HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 UITBREIDING TOELATING

Gelet op de aanvraag d.d. 22 november 2013 (20131539 NLKUGB) van

Dow AgroSciences B.V.
Sneeuwbeslaan 20 bus 10
B-2610 WILRIJK
BELGIË

tot uitbreiding van de gebruiksdoeleinden van de toelating van het gewasbeschermingsmiddel, op basis van de werkzame stof spinosad

TRACER

gelet op artikel 51 (EG) nr 1107/2009 en artikel 2.2 Regeling gewasbescherming en biociden,

BESLUIT HET COLLEGE als volgt:

1.1 Uitbreiding

1. Het gebruiksgebied van het middel TRACER wordt met ingang van datum dezes uitgebreid met de toepassing in de onbedekte teelt van braam- en framboosachtigen, sla, andijvie, rucola, tuinkers, veldsla, courgette, augurk, vruchtgroenten van *Cucurbitaceae* met niet-eetbare schil, stengelkool, kruidenteelt vers of gedroogd; de teelt van aardbei, spinazie-achtigen en witlof (trekteelt); en de bedekte teelt van boon met peul, sluitkoolachtigen, bloemkool en broccoli, Chinese kool, koolraap en koolrabi. Voor de gronden waarop dit besluit berust wordt verwezen naar bijlage II bij dit besluit.
2. De toelating geldt tot 1 mei 2020.

1.2 Samenstelling, vorm en verpakking

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

1.3 Gebruik

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

1.4 Classificatie en etikettering

Gelet op artikel 31 en artikel 65 van de Verordening EG/1107/2009 worden voorschriften gegeven.

Dit leidt tot de volgende voorschriften:

De aanduidingen, welke moeten worden vermeld, worden hierbij vastgesteld als volgt:

aard van het preparaat: Suspensie concentraat

werkzame stof:	*gehalte:*
spinosad	480 g/l

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:

-

PICTOGRAM(MEN)

pictogram:
GHS09-milieu

SIGNAALWOORD

Waarschuwing

Gevarenaanduidingen

H410	Zeer giftig voor in het water levende organismen, met langdurige gevolgen.

Voorzorgsmaatregelen

SP 1	-Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
P391	Gelekte/gemorste stof opruimen.
P501	Inhoud/verpakking afvoeren naar inzamelpunt voor gevaarlijk of bijzonder afval.

Aanvullende etiketelementen

EUH208	Bevat 1,2-benzisothiazolin-3-one. Kan een allergische reactie veroorzaken.
EUH401	Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.

Behalve de voorgeschreven aanduidingen en vermeldingen moeten op de verpakking voorkomen:

a. letterlijk en zonder enige aanvulling:
het wettelijk gebruiksvoorschrift
De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I.
b. bij het toelatingsnummer een cirkel met daarin de aanduiding W.4.

De nieuwe etikettering dient bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. Oude verpakkingen mogen worden opgemaakt.

2 DETAILS VAN DE AANVRAAG

2.1 Aanvraag

Het betreft een aanvraag tot uitbreiding van het gebruiksgebied van het middel TRACER (12567 N), een middel op basis van de werkzame stof spinosad. Het middel is bij besluit van 4 juni 2004 en uitbreiding van 10 juni 2011 reeds toegelaten als
- d.m.v. een gewasbehandeling:
  a. in de bedekte teelt van aardbei;
  b. In de bedekte teelt van sla;
  c. in de bedekte teelt van andijvie-achtigen;
  d. in de bedekte teelt van rucola, tuinkers en veldsla;
  e. in de bedekte teelt van courgette, augurk, pompoen-achtigen, meloen en watermeloen;
  f. in de bedekte teelt van komkommer;
  g. in de bedekte teelt van aubergine, tomaat, paprika en Spaanse peper,
  h. in de teelt van sluitkool (rode kool, savooie kool, spitskool, witte kool), spruitkool en bloemkool;
  i. in de teelt van zaaiui, 1e en 2e jaars plantui, bosui, zilverui, picklers, zaai- en plantsjalotten;
  j. in de teelt van prei, met uitzondering van de opkweek van preiplantgoed;
  k. In de bedekte aspergeveredeling, -opkweek en -zaadteelt;
  l. In de bedekte teelt van kruiden.
-d.m.v. een trayplaatbehandeling
  m. In de teelt van sluitkool (rode kool, savooie kool, spitskool, witte kool), spruitkool, bloemkool, broccoli, Chinese kool (incl. Oosterse bladkolen), koolraap en koolrabi.

Het middel is bij dit besluit toegelaten tot 1 mei 2020. Met onderliggende aanvraag wordt toelating gevraagd als insectenbestrijdingsmiddel in de onbedekte teelt van sla, andijvie, rucola, tuinkers, veldsla, courgette, augurk, vruchtgroenten van *Cucurbitaceae* met niet-eetbare schil, stengelkool, kruidenteelt vers of gedroogd; de teelt van aardbei, druiven, braam- en framboosachtigen, spinazie-achtigen en witlof (trekteelt); en de bedekte teelt van boon met peul, sluitkoolachtigen, bloemkool en broccoli, Chinese kool, koolraap en koolrabi.

2.2 Informatie met betrekking tot de stof

De werkzame stof spinosad is bij Richtlijn 2007/6/EG van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 91/414/EEG.

2.3 Karakterisering van het middel

Spinosad is een insecticide welke is afgeleid van de actinomyceet *Saccharopolyspora spinosa*. Het product bestaat uit een mengsel van twee structuur gerelateerde metabolieten, Spinosyn A and Spinosyn D. Beide componenten vertonen vergelijkbare insecticide activiteit.
Spinosad is werkzaam via zowel inname als extern contact. Beide componenten zijn weinig systemisch, maar worden in de plant opgenomen via het bladoppervlak. Spinosad is zowel werkzaam tegen een groot aantal soorten *Lepidoptera*, *Thysanoptera* and *Diptera*, als ook tegen een aantal blad-etende *Coleoptera* plagen. Spinosad doodt gevoelige soorten door snelle excitatie van het zenuwstelsel van het insect. De stof heeft een relatief snelle werking; 1-2 dagen na opname worden de insecten gedood.

2.4 Voorgeschiedenis
De aanvraag is op 28 november 2013 ontvangen; op 19 december 2013 zijn de verschuldigde aanvraagkosten ontvangen. Bij brief d.d. 11 juni 2014 is de aanvraag in behandeling genomen.

3 RISICOBEOORDELINGEN
De beoordeling van deze aanvraag is conform RGB (Hoofdstuk 2) bestaande uit de werkinstructies RGB (tox en mil) en voor de overige aspecten HTB 1.0.

3.1 Fysische en chemische eigenschappen
De identiteit en de fysische en chemische eigenschappen van het middel en de werkzame stof wijzigen niet.

3.2 Analysemethoden
De analysemethoden voor de werkzame stoffen en het middel wijzigen niet. Voor de toegelaten toepassingen voldoen de vereiste residuanalysemethoden.

3.3 Risico voor de mens
Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu
Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid
Gelet op artikel 51 Verordening (EG) 1107/2009 is de aanvraag niet beoordeeld voor het aspect werkzaamheid (inclusief fytotoxiciteit).

3.6 Eindconclusie
Bij gebruik volgens het Wettelijk Gebruiksvoorschrift heeft het middel TRACER op basis van de werkzame stof spinosad geen schadelijke uitwerking op de gezondheid van de mens en het milieu.

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 7 januari 2015

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

ir. J.F. de Leeuw
voorzitter

Dit middel is uitsluitend bestemd voor professioneel gebruik

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I bij het besluit d.d. 7 januari 2015 tot uitbreiding van de toelating van het middel TRACER, toelatingnummer 12567 N

Wettelijk Gebruiksvoorschrift
Toegestaan is uitsluitend het professionele gebruik als insectenbestrijdingsmiddel in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximale dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen
Komkommer	Gewasbehandeling	trips[2]	0,02% (20 ml/100 l)	0,3 l/ha	3 per teeltcyclus en 5 per 12 maanden	7	1
Tomaat	Gewasbehandeling	trips[2]	0,02% (20 ml/100 l)	0,3 l/ha	5 per 12 maanden	7	1
Paprika	Gewasbehandeling	trips[2]	0,02% (20 ml/100 l)	0,3 l/ha	5 per 12 maanden	7	1
Sluitkoolachtigen (onbedekte teelt)	Gewasbehandeling	rupsen[1]	0,2 l/ha	0,2 l/ha	4 per 12 maanden	10	3
	Traybehandeling	Vliegen en muggen[4]	12,5 ml/1000 planten	12,5 ml/1000 planten	1 per teeltcyclus	-	-
Bloemkool (onbedekte teelt)	Gewasbehandeling	rupsen[1]	0,2 l/ha	0,2 l/ha	4 per 12 maanden	10	3
	Traybehandeling	Vliegen en muggen[4]	12,5 ml/1000 planten	12,5 ml/1000 planten	1 per teeltcyclus	-	-
Broccoli (onbedekte teelt)	Traybehandeling	Vliegen en muggen[4]	12,5 ml/1000 planten	12,5 ml/1000 planten	1 per teeltcyclus		
Uien	Gewasbehandeling	trips[3]	0,2 l/ha	0,2 l/ha	4 per 12 maanden	10	7
Sjalotten	Gewasbehandeling	trips[3]	0,2 l/ha	0,2 l/ha	4 per 12 maanden	10	7
Bosuien (onbedekte teelt)	Gewasbehandeling	trips[3]	0,2 l/ha	0,2 l/ha	4 per 12 maanden	10	7
Prei (met uitzondering	Gewasbehandeling	trips[3]	0,2 l/ha	0,2 l/ha	4 per 12 maanden	10	7

van preiplantgoed) (onbedekte teelt)							

[1] Koolwitje (*Pieris rapae*), kooluil (*Mamestra brassicae*), koolmot (*Plutella xylostella*)
[2] Californische trips (*Frankliniella occidentalis*)
[3] Tabakstrips (*Thrips tabaci*)
[4] Koolvlieg (*Delia brassica*)

Het gebruik in de bedekte teelt van aardbei, sla, andijvie, rucola, tuinkers, veldsla, courgette, augurk, vruchtgroenten van *Cucurbitaceae* met niet-eetbare schil, aubergine, asperge en kruidenteelt vers of gedroogd; en de onbedekte teelt van Chinese kool, koolraap en koolrabi is op basis van een “derdenuitbreiding”. Deze “derdenuitbreiding” is aangevraagd door de Stichting Trustee Bijzondere Toelatingen. Er is voor deze uitbreiding geen werkzaamheids- en fytotoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in deze toepassingsgebieden, komt voor risico en verantwoordelijkheid van de gebruiker.

Het gebruik in de onbedekte teelt van aardbei, braam- en framboosachtigen, sla, andijvie, rucola, tuinkers, veldsla, courgette, augurk, vruchtgroenten van *Cucurbitaceae* met niet-eetbare schil, stengelkool, kruidenteelt vers of gedroogd; de teelt van spinazie-achtigen en witlof (trekteelt); en de bedekte teelt van boon met peul, sluitkoolachtigen, bloemkool en broccoli, Chinese kool, koolraap en koolrabi is op basis van een “derdenuitbreiding” en beoordeeld conform artikel 51 EG 1107/2009. Deze “derdenuitbreiding” is aangevraagd door de Stichting Trustee Bijzondere Toelatingen. Er is voor deze uitbreiding geen werkzaamheids- en fytotoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in dit/deze toepassingsgebied(en), komt voor risico en verantwoordelijkheid van de gebruiker.

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximale dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen
Aardbei	Gewasbehandeling	trips, rupsen, vliegen en muggen[5]	0,15 l/ha	0,15 l/ha	3 per 12 maanden	7	1
Braam- en framboosachtigen (onbedekte teelt)	Gewasbehandeling	trips, rupsen, vliegen en muggen[5]	0,16-0,2 l/ha	0.2 L/ha	2 per 12 maanden	10	3
Sla (*Lactuca* spp)	Gewasbehandeling	trips, rupsen	0,2 l/ha	0,2 l/ha	3 per teeltcyclus en 5 per 12 maanden	7	3
Andijvie	Gewasbehandeling	trips, rupsen	0,2 l/ha	0,2 l/ha	3 per teeltcyclus en 5 per 12 maanden	7	3

Spinazie-achtigen	Gewasbehandeling	vliegen en muggen[6], mineervlieg, rupsen	0,2 l/ha	0,6 l/ha	3 per teeltcyclus	7-10	3
Witlof (trekteelt)	Gewasbehandeling op de kraag	Mineervlieg[7]	0,5 mL/m²	0,5 mL/m²	1 per teeltcyclus	-	18
Tuinkers	Gewasbehandeling	trips, rupsen	0,2 l/ha	0,2 l/ha	3 per teeltcyclus en 5 per 12 maanden	7	3
Veldsla	Gewasbehandeling	trips, rupsen	0,2 l/ha	0,2 l/ha	2 per teeltcyclus en 5 per 12 maanden	7	14
Rucola	Gewasbehandeling	trips, rupsen	0,2 l/ha	0,2 l/ha	3 per teeltcyclus en 5 per 12 maanden	7	3
Boon met peul (bedekte teelt)	Gewasbehandeling	trips, rupsen	0,08-0,25 l/ha	0,75 l/ha	2 per teeltcyclus	7	7
Augurk	Gewasbehandeling	trips, rupsen	0,02% (20 ml/100 l)	0,16 l/ha	5 per 12 maanden	7	1
Courgette	Gewasbehandeling	trips, rupsen	0,02% (20 ml/100 l)	0,2 l/ha	5 per 12 maanden	7	1
Vruchtgroenten van *Cucurbitaceae* met niet-eetbare schil	Gewasbehandeling	trips, rupsen	0,02% (20mL/100 L)	0,2 l/ha	5 per 12 maanden	7	1
Aubergine	Gewasbehandeling	trips[2]	0,02% (20 ml/100 l)	0,2 l/ha	5 per 12 maanden	7	1
Sluitkoolachtigen (bedekte teelt)	Traybehandeling	vliegen en muggen[4]	12,5 ml/1000 planten	12,5 ml/1000 planten	1 per teeltcyclus	-	-
Bloemkool (bedekte teelt)	Traybehandeling	vliegen en muggen[4]	12,5 ml/1000 planten	12,5 ml/1000 planten	1 per teeltcyclus	-	-
Broccoli (bedekte teelt)	Traybehandeling	vliegen en muggen[4]	12,5 ml/1000 planten	12,5 ml/1000 planten	1 per teeltcyclus	-	-
Chinese Kool	Traybehandeling	vliegen en muggen[4]	12,5 ml/1000 planten	12,5 ml/1000 planten	1 per teeltcyclus	-	-
Koolrabi	Traybehandeling	vliegen en muggen[4]	12,5 ml/1000 planten	12,5 ml/1000 planten	1 per teeltcyclus	-	-
Koolraap	Traybehandeling	vliegen en muggen[4]	12,5 ml/1000 planten	12,5 ml/1000 planten	1 per teeltcyclus	-	-

Asperge (veredeling, opkweek, zaadteelt) (bedekte teelt)	Gewasbehandeling	trips	0,02% (20 ml/100 l)	0,2 l/ha	3 per teeltcyclus	7	-
Kruidenteelt vers of gedroogd	Gewasbehandeling	trips, rupsen	0,2 l/ha	0,2 l/ha	3 per teeltcyclus en 5 per 12 maanden	7	3

[2] Californische trips (*Frankliniella occidentalis*)
[4] Koolvlieg (*Delia brassica*)
[5] Suzuki fruitvlieg (*Drosophila suzuki*)
[6] Bietenvlieg (*Pegomya hyoscyami*)
[7] Witlofmineervlieg (*Napomyza cichorii*)

Toepassingsvoorwaarden
De traybehandeling in de teelt van sluitkool, spruitkool, bloemkool, broccoli, Chinese kool, koolraap en koolrabi, en de kraagbehandeling in witlof, moet worden uitgevoerd op een ondoordringbaar oppervlak (bv. beton).

Om het grondwater te beschermen mag dit product niet worden toegepast in grondwaterbeschermingsgebieden.

Om in het water levende organismen te beschermen is toepassing in de onbedekte teelt van sluitkool, spruitkool, bloemkool, uien, sjalotten, bosuien en prei op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van 90% drift reducerende doppen.

Om water levende organismen en niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing in de onbedekte teelt van aardbei, sla, andijvie, spinazie-achtigen, rucola, tuinkers, veldsla, boon met peul, courgette, augurk, vruchtgroenten van *Cucurbitaceae* met niet-eetbare schil en kruiden uitsluitend toegestaan wanneer in de eerste 14 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van spuitapparatuur met lage spuitboomhoogte (maximaal 30 cm boven de top van het gewas) met driftarme Venturidoppen en een kantdop en luchtondersteuning in combinatie met een teeltvrije zone van 1,5 meter (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens).

Om water levende organismen en niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing in braam- en framboosachtigen uitsluitend toegestaan wanneer in de eerste 20 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van één van onderstaande maatregelen:
-Venturidoppen (minimaal 90% driftreducerend) met ventilatorstand ‘laag’ in combinatie met éénzijdige bespuiting van de laatste bomenrij in de richting van het perceel met inachtneming van een teeltvrije zone van tenminste 4,5 meter;
- een Wannerspuit met reflectieschermen en venturidoppen (minimaal 90% driftreducerend) (Lechler ID 90-015C) met inachtneming van een teeltvrije zone van tenminste 4,5 meter;

-een KWH k1500-3R2 VLOS 3-rijenspuit met variabele luchtondersteuning en minimaal 90% driftreducerende spuitdoppen en ventilatorstand "laag" in de eerste 20 meter van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij met inachtneming van een teeltvrije zone van tenminste 3 meter.

Om de zoogdieren te beschermen is toepassing in braam- en framboosachtigen uitsluitend toegestaan na BBCH 51 (ontwikkeling bloeiwijze).

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 in de buurt van in bloei staand onkruid. 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. Verwijder of bedek bijenkorven en hommelkasten tijdens het gebruik van het product en gedurende één dag na de behandeling en vergewis u ervan dat de spuitvloeistof volledig opgedroogd is in de kas. Voorkom dat bijen en andere bestuivende insecten de kas binnenkomen door alle openingen met insectengaas af te sluiten.

Dit middel is schadelijk voor natuurlijke vijanden. Vermijd onnodige blootstelling.

Indien nog geen ervaring met het middel is opgedaan dient middels een proefbespuiting vastgesteld te worden of het gewas of het ras het middel verdraagt.

<u>Resistentiemanagement</u>
Dit middel bevat de werkzame stof spinosad. Spinosad behoort tot de spinosynen. De Irac code is 5. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 7 januari 2015 tot uitbreiding van de toelating van het middel TRACER, toelatingnummer 12567 N

Bijlage II

RISKMANAGEMENT

Contents

1. Identity of the plant protection product

1.1 Applicant

Dow AgroSciences B.V.
Sneeuwbeslaan 20 bus 10
2160 Wilrijk
Belgium

1.2 Identity of the active substance

The identity of the active substance(s) does not change.

Common name	Spinosad
Name in Dutch	Spinosad
Chemical name	IUPAC name: mixture of 50-95% of (2*R*,3a*S*,5a*R*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-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-1*H*-8-oxacyclododeca[*b*]*as*-indacene-7,15-dione and 50-5% (2*S*,3a*R*,5a*S*,5b*S*,9*S*,13*S*,14*R*,16a*S*,16b*R*)-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-1*H*-8-oxacyclododeca[*b*]*as*-indacene-7,15-dione
CAS no	168316-95-8 (131929-60-7 + 131929-63-0)
EC no	Not allocated

The active substance was included in Annex I of Directive 91/414/EEC on 1 February 2007. From 14 June 2011 forward, according to Reg. (EU) No 540/2011 the substance is approved under Reg. (EC) No 1107/2009, repealing Directive 91/414/EEC.

1.3 Identity of the plant protection product

The identity of the plant protection product does not change.

Name	TRACER
Formulation type	SC
Content active substance	480g/L pure spinosad

The formulation is identical to that assessed for the inclusion of the active substance in Annex I of Directive 91/414/EEC.

1.4 Function

Insecticide.

1.5 Uses applied for

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation**	**F G or I**	**Pests or Group of pests controlled**	**Application**			**Application rate per treatment**			**PHI** (days)	**Remarks:** a) max. no. of applications per crop and season b) Maximum product rate per season c) additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	kg, L product / ha	kg as/ha	Water L/ha min / max		
Minor uses according to article 51												
18	NL	Strawberry	G	thrips & caterpillar drosophila suzukii	Foliar treatment	19-87 Feb-nov	1-3 (7)	0.15-0.15	0.072-0.072	1000-1500	1	
27	NL	Pumpkin species	G	Thrips & caterpillars	Foliar treatment	21-71 Feb-nov	1-5 (7)	0.1-0.2	0.048-0.096	500-1000	1	
38	NL	Lettuce	F	Thrips & caterpillars	Foliar treatment	13-49 Jun-Sept	1-3 (7)	0.2-0.2	0.096-0.096	200-800	3	
39	NL	Endive species	F	thrips & caterpillar	Foliar treatment	13-49 Jun-Sept	1-3 (7)	0.2-0.2	0.096-0.096	200-800	3	
40	NL	Rocket	F	Thrips & caterpillars	Foliar treatment	13-49 Jun-Sept	1-3 (7)	0.2-0.2	0.096-0.096	200-800	3	
41	NL	Garden cress	F	Thrips & caterpillars	Foliar treatment	13-49 Jun-Sept	1-3 (7)	0.2-0.2	0.096-0.096	200-800	3	
42	NL	Lambs Lettuce	F	Thrips & caterpillars	Foliar treatment	13-49 Jun-Sept	1-2 (7)	0.2-0.2	0.096-0.096	200-800	14	
43	NL	Zucchini	F	Thrips & caterpillars	Foliar treatment	21-71 Jun-Sept	1-5 (7)	0.1-0.2	0.048-0.096	200-800	1	
44	NL	Gherkin	F	thrips & caterpillar	Foliar treatment	21-71 Jun-Sept	1-5 (7)	0.1-0.2	0.048-0.096	200-800	1	
45	NL	Pumpkin species	F	Thrips & caterpillars	Foliar treatment	21-71 Jun-Sept	1-5 (7)	0.1-0.2	0.048-0.096	200-800	1	
46	NL	Melon	F	Thrips & caterpillars	Foliar treatment	21-71 Jun-Sept	1-5 (7)	0.1-0.2	0.048-0.096	200-800	1	
47	NL	Watermelon	F	Thrips & caterpillars	Foliar	21-71	1-5 (7)	0.1-0.2	0.048-0.096	200-800	1	

					treatment	Jun-Sept						
48	NL	Herbs	F	Thrips & caterpillars	Foliar treatment	13-49 Jun-Sept	1-3 (7)	0.2-0.2	0.096-0.096	200-800	3	3 treatments per cropcycle and 5 treatments per 12 months
49	NL	Witloof	I	Liriomyzae leafminer *Napomyza cichorii*	Collar treatment	directly after filling forcing container 'intafelen'	1	0.5 mL/m²	0.24 g as/m²	1-3L/m²	18	
50	NL	Cauliflower	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
51	NL	Broccoli	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
52	NL	Head cabbage	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
53	NL	Brussels sprouts	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
54	NL	Chinese cabbage	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
55	NL	Swede	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
56	NL	Kohlrabi	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
57	NL	Eastern leaf Cabbage	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
58	NL	Strawberry	F	thrips & caterpillars drosophila suzuki	Foliar treatment	19-87 May-Oct	1-3 (7)	0.15-0.15	0.072-0.072	1000-1500	1	
59	NL	Wine grapes	F	thrips & caterpillars drosophila suzuki	Foliar treatment	unspecified May-Oct	1-3 (14)	0.0725-0.15	0.0384-0.072	800-1500	14	
60	NL	Table grapes	G	thrips & caterpillars drosophila suzuki	Foliar treatment	unspecified May-Oct	1-3 (14)	0.0725-0.15	0.0384-0.072	800-1500	14	
61	NL	Raspberry	F	thrips & caterpillars	Foliar	unspecified	1-2 (10)	0.16-0.2	0.077-0.096	800-1500	3	

				drosophila suzuki	treatment	Jun-Sept						
62	NL	Raspberry	G	thrips & caterpillars drosophila suzuki	Foliar treatment	unspecified May-Nov	1-2 (10)	0.16-0.2	0.077-0.096	800-1500	3	
63	NL	Blackberry	F	thrips & caterpillars drosophila suzuki	Foliar treatment	unspecified Jun-Sept	1-2 (10)	0.16-0.2	0.077-0.096	800-1500	3	
64	NL	Blackberry	G	thrips & caterpillars drosophila suzuki	Foliar treatment	unspecified May-Nov	1-2 (10)	0.16-0.2	0.077-0.096	800-1500	3	
65	NL	Spinach family	F	Leafminers, beetfly, caterpillars	Foliar treatment	13-49 Apr-Sept	1-3 (7-10)	0.2-0.2	0.096-0.096	200-800	3	
66	NL	Beans with pods	G	Caterpillars, Thrips	Foliar treatment	up to BBCH 79 Mar-Oct	1-3 (7-10)	0.08-0.25	0.038-0.12	200-1000	7	

Red = new minor use

1.6 Background to the application
It concerns a simplified extension of the authorization with minor uses.

1.7 Packaging details

1.7.1 Packaging description
Packaging does not change.

2. Physical and chemical properties

The physical and chemical properties of the active substance(s) and the formulation do not change.

3. Methods of analysis

3.1 Analytical methods in technical material and plant protection product

The analytical methods for the technical material and the plant protection product do not change.

3.2 Residue analytical methods

In the tables below the methods are presented, considered acceptable at the last full evaluation of Tracer.

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	HPLC-UV, column switching method (watery matrices and chili pepper, LOQ: 0.01 mg/kg (Spinosyn A, Spinosyn D, Spinosyn B, Spinosyn K and N-demethyl Spinosyn D individually) ELISA method, LOQ: 0.01 mg/kg (Spinosyn A) LC/MS/MS. LOQ 0.01 mg/kg (Spinosyn A, Spinosyn D, Spinosyn B, Spinosyn K and N-demethyl Spinosyn D individually)
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	*HPLC-UV method GRM 95.03 for the determination of spinosad residues in animal matrices.* *Spinosyn A and D, spinosyn B and N-demethyl-spinosyn D:* *LOQ = 0.01 mg/kg (milk, cream, beef tissue, beef liver, beef kidney, beef fat, eggs, chicken meat, liver, fat)* *Confirmatory method: different HPLC conditions* *ILV: yes, for beef tissues, milk and cream and poultry tissues and eggs.*

Based on the proposed extension for use, residue analytical methods for food/feed of plant origin are required for matrices with a high water content (e.g. swede, grapes, cabbage, melon).

Definition of the residue and MRLs for spinosad		
Matrix	**Definition of the residue for monitoring**	**MRL**
Food/feed of plant	spinosad, sum of spinosyn A and	≥0.02 mg/kg

origin	spinosyn D	
Food/feed of animal origin	spinosad, sum of spinosyn A and spinosyn D	Milk: 0.05 mg/kg Muscle: 0.02 mg/kg Kidney: 0.10 mg/kg Liver: 0.20 mg/kg Fat: 1.0 mg/kg

The residue analytical methods, included in the abovementioned List of Endpoints, are suitable for monitoring of the MRLs. Therefore, the intended extension for use is covered by the risk-envelope of the current authorisation.

The residue analytical methods for air, soil and water were accepted during the assessment of the original authorization of Tracer. This simplified extension does not give rise to re-assess these residue analytical methods.

3.3 Conclusion

The proposed extension for use is covered by the risk envelope of the existing authorisation for the section residue analytical methods.

4. Mammalian toxicology

List of Endpoints

The final list of endpoints presented below is taken from the final review report on spinosad (SANCO/1428/2004 – final, d.d. 14 July 2006). Where relevant, some additional remarks are given in italics.

Absorption, distribution, excretion and metabolism in mammals (Annex IIA, point 6.1)

Rate and extent of absorption:	rapid; spinosyn A: 60%, spinosyn D: 45% (based on urinary and bile excretion, and tissue residues)
Distribution:	widely distributed (perirenal fat, liver, kidneys, thyroid)
Potential for accumulation:	limited (T½ = 2.5 - 42 h)
Rate and extent of excretion:	rapid: > 90% in 168 h
Metabolism in animals	extensive metabolism (N- and O-demethylated spinosyns and/or glutathion conjugates)
Toxicologically significant compounds (animals, plants and environment)	parent compound and metabolites

Acute toxicity (Annex IIA, point 6.2)

Rat LD_{50} oral	> 2000 mg/kg bw (rat)
Rat LD_{50} dermal	> 5000 mg/kg bw (rabbit)
Rat LC_{50} inhalation	> 5.18 mg/l (rat)
Skin irritation	not irritating
Eye irritation	not irritating
Skin sensitisation (test method used and result)	not sensitising (M & K)

Short term toxicity (Annex IIA, point 6.3)

Target / critical effect	vacuolation in several tissues in various species.
Lowest relevant oral NOAEL / NOEL	4.89 mg/kg bw/day (50 ppm: 90-d, dogs)

Lowest relevant dermal NOAEL / NOEL	1000 mg/kg bw/day (21-day, rabbit)
Lowest relevant inhalation NOAEL / NOEL	≥ 9.5 mg/m^3

Genotoxicity (Annex IIA, point 6.4)	no genotoxic potential*

**In vitro: Ames test, mouse lymphoma cell test (TK), Chromosomose aberration (CHO-WB$_L$) and rat liver UDS; in vivo: mouse micronucleus. All negative.*

Long term toxicity and carcinogenicity (Annex IIA, point 6.5)

Target/critical effect	vacuolation in several tissues in various species
Lowest relevant NOAEL / NOEL	2.4 mg/kg bw/day (24 m rat)
Carcinogenicity	no carcinogenic potential

Reproductive toxicity (Annex IIA, point 6.6)

Reproduction target / critical effect	decrease in litter size, survival and body weight at parental toxic levels.
Lowest relevant NOAEL / NOEL	10 mg/kg bw/day (rat) for parental, developmental and reproductive toxicity
Developmental target / critical effect	no developmental effects at maternal toxic levels.
Lowest relevant developmental NOAEL / NOEL	maternal toxicity: 10 mg/kg bw/day (rabbit) developmental toxicity: > 50 mg/kg bw/day (rabbit)

Neurotoxicity / Delayed neurotoxicity (Annex IIA, point 6.7)

no evidence of neurotoxicity in acute, subchronic and chronic studies

Other toxicological studies (Annex IIA, point 6.8)

metabolites: spinosyn B and K; acute oral > 2000 mg/kg bw, Ames test negative. Spinosyn D has a lower toxicity than Spinosyn A. Recovery of vacuolation of the thyroid after 22 w, and of the kidneys after 2 w. Genotoxicity studies *in vitro* (Ames, HGPRT, Chrom. Abber.) with samples from lysimeter study were negative.

Medical data (Annex IIA, point 6.9)

no reports of adverse effects in manufacturing, workers or users

Summary (Annex IIA, point 6.10)

	Value	Study	Safety factor
ADI	0.024 mg/kg bw/day	24-month rat	100
AOEL$_{systemic}$ short-term	0.024 mg/kg bw/day	90-day dog	100, 50% correction for oral absorption
AOEL$_{systemic}$ long-term	0.012 mg/kg bw/day	24-month rat	100, 50%

			correction for oral absorption
ARfD (acute reference dose)	Not allocated, not necessary		

Dermal absorption (Annex IIIA, point 7.3)

0.1% for the concentrated formulation; 2% for a concentration comparable to the spray liquid

Local effects
Spinosad does not produce local effects, neither after a single nor repeated exposure.

Data requirements active substance
No additional data requirements are identified.

4.1 Toxicity of the formulated product (IIIA 7.1)
The formulation TRACER does not need to be classified on the basis of its acute oral (LD_{50} rat >5000 mg/kg bw), dermal (LD_{50} rat > 2000 mg/kg bw) and inhalation toxicology (LC_{50} rat > 5.8 mg/L).
The formulation TRACER is not classifiable as a skin or eye irritant.
The formulation TRACER does not have sensitising properties in a Maximisation test.

4.1.1 Data requirements formulated product
No additional data requirements are identified.

4.2 Dermal absorption (IIIA 7.3)
See List of Endpoints. The values in the List of Endpoints are for the formulation TRACER.

4.3 Available toxicological data relating to non-active substances (IIIA 7.4)
None of the other formulants raise concerns that have not been addressed in the submitted studies.

4.4 Exposure/risk assessments

Overview of the intended uses
An application has been submitted for a minor use extension of the authorisation of the plant protection product Tracer, an insecticide based on the active substance spinosad.

Tracer is an SC formulation and contains 480 g/L spinosad.

4.4.1 Operator exposure/risk
According to the Dutch Plant Protection Products and Biocides Regulations the risk assessment is performed according to a tiered approach. There are four possible tiers:
Tier 1: Risk assessment using the EU-AOEL without the use of PPE
Tier 2: Risk assessment using the NL-AOEL without the use of PPE
Tier 3: Refinement of the risk assessment using new dermal absorption data
Tier 4: Prescription of PPE

<u>Tier 1</u>

Calculation of the EU-AOEL / Tolerable Limit Value (TLV)
For spinosad no TLV has been set. The AOEL will be used for the risk assessment.

For the field uses the application is 1-5 times during June-September, with at least a 7 day interval. For the greenhouse uses the application is 1-3 times during May-November, with at least a 10 day interval. For tray treatment the application is once during January-December. Considering this interval and/or the rather rapid excretion (>90% in 168 h), a semi-chronic exposure is applicable for all new uses.

Since spinosad is included in Annex I of 91/414/EEC, the semi-chronic EU-AOEL of 0.024 mg/kg bw/day (= 1.68 mg/day for a 70-kg operator), based on the 90-day study in dogs, is used for the risk assessment (see List of Endpoints).

Exposure/risk

Exposure to spinosad during mixing and loading and application of Tracer is estimated with models. The exposure is estimated for the unprotected operator. In general, mixing and loading and application is performed by the same person. Therefore, for the total exposure, the respiratory and dermal exposure during mixing/loading and application have to be combined.

In the Table below the estimated internal exposure is compared with the systemic EU-AOEL. For a minor use extension only the intended uses which are not under the risk envelope of the previous authorisation are assessed below.

Table T.1 Internal operator exposure to spinosad and risk assessment for the use of TRACER

	Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Manual downward spraying on strawberry, herbs, garden cress, (uncovered, 0.096 kg a.s./ha, 200 L/ha)				
Mixing/ Loading[c]	Respiratory	< 0.01	1.68	< 0.01
	Dermal	0.0125	1.68	0.01
Application[d]	Respiratory	0.0576	1.68	0.03
	Dermal	0.9792	1.68	0.58
	Total	1.0493	1.68	0.62
Mechanical upward spraying on gherkin, strawberry, wine grapes, raspberry, blackberry (uncovered, 0.096 kg a.s./ha)				
Mixing/ Loading[e]	Respiratory	< 0.01	1.68	< 0.01
	Dermal	0.0115	1.68	0.01
Application[e]	Respiratory	0.0173	1.68	0.01
	Dermal	0.8755	1.68	0.52
	Total	0.9072	1.68	0.54
Manual upward spraying on strawberry, wine grapes, raspberry and blackberry (uncovered, 0.096 kg a.s./ha)				
Mixing/ Loading[c]	Respiratory	< 0.01	1.68	< 0.01
	Dermal	0.0125	1.68	0.01
Application[f]	Respiratory	0.1162	1.68	0.07
	Dermal	1.0679	1.68	0.64
	Total	1.1965	1.68	0.71

a Internal exposure was calculated with:
- biological availability via the dermal route: 0.1% (concentrate) and 2% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.

c External exposure is estimated with EUROPOEM (dermal) and NL-model (inhalation).
d External exposure is estimated with UK POEM model.
e External exposure is estimated with EUROPOEM.
f External exposure is estimated with German model (90th percentile).

Since the EU-AOEL is not exceeded without the use of PPE, a higher tier assessment is not required.

4.4.2 Bystander exposure/risk

The exposure is estimated for the unprotected bystander. In Table T.2 the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.2 Internal bystander exposure to spinosad and risk assessment during application of TRACER

Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Bystander exposure during application in gherkin, strawberry, wine grapes, raspberry, blackberry (uncovered, 0.096 kg a.s./ha)			
Respiratory	0.036	1.68	0.02
Dermal	0.019	1.68	0.01
Total	0.055	1.68	0.03

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 2% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.

4.4.3 Worker exposure/risk

Tier 1

Shortly after application it is possible to perform re-entry activities during which intensive contact with the treated crop will occur. Therefore, worker exposure is calculated.
The exposure is estimated for the unprotected worker. In Table T.3 the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.3 Internal worker exposure to spinosad and risk assessment after application of Tracer

Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Re-entry activities in small fruits (uncovered, 0.096 kg as/ha, TC of 0.3 m^2/hour)			
Respiratory	-	1.68	-
Dermal	0.104	1.68	0.06
Total	0.104	1.68	0.06

a External exposure was estimated with Dutch greenhouse model/ EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 2% (see 4.2)
- biological availability via the respiratory route: not applicable, no inhalation exposure expected.

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.

Since the EU-AOEL is not exceeded without the use of PPE, a higher tier assessment is not required.

4.4.4 Re-entry
See 4.4.3 Worker exposure/risk.

Overall conclusion of the exposure/risk assessments of operator, bystander, and worker
The product complies with the Uniform Principles.

Operator exposure
Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected operator after respiratory and dermal exposure to spinosad as a result of the application of Tracer in the crops applied for.

Bystander exposure
Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected bystander due to exposure to spinosad during application of Tracer in the crops applied for.

Worker exposure
Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected worker after respiratory and dermal exposure during re-entry activities in crops applied for due to exposure to spinosad after application of Tracer.

4.5 Appropriate mammalian toxicology and operator exposure end-points relating to the product and approved uses
See List of Endpoints.

4.6 Data requirements
Based on this evaluation, no additional data requirements are identified.

4.7 Combination toxicology
Tracer contains only one active substance and it is not described that it should be used in combination with other formulations.

5. Residues

List of Endpoints
The most recent List of Endpoints is available on CIRCABC, dated March 2006.

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	fruits (grapes, apples and tomatoes), leafy crops (cabbage), root vegetables (turnips), and pulses and oilseeds (cotton).
Rotational crops	cereals (wheat), leafy crops (lettuce) and root vegetables (radish)
Plant residue definition for monitoring	spinosad, sum of spinosyn A and spinosyn D
Plant residue definition for risk assessment	spinosad, sum of spinosyn A and spinosyn D
Conversion factor (monitoring to risk assessment)	not applicable

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	lactating goat

	laying hen
Animal residue definition for monitoring	not applicable
Animal residue definition for risk assessment	not applicable
Conversion factor (monitoring to risk assessment)	No
Metabolism in rat and ruminant similar (yes/no)	Yes
Fat soluble residue: (yes/no)	Yes

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

no significant residue levels are expected

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

all spinosyns appeared to be stable at ca. -20°C for at least six (apples), three (apple juice), twelve (tomatoes) to nineteen months (grapes, pepper, strawberry and wine). No storage stability data are required for animal products.

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Intakes by livestock [3] 0.1 mg/kg diet/day:	Ruminant: no	Poultry: no	Pig: no
Muscle	not applicable		
Liver	not applicable		
Kidney	not applicable		
Fat	not applicable		
Milk	not applicable		
Eggs	not applicable		

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)

Cop/processed crop	Number of studies	Transfer factor[1]	% Transference
Grapes	3		
pomace		2.5	n.d.
must		1.5	
wine at bottling		<0.5	
wine after 4 months		<0.5	
Tomatoes	2		
washed tomatoes		0.3	n.d.
juice		0.3	
puree		0.7	
canned		0.3	
paste		2.0	
wet pomace		8.4	
dry pomace		14	

[1] The transfer factor is based on the highest processing factor measured.

N.D.: not determined, no balance information was provided. As such, the percentage transference could not be calculated.

5.1. Summary of residue data

Residue data are summarised in the original DAR (The Netherlands, 2001), the List of Endpoints (dated March 2006), Reasoned Opinions on the modification of the existing MRLs for spinosad in various crops (EFSA Journal 2011;9(9):2352; FSA Journal 2012;10(6):2770);and EFSA Journal 2013;11(11):3447), the Reasoned opinion on the review of the existing maximum residue levels (MRLs) for spinosad according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2012;10(3:2630), and on additionally submitted residue trials evaluated in the Evaluation Report on residues of spinosad in witloof (indoor), grapes (outdoor) and beans with pods (indoor) (Ctgb, july 2014).

5.1.1 Metabolism in plants

Primary crop metabolism of spinosad was investigated following foliar application in grapes, apples, tomatoes, cabbage, turnips and cotton, hereby covering four different crop groups. Results of these studies were discussed during an expert meeting. Although metabolic patterns in the different studies were not shown to be similar - results on leafy vegetables (cabbage, turnip leaves) were not in line with the ones obtained on fruits (apples, grapes) and fruiting vegetables (tomatoes) - these contradictions were considered not to have any consequence on the outcome of the risk assessment. The final residue contains mainly parent spinosyn A and spinosyn D. For the uses under consideration, the metabolism of spinosad in plants is sufficiently addressed.

5.1.2 Metabolism in livestock

The metabolism of spinosad in livestock was assessed in lactating goats (dosed with radiolabelled spinosad for 3 days containing 10 mg/kg feed) and laying hens (dosed with spinosad for 5 days at 10 mg/kg feed). The metabolic patterns identified on goats and hens were consistent with the rat metabolism. Further details of the metabolism studies are reported in the DAR of spinosad (The Netherlands, 2001) and the EFSA Reasoned Opinion on the review of the existing MRLs (EFSA Journal 2012;10(3:2630). For the uses under consideration, the metabolism of spinosad in livestock is sufficiently addressed.

5.1.3 Residue definition

Plant

The peer review established the residue definition for risk assessment and enforcement as “spinosad, sum of spinosyn A and spinosyn D, expressed as spinosad” for all crops. In the framework of the MRL review, EFSA confirmed the residue definition for enforcement, which corresponds to that established in Regulation (EC) No 396/2005. However, EFSA recommended rewording the text into “spinosad, sum of spinosyn A and spinosyn D”, taking into account that the parent compound spinosad is a mixture of two compounds which have slightly different molecular weights. The residue definition applies to all crops.

Animal

During the peer review an animal residue definition was concluded not to be applicable, but in the Reasoned Opinion on the modification of the existing MRLs for spinosad in small fruit and berries and several commodities of animal origin (EFSA Journal 2013;11(11):3447), the residue definition as spinosad, sum of spinosyn A and spinosyn D, was established for enforcement and risk assessment in the commodities of animal origin with the exception of poultry liver and bird’s eggs. In these products the residue definition for risk assessment was proposed as spinosad, sum of spinosyn A, spinosyn D, O-demethylated spinosyn D and N-demethylated spinosyn D. Tentative conversion factors for enforcement to risk assessment of 4 (liver) and 1.5 (eggs) were derived from the metabolism studies.

5.1.4 Stability of residues

The storage stabilities of spinosyn A and spinosyn D were demonstrated for a period of 19 months at -20 ℃ in high water content (pepper) and acidic (grapes, strawberries)

commodities (The Netherlands, 2001; EFSA, 2012a). Storage of samples was within the demonstrated period of storage stability.

5.1.5 Residue data

Pumpkin species, indoor
cGAP-NL: 5x 0.096 kg/ha, PHI 1d
The proposed extension for pumpkin species is covered by the risk envelope of the existing authorisation for pumpkin.

Lettuce, endive species, rocket, garden cress, outdoor
cGAP-NL: 3x 0.096 kg/ha, PHI 3d
The proposed extension for outdoor uses in lettuce, endive species, rocket and garden cress is covered by the risk envelope of the existing authorisation for indoor uses, since indoor uses are considered more critical.

Lamb's lettuce, outdoor
cGAP-NL: 2x 0.096 kg/ha, PHI 14d
The proposed extension for outdoor uses in lamb's lettuce is covered by the risk envelope of the existing authorisation for indoor uses, since indoor uses are considered more critical.

Zucchini, gherkin, pumpkin species, melon, watermelon, outdoor
cGAP-NL: 5x 0.096 kg/ha, PHI 1d
The proposed extension for outdoor uses in zucchini, gherkin, pumpkin species, melon and watermelon is covered by the risk envelope of the existing authorisation for indoor uses, since indoor uses are considered more critical.

Herbs, outdoor
cGAP-NL: 3x 0.096 kg/ha, PHI 3d
The proposed extension for outdoor uses in herbs is covered by the risk envelope of the existing authorisation for indoor uses, since indoor uses are considered more critical.

Cauliflower, broccoli, head cabbage, Brussels sprouts, tray treatment indoor
cGAP-NL: 1x 0.006 as/1000 plants, BBCH 12-14
The proposed extension involves an indoor tray treatment of cauliflower, broccoli, head cabbage and Brussels sprouts followed by outdoor planting. Since the crops are grown outdoor immediately after treatment, the proposed extension is covered by the risk envelope of the existing authorisation for outdoor uses in cauliflower, broccoli, head cabbage and Brussels sprouts.

Chinese cabbage, swede, kohlrabi, Eastern leaf cabbage, indoor
cGAP-NL: 1x 0.006 as/1000 plants, BBCH 12-14, tray treatment
The proposed extension involves an indoor tray treatment of Chinese cabbage, swede, kohlrabi and Eastern leaf cabbage followed by outdoor planting. Since the crops are grown outdoor immediately after treatment, the proposed extension is covered by the risk envelope of the existing authorisation for outdoor uses in Chinese cabbage, swede, kohlrabi and Eastern leaf cabbage.

Strawberry, outdoor
cGAP-NL: 3x 0.072 kg as/ha, PHI 1d
The proposed extension for outdoor uses in strawberries is covered by the risk envelope of the existing authorisation for indoor uses, since indoor uses are considered more critical.

Spinach family, outdoor
cGAP-NL: 3x 0.096 kg as/ha, PHI 3d

Residue data for the whole spinach and similar (leaves) group can be extrapolated from lettuce (8 trials, with a minimum of 4 trials on open leaf varieties).The proposed extension for outdoor uses in the spinach family is covered by the trials that were submitted to support the existing uses in lettuce. Eight supervised trials with lettuce were submitted, four of which performed exactly according to cGAP-NL and four trials performed with a too high dosage (+/- 2N, 0.220 kg as/ha). Additionally, three trials with open lettuce varieties (lollo rosso and rucola) were also submitted previously to support the existing uses in lettuce. These trials were performed with a 1.5 N dosage (0.144 kg as/ha) and sampled at PHI 0 and 7d. Residue values at PHI 0d will give an overestimation, the PHI of 7 days is too long, but since the dosage is 1.5N, this value is considered to give an indication of the residue level in open lettuce varieties. The trials show clearly that the EU-MRL for spinosad (sum of spinosyn A and spinosyn D, expressed as spinosad) in spinach and similar (leaves) of 10 mg/kg will not be exceeded.

Table grapes, indoor
cGAP-NL: 3x 0.072 kg as/ha, PHI 14d
The applicant did not submit studies to support the indoor use of TRACER in table grapes. Table grapes are a minor crop in northern Europe for which a minimum of four residue trials in indoor grapes is required. Since insufficient data are available, the applicant has withdrawn the use on indoor table grapes from the label.

Wine grapes, outdoor
cGAP-NL: 3x 0.072 kg as/ha, PHI 14d
Six outdoor field trials in Germany (Northern Europe) were submitted by the applicant to support the intended use of spinosad in wine grapes. Two trials were conducted in the same field, with the same variety. The field conditions and application were exactly the same. The trials can therefore not be considered as independent trials. All trials deviate from the GAP applied for, regarding number of applications, application rate and spraying interval. In the trials, spinosad was applied five times: one application was made at petal fall and one before cluster close, followed by a third application 14 days later. The last two applications were made at 28-33 and 14 days prior to normal harvest. The total seasonal application rate in the trials was 0.326 – 0.382 kg as/ha, which is higher than the cGAP (0.216 kg/as/ha). However, the total seasonal application rate is of minor importance, since the residue levels at harvest appear to be determined by the final application (residues measured before the final application are below LOQ). Three out of five independent trials were conducted with a final application of 0.048 kg as/ha deviating more than 25% from the intended GAP. Only two trials were conducted with a final application of 0.080 kg as/ha, sufficiently reflecting the final application rate of the cGAP. In both trials residues of spinosad were below the LOQ. Selected residue levels from acceptable trials with spinosad in grapes are presented in table R1.

Wine grape is a major crop in northern Europe for which 8 trials are required. Only two acceptable trials are available to support the intended outdoor GAP for wine grapes. Six trials complying with the intended GAP are still required. Taking into account that residues of spinosad were below the LOQ in the two acceptable trials, the number of additional trials could be reduced to two if these trials confirm that residues of spinosad are below LOQ at harvest.
Since insufficient data are available, the applicant has withdrawn the use on outdoor wine grapes from the label.

Raspberry, blackberry, indoor & outdoor
cGAP-NL: 2x 0.096 kg as/ha, PHI 3d
In support of the intended outdoor GAP on raspberries and blackberries the applicant submitted 4 outdoor residue trials on raspberries conducted in Belgium (2007). These trials have already been evaluated for MRL-setting by EFSA. One trial was overdosed and

therefore disregarded by EFSA. EFSA concluded in its Reasoned Opinion on the modification of the existing MRLs for spinosad in various crops (EFSA Journal 2011;9(9):2352) that the number of submitted residue trials (3 outdoor trials) is not sufficient to propose an MRL in raspberries and to extrapolate the residue data to blackberries. However, in the meantime the MRL is raised to 1.5 mg/kg based on the intended indoor use on raspberries and blackberries in the United Kingdom (Reasoned Opinion on the modification of the existing MRLs for spinosad in celery, fennel, raspberries and blackberries, EFSA Journal 2012;10(6):2770). Since the residue level in the overdosed trial is well within the range of the MRL, the overdosed trial is acceptable to support the authorisation of the use in raspberries in the Netherlands. Raspberry is a minor crop in Europe, therefore, a minimum of four GAP compliant trials is required and the extrapolation of residues from raspberries to blackberries is acceptable. Selected residue levels from acceptable trials with spinosad in outdoor raspberries are presented in table R1.

The applicant did not submit studies to support the indoor use of TRACER in raspberries and blackberries. Reference was made to trials in raspberries determining residues of spinosad, after 2 applications of a formulation containing spinosad. However, these studies were not available to the assessor and were not previously evaluated for MRL setting. To support the indoor use of TRACER in raspberries and blackberries a minimum of 4 trials is still required. Since insufficient data are available to support the use on raspberries and blackberries, the applicant has withdrawn this use from the label.

Witloof, indoor, directly after filling forcing container 'intafelen'
cGAP-NL: 1x 0.24 g as/m^2, PHI 18d
Four residue trials were carried out in 2005 in Belgium (NEU) to determine residues of spinosad at commercial harvest after treatment with TRACER directly after filling forcing container at the start of witloof forcing. Residues of spinosad were below LOQ in all trials at 22 days after application. Considering dose rate, the trials comply with the intended GAP. All samples were taken 22 days after harvest, which deviates from intended the PHI of 18 days. No decline trials were conducted and no trials are available confirming residue levels at 18 days after application. However, since the MRL for spinosad is 10 mg/kg, exceedance of the MRL at a PHI of 18 days can be excluded. Selected residue levels from trials with spinosad in witloof at PHI 22 days are presented in table R1.

Beans with pods, indoor
cGAP-NL: 2x 0.12 kg as/ha, PHI 7d
Eight residue trials were submitted to support the intended use in green beans with pods indoor. The trials were carried out in 2010 and 2011 in Spain, Southern France, Greece and Italy to determine residues of spinosad in green beans (with pods) under protected glasshouse conditions following two applications at the target rate of 0.120 kg as/ha. The trials are performed according to the cGAP-NL. The trials are therefore acceptable in support of the intended GAP.
Beans with pods are a major crop for which 8 trials are required. Sufficient trials are available. Residue levels are covered by the MRL of 0.3 mg/kg.

Table R1: Overview of selected residue levels from trials with spinosad

Crop	spinosad: sum of spinosyn A and spinosyn D, expressed as spinosad. (mg/kg)	STMR (mg/kg)	HR (mg/kg)
Grapes	2x <0.02		
Raspberry, outdoor	0.082, 0.085, 0.107, 0.118	0.096	0.118
Witloof indoor (PHI 22days)	4x <0.02	<0.02	<0.02
Beans with pods,	<0.02; 0.024; 0.050; 0.064; 0.073; 0.075;	0.069	0.146

indoor	0.129; 0.146		

5.1.6 Residues in succeeding crops

Following the assessment of the confined rotational crop study during the peer review of spinosad, it was concluded that the metabolic pattern in rotational crops is similar to primary crops and that no significant residue levels are expected in rotational crops.

5.1.7 Residues from livestock feeding studies

The proposed extension of authorisation does not change the dietary burden. The assessment of residues in livestock is covered by the risk envelope of the existing authorisation.

5.1.8 Calculation of the ADI and the ARfD

The ADI is part of the List of Endpoints for Human Toxicology and is set at 0.024 mg/kg bw/day based on the NOAEL of the 2y oral study with rats and using a default safety factor of 100.

The ARfD is part of the List of Endpoints for Human Toxicology and was found to be not necessary since spinosad showed no acute toxic properties.

5.2 Maximum Residue Levels

MRLs for spinosad are present in Annex IIIA of Regulation (EC) 396/2005.
The MRLs for spinosad cover the intended use.

5.3 Consumer risk assessment

Risk assessment for chronic exposure through diet
In the framework of the review of the existing MRLs for spinosad according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account only the existing uses of spinosad at EU level supported by data and the existing acceptable CXLs. Those food commodities for which no uses of spinosad were reported in the framework of Article 12 of Regulation (EC) No 396/2005 were excluded from the exposure calculation assuming that there is no use on these crops. The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). EFSA updated the risk assessment in a recent Reasoned Opinion (EFSA Journal 2013;11(11):3447). The total calculated intake accounted for 62 % of the ADI (WHO Cluster diet B).

Risk assessment for acute exposure through diet
An ARfD was not set; a NESTI calculation is not needed.

Conclusion

Based on the assessment for residues, no risk for the consumer is currently expected due to the intended use of the product TRACER on:
- Strawberry, indoor
- Pumpkin species, indoor
- Lettuce, endive species, rocket, garden cress, outdoor
- Lambs lettuce, outdoor
- Zucchini, gherkin, pumpkin species, melon, watermelon, outdoor
- Herbs, outdoor
- Cauliflower, broccoli, head cabbage, Brussels sprouts, indoor
- Chinese cabbage, swede, kohlrabi, Eastern leaf cabbage, indoor
- Strawberry, outdoor
- Spinach family, outdoor
- Raspberries and blackberries, outdoor
- Witloof, indoor

- Beans with pods, indoor

The assessment of the intended uses on indoor table grapes, outdoor wine grapes, and indoor raspberry and blackberry could not be finalised due to insufficient data. Therefore, the applicant has withdrawn these intended uses from the label.

5.4 Data requirements
No data requirements were identified.

6. Environmental fate and behaviour

The *Plant Protection Products and Biocides Regulations* (RGB) published in the Government Gazette (Staatscourant) 188 of 28 September 2007 came into effect on 17 October 2007, while repealing the *Uniform Principles Decree on Plant Protection Products* (BUBG) and the *Regulation elaborating the uniform principles for plant protection products* (RUUBG).

For applications for formulations received and taken into the assessment procedure before 17-10-2007 containing active substances of the following category
- active substances which have already been included in Annex I of directive 91/414/EEC
- "new" active substances;
risk assessment is done in accordance with HTB 1.0. This means that for the current application of Tracer, risk assessment is done in accordance with HTB 1.0.

The List of Endpoints is derived from the final review report SANCO/1428/2001 – rev. final (14-07-2006).

After the initial assessment the applicant submitted one study (Knowles S., 2010). A kinetic evaluation of the aerobic soil degradation studies in order to refine additional question for the leaching problem of the metabolites of spinosad A and D. The kinetic evaluations of the soil degradation study was evaluated. The aerobic soil laboratory study is acceptable and used for refinement of the PEC_{gw} calculations. The refined endpoint are included in the list of endpoints (below). The refined assessment is included in the PECgw paragraph.

List of Endpoints Fate/behaviour (Final Review report dd. 14-07-2006)

Fate and Behaviour in the Environment	**Route of degradation (aerobic) in soil** (Annex IIA, point 7.1.1.1.1)
Mineralisation after 100 days	**spinosyn A** nd – 6.3% of AR after 80 – 91 d **spinosyn D** 1.3 – 8.7% of AR after 84 – 91 d
Non-extractable residues after 100 days	**spinosyn A** 8.1 – 39% of AR after 80 – 91 d **spinosyn D** 12 – 33% of AR after 84 – 91 d
Relevant metabolites - name and/or code, % of applied (range and maximum)	**spinosyn B** (metabolite of spinosyn A) 39 – 67% of AR after 28 – 182 d **N-demethylated spinosyn D** (metabolite of spinosyn D) 28 – 68% of AR after 28 – 237 d

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	not available
Soil photolysis	air-dried soil: **spinosyn A** mineralisation: 1.9% of AR after 30 d bound residue: 5.6% of AR after 30 d no major metabolites (>10% of AR) **spinosyn D** mineralisation: 2.1% of AR after 30 d bound residue: 3.7% of AR after 30 d no major metabolites (>10% of AR) moist soil: **spinosyn A** mineralisation: 0.34% of AR after 30 d bound residue: 12% of AR after 30 d metabolites: spinosyn B, maximal 15% of AR after 18 days
Field dissipation	**spinosyn A** mineralisation: dissipation half-live based on loss of AR were 205 and 218 d bound residue: 30 and 41% after 93 or 98 d metabolites: the main degradation product of spinosyn A in the laboratory studies – spinosyn B – was not detected in two field studies (Mississippi and California, USA); instead three groups of multiple degradates were detected 1 to 4 days after application, at maximum levels of 10 to 21% of AR. Detailed chromatographic analysis of these three regions of radioactivity revealed over 60 individual components. All unidentified degradates represented <10% of applied and the vast majority were considerably <5% of applied. The field study is considered representative for southern European regions only, not for the entire European Union. **spinosyn D** not available

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	non-linear regression of first-order kinetics

Laboratory studies (range or median, with n value, with r^2 value)	$DT_{50, lab}$ (20°C, aerobic): **spinosyn A** 21 d (n=6, r^2 0.96, result from a test at 25°C, $DT_{50, 25°C}$ was 14 d, converted assuming a Q_{10} value of 2.2) 11 d (n=5, r^2 0.99, result from a test at 25°C, $DT_{50, 25°C}$ was 7.1 d, converted assuming a Q_{10} value of 2.2) 24 d (n=3, r^2 1.0) 38 d (n=6, r^2 0.89) 42 d (n=3, r^2 1.0) 29 d (n=3, r^2 1.0) average DT_{50} value: 28 d **spinosyn D** 16 d (n=6, r^2 0.97, result from a test at 25°C, $DT_{50, 25°C}$ was 11 d, converted to 20°C assuming a Q_{10} value of 2.2) 32 d (n=6, r^2 0.72) 63 d (n=6, r^2 0.96) 56 d (n=6, r^2 0.90) 39 d (n=6, r^2 0.86) average DT_{50} value: 41 d **spinosyn B (degradation product of spinosyn A)** Calculated using the highest occurring concentration as start value: 194 d (n=5, r^2 0.73, result from a test at 25°C, $DT_{50, 25°C}$ was 130 d, converted to 20°C assuming a Q_{10} value of 2.2) 157 d (n=6, r^2 0.96, result from a test at 25°C, $DT_{50, 25°C}$ was 105 d, converted to 20°C assuming a Q_{10} value of 2.2) average DT_{50} value: 176 d **N-demethylated spinosyn D (degradation product of spinosyn D)** Calculated using the highest occurring concentration as start value: 531 d (n=4, r^2 0.56, result from a test at 25°C, $DT_{50, 25°C}$ was 356 d, converted to 20°C assuming a Q_{10} value of 2.2)
	$DT_{90, lab}$ (20°C, aerobic): extrapolated from average DT_{50} values assuming first order exponential decay as $3.3 \cdot DT_{50}$ **spinosyn A** 93 d **spinosyn D** 136 d **spinosyn B (degradation product of spinosyn A)** 585 d **N-demethylated spinosyn D (degradation product of spinosyn D)** 1760 d

	$DT_{50, lab}$ (10°C, aerobic): extrapolated from average DT_{50} (20°C, aerobic) with a Q10 of 2.2: **spinosyn A** 62 d **spinosyn D** 90 d **spinosyn B (degradation product of spinosyn A)** 387 d **N-demethylated spinosyn D (degradation product of spinosyn D)** 1168 d
	$DT_{50, lab}$ (20°C, anaerobic): not available
	degradation in the saturated zone: not available
Field studies (state location, range or median with n value)	$DT_{50, field}$: **1)** **spinosyn A** <1 d (Mississippi, USA, average soil temperature at 10 cm depth 28°C) <1 d (California, USA, average soil temperature at 10 cm depth 32°C) The field study is considered representative for southern European regions only, not for the entire European Union. **spinosyn D** not available
	2) UK DT_{50} first order multi-compartment (FOMC) best fit and 0-10 cm. **spinosyn A** 2.37 d **spinosyn D** 3.51 d **spinosyn B** 2.11 d **N-demethylated spinosyn D** 3.77 d

	3) mini lysimeter dissipation study Location: UK, Letcombe **spinosyn A** 8.4 d **spinosyn D** 9.5 d Due to the uncertainties in the mass balance and the unsuitability of the test system the DT_{50} values are considered indicative. N-demethylated spinosyn D varied from 5.7% at t=0 to <LOQ from t=14 days onwards. Spinosyn B was around a value of 3.5% (range <LOQ – 4.4%) at all timepoints. When present above LOQ, the residues were not monotonically decreasing. These data do not warrant an evaluation of the degradation rate of these compounds. Up to 8 individual polar compounds were found, in individual amounts up to 12.4% at t=1 day, 13.2% and 11.0% at 14 days, 11.4% at 31 days and 14.0% at t=62 days. The total maximum amount of polar compounds in the 0-10 cm segment was 58.0% of AR at t=14 days. The high amount of unidentified metabolites needs additional investigation to the identity.
	$DT_{90, field}$: extrapolated from average DT_{50} values assuming first order exponential decay as $3.3 \cdot DT_{50}$ **spinosyn A** <3.3 d **spinosyn D** not available
Soil accumulation and plateau concentration	not relevant

Rate of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	not available
Soil photolysis	DT_{50}: **spinosyn A** 74 d (air dried soil, n=12, r^2 0.88, test temperature 25℃, natural sunlight, Indianapolis USA, 40° northern latitude) 13 d (moist soil, n=16, r^2 0.97, test temperature 25℃, natural sunlight, Indianapolis USA, 40° northern latitude) **spinosyn D** 42 d (air dried soil, n=12, r^2 0.90, test temperature 25 ℃, natural sunlight, Indianapolis USA, 40° northern latitude)

The kinetic evaluation and normalisation of the laboratory DT_{50} values of the aerobic soil degradation study resulted in the normalised median DT_{50} endpoint for **spinosyn A** of **17.3 days** (n= 6, 11.3, 23.2, 26.6, 16.6 7.25 and 17.9 days). For **spinosyn D** a geometric mean DT_{50} of **17.6 days** was obtained (n=5, 7.95, 32.2, 32.1, 16.0 and 12.7 days). The kinetic evaluation and normalisation of the laboratory DT_{50} values of the aerobic soil degradation study resulted in the normalised median endpoint for **spinosyn B** (metabolite of spinosyn A) of **77.5 days** (n=6, 33.3, 146.6, 41.8, 63.2, 91.8 and 96.6 days) with an arithmetic mean formation fraction of **0.852** (n=6, 0.934, 0.852, 1.0, 0.669, 0.811 and 0.849). For **N-demethylated spinosyn D** (metabolite of spinosyn D) a geometric mean DT_{50} of **123.5 days** was calculated (n=3, 84.1, 202 and 111 days) with an arithmetic mean formation fraction of **0.882** (n=3, 0.804, 0.994 and 0.849). The obtained endpoints for spinosyn A and D and metabolites spinosyn B and N-demethylated spinosym D were used as model input parameters.

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_F / K_{OC} / $K_{S/L}$ pH dependence (yes / no) (if yes type of dependence)	**spinosyn A** K_F values: 8.5, 5.4, 25, 337, and 312 L/kg K_F was better correlated with the clay content than with organic matter content of the soil. Corresponding K_{clay} values: 163, 68, 250, 1465, and 975 L/kg (average 584 L/kg) Corresponding K_{OC} values: 2890, 835, 4250, 143225 and 26520 L/kg (average 35024 L/kg) no pH dependence **spinosyn D** not available it is assumed that spinosyn D has sorption characteristics equal to spinosyn A **spinosyn B (degradation product of spinosyn A)** K_F values: 6.2, 4.3, 17, and 178 L/kg K_F was better correlated with the clay content than with organic matter content of the soil. Corresponding K_{clay} values: 119, 54, 170, 774 L/kg (average 279 L/kg) Corresponding K_{OC} values: 2108, 665, 2890 and 75650 L/kg (average 20328 L/kg) no pH dependence **N-demethylated spinosyn D (degradation product of spinosyn D)** not available it is assumed that N-demethylated spinosyn D has sorption characteristics equal to spinosyn B

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching	sand soil, leached for 2 d at 10 cm water/d **spinosyn A** 87% 0 – 5 cm soil layer <1% 5 – 30 cm <1% in the leachate **spinosyn D** 97% 0 – 5 cm soil layer <1% 5 – 30 cm <1% in the leachate

Aged residues leaching	biologically aged for 34 d, sand soil, leached for 2 d at 10 cm water/d **spinosyn A** after ageing, spinosyn A was reduced to 36% of AR, 18% of AR was present as spinosyn B, 21% of AR as unknown metabolites, and 11% as non-extractable residue after leaching, 86% of AR was recovered from the 0 – 5 cm soil layer, 4.3% of AR from the 5 – 30 cm soil layer, and 1.7% of AR in the leachate
	spinosyn D after ageing, spinosyn D was reduced to 31% of AR, 15% of AR was present as N-demethylated spinosyn D, 26% of AR as unknown metabolites, and 0.7% as non-extractable residue after leaching, 84% of AR was recovered from the 0 – 5 cm soil layer, 8.5% of AR from the 5 – 30 cm soil layer, and 1.8% of AR in the leachate photolytically aged for 16 h, sand soil, leached for 2 d at 10 cm water/d
	spinosyn A after ageing, spinosyn A was reduced to 15% of AR, 4.5% of AR was present as spinosyn B, 41% of AR as unknown metabolites, and 13% as non-extractable residue after leaching, 61% of AR was recovered from the 0 – 5 cm soil layer, 18% of AR from the 5 – 30 cm soil layer, and 10% of AR in the leachate
	spinosyn D after ageing, spinosyn D was reduced to 10% of AR, 1.4% of AR was present as N-demethylated spinosyn D, 53% of AR as unknown metabolites, and 8.1% as non-extractable residue after leaching, 67% of AR was recovered from the 0 – 5 cm soil layer, 13% of AR from the 5 – 30 cm soil layer, and 7.0% of AR in the leachate

Lysimeter/field leaching studies	mini lysimeter study Location: UK, Letcombe Number of application: 1 year, 3 applications 465-471 g as/ha each) Average annual rainfall: 875 mm Average annual lechate volume: 418 –721 mm Spinosyn A (2 lysimeters): Leaching of total radioactivity was 5.6-7.0% of AR. HPLC analysis showed that neither the parent compound (0.01-0.02 µg/L), nor its major metabolite spinosyn B (0.01-0.06 µg/L) leached in significant amounts. However 8 distinct metabolites were found, all in max. concentrations of 1.20-8.58 µg/L and average concentrations of 0.85-5.89 µg/L over the period 141-280 days after the 1st application. Spinosyn D (2 lysimeters): Leaching of total radioactivity was 3.2-6.8% of AR. HPLC analysis showed that neither the parent compound (0.01-0.02 µg/L), nor its major metabolite N-demethylated spinosyn D (0.01-0.06 µg/L) leached in significant amounts. However 10 distinct metabolites were found, all in max. concentrations of 1.45-10.7 µg/L and average concentrations of 1.01-7.54 µg/L over the period 141-302 days after the 1st application. field dissipation study Results from the field dissipation study conducted in Mississippi and California (USA), showed never more than 8.5% of AR below 15 cm.
	lysimeter Münster, Germany. Four applications of spinosyn A and D were conducted, 216 g as/ha per application. Two lysimeters per test substance were used. No spinosyn A and D were detected in any of the leachate samples. None of the potential metabolites available as reference standards were detected in the leachate samples.

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}, state pH and temperature)	**spinosyn A** pH 5, 25℃: stable pH 7, 25℃: stable pH 9, 25℃: 9.0% hydrolysed after 30 d, DT_{50} 200 d **spinosyn D** pH 5, 25℃: stable pH 7, 25℃: stable pH 9, 25℃: 5.1% hydrolysed after 30 d, DT_{50} 259 d

Photolytic degradation of active substance and relevant metabolites	natural sunlight, 40° northern latitude **spinosyn A** distilled water, pH 7, 25℃: DT_{50} 0.96 d pond water, pH 9.2, 25℃: DT_{50} 0.18 d metabolites (max): A1: 24.9% AR (β isomer of 13,14-dihydro of pseudoaglycone of spinosyn A) A2: 7.3% AR (rearrangement of spinosyn A) A3: 9.4% AR (spinosyn A with an added water molecule) **spinosyn D** distilled water, pH 7, 25℃: DT_{50} 0.84 d pond water, pH 9.2, 25℃: DT_{50} 0.18 d metabolites (max): D1 (≅ A1): 10.2% AR D2: 7.5% AR (could not be interpreted) D3: 6.3% AR (could not be interpreted) D4 (≅ A3): 4.2% AR
Readily biodegradable (yes/no)	not readily biodegradable
Degradation in water/sediment (range or median, with n value, with r^2 value, state temperature)	$DT_{50, water}$: aerobic study, 20℃ **spinosyn A** 16 – 27 d **spinosyn D** 14 - 26 d average $DT_{50, water}$ value: 21 d anaerobic study, 25℃ **spinosyn A** <7 d **spinosyn D** <7 d microcosm, 20 – 21℃ (Indiana, USA) **spinosyn A** 27 h (1.1 d, n=7, r^2 0.53) **spinosyn D** 18 h (0.75 d, n=7, r^2 0.51)

$DT_{90, water}$: extrapolated from DT_{50} values assuming first order exponential decay as $3.3 \cdot DT_{50}$ aerobic study, 20℃ **spinosyn A** 53 – 89 d **spinosyn D** 46 - 86 d anaerobic study, 25℃ **spinosyn A** <23 d **spinosyn D** <23 d microcosm, 20 – 21℃ **spinosyn A** 3.7 d **spinosyn D** 2.5 d
$DT_{50, sediment}$: aerobic study, 20℃ not available. anaerobic study, 25℃ **spinosyn A** 267 d (398 d, converted to 20℃, n=8, r^2 0.92) **spinosyn D** 539 d (804 d, converted to 20℃, n=8, r^2 0.85) microcosm, 20 – 21℃ Concentrations were too low to calculate reliable DT_{50} values.
$DT_{90, sediment}$: extrapolated from DT_{50} values assuming first order exponential decay as $3.3 \cdot DT_{50}$ aerobic study, 20℃ - anaerobic study, 25℃ **spinosyn A** 887 d **spinosyn D** 1790 d

	$DT_{50, whole system}$: aerobic study, 20℃ **spinosyn A** 169 - 176 d **spinosyn D** 103 d anaerobic study, 25℃ **spinosyn A** 239 d (357 d, converted to 20℃, n=9, r^2 0.89) **spinosyn D** 443 d (661 d, converted to 20℃, n=9, r^2 0.80) microcosm, 20 – 21℃ Concentrations were too low to calculate reliable DT_{50} values.
	$DT_{90, whole system}$: extrapolated from DT_{50} values assuming first order exponential decay as $3.3 \cdot DT_{50}$ aerobic study, 20℃ **spinosyn A** 558 – 581 d **spinosyn D** 333 d anaerobic study, 25℃ **spinosyn A** 794 d **spinosyn D** 1470 d microcosm, 20 – 21℃ Concentrations were too low to calculate reliable DT_{50} values.
Mineralisation	aerobic study, 20℃ **spinosyn A** max. 0.3% of AR after 120 d **spinosyn D** max. 0.3% of AR after 120 d anaerobic study, 25℃ **spinosyn A** 0.3% of AR after 364 d **spinosyn D** 1.9% of AR after 364 d

Non-extractable residues	aerobic study, 20℃ **spinosyn A** highest value of 21% of AR after 120 d (end of study) **spinosyn D** highest value of 42% of AR after 120 d (end of study) anaerobic study, 25℃ **spinosyn A** highest value of 17% of AR after 364 d (end of study) **spinosyn D** highest value of 16% of AR after 364 d (end of study)
Distribution in water / sediment systems (active substance)	aerobic study, 20℃ Dissipation of spinosyn A and D was dominated by sorption to sediment. **spinosyn A** maximum 68.8% of AR in sediment after 30 days (59.0% at end) 7.2% of AR in water at the end. **spinosyn D** maximum 61.7% of AR in sediment after 58 days (51.3% at end), 3.8% of AR in water. Sediment extractable residues consisted mainly of spinosyn A and D, reaching values of 69% after 120 d for spinosyn A, and 62% after 120 d for spinosyn D. anaerobic study, 25℃ Dissipation of spinosyn A and D was dominated by sorption to sediment. Sediment extractable residues consisted mainly of spinosyn A and D, reaching highest values of 76% after 3 d for spinosyn A, and 74% after 3 d for spinosyn D.
	microcosm dissipation study A mass balance was not established. Supposedly dissipation from the water phase was dominated by sorption to sediment, but concentrations in the sediment remained rather low.

Distribution in water / sediment systems (metabolites)	No degradation products were detected in water or sediment at levels >10% of AR (aerobic). aerobic study, 20℃ **spinosyn A** metabolites in sediment (max): Spinosyn B: 9% AR after 120 d **spinosyn D** metabolites in sediment (max): N-demethylated spinosyn D: 10% AR after 120 d anaerobic study, 25℃ **spinosyn A** metabolites in sediment (max): J: 12% AR after 84 d Unknown: 14% AR after 365 d keto-reverse pseudoaglycone A: 14% AR after 365 d **spinosyn D** metabolites in sediment (max): Unknown: 12% AR after 365 d D2: 7.5% AR (could not be interpreted) D3: 6.3% AR (could not be interpreted) D4 (= A3): 4.2% AR

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air	not available
Quantum yield of direct phototransformation	not available
Photochemical oxidative degradation in air	**spinosyn A** DT_{50}: 20 min (Atkinson calculation) **spinosyn D** DT_{50}: 19 min (Atkinson calculation)

Volatilisation	from plant surfaces: **spinosyn A** 1.6% after 24 h **spinosyn D** 0.1% after 24 h
	from soil: **spinosyn A** -0.1% after 24 h **spinosyn D** -0.4% after 24 h

Definition of the Residue (Annex IIA, point 7.3)

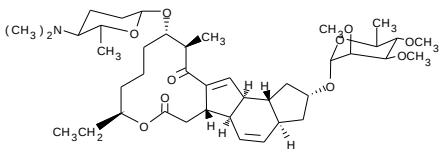
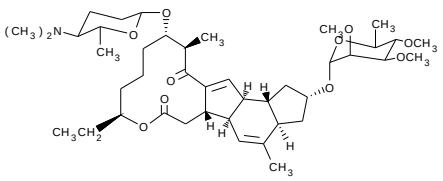
Relevant to the environment	**soil** spinosyn A spinosyn D spinosyn B N-demethylated spinosyn D **surface water and sediment** spinosyn A spinosyn D **groundwater** spinosyn A spinosyn D spinosyn B N-demethylated spinosyn D **air** spinosyn A spinosyn D

Monitoring data, if available (Annex IIA, point 7.4)

Soil (indicate location and type of study)	not available
Surface water (indicate location and type of study)	not available
Ground water (indicate location and type of study)	not available
Air (indicate location and type of study)	not available

Appendix A: Metabolite names, codes and other relevant information of the plant protection product Tracer with active substance spinosad.

The compounds shown below were found in one or more studies involving the metabolism and/or environmental fate of active substance spinosad. The parent compound structure of spinosad is shown first in this list and followed by degradate or related compounds.

Compound name	Code number(s)	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (% of occurrence/ formation)
Spinosad(NAF 85 typically contains 85% spinosyn A and 15% spinosyn D	spinosyn A spinosyn D		$C_{41}H_{65}NO_{10}$ $C_{42}H_{67}NO_{10}$	 	731.98 746.00	
Metabolite	spinosyn B		$C_{40}H_{63}NO_{10}$		717.93	Soil (lab degradation) : 67 %

Metabolite	N-demethylated spinosyn D		$C_{41}H_{65}NO_{10}$		731.98	Soil (lab degradation): 68 %

6.1 Fate and behaviour in soil

6.1.1 Persistence in soil

The *Board for the authorization of plant protection products and biocides* in the Netherlands (Ctgb) has to evaluate persistence in soil. If for the evaluation of the product a higher tier risk assessment is necessary, a standard is to be set according to the MPC-INS[1] method. Currently this method equals the method described in the Technical Guidance Document (TGD). Additional guidance is presented in RIVM[2]-report 601782001/2007[3].

Preceding the harmonisation of the persistence assessment in The Netherlands with regulation 1107/EG, the EU approach for persistence assessment is followed.

For the current application this means the following:

spinosyn A

The following laboratory DT_{50} values are available for the active substance spinosyn A: 21, 11, 24, 38, 42 and 29 days (median 26.5 days, n=6). The mean DT_{50}-value of the a.s. can thus be established to be <90 days. Furthermore it can be excluded that after 100 days there will be more than 70% of the initial dose present as bound (non-extractable) residues together with the formation of less than 5% of the initial dose as CO_2. Two field studies with data for spinosyn A are available, but they are not representative for NL conditions. Furthermore a UK FOMC best-fit of 2.37 days is available.
In this way, the standards for persistence as laid down in the RGB are met.

For the metabolite spinosyn B the following DT_{50}-values are available: 194 and 176 days (geometric mean 174.5 days).

Due to the exceeding of the threshold value of 60 days for the geomean DT_{50} (lab) for metabolite spinosyn B it must be demonstrated by means of field dissipation studies that the field DT_{50} is < 90 days. The following field data are provided: a UK FOMC best-fit of 2.11 days. Due to the fact that photolysis plays an important role in the dissipation of spinosad and its metabolites, it can be expected that under field conditions dissipation half-lives are much shorter than under dark laboratory conditions. This is confirmed by the one available study.
From the results it is shown that the mean field DT50 is < 90 days. Therefore, the standards for persistence as laid down in the RGB are met.

spinosyn D

The following laboratory DT_{50} values are available for the active substance spinosyn D: 16, 32, 63, 56 and 39 days (geometric mean 37.1 days, n=5). The mean DT_{50}-value of the a.s. can thus be established to be <90 days. Furthermore it can be excluded that after 100 days there will be more than 70% of the initial dose present as bound (non-extractable) residues together with the formation of less than 5% of the initial dose as CO_2.
In this way, the standards for persistence as laid down in the RGB are met.

[1] INS: international and national quality standards for substances in the Netherlands.
[2] RIVM: National institute of public health and the environment.
[3] 601782001/2007: P.L.A. van Vlaardingen and E.M.J. Verbruggen, Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Revision 2007'.

For the metabolite N-demethylated spinosyn D the following DT_{50}-value is available 531 days.

Due to the exceeding of the threshold value of 60 days for the geometric mean DT_{50} (lab) for metabolite N-demethylated spinosyn D, it must be demonstrated by means of field dissipation studies that the field DT_{50} is < 90 days. The following field data are provided: a UK FOMC best-fit of 3.77 days. Due to the fact that photolysis plays an important role in the dissipation of spinosad and its metabolites, it can be expected that under field conditions dissipation half-lives are much shorter than under dark laboratory conditions. This is confirmed by the one available study.
From the results it is shown that the mean field DT50 is < 90 days. Therefore, the standards for persistence as laid down in the RGB are met.

PECsoil
The concentration of the active substance spinosad and metabolites spinosyn B and N-demethylated spinosyn D in soil is needed to assess the risk for soil organisms (earthworms, micro-organisms). The PECsoil is calculated for the upper 5 cm of soil using a soil bulk density of 1500 kg/m^3.

As the logPow of the substance is > 3 (logPow spinosyn A: 4.01, logPow spinosyn D: 4.53; pH=7), a PEC_{21days} is needed for the assessment of secondary poisoning of birds and mammals through the consumption of earthworms.

For the glasshouse use in beans with pod exposure of soil organisms is not relevant.

The following input data are used for the calculation:

PEC soil:

Active substance spinosyn A:
Worst case field DT_{50} for degradation in soil: 2.37 days

Molecular mass: 731.98 g/mol

Active substance spinosyn D:
Worst case field DT_{50} for degradation in soil: 3.51 days

Molecular mass: 746.0 g/mol

Metabolite spinosyn B:
Worst case field DT_{50} for degradation in soil (20°C): 2.11 days

Molecular mass: 717.93 g/mol
Correction factor: 67 (maximum observed percentage) * 0.98 (relative molar ratio = M metabolite/M parent) = 0.657

Metabolite N-demethylated spinosyn D:
Worst case field DT_{50} for degradation in soil (20°C): 3.77 days

Molecular mass: 731.98 g/mol
Correction factor: 68 (maximum observed percentage) * 0.98 (relative molar ratio = M metabolite/M parent) = 0.667

See Table M.1 for other input values and results.

Table M.1 PECsoil calculations for active substance spinosad and metabolites spinosyn B and N-demethylated spinonsyn D (5 cm)

Use	Substance	Rate [kg a.s./ha]	Freq.	Interval [days]	Fraction on soil *	$PIEC_{soil}$ [mg a.s./kg] (5 cm)	$PEC_{soil,21d}$ [mg a.s./kg] (5 cm)
Lettuce, Endive species, Rocket, Garden cress[1]	spinosyn A	0.0816	3	7	0.75	0.093	0.015
	spinosyn D	0.0144				0.019	0.004
	spinosyn B	0.0536				0.060	0.009
	N-demethylated spinosyn D	0.0096				0.013	0.003
Lambs lettuce[1]	spinosyn A	0.0816	2	7	0.75	0.092	0.015
	spinosyn D	0.0144				0.018	0.004
	spinosyn B	0.0536				0.059	0.009
	N-demethylated spinosyn D	0.0096				0.012	0.003
Zucchini, Gherkin, Pumpkin species, Melon, Watermelon[2]	spinosyn A	0.0816	5	7	0.50	0.062	0.010
	spinosyn D	0.0144				0.013	0.003
	spinosyn B	0.0536				0.040	0.006
	N-demethylated spinosyn D	0.0096				0.009	0.002
Herbs[3]	spinosyn A	0.0816	3	7	0.75	0.093	0.015
	spinosyn D	0.0144				0.019	0.004
	spinosyn B	0.0536				0.060	0.009
	N-demethylated spinosyn D	0.0096				0.013	0.003
Strawberry[4]	spinosyn A	0.0612	3	7	0.70,	0.057	0.009
	spinosyn D	0.0108			0.50,	0.001	0.000
	spinosyn B	0.0402			0.50	0.038	0.005
	N-demethylated spinosyn D	0.0072				0.007	0.002
Wine grapes[5]	spinosyn A	0.0612	3	14	0.60	0.049	0.008
	spinosyn D	0.0108				0.010	0.002
	spinosyn B	0.0402				0.032	0.005
	N-demethylated spinosyn D	0.0072				0.006	0.002
Raspberry, Blackberry[6]	spinosyn A	0.0816	2	10	0.50	0.057	0.009
	spinosyn D	0.0144				0.011	0.003
	spinosyn B	0.0536				0.037	0.005
	N-demethylated spinosyn D	0.0096				0.007	0.002
Spinach family[1]	spinosyn A	0.0816	3	10	0.75	0.086	0.014
	spinosyn D	0.0144				0.017	0.004
	spinosyn B	0.0536				0.056	0.008
	N-demethylated spinosyn D	0.0096				0.011	0.003

* fraction on soil is detemined as 1 – interception value; interception values derived from Table 1.6 in “generic guidance for FOCUS groundwater scenarios”.
[1] A fraction on soil of 0.75 is appropriate for lettuce, endive species, rocket, garden gress, lambs lettuce and spinach family at growth stage BBCH 13-49 (based on the interception values of beans (field and vegetable)).
[2] A fraction on soil of 0.50 is appropriate for zucchini, gherkin, pumpkin species, melon and water melon at growth stage BBCH 21-71 (based on the interception values of potatoes).
[3] For the use in herbs, 5 cropcycles per 12 months were modelled, each consisting of 3 treatments. A fraction on soil of 0.75 is appropriate for herbs at growth stage BBCH 13-71 (based on the interception values of beans (field and vegetable)).
[4] A fraction on soil of 0.70 is appropriate for strawberries at growth stage BBCH 19, a fraction on soil of 0.50 (2x) is appropriate at growth stage BBCH 20-87.
[5] No BBCH growth stage is mentioned at the label (unspecified). A conservative fraction on soil of 0.6 is assumed for wine grapes (without leaves growth stage).
[6] No BBCH growth stage is mentioned at the label (unspecified). A conservative fraction on soil of 0.5 is assumed for raspberry and blackberry (based on the growth stage: 'without leaves' of bushberries).

These exposure concentrations are examined against ecotoxicological threshold values in section 7.5.

6.1.2 Leaching to shallow groundwater

The leaching potential of the active substance spinosad and metabolites spinosyn B and N-demethylated D is calculated in the first tier using Pearl 4.4.4 and the FOCUS Kremsmünster scenario. Input variables are the actual worst-case application rate ranging 0.072-1.2 kg/ha (85% for spinosyn A and 15% for spinosyn D), the crop Field beans for Beans with pod, strawberries for strawberries and Winter cereals for all remaining crops, and an interception value appropriate to the crop stage ranging 0-0.50. First date of yearly application is May 25th/ June 1st (depending on GAP) for the spring scenario (March-August), September 1st for the autumn scenario (September-February).

For metabolites all available data concerning substance properties are regarded. Metabolites spinosyn B and N-demethylated spinosyn D are included in the calculations. No other metabolites occurred above > 10 % of AR, > 5 % of AR at two consecutive sample points or had an increasing tendency.

The other aspects were not updated since no additional information was requested for these aspects. The indoor tray treatments are not taken into account since exposure of the groundwater is not expected for these uses.

The following input data are used for the calculation:

PEARL:

Active substance spinosyn A:
Median normalised DT_{50} for degradation in soil (20°C): 17.2 days (n=6)
Arithmetic mean K_{om} (pH-independent): 717 L/kg (calculated from K_{clay} 584 L/kg related to organic matter)
1/n: 0.9 (default for active substance)

Saturated vapour pressure: 3 x 10^{-11} Pa (25 ºC)
Solubility in water: 0.089 g/L (20 ºC)
Molecular weight: 732 g/mol

Plant uptake factor: 0.5
Q10: 2.58 (used in the kinetic evaluation report for normalisation)

Active substance spinosyn D:
Geometric mean normalised DT_{50} for degradation in soil (20°C): 17.6 days (n=5)

Arithmetic mean K_{om} (pH-independent): 717 L/kg
1/n: 0.9 (default for active substance)

Saturated vapour pressure: 2 x 10^{-11} Pa (25ºC)
Solubility in water: 0.495 x 10^{-3} g/L (20ºC)
Molecular weight: 746 g/mol

Plant uptake factor: 0.5
Q10: 2.58 (used in the kinetic evaluation report for normalisation)

Metabolite spinosyn B from spinosyn A:
Median normalised DT_{50} for degradation in soil (20°C): 77.5 days (n=6)
Arithmetic mean K_{om} (pH-independent): 342 L/kg
1/n: 1.0 (default for metabolite)
Arithmetic mean formation fraction: 0.852

Saturated vapour pressure: 3 x 10^{-11} Pa (25ºC; parent value)
Solubility in water: 0.089 g/L (20ºC; parent value)
Molecular weight: 718 g/mol

Plant uptake factor: 0.0 (default for metabolite)
Q10: 2.58 (used in the kinetic evaluation report for normalisation)

Metabolite N-demethylated spinosyn D from spinosyn D:
Geometric mean DT_{50} for degradation in soil (20°C): 123.5 days (n=3)
Arithmetic mean K_{om} (pH-independent): 342 L/kg
1/n: 1.0 (default for metabolite)
Arithmetic mean formation fraction: 0.882

Saturated vapour pressure: 2 x 10^{-11} Pa (25ºC; parent value)
Solubility in water: 0.495 x 10^{-3} g/L (20ºC; parent value)
Molecular mass: 732 g/mol

Plant uptake factor: 0.0 (default for metabolite)
Q10: 2.58 (used in the kinetic evaluation report for normalisation)

Other parameters: standard settings of PEARL 3.3.3 (recalculations were performed with PEARL 4.4.4)

The following concentrations are predicted for the active substance spinosad and metabolites spinosyn B and N-demethylated spinosyn D following the realistic worst case GAP, see Table M.2a.

Table M.2a Leaching of active substance spinosad (85% spinosyn A and 15% spinosyn D) and metabolites spinosyn B and N-demethylated spinosyn D as predicted by PEARL 4.4.4 (values ≥0.1 µg/L are indicated in bold, values ≥0.01-<0.1 µg/L are underlined)

Use	Substance	Rate substance [kg/ha]	Freq. / Int. [days]	Fraction Intercepted *	PEC groundwater [µg/L]	
					spring	autumn
Lettuce,	spinosyn A	0.0816	3 / 7	0.25	<0.001	<0.001

Use	Substance	Rate substance [kg/ha]	Freq. / Int. [days]	Fraction Intercepted *	PEC groundwater [µg/L]	
Endive species, Rocket, Garden cress[1]	spinosyn D	0.0144			<0.001	<0.001
	spinosyn B	**			0.024	0.025
	N-demethylated spinosyn D	**			0.035	0.037
Lambs lettuce[1]	spinosyn A	0.0816	2 / 7	0.25	<0.001	<0.001
	spinosyn D	0.0144			<0.001	<0.001
	spinosyn B	**			0.016	0.017
	N-demethylated spinosyn D	**			0.023	0.024
Zucchini, Gherkin, Pumpkin species, Melon, Watermelon[2]	spinosyn A	0.0816	5 / 7	0.50	<0.001	<0.001
	spinosyn D	0.0144			<0.001	<0.001
	spinosyn B	**			0.026	0.029
	N-demethylated spinosyn D	**			0.038	0.041
Herbs[3]	spinosyn A	0.0816	3 / 7	0.25	<0.001	<0.001
	spinosyn D	0.0144			<0.001	<0.001
	spinosyn B	**			0.031	
	N-demethylated spinosyn D	**			0.046	0.035
						0.048
Strawberry[4]	spinosyn A	0.0612	3 / 7	0.30, 0.50, 0.50	<0.001	<0.001
	spinosyn D	0.0108			<0.001	<0.001
	spinosyn B	**			0.011	0.012
	N-demethylated spinosyn D	**			0.017	0.018
Wine grapes[5]	spinosyn A	0.0612	3 / 14	0.40	**	**
	spinosyn D	0.0108				
	spinosyn B	**				
	N-demethylated spinosyn D	**				
Raspberry, Blackberry[6]	spinosyn A	0.0816	2 / 10	0.50	**	**
	spinosyn D	0.0144				
	spinosyn B	**				
	N-demethylated spinosyn D	**				
Spinach family[1]	spinosyn A	0.0816	3 / 7	0.25	<0.001	<0.001
	spinosyn D	0.0144			<0.001	<0.001
	spinosyn B	**			0.024	0.025
	N-demethylated spinosyn D	**			0.035	0.037
Beans with pods (G)[7]	spinosyn A	0.102	3 / 7	0	<0.001	-
	spinosyn D	0.018			<0.001	-
	spinosyn B	**			0.031	-
	N-demethylated spinosyn D	**			0.047	-
Beans with pods (F)[7]	spinosyn A	0.0816	3 / 7	0	<0.001	<0.001
	spinosyn D	0.0144			<0.001	<0.001
	spinosyn B	**			0.025	0.027

Use	Substance	Rate substance [kg/ha]	Freq. / Int. [days]	Fraction Intercepted *	PEC groundwater [µg/L]	
	N-demethylated spinosyn D	**			0.038	0.040

* interception values derived from Table 1.6 in “generic guidance for FOCUS groundwater scenarios”.

** Beans with pods is the worst case scenario for wine grapes and rasp- and blackberry so for these uses are not modelled.

[1] An interception of 0.25 is appropriate for lettuce, endive species, rocket, garden gress, lambs lettuce and spinach family at growth stage BBCH 13-49 (based on the interception values of beans (field and vegetable)).

[2] An interception of 0.50 is appropriate for zucchini, gherkin, pumpkin species, melon and water melon at growth stage BBCH 21-71 (based on the interception values of potatoes).

[3] For the use in herbs, 5 cropcycles per 12 months were modelled, each consisting of 3 treatments. An interception of 0.25 is appropriate for herbs at growth stage BBCH 13-71 (based on the interception values of beans (field and vegetable)).

[4] An interception of 0.30 is appropriate for strawberries at growth stage BBCH 19, an interception of 0.50 (2x) is appropriate at growth stage BBCH 20-87.

[5] No BBCH growth stage is mentioned at the label (unspecified). A conservative fraction on soil of 0.6 is assumed for wine grapes (without leaves growth stage).

[6] No BBCH growth stage is mentioned at the label (unspecified). A conservative fraction on soil of 0.5 is assumed for raspberry and blackberry (based on the growth stage: 'without leaves' of bushberries).

[7] No specific lower limit of the BBCH growth stage is mentioned at the label. A conservative fraction on soil of 1 is assumed for beans with pod (based on the interception values for BBCH growth stage 00-09 of beans (field and vegetable)).

** calculated using transformation scheme

Results of Pearl 3.3.3 using the Kremsmünster scenario are examined against the standard of 0.01 µg/L. This is the standard of 0.1 µg/L with an additional safety factor of 10 for vulnerable groundwater protection areas (NL-specific situation).

From Table M.2a it reads that the expected leaching based on the PEARL-model calculations for the active substance spinosad is smaller than 0.01 µg/L for all proposed applications. Hence, the applications meet the standards for leaching as laid down in the RGB.

Furthermore, it reads that the expected leaching for the metabolites spinosyn B and N-demethylated-spinosyn D are eq ual to or larger than 0.01 µg/L but smaller than 0.1 µg/L. The applications meet the standards for leaching. However, as the predicted concentration for both metabolites is larger than 0.01 µg/L, a restriction sentence on the use in groundwater protection areas should be placed on the label. The applicant proposed the following restriction sentence and therefore no further assessment is preformed.

Om het grondwater te beschermen mag dit product niet worden toegepast in grondwaterbeschermingsgebieden.

Lysimeter/field leaching studies

From a study with mini lysimeters it appears that neither the active substance nor the metabolites spinosyn B and N-demethylated spinosyn D are detected in the leachate in concentrations >0.1 µg/L. Measured concentrations are however higher than the concentrations calculated with the PEARL model. A number of 10 non-identified metabolites were detected with maximum concentrations between 1.2 and 10.7 µg/L (total amount of all non-identified metabolites). These polar metabolites should be identified and their potential for leaching must be classified. Based on the differences between measured concentrations in the leachate of the mini-lysimeters and the simulated concentration of the PEARL model, the lysimeter results should be standardised. Within the experiment large differences in water

flow were determined possibly caused by preferential flow. Furthermore, the used lysimeter columns were not made of a non-reactive material.

A second lysimeter study revealed the following results; Münster, Germany. Four applications of spinosyn A and D were conducted, 216 g as/ha per application. Two lysimeters per test substance were used. No spinosyn A and D were detected in any of the leachate samples. None of the potential metabolites available as reference standards were detected in the leachate samples. However, the beta-13,14-dihydropseudoaglycone metabolite of spinosyn A and D (major photo metabolite) were not included as reference substance in the analysis. Since the annual average equivalent concentration exceeded 0.1 µg/L in each lysimeter in both years (1.58 µg/L to 4.07 µg/L equivalent in the first monitoring year, and 3.07 µg/L to 5.02 µg/L in the second year) it could at first not be excluded that the beta-13,14-dihydropseudoaglycone metabolite of spinosyn A and D was present in the leachate at concentrations > 0.1 µg/L. From thorough re-analysis of the lysimeter leachate however, it can be concluded that the beta-13,14-dihydropseudoaglycone metabolites of spinosyn A and D (major photo metabolite) is not present in the leachate.

Monitoring data
There are no data available regarding the presence of the substance spinosad in groundwater.

Conclusions
The active substance spinosad and metabolites spinosyn B and N-demethylated spinonsyn D comply with the requirements laid down in the RGB concerning persistence in soil.

The proposed applications of the product complies with the requirements laid down in the RGB concerning leaching in soil, provided that the following restriction sentence is placed on the label *Om het grondwater te beschermen mag dit product niet worden toegepast in grondwaterbeschermingsgebieden.*

6.2 Fate and behaviour in water

6.2.1 Rate and route of degradation in surface water
The exposure concentrations of the active substance spinosad in surface water have been estimated for the various proposed uses using calculations of surface water concentrations (in a ditch of 30 cm depth), which originate from spray drift during application of the active substance. The spray drift percentage depends on the use. The applicant proposed the following restriction sentence for all uses applied for except the use in wine grapes:

Om in het water levende organismen te beschermen is toepassing in onbedekte teelten op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 90% driftreducerende spuitdoppen.

The use of 90% driftreducing nozzles corresponds with a drift percentage of 0.2% to be used in TOXSWA modelling. For the glasshouse use in beans with pod, a default emission percentage of 0.1% has been used.

For the use in wine grapes, the following restriction sentence was proposed:

- *Toepassing na 1 mei*
- *Haalbare driftreducerende maatregelen: driftarme doppen (~Venturi doppen, 90 % DR doppen) en het gebruik van een windhaag.*

No NL drift percentages for vines are available; as a default a drift percentage of 7% is used comparable to the EU drift percentages. No reference towards application of the product before or after May 1st is considered necessary for the use in wine grapes.
For the second restriction sentence proposed by the applicant, no corresponding drift value is available in the Evaluation Manual. After consultation of the applicant, the following restriction sentence was proposed:

Permitted is only the use as insecticide in the culture of wine grapes on the understanding that application on fields adjacent to waterways is only permitted if the product on the first 20 m adjacent to the waterway is sprayed with a Venturi nozzle where the last tree row must be sprayed from one side and reduced air fan setting.

This corresponds with a drift value for the use in wine grapes of 0.3%.

Concentrations in surface water are calculated using the model TOXSWA. The following input data are used for the calculation:

TOXSWA:
Active substance:
Mean DT_{50} for degradation in water at 20°C: 139 days (mean of spinosyn A+D)
DT_{50} for degradation in sediment at 20°C: 1000 days (default)

Arithmetic mean K_{om} for suspended organic matter: 20316 L/kg (see LoEP)
Arithmetic mean K_{om} for sediment: 20316 L/kg (see LoEP)
1/n: 0.9 (default for active substance)

Saturated vapour pressure: 2 x 10^{-11} Pa (25°C; value of spinosyn A)
Solubility in water: 0.089 g/L (20ºC; value of spinosyn A)
Molecular weight: 732 g/mol, value of spinosyn A

Other parameters: standard settings TOXSWA

When no separate degradation half-lives (DegT50 values) are available for the water and sediment compartment (accepted level P-II values), the system degradation half-life (DegT50-system, level P-I) is to be used as input for the degrading compartment and a default value of 1000 days is used for the compartment in which no degradation is assumed. This is in line with the recommendations in the FOCUS Guidance Document on Degradation Kinetics.

For metabolites, the level M-I values are used (system DegT50 value) only, since level M-II criteria have not been fully developed under FOCUS Degradation Kinetics.

In Table M.3a, the drift percentages and calculated surface water concentrations for the active substance spinosad for each intended use are presented.

Table M.3a Overview of surface water concentrations for active substance spinosad following spring application in the edge-of-field ditch

Use	Substance	Rate a.s. [kg/ha]	Freq.	Inter-val	Drift [%]	PIEC [µg/L] *	PEC21 [µg/L] *	PEC28 [µg/L] *
Lettuce, Endive species, Rocket, Garden cress, Lambs lettuce	spinosad	0.096	3	7	0.2	0.1417	0.0896	0.0801
Zucchini,	spinosad	0.096	5	7	0.2	0.1869	0.1311	0.1255

Use	Substance	Rate a.s. [kg/ha]	Freq.	Inter-val	Drift [%]	PIEC [µg/L] *	PEC21 [µg/L] *	PEC28 [µg/L] *
Gherkin, Pumpkin species, Melon, Watermelon								
Herbs**	spinosad	0.096	3	7	0.2	0.2358	0.1826	0.1747
Strawberry	spinosad	0.072	3	7	0.2	0.1055	0.0666	0.0618
Wine grapes	spinosad	0.072	3	14	0.3	0.1398	0.0838	0.0818
Raspberry, blackberry	spinosad	0.096	2	10	0.2	0.1079	0.0590	0.0561
Spinach family	spinosad	0.096	3	10	0.2	0.1322	0.0831	0.0785
Beans with pod	spinosad	0.12	3	10	0.1	0.0816	0.0688	0.0483

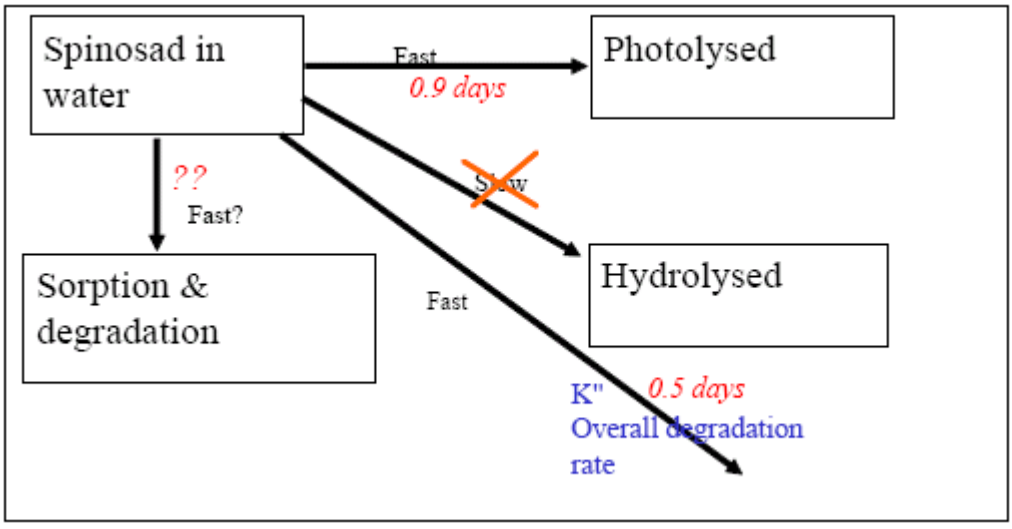
* calculated according to TOXSWA

** For the use in herbs, 5 cropcycles per 12 months were modelled, each consisting of 3 treatments.

Refinement of PECsw calculation

More refined information on degradation in water sediment systems was submitted in form of a mesocosm study where fate and behaviour of the substance was measured. From a level P-I analysis according to FOCUS Kinetics a $DT_{50system}$ for the mesocosm of 2.7 days was derived. This P-I analysis is based upon measurements from 24 h onwards, and so, not on processes occurring only the first 24 h after spraying. This approach was chosen to cover for all uncertainties in the study like mixing depth, solvability, and also initial photolysis of the compound available at the near surface of the test system.

If the P-I analysis is performed including the data point from the first 24 hours, looking at the contribution of hydrolysis (from hydrolysis study) and photolysis (from photolysis study), a $DT_{50system}$ of 1.13 days is derived. The hydrolysis and photolysis processes are included in the level P-I conceptual model to fit the overall system degradation.



In this case not a real degradation half-life is obtained accounting for biodegradation as required as input for TOXSWA simulations.

The mesocosm experiment was performed at 40ºN and it is clear from the results of the mesocosm study, as well as from the photolysis experiments, photodegradation plays a major role in the degradation of spinosad in water. Therefore, it can be questioned if the results can be used for the registration in the Netherlands.

The applicant submitted further information on the role of photolysis in degradation processes and demonstrated that the results of the mesocosm performed at 40ºN can be extrapolated to the Dutch situation at approx. 52ºN based on quantum yield calculated to be 0.019 and 0.021 respectively for Spinosyn A and D, and molar extinction coefficients. From a statement provided by the applicant it is shown that there is only a slight increase in $DT_{50photolysis}$ if the latitude changes.

Table A1.3. Summary of calculated DT50 values for spinosyn A and D at latitutes between 10° and 70° N in spring, summer, autumn and winter.

	Spinosyn A				Spinosyn D			
	Spring	**Summer**	**Autumn**	**Winter**	**Spring**	**Summer**	**Autumn**	**Winter**
Lat 10°N	0.54	0.54	0.60	0.65	0.47	0.53	0.58	0.63
Lat 20°N	0.54	0.51	0.67	0.82	0.48	0.50	0.66	0.80
Lat 30°N	0.56	0.50	0.80	1.09	0.50	0.49	0.78	1.07
Lat 40°N	0.61	0.51	1.04	1.71	0.54	0.50	1.01	1.67
Lat 50°N	0.69	0.53	1.56	3.41	0.61	0.52	1.53	3.35
Lat 60°N	0.83	0.57	2.92	9.94	0.74	0.56	2.87	9.81
Lat 70°N	1.11	0.63	7.99	NA	0.98	0.61	7.90	NA

Spin A	average 50 - 60N =	0.66 days
Spin D	average 50 - 60N =	0.61 days
	average=	0.63 days

Furthermore the applicant provided information from which it is clear that cloudiness of skies is expected not to influence the photo degradation rate. Clouds mainly absorb in the near- and mid IR- radiation regions. Absorption in the visible region is not affected by cloud cover, this is the region where spinosad absorbs radiation. Although the information was presented in a statement and the original figures where not submitted the conclusion will be used as additional evidence.

Conclusion: from a level P-I analysis of an outdoor mesoscosm study performed at 40ºN latitude excluding uncertain processes a $DT_{50system}$ value of 2.7 days was derived. From a level P-I analysis including the processes hydrolysis and photolysis in the conceptual model a $DT_{50system}$ of 1.13 days was derived. Additional evidence was submitted to demonstrate that the results of the study can be used for the assessment of the Dutch registration. As a result Ctgb decided to use the level P-I analysis results of the mesocosm study of 2.7 days for the TOXSWA calculation.

The following input data are used:

TOXSWA:
Active substance:
DT_{50} for degradation in water at 20°C: 2.7 days (spinosyn A+D)
DT_{50} for degradation in sediment at 20°C: 1000 days (default).

Arithmetic mean K_{om} for suspended organic matter: 20316 L/kg (see LoEP)
Arithmetic mean K_{om} for sediment: 20316 L/kg (see LoEP)
1/n: 0.9 (default for active substance)

Saturated vapour pressure: 2 $x10^{-11}$ Pa (25℃; value of spinosyn A)
Solubility in water: 0.089 g/L (20 ºC; value of spinosyn A)
Molecular weight: 732 g/mol, value of spinosyn A

Other parameters: standard settings TOXSWA

Table M.3b Overview of surface water concentrations for active substance spinosad following spring application in the edge-of-field ditch

Use	Substance	Rate a.s. [kg/ha]	Freq.	Inter-val	Drift [%]	PIEC [µg/L] *	PEC21 [µg/L] *	PEC28 [µg/L] *
Lettuce, Endive species, Rocket, Garden cress	spinosad	0.096	3	7	0.2	0.1037	0.0481	0.0420
Lambs lettuce	spinosad	0.096	3	7	0.2	0.1037	0.0481	0.0420
Zucchini, Gherkin, Pumpkin species, Melon, Watermelon	spinosad	0.096	5	7	0.2	0.1138	0.0615	0.0586
Herbs**	spinosad	0.096	3	7	0.2	0.1204	0.0682	0.0649
Strawberry	spinosad	0.072	3	7	0.2	0.0773	0.0358	0.0312
Wine grapes	spinosad	0.072	3	14	0.3	0.1005	0.0409	0.0361
Raspberry, blackberry	spinosad	0.096	2	10	0.2	0.0888	0.0339	0.0286
Spinach family	spinosad	0.096	3	10	0.2	0.0950	0.0404	0.0388
Beans with pod	spinosad	0.12	3	10	0.1	0.0588	0.0249	0.0239

* calculated according to TOXSWA

** For the use in herbs, 5 cropcycles per 12 months were modelled, each consisting of 3 treatments.

Further refinement of the $PEC_{surfacewater}$ values is possible if the degradation behaviour in the outdoor mesocosm is considered bi-phasic, where the first phase is considered attributed to the non biodegradation processes photolysis and hydrolysis and the second phase is attributed to biodegradation. The first phase degradation by photolysis/hydrolysis was calculated to have a $DT_{50system}$ of 1.13 days. The second phase degradation is considered to be described by the system degradation half life in the dark water/sediment system ($DT_{50system}$ = 139 days). As TOXSWA is only suitable for input values that result from 'real' degradation (other transformation processes should be excluded) the bi-phasic proces is simulated by assuming that after 1 day half of the dose rate is transformed by photolysis/hydrolysis and the resulting half of the dose rate is available for transformation by biodegradation. The input to TOXSWA is the geomean laboratory half-life of 139 days from the dark water sediment studies and half of the dose rate.

In table M.3c the results of the initial surface water concentration calculated following this approach are reported.

Table M.3c Overview of surface water concentrations for active substance spinosad following spring application in the edge-of-field ditch

Use	Substance	Rate a.s. [kg/ha]	Freq.	Inter-val	Drift [%]	PIEC [µg/L] *	PEC21 [µg/L] *	PEC28 [µg/L] *
Lettuce, Endive species, Rocket, Garden cress	spinosad	0.048**	3	7	0.2	0.0697	0.0438	0.0406
Lambs lettuce	spinosad	0.048**	3	7	0.2	0.0697	0.0438	0.0406
Zucchini, Gherkin, Pumpkin species, Melon, Watermelon	spinosad	0.048**	5	7	0.2	0.0916	0.0639	0.0612
Herbs***	spinosad	0.048**	3	7	0.2	0.1191	0.0954	0.0917
Strawberry	spinosad	0.036**	3	7	0.2	0.0348	0.0129	0.0107

Use	Substance	Rate a.s. [kg/ha]	Freq.	Inter-val	Drift [%]	PIEC [µg/L] *	PEC21 [µg/L] *	PEC28 [µg/L] *
Wine grapes	spinosad	0.036**	3	14	0.3	0.0495	0.0201	0.0177
Raspberry, blackberry	spinosad	0.048**	2	10	0.2	0.0532	0.0289	0.0275
Spinach family	spinosad	0.048**	3	10	0.2	0.0649	0.0407	0.0383
Beans with pod	spinosad	0.06**	3	10	0.1	0.0401	0.0250	0.2355

* calculated according to TOXSWA
** input to TOXSWA is half of the dose rate applied for
*** For the use in herbs, 5 cropcycles per 12 months were modelled, each consisting of 3 treatments.

The exposure concentrations in surface water are compared to the ecotoxicological threshold values in section 7.2.

Monitoring data
Article 2.10b of the *Plant Protection Products and Biocides Regulations* (RGB) describes the use of the 90th percentile.

In April 2014, version 3.0 of the Pesticide Atlas was launched, which includes a statistical correlation analysis between concentrations, threshold exceedance and land use, which may indicate probable relationships. In this version also the correlation analysis of land use with the environmental quality standards (EQS) of the Water Framework Directive (WFD) is included.

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards (MKN in Dutch, data source http://www.rivm.nl/rvs/Normen). These environmental quality standards consist either of the harmonised WFD thresholds derived according to the Fraunhofer methodology[4] (AA-EQS and MAC-EQS) or of an MPC value (which is usually derived on the basis of outdated guidance). When EQS values according to the Water Framework Directive are available, the MPC value is not used further in the analysis of monitoring data for the purpose of the registration.

For examination against the drinking water criterion, another database (VEWIN) is used, since the drinking water criterion is only examined at drinking water abstraction points. For the assessment of the proposed applications regarding the drinking water criterion, see next section.

<u>spinosad</u>
The active substance was observed in the surface water (most recent data from 2012). In Table M.4 the number of observations in the surface water are presented. The authorisation threshold equals 0.12 µg a.s./L (consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case 0.01*NOEC Daphnia).

The relevant EQS for this substance is the MPC and equals 0.024 µg/L. The currently available MPC value is reported here for information purposes when no EQS values are available.

[4] P.L.A. van Vlaardingen and E.M.J. Verbruggen, Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Revision 2007'. RIVM report 601782001.

Table M.4 Monitoring data in Dutch surface water for (from www.pesticidesatlas.nl, version 3.0)

Total no of locations (2012)	*n* > authorisation threshold	*n* > EQS		
		MAC-EQS	AA-EQS	MPC (ad-hoc/indicative)
316*	12 (5 x 1-2*threshold, 5 x 2-5*threshold, 2 x >5*threshold)	n.a.	n.a.	14 (2 x 2-5*threshold, 12 x >5*threshold)

* the number of observations at each location varies between 1 and 30, total number of measurements is 2185 in 2012.
** n.a. not available

Several locations show an exceedance of the authorisation threshold and ad hoc MPC threshold. Therefore it is assessed whether there is a correlation between the observed exceedances and land use types. The correlation analysis as included in the Pesticide Atlas uses a progressive three-year period to assess whether there is a relation. The last three available years, in this case 2010-2012 are used to establish the relation.

The observed exceedance of the water quality standards authorisation threshold and ad hoc MPC threshold is not significantly correlated to the proposed uses assessed in this risk assessment.

Therefore, no consequences can be drawn from the observed exceedance.

Drinking water criterion
It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, the Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion 'surface water intended for drinking water production'.
The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635[5].

Substances are categorized as new substances on the Dutch market (less than 3 years authorisation) or existing substances on the Dutch market (authorised for more than 3 years).

- For new substances, a preregistration calculation is performed.
- For existing substances, the assessment is based on monitoring data of VEWIN (drinking water board).
    - If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.
    - If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90th percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

Active substance spinosad has been on the Dutch market for > 3 years (authorised since 13-09-2002). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active

[5] Adriaanse et al. (2008). Development of an assessment methodology to evaluate agricultural use ofplant protection products for drinking water production from surface waters - A proposal for the registration procedure in the Netherlands. Alterra-Report 1635

substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water as laid down in the RGB are met.

6.3 Fate and behaviour in air

Route and rate of degradation in air
Active substance spinosad (spinosyn A and spinosyn D)
The vapour pressure is 2 x 10^{-11} respectively 3x10^{-11} Pa at 25°C. The Henry constant is 1.89 x 10^{-7}, respectively 2.32 x 10^{-5} Pa.m^3.mol at 20°C. The half-life in air is 20 and 19 minutes respectively.

Since at present there is no framework to assess fate and behaviour in air of plant protection products, for the time being this issue is not taken into consideration.

6.4 Appropriate fate and behaviour endpoints relating to the product and approved uses

See List of Endpoints.

6.5 Data requirements

For metabolites spinosyn B and N-demethylated spinosyn D a full non relevance assessment for groundwater metabolites should be provided.

The following restriction sentences were proposed by the applicant:
Om het grondwater te beschermen mag dit product niet worden toegepast in grondwaterbeschermingsgebieden.

Om in het water levende organismen te beschermen is toepassing in onbedekte teelten op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 90% driftreducerende spuitdoppen.

Permitted is only the use as insecticide in the culture of wine grapes on the understanding that application on fields adjacent to waterways is only permitted if the product on the first 20 m adjacent to the waterway is sprayed with a Venturi nozzle where the last tree row must be sprayed from one side and reduced air fan setting.

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use (WG):
Om het grondwater te beschermen mag dit product niet worden toegepast in grondwaterbeschermingsgebieden.

Om in het water levende organismen te beschermen is toepassing in onbedekte teelten op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 90% driftreducerende spuitdoppen.

Permitted is only the use as insecticide in the culture of wine grapes on the understanding that application on fields adjacent to waterways is only permitted if the product on the first 20 m adjacent to the waterway is sprayed with a Venturi nozzle where the last tree row must be sprayed from one side and reduced air fan setting.
(to be confirmed by ecotox)

6.6 Overall conclusions fate and behaviour

It can be concluded that:

1. the active substance spinosad meets the standards for persistence in soil as laid down in the RGB.
2. all proposed applications of the active substance spinosad meet the standards for leaching to the shallow groundwater as laid down in the RGB.
3. all proposed applications of metabolites spinosyn B and N-demethylated spinosyn D meet the standards for leaching to shallow groundwater as laid down in the RGB, provided that the following restriction sentence is placed on the label of the product for useage in ground water protection areas *Om het grondwater te beschermen mag dit product niet worden toegepast in grondwaterbeschermingsgebieden.*
4. all proposed applications of the active substance spinosad meet the standards for surface water destined for the production of drinking water.

7. Ecotoxicology

The *Plant Protection Products and Biocides Regulations* (RGB) published in the Government Gazette (Staatscourant) 188 of 28 September 2007 came into effect on 17 October 2007, while repealing the *Uniform Principles Decree on Plant Protection Products* (BUBG) and the *Regulation elaborating the uniform principles for plant protection products* (RUUBG).

For applications for formulations received and taken into the assessment procedure before 17-10-2007, risk assessment is done in accordance with HTB 1.0.
This means that for the current application of Tracer, risk assessment is done in accordance with HTB 1.0.

Conclusion with respect to comparability – background information from the dossier's compllteness check

The risk of the applied uses in indoor (**I**) in head cabbage, cauliflower, broccoli, Brussels sprouts, Chinese cabbage, swede, kohlrabi, Eastern leaf cabbage and chicory collar treatment is equal to or lower than the risk of the authorised uses with regard to the environment for all aspects addressed above. No additional sentences are required as the proposed restriction sentences are not specified for a specific use.

The risk of the applied uses in glasshouses (**G**) in table grapes and beans with pods is equal to or lower than the risk of the authorised uses with regard to the environment for all aspects addressed above. No additional sentences are required as the proposed restriction sentences are not specified for a specific use.

The risk of the use applied for lettuce, endive species, rucola, garden cress, herbs, lambs lettuce, spinach, beans with pods (**F**) is not included in the risk envelope for the aspects bees and bumblebees, and non-target arthropods. Furthermore, as PEC soil will be higher also the aspects birds, mammals (secondary poisoning via earthworms) and soil organisms should be assessed. For these aspects a separate risk assessment is required.

The risk of the use applied for courgette, gherkin, pumpkin, melon, water melon (**F**) is not included in the risk envelope for the aspects aquatic organisms, birds and mammals, bees and bumblebees, and non-target arthropods. For these aspects, a separate risk assessment is required.

The risk of the use applied for strawberry (**F**) is not included in the risk envelope for the aspects bees and bumblebees, and non-target arthropods. For these aspects, a separate risk assessment is required.

The risk of the use applied for raspberry and blackberry (**F**) is not included in the risk envelope for the aspects mammals, bees and bumblebees, and non-target arthropods. For these aspects, a separate risk assessment is required.

The risk of the use applied for wine grapes (**F**) is not included in the risk envelope for the aspects aquatic organisms, birds (secondary poisoning via fish and drinking water only) and mammals, bees and bumblebees, and non-target arthropods. For these aspects, a separate risk assessment is required.

List of Endpoints Ecotoxicology

The active substance Spinosad was included on February 1st, 2007 in Annex I of Directive 91/414/EEC. The ecotoxicological risk assessment for the plant protection product Tracer is based on the list of endpoints as copied from the extension of uses decision (Ctgb decision 10-06-2011), since it contains information relevant for this assessment. On 16 March 2009 additional information on two arthropod studies was presented; the studies were summarized by Ctgb. The result is presented below the LoE.
Data submitted for the Dutch authorisation, or remarks from Ctgb, are included in *italics*.

Spinosad = a.s. = mixture of 50-95% of Spinosyn A and 50-5% Spinosyn D.
The active substance is included in Annex 1 list of directive 91/414/EC.
Tracer = NAF-85 = 480 g/L SC formulation.

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Acute toxicity to mammals	LD_{50} >2000 mg/kg bw (rat)
Reproductive toxicity to mammals	NOEL 50 mg/kg feed (13-wk rat, based on biochemical parameters) NOEC 100 mg/kg feed (2-generation rat, based on litter size, bodyweight and food consumption)
Acute toxicity to birds	LD_{50} >2000 mg/kg bw (mallard duck and bobwhite quail)
Dietary toxicity to birds	LC_{50} >5253 mg/kg feed (bobwhite quail) LC_{50} >5156 mg/kg feed (mallard duck)
Reproductive toxicity to birds	NOEC 550 mg/kg *feed* (mallard duck and bobwhite quail)

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg as/L)
Laboratory tests				
Algae *Anabaena flos-aquae*	spinosad	120 h	EC_{50}	6.1 (nominal)
Algae *Selenastrum capricornutum*	NAF-85	120 h	EC_{50}	>48 (nominal)
Diatoms *Navicula pelliculosa*	spinosad	120 h	EC_{50}	0.079 (mean measured)
Diatoms *Navicula pelliculosa*	NAF-85	120 h	EC_{50}	0.35 (mean measured)
Diatoms *Navicula pelliculosa*	Spinosyn B	120 h	EC_{50}	0.077 (mean measured)
Diatoms *Navicula pelliculosa*	N-demethylated Spinosyn D	120 h	EC_{50}	0.25 (mean measured)
Diatoms *Navicula pelliculosa*	ß-13,14-dihydro-pseudogly-cone of Spinosyn A	72 h	EC_{50}	38.8 (nominal)
Diatoms *Navicula pelliculosa*	ß-13,14-dihydro-pseudogly-cone of Spinosyn D	96 h	EC_{50}	28 (mean measured)
Invertebrates *Daphnia magna*	spinosad	48 h	EC_{50}	>1.0 (nominal)
Invertebrates *Daphnia magna*	NAF-85	48 h	EC_{50}	9.1 (nominal)
Invertebrates *Daphnia magna*	Spinosyn B	48 h	EC_{50}	6.5 (mean measured)
Invertebrates *Daphnia magna*	N-demethylated Spinosyn D	48 h	EC_{50}	3.8 (mean measured)
Invertebrates *Daphnia magna*	ß-13,14-dihydro-pseudogly-cone of Spinosyn A	48 h	EC_{50}	> 197 (mean measured)
Invertebrates *Daphnia magna*	ß-13,14-dihydro-pseudogly-cone of Spinosyn D	48 h	EC_{50}	65.8 (mean measured)

Fish *Cyprinus carpio*	spinosad	96 h	LC_{50}	4.0 (nominal)
Fish *Cyprinus carpio*	NAF-85	96 h	LC_{50}	>49 (nominal)
Higher plants *Lemna minor*	spinosad	14 d	EC_{50}	6.6 (mean measured)
Fish *Oncorhynchus mykiss*	spinosad	80 d	NOEC (ELS)	0.50 (nominal)
Invertebrates *Daphnia magna*	spinosad	21 d	NOEC (flow-through) NOEC (semi-static)	0.0012 mg/L (mean measured) 0.0080 mg/L (nominal)
Invertebrates *Daphnia magna*	Spinosyn B	21 d	NOEC (flow-through)	0.00095 (mean measured)
Invertebrates *Daphnia magna*	N-demethylated Spinosyn D	21 d	NOEC (flow-through) NOEC (semi-static)	0.001 (mean measured)
Invertebrates *Daphnia magna*	ß-13,14-dihydro-pseudogly-cone of Spinosyn A	21 d	NOEC (flow-through) NOEC (semi-static)	1.25 (nominal)
Invertebrates *Daphnia magna*	ß-13,14-dihydro-pseudogly-cone of Spinosyn D	21 d	NOEC (flow-through) NOEC (semi-static)	4.85 (mean measured)
Sediment-dwelling invertebrates *Chironomus riparius*	spinosad	25 d	NOEC (initial concentration in overlying water)	0.0016 mg/L (initial measured)
Sediment-dwelling invertebrates *Chironomus riparius*	Spinosyn B	28 d	NOEC (initial concentration in overlying water)	0.0032 (measured initial)
Sediment-dwelling invertebrates *Chironomus riparius*	N-demethylated Spinosyn D	28 d	NOEC (initial concentration in overlying water)	0.0024 (measured initial)
Sediment-dwelling invertebrates *Chironomus*	ß-13,14-dihydro-pseudogly-cone of Spinosyn A	28 d	NOEC (initial concentration in overlying water)	≥ 1.12 (measured initial)

riparius				
Sediment-dwelling invertebrates *Chironomus riparius*	ß-13,14-dihydro-pseudogly-cone of Spinosyn D	28 d	NOEC (initial concentration in overlying water)	≥ 0.731 (measured initial)
Microcosm or mesocosm tests				
not provided				

Bioconcentration

Bioconcentration factor (BCF)	**Spinosyn A** 114 L/kg **Spinosyn D** 115 L/kg
Annex VI Trigger for the bioconcentration factor	100 for not readily biodegradable compounds
Clearance time	CT_{50}: **Spinosyn A** <5 d **Spinosyn D** 2 – 4 d
	CT_{90}:
Level of residues (%) in organisms after the 14 day depuration phase	

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

Acute oral toxicity honeybees	LD_{50} 0.057 µg/bee (spinosad) LD_{50} 0.049 µg as/bee (NAF-85)
Acute contact toxicity honeybees	LD_{50} 0.0036 µg/bee (spinosad) LD_{50} 0.050 µg as/bee (NAF-85)
Acute oral toxicity bumblebees	LD_{50} 0.37 µg as/bee (NAF-85)
Acute contact toxicity bumblebees	LD_{50} 17.2 µg/bee (NAF-85)

Field or semi-field tests					
Species	Test type	Dose [kg as/ha]	Dose [g as/L]	Parameter	Effect
Apis mellifera	Cage	0.144 (morning before bee activity)	-	mortality foraging brood	no effect small effect (only first day after treatment) no effect
Apis mellifera	Cage	0.540 (morning before bee activity)	-	mortality foraging behaviour brood development	no effect significant effect (several timepoints) indication of effect
Apis mellifera	Semi field	0.216 (during bee activity)		- mortality - foraging - brood and food store condition	- 66% after 1 day, - 48% after 2 days - no effects
Apis mellifera	Semi field	4 x 0.216 (during bee activity)		- mortality - foraging - brood and food store condition	- 66% after 1 day, - 66% at day 0, 90% after 2 days, 78% after 3 days - no effects
Bombus terrestris	Semi field	-	0.36 (bee released day after applica-tion)	mortality foraging behaviour brood development	1% after 7 days 65% after 2 days, 18% after 4 days, 13% after 6 days 27% after 16 days (all effects are not significant)

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Test type and exposure duration	Test Substance	Dose (g as/ha)	Endpoint	Adverse Effect* (%)	Annex VI Trigger (%)
Laboratory tests						
Predatory mites						
Typhlodromus pyri	Lab, residue on glass, 14 days	spinosad	31	mortality	100	30
Typhlodromus pyri	Lab, residue on glass, 7 days	NAF-85[4]	40 – 320	mortality	100	30
Phytoseiulus persimilis	Extended lab, residue on plants, 6 days	NAF-85	2x0.36 g as/L until run-off, interval 14 d	mortality	93	50
Foliage dwelling predators						
Chrysoperla carnea	Extended lab, residue on plants, 12 days	NAF-85	2x0.36 g as/L until run-off, interval 14 d	mortality fecundity	25 18	50
Coccinella septempunctata	Lab, residue on glass, 14 weeks (fecundity)	NAF-85	40	mortality fecundity	11 43	30
Coccinella septempunctata	Lab, residue on glass, 14 weeks (fecundity)	NAF-85	160	mortality fecundity	8 40	30
Coccinella septempunctata	Lab, residue on glass, 14 weeks (fecundity)	NAF-85	320	mortality fecundity	19 20	30
Coccinella septempunctata	Extended lab, residue on leaves, 8 weeks minimum	NAF-85	2x0.36 g as/L, until run-off, interval 14 d	mortality	16	50
Episyrphus balteatus	Lab, residue on glass, 10 days	spinosad	45 g as/L, until run-off	mortality fecundity	80 75	30
Coccinella septempunctata	Lab, residue on glass, 10 weeks (fecundity)	spinosad	17 g as/L, until run-off	mortality fecundity	-1.1 +9.3	30
Parasitoids						
Aphidius rhopalosiphi	Lab, residue on glass, 24 hour	NAF-85	40 – 320	mortality	100	30
Aphidius rhopalosiphi	Extended lab, residue on plants, 13 days	NAF-85	4.8 9.6 19 38	mortality mortality mortality mortality LR_{50}	13 40 67 80 *12.8*[5]	50

Aphidius rhopalosiphi (protected life stage)	Lab, direct spray of mummified aphids on glass, 9 days	NAF-85	38	mortality	20	30
Aphidius rhopalosiphi (protected life stage)	Extended lab, direct spray of mummified aphids on plants, 7 days	NAF-85	38	mortality	47	30
Aphidius colemani	Extended lab, residue on plants, 2 days	NAF-85	540, aged 0-5 d 540, aged 7 d 1080, aged 0-7 d	mortality mortality mortality	100 98 100	50
Aphidius colemani	Extended lab, residue on leaves, 2 days	NAF-85	0.36 g as/L until run-off, aged 0-29 d	mortality	100	50
Aphidius colemani *(protected life stage)*	Extended lab, direct spray of mummified aphids on plants, 7 days	NAF-85	0.36 g as/L until run-off	emergence	82	50
Ground dwelling predators						
Poecilus cupreus	Lab, direct spray of beetles and food on sand, 14 days	NAF-85	50-400	mortality food consump-tion	0-3.3 ns	30
Poecilus cupreus	Lab, direct spray of beetles and food on sand, 29 days	NAF-85	1×540	mortality food consump-tion	6.7 4	30
Poecilus cupreus	Lab, direct spray of beetles and food on sand, 29 days	NAF-85	2×540, interval 8 d	mortality food consump-tion	63 19	30
Poecilus cupreus	Lab, direct spray of beetles and food on sand, 29 days	NAF-85	3 × 540, interval 8 d	mortality food consump-tion	81 41	30
Field or semi-field tests						
Typhlodromus pyri	Field, sprayed vineyard, ±7 weeks	NAF-85	24 and 48	abundance	<25	25
Typhlodromus pyri	Field, sprayed vineyard, ±7 weeks	NAF-85	96	abundance	43 after 7 d <25 from 16 d	25
Typhlodromus pyri	Field, sprayed vineyard	NAF-85	4 applica-tions 29-38-67-77	abundance	- 34 < 25% (after 4th	25

					treatment)	
Typhlodromus pyri	Field, sprayed vineyard	NAF-85	4 applications 29-38-67-77	abundance	< 25%	25
Typhlodromus pyri	Field experiment, sprayed vineyard 75 days[3]	NAF-85	2 applications; 3.8[1] 3 applications; 3.2[2]	abundance	23.5 % (max.) after 35 d.	25
Typhlodromus pyri	Field experiment, sprayed vineyard, 75 days	NAF-85	2 applications; 58[1] 3 applications; 48[2]	abundance	31.6% (max.) after 14 d.	25
Typhlodromus pyri	Field experiment, apple orchard, 122 days[3]	NAF-85	2 applications; 39[1] 3 applications; 18[2]	abundance	34.1 % (max.) after 93 d.	25
Typhlodromus pyri	Field experiment, apple orchard, 122 days	NAF-85	4 applications; 166	abundance	26% positive effect (max.) after 122 d.	25
Typhlodromus pyri	Field sprayed vineyard, Freiburg	NAF-85	4 applications 29-39-68-78	abundance	24.6 (positive)	25
Macrolophus caliginosus	Semi-field, direct spray of bugs on plants, 14 days	NAF-85	0.096 g as/L, until run-off	abundance	23 (1-7 days) 0 (14 days)	25
Macrolophus caliginosus	Semi-field, direct spray of bugs on plants, 14 days	NAF-85	0.36 g as/L, until run-off	abundance	49 (1 day) 75 (3 days) 64 (7 days) 32 (14 days)	25
Chrysoperla carnea	Semi-field, 75 d.	NAF-85	(2x26; 2x11)	survival fecundity hatching succes	16.5 +30 +0.4	25
Aphidius colemani	Semi-field, direct spray of aphids on plants, 12 days	NAF-85	0.096 g as/L until run-off 0.36 g as/L until run-off	parasitism parasitism	70 88	25
Aphidius colemani	Semi-field, residue on plants, 12 days	NAF-85	0.096 g as/L until run-off, aged 1 d	parasitism	98	25
Aphidius colemani	Semi-field, residue on plants, 12 days	NAF-85	0.096 g as/L until run-off, aged 7 d	parasitism	41	25
Aphidius colemani	Semi-field, residue on plants, 12 days	NAF-85	0.096 g as/L until run-off, aged 14 d	parasitism	46	25

Aphidius colemani	Semi-field, residue on plants, 12 days	NAF-85	0.36 g as/L until run-off, aged 1 d	parasitism	98	25
Aphidius colemani	Semi-field, residue on plants, 12 days	NAF-85	0.36 g as/L until run-off, aged 7 d	parasitism	36	25
Aphidius colemani	Semi-field, residue on plants, 12 days	NAF-85	0.36 g as/L until run-off, aged 14 d	parasitism	27	25
Aphidius colemani	Semi-field (greenhouse); extended lab	NAF-85	-(4x109), 46 d, fresh residue -(4x109), 60 d., aged 14 d.	survival	95% (max.) after 1 d. 0% after 14 d.	25
Aphidius colemani	Semi-field (greenhouse); extended lab[3]	NAF-85	-(2x26; 2x11), 46 d, fresh residue -(2x 26;2 x11), 60 d., aged 14 d.	survival	45% (max.) after 1 d. 0% (max). after 14 d.	25

*[*1] Adverse effect means:*
x % effect on mortality = x % increase of mortality compared to control
y % effect on a sublethal parameter = y % decrease of sublethal paramether compared to control (sublethal parameters are e.g. reproduction, parasitism, food consumption)

When effects are favourable for the test organisms, a + sign is used for the sublethal effectpercentages (i.e. increase compared to control) and a – sign for mortality effectpercentages (i.e. decrease compared to control).

[1] first and second application
[2] third, fourth and fifth application
[3] lower application rate to simulate exposure due to drift
[4] NAF-85 is identical to the formulation Tracer
[5] LR50 was calculated by Ctgb

Effects on earthworms (Annex IIA, point 8.4, Annex IIIA, point 10.6)

Acute toxicity	Spinosad: LC_{50} >916 mg as/kg (*tested as* NAF-85); *OC*-corrected value is > 458 mg *as*/kg. Spinosyn B: LC_{50} > 1000 mg/kg soil (*OC*-corrected value: > 500 mg/kg soil) N-demethylated Spinosyn D: LC_{50} > 1000 mg/kg soil (*OC*-corrected value: > 500 mg/kg soil)
Reproductive toxicity	Spinosad: NOEC $\geq$ 2700 g as/ha (*tested as* NAF-85); *OC*-corrected value is $\geq$ 1350 g as/ha. Spinosyn B: NOEC $\geq$ 3.582 mg/kg soil (*OC*-corrected value: $\geq$ 1.791 mg/kg soil) N-demethylated Spinosyn D: NOEC $\geq$ 1.928 mg/kg soil (*OC*-corrected value: $\geq$ 0.964 mg/kg soil)

Effects on other soil macro-organisms (Annex IIIA, point 10.6.2)

Litter bag study	Application of 0.864 kg as/ha followed by a second application one month later of 0.432 kg as/ha had no adverse on the rate of breakdown of straw litter in soil (+1.4% after 7 months when compared to control).

Effects on soil micro-organisms (Annex IIA, point 8.5, Annex IIIA, point 10.7)

Nitrogen mineralisation	Spinosad: Negative effects on nitrification (tested at 0.72 and 7.2 mg/kg) were maximally -55% (after 14 days at 7.2 mg/kg). At test termination, all effects (positive and negative) were <25% compared to the control. Spinosyn B: No unacceptable effects at 0.7164 and 3.582 mg/kg soil N-demethylated Spinosyn D: No unacceptable effects at 0.3855 and 1.928 mg/kg soil
Carbon mineralisation	Spinosad: Effects of spinosad on respiration (tested at 0.72 and 7.2 mg/kg) were never higher than 25% compared to the control. Spinosyn B: No unacceptable effects at 0.7164 and 3.582 mg/kg soil N-demethylated Spinosyn D: No unacceptable effects at 0.3855 and 1.928 mg/kg soil

Spinosad was tested for its effect on fungal growth and disease control. At screening rates of 10 mg/L for *in vitro* growth inhibition and 100 mg/L for disease control. Spinosad appeared to be completely inactive *in vitro* and had only a slight reduction on disease expression on the oömycete *Plasmopara viticola* (mildew of grape), 27%.

A test with NAF-85 on phytotoxicity was performed using application rate of 0.227 kg a.s./ha. Species tested were carrot, corn, cucumber, oat, onion, radish, soybean, sunflower, tomato and wheat. Data collected included the percent emerge, shoot lengths, shoot weight and visual phytotoxicity from the emergence test and vegetative vigor test. ANOVA was used to determine the significant difference between the treatment and pooled controls. The maximum reduction compared to the control for the emergence of sunflower (not significant) was 12%. For the emergence shoot weight for cucumber, there was a maximum increase of 20%.

Study with the formulation Tracer
Two studies were submitted for Dutch registration of Tracer and summarised and evaluated by Ctgb (Tracer_ecotox_interne sava_20091227.doc).

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Test type and exposure duration	Test Substance	Dose (g as/ha)	Endpoint	Adverse Effect[*1] (%)	Annex VI Trigger (%)
Laboratory tests						
Predatory mites						
Typhlodromus pyri [2]	*Extended lab, residue on leaves, day 1-7*	*Tracer (GF-976) a.s. Spinosad 485 g/L*	*0.3513*	*mortality*[1] *LR50*	*50*	*50*
Typhlodromus pyri	*Extended lab, residue on leaves tested under outside conditions, day 1-7*	*Tracer (GF-976) a.s. Spinosad 485 g/L*	*4.871*	*mortality*[1] *LR50*	*50*	*50*
Typhlodromus pyri [2]	*Extended lab, residue on leaves, day 7-14*	*Tracer (GF-976) a.s. Spinosad 485 g/L*	*0.625*	*reproduction1* $ER_{repro}50$	*6.7*	*50*
Typhlodromus pyri	*Extended lab, residue on leaves tested under outside conditions, day 7-14*	*Tracer (GF-976) a.s. Spinosad 485 g/L*	*6.25*	*reproduction1* $ER_{repro}50$	*2.67*	*50*

[*1] *Adverse effect means:*
x % effect on mortality = x % increase of mortality compared to control
y % effect on a sublethal parameter = y % decrease of sublethal paramether compared to control (sublethal parameters are e.g. reproduction, parasitism, food consumption)

When effects are favourable for the test organisms, a + sign is used for the sublethal effectpercentages (i.e. increase compared to control) and a – sign for mortality effectpercentages (i.e. decrease compared to control).

1 Data summarized by Ctgb (2009).
[2] In the former risk assessment (2007) Ctgb concluded that the study with T. pyri is not available and that the endpoint is not mentioned in the endpoint list of the DAR. Therefore Ctgb requested this study to be submitted.

Studies with the formulation Tracer (GF-976) (a.s. spinosad 480 g/L)

Two studies were submitted for Dutch registration of Tracer and summarised and evaluated by WIL Research.

Effects on bees *(Annex IIA, point 8.3.1, Annex IIIA, point 10.4)*

Species	*Test type and exposure duration*	*Test Substance*	*Dose (g as/ha)*	*Parameter*	*Effect*
Semi-field cage study					
Honey bee (Apis mellifera L.)	*7 days during exposure followed by 42 days after transfer to untreated area.*	*GF-976*	*3, 6, 12, 24 and 48 g a.s./ha (single application)*	*- flight activity and foraging efficiency* *- mortality* *-condition of the colonies* *-brood development*	*No effect on the specified parameters up to 48 g a.s./ha.*

A semi-field cage study was performed in South-West France in May-July 2011 to assess the effects of honeybee exposure to a flowering crop of Phacelia tanacetifolia treated with spinosad (one application at 3, 6, 12, 24 and 48 g a.s./ha) on mortality, behaviour and colony condition according to OECD and EPPO guidelines. The reviewer found the study not acceptable based on the absence of clarification on presence of bee attractve crops. In other words, in order for the study to be acceptable for the reviewer , the applicant is requested to confirm the absence of crops attractive to bees within a radius of 3 km of the apiary during the post-exposure study period. According to OECD 75 this is a requirement in order to ensure that after the exposure period the contaminated food in the test colonies will be assimilated by the colony. According to the reviewer: "It was reported that during the first two weeks after transfer to the apiary there was a clear increase in the number of brood cells (eggs, larvae and capped brood), whereas the food reserves remained constant, but over the next three weeks food increased strongly while the brood cells decreased".
Ctgb opinion is that the reviewer's interpretation of the OECD75 is correct; however it is not necessary to invalidate the study based on this point only. Semi-field studies are often conducted under a combination of OECD and EPPO (as was the current study) and it is not usual to strictly impose the requirements of one guideline. EPPO requires that at the monitoring site there is no further pesticide exposure (i.e. no flowering crops present). Given that no effects on brood was observed it can be assumed that no exposure to other crops attractive to bees occurred. The collection of untreated pollen and nectar from non-crop plants by the test colonies at this stage cannnot be avoided and reflects normal field conditions. In the semi- field studies evaluated so far by Ctgb, it is sufficient to demonstrate in the monitoring phase that the colony is in an area free from intensive farming (so that there is no other pesticide exposure). The bees may forage on non-crop plants, however, and therefore the food supplies usually increase as soon as the bees are removed from the tunnel. Ctgb is of opinion that in practice it is impossible to maintain the bees without them having the possibility to forage outside.

Effects on other arthropod species *(Annex IIA, point 8.3.2, Annex IIIA, point 10.5)*

Species	*Test type and exposure duration*	*Test Substance*	*Dose (g as/ha)*	*Endpoint*
Field study (off-crop)				
Field populations of arthropods	*Field, 1 spray application on grassland, 8 weeks*	*GF-976*	*0.375, 1.5, 6, 24 and 96*	*community NOER 6 g a.s./ha, community NOEAER 24 g a.s./ha;* ***population NOER 1.5*** *g a.s./ha, population NOEAER 24 g a.s./ha*

The effect of GF-976 (480 g/L spinosad) on off-field non-target arthropod populations was investigated near Fources, Gers, South-France, under field conditions after 1 spray application on grassland at dose levels of 0.375, 1.5, 6, 24 and 96 g a.s./ha on 09 July 2012. The soil-surface and plant-dwelling arthropod communities were sampled just before application (3 days before treatment), 4 days after application and 1, 2, 4 and 8 weeks after application. The soil moisture and environmental conditions were recoreded. The vegetation species composition was as well determined. Agrostis capillaris (common bent grass), Cynodon dactylon (bermudagrass) and Trifolium repens (white clover) were dominant species in this test. Arthropod taxa with sufficiently high numbers for univariate analysis and acceptable CV were (list not exhaustive, includes most abundant taxa):

- *Acari: 20 taxa were analysed (Phytoseiid female mites (Amblyseius obtusus, Graminaseius graminis, and two Neoseiulus species); female Gamasida (including 3 Hypoaspis species); Prostigmata (including Tarsonemidae and Tydeoidea); Acaridae; Oribatidae (including Micropia minus and Zygoribatula undulata).*
- *Araneae: 13 taxa were analysed (Linyphiidae; Lycosidae (predominantly Pardosa); Pachygnatha (Tetragnathidae).*
- *Coleoptera: 11 taxa were analysed (Carabidae, Staphylinidae, Cucujoidea, Aleocharinae, Coccinellidae, Alticinae, Histeridae).*
- *Hymenoptera: 11 taxa were analysed (Formicidae, Ichneumonoidea, Braconidae, Mymaridae, Trichogrammatidae, Diapriidae, Platygastridae, Ceraphronidae, Scelionidae, Cynipoidea).*
- *Collembola: 9 taxa were analysed (Entomobrya lanuginose, Sminthurinus elegans, Sminthurididae, Bourletiellidae, Sminthuridae).*
- *Diptera: 8 taxa were analysed (Cecidomyiidae, Sciaridae, Ephydridae, Sphaeroceridae).*
- *Homoptera/ Heteroptera: 6 taxa were analysed (Cicadellidae, Aphidoidea, Delphacidae, Cercopidae, Miridae).*
- *Other arthropods: 3 taxa were analysed (Orthoptera (Gryllidae and Acrididae) and Thysanoptera).*

The following results were obtained:

- community NOER 6 g a.s./ha (n.b. no statistically significant adverse community effects up to and including 6 g a.s./ha),

- community NOEAER 24 g a.s./ha (n.b. statistically significant at an alpha level of 0.1 four days and one week after treatment, recovery two weeks after treatment, response mainly induced by collembolan taxa);

- population NOER 1.5 g a.s./ha (n.b. the author of the report concluded that effect class (0) is applied to S. elegans at 6 g a.s./ha. According to the reviewer, effect class (0) was added, for statistically significant adverse effects occurring only once during the additional sample immediately (4 days) after treatment. These effects were not taken into account by the author of the report for final decisions concerning NOER/NOEAER or LOER/LOEAER rates, without a justification. If treatment related effects occur under field conditions at 4 days after application, there is no reason why these effects should be ignored when setting the NOER/ NOEAER. Therefore the population NOER is not 6 g a.s./ha as proposed by the author of the report, but 1.5 g a.s./ha).

- population NOEAER 24 g a.s./ha (n.b. adverse population effects in the 24 g a.s./ha rate for three Collembola taxa (Sminthurinus elegans, Bourletiellidae and Sminthuridae), recovery at the last sampling).

As several parts of several extentions already fall within the exsisting risk envelope, not all parts need to be assessed. Below is a list showing which use has to be assessed for each aspect:

Birds: outdoor uses in courgette, gherkin, pumpkin, melon, water melon
- lettuce, endive species, rucola, garden cress, herbs, lambs lettuce, spinach, beans with pods, wine grapes

Aquatic organisms: outdoor uses in courgette, gherkin, pumpkin, melon, water melon, wine grape

Mammals: outdoor uses in courgette, gherkin, pumpkin, melon, water melon, raspberry and blackberry, wine grape
- lettuce, endive species, rucola, garden cress, herbs, lambs lettuce, spinach, beans with pods (only for secondary poisoning)

Bees: all extensions for outdoor uses
Non-target arthropods: all extensions for outdoor uses
Soil organisms: outdoor uses in lettuce, endive species, rucola, garden cress, herbs, lambs lettuce, spinach, beans with pods
Activated sludge and non-target plants: no additional risk assessment required.

7.1 Effects on birds

Birds can be exposed to the active substance spinosad via natural food (sprayed insects, seeds, leafs), drinking water and as a result of secondary poisoning.

According to the screening, the following uses do not fall within the exsisting risk envelope for exposure via natural food: courgette, gherkin, pumpkin, melon, water melon. And for secondary poisoning for the use in lettuce, endive species, rucola, garden cress, herbs, lambs lettuce, spinach and wine grapes.

The threshold value for birds is based on the trigger from the RGB. This means that Toxicity-Exposure Ratio's (TERs) for acute and short-term exposure should be ≥ 10 and TER for chronic exposure should be ≥ 5.
Table E.1 presents an overview of toxicity data.

Table E.1: Overview of toxicity data for birds for substance Spinosad

	Endpoint	Value
Acute toxicity to birds:	LD_{50}	>2000 mg a.s./kg bw
Dietary toxicity to birds:	LC_{50} [#]	>1804.6 mg a.s./kg bw/d
Reproductive toxicity to birds:	NOEL [#]	82.5 mg a.s./kg bw/d

[#] LC_{50} (5156 mg a.s./kg feed) is recalculated, using the default conversion factors for the ratio daily food intake/body weight (0.35 for the LC50 (juvenile birds) and NOEC (550 mg a.s./kg feed) is recalculated using the default conversion factor 0.15 for the NOEC (adult birds)) according to an advice of EFSA.

7.1.1 Natural food and drinking water

Sprayed products
Procedures for risk assessment for birds comply with the recommendations in the Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (Sanco/4145/2000).

For the current application, uses can be categorized as leafy crops. Depending on the crop category, different indicator species are chosen. Table E.2 shows which indicator species are relevant for which uses.

Table E.2 Indicator species per use

Use	Crop	Indicator species
Courgette, gherkin, pumpkin, melon, water melon (F)	Leafy crops	medium herbivorous and insectivorous

Table E.3a-c show the TER values for birds. The estimated daily uptake values (ETE, Estimated Theoretical Exposure) for acute, short-term and long-term exposure are calculated using the Food Intake Rate of the indicator species (FIR) divided by the body weight of the indicator species (bw), the Residue per Unit Dose (RUD), a time-weighted-average factor (f_{TWA}, only for long term) and the application rate. For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. The ETE is calculated as application rate * (FIR/bw) * RUD * MAF [* $f_{TWA,}$ only for long term]. The ETE is compared to the relevant toxicity figure. TER should be above the trigger for an acceptable risk.

Table E.3a: Acute ETE in terms of daily dose (mg/kg bw) for Spinosad

Use	Indicator species	FIR / bw	RUD (90%)	MAF	Application rate (kg a.s./ha)	Acute ETE (mg/kg bw/d)
Courgette, gherkin, pumpkin, melon, water melon (F)	Medium herbivorous bird	0.76	87	1.9	0.096	12.06
	Insectivorous bird (small insects)	1.04	52	1	0.096	5.19

Table E.3b: Short-term ETE in terms of daily dose (mg/kg bw) for Spinosad.

Use	Indicator species	FIR / bw	RUD (90%)	MAF	Application rate (kg a.s./ha)	Short-term ETE (mg/kg bw/d)
Courgette, gherkin, pumpkin, melon, water melon (F)	Medium herbivorous bird	0.76	40	2.4	0.096	7.00
	Insectivorous bird (small insects)	1.04	29	1	0.096	2.90

Table E.3c: Long-term ETE in terms of daily dose (mg/kg bw) for Spinosad

Use	Indicator species	FIR / bw	RUD (90%)	MAF	f_{TWA}	Application rate (kg a.s./ha)	Long-term ETE (mg/kg bw/d)
Courgette, gherkin, pumpkin, melon, water melon (F)	Medium herbivorous bird	0.76	40	2.4	0.53	0.096	3.71
	Insectivorous bird (small insects)	1.04	29	1	1	0.096	2.90

Table E.4: Toxicity Exposure Ratios for exposure of medium herbivorous birds to Spinosad in food.

Time scale	Substance	Toxicity (LD_{50}/ LC_{50}/ NOEL)	ETE value (mg a.s./kg diet/bw/d)	TER value	Trigger value
Courgette, gherkin, pumpkin, melon, water melon (F)					
Acute	Spinosad	>2000	12.06	>166	10
Short-term	Spinosad	>1804.6	7.00	>257.8	10
Long-term	Spinosad	82.5	3.71	22.2	5

Note: exposure to insectivorous birds is lower thus the risk to insectivorous birds is acceptable as well.

Taking the results in Table E.4 into account, it appears that all proposed uses meet the standards laid down in the RGB.

Drinking water

The risk from exposure through drinking surface water is calculated for a small bird with body weight 10 g and a DWI (daily water intake) of 2.7 g/d. Surface water concentrations are calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account. The highest $PIEC_{water}$ is 0.00024 mg/L for the use in herbs (in refined PIEC). It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (>2000 * 0.010) / (0.00024 * 0.0027) = > 1000. Since TER is > 10, the risk is acceptable.

7.1.2 Secondary poisoning

The risk as a result of secondary poisoning is assessed based on bioconcentration in fish and worms. Examination takes place against the threshold value for chronic exposure of 0.2 times the NOEC value. This means that the TER should be ≥ 5.

Fish

For Spinosyn A and D a BCF of 114, respectively 115 L/kg is available.
The highest $PEC_{water(21)}$ (taken from paragraph 6.2.1.) amounts 0.1826 µg/L = 0.1826×10^{-3} mg/L in the use herbs.
Indicator species is a 1000-g bird eating 206 g fresh fish per day.

The TER is then calculated as NOEL / ($PEC_{water(21)}$ * BCF_{fish} * (FIR/bw) = 82.5 / ($0.1826x10^{-3}$* 115 * 0.21) = > 1000. Since this is >> 5, the risk for birds as a result of consumption of contaminated fish is considered to be low for all uses.

Earthworms
Since there are no experimental data, the bioconcentration factor for earthworms (BCF_{worm}) is calculated according to the following formula: BCF = (0.84 + 0.01 * Kow) / f_{oc} * K_{oc}.
The logKow of Spinosad is 4.38 (worst-case value for Spinosyn D); average Koc Spinosyn A is 35024 L/kg, which leads to a BCF_{worm} = 0.344 kg soil/kg worm.

The highest $PEC_{soil(21)}$ taken from paragraph 6.1.1) is reached at the use in Lettuce, Endive species, Rocket, Garden cress, Lambs lettuce and herbs, and amounts 0.019 mg a.s./kg soil (sum of spinosyn A and D).
Indicator species is a 100-g bird eating 113 g fresh worms per day.
The risk is then calculated as NOEL / $PEC_{soil(21)}$ * BCF_{worm} * (FIR/bw) = 82.5 / (0.019 * 0.344 * 1.1) = > 1000.
Since this is > 5 the risk for birds as a result of consumption of contaminated worms is considered to be small.

Taking the results for secondary poisoning through fish and earthworms into account, the proposed uses meet the standards for secondary poisoning as laid down in the RGB.

Conclusions birds
The product complies comply with the RGB.

7.2 Effects on aquatic organisms

7.2.1 Aquatic organisms
The risk for aquatic organisms for the various uses of the active substance Spinosad and its metabolites is assessed by comparing toxicity values with surface water exposure concentrations from section 6.2. Risk assessment is based on toxicity-exposure ratio's (TERs).
In Table E.5 the acute and chronic toxicity data (a.s. and metabolites) for aquatic organisms are presented. The endpoints to be used are indicated in bold.

Table E.5: Overview toxicity endpoints and threshold values for the active substance and metabolites

Substance	Organism	Lowest		Toxicity value
		L(E)C_{50} [mg/L]	**NOEC [mg/L]**	**[µg/L]**
Spinosad	*Acute*			
	Algae	0.079		**79**
	Daphnids	>1		>**1000**
	Fish	4		**4000**
	Macrophytes	6.6		**6600**
	Chronic			
	Daphnids		0.0012	**1.2**
	Fish		0.5	**500**
Spinosyn B	*Acute*			
	Algae	0.077		77
	Daphnids	6.5		6500
	Fish	-		
	Chronic			
	Daphnids		0.00095	0.95
N-demethylated Spinosyn D	*Acute*			
	Algae	0.25		250
	Daphnids	3.8		3800
	Fish			
	Chronic			
	Daphnids		0.001	1
ß-13,14-dihydro-pseudogly-cone of Spinosyn A	*Acute*			
	Algae	38.8		38800
	Daphnids	>197		197000
	Fish			
	Chronic			
	Daphnids		1.25	1250
ß-13,14-dihydro-pseudogly-cone of Spinosyn D	*Acute*			
	Algae	28		28000
	Daphnids	65.8		65800
	Fish			
	Chronic			
	Daphnids		4.85	4850

N.B. chronic data are not a prerequisite for the metabolite

These toxicity values are compared to the surface water concentrations calculated in section 6.2. Trigger values for acute exposure are 100 for daphnids and fish (0.01 times the lowest L(E)C_{50}-value) and 10 for algae and macrophytes (0.1 times the lowest EC_{50}-value). Trigger values for chronic exposure are 10 for daphnids and fish (0.1 times the lowest NOEC-values).
For acute and chronic risk, the initial concentration is used (PIEC) for TER calculation.

The applicant proposed the following restriction sentence for all uses applied for except the use in wine grapes:

Om in het water levende organismen te beschermen is toepassing in onbedekte teelten op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 90% driftreducerende spuitdoppen.

For the use in wine grapes, the following restriction sentence was proposed:

- *Toepassing na 1 mei*
- *Haalbare driftreducerende maatregelen: driftarme doppen (~Venturi doppen, 90 % DR doppen) en het gebruik van een windhaag.*

No NL drift percentages for vines are available; as a default a drift percentage of 7% is used comparable to the EU drift percentages. No reference towards application of the product before or after May 1st is considered necessary for the use in wine grapes.
For the second restriction sentence proposed by the applicant, no corresponding drift value is available in the Evaluation Manual. After consultation of the applicant, the following restriction sentence was proposed:

Permitted is only the use as insecticide in the culture of wine grapes on the understanding that application on fields adjacent to waterways is only permitted if the product on the first 20 m adjacent to the waterway is sprayed with a Venturi nozzle where the last tree row must be sprayed from one side and reduced air fan setting.

All PIECsw concentrations are calculated on the basis of the above mentioned drift reducing measures. For this assessment the refined PIEC (after drift reduction and DT50 refinement) is calculated.

Table E. 6a TER values: acute

Use	Substance	PECsw [µg a.s./L]	TER_{st} (trigger 10) Algae	TER_{st} (trigger 100) Invertebrates	TER_{st} (trigger 100) Fish	TER_{st} (trigger 10) Macrophytes
Herbs*	Spinosad	0.119	335	> 1000	>1000	>1000

Table E. 6b TER values: chronic

Use	Substance	PECsw [µg a.s./L]	TER_{lt} (trigger 10) Invertebrates	TER_{lt} (trigger 10) Fish
Herbs*	Spinosad	0.119	10	> 1000

*Note there has been a small mistake in the PEC calculation, which assumes 5 crocycli in a year. Therefore the value can be seen as worst-case

Taking the results in Table E.6a and b into account, the acute TERs for fish and daphnids are above the relevant Annex VI triggers of 100 and the acute TERs for algae and macrophytes are above the relevant Annex VI triggers of 10. The chronic TERs for daphnids and fish are above the relevant Annex VI triggers of 10. Therefore the acute long-term risk of spinoad for aquatic organisms is acceptable, provided the appropriate drift reducing measures are taken.

Risks of metabolites
There is no information on the acute and chronic concentrations of the metabolites, therefore no TERs for the metabolites could be calculated.

Spinosyn A and D are defined as residues relevant for water and sediment. In the semi-field fate-cosm experiment, the metabolites Spinosyn B and N-demethylated Spinosyn D did not

reach levels of >10 % of AR in the water phase. In the laboratory study N-demethylated Spinosyn D reached a maximum of 10%. Because the toxicity of this metabolite for the most sensitive organism is comparable with the active substance and the exposure is lower than that to the active substance, the metabolite N-demethylated Spinosyn D meets the standards for toxicity for aquatic organisms (lowest TER [spring; all other uses] is 1082).
Metabolite β-13,14-dihydropseudo-aglycone of Spinosyn A and D were not analysed in the laboratory and semi-field study, but may be present under field conditions as they were identified as major photometabolites. As formation percentages are lacking, a PEC_{SW} for these metabolites cannot be calculated. When, however, the PEC_{SW} for Spinosad is used, thus assuming a formation percentage of 100%, the threshold values for diatoms and *D. magna* are above 100 and a risk is not expected.

7.2.2 Risk assessment for bioconcentration

For the active substance a BCF-value of 115 L/kg is available, the worst case value from Spinosyn D.
Since the BCF is above 100 L/kg and the substance does not rapidly biodegrade, there is a risk for bioconcentration. According to the guidance document on aquatic ecotoxicology the following points should be checked:

1) Direct long-term effects in fish due to bioconcentration;
2) Secondary poisoning for birds and mammals;
3) Biomagnification in aquatic food chains.

On the basis of this it has to be demonstrated by means of an adequate risk assessment that the risk for bioconcentration is acceptable.
Ad 1: an ELS study should be available if 100 < BCF < 1000 and EC_{50} Spinosad for fish <0.1 mg/L. The trigger is hardly exceeded for BCF, but not for EC_{50} fish (actually 4.0 mg/L).
Taking into account ad 2, it seems not necessary to conduct an ELS study.
Ad 2: from the risk assessment of secondary poisoning for birds and mammals a low risk is indicated. Furthermore the chronic risk for fish is low.
Ad 3: BCF <1000 (trigger value).

Hence, the active substance Spinosad meets the standards for bioconcentration as laid down in the RGB.

7.2.3 Risk assessment for sediment organisms

Since the NOEC for daphnids is below 0.1 mg/L and the water–sediment study indicates that over 10% of the active substance is found in the sediment after 14 days, there is a potential risk for sediment organisms.

The NOEC value for *Chironomus* is 0.0016 mg/L. In Table E.7, this value is examined against the highest PIEC in water (spring application).

Table E.7 Threshold exceeding factors for the active substance regarding the chronic toxicity of *Chironomus riparius.*

Use/ application/	PIEC (µg/L)*	TER (trigger = 10) *Chironomus* spring
Herbs	0.119	13.4

* Using the refined PIECsw, and using nozzles from drift reduction class 90%

The TER values are above the trigger value of 10. Therefore, the active substance Spinosad meets the standards for sediment organisms as laid down in the RGB.

Conclusions sediment organisms
The proposed applications of the product comply with the RGB.

Conclusions aquatic organisms
The proposed applications meet the standards for aquatic organisms provided the following drift reducing measures are taken for all uses except wine grapes:

Om in het water levende organismen te beschermen is toepassing in onbedekte teelten, met uitzondering van druiven, uitsluitend toegestaan wanneer in perceelsstroken die grenzen aan oppervlaktewater in de eerste 14 m vanaf de insteek van de sloot gebruik wordt gemaakt van minimaal 90% driftreducerende spuitdoppen.

And in wine grapes:

Om in het water levende organismen te beschermen is toepassing in druif, framboos en bramen uitsluitend toegestaan wanneer in perceelsstroken die grenzen aan oppervlaktewater in de eerste 20 m vanaf de insteek van de sloot het middel verspoten wordt met een Venturidop (90% driftreductie) in combinatie met ventilatorstand 'laag', waarbij de laatste plantenrij éénzijdig in de richting van het perceel bespoten dient te worden .

These sentences will be combined with other restriction sentences in the final part of the risk assessment.

7.3 Effects on terrestrial vertebrates other than birds
Mammals can be exposed to the active substance Spinosad by natural food (sprayed insects, seeds, leafs), drinking water and as a result of secondary poisoning.

According to the screening, the following uses do not fall within the exsisting risk envelope for exposure via natural food: raspberry and blackberry, and wine grapes; and secondary poisoning: courgette, gherkin, pumpkin, melon, water melon, lettuce, endive species, rucola, garden cress, herbs, lambs lettuce, spinach, wine grapes, raspberry and blackberry, and wine grapes.

7.3.1 Natural food and drinking water
The threshold value for mammals is based on the trigger from the RGB. This means that Toxicity-Exposure Ratio (TER) for acute exposure should be ≥ 10 and TER for chronic exposure should be ≥ 5. Dietary toxicity is not taken into account for mammals.
Table E.8 presents an overview of toxicity data.

Table E.8 Overview of toxicity data for mammals for substance Spinosad

	Endpoint	Value
Acute toxicity to mammals:	LD_{50}	>2000 mg a.s./kg bw
Reproductive toxicity to mammals:	NOEL	10 mg a.s./kg bw/d[#]

[#] value taken from DAR_Spinosad (value not in LoEP).

Sprayed products
Procedures for risk assessment for mammals comply with the recommendations in the Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (Sanco/4145/2000).
For the current application, uses can be categorized as leafy crops and Orchard/vine/hops.
For greenhouse applications exposure of mammals via food items is not considered realistic.

As Spinosad is not systemic, exposure of mammals after tray treatment of cabbage, cauliflower, broccoli and Brussels sprouts is not considered realistic.

Depending on the crop category different indicator species are chosen. Table E.9 shows which indicator species are relevant for which uses.

Table E.9 Indicator species per use

Use	Crop	Indicator species
Courgette, gherkin, pumpkin, melon, water melon (F)	Leafy crops	medium herbivorous mammal
Raspberry, blackberry	Orchard/vine/hops	Small herbivorous mammal

The use in raspberry and blackberry will cover for the risk in grape vine under the SANCO guidence.

Tables E.10a-b show the estimated daily uptake values (ETE, Estimated Theoretical Exposure) of Spinosad for acute and long-term exposure, using the Food Intake Rate of the indicator species (FIR) divided by the body weight of the indicator species (bw), the Residue per Unit Dose (RUD), a time-weighted-average factor (f_{TWA}, only for long term) and the application rate. For uses with frequency of >1, a MAF (Multiple Application Factor) may be applicable.

Table E.10a Acute ETE in terms of daily dose (mg/kg bw) for Spinosad

Use	Indicator species	FIR / bw	RUD (90%)	MAF	Application rate (kg a.s./ha)	Acute ETE (mg/kg bw/d)
Courgette, gherkin, pumpkin, melon, water melon (F)	Medium herbivorous mammal	0.28	87	1.9	0.096	4.44
Raspberry, blackberry	Small herbivorous mammal	1.39	85	1.3	0.096	14.7

Table E.10b Long-term ETE in terms of daily dose (mg/kg bw) for Spinosad

Use	Indicator species	FIR / bw	RUD (mean)	MAF	f_{TWA}	Application rate (kg a.s./ha)	Long-term ETE (mg/kg bw/d)
Courgette, gherkin, pumpkin, melon, water melon (F)	Medium herbivorous mammal	0.28	40	2.4	0.53	0.096	1.37
Raspberry, blackberry	Small herbivorous mammal	1.39	46	2.4	0.53	0.096	7.81

Based on the ETE-values in Table E.11a-b the TER-values for the acute and long-term risk are presented in Table E.11.

Table E.11 Toxicity Exposure Ratios for exposure of mammals to Spinosad in food

Use	Time scale	Toxicity (LD_{50} resp. NOEL) (mg a.s./kg diet/bw/d)	ETE value (mg a.s./kg diet/bw/d)	TER value	Trigger value
Courgette, gherkin, pumpkin, melon, water melon (F)	Acute	>2000	4.44	>450	10
	Long-term	10[#]	1.37	7.31	5
Raspberry, blackberry	Acute	> 2000	14.7	136	10
	Long-term	10[#]	7.81	**1.28**	5

[#] value taken from DAR_Spinosad (value not in LoEP).

Taking the results in Table E.11 into account, it appears that the use in raspberry and blackberry does not meet the trigger for an accxeptable long-term risk for small herbivorous mammals. For wine grape, the risk will be lower, however, the difference in exposure between wine grapes and berries in only small. Thus a risk is also expected for wine grapes. The other uses meet the standards laid down in the RGB.

A refined risk assessement will be performed according to the EFSA 2009 guidance for birds and mammals in order to refine the long-term risk in bush and cane fruit and vineyard.

Table E.12a Refined long-term risk for exposure of mammals to Spinosad in food in bush and cane fruit (raspberry and blackberry)

Scenario	Generic focal species	NOEC [mg a.s./kg bw/d]	Application rate [kg a.s./ha]	SV_{mean}	MAF_m * ftwa	DDD [mg a.s./kg bw/d]	TER	trigger
Bush and cane BBCH 10-19	Small insectivorous mammal "shrew"	10	0.096	4.2	0.79	0.32	31.2	5
BBCH ≥ 20	Small insectivorous mammal "shrew"	10	0.096	1.9	0.79	0.15	69.0	5
BBCH 10-19	Small herbivorous mammal "vole"	10	0.096	43.4	0.79	3.31	**3.0**	5
BBCH 20-39	Small herbivorous mammal "vole"	10	0.096	36.1	0.79	2.76	**3.6**	5
BBCH ≥ 40	Small herbivorous mammal "vole"	10	0.096	21.7	0.79	1.66	6.0	5
Fruit stage BBCH 71-79 currants	Frugivorous mammal "dormouse"	10	0.096	9.7	0.79	0.74	13.5	5

BBCH 10-19	Small omnivorous mammal "mouse"	10	0.096	4.7	0.79	0.36	27.9	5
BBCH 20-39	Small omnivorous mammal "mouse"	10	0.096	3.9	0.79	0.30	33.6	5
BBCH ≥ 40	Small omnivorous mammal "mouse"	10	0.096	2.3	0.79	0.18	57.0	5

Table E.12b Refined long-term risk for exposure of mammals to Spinosad in food in vineyard (wine grapes)

Scenario	Generic focal species	LC50 [mg a.s./kg bw/d]	Application rate [kg a.s./ha	SV_{mean}	MAF_m * ftwa	DDD [mg a.s./kg bw/d]	TER	trigger
Vineyard Application ground directed	Large herbivorous mammal "lagomorph"	10	0.072	11.1	0.79	0.63	15.9	5
BBCH 10-19	Large herbivorous mammal "lagomorph"	10	0.072	6.7	0.79	0.381	26.2	5
BBCH 20-39	Large herbivorous mammal "lagomorph"	10	0.072	5.5	0.79	0.313	31.9	5
BBCH ≥ 40	Large herbivorous mammal "lagomorph"	10	0.072	3.3	0.79	0.188	53.2	5
BBCH 10-19	Small insectivorous mammal "shrew"	10	0.072	4.2	0.79	0.239	41.8	5
BBCH ≥ 20	Small insectivorous mammal "shrew"	10	0.072	1.9	0.79	0.108	92.6	5
Application ground directed	Small herbivorous mammal "vole"	10	0.072	72.3	0.79	4.11	**2.43**	5
Application	Small	10	0.072	43.4	0.79	2.47	**4.04**	5

crop directed BBCH 10-19	herbivorous mammal "vole"							
Application crop directed BBCH 20-39	Small herbivorous mammal "vole"	10	0.072	36.1	0.79	2.05	**4.88**	5
Application crop directed BBCH ≥ 40	Small herbivorous mammal "vole"	10	0.072	21.7	0.79	1.23	8.13	5
Application ground directed	Small omnivorous mammal "mouse"	10	0.072	7.8	0.79	0.44	22.7	5
Application crop directed BBCH 10-19	Small omnivorous mammal "mouse"	10	0.072	4.7	0.79	0.267	37.4	5
Application crop directed BBCH 20-39	Small omnivorous mammal "mouse"	10	0.072	3.9	0.79	0.221	45.2	5
Application crop directed BBCH ≥ 40	Small omnivorous mammal "mouse"	10	0.072	2.3	0.79	0.131	76.3	5

Based on the above risk assessment the triggers for scenarios small herbivorous mammal “vole” at BBCH 10-19 and 20-39 in bush and cane fruit are below the Annex VI trigger of 5. The applications are acceptable provided that the product is applied after BBCH 40. Given that the BBCH monograph does no indicate the stages between 40-50, the restriction sentence should be applicable from inflorescence emergence thus starting at BBCH 51.

Om de zoogdieren te beschermen is toepassing in frambozen en bramen uitsluitend toegestaan na BBCH 51 (wanneer bloeiwijze opkomst).

In case of the applications in vines, the triggers for scenarios small herbivorous mammal “vole” at “applications ground directed”, BBCH 10-19 and 20-39 are below the Annex VI trigger of 5. The applications in vines are acceptable provided that the product is not applied ground directed and that the product is applied after BBCH 40. Given that the BBCH monograph does no indicate the stages between 20-51, the restriction sentence should be applicable from inflorescence emergence thus starting at BBCH 53.

Om de zoogdieren te beschermen is toepassing uitsluitend toegestaan in druif na BBCH 53 (wanneer bloeiwijze opkomst).

These can be combined to:
Om de zoogdieren te beschermen is toepassing in druif, frambozen en bramen uitsluitend toegestaan na BBCH 51 (wanneer bloeiwijze opkomst).

All other uses meet the standards as laid done in the RGB.

Drinking water
The risk from exposure through drinking from surface water is calculated for a small mammal with body weight 10 g and a DWI (daily water intake) of 1.57 g/d. Surface water concentrations are calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account. The highest $PIEC_{water}$ is 0.2358 µg/L for the use in hrebs. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (>2000 * 0.010) / ($0.2358x10^{-3}$ * 0.00157) = >1000. Since the TER is >> 10, the risk is acceptable.

7.3.2 Secondary poisoning
The risk as a result of secondary poisoning is assessed based on bioconcentration in fish and worms. Examination takes place against the threshold value for chronic exposure of 0.2 times the NOEC value. This means that the TER should be ≥ 5.

Fish
For Spinosad a BCF_{fish} of 115 L/kg is available.
Indicator species is a 3000-g mammal eating 390 g fresh fish per day. The highest $PEC_{water(21}$= 0.1826 mg/L is taken from the use in herbs.
The TER is then calculated as NOEL / ($PIEC_{water}$ * BCF_{fish} * (FIR/bw) = 10 / 0.0001826* 115 * 0.13 = > 1000. Since this is ≥ 5, the risk for mammals as a result of consumption of contaminated fish is considered to be small.

Earthworms
Spinosad
Since there are no experimental data the bioconcentration factor for earthworms (BCF_{worm}) is calculated according to the following formula: BCF = (0.84 + 0.01 * Kow) / f_{oc} * K_{oc}.
The logKow of Spinosad is 4.38 (worst-case value for Spinosyn D); average Koc Spinosyn A is 35024 L/kg, which leads to a BCF_{worm} = 0.3437 kg soil/kg worm.

Indicator species is a 10-g mammal eating 14 g fresh worms per day.
The highest $PEC_{soil(21)}$ taken from paragraph 6.1.1) is reached at the use in Lettuce, Endive species, Rocket, Garden cress, Lambs lettuce and herbs, and amounts 0.019 mg a.s./kg soil (sum of spinosyn A and D).

The risk is then calculated as NOEL / $PEC_{soil(21)}$ * BCF_{worm} * (FIR/bw) = 10 / (0.019 * 0.3437 * 1.4) = > 1000. Since this is ≥ 5, the risk for mammals as a result of consumption of contaminated worms is considered to be small.

Taking the results for secondary poisoning through fish and earthworms into account, the proposed uses meet the standards for secondary poisoning as laid down in the RGB.

Conclusions mammals
The product does not comply with the RGB for the long-term risk for mammals in the use in raspberry and blackberry and wine grape at early BBCH codes.

7.4 Effects on bees
The risk assessment for bees is based on the Hazard Quotient (HQ), the ratio between the highest single application rate and toxicity endpoint (LD_{50} value). An overview of the risk at the proposed uses is given in Table E.13.

Table E.13 In-field risk for bees

Use	Substance	Application rate	LD_{50}	HQ (Rate/LD_{50})	Trigger value

		[g a.s./ha]	[µg/bee]		
lettuce, endive species, rucola, garden cress, herbs, lambs lettuce, spinach, beans with pods courgette, gherkin, pumpkin, melon, water melon, raspberry and blackberry	Tracer	96	0.049 (oral)	**1959**	50
	Spinosad		0.0036 (contact)	**26667**	50
Strawberry, wine grapes	Tracer	72	0.049 (oral)	**1469**	50
	Spinosad		0.0036 (contact)	**20000**	50

Since the HQ is above 50, there is a potentially high risk for bees. Hence, a risk to bees in-field cannot be excluded.

Higher tier studies (cage and semi-field) are available. These studies show that at relevant application rates (144 – 864 g a.s/ha) significant effects on bees and bumblebees are to be expected.

The following restriction sentence was proposed by the applicant in the WG:

"*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 in de buurt van in bloei staand onkruid. 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. Verwijder of bedek bijenkorven en hommelkasten tijdens het gebruik van het product en gedurende één dag na de behandeling en vergewis u ervan dat de spuitvloeistof volledig opgedroogd is in de kas. Voorkom dat bijen en andere bestuivende insecten de kas binnenkomen door alle openingen met insectengaas af te sluiten*".

For the current request for authorization of field uses the restriction sentence "*Gebruik is wel toegestaan op bloeiende planten in de kas mits er geen bijen of hommels in de kas actief naar voedsel zoeken. Verwijder of bedek bijenkorven en hommelkasten tijdens het gebruik van het product en gedurende één dag na de behandeling en vergewis u ervan dat de spuitvloeistof volledig opgedroogd is in de kas. Voorkom dat bijen en andere bestuivende insecten de kas binnenkomen door alle openingen met insectengaas af te sluiten*" is not applicable.

Furthermore, bees can be exposed off-field, in flowering margins and/or bordering fields. An off-field risk assessment is necessary if the in-field risk assessment indicates a risk. Since the HQ trigger is breached based on the full, in-field, dose, and the risk mitigation sentence only addresses in-field risk, the off-field risk needs to be calculated as well. The same HQ approach is used as for in-field. The off-field exposure is calculated with the drift values used for the off-field risk assessment for other non-target arthropods (see section 7.5). The relevant drift value for the use in grapes is 15% of the application rate while for the other field uses is 10% of the application rate.

Table E.14 Off-field risk to bees for spinosad

Use	Application rate	Drift value	Off-field rate	LD_{50}	HQ (off-field rate/LD_{50})	Trigger value
	[g a.s./ha]	%	[g a.s./ha]	[µg/bee]		
lettuce, endive species, rucola, garden cress, herbs, lambs lettuce, spinach, beans with pods, courgette, gherkin, pumpkin, melon, water melon, raspberry and blackberry	96	10	9.6	0.049 (oral)	**196**	50
				0.0036 (contact)	**2667**	
strawberry	72	10	7.2	0.049 (oral)	**147**	
				0.0036 (contact)	**2000**	
Wine grapes	72	15	10.8	0.049 (oral)	**220**	50
				0.0036 (contact)	**3000**	50

Table E.14 shows that the HQ values are above 50, indicating that there is a potential risk to bees off-field.
For the current application, the applicant had submitted a semi-field cage study was performed in South-West France in May-July 2011 to assess the effects of honeybee exposure to a flowering crop of *Phacelia tanacetifolia* treated with spinosad (one application at 3, 6, 12, 24 and 48 g a.s./ha) on mortality, behaviour and colony condition. No effects on flight intensity, bee mortality, colony strength and brood development were recorded. Given that the current off-field doses fall within the tested range of the field test, no off-field effects on bees is then expected from the application of Tracer.

Conclusions bees
The product complies with the RGB.

7.5 Effects on any other organisms (see annex IIIA 10.5-10.8)

7.5.1 Effects on non-target arthropods

The risk for non-target arthropods is assessed by calculating Hazard Quotients. For this, Lethal Rate values (LR_{50}) are needed. Based on LR_{50}-values from studies with the two standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* an in-field and an off-field Hazard Quotient (HQ) can be calculated according to the assessment method established in the SETAC/ESCORT 2 workshop and described in the HTB (v 1.0). Hazard Quotients should

be below the trigger value of 2 to meet the standards. In the first tier (see LoEP) 100% mortality was observed. Therefore a second tier assessment is carried out. In the second tier, lethal and sublethal effects should be < 50% at relevant applications, which means that the HQ should be < 1. For the extension of authorization of Tracer (12567 N), the applicant has submitted two new extended laboratory studies with *Typhlodromus pyri*. In one study LR50 was 0.3513 g a.s./ha. In the other study, the residue on the plants was kept under outside conditions. In this study LR50 was 4.871 g a.s./ha. For *A. rhopalosiphi* an LR50 value of 12.8 g a.s./ha is available from an extended laboratory study (see LoEP). For both *A. rhopalosiphi* and *T. pyri* no effects were found on reproduction.

Table E.15 shows HQ-values for all the uses.

Table E.15 HQ-values for *A. rhopalosiphi* and *T. pyri*

	Application rate (kg a.s./ha)	**MAF[1]**	**Drift factor/ Vegetation factor[2]**	**Safety factor[2]**	**LR_{50}* (kg a.s./ha)**	**HQ**
lettuce, endive species, rucola, garden cress, spinach family, beans with pods						
In-field						
A. rhopalosiphi	0.096	2.3	-	-	0.0128	**17.3**
T. pyri	0.096	2.3	-	-	0.0003513	**628.5**
					0.004871**	**45.3**
Lambs lettuce						
In-field						
A. rhopalosiphi	0.096	1.7	-	-	0.0128	**12.8**
T. pyri	0.096	1.7	-	-	0.0003513	**464.6**
					0.004871**	**33.5**
courgette, gherkin, pumpkin, melon, water melon, herbs						
In-field						
A. rhopalosiphi	0.096	3	-	-	0.0128	**22.5**
T. pyri	0.096	3	-	-	0.0003513	**819.8**
					0.004871**	**59.1**
strawberry						
In-field						
A. rhopalosiphi	0.072	2.3	-	-	0.0128	**12.9**
T. pyri	0.072	2.3	-	-	0.0003513	**471.4**
					0.004871**	**34.0**
rasberry and blackberry						
In-field						
A. rhopalosiphi	0.096	1.7	-	-	0.0128	**12.8**

T. pyri	0.096	1.7	-	-	0.0003513	**464.6**
					0.004871**	**33.5**
wine grapes						
In-field						
A. rhopalosiphi	0.072	2.3	-	-	0.0128	**12.9**
T. pyri	0.072	2.3	-	-	0.0003513	**471.4**
					0.004871**	**34.0**
lettuce, endive species, rucola, garden cress, spinach family, beans with pods						
Off-field						
A. rhopalosiphi	0.096	2.3	0.1	5	0.0128	**8.6**
T. pyri	0.096	2.3	0.01	5	0.0003513	**31.4**
					0.004871**	**2.3**
Lambs lettuce						
Off-field						
A. rhopalosiphi	0.096	1.7	0.1	5	0.0128	**6.4**
T. pyri	0.096	1.7	0.01	5	0.0003513	**23.2**
					0.004871**	**1.7**
courgette, gherkin, pumpkin, melon, water melon, herbs						
Off-field						
A. rhopalosiphi	0.096	3	0.1	5	0.0128	**11.3**
T. pyri	0.096	3	0.01	5	0.0003513	**41.0**
					0.004871**	**3.0**
strawberry						
Off-field						
A. rhopalosiphi	0.072	2.3	0.1	5	0.0128	**6.5**
T. pyri	0.072	2.3	0.01	5	0.0003513	**23.6**
					0.004871**	**1.7**
rasberry and blackberry						
Off-field						
A. rhopalosiphi	0.096	1.7	0.1	5	0.0128	**6.4**
T. pyri	0.096	1.7	0.01	5	0.0003513	**23.2**
					0.004871**	**1.7**
wine grapes						
Off-field						
A. rhopalosiphi	0.072	2.3	0.15	5	0.0128	**9.7**
T. pyri	0.072	2.3	0.015	5	0.0003513	**35.4**
	0.072	2.3	0.015	5	0.004871**	**2.5**

*Reproduction was not affected.
**with photochemical degradation
[1]: Multiple Application Factor
[2]: off-field: drift factor = 10% for arable crops and for grape vines 15%, vegetation dilution factor = 10, not applicable at sprayed plants (i.e. for *A. rhopalosiphi*), safety factor = 5 (default value for extended lab)

As the above table shows, all in- and off-field HQ values are above the trigger value of 1. Therefore, the risk should be further addressed.

Parasitoids

For *A. rhopalosiphi,* it was shown that the main effects of spinosad is mortality. Reproduction is less sensitive. Also protected life stages seem to be less sensitive. In the DAR it was concluded that recovery might be expected after a short period, but that higher tier studies are considered to be necessary. No further field studies are available for *A. rhopalosiphi*, however (semi) field studies are available for *A. colemani.* Laboratory studies showed that this species seem to be even more sensitive than *A. rhopalosiphi*. Refinement for this species is therefore acceptable.

For most of the (semi) field studies, the tested doses cannot be extrapolated to the proposed doses. However an extended laboratory study showed that 4 x 109 g a.s./ha lead to a high mortality, directly after applications, but no effects are found after 14 days aging. This indicates that recovery can take place within an ecological relevant period.

Predatory mites

Several field studies are available for *T. pyri*. In these studies slight effects (but not significant) were found at relevant application rates. The studies show that no long-term effects are to be expected in-field. However, the field studies in vineyards with *T. pyri* are not acceptable to address the off field risk. The off-field population may consist of slow reproducing species that are not adapted to pesticides, which makes the potential for recovery within an ecologically acceptable period not self-evident. The applicant submitted a field study with arthropods including predatory mites, see risk assessment below.

Other arthropods

Information in the DAR showed that other arthropods are less sensitive or as sensitive as *T. pyri. Coccinella septempunctata* showed effects < 50% at 320 g a.s./ha in a standard laboratory test, *Crysoperla carnea* showed < 50% effects at 2 x 0.36 g a.s./ha. In a semi field-study, effect on *Macrolophus caliginosus* was < 50% after 14 days ageing. For *Poecilus cupreus* no effects were found at a relevant application rate of 1 x 540 g a.s./ha.

The applicant further indicates that the DT_{50} is 1.9 days and that therefore the MAF should be 1. However, this DT50 is derived from studies performed in California, and are therefore not to be used in current risk assessment, although it is acknowledged that spinosad will dissipate from leaves more quickly than assumed in default values.

Field study

For the current application for minor uses the applicant submitted a non-target arthropod field study. The product was applied once at 0.375, 1.5, 6, 24 and 96 g a.s./ha to grassland meadow. The No Observed Effect Rate (NOER) and the No Observed Ecologically Adverse Effect Rate (NOEAER) were defined at the community and population level as the rate at which statistically significant adverse responses were observed, but recovery was demonstrated within two months after applications. These results were as follows: community NOER 6 g a.s./ha, community NOEAER 24 g a.s./ha; population NOER 1.5 g a.s./ha, population NOEAER 24 g a.s./ha.

For the current request for authorization, the application of the product is up to 5 times which means that in practice the frequency of application is much higher than what was tested in the field study. Therefore, according to Ctgb it is appropriate to use the NOER of 1.5 g a.s./ha for the risk assessment. Currently no specific assessment factors are proposed for the mesocosm studies with arthropods. For the current assessment a safety factor of 2 as per the new aquatic GD on tiered RA for edge-of-field surface water EFSA Journal 2013; 11(7): 3290.

By applying this assessment factor the NOER is 0.75 g a.s./ha.

For the current application the off-field rates vary from 1.63 g a.s./ha (lambs lettuce and raspberry and blackberry *T. pyri*) to 28.8 g a.s./ha (courgetter, gherkin, pumpkin, melon and water melon *A. rhopalosiphi*). Based on this it can be concluded that the exposure is 2.2 to 38.4 times higher than the NOER.
Acceptable off-field rates can be obtained by applying the new off-field drift mitigation measures as per EM 2.0. Although this dossier must be assessed under HTB 1.0, the off-field drift mitigation measures as per EM 2.0 are considered state of the art and can be applicable here as well, especially since no drift reduction options are presented in HTB 1.0.

Table E.15a Drift percentage necessary for an acceptable off-field risk to arthropods

Application rate (kg a.s./ha)	MAF	Exposure (kg a.s./ha)	NOER (kg a.s./ha)	Drift Percentage (%)
lettuce, endive species, rucola, garden cress, herbs, spinach family, beans with pods				
Off-field 0.096	2.3	0.2208	0.00075	0.34
Lambs lettuce				
Off-field 0.096	1.7	0.1632	0.00075	0.46
courgette, gherkin, pumpkin, melon, water melon				
Off-field 0.096	3	0.288	0.00075	0.26
strawberry				
Off-field 0.072	2.3	0.1656	0.00075	0.45
raspberry and blackberry				
Off-field 0.096	1.7	0.1632	0.00075	0.46
wine grapes				
Off-field 0.072	2.3	0.1656	0.00075	0.45

The required drift reduction is possible, which would lead to the inclusion of the following restriction sentence:

Om niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing in sla, andijvie species, rucola, tuinkers, kruiden, spinazie familie, peulvruchten, veldsla, courgette, augurk, pompoen, meloen, watermeloen, aardbei uitsluitend toegestaan wanneer in perceelsstroken die niet grenzen aan oppervlaktewater in de eerste 14 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van spuitapparatuur met lage spuitboomhoogte (maximaal 30 cm boven de top van het gewas) met driftarme Venturidoppen en een kantdop en luchtondersteuning in

combinatie met een teeltvrije zone van 1,5 meter (gemeten vanaf het midden van de laatste gewasrijd tot aan de perceelsgrens).

Om niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing in frambozen en bramen en druif uitsluitend toegestaan wanneer in uitsluitend toegestaan wanneer in perceelsstroken die niet grenzen aan oppervlaktewater in de eerste 20 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van één van onderstaande maatregelen
-Venturidoppen (minimaal 90% driftreducerend) in combinatie met éénzijdige bespuiting laatste bomenrij in de richting van het perceel in combinatie met een teeltvrije zone van 4,5 meter (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens.
- een Wannerspuit met reflectieschermen en venturidoppen (minimaal 90% driftreducerend) (Lechler ID 90-015C) met inachtneming van een teeltvrije zone van tenminste 4,5 meter
-een KWH k1500-3R2 VLOS 3-rijenspuit met variabele luchtondersteuning en minimaal 90% driftreducerende spuitdoppen en ventilatorstand "laag" in de eerste 20 meter grenzend aan het oppervlaktewater met inachtneming van een teeltvrije zone van tenminste 3 meter

These sentences will be combined with other restriction sentences in the final part of the risk assessment.

With this restriction measure the HQ for *T.pyri* for applications in courgette, gherkin, meloen, and water meloen will be 1.2. This is based on the data from laboratory extended studies. Data is also available from extended laboratory tests where the mites were exposed to a product undergoing a photochemical degradation. In this case the LR50 was much higher, indicating that the product was less toxic. Based on these, the risk to *T.pyri* is considered acceptable provided that the restriction sentence is placed on the label.

Conclusions non-target arthropods
The product complies with the RGB provided that restriction sentences are placed on the label.

7.5.2 Earthworms

The acute risk for earthworms is calculated as a TER-value (trigger value 10). Since the logPow of the active substance in water is >2 (3.91 Spinosyn A; 4.38 Spinosyn D), a correction to the reference soil containing 4.7% organic matter is necessary. The (corrected) toxicity value for earthworms based on the 14-day LC_{50} (>916 mg a.s./kg) of the active substance amounts therefore >458 mg a.s./kg. Exposure is expressed as the initial PEC soil. PEC soil is calculated for a soil layer of 5 cm taking into account the application rate, application frequency, fraction on soil, soil bulk density, and degradation of the substance (see also section 6.1.1).
Table E.16 presents the PECsoil and the TERs for the active substance and its metabolites for the worst case uses.

Table E.16: Overview of soil concentrations and acute TERs for Spinosad and its metabolites (trigger value = 10)

Application/ Use	Substance	Application rate [kg a.s./ha]	Freq	Inter-val [day]	PIEC soil 5 cm [mg/kg]	LC50 [mg/kg]	TER (trigger = 10)
Lettuce, Endive species, Rocket, Garden cress , beans with pods(field)	Spinosad	0.096	3	7	0.112**	>458	>4089
	Spinosyn B				0.060	>500	>8333

Application/ Use	Substance	Application rate [kg a.s./ha]	Freq	Inter-val [day]	PIEC soil 5 cm [mg/kg]	LC50 [mg/kg]	TER (trigger = 10)
	N-demethylated Spinosyn D				0.013	>500	>38461

** sum of spinosyn A + spinosyn B.

In view of the results presented in Table E.16, a low risk for earthworms is expected at the proposed use. Since the frequency of application in the field is ≥4 per season (o.a. Zucchini, Gherkin, Pumpkin species, Melon, Watermelon) and the DT_{90}-value of the active substance spinosyn D >100 days (136 days in lab. test; there is no information on this a.s. in the field), sub-lethal studies are required.
In the subchronic risk assessment for earthworms, a long-term TER-value is calculated. The (corrected) long-term toxicity value for earthworms, based on the NOEC (≥3.6 mg/kg soil) of the active substance amounts ≥1.8 mg/kg soil. This value is examined against the initial PEC soil (see above). See Table E.17 (only the worst-case use is presented).

Table E.17: Overview of soil concentrations and chronic TERs for Spinosad and its metabolites (trigger value = 5)

Application/ Use	Substance	Application rate [kg a.s./ha]	Freq	Inter-val [day]	Frac-tion on soil	PIEC soil 5 cm [mg/kg]	$NOEC_{corr}$ [mg/kg]	TER (trigger = 5)
Lettuce, Endive species, Rocket, Garden cress, beans with pods (f)	Spinosad	0.096	3	7	0.75	0.112**	≥3.6	≥32
	spinosyn B					0.060	≥1.791	≥30
	N-demethylated spinosyn D					0.013	≥0.964	≥74

* sum of spinosyn A and D

The threshold value for earthworms at chronic exposure to the active substance and to the metabolites is not exceeded in all of the proposed applications. The proposed applications of the product therefore meet the standards as laid down in the RGB.

7.5.3 Effects on soil micro-organisms

Risk assessment field uses(planting of cabbage plants in the field after tray treatment): In the tested soils no effects are observed on nitrogen transformation and carbon respiration processes at relevant application rates with the active substance spinosad and its major soil metabolites. Since the reduction percentage is below 25% after 100 days, the standards from the RGB regarding soil micro-organisms are met.

7.5.4 Effects on activated sludge

No risk assessment is required since all new applications fall within the exsisting risk envelope.

7.5.5 Effects on non target-plants

No risk assessment is required since all new applications fall within the exsisting risk envelope.

Conclusions any other organisms
The product does comply with the RGB for the aspects earthworms, soil micro-organisms, activated sludge and non-target plants. For the aspect non-target arthropods the product complies with RGB provided that restriction sentences are placed on the label.

7.6 Appropriate ecotoxicological endpoints relating to the product and approved uses

See List of Endpoints.

7.7 Data requirements

None.

7.8 Restriction sentences

The following restriction sentences were proposed by the applicant:

Om in het water levende organismen te beschermen is toepassing in onbedekte teelten op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 90% driftreducerende spuitdoppen.

Permitted is only the use as insecticide in the culture of wine grapes on the understanding that application on fields adjacent to waterways is only permitted if the product on the first 20 m adjacent to the waterway is sprayed with a Venturi nozzle where the last tree row must be sprayed from one side and reduced air fan setting.

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 in de buurt van in bloei staand onkruid. 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. Verwijder of bedek bijenkorven en hommelkasten tijdens het gebruik van het product en gedurende één dag na de behandeling en vergewis u ervan dat de spuitvloeistof volledig opgedroogd is in de kas. Voorkom dat bijen en andere bestuivende insecten de kas binnenkomen door alle openingen met insectengaas af te sluiten.

Dit middel is schadelijk voor natuurlijke vijanden. Vermijd onnodige blootstelling.

Based on the current assessment <u>and</u> the already allowed authorization 12567N, the following has to be stated in the GAP/legal instructions for use:

Om de zoogdieren te beschermen is toepassing in braam- en framboosachtigen uitsluitend toegestaan na BBCH 51 (ontwikkeling bloeiwijze).

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 in de buurt van in bloei staand onkruid. 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. Verwijder of bedek bijenkorven en hommelkasten tijdens het gebruik van het product en gedurende één dag na de behandeling en vergewis u ervan dat de spuitvloeistof volledig opgedroogd is in de kas. Voorkom dat bijen en andere

bestuivende insecten de kas binnenkomen door alle openingen met insectengaas af te sluiten.

Dit middel is schadelijk voor natuurlijke vijanden. Vermijd onnodige blootstelling.

Om water levende organismen en niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing in sla, andijvie species, rucola, tuinkers, kruiden, spinazie familie, peulvruchten, veldsla, courgette, augurk, pompoen, meloen, watermeloen, aardbei uitsluitend toegestaan wanneer in de eerste 14 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van spuitapparatuur met lage spuitboomhoogte (maximaal 30 cm boven de top van het gewas) met driftarme Venturidoppen en een kantdop en luchtondersteuning in combinatie met een teeltvrije zone van 1,5 meter (gemeten vanaf het midden van de laatste gewasrijd tot aan de perceelsgrens).

Om water levende organismen en niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing in frambozen en bramen en druif uitsluitend toegestaan wanneer in de eerste 20 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van één van onderstaande maatregelen:
-Venturidoppen (minimaal 90% driftreducerend) met ventilatorstand ‘laag’ in combinatie met éénzijdige bespuiting van de laatste bomenrij in de richting van het perceel met inachtneming van een teeltvrije zone van tenminste 4,5 meter;
- een Wannerspuit met reflectieschermen en venturidoppen (minimaal 90% driftreducerend) (Lechler ID 90-015C) met inachtneming van een teeltvrije zone van tenminste 4,5 meter;
-een KWH k1500-3R2 VLOS 3-rijenspuit met variabele luchtondersteuning en minimaal 90% driftreducerende spuitdoppen en ventilatorstand "laag" in de eerste 20 meter van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij met inachtneming van een teeltvrije zone van tenminste 3 meter.

7.9 Overall conclusions regarding ecotoxicology

It can be concluded that:

1. all proposed applications of the formulated product tracer meets the standards for birds as laid down in the RGB.
2. all proposed applications of the the formulated product tracer meet the standards for aquatic organisms as laid down in the RGB, provided that restriction sentences are placed on the label.
3. the active substance spinosad meets the standards for bioconcentration as laid down in the RGB.
4. all proposed applications of the the formulated product tracer meet the standards for mammals as laid down in the RGB provided that restriction sentences are placed on the label.
5. all proposed applications of the the formulated product tracer meet the standards for bees as laid down in the RGB, provided that a restriction sentence is placed on the label.
6. all proposed applications of the the formulated product tracer meet the standards for non-target arthropods as laid down in the RGB, provided that a restriction sentence is placed on the label.
7. all proposed applications of the the formulated product tracer meet the standards for earthworms as laid down in the RGB.
8. all proposed applications of the the formulated product tracer meet the standards for soil micro-organisms as laid down in the RGB.
9. all proposed applications of the active substance spinosad meet the standards for activated sludge as laid down in the RGB *or* cannot be examined against the

standards as laid down in the RGB; for the time being this issue is not taken into consideration.

10. all proposed applications of the the formulated product tracer meet the standards for non-target plants as laid down in the RGB

8. Efficacy

The uses applied for are minor uses. According article 51 of Regulation no.1107/2009 no efficacy data is needed.

9. Conclusion

The following uses are withdrawn by the applicant: wine grapes, table grapes, raspberry (indoor) and blackberry (indoor).
For the other uses applied for the product complies with the Uniform Principles when the following risk sentences are stated on the label:

Om het grondwater te beschermen mag dit product niet worden toegepast in grondwaterbeschermingsgebieden.

Om de zoogdieren te beschermen is toepassing in braam- en framboosachtigen uitsluitend toegestaan na BBCH 51 (ontwikkeling bloeiwijze).

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 in de buurt van in bloei staand onkruid. 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. Verwijder of bedek bijenkorven en hommelkasten tijdens het gebruik van het product en gedurende één dag na de behandeling en vergewis u ervan dat de spuitvloeistof volledig opgedroogd is in de kas. Voorkom dat bijen en andere bestuivende insecten de kas binnenkomen door alle openingen met insectengaas af te sluiten.

Dit middel is schadelijk voor natuurlijke vijanden. Vermijd onnodige blootstelling.

Om water levende organismen en niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing in sla, andijvie species, rucola, tuinkers, kruiden, spinazie familie, peulvruchten, veldsla, courgette, augurk, pompoen, meloen, watermeloen, aardbei uitsluitend toegestaan wanneer in de eerste 14 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van spuitapparatuur met lage spuitboomhoogte (maximaal 30 cm boven de top van het gewas) met driftarme Venturidoppen en een kantdop en luchtondersteuning in combinatie met een teeltvrije zone van 1,5 meter (gemeten vanaf het midden van de laatste gewasrijd tot aan de perceelsgrens).

Om water levende organismen en niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing in frambozen en bramen en druif uitsluitend toegestaan wanneer in de eerste 20 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van één van onderstaande maatregelen:

-Venturidoppen (minimaal 90% driftreducerend) met ventilatorstand ‘laag’ in combinatie met éénzijdige bespuiting van de laatste bomenrij in de richting van het perceel met inachtneming van een teeltvrije zone van tenminste 4,5 meter;
- een Wannerspuit met reflectieschermen en venturidoppen (minimaal 90% driftreducerend) (Lechler ID 90-015C) met inachtneming van een teeltvrije zone van tenminste 4,5 meter;
-een KWH k1500-3R2 VLOS 3-rijenspuit met variabele luchtondersteuning en minimaal 90% driftreducerende spuitdoppen en ventilatorstand "laag" in de eerste 20 meter van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij met inachtneming van een teeltvrije zone van tenminste 3 meter.

10. Classification and labelling

Classification and labelling of the formulation does not change.

Appendix 1 Table of authorised uses

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation**	**F G or I**	**Pests or Group of pests controlled**	**Application**			**Application rate per treatment**			**PHI** (days)	**Remarks:** d) max. no. of applications per crop and season e) Maximum product rate per season f) additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	kg, L product / ha	kg as/ha	Water L/ha min / max		
Minor uses according to article 51 from this application												
18	NL	Strawberry	G	thrips & caterpillar drosophila suzukii	Foliar treatment	19-87 Feb-nov	1-3 (7)	0.15-0.15	0.072-0.072	1000-1500	1	
27	NL	Pumpkin species	G	Thrips & caterpillars	Foliar treatment	21-71 Feb-nov	1-5 (7)	0.1-0.2	0.048-0.096	500-1000	1	Five applications per 12 months
38	NL	Lettuce	F	Thrips & caterpillars	Foliar treatment	13-49 Jun-Sept	1-3 (7)	0.2-0.2	0.096-0.096	200-800	3	3 per crop cycle, up to 5 per 12 months.
39	NL	Endive species	F	thrips & caterpillar	Foliar treatment	13-49 Jun-Sept	1-3 (7)	0.2-0.2	0.096-0.096	200-800	3	3 per crop cycle, up to five per 12 months
40	NL	Rocket	F	Thrips & caterpillars	Foliar treatment	13-49 Jun-Sept	1-3 (7)	0.2-0.2	0.096-0.096	200-800	3	3 per crop cycle, up to 5 per 12 months.
41	NL	Garden cress	F	Thrips & caterpillars	Foliar treatment	13-49 Jun-Sept	1-3 (7)	0.2-0.2	0.096-0.096	200-800	3	3 per crop cycle, up to 5 per 12 months.
42	NL	Lambs Lettuce	F	Thrips & caterpillars	Foliar treatment	13-49 Jun-Sept	1-2 (7)	0.2-0.2	0.096-0.096	200-800	14	3 per crop cycle, up to 5 per 12 months
43	NL	Zucchini	F	Thrips & caterpillars	Foliar treatment	21-71 Jun-Sept	1-5 (7)	0.1-0.2	0.048-0.096	200-800	1	Five applications per 12 months
44	NL	Gherkin	F	thrips & caterpillar	Foliar treatment	21-71 Jun-Sept	1-5 (7)	0.1-0.2	0.048-0.096	200-800	1	Five applications per 12 months
45	NL	Pumpkin species	F	Thrips & caterpillars	Foliar treatment	21-71 Jun-Sept	1-5 (7)	0.1-0.2	0.048-0.096	200-800	1	Five applications per 12 months

46	NL	Melon	F	Thrips & caterpillars	Foliar treatment	21-71 Jun-Sept	1-5 (7)	0.1-0.2	0.048-0.096	200-800	1	Five applications per 12 months
47	NL	Watermelon	F	Thrips & caterpillars	Foliar treatment	21-71 Jun-Sept	1-5 (7)	0.1-0.2	0.048-0.096	200-800	1	Five applications per 12 months
48	NL	Herbs	F	Thrips & caterpillars	Foliar treatment	13-49 Jun-Sept	1-3 (7)	0.2-0.2	0.096-0.096	200-800	3	3 treatments per cropcycle and 5 treatments per 12 months
49	NL	Witloof	I	Liriomyzae leafminer *Napomyza cichorii*	Collar treatment	directly after filling forcing container 'intafelen'	1	0.5 mL/m²	0.24 g as/m²	1-3L/m²	18	
50	NL	Cauliflower	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
51	NL	Broccoli	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
52	NL	Head cabbage	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
53	NL	Brussels sprouts	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
54	NL	Chinese cabbage	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
55	NL	Swede	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
56	NL	Kohlrabi	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
57	NL	Eastern leaf Cabbage	I	Delia	Tray treatment	12-14 Jan-Dec	1-1 (-)	12.5 mL/1000 plants	0.006 as/1000 plants	5L/1200 plants	-	Traytreatment (spray), 12.5 mL/1000 plants
58	NL	Strawberry	F	thrips & caterpillars drosophila suzuki	Foliar treatment	19-87 May-Oct	1-3 (7)	0.15-0.15	0.072-0.072	1000-1500	1	
61	NL	Raspberry	F	thrips & caterpillars drosophila suzuki	Foliar treatment	unspecified Jun-Sept	1-2 (10)	0.16-0.2	0.077-0.096	800-1500	3	

63	NL	Blackberry	F	thrips & caterpillars drosophila suzuki	Foliar treatment	unspecified Jun-Sept	1-2 (10)	0.16-0.2	0.077-0.096	800-1500	3	
65	NL	Spinach family	F	Leafminers, beetfly, caterpillars	Foliar treatment	13-49 Apr-Sept	1-3 (7-10)	0.2-0.2	0.096-0.096	200-800	3	3 per crop cycle, **up to two crop cycles per year**
66	NL	Beans with pods	G	Caterpillars, Thrips	Foliar treatment	up to BBCH 79 Mar-Oct	1-2 (7-10)	0.08-0.25	0.038-0.12	200-1000	7	

Appendix 2 Reference list

This appendix serves only to give an indication of which data have been used for decision making for the first time; as a result of concurring applications for authorisations, the data mentioned here may have been used for an earlier decisions as well. Therefore, no rights can be derived from this overview.
Deze appendix geeft een indicatief overzicht van de gegevens die voor het eerst gebruikt zijn ten behoeve van een besluit; het kan echter voorkomen dat (onder andere) door een samenloop van aanvragen, de hier opgenomen gegevens al eens eerder gebruikt zijn. Aan dit overzicht kunnen dan ook geen rechten ontleend worden.

2013	Exposure of bees to the insecticide GF-976 a 480 g/L SC of spinosad (44.04 % w/w) to flowering *Phacelia* in a semi-field cage design.	Y	Dow AgroSciences	12567N	25 november 2013
2013	A terrestrial mesocosm study to assess the effects of GF-976 (a 480 g/L SC formulation of spinosad) on the non-target, surface- and plant dwelling, arthropod fauna of a grassland habitat in SW France, when exposed to low concentrations during spring.	Y	Dow AgroSciences	12567N	25 november 2013
2005	Determination of residues of spinosad in witloof after treatment with TRACER: 4 harvest residue trials carried out in 2005 in Belgium for FOD. Walloon Agricultural Research Centre (CRA-W)	Y	FOD	12567N	25 november 2013

2007	Validation and determination of residues of spinosad in witloof after treatment with tracer (spinosad 480 g/L SC). BEAGx – CA – LP	Y	FOD	12567N	25 november 2013
2009	Determination of residues of spinosad in raspberries after treatment with TRACER – 4 harvest residue trials carried out in 2007 in Belgium for FOD. Walloon Agricultural Research Centre (CRA-W)	Y	FOD	12567N	25 november 2013
2009	Determination of residues of spinosad in raspberries after treatment with TRACER – 4 harvest residue trials carried out in 2007 in Belgium for FOD. Walloon Agricultural Research Centre (CRA-W) - amendement	Y	FOD	12567N	25 november 2013