Residues of TI-435 (µg/kg)	Residues of TZMU (µg/kg)	Residues of TZNG (µg/kg)
Control Sunflower Nectar A (honey comb)	n.d.	n.d.	n.d.
Control Sunflower Nectar B (honey comb)	n.d.	n.d.	n.d.
Treated Sunflower Nectar A (honey comb)	n.d.	n.d.	n.d.
Treated Sunflower Nectar B (honey comb)	n.d.	n.d.	n.d.
Control Sunflower Pollen A (direct from the head)	n.d.	n.d.	n.d.
Control Sunflower Pollen B (honey comb)	n.d.	n.d.	n.d.
Treated Sunflower Pollen A (direct from the head)	2.3/2.4*	n.d./n.d.*	n.d./n.d.*
Treated Sunflower Pollen B (honey comb)	2.8/2.9*	<LOQ/n.d.*	<LOQ/n.d.*

n.d. : residues below the limit of detection (= 0.3 µg/kg for TI-435, TZMU and TZNG)
LOQ = 1µg/kg for TI-435, TZMU and TZNG
* repetition of first analysis

Maus & Schöning 2001h: Colonies fed with treated pollen at 0, 5, 10 and 20 µg a.s./kg (and untreated sunflower honey as additional food). Observation period: 2 weeks. No effects on mortality, foraging

activity at the pollen and the honey feeder, brood and behaviour. NOEC: 20 ug a.s./kg pollen.
Maus & Schöning 2001i: Colonies fed with treated sunflower honey at 0, 5, 10 and 20 µg a.s./kg (and untreated pollen as additional food). Observation period: 2 weeks. No effects on mortality, foraging activity at the pollen and the honey feeder, brood and behaviour. NOEC: 20 ug a.s./kg pollen.

Field tests.
Maus & Schöning 2001a: Colonies fed with treated sugar solution. Observation period: 2 weeks. No effects on mortality, foraging activity at the syrup feeder and on behaviour. NOEC: 20 ug a.s./kg syrup.
Scott-Dupree & Spivak 2001: OSR 42 and 30 g a.s./ha. No effects on brood, foraging activity, mortality, honey production and behaviour. Observation period not given in the DAR.

Residue studies.
Maus & Schöning 2001f and 2001g: Residue studies in maize at 53.8 g a.s./ha

Table 9.4.7-08 Summary of the analytical findings of 2 residue studies in maize (Maus Ch. & Schöning R., 2001f and 2001g)

Treatment rate : 53.8 g a.s./ha	Residues of TI-435 µg/kg	Residues of TZMU µg/kg	Residues of TZNG µg/kg
Control Maize Pollen (Test Location Farmland "Laacher Hof")	1.7/1.1/<LOQ*§	n.d./n.d./<LOQ*	n.d./n.d./n.d.*
Treated Maize Pollen (Test Location Farmland "Laacher Hof")	5.4/3.3*	n.d./n.d.*	n.d./n.d.*
Control Maize Pollen (Test Location Farmland "Höfchen")	3.8§	n.d.	n.d.
Treated Maize Pollen (Test Location Farmland "Höfchen")	6.2	n.d.	<LOQ

n.d. : residues below the limit of detection (= 0.3 µg/kg for TI-435, TZMU and TZNG)
LOQ = 1 µg/kg for TI-435, TZMU and TZNG
* repetition of first analysis
§ The source of this contamination could not be traced.

Maus, 2002b and 2002c: Residue studies in maize at 51.4 g a.s./ha

Table 9.4.7-09 Summary of the analytical findings of 2 residue studies in maize (Maus Ch., 2002b and 2002c)

Treatment rate : 51.4 g a.s./ha	Residues of TI-435 µg/kg	Residues of TZMU µg/kg	Residues of TZNG µg/kg
Control Maize Pollen (Test Location Farmland "Laacher Hof")	n.d.	n.d.	n.d.
Treated Maize Pollen (Test Location Farmland "Laacher Hof")	2.4/2.9	n.d.	n.d.
Control Maize Pollen (Test Location Farmland "Höfchen")	n.d.	n.d.	n.d.
Treated Maize Pollen (Test Location Farmland "Höfchen")	2.1	n.d.	n.d.

n.d. : residues below the limit of detection (= 0.3 µg/kg for TI-435, TZMU and TZNG)
LOQ = 1 µg/kg for TI-435, TZMU and TZNG

Dust deposition sugarbeet
Summarised/evaluated by Ctgb, May 2011

Lueckmann, J. & Staedtler, T. 2009
Monitoring of dust drift deposits during and after the sowing of sugar beet pills, treated with Poncho® Beta or Poncho® Beta Plus in Germany with commercially dressed sugar beet pills (nominally 0.60 mg clothianidin & 0.08 mg beta-Cyfluthrin (+ 0.30 mg imidacloprid) per individual sugar beet pill.
All 20 fields were sown with mechanical sowing machines. The test field sizes varied between 1.5 and 21.0 ha. Shortly before sowing, the wind direction was determined and ten Petri-dishes were placed in groups of two at a distance of 1, 3 and 5 m (in total 30 Petri-dishes) at the down-wind border of the field. To monitor a potential dust drift during a 24h-period after sowing ten new Petri-dishes were placed in pairs at the approximate middle of each field side at a distance of 1 m to the field borders. Weather conditions were presented.
The 90th%ile residue levels during the sowing operation and the 24h-sampling were all below the limit of determination (LOD 0.004 g a.s./ha). These results indicate that the dust drift produced during and

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

<u>Nikolakis, A., Schoening, R. 2008</u>
Drift deposition pattern of seed treatment particles abraded from Poncho® Beta Plus treated sugar beet pills and emitted by a typical mechanical sowing machine in Germany with commercially treated sugar beet pills, treated with Poncho® Beta Plus, which contains the neonicotinoid active substances clothianidin and imidacloprid (analysed neonicotinoid seed loading: 0.589 mg clothianidin a.s./pill, 0.325 mg imidacloprid a.s./pill). The actual machine tested was a Kverneland Accord Monopill SE, a 12-row mechanical precision sugar beet planter (12 hoppers). The size of each drilling plot was about 1.0 ha with an orientation of the sampling devices 180° ± 30° to the prevailing wind direction. An average wind speed of 2 - 5 m/s and a deviation of wind direction of maximum ± 30° to the perpendicular wind direction (i.e., 180° to the sampling devices) were the target conditions during drilling.
All clothianidin-containing dust and abrasion particles which deposited at 1, 3, 5, 10, 20, 30 and 50 metres distance from the drilling area during sugar beet sowing ("primary drift") were sampled in polystyrene Petri-dishes (Ø 13.7 cm, 147.41 cm²), filled with an acetonitrile-water mixture (2/8, v/v). For each sampling distance, three arrays of 10 Petri-dishes each were installed with a distance of 1 metre between the dishes and 50 m between the arrays.
Passive dust-drift collectors were installed at 1 m, 2 m, 3 m, 4 m and 5 m above the soil surface. The dust collectors were made of a polypropylene fabric mesh, built up of filaments with a 0.80 × 0.18 mm cross-section. This type of collector has a slightly oval shape with a length of ≈ 85 mm and a diameter of ≈ 65 mm; at its poles, the diameter is ≈ 50 mm. The polypropylene fabric mesh collectors were pinned on each end of horizontal metal rods, which in turn were mounted at the respective height on a vertical tripod-pylon (height ≈ 5 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 suger 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.

Dust deposition maize
<u>Nikolakis, A.; Casadebaig, J.; Appert, C.; Schoening, R. 2009</u> *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 90th%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, 2006 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 toxicity
Bakker 2010, summarised/evaluated by Ctgb, May 2011 (whole summary presented below since no separate evaluation report was made)

The objective of the study was to determine the effect of clothianidin applied as dust obtained by mechanical abrasion of maize seeds treated with Clothianidin FS 600 (only particles <100 µm used) and as spray treatment with liquid formulation Clothiandin FS 600B G on the honeybee, Apis mellifera L. in cage tests.

30 cages of 20 m^2 were set up with flowering Phacelia tanacetifolia and one small bee colony was placed in each tunnel 6 days before the applications (5 control, 3 per treatment, 7 not used for the test except as reference for the effect of the test cages itself on colony development). Tested doses were 0.5, 2 and 4 g a.s./ha (nominal), both for the spray and dust treatment. Application was during bee flight. Control units were left untreated.

Mortality, behaviour and foraging activity were assessed daily over 7 days during the time of exposure in the tunnels. Colonies were then moved to a monitoring site for a post-exposure monitoring phase of 43 days.

Mortality was assessed with dead bee traps in front of the colony (DAA -6 till DAA +49) and on white cloth surrounding the crop, bordering the cage walls (DAA -6 till +7). Flight activity was assessed by determining the number of bees that were visiting flowers (DAA -5/3 till +7). The condition of the colonies and the development of the bee brood were assessed once before application and at DAA +7 and +28. Statistical analysis: graphically using box plots; specific hypotheses tested using repeated measures ANOVA techniques.

The results suggest that the two treatment groups (dust application and spray application) tested differed in the level of effect they caused on adult honeybee mortality. This difference could not be related to e.g. reduced foraging in the cages treated with the spray application and therefore there is evidence that exposure to dust particles resulted in stronger effects than exposure to spray deposits with comparable amounts of active substance.

The liquid formulation was homogeneously and accurately applied to the test crop, therefore nominal rates can be used to set the spray endpoints. However, the amount of dust was variable in space, in time and with dose. This was determined in separate runs (without bees) by collecting dispersed dust on glass plates over a regular grid and assessing the dust density at the various grid points using fluorescence techniques.

Space: The large variation between individual glass plates was attributed by the author to inhomogeneous particle distribution (it is very difficult to achieve a homogeneous distribution in air of particles with settling velocities in the order of several cm/sec).

Time: There was no trend in time, implying that all dust had settled before the first collection (after 3 h) independent of dose rate.

Dose: In proportion to the equivalent of the hectare rates applied, the recovery in the three treatment regimes were 108%, 63% and 51% for 0.5, 2 and 4 g a.s./ha, respectively. Deviations from expected deposits on individual glass plates ranged from -71% to +379% for the 0.5 g a.s./ha, from -100% to +170% for 2 g a.s./ha and from -99% to +39% to 4 g a.s./ha. Even though the low recovery of particles at higher concentrations is not conclusively explained, it can be assumed that the average amount of particles collected on the glass plates is indicative of the average amount of particles expected on the test plants. Since all particles are expected to have settled within 3 hours, measurements of all time periods can be analyzed together to infer particle concentrations on the plants. This means that in the 0.5 g a.s./ha treatment all plants had on average a residue close to the expected dose (namely 0.54 g a.s./ha). For the 2 and 4 g a.s./ha treatments an average plant would have the equivalent of 1.26 and 2.04 g a.s./ha., respectively.

However, because for each cage it is known that the exact amount corresponding to the target rate was dispersed in the cage, this finding implies that a fraction of the surface received a much higher loading. The flattening of the frequency distributions indicates that with increasing rate we do indeed expect more extreme values.

Ctgb considers that since it has not been proven that exposure in the drift study was indeed to the nominal dose of the two higher dose rates, the measured values will be used to set the dust endpoints.

Mortality was measured both in dead bee traps and on white cloths on the edges of the cages. The data from the white cloths are considered less relevant for the present study since the temperature during the study was very high. It is expected that bees would have been flying around a lot to cool off, land on the cage walls for the night and then end up dead on the white cloth in the morning, which

would mask a possible treatment effect. Furthermore, dust particles will be taken into the hive and transferred from bee to bee, e.g. when dead bees are thrown out of the hive. Therefore, for the dust study the dead bee traps may show an increased effect as compared to the white cloth. For these reasons, the mortality data should be analysed for the dead bee traps and the white cloth separately and results for the dead bee traps are most important.
Dust: Mortality was statistically significantly increased in the dead bee traps at all dose rates during the exposure phase. Thus, the NOER for mortality is set at <0.5 g a.s./ha. Flight activity was not significantly reduced at any test rate: NOER flight activity: 2 g a.s./ha (actual measured).
Spray: The study author concluded that mortality was not significantly reduced at any test rate. However, from the box plots presented in the study report it is clear that there was much higher mortality in the dead bee traps at day 1 in the two highest dose rates and at day 2 at the highest dose rate. Therefore, the NOER for mortality should be set at 0.5 g a.s./ha for the spray treatment. Flight activity was significantly reduced at 4 g a.s./ha only. Thus, the NOER for flight activity is 2 g a.s./ha (nominal).
Both in the spray and the dust treatment, mortality returned to normal levels immediately after moving the hives to an uncontaminated area. No effects of the treatments on colony condition were observed. However the placement in the cages resulted in depletion of food stocks in all hives, including the control.

Garrido 2010. Summarised/evaluated by Bioresearch & Promotion, Report May 2011
Assessment of Potential Impacts on Honey bee Colony Development and Monitoring of Aerial Dust Drift During the Sowing of Clothianidin FS 600 Treated Maize Seeds with Modified Seeding Technology Directly Adjacent to Full- Flowering Winter Oil-seed Rape in Austria.
Acceptable: Yes (but some limitations on the study conduct and data analysis were noted)
NB This study is still running and the final report, scheduled for summer 2011, will include an assessment of the overwintering performance of the colonies.
Maize seeds treated with Clothianidin FS 600B G (612.5 g a.s./L). Nominal seed loading of 1.25 mg a.s./seed (analysed seed loading 1.255 mg a.s./seed). Furthermore treatment with fungicide Maxim® XL (active ingredients: fludioxonil and metalaxyl-M), the film coating Impranil® DLN W 50 and Talcum Gloss® powder. One treatment and one control field.

During sowing (April 2010), the neighbouring oil seed rape field was in full bloom, and bees were active during applications. The sowing rate was ca 100,000 maize seeds/ha. Actual application rate 132.9 g a.s./ha. Drilling was performed with a vacuum-pneumatic maize sowing machine.
Dust was sampled with glycerol-wetted gauze netting (3 m from the field; 0.65 m height). Residues of clothianidin as determined in the gauze samples collected on the treatment field at the day of maize sowing ranged from < 1.2 mg (LOD) to 800 mg a.s./ha. Residues were distinctly higher at the downwind borders of the maize sowing area than at upwind borders. Seed-treatment dust, abraded and released during the sowing operation with modified (deflected) vacuum-pneumatic sowing equipment, resulted in a measurable off-crop exposure (in the oil seed rape field). The average vertical dust deposition corresponded to a drift rate of 420 mg a.s./ha (at the downwind side).
Mortality and colony health of eight treatment and eight control honey bee colonies were followed (mortality for three weeks, population strength and development and food stores for five months).
There were no distinct differences in honey bee mortality (dead bees in bee traps) and colony strength and colony development (number of adult bees, brood development and food storage) between control and treatment. Pollen analyses showed that approximately 50% of the pollen collected were of oil seed rape, indicating that exposure of foraging bees to clothianidin dust was likely to have occurred to some extent.
The conclusion that no long term effects are induced by exposure to low levels of abraded dust from clothianidine dressed maize seeds, released during sowing, is probably correct, but it should be confirmed by statistical hypothesis testing (e.g. a pre-post repeated measures design). The addition of results regarding a firm endpoint like overwintering success will further increase the robustness of the final conclusion. Data interpretation is slightly hampered by some flaws in the experimental design (higher mean colony strength in control than in treatment before sowing; no mortality assessment pre-treatment; mortality caused by exposure to abraded dust may have been masked by the high mortality induced by the colony assessment), therefore no firm conclusions can be made regarding potential (moderate) treatment related effects on bee mortality (immediately) after sowing.
NB dust exposure was also studied in the Liepold 2010 studies (see section 'guttation and dust exposure' below).

Bee monitoring after exposure to clothianidin in dust from maize sowing

Summarised/evaluated by Bioresearch & Promotion, Report May 2011

Liebig et al. 2008 and 2009.

Acceptable: Probably yes, but design and description experimental set-up is not transparent.

Conclusions are probably correct (based on observations on very high number of colonies) but could not be verified (incomplete information).

The study aimed to assess duration of adverse effects induced by exposure of colonies to clothianidin residues (through several pathways):

- Affected hives from dust drift incident in Rhine Valley End of April 2008;

- Hives located adjacent to flowering maize grown from treated seeds;

- Effect of contaminated pollen (taken from affected hives from the dust drift incident; concentration 7 or 34 ug a.s./kg)) in clean hives in clean area;

Overwintering succes of all three exposure types was determined.

The conclusion of the study authors are presented below. Due to flaws in experimental design or incomplete or unclear information, some of the conclusions drawn in these studies are not fully supported:

1) Exposure to dust during sowing of maize seeds has adverse effects on bee colony development, but colonies can recover, and successfully overwinter.

Objections:

-The information provided in the study does not show that colonies were indeed affected.

-Pollen combs with contaminated pollen were removed from these test hives, and the conditions of these hives were therefore not representative for conditions of bee colonies residing in areas contaminated with maize seed dust.

- Healthy colonies did not clearly suffer from consumption of the contaminated pollen (the exposure to contaminated pollen was not worst case; a dilution effect may have occurred. However, the tested situation is representative for areas in which not only maize fields are present). The effect of the contaminated pollen on affected colonies was not tested (at least not from worst-case exposure; part of the contaminated was pollen was taken from the colonies and it is not clear from the report how much was left).

-Information from the 2009 report indicates that winter mortality at a site in Upper Swabia "damaged by maize sowing" was 30% (3 out of 10). This means that the conclusion of the study author that recovery and succesfull overwintering occurred after dust damage, is not correct at least for this locality.

2) Bee colonies foraging on the edge of maize fields grown from treated seeds were not adversely affected in terms of colony health and overwintering success. In fact treatment colonies performed much better than the controls.

Objections:

-Comparisons to the control are not useful, because test and control colonies were not of the same origin, and resided at locations far away from the test site (ca 50-70 km) under incomparable (climatic) conditions.

3) Because of an overall winter mortality in Baden-Wurttemberg of 4% it was concluded that damage to colonies due to sowing of flawed maize was only temporary.

Objections:

-It is not clear from the study description which fraction of the monitored colonies was in contaminated areas.

Long-term studies after exposure to flowering maize

(Interim reports; the studies are still running and the final reports are scheduled for summer/autumn 2011).

Hecht-Rost 2009. Assessment of Side Effects of Clothianidin FS 600B G Treated Maize Seed on the Honeybee (Apis mellifera L.) in a Long-Term Field Study in Alsace (France).

Acceptable: Yes (but some limitations on the data analysis and interpretation were noted)

The study was conducted on commercial agricultural land near La Petite Pierre, Alsace, France. There was one treatment field (1.4 ha) and one control field (1.8 ha), located at approximately 4 km distance. Fields were sown in May 2008 with maize. The control treatment consisted of a field sown with untreated maize seeds.

Maize seeds for the treatment field were dressed with Clothianidin FS 600B G at a nominal seed

loading of 0.5 mg a.s./seed. Seeds were drilled in spring 2008 at a rate of 30 kg seeds/ha (application rate not reported but estimated at 60 g a.s./ha).
In each treatment group six colonies were placed for 11 days (summer 2008) at the border of the test fields with flowering maize. Thereafter colonies were kept for monitoring in a remote site without extensive agricultural crops attractive to the bees.
There were no distinct treatment related differences in behaviour (flight and foraging activity) and mortality (dead bees in bee traps and linen sheets) (measured during the 11-d exposure period); and colony strength and colony development (number of adult bees, brood development and food storage; measured three weekly before and once after overwintering) in the first year of observation after exposure to flowering maize grown from clothianidin treated seeds. Low residue levels were found in pollen from bees (3 µg/kg) and from plants (5 µg/kg) in the treatment group but not in the control group. Pollen were collected on the 5th and 6th exposure day from pollen traps attached to the hive entrance of each hive. The mean fraction of maize pollen was 1-3% on the 5th day and 7-9% on the 6th day in both treatment groups.
Results indicate that there are no long term effects induced by exposure to flowering maize grown from clothianidin dressed maize seeds. However, this conclusion was not supported by statistical hypothesis testing. The low fraction of maize pollen collected by bees and the low contents of clothianidin in the analysed pollen samples signifies low exposure in this study, which makes the study not realistic worse case. Colony strength after/before overwintering was approximately 0.5 in both groups, which is rather low.
Unclear effects on flight activity (higher in the treatment group than in the control) and bee mortality (higher in the control) are not adequately explained, but are probably of minor importance since no long term effects were apparent.
<u>Hecht-Rost 2008.</u> *Assessment of Side Effects of Clothianidin FS 600B G Treated Maize Seed on the Honeybee (Apis mellifera L.) in a Long-Term Field Study in Champagne (France).*
Acceptable: Yes (but some limitations on the data analysis and interpretation were noted)
The study was conducted on commercial agricultural land near Chalons en Champagne, Champagne, France. There was one treatment field (2.0 ha) and one control field (1.9 ha), located at approximately 2 km distance. Fields were sown in spring 2008 with maize. The control treatment consisted of a field sown with untreated maize seeds.
Maize seeds for the treatment field were dressed with Clothianidin FS 600B G at a nominal seed loading of 0.5 mg a.s./seed. Seeds were drilled in spring 2008 at a rate of 30 kg seeds/ha (application rate not reported but estimated at 60 g a.s./ha).
In each treatment group six colonies were placed for 10 days (summer 2008) at the border of the test fields with flowering maize. Thereafter colonies were kept for monitoring in a remote site without extensive agricultural crops attractive to the bees.
There were no distinct treatment related differences in behaviour (flight and foraging activity) and mortality (dead bees in bee traps and linen sheets) (measured during the 10-d exposure period); and colony strength and colony development (number of adult bees, brood development and food storage; measured three weekly before and once after overwintering) in the first year of observation after exposure to flowering maize grown from clothianidin treated seeds. Low residue levels were found in pollen from plants (1 µg/kg) in the treatment group but not in the control group. Pollen were collected on the 2nd and 3rd exposure day from pollen traps attached to the hive entrance of each hive. The mean fraction of maize pollen was 0-1% in the control groups and 1-4% (excluding one finding of 21% on one day in a very small sample) in the treatment group. The amount of pollen collected from foraging bees was too small for chemical analysis.
Results indicate that there are no long term effects induced by exposure to flowering maize grown from clothianidin dressed maize seeds. However, this conclusion was not supported by statistical hypothesis testing. The low fraction of maize pollen collected by bees and the low contents of clothianidin in the analysed pollen samples signifies low exposure in this study, which makes the study not a realistic worse case.
Unclear effects on flight activity (higher in the treatment group than in the control) and bee mortality (increased mortality in the treatment group on exposure days 7 and 8 were attributed to robbery of one colony, but this seems unlikely because this colony was the largest colony at that time of the study) are not adequately explained, but are probably of minor importance since no long term effects were apparent.

<u>Hecht-Rost 2008.</u> *Assessment of Side Effects of Clothianidin FS 600B G Treated Maize Seed on the Honeybee (Apis mellifera L.) in a Long-Term Field Study in Languedoc-Roussillon (France).*
Acceptable: No. Conclusions are doubted. Re-evaluation of the data is considered necessary.

The study was conducted on commercial agricultural land near Meynes, Languedoc-Roussillon, France. There was one treatment field (2.1 ha) and one control field (3.2 ha), located at approximately 2.5 km distance. Fields were sown in spring 2008 with maize. The control treatment consisted of a field sown with untreated maize seeds.
Maize seeds for the treatment field were dressed with Clothianidin FS 600B G at a nominal seed loading of 0.5 mg a.s./seed. Seeds were drilled in spring 2008 at a rate of 30 kg seeds/ha (application rate not reported but estimated at 60 g a.s./ha).
In each treatment group six colonies were placed for 10 days (summer 2008) at the border of the test fields with flowering maize. Thereafter colonies were kept for monitoring in a remote site without extensive agricultural crops attractive to the bees.
There were no distinct treatment related differences in behaviour (flight and foraging activity) and mortality (dead bees in bee traps and linen sheets) (measured during the 10-d exposure period); and colony strength and colony development (number of adult bees, brood development and food storage; measured three weekly before and once after overwintering) in the first year of observation after exposure to flowering maize grown from clothianidin treated seeds. Low residue levels were found in pollen from bees and plants (5 µg/kg) in the treatment group but not in the control group. Pollen were collected on the 2nd and 3rd exposure day from pollen traps attached to the hive entrance of each hive. The mean fraction of maize pollen was 7-36% in the control groups and 16-99% in the treatment group.
The proportion of maize pollen collected by the bees was much higher in this study than in the two studies conducted in the North (Alsace and Champagne, see above), hence exposure in this study is likely to have been higher compared to both North studies.
According to the study author there are no long term effects induced by exposure to flowering maize grown from clothianidin dressed maize seeds. However, this conclusion is not accepted.

Study results indicate that there may be adverse treatment related effects on colony development(a consistent trend was observed that mean colony strength gradually decreased over time in the treatment group, whereas strength in the control group remained constant after a slight increase). Despite this graphically observed difference between the two test groups, it is concluded by the study authors that "a treatment effect is not to be assumed behind this figure". However, re-analyses of the data is considered necessary before proper conclusions can be drawn. Reconsideration of the acceptability of the disease level and possible exclusion of individual colonies from analyses may lead to an overall rejection of the study if insufficient data remain for evaluation.

Disease analysis of the three Hecht-Rost studies (prepared by study evaluator)
Nosema and Varroa were found in all three studies. Nosema had no expected influence on overwintering success in both treatment and control groups. The influence of Varroa on colony strength could not be checked. Furthermore, chalkbrood and deformed wing virus both occurred in the Langquedoc-Roussillon study. It cannot be excluded that the combination of diseases observed in the Languedoc-Roussillon study may have influenced certain parameter values. As far as could be deduced from the data provided, the occurrence of the diseases was probably biased towards one of the groups and may have further increased variability, thereby masking potential treatment related effects.
see also Liepold 2010 below

Guttation and dust exposure - maize

Liepold 2010 - Alsace
Acceptable: Guttation yes. For other parameters (mortality, colony health) re-evaluation of the data is considered necessary before conclusions can be drawn.
The study was conducted on commercial agricultural land in Alsace, France. There was one treatment field (1.8 ha) and one control field (2.9 ha), located at approximately 4 km distance.
Maize seeds for the treatment field were dressed with a nominal seed loading of 0.5 mg a.s./seed. Seeds were drilled at a rate of 100,000 seeds/ha (dose rate 50 g a.s./ha). The control treatment consisted of a field sown with untreated maize seeds. A Monosem NG 3 plus (6 rows) with Syngenta reflector kit was used for drilling (precision planter using vacuum metering system).
Six colonies per field were placed at the border of the test fields 19 days before seed drilling and kept there for 62 days, after which they were transferred to a moitoring site. In total colonies were monitored for 113 days.
For 53 days after emergence of the seedlings, the occurrence of guttation was observed

systematically by inspecting the field daily several times from ca 6-7 to ca 12-13 hr in 5 different observation zones (1 off- and 4 in-field). In each zone, the number of bees resting on plants or on the ground, and the number of bees actually making contact with guttation fluid was recorded. In addition, the proportion of guttating plants in all rows of the observation zones was estimated using a classification scheme. Furthermore the occurrence of dew was recorded.
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.

The study sufficiently demonstrated that exposure to and consumption of guttation fluid by foraging bees is unlikely to happen, or only at a very low rate. However, results for bee mortality, flight activity and colony assessments were not accepted. Results concerning bee mortality and colony health were influenced by flaws in the experimental set-up, inferior health of some of the test colonies (3 out of 12 colonies died during the experiment), and unforeseen causes (robbing, which also indicates weakness of the colonies). Furthermore, data may be influenced by systematic errors in assessment procedures (as in the Languedoc-Roussillon and Aquitaine studies below).
It is not likely that exposure to dust during and shortly after drilling has had considerable effects on bee mortality or colony development during the exposure phase, but re-analyses of the data is considered necessary before proper conclusions can be drawn. Reconsideration of the acceptability of the health status and possible exclusion of individual colonies from analyses may lead to an overall rejection of the study if insufficient data remain for evaluation.

<u>Liepold 2010 - Champagne</u>
Acceptable: Guttation yes. No short term effects on bee endpoints during exposure phase. Re-evaluation of the data is considered necessary before conclusions can be drawn about long term effects.
The study was conducted on commercial agricultural land in Champagne, France. There was one treatment field (1.7 ha) and one control field (1.9 ha), located at approximately 2 km distance.
Maize seeds for the treatment field were dressed with a nominal seed loading of 0.5 mg a.s./seed. Seeds were drilled at a rate of 100,000 seeds/ha (dose rate 50 g a.s./ha). The control treatment consisted of a field sown with untreated maize seeds. A Monosem PNU (4 rows) with Monosem reflector kit was used for drilling (precision planter using vacuum metering system).
Six colonies per field were placed at the border of the test fields 11 days before seed drilling and kept there for 35 days, after which they were transferred to a monitoring site. In total colonies were monitored for 68 days.
For 24 days after emergence of the seedlings, the occurrence of guttation was observed systematically by inspecting the field daily several times from ca 6-7 to ca 12-13 hr in 5 different observation zones (1 off- and 4 in-field). In each zone, the number of bees resting on plants or on the ground, and the number of bees actually making contact with guttation fluid was recorded. In addition, the proportion of guttating plants in all rows of the observation zones was estimated using a classification scheme. Furthermore the occurrence of dew was recorded.
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.
The study sufficiently demonstrated that exposure to and consumption of guttation fluid by foraging bees is unlikely to happen, or only at a very low rate. It is also demonstrated that maize seed drilling and guttation of seedlings had no short term effects on bee colony development during the exposure period (24 days). However, results for bee mortality and colony assessments in the longer-term (after 68 days) were not accepted. Results concerning bee mortality and colony health were influenced by some flaws in the experimental set-up and unforeseen natural causes (swarming, probably in thee colonies, one of which died). The dramatic decrease in colony strength in all colonies after relocation should be explained. Observations from colonies T4, T6 and C4 after relocation should be removed from the dataset for a better presentation of data obtained during the monitoring period.

<u>Liepold 2010 – Languedoc-Roussillon</u>
Acceptable: Guttation yes. Probably no effects on bee endpoints, but data interpretation hampered by systematic errors in assessments
The study was conducted on commercial agricultural land in Languedoc-Roussillon, France. There was one treatment field (2.1 ha) and one control field (2.8 ha), located at approximately 3.3 km distance.

Maize seeds for the treatment field were dressed with a nominal seed loading of 0.5 mg a.s./seed. Seeds were drilled at a rate of 100,000 seeds/ha (dose rate 50 g a.s./ha). The control treatment consisted of a field sown with untreated maize seeds. A Nodet Pneumasem II (4 rows) with Bayer reflector kit was used for drilling (precision planter using vacuum metering system).
Six colonies per field were placed at the border of the test fields 4 days before seed drilling and kept there for 40 days, after which they were transferred to a moitoring site. In total colonies were monitored for 77 days.
For 24 days after emergence of the seedlings, the occurrence of guttation was observed systematically by inspecting the field daily several times from ca 6-7 to ca 10-11 hr in 5 different observation zones (1 off- and 4 in-field). In each zone, the number of bees resting on plants or on the ground, and the number of bees actually making contact with guttation fluid was recorded. In addition, the proportion of guttating plants in all rows of the observation zones was estimated using a classification scheme. Furthermore the occurrence of dew was recorded.
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.
The study 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 study outline (aim, experimental set-up and results) is well described, but results concerning bee mortality and colony health were influenced by flaws in the study design and systematic errors in assessment procedures.
It is probably correct that observed differences are not related to treatment, but with the observed magnitude of effects induced by systematic error, it is believed that the test-system is not sufficiently robust to detect potential treatment related effects of moderate size.

Liepold 2010 – Aquitaine
Acceptable: Guttation yes. Probably no effects on bee endpoints, but data interpretation hampered by systematic errors in assessments and sub-optimal health conditions of test colonies.
The study was conducted on commercial agricultural land in Languedoc-Roussillon, France. There was one treatment field (2.2 ha) and one control field (2.3 ha), located at 6.7 km distance.
Maize seeds for the treatment field were dressed with a nominal seed loading of 0.5 mg a.s./seed. Seeds were drilled at a rate of 100,000 seeds/ha (dose rate 50 g a.s./ha). The control treatment consisted of a field sown with untreated maize seeds. A Gaspardo MT (4 rows) with Gaspardo reflector kit was used for drilling (precision planter using vacuum metering system).

Six colonies per field were placed at the border of the test fields 6 days before seed drilling and kept there for 65 days, after which they were transferred to a moitoring site. In total colonies were monitored for 119 days.
For 24 days after emergence of the seedlings, the occurrence of guttation was observed systematically by inspecting the field daily several times from ca 6-7 to ca 12 hr in 5 different observation zones (1 off- and 4 in-field). In each zone, the number of bees resting on plants or on the ground, and the number of bees actually making contact with guttation fluid was recorded. In addition, the proportion of guttating plants in all rows of the observation zones was estimated using a classification scheme. Furthermore the occurrence of dew was recorded.
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.
The study sufficiently demonstrated that exposure to and consumption of guttation fluid by foraging bees is unlikely to happen, or only at a very low rate. It is not likely that exposure to dust during and shortly after drilling has had considerable effects on bee mortality or colony development during the exposure phase, but no firm conclusions can be drawn from the data obtained in this study. Results are influenced by systematic error during assessment procedures and suboptimal health conditions of the test organisms. It is believed that the experimental set-up used in this study is not sufficiently robust to detect potential moderate treatment related effects.
NB Residues in guttation droplets, bees, pollen and nectar were not analysed in any of the Liepold studies.

Lueckmann et al. 2010.
Acceptable: Guttation yes. Probably no effects on bee endpoints, but data interpretation hampered by sub-optimal health conditions of test colonies and the lack of a control reference.

The study was conducted on commercial agricultural land at several locations in two Austrian regions, north of the Alps (Baumgartenberg) and south of the Alps (Jennersdorf). In each of these regions 15 maize fields were monitored, each with two bee hives (hence 60 colonies in total). Test fields were usually larger than 2 ha (five fields were 04 to 1.5 ha). Maize seeds were dressed with Poncho® (0.5 mg clothianidin./seed), except three fields in the Jennersdorf region with Poncho Pro® (1.25 mg clothianidin /seed). Drilling rate was approximately 80-90 thousand seeds/ha in all fields. Different drilling machines were used for sowing, but they were all precision planters using vacuum metering system (the use of a deflector kit was not reported).
Drinking places (e.g. ditches, streams, ponds) for bees were usually more then 300 m away from the experimental fields. To 5 out of 15 fields in each region an artificial water source was offered directly adjacent to the hives (a plastic trough filled with gravel to avoid drowning). Water was slightly salted to increase attractiveness. Water was replenished at least weekly.
There were no control sites.
In each field two colonies were placed at the border of the test fields 2 to 5 days after seed drilling. Due to unexpected low colony strength several colonies were replaced 10-12 days after drilling. Monitoring started 0-4 days after emergence of seedlings. Field observations lasted approximately 3 (Jennersdorf) to 6 (Baumgartenberg) weeks. Thereafter, colonies were relocated to a monitoring site for further brood development assessments. In total, colonies were observed for about 2 months.

The occurrence of guttation was observed systematically by inspecting the field daily several times starting from sunrise till sunset in 5 different observation zones, for 3-6 weeks.
Residues in guttation droplets were measured. Initial concentrations of clothianidin (<one week after emergence) were in the range of 100-200 mg/L. Samples suspected to be diluted with dew, rain or leaf axil fluid showed much lower concentrations. Residue levels decreased exponentially to 1 mg/L and 0.01 mg/L three weeks and five weeks after emergence, respectively. No clear differences in concentrations were found for samples collected in fields treated with Poncho® or Poncho Pro®.
Daily mortality (dead bees in the bee traps) was generally below 20, except for some occurrences of peak mortality.
For the Baumgartenberg region the number of days with increased mortality was statistically significantly lower in colonies with a water supply compared to colonies without this water source in close vicinity of the hive. For colonies in Jennersdorf this relation was not found.
Residues were found on dead bees, but levels were not correlated with mortality rates or to the absence/presence of water supplies.
The 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.
The study also indicates that no measurable long-term influences on colony health occurred. But the overall sub-optimal and variable colony conditions, and the lack of a proper control reference or a more firm endpoint like overwintering success makes this expert statement not very robust.
Bees exposed to guttation fluid (starting a few days after drilling) are also likely to be exposed to dust released during drilling. This potential exposure mode was (partly or entirely) excluded from the experimental set-up used in this study.

Guttation in sugarbeet
Summarised/evaluated by Bioresearch & Promotion, Report May 2011
Keppler, 2009
Acceptable: yes.

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 (North-Rhine). Observations were made in early morning (between 6.10 and 8.30 h) in April/May 2009, at BBCH 10-12 (up to 2 leaves unfolded) to BBCH 14-19 (4-9 leaves unfolded). According to the author, out of 98 visits guttation was observed once (1%) in sugar beet, whereas on 83% of the visits guttation was observed in the adjacent crops/habitats. The author excluded the occurrences that droplets were observed on sugar beet leaves on days with intensive dewfall (16%), since droplets and guttation could not be distinguished. However, this exclusion was not done in adjacent crops/habitat.
Despite this weakness in analysis, the risk via guttation is considered to be low. 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 (personal communication of a professional beekeeper). The risk for bees to be exposed to contaminated guttation fluid is therefore low, regardless of the frequency of guttation to occur (1% or 16%).

Residues

Summarised/evaluated by Bioresearch & Promotion, Report May 2011

Note that residues were also measured in studies which were included in the DAR; see heading Field or semi-field tests above.

Staedtler 2008

Acceptable: Yes, but it is unclear whether results obtained from this study are representative under all sowing circumstances.

The study aimed to assess the amount of clothianidin residues and its metabolites (TZMU=Thiazolylmethylurea and TZNG=Thiazolylnitroguanidine) in maize pollen taken from plants grown in the Upper Rhine Valley from commercial seeds dressed with Poncho Pro® (a.s. clothianidin, nominally 1.25 mg a.s./seed). Additional assessments were made on pollen collected by bees from pollen traps, from bee bread and from dead bees discarded from the hive.

LOQ for clothianidin, TZMU and TZNG (the lowest validated fortification level): 1 µg/kg for all material types. LOD: 0.3 µg/kg (all material types)

From all pollen samples analyzed (pollen collected from plants, 252 samples) 31% contained clothianidin at a rate between 1 and 3 µg/kg and 62% between 3 and 10 µg/kg. One sample with 10.4 µg/kg was found, other samples (9%) were below the LOQ.

The occurrence of clothianidin residues in pollen collected by bees was much lower. From 119 samples analyzed 19% contained clothianidin at a rate between 1 and 3 µg/kg and 3% between 3 and 10 µg/kg. One measurement of 11.4 µg/kg was made. Clothianidin concentrations in bee bread above 3 µg/kg were measured only twice (n=37).

Clothianidin was found on dead bees in 8 out of 38 samples (19%), but concentrations were above 1 µg (below 3 µg) in two samples only (5%).

Concentrations of the derivates in all sample types were almost always below the LOQ (1 µg/kg).

Between the three locations where bee-derived matrices were collected some differences were observed, but these were usually below a factor 2.

Mean and maximum values of clothianidin and it derivates measured in this study are presented in the table below (in µg/kg).

a.s. content in µg/kg	clothianidin		TZNG		TZMU	
	mean	maximum	mean	maximum	mean	maximum
Pollen from field	3.4	10.4	0.6	1.0	0.4	<LOQ
Pollen from bees	1.1	11.4	0.4	1.8	0.3	<LOQ
Bee bread	1.0	3.3	0.4	1.3	<LOD	<LOD
Dead bees	0.5	1.2	0.4	1.2	<LOD	<LOD

Because the sowing part of this study was not described, not conducted under GLP and not performed by the testing facility, it is difficult to assess wether the sowing circumstances are relevant for all circumstances (e.g. seed dressing method, maize variety, sowing operating machinery, sowing period, wheather conditions).

Residues in succeeding crops

Five studies were submitted by Bayer (26/05/2011, CD no. 5182) and summarised and evaluated by Ctgb (RES, 16/06/2011):

1) Neumann et al 2005 (Laacher Hof, maize, replanting interval 42 days).

Acceptable: Yes.

In spring 2005 clothianidin was applied and incorporated down to 20 cm soil depth (Laacher Hof, Germany). The rate corresponded to 90 g as/ha and the application was performed to represent a long-term soil plateau concentration of clothianidin simulating the consecutive use of clothianidin on the same plot over several years. In order to consider a certain period of equilibration in soil, all study plots were drilled with maize 42 days after spray application and incorporation. The control plot (untreated soil) and treatment plot 3 (treated soil) were drilled with untreated maize seeds (= only fungicide dressed seeds). Treatment plot 1 (untreated soil) was drilled with clothianidin dressed maize seeds (0.45 mg a.s./kernel) as well as treatment plot 2, which was treated with a clothianidin spray application before as well. The drilling rate for all study plots was 100 000 seeds/ha.

To determine potential background residues of clothianidin, soil samples were taken prior application of the test item on all study plots at 10 cm soil depth. Immediately after application and incorporation of the plateau concentration, further soil samples from the soil treated plots (2 and 3) were taken to verify

the applied and incorporated plateau concentration of clothianidin (LOQ 5 µg/kg, LOD 2 µg/kg).
On three different sampling days during the flowering period of maize, maize pollen was collected from each study plot by hand.
Results:
Soil concentrations in the upper 20 cm: Directly after spray application and incorporation, mean measured concentration of clothianidin was 19.7 µg/kg dry soil in treatment 2&3. Directly before drilling of the maize, mean measured concentration of clothianidin was 19.2 µg/kg dry soil in treatment 2&3.
For residues in maize pollen see table:

Residues in maize pollen [mg a.s./kg pollen]					
Study plot	Clothianidin soil treatment	Clothianidin dressed seeds	Clothianidin	TZNG	TZMU
Treatment Variant 1	-	x	0.0012	< LOQ	< LOQ
Treatment Variant 2	x	x	0.0013	< LOQ	< LOQ
Treatment Variant 3	x	-	< LOQ	< LOQ	< LOQ
Control	-	-	< LOQ	< LOQ	< LOQ

LOQ = 0.001 mg/kg for all test items

No residues (< LOQ) were found in the treatment variant 3 (Clothianidin spray application to the soil) and at the control plot. Clothianidin residues in pollen from seed-dressed maize in pre-treated soil were in the same order of magnitude (difference 0.0001 mg a.s./kg) as residues in pollen from seed-dressed maize in untreated soil: 0.0018 mg a.s./kg at treatment variant 1 (Clothianidin dressed seeds) and 0.0019 mg a.s./kg at treatment variant 2 (Clothianidin spray application to the soil and Clothianidin seed dressing).

2) Neumann et al 2005 (Laacher Hof, maize; replanting interval 55 days).
Acceptable: Yes.
In spring 2005 clothianidin was applied and incorporated down to 20 cm soil depth (Laacher Hof, Germany). The rate corresponded to 90 g as/ha and the application was performed to represent a long-term soil plateau concentration of clothianidin simulating the consecutive use of clothianidin on the same plot over several years. In order to consider a certain period of equilibration in soil, all study plots were drilled with maize 55 days after spray application and incorporation. The control plot (untreated soil) and treatment plot 3 (treated soil) were drilled with untreated maize seeds (= only fungicide dressed seeds). Treatment plot 1 (untreated soil) was drilled with clothianidin dressed maize seeds (0.45 mg a.s./kernel) as well as treatment plot 2, which was treated with a clothianidin spray application before as well. The drilling rate for all study plots was 100 000 seeds/ha.
To determine potential background residues of clothianidin, soil samples were taken prior application of the test item on all study plots at 10 cm soil depth. Immediately after application and incorporation of the plateau concentration, further soil samples from the soil treated plots (2 and 3) were taken to verify the applied and incorporated plateau concentration of clothianidin (LOQ 5 µg/kg).
On three different sampling days during the flowering period of maize, maize pollen was collected from each study plot by hand.
Results:
Soil concentrations in the upper 20 cm: Directly after spray application and incorporation, mean measured concentration of clothianidin was 22.8 µg/kg dry soil in treatment 2&3. Directly before drilling of the maize, mean measured concentration of clothianidin was 18.0 µg/kg dry soil in treatment 2&3.
For residues in maize pollen see table:

Residues in maize pollen [mg a.s./kg pollen]					
Study plot	Clothianidin soil treatment	Clothianidin dressed seeds	Clothianidin	TZNG	TZMU
Treatment Variant 1	-	x	0.0018	< LOQ	< LOQ
Treatment Variant 2	x	x	0.0019	< LOQ	< LOQ
Treatment Variant 3	x	-	< LOQ	< LOQ	< LOQ
Control	-	-	< LOQ	< LOQ	< LOQ

LOQ = 0.001 mg/kg for all test items

No residues (< LOQ) were found in the treatment variant 3 (Clothianidin spray application to the soil)and at the control plot. Clothianidin residues in pollen from seed-dressed maize in pre-treated soil were in the same order of magnitude (difference 0.0001 mg a.s./kg) as residues in pollen from seed-dressed maize in untreated soil: 0.0012 mg a.s./kg at treatment variant 1 (Clothianidin dressed seeds) and 0.0013 mg a.s./kg at treatment variant 2 (Clothianidin spray application to the soil and Clothianidin seed dressing).

3) Neumann et al 2005 (oilseed rape: replanting interval 55 days):
Acceptable: Yes.
During the spring of 2005, Clothianidin FS 600 was applied and incorporated into the soil of a test plot at a rate of 90 g a.s./ha to cover a plateau concentration after long-term use of Clothianidin. Another test plot remained without any Clothianidin spray application and served as control plot. After an ageing period of twenty-two days after the spray application and incorporation of Clothianidin, "undressed" (= only fungicide treated) summer rape seeds were sown on the test plots. With begin of the flowering period (BBCH growing stage 62 - 63) a gauze tunnel (approximately 50 m²) was set up at each study plot. A bee colony of about 3000 bees (Apis mellifera carnica) was installed into each of the tunnels. During the flowering period of summer rape, nectar and pollen sampling bees were manually collected in the tunnels and stored deep frozen. Afterwards the frozen bees were worked up by separating pollen load from the bee legs and by extracting sampled nectar by puncturing the honey bulbs of the bees with an ultra-fine needle. Afterwards, extracted pollen and nectar was analyzed to determine potential residues of Clothianidin and its metabolites TZMU and TZNG.
To determine potential background residues of Clothianidin, soil samples were taken prior to application of the test item on both study plots at 10 cm soil depth (LOQ 5 µg/kg, LOD 2 µg/kg).
Results:

Soil concentrations in the upper 20 cm: Directly after spray application and incorporation, mean measured concentration of clothianidin was 25.8 µg/kg dry soil in the treatment. Directly before drilling of the OSR, mean measured concentration of clothianidin was 21.0 µg/kg dry soil in the treatment.

For residues in pollen and nectar see table:

Sample attribute	Sample ID	Sampling date	Netto weight [g]	mg a.s./kg		
				Clothianidin	TZNG	TZMU
Control	Pollen 1	2005-06-25 & 2005-06-27	0.75	< LOQ	< LOQ	< LOQ
	Pollen 2	2005-06-28 & 2005-06-29	0.63	< LOQ	< LOQ	< LOQ
	Pollen 3	2005-07-03 & 2005-07-04 & 2005-07-06	0.83	< LOQ	< LOQ	< LOQ
Treatment	Pollen 4	2005-06-25 & 2005-06-27	0.34	0.00356	< LOQ	< LOQ
	Pollen 5	2005-06-28 & 2005-06-29	0.72	0.00359	< LOQ	< LOQ
	Pollen 6	2005-07-03 & 2005-07-04	0.66	0.00400	< LOQ	< LOQ
	Pollen 7	2005-07-06	0.26	0.00283	< LOQ	< LOQ
Average treatment pollen 4 - 7				0.00350	< LOQ	< LOQ
Control	Nectar	2005-06-25 until 2005-07-06	0.86	< LOQ	< LOQ	< LOQ
Treatment	Nectar	2005-06-25 until 2005-07-06	1.23	0.00215	< LOQ	< LOQ

Limit of quantitation (LOQ) for Clothianidin, TZNG and TZMU = 0.001 mg/kg

Residue levels are based on the fresh weight of the sample material and are not corrected with respect to the recovery rates

Under worst case conditions (long-term plateau concentration applied and incorporated into soil twenty-two days before sowing of summer rape) average residues of 0.0035 mg Clothianidin/kg (pollen) and 0.0022 mg Clothianidin/kg (nectar) grown in the treated soil were analysed.

4) Przygoda et al 2006 (Laacher Hof, oilseed rape; replanting interval 11 months):

Acceptable: Yes.

In autumn 2005 clothianidin was applied and incorporated down to 15 cm soil depth (Laacher Hof, Germany). The rate corresponded to 90 g clothianidin/ha and the application was performed to represent a long-term soil plateau concentration of clothianidin simulating the consecutive use of clothianidin on the same plot over several years. On the same day, clothianidin-treated winter barley seeds were sown at a nominal sowing rate of 160 kg seeds/ha. The winter wheat was harvested at 10 July 2006 and clothianidin-free oil-seed rape seeds were sown on 23 August 2006. 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.

Additionally soil samples were collected directly after the application and incorporation and after a period of nearly 11 months, directly before sowing winter oil-seed rape (LOD 2 ug/kg soil).

Results:

Soil concentrations in the upper 15 cm: Directly after spray application and incorporation, mean measured concentration of clothianidin was 20.3 µg/kg dry soil in the treatment. Directly before drilling of the winter rape, mean measured concentration of clothianidin was 11.9 µg/kg dry soil in the treatment.

For residues in pollen and nectar see table:

Sample attribute	Sample ID	Sampling date	Netto weight [g]	mg a.s./kg		
				Clothianidin	TZNG	TZMU
Control	Pooled Nectar 001 + 004	2007-04-10	0.6954	< LOD	< LOD	< LOD
		2007-04-11	0.9714			
	Nectar 006	2007-04-12	0.9816	LOD	< LOD	< LOD
	Nectar 008	2007-04-13	1.4645	< LOD	< LOD	< LOD
Treatment	Pooled Nectar 001 + 004	2007-04-10	0.6737	< LOQ	< LOD	< LOD
		2007-04-11	0.6777			
	Nectar 006	2007-04-12	0.9408	< LOQ	< LOD	< LOD
	Nectar 008	2007-04-13	1.6081	< LOQ	< LOD	< LOD
Control	Pooled Pollen 2/003	2007-04-10	0.3577	< LOD	< LOD	< LOD
		2007-04-11	0.6525			
	Pooled Pollen 005/007	2007-04-12	0.2616	< LOD	< LOD	< LOD
		2007-04-13	0.2481			
Treatment	Pooled Pollen 002/003	2007-04-10	0.1074	< LOQ	< LOD	< LOD
		2007-04-11	1.1504			
	Pollen 005	2007-04-12	0.5431	0.001	< LOD	< LOD
	Pollen 007	2007-04-13	0.5552	< LOQ	< LOD	< LOD

Limit of quantitation (LOQ) for clothianidin, TZNG and TZMU = 0.001 mg/kg
Limit of determination (LOD) for clothianidin, TZNG and TZMU = 0.0003 mg/kg
Residue levels are based on the fresh weight of the sample material and are not corrected with respect to the recovery rates

Under worst case conditions (long-term clothianidin plateau concentration conservatively simulated by fresh application and incorporation of clothianidin into the soil at the day of sowing clothianidin-dressed winter wheat, followed by untreated winter oil-seed rape as a succeeding crop), residues of clothianidin in oil-seed rape nectar collected on the clothianidin treatment test plot were always below the limit of quantification (LOQ). The clothianidin concentration in was 0.001 mg a.s./kg in one sample and in two samples below LOQ.
The TZNG and TZMU concentration of all pollen and nectar samples from the treatment test plot was always below the limit of detection (LOD).

5) Przygoda et al 2006 (Höfchen, oilseed rape; replanting interval 11 months):
Acceptable: Yes.
In autumn 2005 clothianidin was applied and incorporated down to 15 cm soil depth (Höfchen, Germany). The rate corresponded to 90 g clothianidin/ha and the application was performed to represent a long-term soil plateau concentration of clothianidin simulating the consecutive use of clothianidin on the same plot over several years. On the same day, clothianidin-treated winter barley seeds were sown at a nominal sowing rate of 160 kg seeds/ha. The winter wheat was harvested at 14 July 2006 and clothianidin-free oil-seed rape seeds were sown on 5 September 2006.
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. Additionally soil samples were collected directly after the application and incorporation and after a period of nearly 11 months, directly before sowing winter oil-seed rape (LOD 2 ug/kg soil).
Results:
Soil concentrations in the upper 15 cm: Directly after spray application and incorporation, mean measured concentration of clothianidin was 33.6 µg/kg dry soil in the treatment. Directly before drilling of the winter rape, mean measured concentration of clothianidin was 12.6 µg/kg dry soil in the treatment.
For residues in pollen and nectar see table:

Sample attribute	Sample ID	Sampling date	Netto weight [g]	mg a.s/kg		
				Clothianidin	TZNG	TZMU
Control	Pooled Nectar 002 + 004 + 006	2007-04-12	0.1531	< LOD	< LOD	< LOD
		2007-04-13	0.1471			
		2007-04-24	0.0457			
Treatment	Nectar 002	2007-04-12	0.4655	< LOD	< LOD	< LOD
	Nectar 004	2007-04-13	0.7138	< LOD	< LOD	< LOD
	Nectar 006	2007-04-24	0.7454	< LOQ	< LOD	< LOD
Control	Pollen 001	2007-04-12	0.5956	< LOD	< LOD	< LOD
	Pollen 003	2007-04-13	0.7117	< LOD	< LOD	< LOD
	Pollen 006	2007-04-24	0.7441	< LOD	< LOD	< LOD
Treatment	Pollen 001	2007-04-12	0.5035	< LOQ	< LOD	< LOD
	Pollen 003	2007-04-13	1.0213	< LOQ	< LOD	< LOD
	Pollen 006	2007-04-24	0.6338	< LOQ	< LOD	< LOD

Limit of quantitation (LOQ) for clothianidin, TZNG and TZMU = 0.001 mg/kg
Limit of determination (LOD) for clothianidin, TZNG and TZMU = 0.0003 mg/kg
Residue levels are based on the fresh weight of the sample material and are not corrected with respect to the recovery rates

Under worst case conditions (long-term clothianidin plateau concentration conservatively simulated by fresh application and incorporation of clothianidin into the soil at the day of sowing clothianidin-dressed winter wheat, followed by untreated winter oil-seed rape as a succeeding crop), residues of clothianidin in oil-seed rape nectar and pollen collected on the clothianidin treatment test plot were always below the limit of quantification (LOQ).

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-Delegue 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.
Hendrikx, Chauzat, Debin, Neuman, Fries, Ritter, Borwn, Mutinelli, Le Conte, Gregorc 2009. Scientific report submitted to EFSA. Bee morlitaty and bee surveillance in Europe. CFP/EFSA/AMU/2008/02. Accepted for publication 03 December 2009.
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.
Van der Zee (2010). Colony losses in the Netherlands. Journal of Apicultural Research 49(1): 121-123
Van der Zee & Pisa (2011). Monitor Bijensterfte Nederland 2009-2010. NBC rapporten 2011 nr 1.
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.

Bijlage II-2 thiamethoxam

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 thiamethoxam. Deze middelen zijn in onderstaande tabel weergegeven.

Gewasbeschermingsmiddelen op basis van thiamethoxam

Toelating-nr	Middel-naam	Toelating-houder	werkzame stoffen	Toepas-sing	formulering	Toepassing
12679	ACTARA	Syngenta Crop Protection B.V.	thiamethoxam 25%	Professio-neel	Water dispergeer-baar granulaat	Gewasbehandeling in aardappelen, bedekte teelt van knol-en-bolbloemgewassen, onbedekte en bedekte teelt van bloemisterij- en boomkwekerij gewassen en vaste planten; Grondbehandeling van aardappelen.
12913	CRUISER 350 FS	Syngenta Crop Protection B.V.	thiamethoxam 350G/L	Professio-neel	Suspensie concentraat voor zaadbehan-deling	Zaadcoating in maïs, erwten, peulen, kapucijners.
12863	CRUISER SB	Syngenta Crop Protection B.V.	thiamethoxam 600G/L	Professio-neel	Suspensie concentraat voor zaadbehan-deling	Zaadcoating in bieten.
12852	CRUISER 70 WS	Syngenta Crop Protection B.V.	thiamethoxam 70%	Professio-neel	Water dispergeer-baar poeder voor vochtige zaadbehan-deling	Zaadcoating in sla en andijvie.
13215	AXORIS QUICK-GRAN	Compo Benelux N.V.	thiamethoxam 12,00G/KG	Niet-professio-neel	Granulaat	Granulaat voor in potten en bakken van sierplanten binnenshuis.
13216	AXORIS QUICK-STICKS	Compo Benelux N.V.	thiamethoxam 12,00G/KG	Niet-professio-neel	Planten-staafje	Pin voor in potten en bakken van sierplanten binnenshuis.

Biociden op basis van thiamethoxam

Toelating-nr	Middel-naam	Toelating-houder	werkzame stoffen	toepassing	formulering	Toepassing
13399	AGITA 10 WG	Novartis Consumer Health B.V.	thiamethoxam 10%	Professio-neel	Water dispergeer-baar granulaat	Tegen vliegen. Korrels om op te lossen en dan op oppervlakten te smeren in dierverblijf-plaatsen.

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.

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

"PART A

Only uses as insecticide may be authorised.

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

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

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

Member States shall ensure that:

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

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

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

The risk assessment is based on the final LoEP of July 2006 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.1.1 Professional uses of plant protection products: spray treatments

toelating -nr	middelnaam	Toelating-houder	werkzame stoffen	Toepas-sing	formulering	Toepassing(en)
12679	ACTARA	Syngenta Crop Protection B.V.	Thiamethox-am 25%	Profes-sioneel	Water dispergeerbaar granulaat	Gewasbehandeling in aardappelen, bedekte teelt van knol-en bolbloemgewassen, onbedekte en bedekte teelt van bloemisterij- en boomkwekerij gewassen en vaste planten; Grondbehandeling van aardappelen.

Risk assessment for bees.

Actara is currently used in a number of crops:

I. Foliar spray in
- potatoes
- floriculture, tree nursery and perennials, outdoor use; application only allowed before flowering until first flower buds are visible, and after flowering (high dose rate against white fly, low dose rate against aphids)
- floriculture, tree nursery and perennials, indoor use (high dose rate against white fly, low dose rate against aphids)
- bulbflowers and flowerbulbs, indoor use

II. Soil application in
- potatoes (during planting)

For the current assessment, the application of Actara in outdoor grown ornamentals (floriculture, tree nursery and perennials) against white fly (high dose rate) is withdrawn by the applicant. This use is therefore not included in the risk assessment.

Exposure to honeybees may occur via several routes, which will be discussed separately below.

Direct exposure via spray

1) In-field risk

For the spray uses, the risk assessment for direct exposure is based on the ratio between the highest single application rate and the lowest toxicity endpoint (LD_{50} value). An overview of the risk of thiamethoxam at the proposed uses is given in Table E.1. Direct overspray is not expected for the use as soil application during planting of potato (application on the soil in bare soil situation).

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

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

Table E.1 shows that since the HQ is above 50, there is a potential high risk for bees for all spray uses.

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

To refine the in-field risk for the field uses, the available semi-field and field studies at relevant dose rates will be considered (see LoE, section *field or semi-field tests, aimed at spray treatment*).

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

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

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

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

Regarding the spray use in potatoes: this crop will 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. Thiamethoxam is of the same toxicity to bumblebees and honeybees (see LoE, section *acute toxicity*). Since the dose rate in the potato uses are covered by the dose rate tested in the honeybee field studies, the direct risk from overspray to bumblebees is considered to be acceptable provided that risk mitigation measures are prescribed.

The following sentences must be included in the Statutory Instructions for Use (already on the label):

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

Also, crop-specific restrictions in application timing should be included for the outdoor uses. [These sentences are mentioned here for reasons of clarity but it is noted that they are not taken to the Statutory Instructions for Use, since they are changed below due to risks via another exposure route (indirect exposure):
Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel als
I. Gewasbehandeling
- in de teelt van aardappels, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei
- in de onbedekte teelt van bloemisterijgewassen, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei
- in de onbedekte teelt van boomkwekerijgewassen en vaste planten, met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot het zichtbaar worden van de eerste bloemknoppen alsmede na de bloei]

With these restrictions, the period between application and flowering is at least 4 days, which is the period tested to be safe at 60 g a.s./ha. Therefore, these provisions cover the risk of the low dose in floriculture, tree nursery and perennials (25 g a.s./ha, against aphids) and potatoes (20 g a.s./ha).

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

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

Use (Field / Glasshouse)	Application rate a.s. [g/ha]	Drift %	Exposure [g/ha]	LD_{50} [µg/bee]	HQ [Exposure/LD_{50}]	Trigger value
Potatoes, foliar spray (F)	20	10%	2	0.005	**400**	50
Floriculture, tree nursery and perennials (F) *(against aphids)*	25	10%	2.5	0.005	**500**	50
tree nursery: high trees (F) *(against aphids)*	25	6.3%	1.6	0.005	**315**	50

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

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

There is one cage test in which effects of low dose rates (1 and 5 g a.s./ha) were checked (Nengel 1998a, see LoE, section *field or semi-field tests, aimed at spray treatment*). At 5 g a.s./ha, mortality was slightly increased on the first day after application only (checked for 7 days), both when applied during and after bee flight. Also, behavioural effects and reduced foraging activity were seen. At 1 g a.s./ha, the only effect seen was a slight decrease of foraging activity on the first day after application. No effects on brood development and colony strength were found at both dose rates (checked until 27 days after treatment).

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

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

Use (Field / Glasshouse)	Appl. rate [g/ha]	Maximum acceptable concen-tration [g/ha]	Required drift rate %	Available drift reducing measure
Potatoes, foliar spray (F)	20	1	5%	Spuitboomverlaging (30 cm boven de top van het gewas) + driftarme spuitdoppen (dopafstand 25 cm) + kantdop; of Driftarme spuitdop + kantdop + luchtondersteuning
Floriculture, tree nursery and perennials (F) *(against aphids)* - except high trees	25	1	4%	Spuitboomverlaging (30 cm boven de top van het gewas) + driftarme spuitdoppen (dopafstand 25 cm) + kantdop; of Driftarme spuitdop + kantdop + luchtondersteuning

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

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

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

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

In aardappels:
- ***spuitboomverlaging (30 cm boven de top van het gewas) in combinatie met driftarme spuitdoppen (dopafstand 25 cm) en een kantdop; of***
- ***conventionele spuitmachine met een driftarme spuitdop en een kantdop in combinatie met luchtondersteuning.***

In bloemisterijgewassen, boomkwekerijgewassen en vaste planten (tegen luis), neerwaartse bespuiting:
- ***spuitboomverlaging (30 cm boven de top van het gewas) in combinatie met driftarme spuitdoppen (dopafstand 25 cm) en een kantdop; of***
- ***conventionele spuitmachine met een driftarme spuitdop en een kantdop in combinatie met luchtondersteuning.***

In boomkwekerijgewassen (laanbomen) (tegen luis), opwaartse bespuiting:
Het middel in de onbedekte teelt van hoge boomkwekerijgewassen niet toepassen in de buitenste 5 meter van het gewas; daarnaast dienen op een strook van 5 meter vanaf het midden van de laatste bomenrij geen bloeiende planten aanwezig te zijn.

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

Indirect exposure via systemic working mechanism

Nectar and pollen of the crop
Thiamethoxam is a systemic substance. It has many applications as seed treatment, where the substance and its metabolites are taken up by the plant and distributed to (among other plant parts) nectar and pollen. This may lead to a risk from flowering crops. It is not known how well the substance is taken up by the plant when it is sprayed. No residue data are available for spraying applications (in contrast to seed treatments), but due to the persistent nature of the a.s., it has to be investigated whether bees would still be at risk if they fly on crops which flower after spray application.

As discussed above, no short-term adverse effects on adult bees are expected from the proposed field applications of Actara in floriculture, tree nursery and perennials against aphids, and in the spray treatment of potatoes with application rate below 60 g a.s./ha, as long as the appropiate restrictions are followed; see above (direct spray). Long-term effects can not be addressed with (semi-) field studies. In the spray field studies, colony effects were monitored for a period of at most eight weeks. Overwintering was not studied.

For the seed treatment uses (see below), long-term effects have been studied for up to four years in monitoring trials, but it is not known how relevant these trials are for the exposure level expected after the spray treatments of Actara.

However, laboratory studies are available for thiamethoxam which provide NOEC values for chronic mortality and behavioural effects and these can be used to consider longer-term effects.

The EPPO scheme (2010) indicates that when risks from systemic substances are expected, effects from longer-term exposure should be considered e.g. by performing a chronic (10-d) toxicity study. For thiamethoxam and its metabolite CGA 322704 (which is an active substance itself, clothianidin), these studies were done. The 10-d NOEL was 10 µg/L for both substances (8.4 µg/kg based on sucrose solution density of 1.19 kg/L), which corresponds to values of 1.845 ng thiamethoxam/bee and 1.892 ng CGA 322704/bee (cumulative doses over 10 days). To facilitate the calculations, a NOEL of 1.8 ng/bee will be used for both thiamethoxam and CGA 322704.

Also, a test on honeybee larvae was performed. The NOEC for larvae development was determined at 12.5 µg/kg.

Furthermore, tests were performed to determine effects on sublethal parameters in the laboratory (see LoE, section *summary of additional, non-guideline studies*). No adverse effects on return flight ability are expected at concentrations of 25 µg/kg for thiamethoxam (3 ng/bee) and 25 µg/kg for CGA 322704 (0.8 ng/bee). No adverse effects on feed consumption and trophalactic interactions are expected at concentrations of 100 µg/kg for thiamethoxam (5.0 ng/bee) and 100 µg/kg for CGA 322704 (2.8 ng/bee).
For thiamethoxam, the NOEC values determined in these studies are close to the oral LC50 value. This was explained by looking at the exposure duration. In the acute oral toxicity study, mortality is checked after 24 and 48 hours. In the current studies however, the test duration was much shorter. Therefore it is expected that the tested doses were not fully consumed in the sublethal toxicity studies. It was estimated by Anses (France) that about one third of the dose could have been consumed during the return flight ability test.
It is unclear if the NOEC values for return flight ability, feed consumption and trophalactic interactions would be lower than 25 and 100 µg/kg, respectively, if those studies would have had a longer duration. Therefore, no clear endpoint could be derived from them. However, the studies are not required according to the state of the art of the risk assessment and the endpoints given by the study authors are higher than the other available endpoints. Therefore, the most important endpoints for the risk assessment are considered to be the 10-d NOEC for adult mortality (8.4 µg/kg) and the NOEC for larvae development (12.5 µg/kg).

However, residue data in plant matrices relevant for the proposed uses of Actara are lacking, so these NOEC values cannot be compared with relevant exposure values for Actara.

Since there are currently no data available to estimate the long-term effects via systemic uptake after spraying, the applicant proposes to restrict the application of Actara for <u>outdoor</u> uses to "after flowering only". With this restriction, exposure via flowering crops can be excluded and this risk is acceptable.

The following sentences must be included in the Statutory Instructions for Use (only outdoor uses shown):

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

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

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

Based on this, exposure of bees to flowering weeds which have been sprayed with Actara (both during and before flowering) can be excluded. Therefore, this risk is acceptable.

Nectar and pollen in succeeding crops
Thiamethoxam is persistent in soil (in the final LoE for fate and behaviour, the following values are given for DT_{50lab} (20°C, aerobic): thiamethoxam 34 to 276 days, CGA322704 DT_{50lab} (20°C, aerobic)=178 to 284 days). It has been shown that after use of the substance as seed treatment, residues of thiamethoxam and metabolite CGA322704 were found in nectar and pollen of succeeding crops. The risk of succeeding crops should therefore be addressed. The French authorisation agency Anses have already evaluated this point for the use of Actara. They used the rotational crop studies from the DAR in which thiamethoxam and metabolite CGA322704 levels were measured in green parts of untreated crops following a bare soil application with 200 g/ha thiamethoxam (crops drilled 29, 104, 119 and 180 days after a soil application of the product). The concentrations in green parts can be considered as worst case compared to the concentrations that could be found in nectar and pollen (ICPBR, 2009). The mean concentrations of thiamethoxam (residue definition is thiamethoxam + CGA322704 expressed as thiamethoxam) are 0.0034, 0.0014 and 0.00017 mg/kg at 29, 104 and 119 days after treatment (the concentrations are recalculated for a dose rate of 38 g/ha which is considered to be the maximum dose rate reaching the soil after interception of the crop).

Using these measurements, the risk to bees foraging on pollen or nectar can be estimated by using the data on daily intake from Rortais et al. (2005), as indicated in EPPO 2010. For the chronic risk assessment, mean residue values are appropiate (see EPPO 2010, note 10).
The chronic risk to nectar foragers is estimated, as this leads to the worst case exposure for all bee categories.

Nectar foragers are expected to 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. 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.

Using the measured residue value after 29 d in a succeeding crop plant as a worst case estimate of the residue value in nectar (3.4 µg/kg), the risk can be calculated as 3.4 ng/g * 0.321 g/bee/d = 1.09 ng/bee/day. This value compared to the chronic NOEL for adult bees of 0.18 ng/bee/day (calculated from 1.845 ng/bee in 10 days) leads to a TER of 0.17.
Thus, the expected exposure from foraging on nectar in succeeding crops planted after 29 days is potentially higher than the NOEL for adults (it is noted that the EPPO scheme does not give a trigger value to compare the TER with).

After 104 days, the calculated exposure is 1.4 ng/g * 0.321 g/bee/d = 0.45 ng/bee/day, which is still above the NOEL, but after 119 days, the calculated exposure is 0.17 ng/g * 0.321 g/bee/d = 0.055 ng/bee/day, which is below the NOEL.
The French authorisation agency, ANSES, concluded in a preliminary risk assessment of Actara (not yet available online) that a waiting period of 3.5 months (104 days) would be sufficient to protect honeybees from risks via attractive succeeding crops. They state that at day 104, 119 and 180 only a single exceedance was calculated by ANSES for pollinators consuming extreme high amounts of nectar and this will not affect the development of a bee colony because of the large size of the bee colonies.
Ctgb can agree with the proposed 3.5 months waiting period in view of the worst-case assumptions used for the calculations (residue in the plant used as estimate for residue in nectar; extreme value for nectar consumption used) and the fact that after 119 days (4 months) the worst-case calculated risk is acceptable, and having in mind harmonisation of restrictions within EU.

Furthermore, the concentrations in the soil 3 months after application with Actara are shown in the table below. These concentrations correspond with the concentrations found in the succeeding crop studies studies. After 90 d, the concentrations in soil are in the range of the concentrations used as starting point of the succeeding crop trials (0.004-0.024 mg a.s./kg (see the assessment for seed treatment products for details). This confirms that a 3.5 months period as proposed by ANSES is acceptable to reduce the risk for bees. The method is further explained in the risk assessment of the seed treatment uses.

Table E.4a PECsoil thiamethoxam
(calculation based on max DT_{50} of 172 d)

Product	Use	Method of application	Dose, frequency, interval, interception	PIEC (5 cm) [mg/kg]	PEC_{90d} (20 cm) [mg/kg]	PEC_{180d} (20 cm) [mg/kg]	PEC_{365d} (20 cm) [mg/kg]
Actara	potatoes	soil treatment	25 g/ha, 1x, n.a., no interception	0.033	0.0058	0.0040	0.0019
	potatoes	spray treatment	20 g/ha, 4x, 7 d, 50% interception	0.051	0.0090	0.0063	0.0030
	ornamentals	spray treatment	25 g/ha, 3x, 7 d, 50% interception	0.049	0.0085	0.0060	0.0029

Table E.4b PECsoil CGA322704
(calculation based on max DT_{50} of 228 d and transformation factor of 0.31)

Product	Use	Method of application	Dose, frequency, interval, interception	PIEC (5 cm) [mg/kg]	PEC_{90d} (20 cm) [mg/kg]	PEC_{180d} (20 cm) [mg/kg]	PEC_{365d} (20 cm) [mg/kg]
Actara	potatoes	soil treatment	25 g/ha, 1x, n.a., no interception	0.010	0.0018	0.0015	0.0008
	potatoes	spray	20 g/ha, 4x, 7	0.016	0.0028	0.0023	0.0013

		treatment	d, 50% interception				
	ornamentals	spray treatment	25 g/ha, 3x, 7 d, 50% interception	0.015	0.0036	0.0023	0.0013

Thus, Ctgb agrees with the proposal of the applicant to add the following restriction to the label:

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

With this restriction, the risk from succeeding crops is acceptable.

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

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

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

toelatingnr	middel-naam	toelating-houder	werkzame stoffen	dosering	formulering	Toepassing
12913	CRUISE R 350 FS	Syngenta Crop Protection B.V.	thiamethoxam 350G/L	mais: 63 g a.s./ha erwt: 104-110 g a.s./ha	Suspensie concentraat voor zaadbehandeling	Zaadcoating in mais, erwten, peulen, kapucijners.
12863	CRUISE R SB	Syngenta Crop	thiamethoxam 600G/L	60 g a.s./ha	Suspensie concentraat	Zaadcoating in bieten.

		Protection B.V.			voor zaadbehande-ling	
12852	CRUISE R 70 WS	Syngenta Crop Protection B.V.	thiamethoxam 70%	107 g a.s./ha	Water dispergeerbaar poeder voor vochtige zaadbehande-ling	Zaadcoating in sla en andijvie.

Risk assessment for bees

Exposure to honeybees may occur via several routes, which will be discussed separately below.

Direct exposure

1) In-field

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

2) Off-field - dust from treated seed

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

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

Maize seeds are coated with a normal/basic coating, so dust formation cannot be excluded. Whether this dust can be expelled outside the field depends on the type of machinery.
The sowing of maize is done with pneumatic machines. The pneumatic machines used for maize sowing have been adapted since 01/2010 to ensure that the air flow is sent downwards, towards the maize field and not upwards. Furthermore, the dust level of maize seeds is kept to a minimum and sowing is not done under windy weather conditions. If those conditions are met, no exposure is expected outside the field where flowering plants may be present.

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 (see LoE, section *dust deposition*).

Since the application rate for maize is 63 g a.s./ha, the expected off-field dose is 0.0055*63 = 0.35 g a.s./ha. A dust toxicity study showed that the NOEC for dust exposure is < 1 g a.s./ha, but that effects do not last (see LoE, section *dust toxicity*). The study author set the NOAEC at 5 g a.s./ha. However, at this rate increased mortality was seen for two weeks after application. At 1 g a.s./ha, effects only lasted three days. Therefore, Ctgb considers that 1 g a.s./ha can be used as endpoint for the risk assessment. Since the off-field rate for maize is a factor of 3 below this endpoint, the risk from dust exposure from maize sowing is consdered to be acceptable, 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 (strong wind as defined for spray applications: ≥ 5 m/s). Incidents at sowing of insecticide-treated maize seeds 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.

Peas are coated with a normal/basic coating, so dust formation cannot be excluded. However, the sowing of peas is done with mechanical or pneumatic machines. No air is involved in mechanical sowing, so this method has no dust drift risk. The pneumatic machines used for pea sowing send the air flow downwards, towards the pea field and not upwards. Therefore, no exposure is expected outside the field where flowering plants may be present, as long as sowing is not done under windy weather conditions. However, labelling of seed packages is currently not feasible for pea seed bags, as opposed to for maize seed bags, for which this has been developed after the incidents with bees at maize sowing. Labelling of seed packages in general will be further developed in a European context.
Until this has been finished, the seed quality of treated pea seeds should be as high as possible to prevent off-field exposure.

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

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

Thus, the risk from dust exposure from pea sowing is acceptable, provided that the following restriction is mentioned on the label for peas ((already prescribed on the label; note that this is a restriction for the coating facility):

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

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

Indirect exposure via systemic working mechanism
Due to its systemic nature, the a.s. can be taken up by plants. If this plant carries flowers, bees may be exposed to thiamethoxam or its bee-toxic metabolite CGA322704 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.

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

The risk for these route can be estimated with laboratory and higher tier data. These are summarised below.

Laboratory studies
The EPPO scheme (EPPO 2010) indicates that when risks from systemic substances are expected, toxicity after longer-term exposure should be considered. If risk are expected in a first-tier screening step, a chronic (10-d) toxicity study should be performed.
For thiamethoxam and its metabolite CGA 322704 (which is an active substance itself, clothianidin), these studies were done. The 10-d NOEL was 10 µg/L for both substances (8.4 µg/kg based on sucrose solution density of 1.19 kg/L), which corresponds to values of 1.845 ng thiamethoxam/bee and 1.892 ng CGA 322704/bee (cumulative doses over 10 days).
To facilitate the calculations, a NOEL of 1.8 ng/bee will be used for both thiamethoxam and CGA 322704.

Also, a test on honeybee larvae was performed. The NOEC for larvae development was determined at 12.5 µg/kg.

Furthermore, tests were performed to determine effects on sublethal parameters in the laboratory (see LoE, section *summary of additional, non-guideline studies*). No adverse effects on return flight ability are expected at concentrations of 25 µg/kg for thiamethoxam (3 ng/bee) and 25 µg/kg for CGA 322704 (0.8 ng/bee). No adverse effects on feed consumption and trophalactic interactions are expected at concentrations of 100 µg/kg for thiamethoxam (5.0 ng/bee) and 100 µg/kg for CGA 322704 (2.8 ng/bee).
For thiamethoxam, the NOEC values determined in these studies are close to the oral LC50 value. This was explained by looking at the exposure duration. In the acute oral toxicity study, mortality is checked after 24 and 48 hours. In the current studies however, the test duration was much shorter.

Therefore it is expected that the tested doses were not fully consumed in the sublethal toxicity studies. It was estimated by Anses (France) that about one third of the dose could have been consumed during the return flight ability test.
It is unclear if the NOEC values for return flight ability, feed consumption and tropholactic interactions would be lower than 25 and 100 µg/kg, respectively, if those studies would have had a longer duration. Therefore, no clear endpoint could be derived from them.
However, the studies are not required according to the state of the art of the risk assessment and the endpoints given by the study authors are higher than the other available endpoints. Therefore, the most important endpoints for the risk assessment are considered to be the 10-d NOEC for adult mortality (8.4 µg/kg) and the NOEC for larvae development (12.5 µg/kg).

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

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

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

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

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

These studies therefore only address long-term effects of up to three weeks of exposure per year.

Residues

Residue measurements were done in a large number of studies.

In the cage, tunnel and field tests of 1999-2001, residue data were measured in plant tissues relevant for honeybee exposure (pollen and nectar, (as indication) flower heads, fresh honey, honey stomachs, pollen loads) (see LoE, section *summary of the analysis for residues of thiamethoxam and the metabolite CGA 322704 in plant, honey, pollen and nectar samples*). Residues in leaves were also measured but these are considered less relevant for honey bees.
Results for oilseed rape at dose rates of up to 100.8 g a.s./ha: maximum 7.55 µg/kg thiamethoxam and 1.3 µg/kg CGA322704.
Results for sunflower at dose rates up to 52.5 g a.s./ha: maximum 3.0 µg/kg thiamethoxam and 1.0 µg/kg CGA322704.

Also trials in maize from 2007 are available in which treated maize was sown for two years in the same field (see LoE, section *summary of further trials to estimate residue levels*). For bee exposure, the measurements in pollen (done both in pollen taken from the plants and in hive pollen collected by bees) are relevant. The residue level is always < 10 ug/kg (pollen loads: thiamethoxam: maximum 7.17, mean 3.45 µg/kg; CGA322704 4.48, mean 2.01 µg/kg).
No increase of residue levels in pollen loads were observed the second year.

Residue measurements were done in three trials (2007) with treated oilseed rape (12.6 g a.s./ha) (see LoE, section *summary of further trials to estimate residue levels*).
Maximum residues:
Whole oilseed rape plants: 7 µg/kg thiamethoxam; 2 µg/kg CGA322704.
Bee pollen: 4 µg/kg thiamethoxam; CGA322704 < LOQ.
Hive pollen: 3 µg/kg thiamethoxam; CGA322704 <LOQ.
Nectar and honey: 9 µg/kg thiamethoxam; <LOQ.

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

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

Exposure via nectar and pollen of flowering crops

a) maize

The risk to adult bees foraging on maize pollen can be estimated by using the daily intake data from Rortais et al. (2005), as indicated in EPPO 2010. Nurse bees are expected to consume the highest amount of pollen of all categories of bees: 65 mg/bee in 10 days.

For the chronic risk assessment, mean residue values are appropiate (see EPPO 2010, note 10). A mean value over all available trials was not calculated. Instead, the highest available mean residue value from the trials in maize was used. This was a value from the two year studies in maize, in pollen taken from bees: 3.45 µg/kg (this value is worst case, as the dose rate in this study is higher than that proposed for the Netherlands; note that it is furthermore higher than found in the four-year monitoring trials). This value leads to an possible intake of thiamethoxam by nurse bees of (65 mg*3.45 pg/mg=) 0.224 ng/bee in 10 days. This value can be compared to the chronic NOEL for adult bees of 1.8 ng/bee in 10 days, which leads to a TER of 8, indicating the exposure is lower than the NOEL (no trigger value is given in the EPPO scheme). Note that 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 2008). Thus, the risk to adult bees from foraging on seed-treated maize is expected to be low.

Furthermore, in most of the residue trials, levels of thiamethoxam and metabolite were low and below 12.5 µg/kg, at which level no effects are expected on larvae development.
Thus, no effects are expected on larvae either.

This is confirmed with the results of the semi-field, field and especially the monitoring studies, from which it can be concluded that exposure of up to three weeks to the tested flowering crops grown from thiamethoxam-treated seed does not have adverse long-term effects on honey bee colonies. The dose rate and the exposure period tested in the maize studies are relevant for the currently proposed dose rate in maize in the Netherlands.

b) peas

Residue values in pea flowers are not available. It will be considered whether it is likely that the residue level will be high enough to exceed the NOEC for adult bees.

As explained above, for pollen intake a value of 65 mg/bee in 10 days is assumed.
The acceptable level in pea pollen can be calculated with these data and with the chronic NOEL for adult bees of 1.8 ng/bee/10 days.
Measured residues in pea pollen should be below 28 µg/kg (calculated as: x ng/g * 0.065 g/bee/10 d should be <1.8 ng/bee/ 10 d).
Looking at the residue trials in oilseed rape at a dose comparable to that of peas (ca. 100 g a.s./ha), the levels in flowers and leaves never reach 28 µg/kg. These can be used as worst-case estimation for the levels in pollen. Thus, a risk from feeding on pea pollen is not expected.

Considering nectar, nectar foragers are expected to 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.

The acceptable level in pea nectar or honey can be calculated with these data and with the chronic NOEL for adult bees of 0.18 ng/bee/day (calculated from 1.8 ng/bee in 10 days). Measured residues in pea nectar should be below 0.56 µg/kg (calculated as: x ng/g * 0.321 g/bee/day should be <0.18 ng/bee/day).
Measured residues in pea honey should be below 1.13 µg/kg (calculated as: x ng/g * 0.160 g/bee/day should be <0.18 ng/bee/day.
It is clear from the residue trials that such levels can occur in the field. Therefore, a risk cannot be excluded based on these (worst-case) calculations and higher tier studies should be considered.

The period of flowering for peas is considered to be covered by the exposure period tested in the monitoring studies (up to three weeks). The dose rate in peas (104 g a.s./ha) is comparable with dose rates in the maize monitoring studies (79 -103 g/ha) with short exposure period (5-8 days), but higher than in the maize monitoring studies (55-70 g/ha) with long exposure period (20-24 days) and the oilseed rape monitoring studies (12-16 g/ha) with 12-22 days exposure time. It was therefore questioned whether the monitoring trials cover the use in peas regarding the length of exposure in combination with the relevant dose rate.

According to the applicant, detectable residues in pollen and nectar are not related to dose rate per ha (occasionally present in maize pollen both at low and high rate and almost always in oilseed rape pollen and nectar at low dose rate). They provided a table in which the residue concentrations are summarised:

Thiamethoxam/CGA322704 residues in long-term monitoring studies (maize and oilseed rape) (table from the applicant)

study	jaar	actual dose rate in gram per ha	Exposure period in days	Thiam. in plant in ng/g	Thiam. in pollen in ng/g	Thiam. in nectar in ng/g	CGA 322704 in plant in ng/g	CGA 322704 in pollen in ng/g	CGA 322704 in nectar in ng/g
maize (1138F1)	2006	79	5	24	< 1		10	< 1	
	2007	103	8	30	< 1		3	< 1	
	2008	98	6	7	2		5	2	
	2009	54-71	24	1.6	< 1		1.9	< 1	
maize (1138F2)	2006	89	5	6	< 1		4	< 1	
	2007	102	8	5	< 1		6	< 1	
	2008	98	7	4	1		5	1	
	2009	57-70	20	3	1		4	2	
maize (1138F3)	2006	93	6	10	1		6	2	
	2007	81	6	10	< 1		8	1	
	2008	100	6	6	< 1		5	1	
	2009	55-57	23	7.3	< 1		7.3	4.6	
OSR (1041F1)	2006	16	19	2	1	1.7	< 1	< 1	< 1
	2007	13	13	< 1	< 1	<0.5	1	< 1	< 1
	2008	15	22	< 1	1	3	1	< 1	< 1
OSR (1041F1)	2006	13	16	< 1	1	0.7	< 1	< 1	< 1

	2007	12	12	< 1	< 1	0.7	< 1	< 1	< 1
	2008	14	21	< 1	< 1	0.7	< 1	< 1	< 1

This table indicates that residue levels are variable. It is however not completely clear that the residue level is independent of the dose rate per ha. Looking at the other available residue trials in the LoE, there does seem to be a trend towards higher residue level with dose increase (see the trials of Schur, 2001a, measurements in oilseed rape flowers).

Based on the long term monitoring studies in both maize and oilseed rape with long exposure time in which colony survival and condition was not affected, no adverse lethal and sublethal effects are expected in peas and the risk is therefore acceptable.

Flowering weeds

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

Succeeding crops

Exposure may occur via flowering succeeding crops. The flowering period of these may be variable, but in some cases exceed the period of 3 weeks which is the exposure period which has been studied in the monitoring trials. Therefore, the risk of succeeding crops is not be completely covered with the monitoring trials.

Three trials (2010) were done in which residues were measured in untreated bee-attractive crops, alfalfa, Phacelia and OSR) which were sown in spring in soil in which in the previous year first treated maize (spring-summer) and then treated barley (autumn-winter) were grown. It was shown that the untreated succeeding crops contained thiamethoxam and metabolite CGA322704.

The residues over all three trials are presented here, and summarised in the table below:

Soil (just before drilling of the flowering crop): range 4-24 µg/kg thiamethoxam; 2-5 µg/kg CGA322704

Whole plants:

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

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

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

Thiamethoxam/CGA322704 residue levels in succeeding flowering crops in ng/g											
		TMX residues									total
matrix	analysis	alfalfa 1	alfalfa 2	alfalfa 3	Phacelia 1	Phacelia 2	Phacelia 3	oilseed r 1	oilseed r 2	oilseed r 3	
soil	number	1	1	1	1	1	1	2	2	2	
	range	9	24	9	11	9	4	8-8	13-15	8-12	
plant	number	9	9	9	9	9	9	9	9	1	
	range	1-4	2-5	<1 - 5	<1	1-6	<1	1-3	3-12	7	
	average	2.0	3.1	2.0	<1	3.2	<1	2.0	6.3	7	
nectar	number	27	27	18	27	27	27	17	25		195
	range	< 0.5 - 0.6	<0.5 - 0.5	<0.5 - 2.2	<0.5	0.3-1.4	<0.5	<0.5-2.2	<0.5-5.2		
	number <LOQ	26	25	17	27	0	27	8	1		131
	number <10 ng	27	27	18	27	27	27	17	25		195
	average	0.5	0.5	0.6	<0.5	0.7	<0.5	0.8	1.9		0.75
pollen	number	1	1		24	19	25	20	27		117
	range	51	<1		<1 - 39	<1 -1	<1	<1-1	3-8		
	number <LOQ	0	1		11	16	25	16	0		69
	number <10 ng	0	1		23	19	25	20	27		115
	average	51.0	<1		3.8	1.0	<1	1.0	5.6		3.04
		CGA322704 residues									
matrix	analysis	alfalfa 1	alfalfa 2	alfalfa 3	Phacelia 1	Phacelia 2	Phacelia 3	oilseed r 1	oilseed r 2	oilseed r 3	
soil	number	1	1	1	1	1	1	2	2	2	
	range	3	5	4	4	3	2	2-3	3-3	2-2	
plant	number	9	9	9	9	9	9	9	9	1	
	range	2-5	1-5	2-5	2-3	5-12	2-6	2-4	4-11	4	
	average	2.2	2.9	3.8	2.55	8.1	4.33	2.2	6	4	
nectar	number	27	27	18	27	27	27	17	25		195
	range	< 1	<1	<1-1.1	<1-1	<1	<1	<1	<1-2.3		
	number <LOQ	27	27	17	26	27	27	17	22		190
	number <10 ng	27	27	18	27	27	27	17	25		195

	average	<1	<1	1	1	<1	<1	<1	1.06		1.04
pollen	number	1	1		24	19	25	20	27		117
	range	2	<1		<1-2	<1-3	<1-3	<1-3	1-3		
	number <LOQ	0	1		17	2	4	3	0		27
	number <10 ng	1	1		24	19	25	20	27		117
	average	2.0	<1		1.2	1.9	1.6	1.6	2.0		1.66

For calculating average < LOQ=LOQ

These succeeding crop residue trials indicate that residues in pollen and nectar stay below the NOEC of 8.4 µg/kg. In the succeeding crops trials only two samples were above 10 µg/kg: however the average is far below 8.4 µg/kg. It can be concluded that the risk for bees via flowering succeeding crops is acceptable when these crops are grown in soils with residue levels up to 24 µg/kg thiamethoxam and 2-5 µg/kg CGA322704.

The residues in soil calculated for the registered uses of Cruiser are shown in the Tables E.5a and b. The first concentration below the required level is indicated in bold.

Table E.5a PECsoil thiamethoxam (calculation based on max DT_{50} of 172 d)

Product	Use	Method of application	Dose, frequency, interval, interception	PIEC (5 cm) [mg/kg]	PEC_{90d} (20 cm) [mg/kg]	PEC_{180d} (20 cm) [mg/kg]	PEC_{365d} (20 cm) [mg/kg]
Cruiser 350 FS	maize	seed treatment	63 g/ha, 1x, n.a., geen interceptie	0.084	**0.0145**	0.0102	0.0048
	peas	seed treatment	110 g/ha, 1x, n.a., no interception	0.147	0.0255; [**0.0225** (120 d)]	0.0178	0.0085
Cruiser 70 WS	lettuce, endive	seed treatment	107 g/ha, 2x, 90 d, no interception	0.242	0.0420	0.0292	**0.0140**
	lettuce, endive	seed treatment	107 g/ha, 1x, n.a., no interception	0.143	0.0248	**0.0173**	0.0083
Cruiser 70 WS	cabbages*	seed treatment	98 g/ha, 1x, n.a., no interception	0.131	**0.0228**	0.0158	0.0075
Cruiser 600 FS	beets	seed treatment	72 g/ha, 1x, n.a., no interception	0.096	**0.0168**	0.0115	0.0055

* There is currently no authorisation for cabbages of Cruiser 70WS.

Table E.5b PECsoil CGA322704 (calculation based on max DT_{50} of 228 d and transformation factor of 0.31)

Product	Use	Method of application	Dose, frequency, interval, interception	PIEC (5 cm) [mg/kg]	PEC_{90d} (20 cm) [mg/kg]	PEC_{180d} (20 cm) [mg/kg]	PEC_{365d} (20 cm) [mg/kg]
Cruiser 350 FS	maize	seed treatment	63 g a.s./ha, 1x, nvt, geen interceptie	0.026	**0.005**	0.0038	0.0023
	peas	seed treatment	110 g a.s./ha, 1x, nvt, geen interceptie	0.045	0.0088	0.0065	**0.0038**
Cruiser 70 WS	lettuce, endive	seed treatment	107 g a.s./ha, 2x, 90 d, geen interceptie	0.078	0.0148	0.0113	0.0065
	lettuce, endive	seed treatment	107 g a.s./ha, 1x, n.a., no interception	0.044	0.0085	0.0065	**0.0038**
Cruiser 70 WS	cabbages*	seed treatment	98 g a.s./ha, 1x, nvt, geen interceptie	0.041	0.0078	0.0058	**0.0033**
Cruiser 600 FS	beets	seed treatment	72 g a.s./ha, 1x, nvt, geen interceptie	0.030	0.0058	**0.0043**	0.0025

* There is currently no authorisation for cabbages of Cruiser 70WS.

For Cruiser SB (600 FS) use in sugarbeets the residue level is 16.8 µg a.s./kg after 90 days, but for the metabolite, the level is below 5 µg/kg after 180 days. The cultivation period of sugarbeets is about 6 months and sugarbeets are normally grown in rotation with other arable crops in the next year. The risk for flowering succeeding crops is acceptable since in the cases that flowering crops are grown after a sugarbeet crop, the residue levels in soils are already at an acceptable level after 6 months. Therefore no restriction is necessary.

For Cruiser 350 FS use in maize residue levels are 14.5 µg/kg after 90 days and 10.2 µg/kg after 180 days. The cultivation period of maize is about 5 - 6 months and maize is normally grown in rotation with maize, other arable crops or grassland in next year. The risk for flowering succeeding crops is acceptable since in the cases that flowering crops are grown after a maize crop the residue levels in soils are already at an acceptable level after 3 months (confirmed also for the metabolite). Therefore no restriction is necessary.

For Cruiser 350 FS use in peas residue levels are 25.5 µg/kg after 90 days, 22.5 µg/kg after 120 days and 17.8 µg/kg after 180 days. The cultivation period of peas is about 4 - 5 months.
Another crop may be sown in the same year. Regarding only the parent substance, the risk for flowering succeeding crops is acceptable since in the cases flowering crops are grown after a pea crop the residue levels in soils are already at an acceptable level after 4 months. However, the metabolite level stays high and only drops below 5 µg/kg after 365 days.

For Cruiser 70 WS use in cabbage (currently not yet authorised) residue levels are 22.8 µg/kg after 90 days and 15.6 µg/kg after 180 days. These cases are worst case since no degradation from sowing to transplanting is taken into account. The cultivation period of cabbage is about 3 - 5 months after transplanting. Regarding only the parent substance, the risk for flowering succeeding crops is acceptable since in the cases flowering crops are grown after a cabbage crop the residue levels in soils are already at an acceptable level after 3 months. However, the metabolite level stays high and only drops below 5 µg/kg after 365 days.

For Cruiser 70 WS use in lettuce/endive residue levels are 42 µg/kg after 90 days and 29.2 µg/kg after 180 days after 2 succeeding cultures. After a single culture, residue levels are 24.8 µg/kg after 90 days (so almost at the level of 24 µg/kg) and 17.3 µg/kg. These calculations are worst case since no degradation from sowing to transplanting is taken into account. The cultivation period of lettuce is about 2 – 3 months after transplanting and 1 month before transplanting. Regarding the parent substance only, in the case that flowering crops are grown after a single cultivation of a lettuce/endive crop the residue levels in soils are expected to be at an acceptable level already after 3 months. However a risk can not be excluded in case of 2 succeeding cultures per year. For the metabolite, the level is acceptable after 1 year, but only at one culture per year.

It is therefore proposed to add the following warning to the label of Cruiser 70 WS (for all uses) and Cruiser 350 FS (for peas):

> *In verband met het risico voor bijen mogen binnen een periode van een jaar (365 d) gerekend vanaf zaai of uitplanten op het veld geen voor bijen aantrekkelijke gewassen worden gezaaid of geplant.*

With this sentence, the risk from succeeding crops is acceptable for all seed treatment uses of thiamethoxam.

The risks to bees in a crop failure scenario were also considered. Of the crops in which thiamethoxam is used, 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.

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

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

A.2 Non-professional plant protection uses

toelatingnr	Middel-naam	Toelating-houder	werkzame stoffen	toepassing	formulering	Toepassing(en)
13215	AXORIS QUICK-GRAN	Compo Benelux N.V.	thiamethoxam 12,00G/KG	Niet-professio-neel	Granulaat	Granulaat voor in potten en bakken van sierplanten binnenshuis.
13216	AXORIS QUICK-STICKS	Compo Benelux N.V.	thiamethoxam 12,00G/KG	Niet-professio-neel	Planten-staafje	Pin voor in potten en bakken van sierplanten binnenshuis.

Axoris Quick-Gran and Axoris Quick-Sticks are used as treatment of potting soil for non-professional use. Since thiamethoxam is systemic, the active substance might occur in nectar and pollen, and in honeydew. The formulations can be used all through the year, and flowering during treatment is expected. Based on the high toxicity and symtemicity of the substance, a risk for bees is present if these products would be used outdoors. If the products are only used indoors, the risk to bees is considered to be small. Although individual bees might theoretically enter houses to forage on potted plants, it is unlikely that a significant number will be attracted to come inside.

Furthermore, large groups of bees would not be allowed inside by the occupants of those houses.

The risk of Axoris Quick-Gran and Axoris Quick-Sticks is acceptable, since the label clearly mentions that application is only allowed indoors:
Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel op sierplanten in potten en bakken binnenshuis.

B. Biocides

B.1 Professional biocidal uses

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	formulering	Toepassing(en)
13399	AGITA 10 WG	Novartis Consumer Health B.V.	thiamethoxam 10%	Water dispergeerbaar granulaat	Tegen vliegen. Korrels om op te lossen en dan in dierverblijfplaatsen op oppervlakten als muren te smeren.

The risk to honeybees of Agita 10 WG was not assessed in previous Dutch risk assessments nor in the draft CAR. However, thiamethoxam has systemic properties and is persistent in soil. When manure from treated stables is spread over arable fields on which flowering crops are then grown, honeybees may be exposed via nectar and/or pollen of these crops. There are no studies available in which residue levels in nectar or pollen were measured in plants grown on soil on which contaminated manure was spread. To estimate the potential for exposure, therefore the initial concentrations in soil of thiamethoxam and metabolite CGA322704 (clothianidin) have been calculated.

The predicted environmental concentration (PEC) of the active substance in soil has been determined following the directions of the ESD for Insecticides for Stables and Manure Storage Systems edited by the OECD (OECD series on emission scenario documents, Number 14).
The PECs are thus similar to the 1[st] tier calculations presented in the draft CAR, except that in this risk assessment the nitrogen standard for Dutch soils was used (in the draft CAR the worse case standard is used). For the proposed indoor application, exposure of soil is expected by the distribution of manure from animal housings for cattle, pigs and poultry on land.

The fraction of the biocide reaching the manure storage system will depend on the animal species and category considering (i.e. the type of housing and manure collection system), the way of application and the way of action of the biocide. All eighteen categories of animals (housings) presented in the ESD (see Table 1) were taken into account in the risk assessment. As the product is smeared onto window sills, walls, ceilings, etcetera, a fraction of 0.35 is assumed to be emitted to the slurry pit (ESD, table 5.4, page 40).

Table 1: Overview of the different categories in the ESD.

index (i1)	Cat	Subcatergory
1	Cattle	Dairy cattle (housed during grazing season)
		Dairy cattle (outdoors during grazing season
2		Beef cattle (housed during grazing season)
		Beef cattle (outdoors during grazing season)
3		Veal calves
4	Pigs	Sows
5		Sows in groups
6		Fattening pigs

index (n)	Cat	Subcatergory
7	Poultry	Laying hens in battery without treatment (aeration)
8		Laying hens in battery with treatment (belt drying)
9		Laying hens in battery cages with forced drying (deep pit, high rise)
10		Laying hens in compact battery cages
11		Laying hens in free ranges with litter floor (partly litter floor, partly slatted)
12		Broilers in free range with litter floor
13		Laying hens in free range with grating floor (aviary system)
14		Parent broilers in free range with grating floor
15		Parent broilers in rearing with grating floor
16		Turkeys in free range with litter floor
17		Ducks in free range with litter floor
18		Geese in free range with litter floor

PEC_{soil} values were calculated for a single application of manure to arable land and for four cumulative applications to grassland. Manure application is controlled by two standards, the nitrogen (N) standard and phosphate (P_2O_5) standard for manure application to land. The PEC_{soil} values were calculated for the N standard was set to 170 N. $ha^{-1}.year^{-1}$ for arable and grassland.

The risk assessment of soil is based on a worst case scenario that thiamethoxam did not degrade in manure/slurry during storage. In the Netherlands, the period of storage in certain animal housings is < 2 weeks and therefore there may be a very short time period available for degradation. Furthermore, anaerobic degradation data for thiamethoxam were assessed in inundated soil or sediment systems and it is uncertain how these experimental set ups translate to slurry or dry manure storage. The ESD acknowledges that the translation of soil anaerobic degradation studies to anaerobic degradation in manure holds many uncertainties and should be treated with caution. We therefore concluded that anaerobic degradation in manure could not be taken into account due to the lack of degradation studies in manure itself for Agita 10 WG and the potential short period of manure storage.

Metabolites of anaerobic degradation
The assumption that anaerobic degradation does not occur is only conservative if the toxicity of anaerobically formed metabolites is less severe than the toxicity of the parent. The anaerobic degradation of thiamethoxam renders metabolite NOA 407475 up to 62.3 % (worst case scenario). Toxicity data of NOA 407475 shows similar toxicity to its parent for fish, crustaceans and earthworms. NOA 407475 shows a lower toxicity than its parent for sediment organisms. It can therefore be concluded that the risk assessment of thiamethoxam will also be protective for the potential effects of NOA 407475.

Predicted initial expected concentration (PIEC)
For arable land, the maximal $PIEC_{soil}$ was used in the risk assessment, which is directly after applying the manure, thereby not considering any aerobic degradation of thiamethoxam in soil.

For grassland, maximal $PIEC_{soil}$ in land was calculated after four applications, including aerobic degradation and considering carry over of thiatmethoxam in soil. The ESD method was followed using the equation:

$$\text{Qai max in soil} = \text{Qai}\,(1-e^{-nkt})/(1-e^{-kt}) \qquad \text{(Eq. 2)}$$

With for grassland t = 53 days (n = 4) and a $DT50_{aerobic}$ = 72 d (lowest degradation rate observed) and the dissociation constant Kd was $Kd_{aerobic}$

CGA 322704 is formed up to 35.7% as a consequence of aerobic degradation of thiamethoxam in soil. The calculation of maximum $PIEC_{soil}$ metabolite CGA 322704 was also conform equation 2 and thus included aerobic degradation of CGA 332704 in soil. As a worst case, 35.7% of the Qai of thiamethoxam (this Qai does not include aerobic degradation of thiamethoxam) with a molecular weight correction was taken as the Qai for CGA 322704 (Equation 2). A DT_{50} of 338 days at 12 °C was used to account for degradation in soil for CGA 322704, which was based on a worst case degradation study from the CAR.

Table 2. PIECsoil for thiamethoxam and clothianidin for arable and grassland for nitrogen standard.

		Thiamethoxam		Clothianidin	
index	Category	Arable land PIEC soil# (mg a.i. /kg soil)	Grassland PIECsoil after 4th application* (mg a.i. /kg	Arable land PIEC soil# (mg a.i. /kg soil)	Grassland PIECsoil after 4th application* (mg a.i. /kg
1	Cattle	3.14E-03	5.42E-03	9.57E-04	2.62E-03
		7.42E-03	1.30E-02	2.27E-03	6.22E-03
2		1.98E-03	3.44E-03	6.03E-04	1.66E-03
		4.43E-03	7.67E-03	1.35E-03	3.71E-03
3		1.33E-02	2.31E-02	4.05E-03	1.11E-02
4	Pigs	7.54E-03	1.31E-02	2.30E-03	6.31E-03
5		8.20E-03	1.43E-02	2.50E-03	6.86E-03
6		6.02E-03	1.04E-02	1.84E-03	5.04E-03
7	Poultry	4.45E-03	7.80E-03	1.36E-03	3.73E-03
8		6.39E-03	1.11E-02	1.95E-03	5.35E-03
9		4.15E-03	7.27E-03	1.27E-03	3.48E-03
10		3.75E-03	6.48E-03	1.14E-03	3.14E-03
11		9.59E-03	1.84E-02	2.93E-03	8.79E-03
12		2.68E-03	4.63E-03	8.18E-04	2.24E-03
13		5.61E-03	9.76E-03	1.71E-03	4.70E-03
14		2.23E-03	3.83E-03	6.79E-04	1.86E-03
15		4.77E-03	8.33E-03	1.46E-03	4.00E-03
16		5.04E-03	8.86E-03	1.54E-03	4.22E-03
17		5.42E-03	9.52E-03	1.66E-03	4.54E-03
18		3.81E-03	6.61E-03	1.16E-03	3.19E-03

*# maximum $PIEC_{soil}$ is directly after manure application on arable land; * maximum $PIEC_{soil}$ is directly after 4th manure application, including aerobic degradation in soil and carryover between applications.*

Refinement of initial calculations:

During the assessement for efficacy it was decided that the number of applications of the product had to be put down to 5 times a year. The original calculations had 6 (a factor of 0.83)

The grassland was as a worse case incorporated to 5 cm depth. However, injection of manure is mandatory in the Netherlands and injection has an incorporation depth of 10 cm according to the ESD (page 50) which is another factor of 0.5 on the concentration. The concentrations are thus:

Table 3. Refined PIECsoil for thiamethoxam and clothianidin for arable and grassland for nitrogen standard.

		Thiamethoxam		Clothianidin	
index	Category	Arable land PIEC soil[a] (mg a.i. /kg soil)	Grassland PIECsoil after 4[th] application[*] (mg a.i. /kg soil)	Arable land PIEC soil[a] (mg a.i. /kg soil)	Grassland PIECsoil after 4[th] application[*] (mg a.i. /kg soil)
1	Cattle	2.62E-03	2.26E-03	7.98E-04	1.09E-03
		6.18E-03	5.42E-03	1.89E-03	2.59E-03
2		1.65E-03	1.43E-03	5.03E-04	6.92E-04
		3.69E-03	3.20E-03	1.13E-03	1.55E-03
3		1.11E-02	9.63E-03	3.38E-03	4.63E-03
4	Pigs	6.28E-03	5.46E-03	1.92E-03	2.63E-03
5		6.83E-03	5.96E-03	2.08E-03	2.86E-03
6		5.02E-03	4.33E-03	1.53E-03	2.10E-03
7	Poultry	3.71E-03	3.25E-03	1.13E-03	1.55E-03
8		5.33E-03	4.63E-03	1.63E-03	2.23E-03
9		3.46E-03	3.03E-03	1.06E-03	1.45E-03
10		3.13E-03	2.70E-03	9.50E-04	1.31E-03
11		7.99E-03	7.67E-03	2.44E-03	3.66E-03
12		2.23E-03	1.93E-03	6.82E-04	9.33E-04
13		4.68E-03	4.08E-03	1.43E-03	1.96E-03
14		1.86E-03	1.60E-03	5.66E-04	7.75E-04
15		3.98E-03	3.47E-03	1.22E-03	1.67E-03
16		4.20E-03	3.69E-03	1.28E-03	1.76E-03
17		4.52E-03	3.97E-03	1.38E-03	1.89E-03
18		3.18E-03	2.75E-03	9.67E-04	1.33E-03

Toxicity threshold

As a worst-case approach, the values in soil calculated in Table 3 will be taken as expected residue levels in nectar and pollen (this assumes 100% uptake in the plant and 100% transfer to nectar and pollen).

Long-term endpoints for bees are available in the Plant Protection Product dossier of Syngenta. NOEC values are 0.0125 mg/kg for larvae development and 0.0094 mg/kg for chronic adult mortality (10-d exposure), for both thiamethoxam and CGA320744.

The ratio of the PIEC soil to the lowest NOEC for bees is given in Table 4.

Table 4. Risk for the soil compartment from thiamethoxam and clothianidin in AGITA 10 WG in the arable land scenario and grassland scenario.

		Thiamethoxam		CHA322704	
index	Category	PIEC soil / NOEC bees Arable land	PIEC soil / NOEC bees Grassland	PIEC soil / NOEC bees Arable land	PIEC soil / NOEC bees Grassland
1	Cattle	0.31	0.27	0.09	0.13
		0.74	0.64	0.23	0.31
2		0.20	0.17	0.06	0.08
		0.44	0.38	0.13	0.18
3		**1.32**	**1.15**	0.40	0.55

		Thiamethoxam		CHA322704	
Index	Category	PIEC soil / NOEC bees Arable land	PIEC soil / NOEC bees Grassland	PIEC soil / NOEC bees Arable land	PIEC soil / NOEC bees Grassland
4	Pigs	0.75	0.65	0.23	0.31
5		0.81	0.71	0.25	0.34
6		0.60	0.52	0.18	0.25
7	Poultry	0.44	0.39	0.13	0.19
8		0.63	0.55	0.19	0.27
9		0.41	0.36	0.13	0.17
10		0.37	0.32	0.11	0.16
11		0.95	0.81	0.29	0.44
12		0.27	0.23	0.08	0.11
13		0.56	0.49	0.17	0.23
14		0.22	0.19	0.07	0.09
15		0.47	0.41	0.14	0.20
16		0.50	0.44	0.15	0.21
17		0.54	0.47	0.16	0.23
18		0.38	0.33	0.12	0.16

The table shows that the concentration in soil is too high in only one scenario, and only for thiamethoxam: veal calves show a exceedance of the limit, being 1.32 and 1.15, which indicates that for safe use a reduction is necessary in soil concentration of 24% for arable lands and 13% in grassland. The emission scenario document has some stringent worse case assumptions:

1. No degradation in manure.
2. no degradation in soil for arable lands (the PIEC is presented which does not incorporate degradation; only grassland takes into account degradation between the 4 applicatons a year in the model).
3. 100% bioavailability/uptake of the substances in the plant.
4. Anaerobic studies in water/sediment system showed that degradation under anaerobic conditions is 14.5 – 24.2 days (at 12 °C). Aerobic degradation in field dissipation studies show a geometric mean of DT_{50} was 59.4 at 12 °C.

Furthermore, all PIEC concentration are below 0.024 mg/kg soil. Studies owned by Syngenta and recently submitted to Ctgb for the evaluation of plant protection uses of thiamethoxam show that the residues in nectar and pollen in flowering crops are expected to be safe to honeybees when these crops are grown on soils containing up to 0.024 mg/kg.

Based on the above, the risk to honeybees from the use of Agita 10WG is acceptable.
This conclusion is based on studies owned by another company (Syngenta) to which Novartis has access.

B.2 Non-professional biocidal uses
None.

Public literature:
The above risk assessment, based on protected data from the applicant, indicates that the risks of the proposed uses of thiamethoxam are expected to be acceptable for bees, provided that restrictions are mentioned on the labels. In this section it will be considered whether studies available in the public literature domain confirm or contradict this risk assessment. A preliminary search on public literature has been carried out recently. The included references are presented in Annex II and the main results are summarised below.

Laboratory and semi-field studies
Aliouane *et al.* 2009 finds no sigificant mortality in honeybees at 0.1 and 1 ng/bee/d at 11-d exposure in a laboratory test. This finding does not contradict the NOEL for adult mortality after 10-d exposure of 0.18 ng/bee/d available in the protected dossier.
In the same article and in El Hassani *et al.* 2008, sublethal effects were investigated, also in a laboratory setting. The topical exposure results are not considered here, since topical exposure (e.g. overspray) is not relevant since for the proposed uses, direct exposure is either not relevant or avoided with restrictions. After oral exposure to 1 ng/bee, there were no effects on ' locomotor activity' and ' sucrose and water responsiveness' in one of the articles, but a lower 'sucrose responsiveness' was found in the other. However, no adverse effects were seen after oral exposure to 0.1 ng/bee, which indicates that the NOEL for adult mortality after 10-d exposure of 0.18 ng/bee/d may be protective also for sublethal effects.

Wu (2011) measured thiamethoxam in brood combs in the USA. The substance was found in 1 of the 13 samples, at a level of 38 ppb. The combs were contaminated with many other substances. Most frequently detected were a number of miticides used by beekeepers against Varroa. Delayed development was observed in bees reared in contaminated combs in a cage set-up. However, it is difficult to correlate this effect specifically to thiamethoxam because combs were contaminated with a cocktail of substances and may have contained also more pathogens than control combs, and because no information is available on how thiamethoxam contamination could have occurred (relation with agricultural use is therefore unclear). 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.

Girolami et al (2009) measured residue levels in guttation droplets from plants grown from treated seeds and found high concentrations, which had a significant effect on honey bees. However, as indicated by Thompson (2010), these findings should be treated with caution as the data were generated by feeding collected droplets directly to bees, and in many cases sucrose was added to ensure that the honey bees consumed the dose. Furthermore, from studies in the protected dossiers on the relevance of guttation in the field it is concluded that guttation does not lead to risks in practice.
Cresswell (2011) performed a meta-analysis of imidacloprid laboratory and semi-field studies, which result questions the statistical power of honeybee semi-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 in this working group. Ctgb will assess using the European harmonized methodologies until the impact of this paper has been clarified in the European framework.

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

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

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

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

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

Bee colony losses in the Netherlands

In the Netherlands, relatively high bee losses have been seen in recent years (increased mortality after winter). A scientific report on bee mortality and bee surveillance in Europe, submitted to EFSA (Hendrikx *et al.* 2009), reported the results regarding The Netherlands and Belgium as shown in the table below.

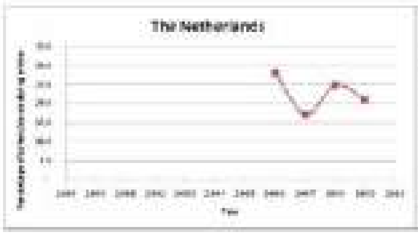

Figure 47. Percentage of winter colony losses in the Netherlands from 2000 to 2009

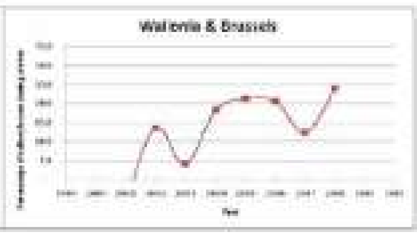

Figure 48. Percentage of winter colony losses in Wallonia & Brussels from 2000 to 2009

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

These losses have mainly been attributed to beekeeping practice with regard to pests and diseases, especially the *Varroa* mite, since it has been found that adequate and timely Varroa treatment reduces winter mortality (Van der Zee & Pisa 2011; personal communication bijen@wur and professional beekeepers). Also, reduction of forage is likely to play a role. The relationship between pesticides and bee mortality has not been studied in the Netherlands so far.

<u>Europe</u>
A report submitted to EFSA on bee mortality and bee surveillance in Europe (Hendrikx *et al.* 2009), concluded on results derived from surveillance systems in 27 European countries and a thorough literature search of the existing databases, as well as relevant grey literature about causes of colony losses:
• General weakness of most of the surveillance systems in the 24 countries investigated;
• Lack of representative data at country level and comparable data at EU level for colony losses;
• General lack of standardisation and harmonisation at EU level (systems, case definitions and data collected);
• Consensus of the scientific community about the multifactorial origin of colony losses in Europe and in the United States and insufficient knowledge of causative and risk factors for colony losses.

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

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

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

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

Based on the information as shown above, it cannot be concluded that there is a link between thiamethoxam and the relatively high winter mortality in honeybee colonies observed in the Netherlands in recent years. Clearly, bee decline is caused by (an interaction of) a number of factors. There is currently no evidence that thiamethoxam or other neonicotinoid products significantly contribute to bee decline based on the referred public literature.
It should be noted that other (European and elsewhere) countries have not withdrawn these substances from the market either (with some exceptions where clear acute bee poisoning due to suboptimal sowing circumstances was observed; this has not been the case in the Netherlands).
Finding associations between bee decline and all possible environmental factors is a complex issue that has to be established the coming years in a scientific way.
Long-term monitoring studies investigating the effects of yearly repeated exposure on honeybee colonies to thiamethoxam-treated maize are available and show that adverse effects on honeybee colonies are not expected. It is therefore considered that further monitoring of the effects of thiamethoxam on honeybees (as is suggested in the 'Inclusion Directive') is currently not necessary.

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

After inclusion in Annex I, the List of Endpoints was changed by the RMS, so that the most recent version is that of November 2007. However, no changes were made in the ecotox section. Therefore, the final List of Endpoints of thiamethoxam as determined at inclusion in Annex I of 91/414/EEC is used (from final Review Report dd. 14 July 2006). In the List of Endpoints in cursive text clarifications and additional information and studies submitted by the applicant are included by Ctgb.

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

Acute oral toxicity	Technical a.s LD50 oral = 0.005 µg a.s/bee (*Apis mellifera*) Formulation (WG 25%) LD50 oral = 0.02 µg formulation/bee (*Bombus terrestris*) CGA 322704: LD50 oral = 0.0166 µg/bee (*Apis mellifera*)
Acute contact toxicity	Technical a.s LD50 contact = 0.024 ug/bee (*Apis mellifera*) Formulation (WG 25%) LD50 contact = 0.11 µg formulation/bee (*Bombus terrestris*) CGA 322704: LD50 oral = 0.0275 µg/bee

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

The number of bees observed visiting the flowers of the broad beans very low during the whole evaluation period.
Barth (2000): Field study to assess the side effects of Actara on honeybee in pome fruits orchards after application during bee-flight. 2 X 400 g formulation/ha; 7-days interval between application. *Weeds were mulched. Flight intensity in the treated plots was low. Mortality and behaviour checked for 21 days after application.* No behavioral impacts. Number of dead bees slightly higher compared to the control *but these* differences were observed before and after application of test substance. No effects on brood development (*checked for 8 weeks after application*).

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

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

Cage tests

Summary of cage tests conducted with thiamethoxam seed treatment formulations.

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

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

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

Tunnel tests

Summary of tunnel tests conducted with thiamethoxam seed treatment formulations.

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

In a tunnel test by Barnavon (1999), honey bees were exposed to flowering sunflowers grown from seeds treated with CRUISER 70 WS at 350 g and 700 g ai/100 kg seed (equivalent to 26.25 g and 52.5 g ai/ha). Exposure to CRUISER-treated sunflowers did not have any significant effect on mortality, foraging activity in treated or refuge zones, flight intensity or behaviour relative to the control.

Similarly, there were no adverse effects reported following exposure to the reference product 'Gaucho' applied at 1050 g ai/100 kg seed (NB this study was also evaluated in the DAR, but for unknown reasons not included in the LoE).

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

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

Field tests

Summary of field studies conducted with thiamethoxam seed treatment formulations.

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

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

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

brood development. The pollen analysis showed that there were 10 times as many exposed experimental bees in treated colonies than in control ones.

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

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

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

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

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

measurements.

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

Summary of additional, non-guideline studies

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

Tests to determine the return flight ability of honey bees

Thiamethoxam, fed to hungry forager bees at 50 µg/kg sucrose solution (mean consumed dose of 5.6 ng ai/bee) and 100 µg/kg sucrose solution (mean consumed dose of 13.6 ng ai/bee), affected the ability of bees to return to their hives (von der Ohe, 2001a). The highest concentration tested that did not significantly affect return flight ability was 25 µg/kg sucrose solution (equivalent to 3.0 ng thiamethoxam/bee).

Since tthe no effect dose is very close to the oral LD50 from the acute toxicity study (5 ng/bee, test duration 48 h), it is assumed that the ingested syrup has not been digested before the bees return to the hive after a 500 m flight for 1 hour. In the field, foragers would consume approximately 150 µL nectar at 40% sugar for a 5 hours flight. Therefore, at 25 µg as/kg, the ingested dose of 100 µL 50% sucrose solution would be digested after a 3 hours flight. It is expected that the no effect dose will depend on the distance to hive and the consumption of nectar during the flight. For distances up to 500 m, the no effect dose is 3 ng as/bee of which 1/3 might have been consumed during flight.

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

Tests to determine feed consumption and trophalactic interactions of bees

Thiamethoxam was provided in feed in laboratory studies at up to 100 µg/kg sucrose solution (mean consumed dose of 5.0 ng ai/bee). After 4 hours, no lethal effects were noted. No effects were observed on feed consumption or feed exchange between fed and hungry bees (von der Ohe, 2001a). Since the no effect dose in this study is equal to the oral LD50 from the acute toxicity study (also 5 ng/bee, test duration 48 h), it is assumed that the ingested syrup has not been completely digested during this test.

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

Chronic exposure in the laboratory

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

Chronic toxicity to *Apis mellifera* larvae

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

Observations on foraging activity in the field

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

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

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

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

Reference	Crop	Field rate (g ai/ha)	Residue analysis results (ng/g) – (in brackets is the number of sampling dates on which residues were above the LOD/the total number of sampling dates).						
			Monitored residue	Flowers / heads	Pollen on bees	Honey	Honey stomach	Pollen	Leaves
Schur (2001a)	Oilseed rape	33.6	thiamethoxam	1.8 (1/1)	-	-	-	-	1.0 (1/1)
			CGA 322704	<1.0 (0/1)	-	-	-	-	3.0 (1/1)
		67.2	thiamethoxam	3.9 (1/1)	-	-	-	-	1.7 (1/1)
			CGA 322704	1.3 (1/1)	-	-	-	-	5.7 (1/1)
		100.8	thiamethoxam	2.3 (1/1)	-	-	-	-	1.9 (1/1)
			CGA 322704	< 1.0 (0/1)	-	-	-	-	8.2 (1/1)
		134.4	thiamethoxam	13 (1/1)	-	-	-	-	1.7 (1/1)
			CGA 322704	4.2 (1/1)	-	-	-	-	6.3 (1/1)
		201.6	thiamethoxam	14 (1/1)	-	-	-	-	4.2 (1/1)
			CGA 322704	4.9 (1/1)	-	-	-	-	14 (1/1)
		268.8	thiamethoxam	27 (1/1)	-	-	-	-	5.2 (1/1)
			CGA 322704	10 (1/1)	-	-	-	-	12 (1/1)
Schur (2001b)	Sunflower	26.25	thiamethoxam	< 1.0 (0/1)	-	-	-	-	< 1.0 (0/1)
			CGA 322704	< 1.0 (0/1)	-	-	-	-	< 1.0 (0/1)

Barnavon (1999)	*Sunflower*	*26.25*	*thiamethoxam*	*1.0 (1/1)*	-	*< 1.0 (0/1)*	-	-	-
			CGA 322704	*< 1.0 (0/1)*	-	*< 1.0 (0/1)*	-	-	-
		52.5	*thiamethoxam*	*1.0 (1/1)*	-	*< 1.0 (0/1)*	-	-	-
			CGA 322704	*< 1.0 (0/1)*	-	*< 1.0 (0/1)*	-	-	-
Barnavon (2001)	*Sunflower*	*25.9*	*thiamethoxam*	*< 1.0 (0/1)*	*< 1.0 (0/3)*	*< 1.0 (0/1)*	-	-	-
			CGA 322704	*< 1.0 (0/1)*	*< 1.0 (0/3)*	*< 1.0 (0/1)*	-	-	-
Schuld (2001a)	*Oilseed rape*	*25.0*	*thiamethoxam*	*3.1– 4.2 (3/3)*	*2.5-4.2 (4/4)*	*1.0-< 1.0 (1/3)*	*1.0-2.1 (4/4)*	*2.8 (1/1)*	-
			CGA 322704	*< 1.0 (0/3)*	*< 1.0 (0/4)*	*< 1.0 (0/3)*	*< 1.0 (0/4)*	*< 1.0 (0/1)*	-
Schuld (2001b)	*Oilseed rape*	*29.4*	*thiamethoxam*	*<1.0-4.6 (1/2)*	*< 1.0 (0/3)*	*< 1.0 (0/2)*	-	-	-
			CGA 322704	*<1.0-1.0 (1/2)*	*< 1.0 (0/3)*	*< 1.0 (0/2)*	-	-	-
Balluff (2001)	*Sunflower*	*26.25*	*thiamethoxam*	*3.0 (1/1)*	*< 1.0-1.1 (4/7)*	*< 1.0-1.0 (2/3)*	*< 1.0 (0/6)*	-	*30.0 (1/1)*
			CGA 322704	*1.0 (1/1)*	*< 1.0 (0/7)*	*< 1.0 (0/3)*	*< 1.0 (0/6)*	-	*5.8 (1/1)*
Schur (2001c)	*Sunflower*	*22.8*	*thiamethoxam*	*< 1.0 (0/1)*	*< 1.0-3.2 (2/3)*	*< 1.0 (0/2)*	-	-	*1.9 (1/1)*
			CGA 322704	*< 1.0 (0/1)*	*< 1.0 (0/3)*	*< 1.0 (0/2)*	-	-	*< 1.0 (0/1)*

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

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

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

Author	***Formulation***	***Field rate (g***	***Residue analysis results (ng/g) – (in brackets is the number of sampling dates on which residues were above the LOD/the total number of sampling dates).***

		ai/ha)	Monitored residue	Flowers	Leaves	Fresh honey	Honey stomach	Pollen loads
Schur (2001d)	CRUISER OSR	18.0	thiamethoxam	1.0 (1/1)	1.4 (1/1)	< 1.0 (0/3)	< 1.0 (0/2)	< 1.0 (0/1)
			CGA 322704	< 1.0 (0/1)	4.1 (1/1)	< 1.0 (0/3)	1.0-< 1.0 (1/2)	< 1.0 (0/1)
Barth (2001)	CRUISER OSR	34.0	thiamethoxam	3.6 (1/1)	-	< 1.0 (0/1)	< 1.0 (0/1)	< 1.0-3.6 (4/5)
			CGA 322704	< 1.0 (0/1)	-	< 1.0 (0/1)	< 1.0 (0/1)	1.0-< 1.0 (1/5)
Purdy (2006)	HELIX 289 FS	29.4	thiamethoxam	7.55 - < 0.4 (2/4)	-	(0.94)[a] - < 0.1 (2/4)	(0.053)[a] - < 0.02 (7/8)[b]	(0.66)[a] - < 0.2 (4/4)
			CGA 322704[a]	(0.95)[a] < 0.4 (1/4)	-	< 0.1 (0/4)	(0.034)[a] - < 0.02 (3/8)[b]	(0.24)[a] - < 0.2 (1/4)

[a] values in brackets are trace amounts detected below levels that can be quantified

[b] Values given are for residue analysis on macerated returning forager bees and not bee honey stomachs

Summary of further trials to estimate residue levels

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

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

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

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

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

References	***Hecht-Rost S. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A 10590C treated maize seed, investigating residues in crop, soil and honeybee products in Alsace, France. Final Report No 20051149/F1-BZEU.***
	Hecht-Rost S. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A10590C treated maize seed, investigating residues in crop, soil and honeybee products in Southern France. Final Report No 20051149/F2-BZEU.
	Haergreaves N.J. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A10590C treated maize seed, investigating residues in crop, soil and honeybee products in Northern France. Final Report No T003256-05-REG.
Method	*On three locations, semi-field trials were conducted with the aim to determine the residue levels of thiamethoxam and CGA 322704 in pollens collected by bees as well as in pollen stores and wax. The trials were conducted two successive years (2005 and 2006) on the same plots to account for possible residues in soil.* *Large tunnels were used (36 x 5 m^2). The seeds were treated with an FS formulation A-10590C (420 g thiamethoxam + 3.33 g fudioxonil and 1.33 g metalaxyl-M/L) and the nominal seed concentration was 3150 mg thiamethoxam/kg seed (identical to the treatment with CRUISER 350) . The bees were exposed during flowering from BBCH 63 (start of pollen emission) to BBCH 69 (end of flowering) of the maize grown from treated seeds or untreated seeds (control). Exposure duration ranged from 3 to 9*

days. At the end of flowering the hives were moved to a remote site. Development of bee brood was followed but for a too short period (ca. 1 week) to draw conclusions from.

Thiamethoxam: LOQ = 0.0005 mg/kg (wax and 0.001 mg/kg (pollens)
CGA 322704: LOQ = 0.001 mg/kg (all matrices)

Results

Actual seeding rates (thiamethoxam):
Alsace: 89.27 g as/ha (2005) and 85.77 g as/ha (2006)
Southern France: 90.36 g as/ha (2005) and 84.64 g as/ha (2006)
Northern France: 87.31 g as/ha (2005) and 89.32 g as/ha (2006)

Residue levels in leaves:
Alsace: Residue levels in whole plants were 0.01-0.018 mg thiamethoxam/kg and 0.01-0.016 mg CGA322704/kg in 2005, and 0.003-0.012 mg thiamethoxam/kg and 0.002-0.008 mg CGA322704/kg in 2006.
Southern France: Residue levels in whole plants were 0.009-0.020 mg thiamethoxam/kg and 0.004-0.008 mg CGA322704/kg in 2005, and 0.017-0.050 mg thiamethoxam/kg and 0.006-0.012 mg CGA322704/kg in 2006.
Northern France: Residue levels in whole plants were 0.003-0.006 mg thiamethoxam/kg and 0.002-0.005 mg CGA322704/kg in 2005, and 0.002-0.004 mg thiamethoxam/kg and 0.002-0.004 mg CGA322704/kg in 2006.

Residue levels in soil cores (0-30 cm) before drilling in 2006:
Alsace: < 0.001 mg/kg (thiamethoxam and CGA 322704)
Southern France: < 0.001 mg/kg (thiamethoxam), 0.001 mg/kg (CGA 322704)
Northern France: 0.002 mg/kg (thiamethoxam and CGA 322704)

Residue levels in pollen loads:

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

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

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

Residue levels in hive pollens (2005 and 2006):
Alsace: < 0.001 mg/kg (thiamethoxam and CGA 322704)
Southern France: < 0.001-0.002 mg/kg (thiamethoxam), <0.001-0.001 mg/kg (CGA 322704)
Northern France: < 0.001-0.002 mg/kg (thiamethoxam), <0.001-0.003 mg/kg (CGA 322704)
Residue levels in wax (2005 and 2006):
Alsace: < 0.0005 mg/kg (thiamethoxam), < 0.001 mg/kg (CGA 322704)
Southern France: < 0.0005-0.0009 mg/kg (thiamethoxam), < 0.001 mg/kg (CGA

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

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

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

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

References	***Hecht-Rost S. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A9700B treated spring barley seed followed by A9807C treated winter oilseed rape seed, investigating residues in crop, soil***

		and honeybee products in Northern France. Final Report No T003253-05-REG.
		Hecht-Rost S. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A9700B treated spring barley seed followed by A9807C treated winter oilseed rape seed, investigating residues in crop and honeybee products in Northern France. Final Report No 20051040/F4-BZEU.
		Hecht-Rost S. (2007): Thiamethoxam (CGA 293343) and its metabolite (CGA 322704): A residue study with A9700B treated spring barley seed followed by A9807C treated winter oilseed rape seed, investigating residues in crop, soil and honeybee products in Southern France. Final Report No 20051040/F2-BZEU.
	Method	*On three locations, semi-field trials were conducted with the aim to determine the residue levels of thiamethoxam and CGA 322704 in nectar collected by bees as well as in nectar and honey stores, royal jelly and wax. The trials were conducted on winter oilseed rape sown in 2005 after a treated spring barley and the bees were exposed in 2006 during flowering:* *Northern France 1:* *sowing: spring barley 18/03/2005, winter oilseed rape 31/08/2005* *exposure: 03/05/2006-12/05/2006* *Northern France 2:* *sowing: spring barley 17/03/2005, winter oilseed rape 06/09/2005* *exposure: 02/05/2006-14/05/2006* *Southern France:* *sowing: spring barley 08/03/2005, winter oilseed rape 19/09/2005* *exposure: 07/04/2006-17/04/2006* *Large tunnels were used (40 x 5 m^2). The seeds were treated with CRUISER OSR (FS formulation 280 g thiamethoxam + 8 g fludioxonil and 32.3 g mefenoxam/L). The bees were exposed from BBCH 60-62 (start of flowering) of the oilseed rape grown from treated seeds (3 treated tunnels) or fludioxonil+mefenoxam treated seeds (1 control tunnel). Exposure duration ranged from 9 to 10 days. At the end of flowering the hives were moved to a remote site. Strength of the colony and development of bee brood was followed but for a too short period (ca. 10 days) to draw conclusions from.* *Samples were collected up to 18/09/2006 (Northern trials), 28/09/2006 (Southern France)* *Thiamethoxam: LOQ = 0.0005 mg/kg (all matrices except soil), 0.001 mg/kg (soil)* *CGA 322704: LOQ = 0.001 mg/kg (all matrices)*
	Results	*<u>Nominal seeding rates (thiamethoxam):</u>* *Northern France 1: 77 g as/ha (barley), 12.6 g as/ha (oilseed rape)* *Northern France 2: 77 g as/ha (barley), 12.6 g as/ha (oilseed rape)* *Southern France: 77 g as/ha (barley), 12.6 g as/ha (oilseed rape)* *<u>Residue levels in soil at sowing oilseed rape:</u>* *Northern France 1: 0.0035 mg thiamethoxam/kg soil, 0.0020 mg CGA 322704/kg soil* *Northern France 2: 0.0030 mg thiamethoxam/kg soil, 0.0020 mg CGA 322704/kg soil* *Southern France: 0.1027 mg thiamethoxam/kg soil, 0.0316 mg CGA 322704/kg soil* *<u>Residue levels in whole plants:</u>* *Northern France 1: <LOQ-0.002 (thiamethoxam), <LOQ-0.001 mg/kg (CGA 322704)* *Northern France 2: <LOQ (thiamethoxam), <LOQ-0.001 mg/kg (CGA 322704)* *Southern France: <LOQ-0.008 (thiamethoxam), 0.001-0.003 mg/kg (CGA 322704)* *<u>Residue levels in bee pollen:</u>* *Northern France 1: thiamethoxam: <LOQ-0.003 mg/kg; CGA 322704: <LOQ* *Northern France 2: thiamethoxam: <LOQ; CGA 322704: <LOQ* *Southern France: thiamethoxam: 0.001-0.006 mg/kg; CGA 322704: <LOQ-0.002 mg/kg* *<u>Residue levels in hive pollen:</u>* *Northern France:* *thiamethoxam: <LOQ-0.001 mg/kg (during exposure, only one detection at 0.001*

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

Overall summary of residues in bee nectar:

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

Dust deposition

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

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

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

Dust deposition decreases with increasing distance to a level of 0.004% at 50 m distance.

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

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

Dust toxicity
Studies evaluated by Ctgb (March 2011)

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

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

The following endpoints were derived:

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

Increased mortality was seen for 3 days after treatment at 1 g dust/ha and for 14 days after treatment at 5 g as./ha. Test item related effects on behaviour were observed until 2 days after treatment.
Residues of thiamethoxam ranging from < 0.001 (T1) to 0.016 (T2) mg/kg were found in the test item samples of DAA+7. In the samples of DAA+27 residues of thiamethoxam ranging from 0.012 to 0.028 mg/kg were detected in the test item treatment groups. No residues of CGA322704 were found in any of the test item or reference item samples except of 0.003 mg/kg in the pollen samples of test item 2 (A9584C; treatment group T3) on DAA+7.

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

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

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

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

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

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

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

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

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

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

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

Six bee colonies per field were exposed to treated oil-seed rape fields (2 ha per field) in each of the four years (2005-2008). Dose rate was 4200 mg a.s./kg seed (ca. 0.02 mg a.s./seed; 13-21 g a.s./ha). Seeds were also treated with metalaxyl-M and fludioxonil.
Colonies were exposed to the flowering fields for as long as flowering lasted. This was:
Alsace: Exposure lasted 19 days (2005, 2006), 13 days (2007) and 22 days (2008).
N-France (Picardie): Exposure lasted 21 days (2005 and 2008), 18 days (2006) and 12 days (2007). .

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

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

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

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

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

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

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

Dr. Silvio Knäbe 2010. Thiamethoxam Thiamethoxam (CGA293343) - A semi-field study with A9700B + A9638A treated maize seed, followed by untreated flowering crop(s), investigating residues in crop(s), soil and honeybee products in Picardie (France), in 2009 Final Report Report number: S08-01284
Syngenta file no A9700B_10914
Maize pre-treated with thiamethoxam was sown in a field plot in the region Picardie, France in spring 2008. The rate of thiamethoxam applied was 76.80 g/ha. The maize was followed by a seeding of winter barley treated with A9700B sown in the same field plot in autumn 2008. The rate of thiamethoxam applied with the seed dressing was 71.78 g/ha. The treated field plots were matched with a similar size control field plot sown with untreated seeds. In spring 2009, untreated flowering crops (alfalfa, oilseed rape and Phacelia tanacetifolia) were planted in both the treated and control field plots. Prior to the onset of flowering, three tunnels were set-up on each flowering crop in the treated field plot and one tunnel on each flowering crop in the control field plot.

In each tunnel one bee colony was placed during the flowering phase. Samples of forager bees (nectar and pollen) and whole plants of all three flowering crop species (oilseed rape / Phacelia / alfalfa) were collected on three days in the flowering period (on day 1/2, 2/3, 5/6). Soil samples were collected (those presented are only those taken before seeding of the flowering crop). Samples were analysed for residues of thiamethoxam and its metabolite CGA322704.
Results:

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

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

Dr. Silvio Knäbe 2010. Thiamethoxam Thiamethoxam (CGA293343) - A semi-field study with A9700B + A9638A treated maize seed, followed by untreated flowering crop(s), investigating residues in crop(s), soil and honeybee products in Burgundy (France), in 2009 Final Report Report number: S08-01285
Syngenta file no A9700B_10916
Maize pre-treated with thiamethoxam was sown in a field plot in the region Burgundy, France in spring 2008. The rate of thiamethoxam applied was 60.03 g/ha. The maize was followed by a seeding of winter barley treated with A9700B sown in the same field plot in autumn 2008. The rate of thiamethoxam applied with the seed dressing was 83.37 g/ha. The treated field plots were matched with a similar size control field plot sown with untreated seed. In spring 2009, untreated flowering crops (alfalfa, oilseed rape and Phacelia tanacetifolia) were planted in both the treated and control field plots. Prior to the onset of flowering, three tunnels were set-up on each flowering crop in the treated field plot and one tunnel on each flowering crop in the control field plot.
In each tunnel one bee colony was placed during the flowering phase. Samples of forager bees (nectar and pollen) and whole plants of all three flowering crop species (oilseed rape / Phacelia / alfalfa) were collected on three days in the flowering period (on day 1/2, 2/5, 5/6; OSR only on day 3). Soil samples were collected (those presented are only those taken before seeding of the flowering crop). Samples were analysed for residues of thiamethoxam and its metabolite CGA322704. Planned analysis of oilseed rape nectar and pollen could not be done because OSR flowers were destroyed by pollen beetle. Planned analysis of alfalfa pollen was not done because the total amount of pollen sampled by forager bees was too low.
Results:

	Thiamethoxam (mg/kg)	CGA322704 (mg/kg)
Soil	0.004-0.009	0.002-0.004
Alfalfa plant	<0.001-0.005	0.002-0.005
Phacelia plant	<0.001	0.002-0.006
OSR plant	0.007 (1 sample)	0.004 (1 sample)
Alfalfa nectar	<0.0005-0.0022	<0.001-0.0011
Phacelia nectar	<0.0005	<0.001-0.0021
Phacelia pollen	<0.001	<0.001-0.003

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

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

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

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

Dust was measured in the neighbouring oilseed rape field with Petri-dishes. The highest amount measured was 0.0036% of the applied, at a distance of 5 m. However, during drilling, wind direction was nearly parallel to the edge of the neighbouring oilseed rape field. Since the wind direction deviated more than 30% from the desired direction perpendicular to the measurement area (criterion used by Plant Research International for drift measurements), the dust drift measurements are not considered acceptable.

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

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

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

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 list

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-Cheo 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.
Hendrikx, Chauzat, Debin, Neuman, Fries, Ritter, Borwn, Mutinelli, Le Conte, Gregorc 2009. Scientific report submitted to EFSA. Bee morlitaly and bee surveillance in Europe. CFP/EFSA/AMU/2008/02. Accepted for publication 03 December 2009.
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.
Van der Zee (2010). Colony losses in the Netherlands. Journal of Apicultural Research 49(1): 121-123
Van der Zee & Pisa (2011). Monitor Bijensterfte Nederland 2009-2010. NBC rapporten 2011 nr 1.
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.

Bijlage II-3 fipronil

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 fipronil. Deze middelen zijn in onderstaande tabel weergeven.

Gewasbeschermingsmiddelen op basis van fipronil

toelatingnr	Middel-naam	Toelating-houder	werkzame stoffen	dosering	Toepas-sing	formulering	Toepassing
12802	MUNDIAL	BASF Nederland B.V.	fipronil 500G/L	1x 5-20 g a.s./ha	Professio-neel	Suspensie concentraat voor zaadbehande-ling	zaadcoating in bloemkool, boerenkool, broccoli, rodekool, savooien-kool spitskool, spruitkool en witte kool.
12977	MUNDIAL	LTO Nederland (LTO coördinator middelenpakket vollegronds-groenten)	fipronil 500G/L	1x 5-15 g a.s./ha	Professio-neel	Suspensie concentraat voor zaadbehande-ling	zaadcoating in Chinese kool, Oosterse bladkolen en koolrabi.
13384	MUNDIAL	Productschap Akkerbouw	fipronil 500G/L	1x 100 g a.s./ha	Professio-neel	Suspensie concentraat voor zaadbehande-ling	zaadcoating in uien en sjalotten

Biociden op basis van fipronil

toelatingnr	Middel-naam	toelatinghouder	Werkzame stoffen	Toepas-sing	Formule-ring	Toepassing
12119	GOLIATH AASSTATI ONS	BASF Nederland B.V.	fipronil 0,05%	Profes-sioneel	lokaas	Bestrijding van kakkerlak-ken in gebouwen.
12120	GOLIATH GEL	BASF Nederland B.V.	fipronil 0,05%	Profes-sioneel	lokaas	Bestrijding van kakkerlak-ken in gebouwen.

Er zijn geen niet-professionele middelen toegelaten op basis van fipronil.

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 based on the most recent guidance documents from EPPO (2010). This includes methodology to assess the risk from systemic substances.

Fipronil is placed on Annex I since 10/01/2007 (2007/52/EC). In Commission Directive 2010/21/EU, the Inclusion Directive of fipronil was amended with additional provisions to avoid accidents with seed treatments. The provisions relevant for honeybees are now as follows.

"PART A

Only uses as insecticide for use as seed treatment may be authorised.

For the protection of non-target organisms, in particular honey bees:

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

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

Member States shall ensure that:

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

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

Part B

Member States must pay particular attention to the protection of honeybees. Conditions of authorisation should include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of further studies to confirm the risk assessment for honeybees, especially bee brood."

For the risk assessment the final LoEP of the EFSA conclusion is used (Word-version d.d. 03/2016), to which additional information and studies are added by Ctgb in italics. The LoEP is presented in Appendix I. Also information from the public literature is taken into account (presented in Appendix II). Abbreviations are explained in Appendix III.

6.1 Professional uses of plant protection products

toelating nr	Middel-naam	toelatinghouder	werkzame stoffen	dosering	Toepassing	formulering	Toepassing(en)
12802	MUNDIAL	BASF Nederland B.V.	fipronil 500G/L	12.5-20 g a.s./ha	Professioneel	Suspensie concentraat voor zaadbehandeling	zaadcoating in bloemkool, boerenkool, broccoli, rodekool, savooienkool, spitskool, spruitkool en witte kool. Uitzaaien in kas (niet-grondgebonden) uitplanten in veld
12577	MUNDIAL	LTO Nederland (LTO coordinator middelenpakket vollegrondsgroenten)	fipronil 500G/L	12.5-15 g a.s./ha	Professioneel	Suspensie concentraat voor zaadbehandeling	zaadcoating in Chinese kool, Oosterse bladkool en [illegible]. Uitzaaien in kas

							(niet-grondgebonden), uitplanten in veld.
13384	MUNDIAL	Productschap Akkerbouw	fipronil 500G/L	1x 100 g a.s./ha	Professioneel	Suspensie concentraat voor zaadbehandeling	zaadcoating in uien en sjalotten

Risk assessment for bees

Exposure to honeybees may occur via several routes, which will be discussed separately below.

Direct exposure via spray
Because of the nature of the application as a seed treatment, no direct exposure of bees via overspray can take place.

Direct exposure via dust drift
Dust drift from seed is not a relevant exposure route for the proposed uses in cabbages because sowing takes place indoors. Onions and shallots are sown outdoors, however, so the risk from dust drift must be assessed. Bees will not be exposed in the field during sowing, but they may be exposed off-field. 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. in the off-field area, depends on the type of coating in combination with the type of sowing. The sowing of onions and shallots is done (for 90% of the seed) with pneumatic machines which send the air flow downwards, towards the onion field and not upwards. Furthermore, in the Netherlands onion and shallot seeds are coated with a filmcoating (rotostat) and for part of the seeds an extra top layer is added, so dust formation can be excluded. This assessment is based on the 'Dust drift matrix' (version of 15/09/2010, see Ctgb website).
Therefore, no exposure is expected outside the field where flowering plants may be present.
No specific restrictions on dust level or sowing method need to be mentioned for the use on onion and shallot seeds. Since exposure outside the field and thus of bees is expected to be minimal, a monitoring programme for dust effects is not required for the current uses of Mundial.

Indirect exposure via systemic working mechanism
If a substance is systemic, it can be taken up by plants. If this plant carries flowers, bees may be exposed to fipronil 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.

- Exposure via nectar/pollen (flowering crops, weeds or succeeding crops)
Cabbages, onions and shallots will not flower during cultivation. Therefore, no exposure via nectar or pollen from the treated crops themselves will take place.

Exposure via flowering weeds is not expected to be very high in the proposed crops since a large amount of flowering weeds in fields is adverse to profitable agriculture.

However, since fipronil and its metabolites are persistent in soil (EFSA conclusion: under laboratory aerobic conditions at 20 or 25 °C fipronil is moderate to high persistent in soil (DT_{50} = 31 – 304 d; new kinetic analysis in the Addendum 1: DT_{50} = 32 – 346 d; Available field studies confirmed that fipronil is medium to high persistent in soil (DT_{50} = 96 – 135 d).), exposure might occur via flowering succeeding crops. The EPPO scheme for risk assessment for bees (2010) includes a risk assessment method for systemic substances which considers the exposure route via exposed food (nectar and pollen).

Risk to adult bees

The EPPO scheme gives a first screening step (in Note 6): a risk is indicated for systemic substances when the LD50 is below 10 ug a.s./bee. Since the LD50 of fipronil is far below this level, a risk cannot be excluded. According to EPPO (2010), the risk can be refined with measured residue data and/or a 10-d toxicity test. If these are not available or still indicate a risk, (semi-)field tests should be performed. For fipronil, no chronic NOEL is available in the dossier but residue measurements were done in the EU-dossier. These residue measurements cover the application rates of sunflower and maize in the DAR, which are 30 g a.s./ha and 50 g a.s./ha, respectively. The applicant has provided

For sunflower, an extensive residue program with results from residue trials and field monitoring has been carried out. The residue program includes data covering two potential exposure scenarios at flowering time: bees foraging on sunflowers treated with fipronil at sowing (as seed treatment or soil spray) and bees foraging in a sunflower crop not treated with fipronil but grown in a field treated in the preceding year(s). The samples were collected from sunflower plants grown under field conditions in several regions of France. The primary matrices analyzed were pollen and nectar collected directly from sunflower at flowering. In addition, other matrices were analyzed in some studies (honey, leaves, and florets). The limit of quantification (LOQ) for nectar and pollen was 0.0020, 0.0010 or 0.0005 mg/kg. The chemicals analyzed were fipronil and metabolites MB46136, MB45950, MB46513 and/or RPA200766.

No residues of fipronil or metabolites MB46136, MB45950, MB46513 or RPA200766 were detected at or above the limits of quantification of 0.0005, 0.0010 or 0.0020 mg/kg in any of the samples of sunflower analyzed. Residue values for risk assessment were derived by making the worst-case assumption that measurements <LOQ are equal to the LOQ.

Results for fipronil in sunflower: arithmetic mean 0.0010 mg/kg (maximum 0.0020 mg/kg; n=44; no. of samples > LOQ: 0).

In maize, studies to determine residues of fipronil and metabolites in pollen from Regent 500FS-treated seeds have been carried out in 2004 in several locations in France, Germany and Spain. Studies included supervised field residue trials with treated and control plots and field monitoring of commercial fields treated with Regent 500FS (no control fields). There were also trials in Spain but due to unexplained residue findings in the controls these were not included. In all the studies, the compounds analyzed were the same (fipronil, MB46136, MB46513, MB45950 and RPA200766) using a limit of quantification of 0.0005 mg/kg. In the residue trials, samples from a total of 12 control and 12 treated plots were analyzed. No residues of fipronil or metabolites at or above the LOQ of 0.0005 mg/kg were found.

In two different studies, samples of pollen were collected in 10 commercial fields in France in which seeds had been treated commercially with Regent TS. No control samples were collected in these field monitoring studies. In eight fields, no residues of fipronil or metabolites at or above the LOQ of 0.0005 mg/kg were found. Residues of fipronil above the LOQ were found in two of the fields, with average residues of 0.00079 and 0.0023 mg/kg. No residues of any of the metabolites were found.

Results for fipronil in maize: median 0.0005 mg/kg (maximum 0.0023 mg/kg; n=22; no. of samples > LOQ: 2).

Based on the residue measurements and the acute oral toxicity values, the RMS concluded in the DAR that for sunflower and maize it is highly unlikely that honeybees foraging on flowering sunflowers grown from treated seeds, in soils treated with fipronil at sowing, or in soils treated with fipronil in the preceding year will be lethally affected by fipronil or its metabolites. This conclusion was made by calculating a TER by converting the LD50 in µg a.s./bee to mg/kg diet and comparing this to the measured residues in nectar and pollen.

EPPO 2010 follows a comparable approach, in which the risk to bees foraging on pollen or nectar can be estimated by using the data on daily intake from Rortais et al. (2005), as indicated in EPPO 2010.

Considering nectar, nectar foragers are expected to 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.
Regarding pollen, nurse bees are expected to consume the highest amount of pollen of all categories of bees: 65 mg/bee in 10 days, which translates to a daily intake of 6.5 mg/bee/d.

As a very worst case, the highest residue level in nectar and pollen encountered in all trials are used (0.0020 and 0.0023 mg/kg, respectively) as residue input. Note that all measurements in nectar and the large majority of measurements in pollen were <LOQ.

Table 1 Estimated risk for adult bees from fipronil

LD_{50}	Food type	Residue level	Food ingestion	Exposure	TER (trigger 10)
[ng a.s./bee]		[mg a.s./kg]	[kg/bee/d]	[ng a.s./bee/d]	
4.17	Nectar	0.0020	80-321*10^{-6}	0.16 - 0.642	26 - **6.5**
	Pollen	0.0023	6.5*10^{-6}	0.015	279

The above table shows that even based on the maximum exposure level of 0.0023 mg a.s./kg in pollen, no risk is indicated to adult bees foraging on pollen. For nectar, the TER based on the highest nectar intake value does not meet the required trigger of 10, while the value based on the lowest nectar intake does meet the trigger. However, the residue level used in the calculation is an extreme worst-case, since it is in fact set at the LOQ, while all measurements in nectar were < LOQ. Furthermore, the TER is based on the extreme value for nectar intake. Considering that the TER is only slightly below the trigger while based on two extreme worst-case assumptions, the risk to adult bees foraging on nectar is also expected to be acceptable.

For the metabolites, no risk is expected either since residue levels were lower and toxicity is also lower. This is confirmed by the fact that in all the semi-field trials, no adverse effects on bees were found. It is in accordance with the conclusion during EU peer review, in which the risk to adult bees for the representative uses as a seed treatment in maize and sunflower was considered to be addressed based on the low exposure situation observed in the field (monitoring) studies and the observation of no adverse effects in the tunnel studies.

The EFSA highlighted in their conclusion that the available monitoring studies were mainly performed in France and MS should consider the relevance of these studies for the circumstances in their country (i.e. consider the extrapolation of the ' no or very low-residue situation' in bee relevant matrices after seed treatment of sunflower as estimated for conditions prevailing in France to the situation for the MS of concern).

Ctgb considers that the studies are relevant for the residue situation in the Netherlands, because also studies from Germany and N-France were included.

The proposed dose rates in the Netherlands are 15-20 g a.s./ha for cabbages and 100 g a.s./ha for onions. The dose rate in the residue trials was not reported in the DAR. However, the applicant provided this information to Ctgb. See the tables below (taken from the EU dossier of fipronil (addendum), application rate added by applicant).

Table 9.4/ 1 and 9.4/4 from addendum to DAR with application rates taken from field reports referenced in column "Information source on origin of field samples"

Table 9.4/ 1 Field residue programs carried out in flowering sunflowers in Europe to measure residues of fipronil and metabolites in bee-relevant matrices (nectar and pollen primarily).

Fipronil product (treated crop)	Application rate g ai /ha	Application year	Sampling year[a]	Country, Region (no. of locations)[b]	Analytical Reports	Information source on origin of field samples[c]
REGENT 500FS (sunflower)	24.5	1999	1999	France, Lyon (2)	Goller 1999, C019729	Roper 2000, 2000/1022785 Maurin 1999, C019707
SCHUSS (800WG) (sunflower)	250	2000	2000	France, Lyon (1) France, Toulouse (1) France, Gennes (1)	Ayoub & Kieken 2001a Ayoub & Kieken 2001b 2001/1024450	Roper 2001a, 2001/1024592
REGENT 500FS (sunflower)	24.5	2000	2000	France, Gennes (1)	Ayoub & Kieken 2001c, 2001/1024450	Roper 2001b, 2001/1024590
REGENT 500FS (sunflower)	24.5	2001	2001	France, Toulouse (1) France, Lyon (1)	Ayoub & Kieken 2002a, 2002/1017629 Ayoub & Kieken 2002b, 2002/1017628 Salvi 2002a, 2002/1017630 Salvi 2002b, C027966	Roper 2002, C027338 Maurin 2001b, 2001/1024591
Bait 0.5% (sunflower)	26	2001	2001	France, Lyon (1)	Ayoub & Kieken 2002, C027963 Salvi 2002, C027968	Maurin 2001a, C018674
TEXAS (cereal seed treatment) year -1 (2000). Sunflowers grown in year 0 (2001)	100	2000	2001	France, Reims (1) France, Amiens (1)	Ayoub & Kieken 2002c, C027959 Ayoub & Kieken 2002d, C027961 Salvi 2002c, C028119 Salvi 2002d, C028120	Orry 2002, 2002/1017908
REGENT 500FS (maize) year -1 (2001). Sunflowers grown in year 0 (2002)	50	2001	2002	France, Lyon (1) France, Toulouse (1)	Ayoub & Kieken 2002e, C027432 Ayoub & Kieken 2002f, C027438 Sole C 2002a, C028180 Sole C 2002b, C028182	Orry 2002, 2002/1017908
Regent 500FS (sunflower)	24.5	2003	2003	France, 5 regions (9)	Benazeraf 2004, 2004/1015950	Orry 2004, 2004/1015923
Regent 500FS (sunflower)	24.5	2004	2004	France, 2 regions (8)	Tisseur & Decourtye 2005, 2005/1006536	Tisseur & Decourtye 2005, 2005/1006536
Regent 500FS (sunflower)	24.5	2004	2004	France, 1 region (2)	Schur 2005, 2005/1006471	Schur 2005, 2005/1006471
Regent 500FS (sunflower)	26.6	2004	2004	France, 1 region (1)	Decourtye & Tisseur 2005, 2005/1006529	Decourtye & Tisseur 2005, 2005/1006529

[a] Time of collection of samples in the field for residue analysis.
[b] Each location represents a different trial or field plot and as such the number of locations are considered as the experimental unit for descriptive statistics
[c] This references are provided because some analytical reports do not provide information on the origin of the samples

Table 8.4/4 Field residue program carried out in maize in Europe to measure residues of fipronil and metabolites in pollen

Fipronil product (treated crop)	Application rate g ai/ha	Application year	Sampling year[a]	Country, Region (no. of locations)[b]	Matrix analyzed (no. of samples)	Chemicals analyzed	LOQ[c] (mg/kg)	References
Regent 500FS (maize)	23-27 (6) 46 – 54 (6)	2004	2004	Spain, 1 region (6)	Pollen (6L, 12T[d])	Fipronil, MB46513, MB45950, MB46136, RPA200766	0.0005	Moreno 2005, 2005/1006472
Regent 500FS (maize)	55-60	2004	2004	France North, 1 region (2)	Pollen (2U, 2T)	Fipronil, MB46513, MB45950, MB46136, RPA200766	0.0005	Schur 2005, 2005/1006470
Regent 500FS (maize)	44-48	2004	2004	France South, 1 region (2)	Pollen (2U, 2T)	Fipronil, MB46513, MB45950, MB46136, RPA200766	0.0005	Schur 2005, 2005/1006470
Regent 500FS (maize)	55-60	2004	2004	Germany, 1 region (2)	Pollen (2U, 2T)	Fipronil, MB46513, MB45950, MB46136, RPA200766	0.0005	Schur 2005, 2005/1006470
Regent 500FS (maize)	50	2004	2004	France, 1 region (4)	Pollen (8T)	Fipronil, MB46513, MB45950, MB46136, RPA200766	0.0005	Bernevon 2005, 2005/1006513 Ker & Mackenroth 2005, 2005/1006489
Regent 500FS (maize)	40-48	2004	2004	France, 2 regions (1)	Pollen (18T)	Fipronil, MB46513, MB45950, MB46136, RPA200766	0.0005	Tisseur & Decourtye 2005 2005/1006536

[a] Time of collection of samples in the field for residue analysis
[b] Each location represents a different trial or field plot and as such the number of locations are considered as the experimental unit for descriptive statistics
[c] LOQ: Limit of quantification
[d] Six samples from seeds treated at the maximum treatment rate (60 mL product/unit of seed) and six samples from seeds treated at half rate (30 mL/unit)

The applicant also provided a statement on the risk from succeeding crops.

" The metabolism of fipronil in plants and the possibility of uptake by following crops has been evaluated as part of the EU peer-review process. The residue behavior is summarized in the Section B7 of the addendum (Final addendum to the Draft Assessment Report (DAR).
It results in the following statement §B.7.3.1 : "The uptake and translocation observed after a soil application or a seed treatment remain low. Less than 5% of the applied radioactivity is transferred in the aerial parts of the treated plants. The majority of the radioactivity remains in the lower parts of the plant. For example, in sunflower, at full flowering stage (BBCH 57), 94% of the TRR is located in the lower and middle leaves and stalks, the heads accounting for less than 4%. This amount increase to 16.7% TRR at harvest stage in heads (6.1% in seeds, 10.6% in heads without seeds)."
The subsequent movement of fipronil and its metabolites following uptake from soil is consistent with a pattern of translocation that is predominated by movement in the xylem with limited movement in the phloem. Consistent with this movement, fipronil residues are found principally in the older photosynthesizing leaves, with limited movement into new foliage. Plant metabolism data confirms that the residues in the reproductive part of the plant such as the flower head or grains are very low. The large amount of peer-reviewed residue data obtained with sunflower and maize confirms the lack of significant exposure via pollen or nectar. It should be noted that the data set which was evaluated in the Draft Assessment Report (Final Addendum part B.9.4.7.2.2 Table 9.4/1 – the table attached hereunder is taken from the addendum and updated with application rates) includes residue trials conducted with an application rate of 250 g ai/ha (Roper 2001a, 2001/1024592). No quantifiable residues are found in pollen or honey samples collected at this rate of application which is higher than 100 g ai/ha, the application relevant for onions. (see Final addendum to the Draft Assessment Report (DAR), table 9.4/4).

The possibility of uptake by following crops has also been evaluated in the Peer review (Final addendum to the Draft Assessment Report (DAR); part B7.9.4). The assessment is based upon different confined and field studies performed at rates typically above 100 g ai/ha (table 7.9.4 of DAR shows application rates between 163 g ai/ha and 340 g ai/ha). It was concluded that "Taking into account the exaggerated dose rate the studies were performed with, it can be concluded that no significant residue levels are expected to be observed in rotational crop following fipronil treated seed planting, especially if the plant-back interval is more than 4-5 months."

This low uptake can be explained by the limited mobility and water solubility of fipronil in soil. The major relevant metabolite MB46136 has also a low water solubility and very low mobility into soil. These peer-review studies show a lack of residue in the grains which is consistent with a pattern of translocation described above.
These results are further corroborated by peer-reviewed residue studies (see Final addendum to the Draft Assessment Report (DAR) part B. 9.7.4.2.2 ; Orry 2002, 2002/1017908) where pollen and nectar samples were collected from sunflower grown on fields where maize or cereal treated seeds where used during the previous year with an application rate of fipronil equivalent respectively to 50 and 100 g ai/ha. Consistent with other data obtained , no quantifiable residues are detected in the succeeding flowering crop (see Addendum table 9.4.2)."

Based on the above, the applicant concludes that the risk to adult bees because of flowering succeeding crops is to be considered very low at the different relevant application rates.

Ctgb notes (from table 9.4/4) that the studies in maize do not include application rates up to 100 g a.s./ha (i.e. the application rate for onions), whilst the highest residue level used for risk assessment was taken from the residue trials in maize. However, taking into account all available information (low systemicity of fipronil, majority of residue measurements below LOQ, exposure not via the treated crops but indirectly via weeds (which will not be present in large amounts) or succeeding crops (for which initial exposure will be lower due to soil tillage and degradation of fipronil), Ctgb agrees with the conclusion from the applicant that the risk to adult bees from fipronil will be low.

The risks to bees in a crop failure scenario are not considered relevant, because crop failure almost never occurs in the crops in which fipronil is used.

Risk to bee brood
According to the EPPO scheme, the risk to bee brood from exposure to nectar and/or pollen should also be assessed. No bee brood feeding test is available, so semi-field or field trials are necessary.

During EU review (91/414/EEG), seed treatments in the flowering crops maize and sunflower were assessed. One bee field test is available in the dossier, but this was not accepted by the RMS.
In the tunnel tests, bee colonies were exposed to flowering sunflower or maize for 10 to 11 days. During this period, the effects on mortality, foraging activity, behaviour, colony status, brood strength and status of the storage combs were evaluated. No adverse effects were found in any of the trials. However, the available tests did not cover a full brood cycle and are therefore not adequate to addres the risk to bee brood. In the EFSA conclusion, it was stated that the risk to bee brood was not adequately addressed with the studies present in the dossier and can only be concluded once 'recently submitted data on the risk to bee brood are evaluated'.

In a new addendum d.d. September 2009 (' Fipronil – Addendum with respect to confirmatory data'), the risk to breed brood was assessed based on a new field study conducted in Spain and on the re-evaluation of several tunnel studies already evaluated during peer-review.

In the addendum, the new field study was considered (*citation from addendum:*) '*particularly valuable to assess effects on brood, including any potential delayed effects, because the hives were observed for almost 3 months after exposure to sunflowers grown from dressed and non-dressed control seeds. Bee brood and overall colony performance were assessed by the quantification of several parameters including colony strength, brood nest size, brood (egg, larvae or pupae) and reserve area development as well as colony weight. Over the entire period of observation from July to October, no short- or long-term treatment related effects on brood development and performance of the honeybee colonies were observed.*'

This conclusion was in line with the results from the tunnel studies, in which no effects on bee brood in the plots treated with Regent 500FS were observed when results are compared to those in the controls plots.

Based on all available studies, in the addendum it was concluded that the risk to bee brood was low for the uses in both sunflower and maize.

NL agrees with the conclusion in the addendum, however it should be considered (as also pointed out in the Addendum and EFSA conclusion), whether the extrapolation of the available field studies to MS situation is acceptable.

The study that is conclusive for the bee brood risk assessment is conducted in Spain. As stated above, the extrapolation of the 'no or very low-residue situation' in bee relevant matrices after seed treatment of sunflower with fipronil to the NL situation is considered acceptable. Further, no difference in sensitivity of honey bees is expected between Spain and The Netherlands. The dose rate in the field study was 34 g a.s./ha. This covers the use in the dose rate for the proposed uses in cabbages, which is 15-20 g a.s./ha. However, the application rate in onions and shallots is 100 g a.s./ha. Even though no exposure is expected from the onion crop itself and no significant exposure is expected from flowering weeds, it was therefore questioned whether the exposure via flowering succeeding crops will not be higher than as occurred in the bee brood field study. For the use in onions and shallots the applicant was therefore requested to address the risk to bee brood from flowering succeeding crops, which might be covered by the applicant's reaction to the question posed for adult bees. The applicant stated that this issue was covered by the argumentation of adult bees in flowering succeeding crops (see above). Taking into account the new argumentation for adult bees and the fact that no effects on bee brood occurred in the available field study, Ctgb agrees. Thus, the risk for bee brood through exposure via nectar/pollen as a result from seed treatment with Mundial in cabbages, onions and shallots is considered acceptable.

- Exposure via honeydew

According to the EPPO (2010) scheme, exposure to contaminated honeydew is not considered relevant in the case of soil and seed treatments, unless the compound is highly selective towards non-aphid insects (see note 4 EPPO scheme; it is assumed that in most cases aphids will be killed by the a.s. (i.e. honey dew exposure can be excluded)). However, this assumption is not valid for fipronil, as indicated by the applicant:

'Fipronil is highly active on hymenopterens, while its activity on aphids is limited. In consequence, aphids are controlled or affected by fipronil if at all only at higher concentrations. The acute oral LD_{50} for bees is 0.00417 µg/bee corresponding to an LC_{50} 160.4 ppb or 0.16 ppm . As comparison the LC_{50} Aphis gossypii is with a value of 6.1 ppm by a factor of 38 or more than one order of magnitude higher. In summary, for fipronil the sensitivity for bees is clearly higher than for aphids.

Therefore, the risk via honeydew should be further considered.

A statement was provided addressing the risk for the use in onions and shallots:

'Leek and onions are rarely infested by aphids. Only one resp. two species are known from Europe to be found on them (Blackman & Eastop 2000), which is a low number of species very few compared with other crops. In addition, their occurrence is mainly described in storage, on potted plants, on bulbs or in greenhouses, but no infestations take place under regular cropping conditions of onion and leek. In fact e.g. onions are used in IPM to reduce aphid infestation in other crops due to their repellency. Thus it can be concluded that honeybees which might seek for honeydew as a sugar source are not exposed to potential residues of fipronil being present therein. Based on this evidence, there is only a low risk of BAS 350 76 I to honeybees via honeydew exposure if applied as seed treatment at the maximum recommended use pattern of 0.2 L or 0.1 L BAS 350 76 l/ha in onions or leek, respectively.'

Based on this statement, the risk to honeybees via honeydew is considered to be low for the use in onions and shallots.

To address the risk in cabbages, the applicant submitted an extended laboratory study (in which exposure of honeybees to honeydew obtained from aphids on potato leaves from potato plants grown on fields treated with fipronil 0.5% granular bait (50 mg a.s./ha) in Spain (N & S) was studied) and an extensive statement. They conclude that the risk is expected to be low, but as an extra precaution propose to exclude the formation of honeydew on the label by including a restriction sentence.

Since this sentence will exclude exposure, the study and statement are not discussed here. The risk via honeydew in cabbages is acceptable based on the restriction (*Aphids need to be controlled in such a way so no honeydew will be formed*). Cabbage seeds or plants are treated indoors, while the risk via honeydew occurs on the field after plants have been distributed to growers. Therefore, the applicant of the product should make sure that the persons buying the treated seeds or plants are aware that honeydew has to be avoided.
Thus, the risk for bees through exposure via honeydew as a result from seed treatment with Mundial in cabbages, onions and shallots is acceptable, provided that the following restriction sentence is placed on the label for the uses in cabbages:

> ***De toepasser dient de afnemer van zaden en/of planten er schriftelijk van op de hoogte te stellen dat bladluizen zodanig bestreden moeten worden dat er geen honingdauw wordt gevormd waar bijen op af kunnen komen.***

- Exposure via guttation
Guttation, the occurrence of water droplets on leaf edges of plants, may cause exposure to honeybees because systemic substances may be found in these water droplets.

The applicant has submitted a new field study that investigated the risk from guttation in potato crops grown on fields treated with fipronil 0.5% granular bait (50 mg a.s./ha) in Germany (Rhineland-Palatinate area). Assessments were made to investigate the attractiveness of guttation droplets to bees, the intensity, duration and daily time pattern of guttation in relation to timing of bee foraging activity.
Guttation occurred in the morning and in the evening on approximately 50% and 23% of the observation days, respectively, in all fields. Periods that guttation and bee foraging activity overlapped ranged from approximately 1 to 3 hours in the morning, and up to one hour in the evening. During a total of 84 observations (30 minutes each), in total ten bees were observed in the examined assessment areas, one of which was drinking dew, three sitting on the ground and six displaying other behaviour. No bees were observed to consume guttation fluid.

The study had some limitations so no decisive conclusions on the attractiveness to bees of guttation droplets in potatoes can be drawn, but it indicates that the risk to honeybees via guttation droplets on potato leaves is low. However, 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).
To reduce possible risks, it is recommended that beekeepers provide their colonies with sufficient water. This is good beekeeping practice already.
Based on the above, Ctgb expects a low risk from guttation.

B. Biocides

B.1 Professional uses of biocides

toelatingnr	middelnaam	toelatinghouder	werkzame stoffen	toepassing	formulering	Toepassing(en)
12119	GOLIATH AASSTATIONS	BASF Nederland B.V.	fipronil 0,05%	Professioneel	lokaas	Bestrijding van kakkerlakken in gebouwen.
12120	GOLIATH GEL	BASF Nederland B.V.	fipronil 0,05%	Professioneel	lokaas	Bestrijding van kakkerlakken in gebouwen.

Exposure to bees is not considered relevant from the above products which are products against cockroaches for indoor use only. 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 fipronil are expected to be acceptable for bees. In this section it will be considered whether studies available in the public literature domain confirm or contradict this risk assessment. A preliminary search on public literature has been carried out recently.

The included references are presented in Annex II and the main results are summarised below.

Laboratory and semi-field studies

In the EU dossier of fipronil, only an acute toxicity endpoint is available, of 4.17 ng/bee.

In the public literature however, two studies were done in which honeybees were exposed to firpronil for 11 days. These studies were both performed to study effects on sublethal parameters, but rendered results on mortality effects as well.

Decourtye et al. (2005)) found 40.6% mortality at 0.075 ng/bee/d and 87.3% mortality at 0.15 ng/bee d. Based on this study, the chronic LD50 was between 0.075 and 0.15 ng/bee/d.

Aliouane et al. (2009) found 100% mortality after 11 d exposure to 0.1 ng/bee/d but no increased mortality compared to control at 0.01 ng/bee/d. The chronic LD50 is this study is therefore between 0.01 and 0.1 ng/bee/d (the authors themselves calculate that the no-observed-effect-dose for fipronil would be 0.07 ng/bee/d but the calculation of this value should be clarified).

Thus, it is clear that toxicity of fipronil increases with increasing duration of exposure. No fixed chronic LD50 was determined in the studies. At 0.075 ng/bee/d, one of the studies found 41% mortality; while the other study estimated that the NOEC would be very close to this value: 0.07 ng/a.s./bee. As an indication, the 0.075 ng/bee/d will be taken as estimation of the chronic LD50.

The risk to bees foraging on pollen or nectar can be estimated by using the data on daily intake from Rortais et al. (2005), as indicated in EPPO 2010 and as was explained in the risk assessment above. For the chronic risk assessment, mean residue values are appropiate (see EPPO 2010, note 10).

Residue trials in sunflower showed a mean residue value of 0.0010 mg/kg for sunflower (based on the LOQ; no residues of fipronil or metabolites were detected >LOQ in any of the analysed samples). Residue trials in maize showed a mean residue value of 0.0005 mg/kg (based in part on the LOQ, since in only two of the eight trials, fipronil was found > LOQ). As a worst case approach, the chronic risk to bees will be calculated assuming a residue level of 0.0010 mg/kg in both nectar and pollen. This level covers the residue levels found in honey and pollen in beehives found in the apiary monitorings described below (with the exception of one very high value in pollen of 28 ppb, but since fipronil was only detected in 1 out of 350 samples in this study, the mean value will still be below 10 ppb).

Estimated chronic risk for adult bees from fipronil

LD_{50}	Food type	Residue level	Food ingestion	Exposure	TER (trigger 10)
[ng a.s./bee]		[mg a.s./kg]	[kg/bee/d]	[ng a.s./bee/d]	
0.075*	Nectar	0.0010	80-321*10^{-6}	0.08 - 0.321	**0.9 – 0.2**
	Pollen	0.0010	6.5*10^{-6}	0.0065	12

The calculations above indicate that a risk from feeding on pollen is still not expected, but there may be a risk from feeding on treated nectar. However, the proposed uses of fipronil in the Netherlands are only on crops which produce no honeybee forage at all (onions, cabbages) and exposure via nectar and pollen would only occur via succeeding crops. The residue levels used in the above calculation are highly theoretical and worst case estimates since the large majority of measures was below the LOQ, and residues in succeeding crops are expected to be even lower than those in directly treated crops. The TER calculated above is furthermore not very much below the trigger of 10. It is therefore considered that the risks from the proposed uses of fipronil in the Netherlands are acceptable also when the estimated chronic LD50 from the public literature is taken into account. Further refinement would be required however for uses in flowering (nectar-producing) crops.

Girolami et al (2009) measured residue levels in guttation droplets from plants grown from treated seeds. Fipronil was never found above its limit of detection. This confirms the conclusion that fipronil poses no risk from exposure via guttation liquid.

Cresswell (2011) performed a meta-analysis of imidacloprid laboratory and semi-field studies, which result questions the statistical power of honeybee semi-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 in this working group. Ctgb will assess using the European harmonized methodologies until the impact of this paper has been clarified in the European framework.

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

In a broad survey of pesticide residues, which was conducted on samples from migratory and other beekeepers across 23 USA states, one Canadian province and several agricultural cropping systems during the 2007–08 growing seasons, Mullin et al (2010) found the following residue levels of fipronil: wax 1.1-36 ppb (detected in 1.4% of 208 samples, mean in pos. samples 12.8 ppb); pollen 28.5 ppb (detected in 1 out of 350 samples); dead honeybees 9.9 and 3060 ppb (detected in 2 out of 140 samples). They also found 98 other pesticides and metabolites in mixtures up to 214 ppm in bee pollen alone, which according to them represents a remarkably high level for toxicants in the brood and adult food of this primary pollinator. They conclude that the effects of these materials in combinations and their direct association with CCD (colony collapse disorder) or declining bee health remains to be determined.

In a study on French apiaries in France (Chauzat et al. 2006), pesticide residues were analysed in pollen loads. 81 samples were analysed for fipronil and its desulfynil compound. 10 and 9 positive samples were found with mean concentrations of 1.2 and 1.3 ppb, respectively. A wide range of other pesticides in pollen loads collected by honeybees was also found. This contamination was common year-round; no season was particularly more represented than another, with the exception of fipronil which showed a peak in March and April, concurring with sunflower sowing.

In another study in France (Chauzat et al, 2009), honeybee colony health was studied in relation to pesticide residues found in colonies. Fipronil and its sulfone and desulfinyl metabolites were analysed in pollen, honey and honeybee samples.
Pollen (185 samples): Fipronil (detected in 11 samples): mean in pos. samples 1.2 ppb. Fipronil sulfone (in 12 samples): mean in pos. samples 1.7 ppb. Fipronil desulfinyl (in 6 samples): mean in pos. samples 1.0 ppb.

Honey (239 samples): never detected.
Honeybees (187 samples, in 9.1% detected). Mean concentration of fipronil residues in pos. samples : 0.5 (a.s.), 1.2 (desulfinyl) and 0.4 (sulfone) ppb in honeybees.
The maximum values of fipronil sulfone and fipronil desulfinyl residues detected were 3.6 and 1.5 g/kg, respectively.
Also, many other pesticidal substances were found in the bee matrices. No signficant relationship was found between the presence of pesticide residues and the abundance of brood and adults, nor between colony mortality and pesticide residues. The authors conclude that more work is needed to determine the role these residues play in affecting colony health.

Higes et al (2010) estimated the prevalence of honey bee colony depopulation symptoms in Spain in a random selected sample (*n* = 61) and explored the implication of different pathogens, pesticides and the flora visited in the area under study. Fipronil was detected in only three of 61 stored pollen samples and imidacloprid was not detected in any. 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.

The residues reported in these publications cannot be linked to a certain (type of) use. Fipronil 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 some countries fipronil 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 have been shown to be linked to overwintering succes, though.

Bee colony losses in the Netherlands

In the Netherlands, relatively high bee losses have been seen in recent years (increased mortality after winter). A scientific report on bee mortality and bee surveillance in Europe, submitted to EFSA (Hendrikx *et al.* 2009), reported the results regarding The Netherlands and Belgium as shown in the table below.

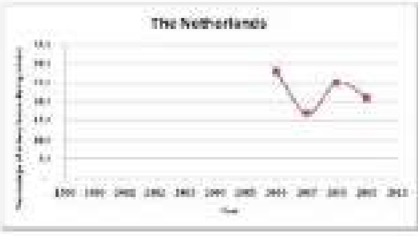

Figure 47. **Percentage of winter colony losses in the Netherlands from 2000 to 2009**

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

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

These losses have mainly been attributed to beekeeping practice with regard to pests and diseases, especially the *Varroa* mite, since it has been found that adequate and timely Varroa treatment reduces winter mortality (Van der Zee & Pisa 2011; personal communication bijen@wur and professional beekeeper). Also, reduction of forage is likely to play a role. The relationship between pesticides and bee decline has not been studied in the Netherlands so far.

Europe
A report submitted to EFSA on bee mortality and bee surveillance in Europe (Hendrikx *et al.* 2009), concluded on results derived from surveillance systems in 27 European countries and a thorough literature search of the existing databases, as well as relevant grey literature about causes of colony losses:
• General weakness of most of the surveillance systems in the 24 countries investigated;
• Lack of representative data at country level and comparable data at EU level for colony losses;
• General lack of standardisation and harmonisation at EU level (systems, case definitions and data collected);
• Consensus of the scientific community about the multifactorial origin of colony losses in Europe and in the United States and insufficient knowledge of causative and risk factors for colony losses.

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

The UNEP report names many possible threats to pollinators:
- Habitat deterioration, with reduction of food sources (and habitat, for certain wild pollinators).
- Increased pathologies.
- Invasive species (the parasitic mite *Varroa destructor* is named as the most serious threat to apiculture globally).

- Pesticide use (chronic herbicide use and spray drift from broad spectrum insecticides; possible effects of chronic sublethal exposure to systemic insecticides, however this still needs to be proven in the field).
- Beekeeping activities.
- Climate change.

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

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

Based on the information as shown above it cannot be concluded that there is a link between fipronil 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 fipronil or neonicotinoid products significantly contribute to bee decline based on the referred public literature.
It should be noted that other (European and elsewhere) countries have not withdrawn these substances from the market either (with some exceptions where clear acute bee poisoning due to suboptimal sowing circumstances was observed; this has not been the case in the Netherlands).
Finding associations between bee decline and all possible environmental factors is a complex issue that has to be established the coming years in a scientific way.

In the 'Inclusion Directive' it is suggested that Member States ask for a monitoring programme to further investigate the role that fipronil plays in bee decline. At this moment a field monitoring on the product Goldor Bait (not authorised in the Netherlands) is in proces, due to a request from Germany. In addition to this monitoring, three field studies related to seed treatment uses on sunflower including the monitoring of hives have been performed by BASF and results are included in three reports, of which one (Schur, 2005) has been part of the EU peer-review, and two (Boksch 2009 a and b) are part of the dossier being evaluated by Spain/Slovakia for the re-registration. Taking the above in consideration, no further monitoring programme will be requested by Ctgb for the currently authorised uses.

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

For the risk assessment, the final LoEP is used (from EFSA conclusion, Word-version d.d. 03/2006), to which additional information and studies are added by Ctgb in *italics*.

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

Acute oral toxicity ‡	Fipronil: LD_{50} = 0.00417 µg/bee equivalent to LC_{50} = 0.160 mg/kg diet MB 46136 *(sulfone metabolite)*: LD_{50} = 0.0064 µg/bee equivalent to LC_{50} = 0.269 mg/kg diet RPA 200761 *(carboxamide metabolite)*: NOEC = 10.3 mg/kg diet equivalent to 0.29 µg/bee
Acute contact toxicity ‡	Fipronil: LD_{50} = 0.00593 µg/bee

Field or semi-field tests/ High tier studies

One field study and three tunnel studies were conducted for the three preparations with sunflower. Of the higher tier studies included and evaluated in the DAR of April 2004, the RMS considered as valid two tunnel studies (C019707 and C013759). In these two studies, no differences were found between bees tested in control and fipronil-treated plots, thus no lethal or sublethal effects linked to fipronil were reported. Similar results (lack of effects) have been obtained in two new tunnel trials conducted in 2004. The study conducted in France by ACTA (2005/1006529) has provided conclusive results based on biological observations and residue results in pollen and nectar while the results of the work in Spain by GAB (2005/1006522 and 2005/1006523) are not conclusive at this time because residues of fipronil and metabolites were found in samples from the control samples. In summary, results for at least three valid higher tier studies with honeybees in sunflowers found no adverse effects on honeybees in plots treated with Regent 500FS.

Ctgb: For more detailed description of the risk assessment and the above mentioned studies we refer to the final addendum of January 2006, which describes the risk to bees more extensively.

Ctgb: An addendum with respect to confirmatory data for Annex I inclusion is available from September 2009. This addendum includes the data to confirm the risk assessment for honeybees, especially bee brood, including a new field study in sunflower grown from fipronil treated seeds in Spain, a re-evaluation of brood development data of several tunnel studies already evaluated during peer-review, and a new risk assessment for bees in maize and sunflower.

Conclusion from re-evaluation of brood development data and evaluation of new field study:
In this study (Schur, 2005), which was conducted under Southern European conditions, a detailed assessment of brood development during the exposure time and a 3-month period afterwards revealed no adverse effects in any of four colonies. This is consistent with the results of several semi-field studies (see above). It can therefore be concluded, that in a "no residues > LOQ in bee-relevant matrices situation", as it was the case in the study of Schur (2005), no adverse effects on honey bee brood are likely to occur. There is generally no indication that brood development in the case of exposure to fipronil would be the more sensitive endpoint compared to adult bee impairment/mortality. In conclusion, both a risk assessment based on intrinsic toxicity and measured residues in bee-relevant matrices under the conditions of mainly one Member State and the results of higher tier studies with honeybees indicate an acceptable risk to honeybees and their brood from the proposed uses of fipronil as a seed treatment (Regent 500 FS) in sunflowers and maize.

Additional studies submitted by applicant (evaluated by Bioresearch and promotion d.d. May 2011):

Reference	:	*Moreno Garcia S. (2009/1110799)*	*Exposure duration*	:	*2 x 8 hours in 48 hours*
			Field rate	:	*50 mg a.s./ha potato at sowing*
Type of study	:	*Honey bee extended lab study*	*Exposure method*	:	*Feeding of contaminated honey dew produced by aphids feeding on treated potato plants*
Year of execution	:	*2009*			
Test substance	:	*BAS 350 89 I (Goldor Bait); granular bait*			

a.s. content	:	Fipronil 0.5%	Conclusion:		In both trials (North and South Spain) mortality of adult honeybees in the group fed with honeydew obtained from potato leaves treated with BAS 350 89 I and in the group of bees fed with honeydew obtained from control potato leaves was very similar. Fipronil used as granular bait applied at a rate of 50 g fipronil/ha to potatoes at sowing time did not cause unacceptable effects on adult honeybees exposed to honeydew produced by aphids feeding on potato plants. Analysis result of fipronil residues in honeydew reported in a separate report (2009/1110798): all samples < LOQ for fipronil and metabolites, except for 1 isolated sample (1.23 µg/kg fipronil). LOQ = 0.5 µg/kg for each analyte)
Species	:	Apis mellifera (honey bee)	Acceptable	:	Yes. Actual consumption of honeydew is not documented, but honeydew residue results can be used for risk assessment.

Reference	:	Muenderle M., Rastell A.	Field rate	:	50 g a.s./ha
Type of study	:	Guttation observation of potato	Exposure method	:	Potential exposure through uptake of contaminated guttation fluid
Year of execution	:	2009	Conclusion	:	Occurrence of guttation and bee foraging activity can overlap for some hours during the day. However, based on the low occurrence of bees visiting the potato fields, and no occurrence of bees consuming guttation fluid, it is concluded that the risk to honey bees of being adversely affected by guttation of potato plants treated with fipronil is nil.
Test substance	:	BAS 350 89 I (Goldor Bait); granular bait			
a.s. content	:	Fipronil 0.5%			
Species	:	Solanum tuberosum (potato, var. Granola) and Apis mellifera (honey bee)			
Exposure duration	:	Approximatel y 1 month	Acceptable	:	Yes, although the study had some limitations: no information was given about surrounding fields and its anticipated attractiveness to honeybees, thus a reference regarding occurrence and behaviour of bees in other (off-crop) habitats was lacking; it is unclear why bee hives were placed so far away from the potato fields under study (98, 118, 209 and 18 m from potato fields) and it was reported that guttation liquid was collected for residue analysis, but no results are presented (From the

					applicant's study summary it appears that derivates found in the guttation liquid were all below the LOQ (0.5 µg/kg)].

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.

Literatuur

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, Thrionet 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, Turionet 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.

Bijlage II-4 imidacloprid

In de Tweede Kamer is op 17 februari 2011 motie 19 aangenomen. Deze motie betreft de herbeoordeling van bestrijdingsmiddelen op basis van neonicotinoiden 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.

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	Zaadcoating van sla, andijvie, kolen, prei.

					zaadbehandeling	
11998 (afgeleide: 12219)	ADMIRE N PIN	Bayer CropScience B.V.	imidacloprid 2,5%	Niet-professioneel	Plantenstaafje	Sierplanten in potten en bakken.
12115 (afgeleides: 12945, 12919)	PROVADO GARDEN	Bayer CropScience B.V.	imidacloprid 5%	Niet-professioneel	Water dispergeerbaar granulaat	Gewasbehandeling in siergewassen en appels en peren of particuliere boomgaard, en aangietbehandeling in gazon.

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	BAYTHION	Bayer CropScience	imidacloprid	Professioneel &	Granulaat	Korrels om bij mierennest te strooien.

(afgeleides: 13026, 12974, 13052, 12979, 12980, 12024)	MIERENMIDDEL N	B.V.	0,0500%	Niet-professioneel		Alleen buiten.
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) 158 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/EEC 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 05/2008 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/EEC, 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.

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

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

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*); met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	Young crop 0.07 Adult crop 0.105	2	7-14 days	April-July;
Apple against rosy apple aphid (*Dysaphis plantaginea*), apple aphid (*Aphis pomi*), rosy leaf-curling aphid (*Dysaphid devecta*, *Dysaphis anthrisci*), apple-grass aphid (*Rhopalosiphum insertum*; met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	Young crop 0.07 Adult crop 0.105	2	7-14 days	April-Sept;
Pear against common green capsid bug (*Lygus pabulinus*), pear sawfly (*Hoplocampa brevis*); met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	Young crop 0.07 Adult crop 0.084	2	7-14 days	April-July;
Pear against pear aphid (*Dysaphis pyri*), pear coltsfoot aphid (*Anuraphis farfarae*), *Melanaphis pyaria*, black bean aphid (*Aphis fabae*); met dien verstande dat toepassing alleen is toegestaan vóór de bloei tot en met het muizenoorstadium alsmede na de bloei van appel en peer;	F	Young crop 0.07 Adult crop 0.084	2	7-14 days	April-Sept;
Aubergine, gherkins, courgettes, cucumber, tomato, red pepper, and sweet pepper on artificial substrate (protected culture) against glasshouse potato aphid (*Aulacorthum solani*), green and red peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean aphid (*Aphis fabae*)	G	2.45 g a.s./1000 plants	2	1 day	March-Nov
Aubergine, gherkins, courgettes, cucumber, tomato, red pepper, and sweet pepper on artificial substrate (protected culture) against greenhouse whitefly (*Trialeurodes vaporariorum*)	G	28 ml/1000 plants	2	1 day	March-Nov
Floriculture crops on artificial substrate (protected culture) against glasshouse potato aphid (*Aulacorthum solani*), green and red peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean aphid (*Aphis fabae*)	G	2.45 g a.s./1000 plants	2	1 day	March-Nov
Floriculture crops on artificial substrate (protected culture) against greenhouse whitefly (*Trialeurodes vaporariorum*)	G	9.8 g a.s /1000 plants	2	1 day	March-Nov
Floriculture crops in the open ground (protected culture) against glasshouse potato aphid (*Aulacorthum solani*), green and red peach aphid (*Myzus persicae*), cotton aphid (*Aphis gossypii*), black bean aphid (*Aphis fabae*)	G	0.084	2	7-10 days	Jan-Dec
Gerbera and chrysanthemum (protected culture)	G	0.084	2	7-10 days	Jan-Dec

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

Tree nursery crops and perennials in the open ground against Boxwood psyllids (*Psylla buxi*); met dien verstande dat toepassing alleen is toegestaan voor de bloei tot het zichtbaar worden 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	F	0,0700	2	7	april-sept

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

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

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 glasshouse)	Application rate a.s. [g/ha]	LD_{50} [µg/bee]	HQ (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 effects 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) (already on the label):

> *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 sentence on 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%	40	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). Higher doses cause enhanced mortality: 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. The statement is presented in full below in italics:

"*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]).

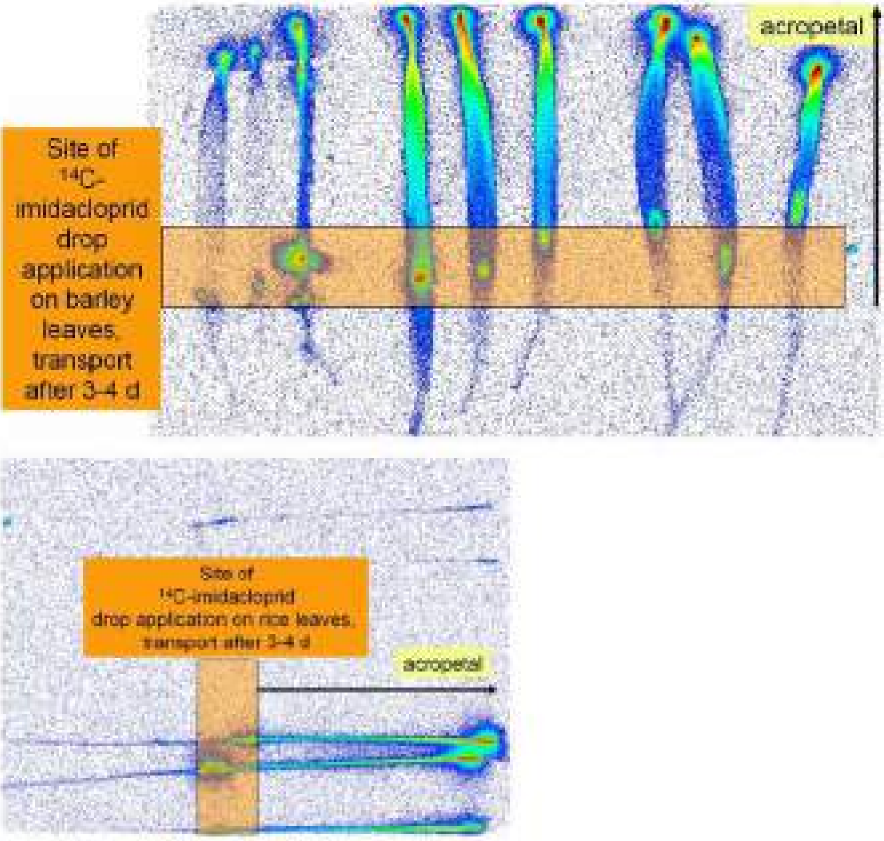

Figure 2.2.1: Illustration of the acropetal transport of imidacloprid after foliar application

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 m² 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: investigation performed for AFFSA, not peer-reviewed]*), 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* [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 to statement of the applicant:</u>
The argumentation on the translocation behaviour of imidacloprid after spraying was accepted based on Ctgb residue expertise. 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 180 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.

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

Expertise on flower attractivity was sought from the bee specialists at Bees@WUR to investigate 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. Thus, a risk in the field cannot be excluded when there are flowers; therefore, flowering should be avoided.

The label currently states that *flowering has to be avoided* for bulbs in the field which have had a dipping treatment. This restriction is maintained. With the restriction, the risk to bees via this route is acceptable.

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 residues of the active substance itself 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 (Nikolakis *et al.*,2011 a+b). 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, (field), before	0.07	1[2]/-	0.8	0.093	0 d	0 d

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	182 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.

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
The applicant (Bayer) did not include studies considering guttation in their imidacloprid dossier. However, several protected studies are available in which the risk via guttation from clothianidin (another neonicotinoid substance)-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 uptake 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

Toelating-nr	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 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 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 to pose a relevant risk 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
The applicant (Bayer) did not include studies considering guttation in the imidacloprid dossier. However, several protected studies are available in which the risk via guttation from clothianidin (another neonicotinoid substance)-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/m² 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-030187-01-1, 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 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 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

The applicant (Bayer) did not include studies considering guttation in their imidacloprid dossier. However, several studies are available in which the risk via guttation from clothianidin (another neonicotinoid substance)-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 uptake 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
The applicant (Bayer) did not include studies considering guttation in their imidacloprid dossier. However, several protected studies are available in which the risk via guttation from clothianidin (another neonicotinoid substance)-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 zaadbehandeling	Zaadcoating in suiker- en voederbieten.
11601	GAUCHO ROOD	Bayer CropScience B.V.	imidacloprid 70%	0.120 kg a.s./ha	Water dispergeerbaar poeder voor vochtige zaadbehandeling	Zaadcoating in mais.
12341	GAUCHO TUINBOUW	Bayer CropScience B.V.	imidacloprid 70%	0.089-0.120 kg a.s./ha	Water dispergeerbaar poeder voor vochtige zaadbehandeling	Zaadcoating van sla, andijvie, kolen, prei.

<u>*Direct exposure*</u>
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.

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

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 of Gaucho Tuinbouw:

> ***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

The applicant (Bayer) did not include studies considering guttation in their imidacloprid dosser. However, several protected studies are available in which the risk via guttation from clothianidin (another neonicotinoid substance)-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-houder	werkzame stoffen	formulering	Toepassing(en)
11998 (afgeleide: 12219)	ADMIRE N PIN	Bayer CropScience B.V.	imidacloprid 2,5%	Plantenstaafje	Sierplanten in potten en bakken.

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

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel bij kamerplanten binnenshuis.

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

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

<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 ([redacted] 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 [redacted] 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 [redacted] 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.***
>
> ***In appels en peren in de tuin of particuliere boomgaard, door middel van een gewasbehandeling met een maximum aantal behandelingen van totaal twee keer per seizoen, met uitzondering van de periode dat de bloemknoppen zichtbaar zijn (zie bijsluiter).***

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

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

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

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

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

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.
13118	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,	BAYTHION MIERENMIDDELN	Bayer CropScience B.V.	imidacloprid 0,0500%	Professioneel & Niet-professioneel	Granulaat	Korrels om bij mierennest te strooien. Alleen buiten.

12979, 12980, 12024)						
13280 (parallel: 13351)	VAPONA RAAMSTICKER	Sara Lee Household and Body Care NL B.V.	imidaclopri d 0,4890%	Niet-professionee l	Diversen	Sticker tegen vliegen. Binnenshuis.
13369	VLIEGENSTICKE R	Bayer CropScienc e B.V.	imidaclopri d 5G/KG	Niet-professionee l	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 for bees, provided that restrictions are mentioned on the labels. In this section it will be considered whether studies available in the public literature domain confirm or contradict the risk assessment as shown above. A preliminary search on public literature has been carried out recently. The included references are presented in Annex II and the main results are summarised below.

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

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

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

Faucon et al (2005) fed two groups of eight honey bee colonies with two different concentrations of imidacloprid in saccharose syrup during summer (each colony was given 1 litre of saccharose syrup containing 0.5 µg/L or 5 µg/L of imidacloprid on 13 occasions). Their development and survival were followed in parallel with control hives (unfed or fed with saccharose syrup) until the end of the following winter. The parameters followed were: adult bee activity (number of bees entering the hive and pollen carrying activity), adult bee population level, capped brood area, frequency of parasitic and other diseases, mortality, number of frames with brood after wintering and a global score of colonies after wintering.

The only parameters linked to feeding with imidacloprid-supplemented saccharose syrup when compared with feeding with non-supplemented syrup were: a statistically non-significant higher activity index of adult bees, a significantly higher frequency of pollen carrying during the feeding period and a larger number of capped brood cells. When imidacloprid was no longer applied, activity and pollen carrying were re-established at a similar level for all groups. Repeated feeding with syrup supplemented with imidacloprid did not provoke any immediate or any delayed mortality before, during or following the next winter. This confirms the expectation made in the risk assessment that exposure to a residue level of 5 ppb does not lead to adverse long-term effects.

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

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

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

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

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

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

In a large study in Germany (Genersch et al., 2010), many pesticides (including miticides) were found in honeybee colonies. Imidacloprid was detected in one of the 215 samples of beebrood. In this study, factors which significantly influenced overwintering succes were 1) high varroa infestation level; 2) infection with deformed wing virus (DWV) and acute bee paralysis virus (ABPV) in autumn; 3) queen age; 4) weakness of the colonies in autumn. No effects could be observed for Nosema spp. or pesticides. The authors however consider that further investigations and controlled experiments are necessary to clarify the relation between pesticides and honeybee colony health in the long-term.

In a study on French apiaries in France (Chauzat et al. 2006), pesticide residues were analysed in pollen loads. Search of imidacloprid and 6-chloronicotinic acid was conducted on 81 samples of pollen loads. Residues of imidacloprid were found in 40 samples. The most frequent residues were imidacloprid (49.4% of samples), 6-chloronicotinic acid (44.4%) and fipronil (12.4%). The proportion of samples with either imidacloprid, 6-chloronicotinic acid, or both was 69.1%. Maximum imidacloprid and 6-chloronicotinic acid concentration found in these positive samples was 5.7 and 9.3 µg/kg (mean: 1.2 and 1.2 ppb), respectively.
In another study in France (Chauzat et al, 2009), honeybee colony health was studied in relation to pesticide residues found in colonies. Imidacloprid metabolites were analysed in pollen, honey and honeybee samples. The most frequent residue in pollen loads, honey, and honey bee matrices was imidacloprid or 6-chloronicotinic acid. Mean concentrations of imidacloprid residue, from those positive samples, were 1.2 µg/kg in honey bees, 0.9 µg/kg in pollen, and 0.7 µg/kg in honey. The concentration obtained for imidacloprid and 6-chloronicotinic acid in pollen loads was above the limits of detection (LOD) in 40% (75/185) and 33% (61/185) of the samples, respectively. When both were found together, the concentrations were above the LOD in 16% (30/185) of the samples.
It is not known to which extent imidacloprid was used in the areas in which the bee samples of the studies of Chauzat et al. were taken. Apart from imidacloprid, many other pesticidal substances were found in the bee matrices.
No signficant relationship was found between the presence of pesticide residues and the abundance of brood and adults, nor between colony mortality and pesticide residues. The authors conclude that more work is needed to determine the role these residues play in affecting colony health.

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

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

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

In a broad survey of pesticide residues, which was conducted on samples from migratory and other beekeepers across 23 USA states, one Canadian province and several agricultural cropping systems during the 2007–08 growing seasons, Mullin et al (2010) found the following residue levels of imidacloprid: wax 2.4-13.6 ppb (detected in 1.0% of 208 samples, mean 8.0 ppb); pollen 6.2-206 ppb (detected in 2.9% of 350 samples, mean 39 ppb). They also found 98 other pesticides and metabolites in mixtures up to 214 ppm in bee pollen alone, which according to them represents a remarkably high level for toxicants in the brood and adult food of this primary pollinator. They conclude that the effects of these materials in combinations and their direct association with CCD (colony collapse disorder) or declining bee health remains to be determined.

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

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

In these matrices usually a mixture is present of many pesticidal substances. So far, no statistical correlation has been found between the presence of pesticide residues in colonies and honeybee health in the long-term. Other factors than pesticides have been shown to be linked to overwintering succes, though.

Bee colony losses in the Netherlands

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

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

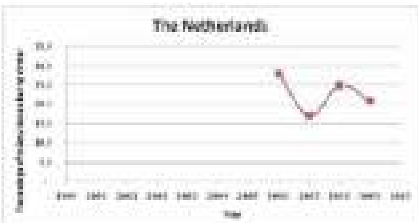

Figure 47. **Percentage of winter colony losses in the Netherlands from 2000 to 2009**

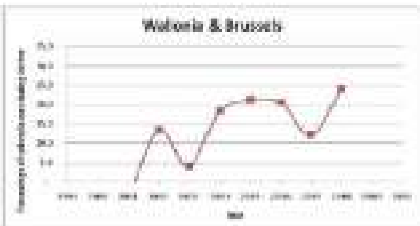

Figure 48. **Percentage of winter colony losses in Wallonia & Brussels from 2000 to 2009**

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

These losses have mainly been attributed to beekeeping practice with regard to pests and diseases, especially the *Varroa* mite, since it has been found that adequate and timely Varroa treatment reduces winter mortality (Van der Zee & Pisa 2011; personal communication bees@wur and professional beekeeper). Also, reduction of forage is likely to play a role. The relationship between pesticides and bee decline has not been studied in the Netherlands so far.

Europe

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

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

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

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

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

International observations

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

The UNEP report names many possible threats to pollinators:

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

The conclusion of the UNEP report shows the complexity of the bee decline issue and is presented here in full:

Currently available global data and knowledge on the decline of pollinators are not sufficiently conclusive to demonstrate that there is a worldwide pollinator and related crop production crisis. Although honey bee hives have globally increased close to 45% during the last 50 years, declines have been reported in several locations, largely in Europe and Northern America. This apparent data discrepancy may be due to interpretations of local declines which may be masked by aggregated regional or global data.

During the same 50-year period, agricultural production that is independent from animal pollination has doubled, while agricultural production requiring animal pollination has increased four-fold (reaching 6.1% in 2006). This appears to indicate that global agriculture has become increasingly pollinator dependant over the last 50 years. However, human activities and their environmental impacts may be detrimental to some species but beneficial to others, with sometimes subtle and counter-intuitive causal linkages. Pollination is not just a free service but one that requires investment and stewardship to protect and sustain it. There should be a renewed focus on the study, conservation and even management of native pollinating species to complement the managed colony tradition. Economic assessments of agricultural productivity should include the costs of sustaining wild and managed pollinator populations.

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

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

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

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

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

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

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

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

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

Furthermore, several chronic tests and studies to investigate sublethal effects (bee behaviour) on honeybees were conducted with the a.s. The chronic lethal and sublethal toxicitywas extensively discussed in the DAR and summarised in the EFSA conclusion on imidacloprid, which has been copied in the beginning of the risk assessment for plant protection products above. In the DAR, NOEC values from the available studies for the acute oral toxicity, sublethal effects (learning behaviour), chronic lethal effects and chronic behavioural impacts including bee hive development were set at 45, 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 then 10 ppb.

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

Cage tests.
seed treatment:

a) Maus 2002. Colonies were fed with pollen from seed-treated maize (1 g a.s./1000 seeds). No effects on foraging activity, behaviour, egg laying activity, breeding succes, pollen and honey stores, colony strength and weight. Exposure and observation duration: 52 days.
b) Maus & Schoening 2001. Colonies were fed with pollen from seed-treated maize (49 g a.s./'unit'). No effects on mortality, foraging activity, behaviour, egg laying activity, pollen and honey stores, colony strength. Exposure and observation duration: 38 days.
c) Schmuck & Schoening 1999. Colonies were exposed to flowering rape seed treated with 1 kg a.s./'dt'. No effects on mortality and behaviour. Exposure and observation duration: 3 days. France.
d) Schmuck & Schoening 1999. Colonies were exposed to flowering rape seed treated with 1 kg a.s./'dt'. No effects on mortality and behaviour. Exposure and observation duration: 3 days. Sweden.
e) Schmuck & Schoening 1999. Colonies were exposed to flowering rape seed treated with 1 kg a.s./'dt'. No effects on mortality and behaviour. Exposure and observation duration: 3 days. UK.
f) Schmuck & Schoening 1999. Colonies were fed with sunflower honey treated with imidacloprid (up to 20 ug/kg) and untreated pollen. No effects on mortality, foraging activity, behaviour, food consumption, storage behaviour, egg laying activity, breeding succes, comb cell production, colony strength and weight. Exposure and observation duration: 39 days.
g) Schmuck & Schoening 1999. Colonies were fed with maize pollen treated with imidacloprid (up to 20 ug/kg) and untreated sunflower honey. No effects on mortality, foraging activity, behaviour, food consumption, storage behaviour, egg laying activity, breeding succes, comb cell production, colony strength and weight. Exposure and observation duration: 39 days.
h) Schmuck et al. 1999. Exposure to flowering sunflowers, which was either seed-treated (52 g a.s./ha) or sown as untreated succeeding crop after imidacloprid use. No effects on mortality and behaviour. Exposure and observation duration: 8 days.
i) Schmuck et al. 1999. Exposure to flowering sunflower, which was either seed-treated (45 g a.s./ha) or sown as untreated succeeding crop after imidacloprid use. No effects on mortality and behaviour. Exposure and observation duration: not reported, but likely 8 days as in similar trial above.
j) Schmuck et al. 1999. Exposure to flowering summer rape, which was either seed-treated (72 g a.s./ha) or sown as untreated succeeding crop after imidacloprid use. No effects on mortality and behaviour. Exposure and observation duration: 8 days.
k) Schmuck et al. 1999. Exposure to flowering summer rape, which was either seed-treated (72 g a.s./ha) or sown as untreated succeeding crop after imidacloprid use. No effects on mortality and behaviour. Exposure and observation duration: 8 days.
l) Wallner 1999. Exposure to flowering Phacelia, seed-treated (50 g a.s./ha). No effects on mortality, disorientation, foraging activity and honey yield. Exposure and observation duration: not reported in DAR.
m) Harris 1999. Exposure to flowering canola (OSR), seed-treated (51 g a.s./ha; 800 g/100 kg seed). No effects on mortality, foraging activity, brood development, colony strength. Exposure and observation duration: 43 days.
n) Brasse 1999. Exposure to flowering summer rape, seed-treated (63 g a.s./ha; 10.5 g/kg seed). No effects on mortality, foraging activity, brood development, colony strength. Exposure and observation duration: 21 days. It is mentioned that both colonies overwintered as full colonies.
r) Colin & Bonmartin 2000 and s) Colin 2003. Not considered valid by RMS.
spray treatment:
o) Schur 2001. Colonies exposed to full flowering apple orchards which had been sprayed during the mouse-ear stage (BBCH 10) at 0.105 kg a.s./L. No effects on mortality, foraging activity, behaviour, condition of the colonies and brood development. Exposure and observation duration: 7 days.
p) Bakker 2001. Colonies exposed to flowering Phacelia which was sprayed with 0.6 – 14 g a.s./ha during bee flight. When applied during bee flight, 0.6 g a.i./ha and 1.2 g a.i./ha of Confidor SL 200 had no effects on foraging activity and mortality of the honeybee Apis mellifera. At a rate of 2.0 g a.i./ha, 4.0 g a.i./ha and 9.0 g a.i./ha foraging activity was reduced on the day of application, but no effects on mortality were observed.
At the highest test rate (14.0 g a.i./ha) statistically significant reduction in foraging was found during the first two days, but no effects on mortality were observed. (Please note that the summary in the DAR states that mortality was significantly higher than control in dose rates 2.0-14.0 g a.s./ha; RMS Germany agrees that this has been a mistake and that in fact no mortality occurred in the study).

q) Bakker 2003. Colonies exposed to flowering Phacelia which had been sprayed with 21 or 35 g a.s./ha 24, 48 and 96 h before exposure. Foraging activity significantly reduced in all treatments. Mortality twice as high as in control.

Field tests.
seed treatment

a) Schmidt et al. 1998. Exposure to flowering sunflowers, seed-treated with 59 g a.s./ha (0.7 mg a.s./seed). No effects on mortality, behaviour, hive weight, foraging, flight and pollen collection activity. Exposure and observation duration: 14 days.

b) Schuld 2001. 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 0.2456 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 36 g a.s./ha. No adverse effects on mortality, foraging activity, behaviour, input of necter 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 1998. 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:
s) Belzunces et al 1996. Marked foragers from small honeybee colonies were followed while foraging on feeders containing sucrose 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 sawn 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, sawn 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 2011a (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 2011b (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 90th%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 & Schoering 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 Sallé, 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 26 fields were sown with mechanical sowing machines. The test field sizes varied between 1.5 and 21.0 ha. Shortly before sowing, the wind direction was determined and ten Petri-dishes were placed in groups of two at a distance of 1, 3 and 5 m (in total 30 Petri-dishes) at the down-wind border of the field.

To monitor a potential dust drift during a 24h-period after sowing ten new Petri-dishes were placed in pairs at the approximate middle of each field side at a distance of 1 m to the field borders. Weather conditions were presented.

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

Nikolakis, A., Schoening, R. 2008
Drift deposition pattern of seed treatment particles abraded from Poncho® Beta Plus treated sugar beet pills and emitted by a typical mechanical sowing machine in Germany with commercially treated sugar beet pills; treated with Poncho® Beta Plus, which contains the neonicotinoid active substances clothianidin and imidacloprid (analysed neonicotinoid seed loading: 0.589 mg clothianidin a.s./pill, 0.325 mg imidacloprid a.s./pill). The actual machine tested was a Kverneland Accord Monopill SE, a 12-row mechanical precision sugar beet planter (12 hoppers). The size of each drilling plot was about 1.0 ha with an orientation of the sampling devices 180° ± 30° to the prevailing wind direction. An average wind speed of 2 - 5 m/s and a deviation of wind direction of maximum ± 30° to the perpendicular wind direction (i.e., 180° to the sampling devices) were the target conditions during drilling.
All clothianidin-containing dust and abrasion particles which deposited at 1, 3, 5, 10, 20, 30 and 50 metres distance from the drilling area during sugar beet sowing ("primary drift") were sampled in polystyrene Petri-dishes (Ø 13.7 cm, 147.41 cm²), filled with an acetonitrile-water mixture (2/8, v/v).
For each sampling distance, three arrays of 10 Petri-dishes each were installed with a distance of 1 metre between the dishes and 50 m between the arrays.
Passive dust-drift collectors were installed at 1 m, 2 m, 3 m, 4 m and 5 m above the soil surface. The dust collectors were made of a polypropylene fabric mesh, built up of filaments with a 0.80 × 0.18 mm cross-section. This type of collector has a slightly oval shape with a length of ≈ 85 mm and a diameter of ≈ 65 mm; at its poles, the diameter is ≈ 50 mm. The polypropylene fabric mesh collectors were pinned on each end of horizontal metal rods, which in turn were mounted at the respective height on a vertical tripod-pylon (height ≈ 6 m), giving in total 10 collectors per pylon (2 at each height). In all arrays, a pylon was installed at 5 and 30 m distance from the drilling area, respectively, resulting in 6 collectors per height per distance.
Weather conditions were presented.

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

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

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.

Hendrikx, Chauzat, Debin, Neuman, Fries, Ritter, Borwn, Mutinelli, Le Conte, Gregorc 2009. Scientific report submitted to EFSA. Bee morlitaty and bee surveillance in Europe. CFP/EFSA/AMU/2008/02. Accepted for publication 03 December 2009.

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. Charscteristics 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.

Van der Zee (2010). Colony losses in the Netherlands. Journal of Apicultural Research 49(1): 121-123
Van der Zee & Pisa (2011). Monitor Bijensterfte Nederland 2009-2010. NBC rapporten 2011 nr 1.
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. Allgemeine 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.

Bijlage III Aangepaste WGGA 's

Wijzigingen zijn cursief weergegeven

Bijlage III-1 Actara (12687)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel als:

I. Gewasbehandeling

a. in de teelt van consumptie-, zetmeel- en pootaardappelen, met dien verstande dat toepassing alleen is toegestaan *na de bloei*
b. in de bedekte teelt van bloembol-, knol- en bolbloemgewassen
c. in de onbedekte teelt van bloemisterijgewassen, met dien verstande dat toepassing alleen is toegestaan *na de bloei of op gewassen die op het veld niet tot bloei komen*
d. in de bedekte teelt van bloemisterijgewassen
e. in de onbedekte teelt van boomkwekerijgewassen en vaste planten, met dien verstande dat toepassing alleen is toegestaan *na de bloei of op gewassen die op het veld niet tot bloei komen*
f. in de bedekte teelt van boomkwekerijgewassen en vaste planten

II. Grondbehandeling

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

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

In aardappels (gewasbehandeling):
- *spuitboomverlaging (30 cm boven de top van het gewas) in combinatie met driftarme spuitdoppen (dopafstand 25 cm) en een kantdop; of*
- *conventionele spuitmachine met een driftarme spuitdop en een kantdop in combinatie met luchtondersteuning.*

In bloemisterijgewassen, boomkwekerijgewassen en vaste planten (tegen luis), neerwaartse bespuiting:
- *spuitboomverlaging (30 cm boven de top van het gewas) in combinatie met driftarme spuitdoppen (dopafstand 25 cm) en een kantdop; of*
- *conventionele spuitmachine met een driftarme spuitdop en een kantdop in combinatie met luchtondersteuning.*

In boomkwekerijgewassen (laanbomen) (tegen luis), opwaartse bespuiting:
Het middel in de onbedekte teelt van hoge boomkwekerijgewassen niet toepassen in de buitenste 5 meter van het gewas; daarnaast dienen op een strook van 5 meter vanaf het midden van de laatste bomenrij geen bloeiende planten aanwezig te zijn.

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

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 is wel toegestaan op bloeiende planten in de kas mits er geen bijen of hommels in de kas actief naar voedsel zoeken. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn. Verwijder onkruid voordat het bloeit. Voorkom dat bijen en andere bestuivende insecten de kas binnenkomen door bijvoorbeeld alle openingen met insectengaas af te sluiten.

Om het grondwater te beschermen is toepassen van Actara in bedekte grondgebonden teelten in grondwaterbeschermingsgebieden niet toegestaan.

Dit middel is schadelijk voor niet-doelwit arthropoden. Vermijd onnodige blootstelling.

Dit middel is uitsluitend bestemd voor professioneel gebruik.

Veiligheidstermijn
De termijn tussen de laatste toepassing en de oogst mag niet korter zijn dan:
7 dagen voor aardappelen

B.
GEBRUIKSAANWIJZING

Algemeen
Actara is een insectenbestrijdingsmiddel met een werking tegen bladluizen, Coloradokever en witte vlieg. Het middel dient door middel van een gewas- of grondbehandeling te worden toegepast. Actara heeft een snelle aanvangswerking en een contact- en maagwerking. Daarnaast heeft het een systemische werking.

Aanvullende informatie over bijen en andere nuttige insecten
Bijen kunnen actief vliegen op niet-bloeiende gewassen, bijvoorbeeld om honingdauw te verzamelen die door luizen is afgescheiden. Pas dit product niet toe als honingdauw aanwezig is in het gewas. Vermijd drift naar bloeiende onkruiden en gewassen in de omgeving van het behandelde gewas.

Het middel heeft een effect op niet-doelwit arthropoden, waaronder natuurlijke vijanden. Bij geïntegreerde teelten dient hier rekening mee gehouden te worden. Vermijd daarom onnodige blootstelling.

Resistentiemanagement
Om de kans op resistentieontwikkeling te beperken, is het aan te bevelen om af te wisselen met insecticiden met een ander werkingsmechanisme, die voor de betreffende toepassing een toelating hebben.

Toepassingen
I. Gewasbehandeling

Teelt van consumptie-, zetmeel- en pootaardappelen, ter bestrijding van groene perzikluis (*Myzus persicae*), boterbloemluis (Aulacorthum solani), katoenluis (*Aphis gossypii*), aardappeltopluis (*Macrosiphum euphorbiae*), vuilboomluis (*Aphis frangulae*) en wegedoornluis (*Aphis nasturtii*).
Een gewasbehandeling uitvoeren zodra de eerste luizen worden waargenomen.

De behandeling zo nodig na 7 – 14 dagen herhalen.
Dosering: 0,08 kg/ha

Teelt van consumptie-, zetmeel- en pootaardappelen, ter bestrijding van Coloradokever (*Leptinotarsa decemlineata*).
Een gewasbehandeling uitvoeren zodra larven in het gewas worden waargenomen.
Dosering: 0,08 kg/ha

Bedekte teelt van bloembol-, bloemknol- en bolbloemgewassen, ter bestrijding van groene perzikluis (*Myzus persicae*), boterbloemluis (*Aulacorthum solani*), katoenluis (*Aphis gossypii*), aardappeltopluis (*Macrosiphum euphorbiae*).
Een gewasbehandeling uitvoeren zodra de eerste luizen worden waargenomen.
De behandeling zo nodig na 7 - 14 dagen herhalen.
Dosering: 0,01% (10 gr per 100 liter water).

Bedekte teelt van bloemisterijgewassen, boomkwekerijgewassen en vaste planten, ter bestrijding van groene perzikluis (*Myzus persicae*), boterbloemluis (*Aulacorthum solani*), katoenluis (*Aphis gossypii*), aardappeltopluis (*Macrosiphum euphorbiae*).
Een gewasbehandeling uitvoeren zodra de eerste luizen worden waargenomen.
De behandeling zo nodig na 7 - 14 dagen herhalen.
Dosering: 0,01% (10 gr per 100 liter water).

Bedekte teelt van bloemisterijgewassen, boomkwekerijgewassen en vaste planten, ter bestrijding van kaswittevlieg.
Een gewasbehandeling uitvoeren zodra een aantasting wordt waargenomen. De behandeling zo nodig na 7-14 dagen herhalen. Maximaal 2 bespuitingen per teelt uitvoeren. Maximaal 1000 liter spuitvloeistof per ha toepassen.
Dosering: 0,04% (40 gr per 100 liter water).

Onbedekte teelt van bloemisterijgewassen, boomkwekerijgewassen en vaste planten, ter bestrijding van groene perzikluis (*Myzus persicae*), boterbloemluis (*Aulacorthum solani*), katoenluis (*Aphis gossypii*), aardappeltopluis (*Macrosiphum euphorbiae*).
Een gewasbehandeling uitvoeren zodra de eerste luizen worden waargenomen.
De behandeling zo nodig na 7-14 dagen herhalen.
Dosering: 0,1 kg/ha

II. Grondbehandeling

Teelt van consumptie-, zetmeel- en pootaardappelen, ter bestrijding van groene perzikluis (*Myzus persicae*), boterbloemluis (*Aulacorthum solani*), katoenluis (*Aphis gossypii*), aardappeltopluis (*Macrosiphum euphorbiae*), vuilboomluis (*Aphis frangulae*) en wegedoornluis (*Aphis nasturtii*).
Dosering: 0,1 kg/ha, toegepast door middel van een grondbehandeling in de rij bij het poten. Het middel heeft een werkingsduur van 8-10 weken. Tijdens het groeiseizoen dient het gewas evenwel regelmatig te worden gecontroleerd op de aanwezigheid van bladluizen. Indien geconstateerd wordt dat zich bladluizen in het gewas vestigen, moeten passende maatregelen (bladluisbestrijding of loofvernietiging) genomen worden.

Opmerking
Het verdient aanbeveling door middel van een proefbespuiting vast te stellen of het gewas of variëteit het middel verdraagt, vooral bij gewassen met open bloemen.

Bijlage III-7 Cruiser 70 WS (12852)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als zaadbehandelingsmiddel ter voorkoming van schade door insecten voor de behandeling van zaden van sla (met uitzondering van veldsla) en andijvie.

Behandelde zaden niet voor menselijke of dierlijke consumptie bestemmen.

In verband met het risico voor bijen mogen binnen een periode van een jaar (365 d) gerekend vanaf zaai of uitplanten op het veld geen voor bijen aantrekkelijke gewassen worden gezaaid of geplant.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Algemeen
Het systemisch werkende middel Cruiser 70 WS bevat de werkzame stof thiamethoxam en behoort tot de chemische klasse van de neonicotinoiden.

Toepassingen

Sla (met uitzondering van veldsla) en andijvie, ter voorkoming van aantasting door bladluizen (o.a. *Nasonovia ribisnigri*, *Macrosiphum euphorbiae*, *Myzus persicae*) en wortelluis (*Pemphigus bursarius*).
Het middel heeft een werkingsduur van minimaal 6 weken vanaf het moment van zaaien.
In de laatste weken voor de oogst kan het nog noodzakelijk zijn te spuiten tegen luizen met een daarvoor toegelaten middel.
Dosering: 85 tot 115 gram middel per eenheid zaden (=100.000 zaden).
Voor botersla zal een dosering van 85 gram per eenheid zaden veelal afdoende zijn.
Voor slasoorten met een langere teeltduur (bijvoorbeeld ijsbergsla) en andijvie kan het raadzaam zijn een dosering van 115 gram per eenheid zaden aan te houden.

Toepassingsmethoden
Bij het toepassen van Cruiser 70 WS gebruik worden gemaakt van één van de onderstaande methoden:

a) Zaadcoating
b) Dummy-pil methode
   Uitsluitend een dummy-behandeling uitvoeren met zaad van hetzelfde gewas.
c) Phyto-drip methode (tijdens het zaaien)

Opmerking
Bij opslag van behandelde partijen bij hoge temperaturen kan de kiemkracht teruglopen. Dit geldt met name voor partijen, die al een zwakke kiemkracht hebben. Zorg daarom voor optimale bewaaromstandigheden van behandelde partijen.
genomen.

Bijlage III-3 Cruiser 350 FS (12913)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel voor behandeling van:

a. zaaizaden van snijmaïs en korrelmaïs
b. zaaizaden van landbouwerwten
c. zaaizaden van doperwten, peulen, asperge-erwten, kapucijners en suikererwten
d. zaaizaden bestemd voor exportdoeleinden, waarbij geldt dat het middel uitsluitend op zaaizaden mag worden aangebracht door bedrijven, die in het bezit zijn van een risico-inventarisatie en -evaluatie zoals omschreven in het Arbeidsomstandighedenbesluit en een vergunning in het kader van de Wet milieubeheer en de Wet verontreiniging oppervlaktewateren.

Om de vogels en zoogdieren te beschermen is de uitzaai van behandeld zaad alleen toegestaan met behulp van precisiezaai, waarbij het behandelde zaad direct met grond bedekt wordt. Bovengronds morsen van het behandelde zaad te allen tijde voorkomen.

Resten van behandeld zaad nooit verspreiden of vervoederen aan dieren

In verband met het risico voor bijen mogen na gebruik in landbouwerwten, doperwten, peulen, asperge-erwten, kapucijners en suikererwten binnen een periode van een jaar (365 d) gerekend vanaf zaai of uitplanten op het veld geen voor bijen aantrekkelijke gewassen worden gezaaid of geplant.

Dit middel is schadelijk voor niet-doelwit arthropoden. Vermijd onnodige blootstelling.

Het middel is uitsluitend bestemd voor professioneel gebruik.

Voor de toepassing in landbouwerwten, doperwten, peulen, asperge-erwten, kapucijners en suikererwten geldt:

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

Voor de toepassing in snijmaïs en korrelmaïs geldt:

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 maïszaad specifieke instructies gevolgd te worden die vermeld staan op de zakken behandeld maïszaad.

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

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.

B.
GEBRUIKSAANWIJZING

Algemeen
De behandeling dient met daarvoor geschikte apparatuur uitgevoerd te worden.
Een goede en regelmatige verdeling over het zaad is noodzakelijk voor een goede werking.

Voor de toepassing op zaaizaad bestemd voor export is geen werkzaamheids- en fytotoxiciteitsonderzoek uitgevoerd.

Toepassingen

Snijmaïs en korrelmaïs, ter bestrijding van ritnaalden (Agriotes soorten) en fritvlieg (Oscinella frit)
Het middel dient met daartoe geëigende apparatuur op het zaad te worden gebracht.
Dosering: 90 ml per eenheid zaden (=50.000 zaden).

Landbouwerwten, ter bestrijding van bladrandkever (Sitona lineatus) en erwtebladluis (Acyrthosiphon pisum). Bij hoge infectiedruk of late aantasting kan het noodzakelijk zijn een aanvullende bespuiting tegen luizen uit te voeren met een daarvoor toegelaten middel.
Dosering: 150 ml product per 100 kg zaad

Doperwten, peulen, asperge-erwten, kapucijners en suikererwten, ter bestrijding van bladrandkever (Sitona lineatus) en erwtebladluis (Acyrthosiphon pisum). Bij hoge infectiedruk of late aantasting kan het noodzakelijk zijn een aanvullende bespuiting tegen luizen uit te voeren met een daarvoor toegelaten middel.
Dosering: 150 ml product per 100 kg zaad

Zaaizaden bestemd voor exportdoeleinden
Te behandelen gewassen, toepassingen en doseringen zijn afhankelijk van het land van bestemming; de voorschriften van het betreffende land dienen in acht te worden genomen.

Bijlage III-4 Mundial (12802)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik voor de behandeling van zaden van bloemkool, boerenkool, broccoli, rodekool, savooienkool, spitskool, spruitkool en witte kool.

Het middel is uitsluitend bestemd voor professioneel gebruik.

De toepasser dient de afnemer van zaden en/of planten er schriftelijk van op de hoogte te stellen dat bladluizen zodanig bestreden moeten worden dat er geen honingdauw wordt gevormd waar bijen op af kunnen komen.

B.
GEBRUIKSAANWIJZING

Algemeen

Mundial is een vloeibaar middel voor de behandeling van zaden ter voorkoming van schade door insecten. Het middel dient te worden toegepast met de daarvoor geëigende zaadbehandelingsmachines (coatingsprocédé), of dient tijdens het oppotten op de zaden te worden gedruppeld met behulp van Fytodripapparatuur. Behandeling van overjarig zaad of partijen met slechte kiemkracht wordt ontraden.

Toepassingen

Zaden van bloemkool, boerenkool, broccoli, rodekool, savooienkool, spitskool, spruitkool en witte kool, ter bestrijding van de larven van de koolvlieg (*Delia brassicae*)
Met de behandeling wordt plantuitval, veroorzaakt door vreterij van de made van de koolvlieg tegengegaan.
Dosering: 25 ml Mundial per 100.000 zaden

Bijlage III-5 Mundial (12977)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel met maximaal 1 toepassing per teelt of teeltseizoen in de teelt van Chinese kool, Oosterse bladkolen en koolrabi:

- voor de behandeling van zaden toegepast met daartoe geëigende zaadbehandelingsmachine (coatingsprocédé) tot 30 september 2011 of;
- tijdens het zaaien van de zaden toegepast door middel van de phytodrip-techniek van 1 april 2011 tot en met 30 juni 2011

Om het grondwater te beschermen is uitplanten in grondwaterbeschermingsgebieden uit met Mundial behandeld zaad niet toegestaan. De toepasser dient de afnemer van zaden en/of planten er *schriftelijk* van op de hoogte te stellen dat planten uit behandeld zaad niet in grondwaterbeschermingsgebieden mogen worden uitgeplant *en dat bladluizen zodanig bestreden moeten worden dat er geen honingdauw wordt gevormd waar bijen op af kunnen komen.*

Schadelijk bij opname door de mond.
Vergiftig: gevaar voor ernstige schade aan de gezondheid bij langdurige blootstelling bij opname door de mond.
Zeer vergiftig voor in het water levende organismen; kan in het aquatisch milieu op lange termijn schadelijke effecten veroorzaken.
Niet roken tijdens gebruik.

Draag geschikte handschoenen.

Bij een ongeval of indien men zich onwel voelt onmiddellijk een arts raadplegen (indien mogelijk hem dit etiket tonen).

Deze stof en de verpakking als gevaarlijk afval afvoeren.

Voorkom lozing in het milieu. Vraag om speciale instructies / veiligheidsgegevenskaart.

Dit middel is uitsluitend bestemd voor professioneel gebruik.

Dit middel is – zij het voor andere toepassingen – tevens toegelaten onder het toelatingsnummer 12802 N.

B.
GEBRUIKSAANWIJZING

Algemeen
Mundial is een vloeibaar middel voor de behandeling van zaden ter voorkoming van schade door insecten. Het middel dient te worden toegepast met de daarvoor geëigende zaadbehandelingsmachines (coatingprocédé), of dient tijdens het zaaien van de zaden te worden gedruppeld met behulp van Fytodripapparatuur. Behandeling van overjarig zaad of partijen met slechte kiemkracht wordt ontraden.

Toepassingen
Zaden van Chinese kool, Oosterse bladkolen en koolrabi, ter bestrijding van de larven van de koolvlieg (*Delia brassicae*).
Met de behandeling wordt plantuitval, veroorzaakt door vreterij van de made van de koolvlieg tegengegaan.

Dosering: 25 ml Mundial per 100.000 zaden

Bijlage III-6 Admire (11483)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel:

a) 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;
b) in de bedekte teelt van aubergine, augurk, courgette, komkommer, tomaat, Spaanse peper en paprika, met dien verstande dat het middel slechts centraal met de voedingsoplossing c.q. door middel van directe kraanvak-injectie mag worden meegegeven, met dien verstande dat het middel op de dag van de oogst niet vóór de oogst mag worden toegepast. Deze toepassingen zijn enkel toegestaan in kassen met een volledig gesloten recirculatiesysteem;
c) bij de opkweek van plantmateriaal (bedekte teelt) van aubergine, augurk, courgette, komkommer, tomaat, Spaanse peper en paprika door middel van een gewasbehandeling;
d) in de bedekte teelt van bloemisterijgewassen door middel van een gewasbehandeling en een druppelbehandeling. De druppelbehandelingen zijn enkel toegestaan in kassen met een volledig gesloten recirculatiesysteem;
e) In de onbedekte teelt van bloemisterijgewassen

- door middel van een gewasbehandeling *vóór de bloemknoppen zichtbaar zijn, met dien verstande dat er binnen 6 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden*;
- door middel van een gewasbehandeling na de bloei, *met dien verstande dat er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;*

f) in de onbedekte teelt van en ten behoeve van de teelt van bloembol-, knol-, knolbloem- en bolbloemgewassen

- *door middel van een éénmalige gewasbehandeling vóór de bloemknoppen zichtbaar zijn;*
- door middel van een gewasbehandeling *na de bloei of na het koppen, met dien verstande dat toepassing alleen is toegestaan indien er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;*

g) in de bedekte teelt van en ten behoeve van de teelt van bloembol-, knol-, knolbloem- en bolbloemgewassen door middel van een gewasbehandeling;
h) in de onbedekte teelt van en ten behoeve van de onbedekte teelt van bloembol-, knol-, knolbloem- en bolbloemgewassen met uitzondering van grofbollige narcissen 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, *en er binnen 10 maanden na planten geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden*;
i) in de bedekte teelt van en ten behoeve van de bedekte teelt van bloembol-, knol-, knolbloem- en bolbloemgewassen met uitzondering van grofbollige narcissen en lelie

door middel van een dompelbehandeling;

j) 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 is toegestaan vóór de bloemknoppen zichtbaar zijn en indien er binnen 6 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;*
- door middel van een gewasbehandeling, *met dien verstande dat in gewassen die in bloei kunnen komen toepassing is toegestaan na de bloei en indien er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;*

k) in de bedekte teelt van boomkwekerijgewassen en vaste planten door middel van een gewasbehandeling.

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. *Na een spuittoepassing percelen nog minimaal twee weken vrijhouden van bloeiende onkruiden. 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.

Dit middel is schadelijk voor niet-doelwitarthropoden. Vermijd onnodige blootstelling.

Om in het water levende organismen *en bijen* te beschermen is toepassing in de teelt van appel en peer als insecticide 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.*

Dit middel is uitsluitend bestemd voor beroepsmatig gebruik.

Veiligheidstermijn

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

B.
GEBRUIKSAANWIJZING

Attentie
Bijen kunnen actief vliegen op niet-bloeiende gewassen, bijvoorbeeld om honingdauw te verzamelen die door luizen is afgescheiden.

Algemeen
ADMIRE is een systemisch middel, het middel wordt bij de druppelbehandeling door de wortels opgenomen en bij de gewasbehandeling door de bladeren en vervolgens in de plant verspreid. De werkingssnelheid wordt mede bepaald door de activiteit van het gewas. Laat in geval van substraatteelt, voordat u het middel toepast, het gewas de matten wat droogtrekken. Dit bevordert de opname. Het middel dient met de voedingsoplossing te worden meegedruppeld.
Het verdient aanbeveling bij gebruik in siergewassen eerst door een proefbespuiting vast te stellen of de in aanmerking komende variëteiten het middel goed verdragen.

Toepassingen

Appel en peer, ter bestrijding van de groene appelwants (*Lygus pabulinus*).
Bij aanwezigheid van larven van de groene appelwants, indien noodzakelijk, een bestrijding uitvoeren.
Dosering: 0,01%

Appel, ter bestrijding van de roze appelluis (*Dysaphis plantaginea*).
Bij aanwezigheid van ingekrulde luizen, indien noodzakelijk, een bestrijding uitvoeren. Indien in de zomer blijkt dat roze appelluis onvoldoende is bestreden, kan gedurende de zomer ook een bestrijding worden uitgevoerd. Ingekrulde luizen worden goed bestreden.
Dosering: 0,01%

Peer, ter bestrijding van de roze perenluis (*Dysaphis pyri*).
Bij aanwezigheid van de roze perenluis, indien noodzakelijk, een bestrijding uitvoeren.
Dosering: 0,01%

Peer, ter bestrijding van de vouwgalluis (*Anuraphis farfarae*).
Bij aanwezigheid van de vouwgalluis, indien noodzakelijk, een bestrijding uitvoeren.
Dosering: 0,01%

Appel, ter bestrijding van de groene appeltakluis (*Aphis pomi*).
Bij aanwezigheid van groene appeltakluis, indien noodzakelijk, een bestrijding uitvoeren.
Dosering: 0,01%

Appel, ter bestrijding van de fluitekruidluis (*Dysaphis anthrisci*).
Bij aanwezigheid van de fluitekruidluis, indien noodzakelijk, een bestrijding uitvoeren.
Dosering: 0,01%

Appel, ter bestrijding van de bloedvlekkenluis (*Dysaphis devecta*).
Bij aanwezigheid van bloedvlekkenluis, indien noodzakelijk, een bestrijding uitvoeren.
Dosering: 0,01%

Appel, ter bestrijding van de appel-grasluis (*Rhopalosiphum insertum*).
Bij aanwezigheid van appel-grasluis, indien noodzakelijk, een bestrijding uitvoeren.
Dosering: 0,01%

Appel, ter bestrijding van de appelzaagwesp.
Bij het vinden van de prikken van de appelzaagwesp gedurende de bloei van appel, direct na de bloei een bespuiting uitvoeren.
Dosering: 0,01%

Peer, ter bestrijding van de zwarte perenluis (*Melanaphis pyaria*).
Bij aanwezigheid van zwarte perenluis, indien noodzakelijk, een bestrijding uitvoeren.
Dosering: 0,01%

Peer, ter bestrijding van de zwarte bonenluis (*Aphis fabae*).
Op het moment van aanwezigheid van de kolonies van de zwarte bonenluis, indien noodzakelijk, een bestrijding uitvoeren.
Dosering: 0,01%

Peer, ter bestrijding van de perenzaagwesp.
Bij het vinden van de prikken van de perenzaagwesp gedurende de bloei van peer, direct na de bloei een bespuiting uitvoeren.
Dosering: 0,01%

Het middel toepassen met ruim water. Toevoeging van uitvloeier kan de effectiviteit verbeteren.

In de bedekte teelt van aubergine, augurk, courgette, komkommer, tomaat, Spaanse peper en paprika op kunstmatig substraat, ter bestrijding van boterbloemluis (*Aulacorthum solanii*), groene en rode perzikluis (*Myzus persicae*), katoenluis (*Aphis gossypii*) en zwarte bonenluis (*Aphis fabae*).
Zodra een aantasting wordt waargenomen een behandeling uitvoeren.
Dosering: 3,5 gram per 1000 planten

In de bedekte teelt van aubergine, augurk, courgette, komkommer, tomaat, Spaanse peper en paprika op kunstmatig substraat, ter bestrijding van larven van kaswittevlieg (*Trialeurodes vaporariorum*).

Zodra een aantasting wordt waargenomen een behandeling uitvoeren.
Dosering: 14 gram middel per 1000 planten

Het verdient aanbeveling middels een proefbehandeling vast te stellen of het gewas de behandeling verdraagt.

Plantmateriaal van aubergine, augurk, courgette, komkommer, tomaat, Spaanse peper en paprika, ter bestrijding van boterbloemluis (*Aulacorthum solanii*), groene en rode perzikluis (*Myzus persicae*), katoenluis (*Aphis gossypii*) en zwarte bonenluis (*Aphis fabae*).
Zodra een aantasting wordt waargenomen een behandeling uitvoeren.
Dosering: 100 gram per ha

In de bedekte teelt van bloemisterijgewassen op kunstmatig substraat, ter bestrijding van boterbloemluis (*Aulacorthum solanii*), groene en rode perzikluis (*Myzus persicae*), katoenluis (*Aphis gossypii*) en zwarte bonenluis (*Aphis fabae*).
Zodra een aantasting wordt waargenomen een behandeling uitvoeren.
Dosering: 3,5 gram per 1000 planten

In de bedekte teelt van bloemisterijgewassen op kunstmatig substraat, ter bestrijding van bladluizen: boterbloemluis, groene perzikluis (incl. rode variant), katoenluis en zwarte bonenluis.
Zodra een aantasting wordt waargenomen, een behandeling uitvoeren. Laat voordat het middel wordt toegepast, het gewas de matten wat droogtrekken. Dit bevordert de opname. Het middel dient met de voedingsoplossing te worden meegedruppeld.
Dosering: 3,5 gram per 1000 planten

In de bedekte teelt van bloemisterijgewassen op kunstmatig substraat, ter bestrijding van kaswittevlieg.
Zodra een aantasting wordt waargenomen, een behandeling uitvoeren. Laat voordat het middel wordt toegepast, het gewas de matten wat droogtrekken. Dit bevordert de opname. Het middel dient met de voedingsoplossing te worden meegedruppeld.
Dosering: 14 gram per 1000 planten

In de bedekte teelt van bloemisterijgewassen in de grond, ter bestrijding van boterbloemluis (*Aulacorthum solanii*), groene en rode perzikluis (*Myzus persicae*), katoenluis (*Aphis gossypii*) en zwarte bonenluis (*Aphis fabae*).
Zodra aantasting wordt waargenomen een gewasbehandeling uitvoeren.
Dosering: 0,01% (10 gram per 100 liter water)

In de bedekte teelt van bloemisterijgewassen, ter bestrijding van bladluizen: boterbloemluis, groene perzikluis (incl. de rode variant), katoenluis, zwarte bonenluis en ter bestrijding van kaswittevlieg.
Zodra een aantasting wordt waargenomen het middel door een gewasbehandeling toepassen.
Zonodig de bespuiting met een interval van 7-10 dagen herhalen. Bij kaswittevlieg kunnen meer dan twee bespuitingen noodzakelijk zijn.
Dosering: 0,01% (10 gram per 100 liter water)

Overjarige bloemisterijgewassen in de vollegrond, ter bestrijding van bladluizen: boterbloemluis, groene perzikluis (incl. de rode variant), zwarte bonenluis en ter bestrijding van kaswittevlieg.
Zodra een aantasting wordt waargenomen het middel door een gewasbehandeling toepassen.

Zonodig de bespuiting met een interval van 7-10 dagen herhalen.
Dosering: 0,01% (10 gram per 100 liter water)

Bloembol- en bolbloemgewassen (gewasbehandeling), ter bestrijding van groene perzikluis, katoenluis en zwarte bonenluis.
Zodra aantasting wordt waargenomen een gewasbehandeling uitvoeren. De behandeling indien nodig herhalen.
Dosering: 100 gram per ha

Gladiolen (gewasbehandeling), ter bestrijding van gladiolentrips.
Bij het verschijnen van het derde blad starten met de bestrijding. De behandeling daarna nog twee keer herhalen met intervallen van 7-10 dagen.
Dosering: 100 gram per ha

Dompelbehandeling van bloembollen en bolbloemen
In deze gebruiksaanwijzing is voor de toepassingen voor bloembollenplantgoed steeds uitgegaan van een standaardontsmettingswijze waarbij gestreefd dient te worden naar minimale restanten door opgebruik.
Voor andere toepassingstechnieken (kort dompelen, schuimen e.d.) zullen afgeleide doseringen nodig zijn. Raadpleeg hiervoor de betreffende voorlichtingspublicaties waarin tevens is aangegeven hoe, de restanten kunnen worden verwerkt.

Bloembol- en bolbloemgewassen (dompelbehandeling), ter bestrijding van groene perzikluis, katoenluis en zwarte bonenluis.
Het plantgoed vóór het planten gedurende 15 minuten dompelen. Het plantgoed dient op het moment van behandeling in rust te zijn. Bij gewassen die in het najaar geplant worden of gewassen die op het dompeltijdstip geen wortels hebben, kan tegen het einde van de teelt een aanvullende bestrijding met een insecticide noodzakelijk zijn. Dompelbehandeling indien mogelijk kort voor het planten uitvoeren. Menging met fungiciden is mogelijk.
Dosering: 0,04% (40 gram per 100 liter water) en maximaal 750 liter dompelvloeistof per ha toepassen. Bij gewassen die in het najaar geplant worden en bijgewassen met weinig wortels op het dompeltijdstip, de dosering verhogen tot 0,05% (50 gram per 100 liter dompelvloeistof) en maximaal 600 liter dompelvloeistof per ha toepassen.

Gladiolen (dompelbehandeling), ter bestrijding van gladiolentrips tijdens de bewaring van de knollen.
Na het pellen en voor de bewaring de knollen dompelen. Menging met fungiciden is mogelijk.
Dosering: 0,04% (40 gram per 100 liter dompelvloeistof) en maximaal 750 liter dompelvloeistof per ha toepassen

In de bedekte teelt van boomkwekerijgewassen en vaste planten, ter bestrijding van bladluizen: boterbloemluis, groene perzikluis (incl. rode variant), katoenluis, zwarte bonenluis, gewone rozeluis, sjalotteluis en groene kortstaartluis.
Zodra een aantasting wordt waargenomen het middel door een gewasbehandeling toepassen.
Zonodig de bespuiting met een interval van 7-10 dagen herhalen.
Dosering: 0,01% (10 gram per 100 liter water)

Boomkwekerijgewassen en vaste planten in de vollegrond, ter bestrijding van bladluizen: boterbloemluis, groene perzikluis (incl. rode variant), zwarte bonenluis, gewone rozeluis, sjalotteluis, groene kortstaart- luis, aardappeltopluis, zwarte kerseluis, groene appeltakluis, groene sparreluis, vogelkersluis en beukebladluis.
Zodra een aantasting wordt waargenomen het middel door een gewasbehandeling toepassen.

Zonodig de bespuiting met een interval van 7-10 dagen herhalen.
Dosering: 0,01% (10 gram per 100 liter water)

Boomkwekerijgewassen en vaste planten in de vollegrond, ter bestrijding van de buxusbladvlo.
Toepassen zodra de larven uit de wintereieren komen.
Dosering: 0,01% (10 gram per 100 liter water)

Bijlage III-7 Amigo Flex (11662)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

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

Om vogels en zoogdieren te beschermen moet het product volledig in de bodem worden ondergewerkt; zorg er voor dat het product ook aan de kop van de akker is ondergewerkt.

Gevaarlijk voor bijen en hommels, om de bijen te beschermen mag u dit product niet gebruiken op in bloei staande gewassen. Gebruik dit product niet op plaatsen waar bijen actief naar voedsel zoeken, gebruik dit product niet in de buurt van in bloei staand onkruid. Verwijder onkruid voordat het bloeit.

Dit middel is uitsluitend bestemd voor beroepsmatig gebruik.

B.
GEBRUIKSAANWIJZING

Algemeen

Amigo is een systemisch werkend insecticide dat vanuit de grond door de wortels van de aardappelplanten wordt opgenomen en zich daarna in de bovengrondse delen van de plant verspreidt.

Er zijn geen beperkingen ten aanzien van het gebruik van de opbrengst voor consumptie-, zetmeelverwerking-, of veevoerdoeleinden.

Toepassingen

Pootaardappelen, ter bestrijding van de groene perzikluis (Myzus persicae) en de vuilboomluis (Aphis nasturtii), ter voorkoming van overdracht van het bladrolvirus.
Andere voorkomende bladluizen worden ook bestreden.
Dosering: 0,5 liter per hectare, toegepast door middel van een grondbehandeling in de rij bij het poten.

Het middel kan gemengd met Monceren-vloeibaar worden toegepast.
Het middel heeft een werkingsduur van 8-10 weken. Tijdens het groeiseizoen dient het gewas evenwel regelmatig te worden gecontroleerd op de aanwezigheid van bladluizen. Indien geconstateerd wordt dat zich bladluizen in het gewas vestigen, moeten passende maatregelen (bladluisbestrijding of loofvernietiging) genomen worden.

Bijlage III-6 Provado Garden (12115)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel:

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

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

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

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

Het middel is uitsluitend bestemd voor niet-professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Algemeen

Provado Garden werkt tegen de meeste op sierplanten in huis en tuin voorkomende zuigende insecten zoals bladluis, wolluis, buxusbladvlo en witte vlieg. Het middel is op appel en peer in te zetten tegen diverse luizen en tegen de appel- en perenzaagwesp. Voor deze toepassingen geldt dat het middel moet worden aangebracht door middel van een gewasbehandeling. Het gazon kan worden behandeld door middel van aangieten ter bestrijding van zowel engerlingen (o.a. larve van de meikever) als emelten (larven van de langpootmug). Door preventief aanbrengen van het middel op het gazon wordt vergeling of zelfs het plaatselijk afsterven van het gazon voorkomen.
Maai het gazon de dag voor de toepassing of vlak voor de toepassing. Breng het middel aan op een windstille, droge dag als de aarde een beetje vochtig is. Pas het middel niet toe bij helder, zonnig weer. Pas het middel tevens niet toe op een drijfnat of juist zeer droog gazon, aangezien de effectiviteit van het middel onder deze omstandigheden vermindert. Het meest geschikte moment om het middel aan te brengen is aan het begin van de avond. Nadat het middel is aangebracht, dient het gazon onmiddellijk te worden beregend (5 tot 15 liter water per m^2. Dit beregenen is nodig om het middel door de gras/bodem laag heen te transporteren. Voorkom dat meer dan 15 l/m^2 wordt aangebracht.

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

Toepassingen

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

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

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

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

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

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

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

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

Gewasbehandeling

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

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

Aanmaken van de oplossing:

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

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

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

Bijsluiter: Ontwikkelstadia bij appel en peer.

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

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

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

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

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

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

Bijlage III-9 Gaucho Tuinbouw (12341)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel voor de behandeling van zaden, (zaadcoating of dummy-pil techniek en voor toepassing a en b ook de phytodriptechniek) voor de

a. opkweek ten behoeve van de onbedekte teelt van sla (met uitzondering van veldsla), Radicchio rosso, groenlof en andijvie, met dien verstande dat maximaal 100.000 planten per hectare worden uitgeplant indien de hoge dosering wordt toegepast *en dat binnen een periode van 10 maanden gerekend vanaf uitplanten op het veld geen voor bijen aantrekkelijke gewassen worden gezaaid of geplant;*
b. opkweek ten behoeve van de onbedekte teelt van sluitkool, spruitkool, bloemkool, broccoli, Chinese kool, Oosterse bladkolen en boerenkool, met dien verstande dat maximaal 60.000 planten per hectare worden uitgeplant;
c. onbedekte teelt van zaaiprei ter voorkoming van aantasting door insecten met dien verstande dat in de teelt van zaaiprei de zaaidichtheid niet hoger is dan 270.000 zaden per hectare;
d. niet-grondgebonden, bedekte opkweek van prei;
e. behandeling van zaaizaden bestemd voor exportdoeleinden, waarbij geldt dat het middel uitsluitend op zaaizaden mag worden aangebracht door bedrijven, die in het bezit zijn van een risico-inventarisatie en –evaluatie zoals omschreven in het Arbeidsomstandighedenbesluit en een vergunning in het kader van de Wet milieubeheer en de Wet verontreiniging oppervlaktewateren.

mits bij de dummy-pil techniek bij de zaai het dummy zaad van hetzelfde gewas is als van het levende zaad.

Dit middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Algemeen
GAUCHO TUINBOUW is een systemisch insecticide, het middel wordt via de wortels opgenomen en door de gehele plant verspreid.

Voor de toepassing op zaaizaad bestemd voor export is geen werkzaamheids- en fytotoxiciteitsonderzoek uitgevoerd.

Toepassingen
Sla (met uitzondering van veldsla), Radicchio rosso, groenlof en andijvie ter voorkoming van aantasting door bladluizen (*Aphidae*).
Bij het gebruik van de hoge dosering in met name ijsbergsla en andijvie wordt de duurwerking verlengd met enkele weken. In de laatste weken voor de oogst dient mogelijk nog tegen luizen te worden gespoten met een daarvoor toegelaten middel.
Dosering: 114 of 171 gram middel per 100.000 zaden.

Sluitkool (rode kool, witte kool, savooienkool, spitskool), spruitkool, bloemkool, broccoli, Chinese kool, Oosterse bladkolen (o.a. amsoi, paksoi) en boerenkool, ter voorkoming van tabakstrips (*Thrips tabaci*).
Het middel heeft ongeveer een werking van 3,5 maanden, gerekend vanaf het moment van zaaien. In de laatste weken voor de oogst kan het nodig zijn nog 1-2 keer tegen trips te spuiten met een daarvoor toegelaten middel.
Dosering: 215 gram middel per 100.000 zaden

Prei: ter voorkoming van tabakstrips (*Thrips tabaci*).

- In de niet-grondgebonden , bedekte opkweek van prei. Later in het seizoen dient door middel van een gewasbehandeling trips bestreden te worden.
- In de onbedekte teelt van zaaiprei, wordt gedurende de eerste maanden na het zaaien de trips bestreden.

Dosering: 80 gram middel per 250.000 zaden

Zaaizaden bestemd voor exportdoeleinden
Te behandelen gewassen, toepassingen en doseringen zijn afhankelijk van het land van bestemming; de voorschriften van het betreffende land dienen in acht te worden genomen.

Toepassingsmethoden:

Bij het toepassen van GAUCHO TUINBOUW in sla (met uitzondering van veldsla), Radicchio rosso, groenlof en andijvie, sluitkool (rode kool, witte kool, savooienkool, spitskool), spruitkool, bloemkool, broccoli, Chinese kool, Oosterse bladkolen (o.a. amsoi, paksoi), boerenkool en de opkweek van prei kan gebruik gemaakt worden van onderstaande methoden:

1. zaadcoating
2. dummy-pil techniek
3. phytodriptechniek (niet relevant voor de opkweek van prei)

Waarschuwing:
GAUCHO TUINBOUW heeft een invloed op kiemkracht van het zaad. Behandel daarom geen partijen met een zwakke kiemkracht. Combinatie met andere gewasbeschermingsmiddelen kan dit effect versterken. Hierdoor kan opkomstvertraging en vertraging in de groei van kiemplanten optreden in de opkweek fase. Deze waarschuwing geldt niet voor de dummy-pil techniek.

Bijlage III-10 Admire O-Teq (12942)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel:

a) 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;

b) in de teelt onder glas van aubergine, augurk, courgette, komkommer, tomaat, Spaanse peper en paprika, met dien verstande dat het middel slechts centraal met de voedingsoplossing c.q. door middel van directe kraanvak-injectie mag worden meegegeven, met dien verstande dat het middel op de dag van de oogst niet vóór de oogst mag worden toegepast; deze toepassingen zijn enkel toegestaan in kassen met een volledig gesloten recirculatiesysteem;

c) in de bedekte teelt van bloemisterijgewassen door middel van een druppelbehandeling. Deze toepassingen zijn enkel toegestaan in kassen met een volledig gesloten recirculatiesysteem;

d) in de bedekte teelt van gerbera en chrysant door middel van een gewasbehandeling.

e) In de onbedekte teelt van bloemisterijgewassen

- door middel van een gewasbehandeling *vóór de bloemknoppen zichtbaar zijn, met dien verstande dat er binnen 6 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden*;

- door middel van een gewasbehandeling na de bloei, *met dien verstande dat er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden*;

f) in de onbedekte teelt van en ten behoeve van de onbedekte teelt van bloembol- en bloemknolgewassen door middel van een dompelbehandeling, met dien verstande dat bloei moet worden voorkomen *en er binnen 10 maanden na planten geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden*;

g) in de onbedekte teelt van en ten behoeve van de teelt van bloembol en bloemknolgewassen

- door middel van een éénmalige gewasbehandeling *vóór de bloemknoppen zichtbaar zijn*;

- door middel van een gewasbehandeling *na de bloei of na het koppen met dien verstande dat toepassing alleen is toegestaan indien er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden*;

h) in de bedekte teelt van en ten behoeve van de teelt van bolbloem- en knolbloem gewassen door middel van een gewasbehandeling en een dompelbehandeling;

i) 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 is toegestaan vóór de bloemknoppen zichtbaar zijn en indien er binnen 6 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden*

- door middel van een gewasbehandeling, *met dien verstande dat in gewassen die in bloei kunnen komen toepassing is toegestaan na de bloei en indien er binnen 1 maand na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden;*

j) in de bedekte teelt van boomkwekerijgewassen en vaste planten door middel van een gewasbehandeling.

k) In de onbedekte teelt van hop door middel van een aanstrijkbehandeling, met dien verstande dat niet meer dan 360 gram middel per ha wordt toegediend.

l) In de pennenteelt van witlof door middel van een behandeling in de zaaivoor, *met dien verstande dat er binnen 2 maanden na toepassen geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden.*

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. *Na een spuittoepassing percelen nog minimaal twee weken vrijhouden van bloeiende onkruiden. 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.

Dit middel is schadelijk voor niet-doelwit arthropoden. Vermijd onnodige blootstelling

Om in het water levende organismen en *bijen* te beschermen is toepassing in de teelt van appel en peer als insecticide in 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; ventilator 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.*

Dit middel is uitsluitend bestemd voor beroepsmatig gebruik.

Veiligheidstermijn
De termijn tussen de laatste toepassing en de oogst mag niet korter zijn dan:
14 dagen voor appels en peren
35 dagen voor hop

B.
GEBRUIKSAANWIJZING

Attentie
Bijen kunnen actief vliegen op niet-bloeiende gewassen, bijvoorbeeld om honingdauw te verzamelen die door luizen is afgescheiden.

Algemeen
ADMIRE O-TEQ is een systemisch middel op basis van imidacloprid. Het middel wordt bij de druppelbehandeling door de wortels opgenomen en bij de gewasbehandeling door de bladeren en vervolgens in de plant verspreid. De werkingssnelheid wordt mede bepaald door de activiteit van het gewas. Laat in geval van substraatteelt, voordat u het middel toepast, het gewas de matten wat droogtrekken. Dit bevordert de opname. Het middel dient met de voedingsoplossing te worden meegedruppeld.
Het verdient aanbeveling bij gebruik in siergewassen eerst door een proefbespuiting vast te stellen of de in aanmerking komende variëteiten het middel goed verdragen.

Toepassingen

Appel en peer, ter bestrijding van de groene appelwants
Bij aanwezigheid van larven van de groene appelwants, indien noodzakelijk, een bestrijding uitvoeren.
Dosering: 0,02%

Appel, ter bestrijding van bladluizen, o.a. roze appelluis, appelgrasluis, groene appeltakluis, fluitenkruidluis, bloedvlekkenluis.
Bij aanwezigheid van de stammoeders van de roze appelluis of zodra aantasting van één van de overige bladluizen wordt waargenomen een bespuiting uitvoeren. Ingekrulde luizen worden goed bestreden.
Dosering: 0,02%

Appel, ter bestrijding van de appelzaagwesp.
Bij het vinden van de prikken van de appelzaagwesp gedurende de bloei van appel, direct na de bloei een bespuiting uitvoeren.
Dosering: 0,02%

Peer, ter bestrijding van bladluizen, o.a. roze pereluis, vouwgalluis, zwarte pereluis, zwarte boneluis
Zodra aantasting wordt waargenomen een bespuiting uitvoeren.
Dosering: 0,02%

Peer, ter bestrijding van de perezaagwesp.
Bij het vinden van de prikken van de perezaagwesp gedurende de bloei van peer, direct na de bloei een bespuiting uitvoeren.
Dosering: 0,02%

Het middel toepassen met ruim water. Toevoeging van uitvloeier kan de effectiviteit verbeteren.

Bedekte teelt van aubergine, augurk, courgette, komkommer, tomaat, Spaanse peper en paprika op kunstmatig substraat, ter bestrijding van boterbloemluis, groene en rode perzikluis, katoenluis en zwarte boneluis.
Zodra een aantasting wordt waargenomen een behandeling uitvoeren. Laat voordat het middel wordt toegepast, het gewas de matten wat droogtrekken. Dit bevordert de opname. Het middel dient met de voedingsoplossing te worden meegedruppeld.
Dosering: 7 ml per 1000 planten

Bedekte teelt van aubergine, augurk, courgette, komkommer, tomaat, Spaanse peper en paprika op kunstmatig substraat, ter bestrijding van larven van kaswittevlieg.
Zodra een aantasting wordt waargenomen een behandeling uitvoeren. Laat voordat het middel wordt toegepast, het gewas de matten wat droogtrekken. Dit bevordert de opname. Het middel dient met de voedingsoplossing te worden meegedruppeld
Dosering: 28 ml middel per 1000 planten

Het verdient aanbeveling middels een proefbehandeling vast te stellen of het gewas de behandeling verdraagt.

Bedekte teelt van bloemisterijgewassen op kunstmatig substraat, ter bestrijding van boterbloemluis, groene en rode perzikluis, katoenluis en zwarte boneluis.
Zodra een aantasting wordt waargenomen een behandeling uitvoeren. Laat voordat het middel wordt toegepast, het gewas de matten wat droogtrekken. Dit bevordert de opname. Het middel dient met de voedingsoplossing te worden meegedruppeld.
Dosering: 7 ml per 1000 planten

Bedekte teelt van bloemisterijgewassen op kunstmatig substraat, ter bestrijding van kaswittevlieg.

Zodra een aantasting wordt waargenomen, een behandeling uitvoeren. Laat voordat het middel wordt toegepast, het gewas de matten wat droogtrekken. Dit bevordert de opname. Het middel dient met de voedingsoplossing te worden meegedruppeld.
Dosering: 28 ml per 1000 planten

Bedekte teelt van gerbera en chrysant, ter bestrijding van bladluizen: boterbloemluis, groene en rode perzikluis, katoenluis en zwarte boneluis en ter bestrijding van kaswittevlieg.
Zodra aantasting wordt waargenomen het middel door een gewasbehandeling toepassen. Zonodig de bespuiting met een interval van 7-10 dagen herhalen.
Dosering: 0,02% (20 ml per 100 liter water)

Onbedekte teelt van bloemisterijgewassen, ter bestrijding van bladluizen: boterbloemluis, groene perzikluis (incl. de rode variant), katoenluis, zwarte boneluis en ter bestrijding van kaswittevlieg.
Zodra een aantasting wordt waargenomen het middel door een gewasbehandeling toepassen.
Zonodig de bespuiting met een interval van 7-10 dagen herhalen. Bij kaswittevlieg kunnen meer dan twee bespuitingen noodzakelijk zijn.
Dosering: 0,02% (20 ml per 100 liter water)

De teelt van bloembol-, bloemknol, knolbloem en bolbloemgewassen (gewasbehandeling), ter bestrijding van groene perzikluis, katoenluis en zwarte bonenluis.
Zodra aantasting wordt waargenomen een gewasbehandeling uitvoeren. De behandeling indien nodig herhalen.
Dosering: 200 ml per ha of 0,02% (20 ml per 100 liter water)

De teelt van gladiolen (gewasbehandeling), ter bestrijding van gladiolentrips.
Bij het verschijnen van het derde blad starten met de bestrijding. De behandeling daarna nog twee keer herhalen met intervallen van 7-10 dagen.
Dosering: 200 ml per ha of 0,02% (20 ml per 100 liter water)

Dompelbehandeling van bloembollen, bloemknollen, knolbloemen en bolbloemen
In deze gebruiksaanwijzing is voor de toepassingen voor bloembollenplantgoed steeds uitgegaan van een standaardontsmettingswijze waarbij gestreefd dient te worden naar minimale restanten door opgebruik. Voor de toegestane wijze van verwerken van restanten ontsmettingsvloeistof wordt verwezen naar de "Beschikking verwijdering dompelvloeistof bloembollen en -knollen".

Voor andere toepassingstechnieken (kort dompelen, schuimen e.d.) zullen afgeleide doseringen nodig zijn. Raadpleeg hiervoor de betreffende voorlichtingspublicaties waarin tevens is aangegeven hoe, overeenkomstig voornoemde Beschikking, de restanten kunnen worden verwerkt.

Bloembol-, bloemknol, knolbloem en bolbloemgewassen (dompelbehandeling), ter bestrijding van groene perzikluis, katoenluis en zwarte bonenluis.
Het plantgoed vóór het planten gedurende 15 minuten dompelen. Het plantgoed dient op het moment van behandeling in rust te zijn. Bij gewassen die in het najaar geplant worden of gewassen die op het dompeltijdstip geen wortels hebben, kan tegen het einde van de teelt een aanvullende bestrijding met een insecticide noodzakelijk zijn. Dompelbehandeling indien mogelijk kort voor het planten uitvoeren. Menging met fungiciden is mogelijk.
Dosering: 0,08% (80 ml per 100 liter water) en maximaal 750 liter dompelvloeistof per ha toepassen. Bij gewassen die in het najaar geplant worden en bijgewassen met weinig wortels op het dompeltijdstip, de dosering verhogen tot 0,1% (100 ml per 100 ml dompelvloeistof) en maximaal 600 liter dompelvloeistof per ha toepassen.

Gladiolen (dompelbehandeling), ter bestrijding van gladiolentrips tijdens de bewaring van de knollen.
Na het pellen en voor de bewaring de knollen dompelen. Menging met fungiciden is mogelijk.
Dosering: 0,08% (80 ml per 100 ml dompelvloeistof) en maximaal 750 liter dompelvloeistof per ha toepassen

Bedekte teelt van boomkwekerijgewassen en vaste planten, ter bestrijding van bladluizen: boterbloemluis, groene en rode perzikluis, katoenluis, zwarte boneluis, gewone rozeluis, sjalotteluis en groene kortstaartluis.
Zodra een aantasting wordt waargenomen het middel door een gewasbehandeling toepassen.
Zonodig de bespuiting met een interval van 7-10 dagen herhalen.
Dosering: 0,02% (20 ml per 100 liter water)

Onbedekte teelt van boomkwekerijgewassen en vaste planten, ter bestrijding van bladluizen: boterbloemluis, groene en rode perzikluis, zwarte boneluis, gewone rozeluis, sjalotteluis, groene kortstaartluis, aardappeltopluis, zwarte kerseluis, groene appeltakluis, groene sparreluis, vogelkersluis en beukebladluis.
Zodra een aantasting wordt waargenomen het middel door een gewasbehandeling toepassen.
Zonodig de bespuiting met een interval van 7-10 dagen herhalen.
Dosering: 0,02% (20 ml per 100 liter water)

Onbedekte teelt van boomkwekerijgewassen en vaste planten, ter bestrijding van de buxusbladvlo.
Toepassen zodra de larven uit de wintereieren komen.
Dosering: 0,02% (20 ml per 100 liter water)

Onbedekte teelt van hop, ter bestrijding van de hopluis.
Zodra aantasting wordt waargenomen een behandeling uitvoeren waarbij het middel door middel van aanstrijken op de stengel wordt gebracht.
Per groeiseizoen één behandeling uitvoeren.
Dosering: per 1000 scheuten 90 ml middel in 1,5 liter water oplossen. Maximaal 360 gram middel per hectare toepassen.

Pennenteelt van witlof in de vollegrond, ter bestrijding van de wollige slawortelluis.
Toepassen via een spray-toepassing in de zaaivoor. De spray na het zaaien voor het dichtstrijken van de zaaivoor richten. Doordat de kieming door de toepassing wat achter kan blijven wordt geadviseerd 5% extra zaad te gebruiken.
Dosering: 500 ml middel per ha

Bijlage IIII-11 MonAmi (13069)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als schimmel- en insectenbestrijdingsmiddel 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.*

Dit middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Algemeen

MonAmi bevat de werkzame stoffen pencycuron en imidacloprid. Pencycuron is een fungicide dat beschermt tegen aantasting door Rhizoctonia vanuit de bodem. Imidacloprid is een systemisch werkend insecticide dat vanuit de grond door de wortels wordt opgenomen en dat zich daarna in de bovengrondse delen van de plant verspreidt.

Het middel heeft een werkingsduur van 8-10 weken tegen bladluizen. Tijdens het groeiseizoen dient het gewas evenwel regelmatig te worden gecontroleerd op de aanwezigheid van bladluizen. Indien geconstateerd wordt dat zich bladluizen in het gewas vestigen moeten passende maatregelen (bladluisbestrijding of loofvernietiging) worden genomen.

Waterhoeveelheid: 200 liter per ha.

Er zijn geen beperkingen ten aanzien van het gebruik van de opbrengst voor consumptie-, zetmeelverwerkings-, of veevoerdoeleinden.

Toepassingen

Pootaardappelen, ter voorkoming van aantasting door Rhizoctonia, ter bestrijding van de groene perzikluis (*Myzus persicae*), de vuilboomluis (*Aphis nasturtii*) en andere voorkomende bladluissoorten en ter voorkoming van overdracht van het bladrolvirus.

Het middel dient te worden toegepast door middel van een grondbehandeling in de rij tijdens het poten.

Dosering: 10 liter middel per hectare

Op sterk humeuze gronden (met meer dan 10% organisch materiaal) kan de Rhizoctoniawerking tegenvallen.

Bijlage III-12 Maxforce Quantum (13074)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van mieren, inclusief de faraomier, de spookmier en de Argentijnse mier, zowel binnen als buiten.

Bij gebruik buiten mag het middel uitsluitend worden aangebracht in de nestingangen van mierennesten.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Algemeen:
Het middel is bijzonder effectief tegen faraomieren (*Monomorium phraonis*) en de zwart-bruine wegmier (*Lasius niger*). Andere (exotische) mieren die met het middel kunnen worden bestreden zijn de spookmier (*Tapinoma melanocephalum*) en de Argentijnse mier (*Linepitheme humile*).

Maxforce Quantum is door zijn visceuze eigenschappen geschikt voor het uitzetten als lokaas, in o.a. de volgende situaties:

Opslag-, verblijfs-en bedrijfsruimten	Huishoudens, restaurants inclusief keukens, slachthuizen, opslagplaatsen, ziekenhuizen, hotels, zwembaden, gemeentehuizen, bioscopen etc.
Buiten	*In de nestingangen van mierennesten*

Maxforce Quantum cartridges dienen te worden gebruikt met behulp van hiervoor geschikte pistolen. Als een cartridge slechts gedeeltelijk wordt gebruikt, deze uit het pistool verwijderen en afsluiten met de bijgevoegde afsluiting.

Toepassing:
Breng het middel aan op plaatsen buiten het bereik en zicht van kinderen en (huis)dieren. Bij gebruik binnen, bewoners aangeven dat schoonmaken en verwijderen van lokaas punten moet worden voorkomen. Breng het middel aan op of naast de looppaden van de mieren. Bij grote infestaties, dienen de lokaaspunten regelmatig te worden gecontroleerd en ververst daar waar nodig. Voorkom het aanbrengen van het middel op zeer stoffige, vochtige of vette plaatsen of plaatsen die veelvuldig worden gewassen. Breng het middel niet aan op oppervlakten waar voedsel wordt bereid, of op oppervlakten die recent zijn behandeld met andere insecticiden of waar het lokaas kan worden vervuild met andere insecticiden.

Dosering binnen: 1 druppel per vierkante meter, bijv. behandel een keuken van 10 m^2 met 10 druppels of 1 druppel per strekkende meter van een mieren looppad.

Bij gebruik buiten, *dient het middel te worden aangebracht in de ingangen van het nest.* Als het mierennest zich bevindt op een onbeschutte plaats, toepassing alleen uitvoeren als geen regen binnen 24 uur wordt verwacht. In het geval er toch regen valt binnen 24 uur, de toepassing herhalen.

Dosering buiten: 2 gram van het middel rechtstreeks in het nest aanbrengen. Na 5 tot 7 dagen controleren of er nog voldoende middel beschikbaar is. Indien het lokaas volledig is verdwenen en de plaag onvoldoende bestreden is, dient de toepassing te worden herhaald.

Een eerste effect op de mierenpopulatie kan worden verwacht 7 dagen na aanbrengen van het middel. De meeste mierennesten zullen na 14 dagen zijn uitgeroeid. Echter onder bepaalde omstandigheden, zoals bij erg grote nesten of bij her-infestatie, kan het plaagdierbeheersingsprogramma 2 maanden duren. Aangebrachte lokaas punten blijven ten minste 12 weken effectief. Zo lang lokaaspunten op de juiste plaats aanwezig zijn, zal her-infestatie worden voorkomen.

Bijlage III-13 Admire (13176)

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als insectenbestrijdingsmiddel met maximaal 1 toepassing per teelt, *met dien verstande dat er binnen 6 maanden na planten geen voor bijen aantrekkelijke gewassen geplant of gezaaid worden*:

- in de teelt van spruitkool

-als traybehandeling vóór het planten vanaf 1 februari 2011 tot en met 30 juni 2011 of
-toegepast door middel van de phytodriptechniek tot en met 30 april 2011.

- in de teelt van bloemkool en broccoli

-als traybehandeling vóór het planten vanaf 1 maart 2011 tot en met 31 juli 2011 of
-toegepast door middel van de phytodrip-techniek vanaf 1 februari 2011 tot en met 30 juni 2011.

Attentie:
Het is niet toegestaan in één teelt of teeltseizoen zowel Gaucho Tuinbouw (zaadbehandeling *of* dummypil) als Admire (traybehandeling *of* phytodriptechniek) toe te passen.

Het middel mag worden toegepast als traybehandeling vóór het planten, dan wel een phytodripbehandeling van spruitkool, met dien verstande dat maximaal 40.000 planten per hectare mogen worden geplant. De traybehandeling is uitsluitend toegestaan op een niet doorlatende ondergrond die niet afwatert op oppervlaktewater of in kassen met een volledig gesloten recirculatiesysteem.

Het middel is schadelijk bij opname door de mond.

Niet roken tijdens gebruik.

Draag geschikte handschoenen en beschermende kleding, ook bij werkzaamheden aan behandeld gewas.

In geval van inslikken onmiddellijk een arts raadplegen en verpakking of etiket tonen.

Dit middel is gevaarlijk voor niet-doelwitarthropoden. Vermijd onnodige blootstelling.

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

Dit middel is uitsluitend bestemd voor professioneel gebruik.

Dit middel is - zij het voor andere toepassingen - tevens toegelaten onder het toelatingsnummer 11483 N.

B.
GEBRUIKSAANWIJZING

Algemeen
Admire is een systemisch werkend middel. Het middel wordt door de wortels opgenomen en door de hele plant verspreid. De werkingssnelheid wordt mede bepaald door de activiteit van het gewas.

ADMIRE kan een invloed hebben op de kiemkracht van het zaad. Behandel daarom geen partijen met een zwakke kiemkracht. Combinatie met andere gewasbeschermingsmiddelen kan dit effect versterken. Hierdoor kan opkomstvertraging en vertraging in de groei van kiemplanten optreden in de opkweekfase.

Met ADMIRE behandelde planten kunnen door stress (groeistilstand na overplanten, schraal weer, nachtvorst) bij de eerste hergroei tijdelijk een iets steilere geknepen bladstand laten zien. Ook kan het blad tijdelijk iets geel verkleuren. Dit effect trekt na 2-3 weken weer weg.

Toepassingen

Spruitkool, ter bestrijding van de koolwittevlieg *(Aleyrodes proletella)*
Phytodriptechniek: het middel tijdens het zaaien toepassen door middel van de phytodriptechniek.
Dosering: 5 gram middel per 1.000 planten.

Spruitkool, ter bestrijding van de koolwittevlieg *(Aleyrodes proletella)*
Traybehandeling: Het middel kort voor het aanplanten aangieten op de tray. Voordat het middel wordt toegediend de planten vochtig maken met 0,2 liter schoon water per m^2 tray. Direct na toepassing (voordat de planten weer aandrogen) de planten afspuiten met 1-2 liter schoon water per m^2 tray.
Dosering: 5 gram middel per 1.000 planten.

Bloemkool en broccoli, ter bestrijding van de koolgalmug (*Contarinia nasturtii*)
Phytodrip-techniek: het middel tijdens het zaaien toepassen door middel van de phytodrip-techniek.
Dosering: 5 gram middel per 1.000 planten

Bloemkool en broccoli, ter bestrijding van de koolgalmug (*Contarinia nasturtii*)
Traybehandeling: Het middel kort voor het planten aangieten op de tray. Voordat het middel wordt toegediend de planten vochtig maken met 0,2 liter schoon water per m^2 tray. Direct na toepassing (voordat de planten weer aandrogen) de planten afspuiten met 1-2 liter schoon water per m^2 tray.
Dosering: 5 gram middel per 1.000 planten.

Bijlage IV Europees en EPPO kader

Guidance document on terrestrial ecotoxicology in the context of Directive 91/414/EEC. Sanco/10392/2002,rev 2 final (2002)
"Chapter 4 Bees
For general background information see the upcoming EPPO scheme (EPPO 2002b)
Data requirements and testing
Acute toxicity to bees (Annex II 8.3.1.1, Annex III 10.4.1)
If honeybees are likely to be exposed to the active substance both acute oral and contact toxicity tests must be conducted as the toxicity by one route of exposure cannot be predicted from the other. Where there is only one relevant route of exposure (e.g. oral exposure in the case of soil application), testing can be restricted to this exposure route. The test result should be presented as µg a.s./bee or µg formulation/bee. If there are problems with solubility of the active substance, then the test should be conducted with a representative formulation.

Toxicity tests should be conducted according to EPPO 170, or OECD 213 and OECD 214 guidelines.

Bee brood feeding test (Annex II 8.3.1.2)
The test method of Oomen et al. (1992), that is recommended in Annex II for insect growth regulators, is a worst case screening test. If no effects are found the conclusion is justified that no brood damage will occur when using the product. In the case of effects further cage/tent/tunnel or field studies are necessary to evaluate the risk under more realistic conditions. If toxicity to honeybee broods can already be predicted from the mode of action of the compound, testing may immediately start with cage/tent/tunnel or field trials.

Residue test (Annex III 10.4.2)
Aged residue tests may be valuable as an additional tool for risk assessment. However, no specific validated methods are yet available. The test should be designed to assess the duration of effects due to residual traces of plant protection products on the crop.

Higher tier tests (Annex III 10.4.3, 10.4.4 and 10.4.5)
For higher tier testing (cage/tent/tunnel or field trials), the recommendations of EPPO guideline 170 should be taken into account.

Testing of systemic plant protection products
For soil-applied systemic plant protection products (e.g. plant protection products applied as seed dressing) the acute oral toxicity of the active substance(s) have to be determined. If potential risks to honeybees are identified (i.e. very low LD50) realistic exposure conditions should be taken into account, i.e. realistic exposure concentrations as expected in nectar and pollen as indicated by residue studies. If a risk is indicated, higher tier studies (cage/tent/tunnel or field studies) with realistic exposure scenarios should be performed.

Metabolite testing
Standard lab tests are normally not required for metabolites. Exceptions may be cases where for example the metabolite is the pesticidal active molecule. Before conducting studies the general guidance given in chapter 2.9 should be observed. If higher tier studies (cage/tent/tunnel or field) are conducted with the plant protection products under realistic exposure conditions, potential risks from metabolites should be covered.
Exposure assessment

For products applied as sprays where risk as assessed according to the HQ approach exposure should be established as the maximum single application rate of the product expressed as g/ha because the HQ was validated on this measure.

For systemic plant protection products, exposure considerations and calculations should be based on the a.s. (or metabolite) present in the respective plant parts (e.g. nectar, pollen) to which honeybees could be exposed. However, it should be noted that estimates of these concentrations are rarely available.

Exposure calculations in higher tier studies are already considered within the experimental design (e.g. honeybees foraging on treated field crops).
Risk assessment
Hazard quotient for bees (Annex III 10.4)
The hazard quotient is stated to be application rate/oral LD50 or application rate/contact LD50, where the LD50 is expressed as µg a.s./bee and the application rate is in g a.s./ha. As stated above, the maximum single application rate should be used to calculate the oral and contact HQ-values. If the oral and contact HQ < 50, low risk to bees is concluded and no further testing is required. If the oral or contact HQ > 50, further higher tier testing is required to evaluate the risk to bees. The critical HQ of 50 was validated against incidents (EPPO 2002b); it is only applicable to spray products.

Higher tier risk assessment for bees
There are no clearly defined endpoints for higher tier studies, therefore, a degree of expert judgement is required to interpret both semi-field and field study results. As regards semi-field trials, where there are replicated studies, there should be a statistical comparison between key parameters, e.g. foraging density, mortality, proportion of adults, larvae and pupae in the hive. It should be noted that the parameters considered should be relevant to the compound under consideration. For example if an insect growth regulator was being assessed then it would be more relevant to concentrate on developmental issues. As regards field trials, key parameters should be compared to either pretreatment levels or to control levels. It is important to consider any effects observed in relation to the overall survival and productivity of the hive. Key parameters which may be considered in a field trial include: mortality (assessed via the use of dead bee traps), behaviour (including foraging behaviour in the crop and around the hive), honey crop (assessed via weighing the hive at appropriate intervals) and state of colony (including an assessment of brood). Depending upon the concern highlighted in the initial risk assessment it may be appropriate to use pollen traps as well as appropriate analysis of dead bees. Analysis of honey and wax may be useful in determining exposure. The use of a toxic standard in both semi-field and field trials along with an untreated control can aid interpretation of the results. For insect growth regulators and other active substances which may cause long-term adverse effects on hive health, evidence is required confirming a lack of effects on hive health over a long time period. It should be noted that further information is available in the EPPO guideline (EPPO 2001). The design of higher tier studies is dependant upon the risks highlighted and therefore it is recommended that applicants should consult the relevant authority.
Risk mitigation options
The risk mitigation measures outlined below are options only. These measures will require consideration at a national level and implementation will depend on local agronomic practice and conditions. If predicted effects to honeybees are considered as not acceptable, the following aspects of the use pattern may be considered for modification in order to mitigate the predicted risk:
application rate
timing of application (e.g. apply in the evening after honeybee flight, do not apply during honeybee flight)
GAP adaptation (e.g. do not apply during crop flowering)

agronomic practice (e.g. mulch ground cover before application of the plant protection products)"

Besluitvorming EPPO richtlijnen
(http://www.eppo.org/PPPRODUCTS/honeybees/honeybees.htm)

EU Regulatory Risk Assessment
"Currently in the EU, regulatory evaluations for the effects of pesticides on honeybees are based on the EPPO/Council of Europe risk assessment scheme for honeybees (EPPO Series PP 3 Environmental Risk Assessment Scheme for Plant Protection Products – Chapter 10: Honeybees; first published in 1993, the latest revision in 2010) and on the standard on the conduct of trials for the evaluation of side-effects of plant protection products on honeybees (PP 1/170).

The ICPBR 'Bee Protection Group' provides the technical input for the EPPO 170 guideline1 and associated risk assessment scheme 2. This in turn currently forms the basis of regulatory evaluations for the effects of pesticides on honey bees in the EU. In addition, more recently, the EPPO 170 guideline has formed the basis of the OECD laboratory test guidelines for acute contact and oral toxicity to honey bees (OECD Guidelines Nos. 213 and 214)."

As part of their ongoing review of pesticide risk assessment for honeybees they identified a number of issues that require further consideration and in response, EPPO asked the group to undertake revision of the two EPPO standards. Within the ICPBR 'Bee Protection Group' the Working Groups (WG) were set up to address the recently emerged problems of systemic effects through seed and soil treatments, of field and semi-field testing, and honeybee brood testing.

At the ICPBR- Bee Protection Group 10th Symposium (Bucharest, 2009-10-08/10 - Proceedings published in the Julius-Kühn-Archiv 423, 2009) the WGs presented proposals for the revision of EPPO Standards, which were discussed in order to hear the expert comments and recommendations of all 79 participants and to reach a consensus. After the Symposium, the WG coordinators elaborated their proposals with these comments and recommendations. Prior to sending them to EPPO, they were circulated to all delegates for final review. As planned at the Symposium, the ad hoc meeting at the EPPO Headquarters took place (2009-10-15) with the WG coordinators, the Chairman and the Secretary of the ICPBR-Bee Protection Group, as well as with the EFSA representative. The final versions of the revised EPPO standards were prepared and sent to EPPO Member Countries for comment in early 2010. The standards were agreed by the Working Party on Plant Protection Products in May 2010 and finally approved by the EPPO Council in September 2010.

Bijlage V Lijst met voor bijen aantrekkelijke gewassen

In bijgaande lijst staan een aantal gewassen opgesomd die aantrekkelijk zijn voor bijen: ze worden bevlogen voor het verzamelen van nectar en/of stuifmeel.
Het overgrote deel van deze lijst is al enkele tientallen jaren geleden opgesteld door de toenmalige Plantenziektenkundige Dienst en zeer waarschijnlijk niet uitputtend (het is bijvoorbeeld inmiddels duidelijk dat vrijwel alle bloemen van bolgewassen aantrekkelijk kunnen zijn voor bijen). Het is wenselijk om deze lijst te updaten en daarbij te streven naar een zo volledig mogelijke opsomming van gewassen die door bijen worden bevlogen voor het verzamelen van nectar en/of stuifmeel. De Definitielijst Toepassingsgebieden Gewasbeschermingsmiddel (DTG-lijst) dient hierbij als uitgangspunt.

Bij een dergelijke update van de lijst zouden in ieder geval de volgende organisaties dienen te worden betrokken (allen vertegenwoordigd in de Werkgroep bestuivende insecten en gewasbeschermingsmiddelen en biociden):
nVWA (voormalige Plantenziektenkundige Dienst en AID)
expertisegroep Bijen van de Wageningen Universiteit (bijen@wur)
DLV-plant
LTO-Nederland/Plantum
Nederlandse Bijenvereniging (NBV)
Artemis
Koppert

Deze organisaties en mogelijk nog andere organisaties zullen gevraagd worden input te leveren bij het updaten van de lijst en indien nodig zal een gezamenlijk overleg worden georganiseerd. Ingeschat wordt dat de doorlooptijd van het project ongeveer 3 maanden zal bedragen.

Crops used by honeybees for pollen or nectar collection
These crops are attractive for honeybees unless flowering is avoided and extrafloral nectaries do not occur or are avoided.

Field crops

Soft fruit:	berry, strawberry, blackberry, raspberry
Top fruit:	apple, cherry, pear, plum
Vegetables:	asparagus, gherkin, beans, courgette, broad beans,
Arable crops:	Chinese radish, phacelia, caraway, white clover, lupine, lucerne, oilseed rape and mustard seed etc., evening primrose, field bean, flax, sunflower maize
Flower bulbs:	crocus, hyacinth, (botanic) tulip and miscellaneous bulbs and corms.

Summer flowers.

Seed production of various vegetables, herbs and flowers, including: endive, brassicae, leek, onion, chicory, carrot.

Nursery stock, public parks and gardens.

Under protection

Vegetables and fruit: blackberry, raspberry, strawberry, berries, peach, plum, gherkin, courgette, aubergine, sweet pepper and melon.

Seed production of various vegetables, herbs and flowers, including: endive, asparagus, gherkin, brassicae, chicory and carrot.

Appendix

Tree species that are important nectar plants and that are sometimes treated with Plant protection products against insects: lime, willow.

Weeds that are important nectar plants and that are sometimes treated with Plant protection products: dandelion, creeping thistle, and weeds growing in agricultural crops (e.g. redshank, sheep sorrel).

Bijlage VI Lijst met afkortingen

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
DT50	period required for 50 percent dissipation (define method of estimation)
DT90	period required for 90 percent dissipation (define method of estimation)
EC50	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
LC50	lethal concentration, median
LD50	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
PECA	predicted environmental concentration in air
PECS	predicted environmental concentration in soil
PECSW	predicted environmental concentration in surface water
PECGW	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

Bijlage VII - Overzicht beslissingen en besluiten van het Ctgb op basis van herbeoordeling

beslissingen van het College om op dat moment niet ambtshalve in te grijpen in de toelating;
besluiten op aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van artikel 45 Verordening 1107/2009/EG;
voorgenomen besluiten tot ambtshalve wijziging van de toelating op basis van artikel 44 Verordening 1107/2009/EG;
besluit tot tijdelijk verbod of tijdelijke inperking van het gebruik en het voorhanden hebben van het middel op basis van artikel 71 Verordening 1107/2009/EG;
advies van het College over de middelen, die tijdelijk zijn verboden, bij besluit Schorsing niet-professioneel gebruik insectenmiddelen (publicatiedatum 6 juni 2011).

Hieronder wordt een overzicht gegeven van de besluiten die het Ctgb genomen heeft op basis van de herbeoordeling van de middelen op basis van de neonicotinoïden clothianidine, thiamethoxam en imidacloprid, en fipronil. De bijbehorende beoordelingen zijn opgenomen in Bijlagen II. De gewijzigde Wettelijk gebruiksvoorschriften/ gebruiksaanwijzingen (WG/GA's) zijn opgenomen in Bijlagen III.

Overzicht voorstellen Collegebesluiten 22 juni 2011

Nr.	
	Beslissing tot niet ingrijpen
	Clothianidine
1	Het College stelt vast dat het middel PONCHO ROOD (13276) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
2	Het College stelt vast dat het middel PONCHO BETA (13044) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG
	Thiamethoxam
3	Het College stelt vast dat het middel AXORIS QUICK GRAN (13215) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
4	Het College stelt vast dat het middel AXORIS QUICK STICKS (13216) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
5	Het College stelt vast dat het middel CRUISER SB (12863) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
6	Het College stelt vast dat het middel AGITA 10WG (13399) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op

	basis van artikel 44 Verordening 1107/2009/EG.
	Fipronil
7	Het College stelt vast dat het middel GOLIATH AASSTATIONS (12119) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
8	Het College stelt vast dat het middel GOLIATH GEL (12120) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
9	Het College stelt vast dat het middel MUNDIAL (13384) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
	Imidacloprid
11	Het College stelt vast dat het middel MERIT TURF (13321) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG. Het besluit op het bezwaar dat momenteel loopt met betrekking tot Merit Turf wordt met inachtneming van het bovenstaande afgedaan.
12	Het College stelt vast dat het middel GAUCHO (11455) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
13	Het College stelt vast dat het middel GAUCHO ROOD (11601) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
14	Het College stelt vast dat het middel ADMIRE N PIN (11998, afgeleide: 12219) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en adviseert derhalve aan het ministerie van EL&I dat er op dit moment geen reden om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG..
15	Het College stelt vast dat het middel LURECTRON FLYBAIT (13160, afgeleide: 13173) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
16	Het College stelt vast dat het middel QUICK BAIT (12665, afgeleide: 13063) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.

17	Het College stelt vast dat het middel QUICK BAIT SPRAY (13116) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
18	Het College stelt vast dat het middel MAXFORCE PRIME (13250) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
19	Het College stelt vast dat het middel MAXFORCE WHITE IC (12094) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
20	Het College stelt vast dat het middel PIRON MIERENLOKDOOS (13055, afgeleiden: 13104, 13127, 13073, 13072, 13121, 13124) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
21	Het College stelt vast dat het middel BAYTHION MIERENMIDDEL (12952, afgeleiden: 13026, 12974, 13052, 12979, 12980, 12024) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
22	Het College stelt vast dat het middel VAPONA RAAMSTICKER (13280, parallel: 13351) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.
23	Het College stelt vast dat het middel VLIEGENSTICKER (13389) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb en beslist derhalve dat er op dit moment geen reden is om over te gaan tot ambtshalve intrekking/wijziging op basis van artikel 44 Verordening 1107/2009/EG.

	Besluit tot instemming met wijziging WGGA op verzoek toelatinghouder
	Thiamethoxam
1	Het College stelt vast dat het middel ACTARA (12679) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren.
2	Het College stelt vast dat het middel CRUISER 70 WS (12852) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren. .

3	Het College stelt vast dat het middel CRUISER 350 FS (12913) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie voor toepassing in erwten en van de levering van genoemde data voor toepassing in erwten en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren. .
	Fipronil
4	Het College stelt vast dat het middel MUNDIAL (12802, 12977) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren. .
	Imidacloprid
5	Het College stelt vast dat het middel ADMIRE-O-TEQ (12942) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren.
6	Het College stelt vast dat het middel ADMIRE (11483, parallel: 11547,13363) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren.
7	Het College stelt vast dat het middel ADMIRE (13176) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG. te honoreren. De toelating loopt zeer binnenkort af (1/8/2011). Besluit wordt niet effectief omdat het College besluit tot 4 weken respijtperiode.
8	Het College stelt vast dat het middel MONAMI (13059) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren.
9	Het College stelt vast dat het middel AMIGO FLEX (11662) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren.
10	Het College stelt vast dat het middel GAUCHO TUINBOUW (12341) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren.
11	Het College stelt vast dat het middel MAXFORCE QUANTUM (13074) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren.

	Advies
	Het College stelt vast dat het middel PROVADO GARDEN (12115, afgeleiden 12945, 12919) voldoet aan de toelatingscriteria voor bijen vastgelegd in artikel 28 van de Wgb onder voorwaarde van voorgestelde restrictie en besluit, onder voorwaarde dat deze toelatingsbesluiten niet worden vernietigd door het ministerie van EL&I, de aanvraag tot wijziging van de toelating op verzoek van de toelatinghouder op basis van art. 45, eerste lid Verordening 1107/2009/EG te honoreren. Het Ctgb adviseert de staatssecretaris van Landbouw dat er geen aanwijzingen zijn dat niet (langer) (Opmerking: door hier het woord langer op t enemen wordt gesuggereert dat ze openig moment niet voldeden aan de criteria. Is dat verstandig?) aan de toelatingsvoorwaarden wordt voldaan.

Bijlage XX (inleiding verwezen) Aangepaste plaatsingsrichtlijnen (Annex I van 91/414/EEG)

Bijlage XXX-1 clothianidin

RICHTLIJN 2006/41/EG VAN DE COMMISSIE

van 7 juli 2006

tot wijziging van Richtlijn 91/414/EEG van de Raad teneinde clothianidin en pethoxamide op te nemen als werkzame stoffen

(Voor de EER relevante tekst)

DE COMMISSIE VAN DE EUROPESE GEMEENSCHAPPEN,

Gelet op het Verdrag tot oprichting van de Europese Gemeenschap,

Gelet op Richtlijn 91/414/EEG van de Raad van 15 juli 1991 betreffende het op de markt brengen van gewasbeschermingsmiddelen [1], en met name op artikel 6, lid 1,

Overwegende hetgeen volgt:

(1) België heeft overeenkomstig artikel 6, lid 2, van Richtlijn 91/414/EEG op 26 september 2001 van Sumitomo Chemical Takeda Agro Company Ltd London een aanvraag ontvangen tot opneming van de werkzame stof clothianidin in bijlage I bij die richtlijn. Bij Beschikking 2002/305/EG van de Commissie [2] is bevestigd dat het dossier „volledig" is, dat wil zeggen dat het in beginsel voldoet aan de voorschriften inzake gegevens en informatie van de bijlagen II en III bij Richtlijn 91/414/EEG.

(2) Duitsland heeft overeenkomstig artikel 6, lid 2, van Richtlijn 91/414/EEG op 16 oktober 2000 van Stähler Agrochemie GmbH & Co. KG (nu Stähler International GmbH & Co. KG) namens de taakgroep Stähler Agrochemie GmbH & Co. KG, Tokuyama Europe GmbH en Cheminova France SAS een aanvraag ontvangen tot opneming van de werkzame stof pethoxamide in bijlage I bij die richtlijn. Bij Beschikking 2001/626/EG van de Commissie [3] is bevestigd dat het dossier „volledig" is, dat wil zeggen dat het in beginsel voldoet aan de voorschriften inzake gegevens en informatie van de bijlagen II en III bij Richtlijn 91/414/EEG.

(3) De uitwerking van deze werkzame stoffen op de gezondheid van de mens en op het milieu is overeenkomstig het bepaalde in artikel 6, leden 2 en 4, van Richtlijn 91/414/EEG beoordeeld voor de door de aanvrager voorgestelde toepassingen. De als rapporteur aangewezen lidstaten hebben op 4 juni 2003 (clothianidin) respectievelijk op 27 augustus 2002 (pethoxamide) bij de Commissie een ontwerp-evaluatieverslag ingediend.

(4) De ontwerp-evaluatieverslagen zijn door de lidstaten en de Commissie onderzocht in het kader van het Permanent Comité voor de voedselketen en de diergezondheid. Dit onderzoek is op 27 januari 2006 afgesloten met evaluatieverslagen van de Commissie voor clothianidin en pethoxamide.

(5) Bij het onderzoek van clothianidin en pethoxamide zijn geen vragen of problemen aan het licht gekomen waarvoor het Wetenschappelijk Comité voor planten of de Europese Autoriteit voor voedselveiligheid — die de rol van dit comité heeft overgenomen — moest worden geraadpleegd.

(6) Uit de verschillende analyses is gebleken dat mag worden verwacht dat gewasbeschermingsmiddelen die de betrokken werkzame stoffen bevatten, in het algemeen zullen voldoen aan de in artikel 5, lid 1, onder a) en b), en lid 3, van Richtlijn 91/414/EEG gestelde eisen, met name voor de toepassingen waarvoor zij zijn onderzocht en die zijn opgenomen in de evaluatieverslagen van de Commissie. Clothianidin en pethoxamide moeten derhalve in bijlage I bij die richtlijn worden opgenomen om ervoor te zorgen dat gewasbeschermingsmiddelen die deze werkzame stoffen bevatten, in alle lidstaten kunnen worden toegelaten overeenkomstig het bepaalde in die richtlijn.

(7) Onverminderd de verplichtingen zoals vastgelegd in Richtlijn 91/414/EEG ten gevolge van de opneming van een werkzame stof in bijlage I, moeten de lidstaten na de opneming een tijdsruimte van zes maanden krijgen om de bestaande voorlopige toelatingen voor gewasbeschermingsmiddelen die clothianidin of pethoxamide bevatten, opnieuw te onderzoeken om ervoor te zorgen dat aan de voorwaarden van Richtlijn 91/414/EEG, met name artikel 13 en bijlage I, is voldaan. De lidstaten moeten de bestaande voorlopige toelatingen omzetten in volwaardige toelatingen, wijzigen of intrekken overeenkomstig het bepaalde in die richtlijn. In afwijking van bovenstaand tijdschema moet een langere termijn worden vastgesteld voor de indiening en beoordeling van het volledige dossier conform bijlage III bij Richtlijn 91/414/EEG voor elk gewasbeschermingsmiddel en elke beoogde toepassing overeenkomstig de in die richtlijn vastgestelde uniforme beginselen.

(8) Richtlijn 91/414/EEG moet daarom dienovereenkomstig worden gewijzigd.

[1] PB L 230 van 19.8.1991, blz. 1. Richtlijn laatstelijk gewijzigd bij Richtlijn 2006/45/EG van de Commissie (PB L 130 van 18.5.2006, blz. 27).
[2] PB L 104 van 20.4.2002, blz. 42.
[3] PB L 217 van 11.8.2001, blz. 14.

(9) De in deze richtlijn vervatte maatregelen zijn in overeenstemming met het advies van het Permanent Comité voor de voedselketen en de diergezondheid,

HEEFT DE VOLGENDE RICHTLIJN VASTGESTELD:

Artikel 1

Bijlage I bij Richtlijn 91/414/EEG wordt gewijzigd zoals aangegeven in de bijlage bij deze richtlijn.

Artikel 2

1. De lidstaten dienen uiterlijk op 31 januari 2007 de nodige wettelijke en bestuursrechtelijke bepalingen vast te stellen en bekend te maken om aan deze richtlijn te voldoen. Zij delen de Commissie de tekst van die bepalingen onverwijld mede, alsmede een tabel ter weergave van het verband tussen die bepalingen en deze richtlijn.

Zij passen die bepalingen toe vanaf 1 februari 2007.

Wanneer de lidstaten die bepalingen aannemen, wordt in die bepalingen zelf of bij de officiële bekendmaking daarvan naar deze richtlijn verwezen. De regels voor die verwijzing worden vastgesteld door de lidstaten.

2. De lidstaten delen de Commissie de tekst van de belangrijkste bepalingen van intern recht mede die zij op het onder deze richtlijn vallende gebied vaststellen.

Artikel 3

1. De lidstaten moeten, overeenkomstig Richtlijn 91/414/EEG, zo nodig bestaande toelatingen voor gewasbeschermingsmiddelen die clothianidine of pethoxamide als werkzame stof bevatten, vóór 31 januari 2007 wijzigen of intrekken. Uiterlijk op die datum verifiëren zij met name dat aan de voorwaarden van bijlage I bij die richtlijn met betrekking tot respectievelijk clothianidine of pethoxamide is voldaan, met uitzondering van de voorwaarden in deel B van de rubriek betreffende die werkzame stoffen, en dat de houder van de toelating in het bezit is van of toegang heeft tot een dossier dat overeenkomstig de voorwaarden van artikel 13 van die richtlijn aan de voorwaarden van bijlage II bij die richtlijn voldoet.

2. In afwijking van lid 1 voeren de lidstaten op basis van een dossier conform bijlage III bij Richtlijn 91/414/EEG en rekening houdend met deel B van de tekst van bijlage I bij die richtlijn wat clothianidine of pethoxamide betreft, overeenkomstig de uniforme beginselen in bijlage VI bij die richtlijn een nieuwe evaluatie uit voor elk toegelaten gewasbeschermingsmiddel dat clothianidine of pethoxamide bevat als enige werkzame stof of als een van een aantal werkzame stoffen die alle uiterlijk op 31 juli 2006 in bijlage I bij die richtlijn zijn opgenomen. Op basis van die evaluatie bepalen zij of het middel voldoet aan de voorwaarden van artikel 4, lid 1, onder b), c), d) en e), van Richtlijn 91/414/EEG.

Daarna zorgen de lidstaten ervoor dat:

a) als clothianidine of pethoxamide de enige werkzame stof in het gewasbeschermingsmiddel is, de toelating indien nodig uiterlijk op 31 januari 2008 wordt gewijzigd of ingetrokken; of

b) als het gewasbeschermingsmiddel naast clothianidine of pethoxamide nog een of meer andere werkzame stoffen bevat, de toelating indien nodig uiterlijk op 31 januari 2008 of, als dat later is, op de datum die voor een dergelijke wijziging of intrekking is vastgesteld in de richtlijnen waarbij die stoffen aan bijlage I bij Richtlijn 91/414/EEG zijn toegevoegd, wordt gewijzigd of ingetrokken.

Artikel 4

Deze richtlijn treedt in werking op 1 augustus 2006.

Artikel 5

Deze richtlijn is gericht tot de lidstaten.

Gedaan te Brussel, 7 juli 2006.

Voor de Commissie
Markos KYPRIANOU
Lid van de Commissie

BIJLAGE

In bijlage I bij Richtlijn 91/414/EEG wordt aan het einde van de tabel de volgende rij toegevoegd:

Nr.	Benaming, identificatienummers	IUPAC-benaming	Zuiverheid (1)	Inwerkingtreding	Vervaldatum	Specifieke bepalingen
„117	Clothianidin CAS-nr. 210880-92-5 CIPAC-nr. 738	(E)-1-(2-chloor-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine	≥ 960 g/kg	1 augustus 2006	31 juli 2016	DEEL A Mag alleen worden toegelaten voor gebruik als insecticide. DEEL B Voor de toepassing van de uniforme beginselen in bijlage VI moet rekening worden gehouden met de conclusies van het evaluatieverslag over clothianidin dat op 27 januari 2006 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd, en met name met de aanhangsels I en II. Bij deze algemene evaluatie moeten de lidstaten: — bijzondere aandacht besteden aan de bescherming van het grondwater, wanneer de werkzame stof wordt gebruikt in qua bodemgesteldheid en/of klimaat kwetsbare gebieden; — bijzondere aandacht besteden aan het risico voor insectenetende vogels en zoogdieren, wanneer de stof wordt gebruikt voor zaadbehandeling. De gebruiksvoorwaarden moeten, indien nodig, risicobeperkende maatregelen omvatten.

Nr.	Benaming, identificatienummers	IUPAC-benaming	Zuiverheid (1)	Inwerkingtreding	Geldig tot en met	Specifieke bepalingen
125	Pethoxamide CAS-nr. 106700-29-2 CIPAC-nr. 665	2-chloro-N-(2-ethoxyethyl)-N-(2-methyl-1-phenylprop-1-enyl)acetamide	≥ 940 g/kg	1 augustus 2006	31 juli 2016	DEEL A De stof mag alleen worden toegelaten voor gebruik als herbicide. DEEL B Voor de toepassing van de uniforme beginselen in bijlage VI moet rekening worden gehouden met de conclusies van het evaluatieverslag over pethoxamide dat op 27 januari 2006 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd, en met name met de aanhangsels I en II. Bij deze algemene evaluatie moeten de lidstaten: — bijzondere aandacht besteden aan de bescherming van het grondwater, wanneer de werkzame stof wordt gebruikt in gebieden met kwetsbare bodem- en/of klimaatomstandigheden; — bijzondere aandacht besteden aan de bescherming van het aquatische milieu, met name hogere waterplanten. De gebruiksvoorwaarden moeten, indien nodig, risicobeperkende maatregelen omvatten. De lidstaten lichten de Commissie overeenkomstig artikel 13, lid 5, in over de specificatie van het technische materiaal zoals commercieel vervaardigd.

(1) Het evaluatieverslag bevat nadere gegevens over de identiteit en de specificaties van de werkzame stoffen.

15.2.2007 NL Publicatieblad van de Europese Unie L 43/13

RICHTLIJNEN

RICHTLIJN 2007/6/EG VAN DE COMMISSIE

van 14 februari 2007

tot wijziging van Richtlijn 91/414/EEG van de Raad teneinde metrafenone, Bacillus subtilis, spinosad en thiamethoxam op te nemen als werkzame stoffen

(Voor de EER relevante tekst)

DE COMMISSIE VAN DE EUROPESE GEMEENSCHAPPEN,

Gelet op het Verdrag tot oprichting van de Europese Gemeenschap,

Gelet op Richtlijn 91/414/EEG van de Raad van 15 juli 1991 betreffende het op de markt brengen van gewasbeschermingsmiddelen (¹), en met name op artikel 6, lid 1,

Overwegende hetgeen volgt:

(1) Het Verenigd Koninkrijk heeft op 8 juni 2002 overeenkomstig artikel 6, lid 2, van Richtlijn 91/414/EEG van BASF AG, Belgium een aanvraag ontvangen tot opneming van de werkzame stof metrafenone in bijlage I bij die richtlijn. Bij Beschikking 2003/105/EG van de Commissie (²) is bevestigd dat het dossier „volledig" is, dat wil zeggen dat het in beginsel voldoet aan de voorschriften inzake gegevens en informatie van de bijlagen II en III bij Richtlijn 91/414/EEG.

(2) Duitsland heeft op 15 april 2000 overeenkomstig artikel 6, lid 2, van Richtlijn 91/414/EEG van AgraQuest een aanvraag ontvangen tot opneming van de werkzame stof Bacillus subtilis stam QST 713 (hierna „Bacillus subtilis" genoemd) in bijlage I bij die richtlijn. Bij Beschikking 2001/6/EG van de Commissie (³) is bevestigd dat het dossier „volledig" is, dat wil zeggen dat het in beginsel voldoet aan de voorschriften inzake gegevens en informatie van de bijlagen II en III bij Richtlijn 91/414/EEG.

(3) Nederland heeft op 19 juli 1999 overeenkomstig artikel 6, lid 2, van Richtlijn 91/414/EEG van Dow AgroSciences een aanvraag ontvangen tot opneming van de werkzame stof spinosad in bijlage I bij die richtlijn. Bij Beschikking 2000/210/EG van de Commissie (⁴) is bevestigd dat het dossier „volledig" is, dat wil zeggen dat het in beginsel voldoet aan de voorschriften inzake gegevens en informatie van de bijlagen II en III bij Richtlijn 91/414/EEG.

(4) Spanje heeft op 17 maart 1999 overeenkomstig artikel 6, lid 2, van Richtlijn 91/414/EEG een aanvraag van Novartis Crop Protection AG (nu Syngenta) ontvangen tot opneming van de werkzame stof thiamethoxam in bijlage I bij die richtlijn. Bij Beschikking 2000/181/EG van de Commissie (⁵) is bevestigd dat het dossier „volledig" is, dat wil zeggen dat het in beginsel voldoet aan de voorschriften inzake gegevens en informatie van de bijlagen II en III bij Richtlijn 91/414/EEG.

(5) De uitwerking van deze werkzame stoffen op de gezondheid van de mens en op het milieu is overeenkomstig het bepaalde in artikel 6, leden 2 en 4, van Richtlijn 91/414/EEG beoordeeld voor de door de aanvragers voorgestelde toepassingen. De aangewezen rapporterende lidstaten hebben op 31 oktober 2003 (metrafenone) bij de Europese Autoriteit voor voedselveiligheid (EFSA) en op 14 mei 2001 (Bacillus subtilis), 5 maart 2001 (spinosad) respectievelijk 21 januari 2002 (thiamethoxam) bij de Commissie ontwerp-evaluatieverslagen over de stoffen ingediend.

(6) Voor metrafenone is het evaluatieverslag door de lidstaten en de EFSA in haar werkgroep Evaluatie intercollegiaal getoetst en op 13 januari 2006 bij de Commissie ingediend in de vorm van het wetenschappelijk verslag van de EFSA voor metrafenone (⁶). Dit verslag is door de lidstaten en de Commissie onderzocht in het kader van het Permanent Comité voor de voedselketen en de diergezondheid. Voor Bacillus subtilis, spinosad en thiamethoxam zijn de ontwerp-evaluatieverslagen door de lidstaten en de Commissie onderzocht in het kader van het Permanent Comité voor de voedselketen en de diergezondheid. Het onderzoek is op 14 juli 2006 afgesloten met de evaluatieverslagen van de Commissie voor metrafenone, Bacillus subtilis, spinosad en thiamethoxam.

(¹) PB L 230 van 19.8.1991, blz. 1. Richtlijn laatstelijk gewijzigd bij Richtlijn 2006/136/EG van de Commissie (PB L 349 van 12.12.2006, blz. 42).
(²) PB L 41 van 14.2.2003, blz. 41.
(³) PB L 2 van 5.1.2001, blz. 23.
(⁴) PB L 64 van 11.3.2000, blz. 14.
(⁵) PB L 57 van 2.3.2000, blz. 35.
(⁶) EFSA Scientific Report (2006) 58, 1-72, Conclusion regarding the peer review of the pesticide risk assessment of the active substance metrafenone (afgerond 13 januari 2006).

(7) Uit de verschillende analyses is gebleken dat mag worden verwacht dat gewasbeschermingsmiddelen die deze werkzame stoffen bevatten, in het algemeen zullen voldoen aan de in artikel 5, lid 1, onder a) en b), en artikel 5, lid 3, van Richtlijn 91/414/EEG gestelde eisen, met name voor de toepassingen waarvoor zij zijn onderzocht en die zijn omschreven in de evaluatieverslagen van de Commissie. Metrafenon, Bacillus subtilis, spinosad en thiamethoxam moeten derhalve in bijlage I bij die richtlijn worden opgenomen, om ervoor te zorgen dat gewasbeschermingsmiddelen die deze werkzame stoffen bevatten, in alle lidstaten kunnen worden toegelaten overeenkomstig het bepaalde in die richtlijn.

(8) Onverminderd de verplichtingen zoals vastgelegd in Richtlijn 91/414/EEG ten gevolge van de opneming van een werkzame stof in bijlage I, moeten de lidstaten na de opneming zes maanden de tijd krijgen om de bestaande voorlopige toelatingen voor gewasbeschermingsmiddelen die metrafenon, Bacillus subtilis, spinosad of thiamethoxam bevatten, opnieuw te onderzoeken om ervoor te zorgen dat aan de voorwaarden van Richtlijn 91/414/EEG, met name in artikel 13 en bijlage I, is voldaan. De lidstaten moeten de bestaande voorlopige toelatingen omzetten in volwaardige toelatingen, wijzigen of intrekken overeenkomstig het bepaalde in die richtlijn. In afwijking van bovenstaande termijn moet een langere termijn worden vastgesteld voor de indiening en beoordeling van het volledige dossier conform bijlage III bij Richtlijn 91/414/EEG voor elk gewasbeschermingsmiddel en elk beoogd gebruik, overeenkomstig de in die richtlijn vastgestelde uniforme beginselen.

(9) Richtlijn 91/414/EEG moet daarom dienovereenkomstig worden gewijzigd.

(10) De in deze richtlijn vervatte maatregelen zijn in overeenstemming met het advies van het Permanent Comité voor de voedselketen en de diergezondheid,

HEEFT DE VOLGENDE RICHTLIJN VASTGESTELD:

Artikel 1

Bijlage I bij Richtlijn 91/414/EEG wordt gewijzigd zoals aangegeven in de bijlage bij deze richtlijn.

Artikel 2

1. De lidstaten dienen uiterlijk op 31 juli 2007 de nodige wettelijke en bestuursrechtelijke bepalingen vast te stellen en bekend te maken om aan deze richtlijn te voldoen. Zij delen de Commissie de tekst van die bepalingen onverwijld mede, alsmede een tabel ter weergave van het verband tussen die bepalingen en deze richtlijn.

Zij passen die bepalingen toe vanaf 1 augustus 2007.

Wanneer de lidstaten die bepalingen aannemen, wordt in die bepalingen zelf of bij de officiële bekendmaking daarvan naar deze richtlijn verwezen. De regels voor die verwijzing worden vastgesteld door de lidstaten.

2. De lidstaten delen de Commissie de tekst van de belangrijkste bepalingen van intern recht mede die zij op het onder deze richtlijn vallende gebied vaststellen.

Artikel 3

1. De lidstaten moeten overeenkomstig Richtlijn 91/414/EEG bestaande toelatingen voor gewasbeschermingsmiddelen die metrafenon, Bacillus subtilis, spinosad of thiamethoxam als werkzame stof bevatten, vóór 31 juli 2007 zo nodig wijzigen of intrekken. Uiterlijk op die datum verifiëren zij met name dat aan de voorwaarden van bijlage I bij die richtlijn met betrekking tot metrafenon, Bacillus subtilis, spinosad respectievelijk thiamethoxam is voldaan, met uitzondering van de voorwaarden in deel B van de tekst betreffende die werkzame stof, en dat de houder van de toelating in het bezit is van of toegang heeft tot een dossier dat overeenkomstig de voorwaarden van artikel 13, lid 2, van die richtlijn aan de voorwaarden van bijlage II bij die richtlijn voldoet.

2. In afwijking van lid 1 voeren de lidstaten op basis van een dossier conform bijlage III bij Richtlijn 91/414/EEG en rekening houdend met deel B van de tekst van bijlage I bij die richtlijn met metrafenon, Bacillus subtilis, spinosad of thiamethoxam betreft, overeenkomstig de uniforme beginselen in bijlage VI bij die richtlijn een nieuwe evaluatie uit voor elk toegelaten gewasbeschermingsmiddel dat metrafenon of Bacillus subtilis of spinosad of thiamethoxam bevat als enige werkzame stof of als een van een aantal werkzame stoffen die alle uiterlijk op 31 januari 2007 in bijlage I bij die richtlijn zijn opgenomen. Op basis van die evaluatie bepalen zij of het middel voldoet aan de voorwaarden van artikel 4, lid 1, onder b), c), d) en e), van Richtlijn 91/414/EEG.

Daarna zorgen de lidstaten ervoor dat:

a) wanneer het een product betreft dat metrafenon of Bacillus subtilis of spinosad of thiamethoxam als enige werkzame stof bevat, indien nodig en uiterlijk op 31 juli 2008 de toelating wordt gewijzigd of ingetrokken; of

b) wanneer het een product betreft dat metrafenon of Bacillus subtilis of spinosad of thiamethoxam als een van de werkzame stoffen bevat, de toelating zo nodig wordt gewijzigd of ingetrokken, en wel uiterlijk op 31 juli 2008 of, indien dit later zijn, op de datum die voor een dergelijke wijziging of intrekking is vastgesteld in de respectieve richtlijn of richtlijnen waarbij de stof of stoffen in kwestie aan bijlage I bij Richtlijn 91/414/EEG is of zijn toegevoegd.

Artikel 4

Deze richtlijn treedt in werking op 1 februari 2007.

Artikel 5

Deze richtlijn is gericht tot de lidstaten.

Gedaan te Brussel, 14 februari 2007.

Voor de Commissie

Markos KYPRIANOU

Lid van de Commissie

BIJLAGE

De volgende rijen worden aan het einde van de tabel in bijlage I bij Richtlijn 91/414/EEG toegevoegd:

Nr.	Benaming, identificatienummers	IUPAC-benaming	Zuiverheid (1)	Inwerkingtreding	Geldigheidsduur	Specifieke bepalingen
„139	Metrafenon CAS-nr. 220899-03-6 CIPAC-nr. 752	3'-broom-2,3,4,6'-tetramethoxy-2',6-dimethylbenzofenon	≥ 940 g/kg	1 februari 2007	31 januari 2017	DEEL A Mag alleen worden toegelaten voor gebruik als fungicide. DEEL B Voor de toepassing van de uniforme beginselen in bijlage VI moet rekening worden gehouden met de conclusies van het evaluatieverslag over metrafenon, met name de aanhangsels I en II, dat op 14 juli 2006 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd. De lidstaten stellen de Commissie overeenkomstig artikel 13, lid 5, in kennis van de specificatie van het technische materiaal zoals commercieel vervaardigd.
140	Bacillus subtilis (Cohn 1872) Stam QST 713, identiek met stam AQ 713 Cultuurcollectie: nr. NRRL B-21661 CIPAC-nr. niet toegekend	Niet van toepassing		1 februari 2007	31 januari 2017	DEEL A Mag alleen worden toegelaten voor gebruik als fungicide. DEEL B Voor de toepassing van de uniforme beginselen in bijlage VI moet rekening worden gehouden met de conclusies van het evaluatieverslag over Bacillus subtilis, met name de aanhangsels I en II, dat op 14 juli 2006 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd.

Nr.	Benaming, identificatienummers	IUPAC-benaming	Zuiverheid (1)	Inwerkingtreding	Geldigheidsduur	Specifieke bepalingen
143	Spinosad CAS nr. 131929-60-7 (Spinosyn A) 131929-63-0 (Spinosyn D) CIPAC nr. 636	**Spinosyn A:** (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-14-methyl-1H-8-oxacyclododeca[b]as-indaceen-7,15-dion **Spinosyn D:** (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetradeoxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-4,14-dimethyl-1H-8-oxacyclododeca[b]as-indaceen-7,15-dion Spinosad is een mengsel van 50-95 % spinosyn A en 5-50 % spinosyn D	≥ 850 g/kg	1 februari 2007	31 januari 2017	DEEL A Mag alleen worden toegelaten voor gebruik als insecticide. DEEL B Voor de toepassing van de uniforme beginselen in bijlage VI moet rekening worden gehouden met de conclusies van het evaluatieverslag over spinosad, met name de aanhangsels I en II, dat op 14 juli 2006 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd. Bij deze algemene evaluatie moeten de lidstaten: — bijzondere aandacht besteden aan de bescherming van waterorganismen; — bijzondere aandacht besteden aan het risico voor regenwormen, wanneer de stof in kassen wordt gebruikt. De gebruiksvoorwaarden moeten, indien nodig, risicobeperkende maatregelen omvatten.

Nr.	Benaming, identificatienummers	IUPAC-benaming	Zuiverheid ([1])	Goedkeuring	Vervaldatum	Specifieke bepalingen
142	Thiamethoxam CAS-nr. 153719-23-4 CIPAC-nr. 637	(EZ)-3-(2-chloor-1,3-thiazool-5-ylmethyl)-5-methyl-1,3,5-oxadiazinaan-4-ylideen(nitro)amine	≥ 980 g/kg	1 februari 2007	31 januari 2017	DEEL A Mag alleen worden toegelaten voor gebruik als insecticide. DEEL B Voor de toepassing van de uniforme beginselen in bijlage VI moet rekening worden gehouden met de conclusies van het evaluatieverslag over thiamethoxam, met name de aanhangsels I en II, dat op 14 juli 2006 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd. Bij deze algemene evaluatie moeten de lidstaten: — bijzondere aandacht besteden aan de mogelijke verontreiniging van het grondwater, met name door de werkzame stof en de metabolieten NOA 459602, SYN 501406 en CGA 322704, wanneer de werkzame stof wordt gebruikt in gebieden met kwetsbare bodem- en/of klimatologische omstandigheden; — bijzondere aandacht besteden aan de bescherming van waterorganismen; — bijzondere aandacht besteden aan het risico op de lange termijn voor kleine herbivore dieren, wanneer de stof wordt gebruikt voor de behandeling van zaad. De gebruiksvoorwaarden moeten, indien nodig, risicobeperkende maatregelen omvatten.”

([1]) Het evaluatieverslag bevat nadere gegevens over de identiteit en de specificatie van de werkzame stof.

17.8.2007 NL Publicatieblad van de Europese Unie L 214/3

RICHTLIJNEN

RICHTLIJN 2007/52/EG VAN DE COMMISSIE

van 16 augustus 2007

tot wijziging van Richtlijn 91/414/EEG van de Raad teneinde ethoprofos, pirimifos-methyl en fipronil op te nemen als werkzame stoffen

(Voor de EER relevante tekst)

DE COMMISSIE VAN DE EUROPESE GEMEENSCHAPPEN,

Gelet op het Verdrag tot oprichting van de Europese Gemeenschap,

Gelet op Richtlijn 91/414/EEG van de Raad van 15 juli 1991 betreffende het op de markt brengen van gewasbeschermingsmiddelen (1), en met name op artikel 6, lid 1,

Overwegende hetgeen volgt:

(1) Bij de Verordeningen (EG) nr. 451/2000 (2) en (EG) nr. 703/2001 (3) van de Commissie zijn de bepalingen voor de uitvoering van de tweede fase van het werkprogramma zoals bedoeld in artikel 8, lid 2, van Richtlijn 91/414/EEG vastgesteld en is een lijst opgesteld van werkzame stoffen die moeten worden beoordeeld met het oog op hun eventuele opneming in bijlage I bij Richtlijn 91/414/EEG. Ethoprofos, pirimifos-methyl en fipronil zijn in deze lijst opgenomen.

(2) Voor deze werkzame stoffen zijn de uitwerking op de menselijke gezondheid en het milieu beoordeeld overeenkomstig de Verordeningen (EG) nr. 451/2000 en (EG) nr. 703/2001 voor een aantal door de kennisgevers voorgestelde toepassingen. Bovendien worden in die verordeningen de als rapporteur optredende lidstaten aangewezen die overeenkomstig artikel 8, lid 1, van Verordening (EG) nr. 451/2000 de desbetreffende beoordelingsverslagen met aanbevelingen bij de Europese Autoriteit voor voedselveiligheid (EFSA) moeten indienen. Voor ethoprofos en pirimifos-methyl was het Verenigd Koninkrijk de rapporterende lidstaat en was alle relevante informatie ingediend op 19 januari 2004 respectievelijk 4 november 2003. Voor fipronil was de rapporterende lidstaat Frankrijk en werd alle relevante informatie ingediend op 10 februari 2004.

(3) De beoordelingsverslagen zijn door de lidstaten en de EFSA intercollegiaal getoetst en zijn op 3 maart 2006 voor ethoprofos, op 18 augustus 2005 voor pirimifos-methyl en op 3 maart 2006 voor fipronil bij de Commissie ingediend in de vorm van de wetenschappelijke verslagen van de EFSA (4). Deze verslagen zijn door de lidstaten en de Commissie in het kader van het Permanent Comité voor de voedselketen en de diergezondheid onderzocht en op 16 maart 2007 afgerond in de vorm van de evaluatieverslagen van de Commissie over ethoprofos, pirimifos-methyl en fipronil.

(4) Uit de verschillende analyses is gebleken dat mag worden verwacht dat gewasbeschermingsmiddelen die ethoprofos, pirimifos-methyl en fipronil bevatten, in het algemeen voldoen aan de in artikel 5, lid 1, onder a) en b), van Richtlijn 91/414/EEG gestelde eisen, met name voor de toepassingen die zijn onderzocht en opgenomen in de evaluatieverslagen van de Commissie. Deze werkzame stoffen moeten derhalve in bijlage I worden opgenomen om ervoor te zorgen dat gewasbeschermingsmiddelen die deze werkzame stoffen bevatten, in alle lidstaten kunnen worden toegelaten overeenkomstig het bepaalde in die richtlijn.

(5) Onverminderd deze conclusie moet ten aanzien van ethoprofos, pirimifos-methyl en fipronil nadere informatie over bepaalde aspecten worden verkregen. In artikel 6, lid 1, van Richtlijn 91/414/EEG wordt bepaald dat aan de opneming van een werkzame stof in bijlage I voorwaarden kunnen worden verbonden. Daarom moet worden geëist dat ethoprofos, pirimifos-methyl en fipronil ter bevestiging van de risicobeoordeling voor sommige toepassingen aan verdere tests worden onderworpen en dat de kennisgevers deze studies voorleggen.

(1) PB L 230 van 19.8.1991, blz. 1. Richtlijn laatstelijk gewijzigd bij Richtlijn 2007/31/EG van de Commissie (PB L 140 van 1.6.2007, blz. 44).
(2) PB L 55 van 29.2.2000, blz. 25. Verordening laatstelijk gewijzigd bij Verordening (EG) nr. 1044/2003 (PB L 151 van 19.6.2003, blz. 32).
(3) PB L 98 van 7.4.2001, blz. 6.

(4) EFSA Scientific Report (2006) 63, 1-72, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance ethoprophos (finalised: 3 March 2006). EFSA Scientific Report (2005) 44, 1-53, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance pirimiphos-methyl (finalised: 30 August 2005). EFSA Scientific Report (2006) 65, 1-110, Conclusion regarding the Peer review of the pesticide risk assessment of the active substance fipronil (finalised: 3 March 2006, version of 12 April 2006).

(6) Er moet worden voorzien in een redelijke termijn voordat een werkzame stof in bijlage I wordt opgenomen, zodat de lidstaten en de belanghebbende partijen zich kunnen voorbereiden op de nieuwe eisen die uit de opneming voortvloeien.

(7) Onverminderd de verplichtingen zoals vastgelegd in Richtlijn 91/414/EEG ten gevolge van de opneming van een werkzame stof in bijlage I, moeten de lidstaten na de opneming zes maanden de tijd krijgen om de bestaande toelatingen voor gewasbeschermingsmiddelen die ethoprofos, pirimifos-methyl en fipronil bevatten, opnieuw te onderzoeken om ervoor te zorgen dat aan de voorwaarden van Richtlijn 91/414/EEG, met name in artikel 13 en bijlage I, is voldaan. De lidstaten moeten de bestaande toelatingen zo nodig vervangen of intrekken overeenkomstig Richtlijn 91/414/EEG. In afwijking van de bovenvermelde termijn moet een langere termijn worden vastgesteld voor de indiening en beoordeling van het volledige in bijlage III vermelde dossier voor elk gewasbeschermingsmiddel en elke beoogde toepassing overeenkomstig de uniforme beginselen van Richtlijn 91/414/EEG.

(8) Bij eerdere opnemingen in bijlage I bij Richtlijn 91/414/EEG van werkzame stoffen die in het kader van Verordening (EEG) nr. 3600/92 van de Commissie [1] zijn onderzocht, is gebleken dat de uitlegging van de verplichtingen van houders van bestaande toelatingen wat de toegang tot gegevens betreft tot problemen kan leiden. Om meer problemen te voorkomen, moeten de verplichtingen van de lidstaten daarom worden verduidelijkt, en met name de plicht om te verifiëren dat de houder van een toelating toegang tot een dossier verschaft en dat deze aan de vereisten van bijlage II bij die richtlijn voldoet. Deze verduidelijking legt de lidstaten of de houders van toelatingen echter ten opzichte van de tot nu toe goedgekeurde richtlijnen tot wijziging van bijlage I geen nieuwe verplichtingen op.

(9) Richtlijn 91/414/EEG moet daarom dienovereenkomstig worden gewijzigd.

(10) De in deze richtlijn vervatte maatregelen zijn in overeenstemming met het advies van het Permanent Comité voor de voedselketen en de diergezondheid,

HEEFT DE VOLGENDE RICHTLIJN VASTGESTELD:

Artikel 1

Bijlage I bij Richtlijn 91/414/EEG wordt gewijzigd overeenkomstig de bijlage bij deze richtlijn.

Artikel 2

De lidstaten dienen uiterlijk op 31 maart 2008 de nodige wettelijke en bestuursrechtelijke bepalingen vast te stellen en bekend te maken om aan deze richtlijn te voldoen. Zij delen de Commissie de tekst van die bepalingen onverwijld mee, alsmede een tabel ter weergave van het verband tussen die bepalingen en deze richtlijn.

Zij passen die bepalingen toe vanaf 1 april 2008.

Wanneer de lidstaten die bepalingen aannemen, wordt in die bepalingen zelf of bij de officiële bekendmaking daarvan naar deze richtlijn verwezen. De regels voor die verwijzing worden vastgesteld door de lidstaten.

Artikel 3

1. De lidstaten moeten overeenkomstig Richtlijn 91/414/EEG zo nodig bestaande toelatingen voor gewasbeschermingsmiddelen die ethoprofos, pirimifos-methyl en fipronil als werkzame stof bevatten, uiterlijk op 31 maart 2008 wijzigen of intrekken.

Uiterlijk op die datum verifiëren zij met name dat aan de voorwaarden van bijlage I bij die richtlijn met betrekking tot ethoprofos, pirimifos-methyl en fipronil is voldaan, met uitzondering van de voorwaarden in deel B van de tekst betreffende die werkzame stof, en dat de houder van de toelating in het bezit is van of toegang heeft tot een dossier dat overeenkomstig de voorwaarden van artikel 13 van die richtlijn aan de eisen van bijlage II bij die richtlijn voldoet.

2. In afwijking van lid 1 moeten de lidstaten op basis van een dossier conform bijlage III bij Richtlijn 91/414/EEG en rekening houdend met deel B van de tekst van bijlage I bij die richtlijn over respectievelijk ethoprofos, pirimifos-methyl en fipronil, overeenkomstig de uniforme beginselen in bijlage VI bij die richtlijn een nieuwe evaluatie uitvoeren van elk toegelaten gewasbeschermingsmiddel dat ethoprofos, pirimifos-methyl en fipronil bevat als enige werkzame stof of als een van een aantal werkzame stoffen die alle uiterlijk op 30 september 2007 in bijlage I bij die richtlijn zijn opgenomen. Op basis van die evaluatie bepalen zij of het middel voldoet aan de voorwaarden van artikel 4, lid 1, onder b), c), d) en e), van Richtlijn 91/414/EEG.

Daarna zorgen de lidstaten ervoor dat:

a) als ethoprofos, pirimifos-methyl of fipronil de enige werkzame stof in het gewasbeschermingsmiddel is, de toelating indien nodig uiterlijk op 30 september 2011 wordt gewijzigd of ingetrokken, of;

[1] PB L 366 van 15.12.1992, blz. 10. Verordening laatstelijk gewijzigd bij Verordening (EG) nr. 2266/2000 (PB L 259 van 13.10.2000, blz. 27).

b) als het gewasbeschermingsmiddel naast ethoprofos, pirimifos-methyl of fipronil nog één of meer andere werkzame stoffen bevat, de toelating uiterlijk verstrijkt op 30 september 2011 of, als dat later is, op de datum die voor een dergelijke wijziging of intrekking is vastgesteld in de richtlijnen waarbij die stoffen aan bijlage I bij Richtlijn 91/414/EEG zijn toegevoegd, wordt gewijzigd of ingetrokken.

Artikel 4

Deze richtlijn treedt in werking op 1 oktober 2007.

Artikel 5

Deze richtlijn is gericht tot de lidstaten.

Gedaan te Brussel, 16 augustus 2007.

Voor de Commissie
Markos KYPRIANOU
Lid van de Commissie

BIJLAGE

Aan het einde van de tabel in bijlage I bij Richtlijn 91/414/EEG wordt de volgende tekst toegevoegd:

Nr.	Benaming, identificatienummers	IUPAC-benaming	Zuiverheid [illegible]	Inwerkingtreding	Geldigheidsduur	Bijzondere bepalingen
161	Ethoprofos CAS-nr. 13194-48-4 CIPAC-nr. 218	O-ethyl-S,S-dipropylfosforodithioaat	≥ 940 g/kg	1 oktober 2007	30 september 2017	DEEL A Alleen gebruik van de stof als nematicide en insecticide bij bodembehandeling mag worden toegestaan. Toelatingen dienen te worden beperkt tot professionele gebruikers. DEEL B Bij het beoordelen van aanvragen voor toelating van gewasbeschermingsmiddelen die ethoprofos bevatten voor andere toepassingen [illegible] aardappelen, moeten de lidstaten bijzondere aandacht besteden aan de criteria in artikel 4, lid 1, onder b), en ervoor zorgen dat de vereiste informatie en gegevens worden verstrekt voordat de toelating wordt verleend. Voor de toepassing van de uniforme beginselen in bijlage VI moet rekening worden gehouden met de conclusies van het beoordelingsverslag over ethoprofos dat op 16 maart 2007 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd, en met name met de aanhangsels I en II. Bij die algemene evaluatie moeten de lidstaten bijzondere aandacht besteden aan: — de residuen en de beoordeling van de blootstelling van de consument via de voeding, met het oog op latere herzieningen van de residumaximumgehalten; — de veiligheid van de gebruikers. De toegestane gebruiksvoorwaarden moeten de toepassing van geschikte persoonlijke beschermingsmiddelen en ademhalingsbeschermingsmiddelen en andere risicobeperkende maatregelen, zoals het gebruik van een gesloten transfersysteem voor de verdeling van het product, voorschrijven; — de bescherming van vogels, zoogdieren, in het water levende organismen en oppervlakte- en grondwater in kwetsbare omstandigheden. De toelatingsvoorwaarden moeten risicobeperkende maatregelen omvatten, zoals bufferzones en de volledige inwerking van de korrels in de bodem. De betrokken lidstaten verzoeken om aanvullende studies ter bevestiging van de risicobeoordeling voor vogels en zoogdieren. Zij dragen er zorg voor dat de kennisgever die om opneming van ethoprofos in deze bijlage heeft verzocht, deze studies binnen twee jaar na inwerkingtreding van deze richtlijn bij de Commissie indient.

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

Nr.	Benaming, identificatienummers	IUPAC-benaming	Zuiverheid (1)	Inwerkingtreding	Expiratiedatum	Specifieke bepalingen
143	Fipronil CAS-nr. 120068-37-3 CIPAC-nr. 581	(±)-5-amino-1-(2,6-dichloor-α,α,α-trifluor-para-tolyl)-4-trifluormethylsulfinylpyrazool-3-carbonitril	≥ 950 g/kg	1 oktober 2007	30 september 2017	DEEL A Alleen toepassingen als insecticide voor gebruik als zaadbehandelingsmiddel mogen worden toegelaten. De zaadcoating mag alleen plaatsvinden in professionele zaadbehandelingsinstallaties. Deze installaties moeten de beste beschikbare technieken gebruiken, zodat kan worden uitgesloten dat er tijdens opslag, vervoer en toepassing stofwolken vrijkomen. DEEL B Voor de toepassing van de uniforme beginselen in bijlage VI moet rekening worden gehouden met de conclusies van het evaluatieverslag over fipronil (en met name met de aanhangsels I en II), dat op 16 maart 2007 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd. Bij de algemene evaluatie moeten de lidstaten bijzondere aandacht schenken aan: — de verpakking van de in de handel gebrachte producten om te voorkomen dat fotodegradatieproducten worden gevormd die aanleiding geven tot problemen; — de mogelijkheid van grondwaterverontreiniging, met name met metabolieten die persistenter zijn dan de oorspronkelijke stof, wanneer de werkzame stof wordt toegepast in gebieden met kwetsbare bodem- en/of klimaatomstandigheden; — de bescherming van zaadetende vogels en zoogdieren, in het water levende organismen, niet tot de doelsoorten behorende geleedpotigen en honingbijen; — het gebruik van geschikte apparatuur waarmee een hoge mate van inwerking in de bodem wordt bereikt en morsen tijdens de toediening tot een minimum wordt beperkt. De toelatingsvoorwaarden moeten, indien nodig, risicobeperkende maatregelen omvatten. De betrokken lidstaten verzoeken om aanvullende studies ter bevestiging van de risicobeoordeling voor zaadetende vogels en zoogdieren, en honingbijen, met name broedsel. Zij dragen er zorg voor dat de kennisgever die om opneming van fipronil in deze bijlage heeft verzocht, deze studies binnen één jaar na inwerkingtreding van deze richtlijn bij de Commissie indient."

(1) Het verslag over de beoordeling van de werkzame stof bevat nadere gegevens over de identiteit en de specificatie van de werkzame stof.

L 337/86 NL Publicatieblad van de Europese Unie 16.12.2008

RICHTLIJNEN

RICHTLIJN 2008/116/EG VAN DE COMMISSIE

van 15 december 2008

tot wijziging van Richtlijn 91/414/EEG van de Raad teneinde aclonifen, imidacloprid en metazachloor op te nemen als werkzame stoffen

(Voor de EER relevante tekst)

DE COMMISSIE VAN DE EUROPESE GEMEENSCHAPPEN,

Gelet op het Verdrag tot oprichting van de Europese Gemeenschap,

Gelet op Richtlijn 91/414/EEG van de Raad van 15 juli 1991 betreffende het op de markt brengen van gewasbeschermingsmiddelen (1), en met name op artikel 6, lid 1,

Overwegende hetgeen volgt:

(1) Bij de Verordeningen (EG) nr. 451/2000 (2) en (EG) nr. 1490/2002 (3) van de Commissie zijn de bepalingen voor de uitvoering van de derde fase van het werkprogramma als bedoeld in artikel 8, lid 2, van Richtlijn 91/414/EEG vastgesteld en is een lijst opgesteld van werkzame stoffen die moeten worden onderzocht met het oog op hun opneming in bijlage I bij Richtlijn 91/414/EEG. Aclonifen, imidacloprid en metazachloor zijn in die lijst opgenomen.

(2) Voor deze werkzame stoffen zijn de uitwerking op de menselijke gezondheid en het milieueffect overeenkomstig de Verordeningen (EG) nr. 451/2000 en (EG) nr. 1490/2002 beoordeeld voor een aantal door de kennisgevers voorgestelde toepassingen. Bovendien worden in die verordeningen de als rapporteur optredende lidstaten aangewezen die overeenkomstig artikel 10, lid 1, van Verordening (EG) nr. 1490/2002 de desbetreffende evaluatieverslagen met aanbevelingen bij de Europese Autoriteit voor voedselveiligheid (EFSA) moeten indienen. Voor aclonifen en imidacloprid was Duitsland de rapporterende lidstaat en werd alle relevante informatie op 11 september 2006 respectievelijk 13 juni 2006 ingediend. Voor metazachloor was het Verenigd Koninkrijk de rapporterende lidstaat en werd alle relevante informatie ingediend op 30 september 2005.

(3) De evaluatieverslagen zijn door de lidstaten en de EFSA intercollegiaal getoetst en op 31 juli 2008 voor aclonifen, op 29 mei 2008 voor imidacloprid en op 14 april 2008 voor metazachloor bij de Commissie ingediend in de vorm van de wetenschappelijke verslagen van de EFSA (4). Deze verslagen zijn door de lidstaten en de Commissie in het kader van het Permanent Comité voor de voedselketen en de diergezondheid onderzocht en op 26 september 2008 afgerond in de vorm van de evaluatieverslagen van de Commissie voor aclonifen, imidacloprid en metazachloor.

(4) Uit de verschillende analyses is gebleken dat mag worden verwacht dat gewasbeschermingsmiddelen die aclonifen, imidacloprid of metazachloor bevatten, in het algemeen voldoen aan de in artikel 5, lid 1, onder a) en b), van Richtlijn 91/414/EEG gestelde eisen, met name voor de toepassingen die zijn onderzocht en zijn opgenomen in de evaluatieverslagen van de Commissie. Deze werkzame stoffen moeten derhalve in bijlage I worden opgenomen om ervoor te zorgen dat gewasbeschermingsmiddelen die deze werkzame stoffen bevatten, in alle lidstaten kunnen worden toegelaten overeenkomstig het bepaalde in die richtlijn.

(5) Onverminderd deze conclusie moet nadere informatie over bepaalde specifieke punten worden ingewonnen. Artikel 6, lid 1, van Richtlijn 91/414/EEG bepaalt dat aan de opneming van een werkzame stof in bijlage I voorwaarden kunnen worden verbonden. Daarom moet worden geëist dat aclonifen aan verdere tests wordt onderworpen ter bevestiging van de residuen in vruchtgewassen en ter bevestiging van de risicobeoordeling voor vogels, zoogdieren, in het water levende organismen en niet tot de doelsoorten behorende planten, dat imidacloprid verder wordt getest ter bevestiging van de risicobeoordeling voor de toedieners en werknemers en het risico

(1) PB L 230 van 19.8.1991, blz. 1.
(2) PB L 55 van 29.2.2000, blz. 25.
(3) PB L 224 van 21.8.2002, blz. 23.
(4) EFSA Scientific Report (2008) 149, Conclusion regarding the peer review of the pesticide risk assessment of the active substance aclonifen (afgerond 31 juli 2008).
EFSA Scientific Report (2008) 148, Conclusion regarding the peer review of the pesticide risk assessment of the active substance imidacloprid (afgerond 29 mei 2008).
EFSA Scientific Report (2008) 145, Conclusion regarding the peer review of the pesticide risk assessment of the active substance metazachlor (afgerond 14 april 2008).

voor regels en toegelaten en dat deze studies door de kennisgever werden ingediend. Verder moet wat metazachloor betreft, voor bepaalde punten nadere informatie worden verlangen. In artikel 6, lid 3, van Richtlijn 91/414/EEG is bepaald dat opneming van een werkzame stof op de voorwaarden kan worden herzien als er aanwijzingen zijn dat niet langer aan de in de leden 1 en 2 van dat artikel genoemde voorwaarden wordt voldaan. De kennisgever heeft informatie ingediend die op dit moment voldoende geacht wordt om de relevantie van bepaalde metabolieten te beoordelen. Metazachloor is echter nog niet definitief ingedeeld overeenkomstig Richtlijn 67/548/EEG van de Raad van 27 juni 1967 betreffende de aanpassing van de wettelijke en bestuursrechtelijke bepalingen inzake de indeling, de verpakking en het kenmerken van gevaarlijke stoffen (¹). Indien hiervoor een indeling wordt genomen, kan nadere informatie over die metabolieten nodig zijn. De door de kennisgever ingediende informatie ter beoordeling van de relevantie van de metabolieten 479M04, 479M08, 479M09, 479M11 en 479M12 ten aanzien van kanker wordt op dit moment voldoende geacht. Indien echter een indeling wordt genomen krachtens Richtlijn 67/548/EEG waarbij metazachloor wordt ingedeeld als „carcinogene effecten zijn niet uitgesloten", is nadere informatie nodig over de relevantie van die metabolieten ten aanzien van kanker. Artikel 6, lid 1, van Richtlijn 91/414/EEG bepaalt dat aan de opneming van een werkzame stof in bijlage I bij die richtlijn voorwaarden kunnen worden verbonden. Aan de opneming van metazachloor moet daarom een voorwaarde worden verbonden betreffende de indiening van nadere informatie ingeval die stof overeenkomstig Richtlijn 67/548/EEG wordt ingedeeld.

(6) Er moet worden voorzien in een redelijke termijn voordat een werkzame stof in bijlage I wordt opgenomen, zodat de lidstaten en de belanghebbende partijen zich kunnen voorbereiden op de nieuwe eisen die uit de opneming voortvloeien.

(7) Onverminderd de verplichtingen zoals vastgelegd in Richtlijn 91/414/EEG ten gevolge van de opneming van een werkzame stof in bijlage I, moeten de lidstaten na de opneming zes maanden de tijd krijgen om de bestaande toelatingen voor gewasbeschermingsmiddelen die adventstoffen, metazachloor of [illegible] bevatten opnieuw te onderzoeken en ervoor te zorgen dat aan de voorwaarden van Richtlijn 91/414/EEG, met name in artikel 13 en bijlage I, is voldaan. De lidstaten moeten de bestaande toelatingen naargelang het geval wijzigen, vervangen of intrekken overeenkomstig Richtlijn 91/414/EEG. In afwijking van de bovenstaande termijn moet een langere termijn worden vastgesteld voor de indiening en beoordeling van het volledige in bijlage III vermelde dossier voor elk gewasbeschermingsmiddel en elke beoogde toepassing overeenkomstig de uniforme beginselen van Richtlijn 91/414/EEG.

(8) Bij eerdere opnemingen in bijlage I bij Richtlijn 91/414/EEG van werkzame stoffen die in het kader van Verordening (EEG) nr. 3600/92 van de Commissie (²) zijn onderzocht, is gebleken dat de uitlegging van de verplichtingen van houders van bestaande toelatingen met die toegang tot gegevens betreft tot problemen kan leiden. Om verdere problemen te voorkomen, moeten de verplichtingen van de lidstaten daarom worden verduidelijkt, en met name de plicht om te verifiëren of de houder van een toelating toegang tot een dossier verschaft dat aan de vereisten van bijlage II bij die richtlijn voldoet. Deze verduidelijking legt de lidstaten of de houders van toelatingen echter ten opzichte van de tot nu toe vastgestelde richtlijnen tot wijziging van bijlage I geen nieuwe verplichtingen op.

(9) Richtlijn 91/414/EEG moet daarom dienovereenkomstig worden gewijzigd.

(10) De in deze richtlijn vervatte maatregelen zijn in overeenstemming met het advies van het Permanent Comité voor de voedselketen en de diergezondheid,

HEEFT DE VOLGENDE RICHTLIJN VASTGESTELD:

Artikel 1

Bijlage I bij Richtlijn 91/414/EEG wordt gewijzigd overeenkomstig de bijlage bij deze richtlijn.

Artikel 2

De lidstaten dienen uiterlijk op 31 januari 2010 de nodige wettelijke en bestuursrechtelijke bepalingen vast te stellen en bekend te maken om aan deze richtlijn te voldoen. Zij delen de Commissie de tekst van die bepalingen onverwijld mede, alsmede een tabel ter weergave van het verband tussen die bepalingen en deze richtlijn.

Zij passen die bepalingen toe vanaf 1 februari 2010.

Wanneer de lidstaten die bepalingen aannemen, wordt in die bepalingen zelf of bij de officiële bekendmaking daarvan naar deze richtlijn verwezen. De regels voor die verwijzing worden vastgesteld door de lidstaten.

Artikel 3

1. De lidstaten moeten overeenkomstig Richtlijn 91/414/EEG, indien nodig bestaande toelatingen voor gewasbeschermingsmiddelen die adventstoffen, [illegible] of metazachloor als werkzame stof bevatten, uiterlijk op 31 januari 2010 wijzigen of intrekken.

(¹) PB 196 van 16.8.1967, blz. 1.

(²) PB L 366 van 15.12.1992, blz. 10.

Uiterlijk op die datum verifiëren zij met name of aan de voorwaarden van bijlage I bij die richtlijn met betrekking tot aclonifen, imidacloprid en metazachloor is voldaan, met uitzondering van de voorwaarden in deel B van de tekst betreffende die werkzame stoffen, en of de houder van de toelating in het bezit is van of toegang heeft tot een dossier dat overeenkomstig de voorwaarden van artikel 13 van die richtlijn aan de eisen van bijlage II bij die richtlijn voldoet.

2. In afwijking van lid 1 voeren de lidstaten op basis van een dossier conform bijlage III bij Richtlijn 91/414/EEG en rekening houdend met deel B van de tekst van bijlage I bij die richtlijn wat aclonifen, imidacloprid en metazachloor betreft, overeenkomstig de uniforme beginselen in bijlage VI bij die richtlijn een nieuwe evaluatie uit voor elk toegelaten gewasbeschermingsmiddel dat aclonifen, imidacloprid of metazachloor bevat als enige werkzame stof of als een van een aantal werkzame stoffen die alle uiterlijk op 31 juli 2009 in bijlage I bij die richtlijn zijn opgenomen. Aan de hand van die evaluatie bepalen zij of het gewasbeschermingsmiddel voldoet aan de voorwaarden van artikel 4, lid 1, onder b), c), d) en e), van die richtlijn.

Daarna zorgen de lidstaten ervoor dat:

a) als aclonifen, imidacloprid of metazachloor de enige werkzame stof in het gewasbeschermingsmiddel is, de toelating indien nodig uiterlijk op 31 januari 2014 wordt gewijzigd of ingetrokken, of

b) wanneer het een product betreft dat aclonifen, imidacloprid of metazachloor als een van de werkzame stoffen bevat, de toelating zo nodig wordt gewijzigd of ingetrokken, en wel uiterlijk op 31 januari 2014 of, mocht dit later zijn, op de datum die voor een dergelijke wijziging of intrekking is vastgesteld in de richtlijn of richtlijnen waarbij de stof of stoffen in kwestie aan bijlage I bij Richtlijn 91/414/EEG is of zijn toegevoegd.

Artikel 4

Deze richtlijn treedt in werking op 1 augustus 2009.

Artikel 5

Deze richtlijn is gericht tot de lidstaten.

Gedaan te Brussel, 15 december 2008.

Voor de Commissie
Androulla VASSILIOU
Lid van de Commissie

BIJLAGE

Aan het einde van de tabel in bijlage I bij Richtlijn 91/414/EEG wordt de volgende rij toegevoegd:

Nr.	Gangbare benaming, identificatienummers	IUPAC-naam	Zuiverheid [1]	Inwerkingtreding	Geldigheidsduur	Specifieke bepalingen
„225	Aclonifen CAS-nr. 74070-46-5 CIPAC-nr. 498	2-Chloor-6-nitro-3-fenoxyaniline	≥ 970 g/kg De verontreiniging fenol wordt als toxicologisch relevant aangemerkt; als specificatie voor het technisch materiaal wordt een maximumgehalte van 5 g/kg vastgesteld.	1 augustus 2009	31 juli 2019	DEEL A Mag alleen worden toegelaten voor gebruik als herbicide. DEEL B Bij het beoordelen van aanvragen voor toelating van gewasbeschermingsmiddelen die aclonifen bevatten voor andere toepassingen dan op zonnebloemen, moeten de lidstaten bijzondere aandacht besteden aan de criteria in artikel 4, lid 1, onder b), en ervoor zorgen dat de vereiste informatie en gegevens worden verstrekt voordat de toelating wordt verleend. Voor de toepassing van de uniforme beginselen in bijlage VI wordt rekening gehouden met de conclusies van het evaluatieverslag over aclonifen, met name met de aanhangsels I en II, dat op 26 september 2008 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd. Bij die algemene evaluatie moeten de lidstaten bijzondere aandacht besteden aan: — de specificatie van het technische materiaal zoals commercieel vervaardigd; die moet bevestigd en met passende analytische gegevens onderbouwd zijn. Het in de toxiciteitsdossiers gebruikte testmateriaal moet worden vergeleken met deze specificatie van het technische materiaal en aan de hand daarvan worden geverifieerd; — de veiligheid van de toedieners. De toegelaten gebruiksvoorwaarden moeten de toepassing van geschikte persoonlijke beschermingsmiddelen en risicobeperkende maatregelen ter vermindering van de blootstelling voorschrijven; — de residuen in wisselgewassen en de evaluatie van blootstelling van de consument via de voeding; — de bescherming van vogels, zoogdieren, in het water levende organismen en niet tot de doelsoorten behorende planten. Ten aanzien van deze risico's moeten zo nodig risicobeperkende maatregelen, zoals bufferzones, worden toegepast. De betrokken lidstaten verzoeken om overlegging van aanvullende studies betreffende residuen in wisselgewassen en relevante informatie ter bevestiging van de risicobeoordeling voor vogels, zoogdieren, in het water levende organismen en niet tot de doelsoorten behorende planten. Zij zorgen ervoor dat de kennisgevers dergelijke gegevens en informatie ter bevestiging van de risicobeoordeling binnen twee jaar na de inwerkingtreding van deze richtlijn aan de Commissie verstrekken.

Nr.	Gangbare benaming, identificatienummers	IUPAC-naam	Zuiverheid (¹)	Inwerkingtreding	Geldig tot	Specifieke bepalingen
212	Imidacloprid CAS nr. 138261-41-3 CIPAC nr. 582	(E)-1-(6-Chloor-3-pyridinyl-methyl)-N-nitroimidazolidin-2-ylideenamine	≥ 970 g/kg	1 augustus 2009	31 juli 2019	DEEL A Mag alleen worden toegelaten voor gebruik als insecticide. Met het oog op de bescherming van niet tot de doelsoorten behorende organismen, met name honingbijen en vogels, bij gebruik als zaadbehandelingsmiddel: — mag de zaadcoating alleen plaatsvinden in professionele zaadbehandelingsinstallaties. Deze installaties moeten de beste beschikbare technische middelen gebruiken, zodat kan worden uitgesloten dat er tijdens opslag, vervoer en toepassing stofwolken vrijkomen; — moet bij de toepassing adequate apparatuur worden gebruikt waardoor een hoge mate van inwerking in de bodem wordt bereikt en morsen tijdens de toepassing en de productie van stofwolken tot een minimum worden beperkt. De lidstaten zorgen ervoor dat op het etiket van behandeld zaad wordt vermeld dat het zaad met imidacloprid is behandeld en dat de in de toelating opgenomen risicobeperkende maatregelen worden aangegeven. DEEL B Bij het beoordelen van aanvragen voor toelating van gewasbeschermingsmiddelen die imidacloprid bevatten voor andere toepassingen dan tomaten in kassen, moeten de lidstaten bijzondere aandacht besteden aan de criteria in artikel 4, lid 1, onder b), en ervoor zorgen dat de nodige informatie en gegevens worden verstrekt voordat de toelating wordt verleend. Voor de toepassing van de uniforme beginselen in bijlage VI moet rekening worden gehouden met de conclusies van het evaluatieverslag over imidacloprid, met name met de aanhangsels I en II, die op 26 september 2008 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd. Bij deze algemene beoordeling moeten de lidstaten bijzondere aandacht besteden aan: — de veiligheid van de toediener en de werknemers, waarbij ervoor moet worden gezorgd dat in de gebruiksvoorwaarden de toepassing van geschikte persoonlijke beschermingsmiddelen wordt voorgeschreven; — de gevolgen voor in het water levende organismen, niet tot de doelsoorten behorende geleedpotigen, regenwormen en andere bodemmacro-organismen, waarbij ervoor moet worden gezorgd dat de toelatingsvoorwaarden zo nodig risicobeperkende maatregelen omvatten; — de bescherming van honingbijen, met name bij sproeitoepassingen, waarbij ervoor moet worden gezorgd dat de toelatingsvoorwaarden zo nodig risicobeperkende maatregelen omvatten. De betrokken lidstaten moeten verzoeken om overlegging van: — informatie voor de verdere beoordeling van het risico voor toediener en werknemers; — informatie voor de verdere beoordeling van het risico voor vogels en zoogdieren. Zij zorgen ervoor dat de kennisgevers die gegevens en informatie ter bevestiging van de risicobeoordeling binnen twee jaar na de inwerkingtreding van deze richtlijn aan de Commissie verstrekken.

Nr.	Benaming, identificatienummers	IUPAC-naam	Zuiverheid (*)	Goedkeuring	Vervaldatum	Specifieke bepalingen
215	Metazachloor CAS-nr. 67129-08-2 CIPAC-nr. 411	2-Chloor-N-(pyrazool-1-yl-methyl)acet-2',6'-xylidide	≥ 940 g/kg De fabricageonzuiverheid tolueen wordt als toxicologisch relevant beschouwd en bevat een maximumgehalte van 0,05 % vastgesteld.	1 augustus 2009	31 juli 2019	DEEL A De stof mag alleen worden toegelaten voor gebruik als herbicide, waarbij slechts één dosis per drie jaar op hetzelfde perceel maximaal 1,0 kg/ha mag worden toegepast. DEEL B Voor de toepassing van de uniforme beginselen in bijlage VI moet rekening worden gehouden met de conclusies van het evaluatieverslag over metazachloor, en met name met de aanhangsels I en II, die op 26 september 2008 door het Permanent Comité voor de voedselketen en de diergezondheid is goedgekeurd. Bij de algemene evaluatie moeten de lidstaten bijzondere aandacht besteden aan: — de veiligheid van de sprayers, waarbij ervoor moet worden gezorgd dat in de gebruiksvoorschriften de toepassing van geschikte persoonlijke beschermingsmiddelen wordt voorgeschreven; — de bescherming van in het water levende organismen; — de bescherming van het grondwater, wanneer de werkzame stof wordt gebruikt in gebieden met kwetsbare bodem- en/of klimatologische omstandigheden. De betrokken lidstaten moeten risicobeperkende maatregelen vaststellen en er moeten zo nodig monitoringprogramma's worden ingesteld om mogelijke grondwaterverontreiniging met de metabolieten 479M04, 479M08, 479M09, 479M11 en 479M12 in kwetsbare gebieden te controleren. Als metazachloor overeenkomstig Richtlijn 67/548/EEG wordt ingedeeld als carcinogeen categorie 3, verzoeken de betrokken lidstaten om overlegging van verdere informatie over de relevantie van de metabolieten 479M04, 479M08, 479M09, 479M11 en 479M12 ten aanzien van kanker. Zij zorgen ervoor dat de kennisgevers die informatie binnen zes maanden na de kennisgeving van een dergelijk indelingsbesluit aan de Commissie verstrekken.'

(*) Het evaluatieverslag bevat nadere gegevens over de identiteit en de specificaties van de werkzame stof.

Toelatingsnr.	Middelnaam	Categorie	Werkzame stof	Wijziging in WGGA
12679	ACTARA	Gewasbeschermingsmiddel	thiamethoxam	ja
13178	ADMIRE	Gewasbeschermingsmiddel	imidacloprid	ja
11483	ADMIRE	Gewasbeschermingsmiddel	imidacloprid	ja
12945	ADMIRE N	Gewasbeschermingsmiddel	imidacloprid	advies
11998	ADMIRE N PIN	Gewasbeschermingsmiddel	imidacloprid	nee
12942	ADMIRE O-TEQ	Gewasbeschermingsmiddel	imidacloprid	ja
13399	AGITA 10 WG	Biocide	thiamethoxam	nee
11662	AMIGO FLEX	Gewasbeschermingsmiddel	imidacloprid	nee
13063	AMOS FLY FINISH	Biocide	imidacloprid	nee
13215	AXORIS QUICK-GRAN	Gewasbeschermingsmiddel	thiamethoxam	nee
13216	AXORIS QUICK-STICKS	Gewasbeschermingsmiddel	thiamethoxam	nee
12952	BAYTHION MIERENMIDDEL N	Biocide	imidacloprid	nee
12913	CRUISER 350 FS	Gewasbeschermingsmiddel	thiamethoxam	ja
12852	CRUISER 70 WS	Gewasbeschermingsmiddel	thiamethoxam	ja
12863	CRUISER SB	Gewasbeschermingsmiddel	thiamethoxam	nee
13104	FINION MIERENLOKDOOS	Biocide	imidacloprid	nee
11455	GAUCHO	Gewasbeschermingsmiddel	imidacloprid	nee
11601	GAUCHO ROOD	Gewasbeschermingsmiddel	imidacloprid	nee
12341	GAUCHO TUINBOUW	Gewasbeschermingsmiddel	imidacloprid	ja
12919	GAZON-INSECT	Gewasbeschermingsmiddel	imidacloprid	advies
12119	GOLIATH AASSTATIONS	Biocide	fipronil	nee
12120	GOLIATH GEL	Biocide	fipronil	nee
13026	HGX KORRELS TEGEN MIEREN	Biocide	imidacloprid	nee
13127	HGX MIERENLOKDOOS	Biocide	imidacloprid	nee
11547	IMEX-IMIDACLOPRID	Gewasbeschermingsmiddel	imidacloprid	ja
13363	KOHINOR 70 WG	Gewasbeschermingsmiddel	imidacloprid	ja
13160	LURECTRON FLYBAIT	Biocide	imidacloprid	nee
12974	MAXFORCE LN	Biocide	imidacloprid	nee
13073	MAXFORCE LN MIERENLOKDOOS	Biocide	imidacloprid	nee
13250	MAXFORCE PRIME	Biocide	imidacloprid	nee
13074	MAXFORCE QUANTUM	Biocide	imidacloprid	ja
12094	MAXFORCE WHITE IC	Biocide	imidacloprid	nee
13321	MERIT TURF	Gewasbeschermingsmiddel	imidacloprid	nee
13052	MIEREN STOP	Biocide	imidacloprid	nee
13059	MONAMI	Gewasbeschermingsmiddel	imidacloprid	ja
13173	MS VB-08	Biocide	imidacloprid	nee
12802	MUNDIAL	Gewasbeschermingsmiddel	fipronil	ja
12977	MUNDIAL	Gewasbeschermingsmiddel	fipronil	ja
13384	MUNDIAL	Gewasbeschermingsmiddel	fipronil	nee
13055	PIRON MIERENLOKDOOS	Biocide	imidacloprid	nee
13072	PIRON MIERENLOKDOOS	Biocide	imidacloprid	nee
12979	PIRON MIERENMIDDEL	Biocide	imidacloprid	nee
12980	POKON MIEREN	Biocide	imidacloprid	nee
13121	POKON MIEREN STOP LOKDOOS	Biocide	imidacloprid	nee
12219	POKON PLANTSTICK	Gewasbeschermingsmiddel	imidacloprid	nee
13044	PONCHO BETA	Gewasbeschermingsmiddel	clothianidine	nee
13276	PONCHO ROOD	Gewasbeschermingsmiddel	clothianidine	nee
12115	PROVADO GARDEN	Gewasbeschermingsmiddel	imidacloprid	advies

12665	QUICK BAYT	Biocide	imidacloprid	nee
13116	QUICK BAYT SPRAY	Biocide	imidacloprid	nee
13124	ROXASECT MIERENLOKDOOS	Biocide	imidacloprid	nee
13351	ROXASECT RAAMSTICKER	Biocide	imidacloprid	nee
13024	ROXASECT TEGEN TUINMIEREN	Biocide	imidacloprid	nee
13280	VAPONA RAAMSTICKER	Biocide	imidacloprid	nee
13369	VLIEGENSTICKER	Biocide	imidacloprid	nee