Bijlage 1

bij het

Advies 2022/01 voor de aanvraag vrijstelling

ex artikel 38 Wet gewasbeschermingsmiddelen en biociden (Wgb)

[artikel 53 Verordening (EU) Nr. 1107/2009]

van het insecticide

Tracer

(spinosad)

in de teelt van kers en druif

Deel 1	Landbouwkundige onderbouwing [NVWA]
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DEEL 1 – Landbouwkundige onderbouwing NVWA

Buiten reikwijdte verzoek

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Landbouwkundige onderbouwing tijdelijke vrijstelling art. 38 Wgb voor de middelen Tracer en Buiten reikwijdte verzoek ter beheersing van Drosophila suzukii in de onbedekte teelt van kers

Opgesteld door:

NVWA, Afdeling Expertise, Team Gewasbescherming en Natuur

Februari 2022

Inleiding

Situatie in het kort

De Nederlandse Fruittelers Organisatie heeft een verzoek tot vrijstelling, conform art. 38 van de WGB, ingediend bij het ministerie van Landbouw, Natuur en Voedselkwaliteit. Het verzoek betreft een vrijstelling voor het middel Tracer, op basis van de werkzame stof spinosad en een vrijstelling voor het middel Buiten reikwijdte verzoek Buiten reikwijdte verzoek ter beheersing van *Drosophila suzukii* (suzuki-fruitvlieg) in de onbedekte teelt van kers.

Teelt

Kersen (CBS 2020: 787 ha) worden verspreid over het land geteeld. Het grootste areaal bevindt zich in Gelderland, Noord-Brabant, Limburg, Utrecht en Zeeland. De oogst van de kersen vindt vooral plaats in de maanden juni tot en met augustus. De kersen zijn bestemd voor consumptiedoeleinden.

Organisme

De suzuki-fruitvlieg legt eieren in vruchten van zacht fruit, die af beginnen te rijpen, maar ook wel in onrijp fruit. De larven ontwikkelen zich in de vruchten. Kleinfruit (o.a. aardbei, frambozen en bessen) en steenfruit (vooral kersen en pruimen) zijn de gewassen die het meest vatbaar zijn voor aantasting door de suzuki-fruitvlieg. Wilde planten en beschadigd fruit zijn ook waard voor dit insect. De larven zitten tijdens de oogst in aangetaste vruchten.

De aanvangspopulatie van de volwassen exemplaren na overwintering is laag, maar de populatie kan zich daarna gedurende het seizoen, door het grote aantal afgezette eieren, weer snel opbouwen. Vanaf het voorjaar gaan de vrouwtjes op zoek naar vruchten om hun eieren in af te zetten. Zij vermeerderen zich dan op vroeg rijpende vruchten (zoals kersen en pruimen), waarna in volgende cycli ook eieren worden afgezet op vruchten die later afrijpen. Vanaf tweede helft mei/begin juni worden aangetaste kersen aangetroffen. Bij warm Nederlands zomerweer is de generatieduur van suzuki-fruitvlieg ruim twee weken. Onder Nederlandse klimaatomstandigheden kunnen zich zes generaties ontwikkelen.

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Landbouwkundige criteria art. 38 Wgb

Bijzondere omstandigheden

Aanleiding

In de afgelopen jaren heeft de suzuki-fruitvlieg zich in Zuid-Europa gevestigd, verspreid en veel schade veroorzaakt. Sinds omstreeks 2011 komt het insect ook in Nederland voor en heeft het zich sinds 2013 verspreid over het hele land.

Concreet perspectief

In 2015 t/m 2021 waren een middel op basis van spinosad en een middel op basis van Buiten reikwijdte verzoek vrijgesteld ter bescherming van de onbedekte teelt van kers tegen suzuki-fruitvlieg.

De werkzame stof spinosad is goedgekeurd tot 30 april 2022 (lijst van goedgekeurde werkzame stoffen van Verordening (EG) nr. 1107/2009). De toelatinghouder streeft ook in Nederland naar een toelating in kers. Na de renewal van de werkzame stof, die verwacht wordt in 2023, zullen de herregistratiedossiers ingediend worden. Dit middel is daarmee niet beschikbaar in 2022.

Buiten reikwijdte verzoek

Sinds 1 juli 2017 geldt voor nieuwe vrijstellingsaanvragen dat er binnen drie jaar perspectief moet zijn op een oplossing. Voor vrijstellingsaanvragen die voor deze datum zijn ingediend, geldt deze termijn vooralsnog niet. De NVWA constateert dat sinds 2015 het verkrijgen van een reguliere toelating in Nederland van een middel op basis van spinosad en een middel op basis van Buiten reikwijdte verzoek zicht gaf op concreet perspectief, maar dat er geen sprake meer is van een kortstondige overbrugging naar een reguliere oplossing. Vanuit het belang van de transitie naar een weerbaar teeltsysteem, zoals beschreven in de Toekomstvisie gewasbescherming 2030, is het gewenst dat de aanvrager op korte termijn inzet op alternatieven.

Conclusie Tracer: De aanvraag voldoet aan de eis van bijzondere omstandigheden. De toelatinghouder en de sector leveren inspanningen om te komen tot een oplossing. Er is perspectief voor de toelating van een middel op basis van spinosad in de onbedekte teelt van kers.

Buiten reikwijdte verzoek

Alternatieven

Maatregelen:

Hygiënische maatregelen, zoals geen fruit op de composthoop gooien, dragen bij aan de beheersing van suzuki-fruitvlieg. Alle rijpe en oogstrijpe vruchten verwijderen, waardoor deze geen besmettingsbron zijn en niet in de handel komen, is niet uitvoerbaar. In de grote steenfruitbomen lukt het niet om alle vruchten te oogsten.

Een open gewas, een kort gemaaide ondergrond en schone zwartstroken zorgen voor minder schaduw en vocht, waardoor de suzuki-fruitvlieg zich minder makkelijk kan vestigen.

Door vroeg te oogsten en snel te koelen is met een beginnende aantasting nog een te verkopen product te realiseren, maar dit kost kwaliteit en kwantiteit.

Er is praktijkervaring opgedaan met het innetten van boomgaarden met insectengaas. Het moment van aantasting kan door innetten worden verlaat, waardoor de aantasting uiteindelijk lager uitkomt. Bij zoete kersen is het een perspectiefvolle optie, die in de praktijk steeds meer wordt toegepast. Inmiddels wordt het toegepast op meer dan 50% van het areaal zoete kersen. Deze methode is bij zure kers minder snel economisch rendabel omdat in deze boomgaarden een basisconstructie voor regenkappen, waar insectengaas aan vastgemaakt kan worden, ontbreekt. Hierdoor is de investering in zure kers veel hoger. Er is sinds december 2020 een mogelijkheid tot MIA/Vamil subsidie van het RVO voor het innetten van fruitgewassen. Mogelijk maakt dit het plaatsen van insectengaas economisch rendabel. Het innetten is niet overal toegestaan op basis van ruimtelijke ordeningsregelingen. Bij zomerse buien en veel wind is er een groot risico op het kapot- en loswaaien van het insectengaas en het omwaaien van de constructie. Wanneer gaten groter dan 1 mm ontstaan, kunnen de fruitvliegjes hier door naar binnen. Daarnaast ontstaat een warmer en vochtiger klimaat onder het net met meer kans op vruchtrot.

Praktijkproeven met parasitaire nematoden geven aan dat 50% doding mogelijk is. Dit is echter alleen effectief tegen de fruitvliegmaden op het moment dat al forse schade is ontstaan in het perceel. Uit (inter)nationaal onderzoek zijn nog geen natuurlijke vijanden naar voren gekomen die in de praktijk kunnen worden ingezet.

In 2021 is in Groot Brittannië in een perceel aardbeien een proef uitgevoerd met het inzetten van steriele mannetjes van de suzuki-fruitvlieg. De resultaten waren goed. In 2022 zal ook onderzoek in kers en framboos worden uitgevoerd en wordt er een pilot voor een productielijn opgezet.

Er zijn praktijkproeven gedaan met vallen voor de monitoring van fruitvliegen. In kersenboomgaarden zijn deze echter onvoldoende effectief, met name door concurrentie met het rijpende fruit. Dit insect komt algemeen voor en kan zich zeer goed verplaatsen. De ei-afzet start zodra de kersen beginnen te kleuren.

Met niet-chemische maatregelen kan de schade worden beperkt. Sommige methoden bevinden zich echter nog in de onderzoeksfase, of kunnen niet onder alle omstandigheden of regio's worden toegepast.

Toegelaten middelen, goedgekeurde basisstoffen en voormalige RUBmiddelen
In de onbedekte teelt van kersen zijn middelen tegen insecten beschikbaar op basis van abamectine, acetamiprid, *Bacillus thuringiensis* subsp. Aizawai, *Bacillus thuringiensis* subsp. Kurstaki, diammoniumfosfaat (basisstof), flonicamid, indoxacarb, *Metarhizium anisopliae* stam F52, pirimicarb, spirotetramat, talk (basisstof), *Urtica* spp. (basisstof) en zepen (voormalig RUBmiddel). Middelen op basis van abamectine, acetamiprid, *Bacillus thuringiensis*, diammoniumfosfaat, flonicamid, indoxacarb, *Metarhizium anisopliae,* pirimicarb, *Urtica* spp. en zepen hebben geen tot onvoldoende werking tegen suzuki-fruitvlieg.

Middelen op basis van spirotetramat hebben een systemische werking, waarbij het essentieel is dat deze op een groeiend gewas worden toegepast. Tijdens de rijpingsperiode is de groei van het gewas echter beperkt waardoor de werking van het middel in die fase onvoldoende is. Uit onderzoek is bekend dat dit middel een beperkte werking heeft tegen suzuki-fruitvlieg. Het werkt alleen tegen de larve in de vrucht. Door de lange veiligheidstermijn van 21 dagen is dit middel voor de beheersing van suzuki-fruitvlieg in de oogstperiode geen alternatief.

Talk is als basisstof toegelaten in de teelt van kers tegen suzuki-fruitvlieg. Het is een repellant (d.m.v. een fysieke barrière). Volgens de aanvrager valt de werking in de praktijk tegen. Bovendien geeft toepassing van talk een wit residu op de vruchten, waardoor deze onverkoopbaar worden.

Met de toepassing van deze maatregelen en middelen kan suzuki-fruitvlieg niet afdoende beheerst worden.

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Landbouwkundige noodzaak voor vrijstelling van 2 middelen:
De oogst in een perceel met diverse kersenrassen duurt 6 tot 8 weken. De werkingsduur van een middel op basis van spinosad is 5 tot 7 dagen en van een middel op basis van Buiten reikwijdte verzoek 10 tot 14 dagen. Beide middelen mogen maximaal 2 keer per 12 maanden worden toegepast. Het is daardoor onvoldoende wanneer alleen één van beide middelen zou worden vrijgesteld. Voor een effectieve beheersing van suzuki-fruitvlieg zijn beide middelen nodig.

Conclusie:
Een landbouwtechnisch doelmatige onbedekte teelt van kers is met het beschikbare pakket aan maatregelen en middelen niet mogelijk.

Gevaar
Suzuki-fruitvlieg komt verspreid over het hele land voor. De larven zitten tijdens de oogst in de vruchten, waardoor de houdbaarheid sterk afneemt. Bovendien is er een nultolerantie bij de afnemers, wat inhoudt dat de hele partij onverkoopbaar is als enkele aangetaste vruchten in een partij aangetroffen worden.

De aantasting van kers door suzuki-fruitvlieg geeft met name in de late oogst vruchtuitval tijdens of na de oogst. Zonder de vrij te stellen middelen, loopt de aantasting aan het einde van het oogstseizoen op late rassen op tot 100%. De aanvrager schat in dat de economische schade gemiddeld over het hele jaar 50% (zoete kers) tot 60% (zure kers) is.

Conclusie:
Een landbouwtechnisch doelmatige onbedekte teelt van kers in Nederland wordt bedreigd door onvoldoende mogelijkheden tot beheersing van suzuki-fruitvlieg.
Eindconclusie Tracer
Vrijstelling conform art. 38 Wgb, van Tracer in de onbedekte teelt van kers voldoet aan de landbouwkundige criteria. Suzuki-fruitvlieg is een teeltbedreigend probleem voor de onbedekte teelt van kers, waarvoor momenteel het beschikbare pakket aan maatregelen en middelen niet afdoende is. De aanvraag voldoet aan de eis van bijzondere omstandigheden, er is perspectief voor de toelating van een middel op basis van spinosad.

Buiten reikwijdte verzoek

Aangevraagde periode
Tracer: 01-05-2022 tot en met 15-08-2022
Buiten reikwijdte verzoek

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DEEL 2A – Voorgesteld WG [NVWA]

Wettelijk Gebruiksvoorschrift
Het middel is uitsluitend toegestaan als insectenbestrijdingsmiddel voor het professionele gebruik door middel van een gewasbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.2 Ctgb juni 2019) onder de hierna vermelde toepassingsvoorwaarden.

Toepassingsvoorwaarden

Toepassings-gebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximale dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen
Kers (onbedekte teelt)	suzuki-fruitvlieg	0,02 %	200 ml/ha	2	7	7

Buiten reikwijdte verzoek

* Toepassing van het middel allen op het deel van het gewas waar zich druiventrossen bevinden.

Overige toepassingsvoorwaarden

Om in het water levende organismen en niet tot de doelsoorten behorende geleedpotigen/insecten te beschermen is toepassing van het middel in de teelt van kersen uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van:
- een techniek uit tenminste de klasse DRT 97,5 in combinatie met een teeltvrije zone van 4,5 meter of
- een techniek uit tenminste de klasse DRT 99.

Buiten reikwijdte verzoek

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Gevaarlijk voor bijen. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen. Gebruik dit product niet op plaatsen waar bijen actief naar voedsel zoeken. Gebruik dit product niet in de buurt van in bloei staand onkruid. Verwijder onkruid voordat het bloeit.

Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg deskundigen (uw leverancier van natuurlijke vijanden, de producent van dit middel, uw adviseur) over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden.
Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg deskundigen (uw leverancier van natuurlijke vijanden, de producent van dit middel, uw adviseur) over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden.

DEEL 2B – Geadviseerd WG [Ctgb]

Wettelijk Gebruiksvoorschrift

Het middel is uitsluitend toegestaan als insectenbestrijdingsmiddel voor het professionele gebruik door middel van een gewasbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.2 Ctgb juni 2019) onder de hierna vermelde toepassingsvoorwaarden.

Toepassingsvoorwaarden

Toepassings-Gebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximale dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen
Kers (onbedekte teelt)	suzuki-fruitvlieg	0,02 %	200 ml/ha	2	7	7
Buiten reikwijdte verzoek						

* Toepassing van het middel allen op het deel van het gewas waar zich druiventrossen bevinden.

Overige toepassingsvoorwaarden

Het risico voor waterorganismen is acceptabel met de volgende restrictiezin:

Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van kersen en druiven in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van een techniek uit tenminste de klasse DRT99 in combinatie met een teeltvrije zone van tenminste 300 centimeter gemeten vanaf het midden van de laatste bomenrij of de laatste boom in de rij tot aan de insteek van de sloot / perceelgrens.

Het risico voor bijen is acceptabel, mits de volgende restrictiezin op het etiket wordt geplaatst:

Gevaarlijk voor bijen. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen. Gebruik dit product niet op plaatsen waar bijen actief naar voedsel zoeken. Gebruik dit product niet in de buurt van in bloei staand onkruid. Verwijder onkruid voordat het bloeit.
Het risico voor niet-doelwit arthropoden is acceptabel, mits de volgende restrictiezinnen en waarschuwingszin op het etiket worden geplaatst:

Om niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing van het middel in de teelt van kersen in percelen die niet grenzen aan watergangen uitsluitend toegestaan indien op het gehele perceel gebruik wordt gemaakt van:
- een techniek uit tenminste de klasse DRT99; of
- een techniek uit tenminste de klasse DRT97,5 in combinatie met een teeltvrije zone van tenminste 450 cm gemeten vanaf het midden van de laatste bomenrij of de laatste boom in de rij tot aan de perceelgrens.

Buiten reikwijdte verzoek

Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg deskundigen (uw leverancier van natuurlijke vijanden, de producent van dit middel, uw adviseur) over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden.

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DEEL 3A – Voorgestelde GAP [NVWA]

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	g, kg as/ha	Water L/ha min / max		
1	NL	kers	F	Drosophila suzukii	Gewasbehandeling	BBCH 77-89 (mei - august)	2 (7)	0,02 % (0,20)	0,096	1000	7	
Buiten reikwijdte verzoek												

DEEL 3B – Geadviseerde GAP [Ctgb]

Die 3A.

DEEL 4 – Beoordeling Humane toxiciteit [Ctgb]

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*.

List of Endpoints

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), Chromosome 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

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 does not need to be classified for skin or eye irritation and 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)

For this article 38 exemption, however, the new EFSA guidance on dermal absorption (2017) is applicable. Therefore, the dermal absorption values were recalculated using the Excel spreadsheet provided with the EFSA guidance (see table below).

	Value	Reference
Concentrate (480 g/L)	0.1%	Based on an *in vitro* study with human skin samples (DAS Study ID 130528)
Spray dilution (0.6 g/L)	9.3%	
Spray dilution (0.01 g/L)	9.1%	

The spray dilution for the use under consideration is 0.096 g/L. Since the dermal absorption for the two tested spray dilutions is approximately the same and the intended spray dilution lies between the two tested ones, a pro rata correction is not considered necessary. As a worst-case approach, the more critical dermal absorption value (9.3%) is taken for the exposure calculations.

4.3 Available toxicological data relating to non-active substances (IIIA 7.4)

The available toxicological data relating to non-active substances will be taken into account in the classification and labelling of the formulated product.

4.4 Exposure/risk assessments

Overview of the intended uses

An application has been submitted for an article 38 exemption of the plant protection product Tracer, an insecticide based on the active substance spinosad.

Tracer is a SC (suspension concentrate) formulation and contains 480 g/L spinosad.

4.4.1 Operator exposure/risk

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.

Since the formulation is applied 2 (cherry) or 4 (grape) times during the period May to August (cherry) or July to October (grape), a semi-chronic exposure duration is applicable for the operator (including contract workers). A semi-chronic AOEL is therefore derived.

Since spinosad is included in Annex I of 91/414/EEC and subsequently approved under Regulation 1107/2009 EC, the semi-chronic EU-AOEL of 0.024 mg/kg bw/day (= 1.44 mg/day for a 60-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 and protected (gloves + coverall) 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.

The intended use in cherry at 0.2 L/ha and 1000 L/ha covers the intended use in grapes at the application rate of 0.16 L/ha and 400-800 L/ha.

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

Route	Estimated internal exposure [a] (mg/kg bw/day)		Systemic AOEL (mg/kg bw/day)	% AOEL [b]	
	Without PPE	With PPE[c]		Without PPE	With PPE
Mechanical upward spraying on cherry and grapes (0.20 L/ha, uncovered)[c]					
Mixing, loading and application	0.0068	-	0.024	29	-
Manual upward spraying on cherry and grapes (0.20 L/ha, uncovered)[c]					
Mixing, loading and application	0.0044	-	0.024	18	-
Mechanical downward spraying on cherry (0.20 L/ha, uncovered)[c]					
Mixing, loading and application	0.0027	-	0.024	11	-
Manual downward spraying on cherry (0.20 L/ha, uncovered)[c]					
Mixing, loading and application	0.0172	-	0.024	72	-

a Internal exposure was calculated with:
- biological availability via the dermal route: 0.1% (concentrate) and 9.3% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The % AOEL is calculated by dividing the internal exposure by the systemic AOEL, multiplying by 100.

c Internal exposure is estimated with EFSA OPEX.

Based on the calculated exposures for spinosad, the exposure of the unprotected operator is considered to be safe.

4.4.2 Bystander exposure/risk

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

Since no AAOEL has been set at EU level the bystander exposure is covered by the resident exposure assessment.

Since different spray volumes are applied the applications in grapes and cherry are calculated separately. The upward spray application will cover the downward spray application.

Table T.2 Internal resident exposure to spinosad and risk assessment for the use of Tracer

	Route	Estimated internal exposure [a] (mg/kg bw/day)	Systemic EU-AOEL (mg/kg bw/day)	% AEL [b]
Upward spraying on cherry (0.096 kg a.s./ha, 1000 L/ha, 2 times, 7-day interval)				
Child	Spray drift	0.0013	0.024	5
	Vapour	0.0011	0.024	4
	Surface deposits	0.0011	0.024	5
	Entry into treated crops	0.0028	0.024	12
	All pathways	0.0049	0.024	21
Adult	Spray drift	0.0007	0.024	3
	Vapour	0.0002	0.024	1
	Surface deposits	0.0003	0.024	1
	Entry into treated crops	0.0015	0.024	6
	All pathways	0.0022	0.024	9

Buiten reikwijdte verzoek

a Internal exposure was calculated with:
- biological availability via the dermal route: 0.1% (concentrate) and 9.3% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The % AOEL is calculated by dividing the internal exposure by the systemic AOEL, multiplying by 100.
c External exposure is estimated with EFSA OPEX.

Based on the calculated exposures for spinosad, the resident exposure of children and adults living next to a field treated with Tracer is considered to be safe.

4.4.3 Worker exposure/risk

Calculation of the EU-AOEL / Tolerable Limit Value (TLV)
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 and protected 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/kg bw/day)		Systemic EU-AOEL (mg/kg bw/day)	% AOEL [b]	
	Without PPE	With PPE[c]		With out PPE	With PPE[c]
Re-entry activities in cherry (2 x 0.096 kg a.s./ha, interval 7 days)					
Total	0.0297	0.0149	0.024	**124**	62
Buiten reikwijdte verzoek					

a External exposure was estimated with EFSA OPEX. Internal exposure was calculated with:
- biological availability via the dermal route: 9.3% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The % AOEL is calculated by dividing the internal exposure by the systemic AOEL, multiplying by 100.

c PPE: gloves

Based on the calculated exposures for spinosad, the worker exposure is considered to be safe only in case PPE (gloves) is worn for the intended use in cherry.

For the use in grapes, no safe use has been shown for the unprotected worker. The EFSA OPEX does not provide a refinement assuming gloves are worn as no TC value is available for grapes assuming gloves.

While no refinement assuming PPE is possible, a DT50 value was derived in the RAR of spinosad of 3.1 days. The estimated worker exposure using this DT50 value is provided in Table T.4.

Table T.4 Internal worker exposure to spinosad and risk assessment after application of Tracer refined DT50 value of 3.1 days

Route	Estimated internal exposure [a] (mg/kg bw/day)		Systemic EU-AOEL (mg/kg bw/day)	% AOEL [b]	
	Without PPE	With PPE[c]		With out PPE	With PPE
Re-entry activities in cherry (2 x 0.096 kg a.s./ha, interval 7 days)					
Total	0.0194	-	0.024	81	-
Buiten reikwijdte verzoek					

a External exposure was estimated with EFSA OPEX. Internal exposure was calculated with:
* biological availability via the dermal route: 9.3% (see 4.2)
* biological availability via the respiratory route: 100% (worst case)

b The % AOEL is calculated by dividing the internal exposure by the systemic AOEL, multiplying by 100.

The refined risk assessment using the DT50 value of 3.1 days shows a safe use for the unprotected worker for the use in cherry.

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

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 cherry and grape.

Bystander exposure

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected bystander, nor for nearby non-work related bystanders and residents, due to exposure to spinosad during application of Tracer in cherry and grape.

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 cherry and grape due to exposure to spinosad after application of Tracer.

4.5 Appropriate mammalian toxicology and operator exposure endpoints 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.

DEEL 5 – Beoordeling Residuen [Ctgb]

List of Endpoints

The List of Endpoints is taken from the Conclusion on the peer review of the pesticide risk assessment of the active substance spinosad. Appendix A, EFSA, 2018. Only the endpoints relevant for the current application on grapes, cherries and plums are presented below. Grapes was one of the representative uses (3 x 96 g as/ha, interval 7 days, BBCH 12-89, PHI 14 days).

Residues in or on treated products food and feed
Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) **OECD Guideline 501**	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Fruit crops	Apples	spinosyn A: 1x 1326 mg/tree spinosyn D: 1x 523 mg/tree	0, 3, 7, 14, 28, 42
			2x 100 g as/ha + 2x 150 g as/ha, 7d interval. spinosyn A or spinosyn D	0, 3
		tomatoes	3x 133 g as/ha ^{14}C-spinosyn A 3x 33 g as/ha ^{14}C-spinosyn D	Fruit: 26 after 1st appl (0d before 2nd) after 3rd appl: 3, 7, 14 Vines: 14 after 3rd appl
		grapes	1x 0.20 ^{14}C-spinosyn A as/bunch 1x 0.22 mg ^{14}C-spinosyn D as/bunch	0, 1, 3, 7, 10, 14 21, 49 0, 3, 7, 14, 21, 49 (foliar application)
	The metabolism studies were conducted either ^{14}C spinosyn A or ^{14}C spinosyn D that were uniformly labelled throughout the macrolide ring system and they were applied under foliar application or soil drench. Spinosad is subjective to photolytic degradation, resulting in faster degradation in unprotected crops exposed to sunlight.			

Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**	^{14}C-spinosyn A	N-demethyl spinosyn A	spinosyn A 17-pseudoaglycone
	20 min, 90°C, pH 4	96.9	1.9	1.2
	60 min, 100°C, pH 5	95.6	2.5	3.4
	20 min, 120°C, pH 6	77.5	6.3	13.4
		^{14}C-spinosyn D	N-demethyl spinosynD	spinosyn A 17-pseudoaglycone D
	20 min, 90°C, pH 4	97.9	<3.3	<3.3
	60 min, 100°C, pH 5	97.5	<3.3	3.8
	20 min, 120°C, pH 6	83.3	<3.3	14.2
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes. Studies conducted with spinosyn A and spinosyn D.			

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Spinosad, sum of spinosyn A and spinosyn D
Plant residue definition for risk assessment (RD-RA)	Sum-of spinosyn A, spinosyn D, spinosyn B, spinosyn K. (Provisional)
Conversion factor (monitoring to risk assessment)	See comments from the residue trials table.

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)
OECD Guideline 506

Plant products (Category)	**Commodity**	**T** (°C)	**Stability** (Month)				
			Spin A	Spin D	Spin B	Spin K	N-demthyl spinosyn D
High acid content	grape, fruit	-20°	18	18	-	-	-
					-	-	-
	strawberries		18	18	-	-	-
Other (processed)	Apple juice	-20^0	23	23	23	23	23
	grape, wine	-20^0	18	18			
Storage stability for spinosyns A, D, B, K residues has been demonstrated for the commodities types of pome fruit and fruiting vegetables/cucurbits in high water category, of grapes and berries in high acid category and of oilseeds the high oil category.							

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop	**Region/ Indoor** (a)	**Residue levels** (mg/kg) **observed in the supervised residue trials relevant to the supported GAPs** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
Representative uses;						
Table and wine grapes	S-EU	**RD for monitoring:** <0.02, 0.021, 0.024, 0.046, 0.050, 0.051, 0.056**,** 0.056, 0.113, 0.122, 0.135, 0.137, 0.171, 0.176, 0.241, 0.359 **RD for risk assessment:** <0.02**,** 0.023, 0.025, 0.029, 0.041, 0.047, 0.050, 0.058, 0.058, 0.102, 0.118, 0.136, 0.145, 0.210, 0.211, 0.241, 0.436	Proportionality was applied since dose rates were -50% to +27% compared to cGAP. Some underdosed trials analysed for spinosyn A, B, D, K, but in none of these trials residues of spinosyn B and K were above the LOQ, hence scaling could not be applied to spinosyn B and K residues nor could a CF be derived from these trials. Therefore, a CF of 1.2 was applied to the whole data set. This CF was derived from the grape metabolism studies with spinosyn A and was used to convert residues of spinosyn B/K based on the trial results for spinosyn A. Calculated residues for spinosyn B/K ranged from 0.003 to 0.059 mg/kg. The values for the RD_{RA} are the sum of spinosyn A_{scaled}, spinosyn B/K_{calc} and spinosyn D_{scaled}. Confirmatory trials to determine actual residue levels of spinosyn B and K are	**0.5**	Pro-visional 0.436	Pro-visonal 0.058

Crop	Region/ Indoor (a)	Residue levels (mg/kg) observed in the supervised residue trials relevant to the supported GAPs (b)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (c)	STMR (mg/kg) (d)
			required (data gap).			
	N-EU	**RD for monitoring**: 8 x <0.02, 2 x 0.02 **RD for risk assessment**: -	Trials analysed only for spinosyn A and D, and not according to the RD_{RA}, hence a CF cannot be derived. The data set is insufficient, however the use in SEU is identified as the critical one, hence this data gap has no impact on the risk assessment and MRL proposal.	0.03	-	-

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
(b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$).

Conversion Factors (CF) for monitoring to risk assessment

No conversion factors could be derived based on the metabolism studies. Field residue trials analysed for all components of the RA-RD are still required (data gap)

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)
OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies[(a)]	Processing Factor (PF)		Conversion Factor (CF_P) for RA[(b)]
		Individual values	Median PF	
Representative uses				
Red wine, pomace	2	2, 2.3		-
Red wine, must	2	1, <0.067		-
Red wine, Wine at bottling	2	<1, <0.067		-
Red wine, wine after 4 moths	1	<1	Not sufficient data (data gap)	-

[(a)]: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
[(b)]: When the residue definition for risk assessment differs from the residue definition for monitoring

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code[(a)]	Commodity/Group	MRL/Import tolerance[(b)] (mg/kg) and Comments	
Representative uses			
0151000	Grapes	0.5	The MRL is derived from the data set on grapes SEU use.

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

5.1. Summary of residue data

The assessment below is based on the Report of the 2001 JMPR FAO/WHO Meeting of Experts, 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), the available residue trials evaluated in the Evaluation Reports on residues of spinosad in grapes (Ctgb, July 2014) and the Conclusion on the peer review of the pesticide risk assessment of the active substance spinosad (EFSA Journal 2018;16(5):5252).

5.1.1 Metabolism in plants

Several primary crops metabolism studies were conducted separately with 14C-spinosyn A and 14Cspinosyn D among others upon foliar spray application in fruits (apple, tomatoes and grapes). Metabolism studies cover the uses on grapes, cherries and plums.

5.1.2 Metabolism in livestock

Since the crops of the intended uses are not normally fed to livestock, metabolism studies in livestock are not required for the current application.

5.1.3 Residue definition

Plant

Spinosad was discussed at the Pesticides Peer Review Experts meeting 171 in December 2017. The risk assessment residue definition in plants is provisionally proposed as: sum of spinosyn A, D, B, K, pending the outcome of residue levels for each representative crop from field trials analysed for the relevant compounds included in the risk assessment residue definition and their toxicological relevance. For monitoring, the residue definition in plants is proposed as sum of spinosyn A and D.

Animal

Since the crops of the intended uses are not normally fed to livestock, a residue definition for animal products is not applicable to the current application.

5.1.4 Stability of residues

Storage stability for spinosyns A, D, B, K residues has been demonstrated for the commodities in high water category and in high acid category and cover the uses on grapes, cherries and plums (refer to List of Endpoints).

5.1.5 Residue data

Cherries and plums

cGAP-NL: 2x0.096kg as/ha, interval 7d, PHI 7d

Currently, no acceptable residue trials in Northern Europe are available to support the outdoor use of Tracer on cherries and plums. However, eight trials on cherry and five trials in plums, conducted in the USA, indicate that residues of spinosad arising from the use of this crops will remain below the current MRL of 0.2 mg/kg, for cherries and plums. The growing conditions in Northern Europe are not considered to be so different that significantly different residue values are expected.

The following data are taken from the Report of the 2001 JMPR FAO/WHO Meeting of Experts (a Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment
and the WHO Core Assessment Group (JMPR)).

*"GAP in the USA permits application of spinosad at 0.14 kg as/ha with harvesting 7 days after the
final application for cherries, plums and prunes or 14 days for peach, nectarine and apricot. The
concentrations of residues, in ranked order, from eight trials on cherry that met GAP in the USA were: <0.02, 0.023, 0.03, 0.04, 0.06, 0.083 and 0.11 (2) mg/kg; those in seven trials on peach were: < 0.02 (3), 0.03, 0.05 and 0.055 (2) mg/kg; and those in five trials on plum were: < 0.02 (5) mg/kg. The Meeting agreed that cherries, peaches and plums represent the stone fruit group and that cherries and peaches would usually have the highest concentrations of residues in the group. Therefore, a maximum residue level could be recommended for stone fruit. The concentrations in ranked order in the 20 trials (median underlined) were: < 0.02 (9), 0.023, 0.03 (2), 0.04, 0.05, 0.055 (2), 0.06, 0.083 and 0.11 (2) mg/kg. The Meeting estimated a maximum residue level of 0.2 mg/kg and an STMR value of 0.03 mg/kg for spinosad in stone fruits."*

This recommendation resulted in internationally recommended CXLs adopted by the Codex Alimentarius Commission CXLs. The CXL of 0.2 mg/kg for cherries and plums is included as MRL in Regulation (EC) No 396/2005.

The residue trial data available are considered sufficient to support the intended use on cherries and plums.

Wine grapes (outdoor)
cGAP-NL: 4x 0.0768 kg as/ha, interval 7 days, PHI=14 days
Six outdoor field trials in Germany (Northern Europe) with spinosad in wine grapes are available to support the intended use of Tracer on wine grapes. The trials were evaluated by Ctgb. 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 the 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 (0.3072 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.

It is noted that the intended use of *4x 76.8 g as/ha, interval 7 days, PHI=14 days* is comparable to the representative uses on grapes in northern Europe evaluated during the peer review (3 x 96 *g as/ha,*, interval 7 days, BBCH 12-89, PHI 14 days). Sufficient data are available according to the residue definition for monitoring. For the renewal of the active substance spinosad the data set in NEU was considered insufficient since trials were analysed only for spinosyn A and D, and not according to the residue definition for risk assessment. However the use in SEU was identified as the critical one (refer to List of Endpoints), hence the data gap had no impact on the risk assessment and MRL proposal.

The residue trial data available are considered sufficient to support the intended use on grapes.

5.1.6 Residues in succeeding crops
Since grapes, cherries and plums are not grown in crop rotation with other crops, the investigation of residues in rotational crops is not required.

5.1.7 Residues from livestock feeding studies
Since grapes, cherries and plums are not normally fed to livestock, the magnitude of spinosad residues in livestock was not assessed in the framework of this application.

5.1.8 Processing factors
The submitted studies for the renewal of spinosad cover data gaps identified during the Art. 12 MRL review (EFSA, 2012): hydrolysis studies in processed commodities. During the peer review transfer factors for grapes were derived (see List of Endpoints).

5.1.9 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.

An ARfD was not set for spinosad in Commission Directive 2007/6/EC. It is however highlighted that in the EFSA conclusion on the peer review of the pesticide risk assessment of the active substance spinosad an acute reference dose (ARfD) of 0.1 mg/kg bw was derived.

5.2 Maximum Residue Levels

MRLs for spinosad are published in Regulation (EU) 2015/603 amending Annexes II, III and V to Regulation (EC) No 396/2005. The regulation applies from 7 December 2015. The current MRLs for spinosad in cherries and plums is 0.2 mg/kg and for spinosad in grapes is 0.5 mg/kg, which is considered sufficient to cover the intended uses.

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 (EFSA Journal 2012;10 (3):2630). The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). EFSA updated the risk assessment in a Reasoned Opinion (EFSA Journal 2013;11(11):3447). The total calculated intake accounted for 62 % of the ADI (WHO Cluster diet B).

It is highlighted that EFSA has recently published the conclusion on the peer review of the pesticide risk assessment of the active substance spinosad under Regulation (EC) No 1077/2009. In the EFSA conclusion, revised residue definitions for risk assessment were proposed on a provisional basis. An indicative consumer risk assessment was conducted for the representative uses on onions, grapes, lettuce, aubergines, peppers and tomatoes considering the residue levels from field trials analysed according to the risk assessment residue definition by using EFSA PRIMo rev.2. The chronic intake was below the ADI, max. theoretical maximum daily intake (TMDI) 15.1% (WHO Cluster diet B). An additional consumer risk assessment using the same approach as for the representative uses was conducted for all the intended uses supported by sufficient data and the EU representative uses whenever more critical. The chronic (TMDI) and acute dietary intakes (IESTI) were below the ADI for all considered European consumer groups (max. ADI 15.3% WHO Cluster diet B).

Risk assessment for acute exposure through diet

An ARfD was not set for spinosad in Commission Directive 2007/6/EC. However, in the meantime, in the framework of the renewal of the approval of spinosad (EU pesticides peer review) an ARfD of 0.1 mg/kg bw was proposed (EFSA, 2018), which has not yet been formally adopted by the European Commission.

An indicative consumer risk assessment is conducted according to the residue definition for plant and animal products derived in the MRL review and based on the highest residue levels expected for grapes, cherries and plums. The calculated short-term exposure to residues in did not exceed the ARfD. The maximum acute intake (IESTI) accounted for 24% ARfD for table grapes.

It is highlighted that the consumer risk assessment should be regarded as provisional considering all the data gaps identified, and the limited number of the field trials analysed according to the proposed risk assessment residue definition. For commodities for which MRLs have been established previously, EFSA also recommends a re-evaluation taking into account the results of the acute risk assessment based on the recently derived ARfD.

Conclusion

The data available are considered sufficient for risk assessment. Exceedance of the current MRLs of 0.2 mg/kg for spinosad in cherries and plums and 0.5 mg/kg for spinosad in grapes as laid down in Reg. (EU) 396/2005 is not expected.

Based on an indicative consumer risk assessment, no risk for the consumer due to the intended use of the product Tracer on grapes, cherries and plums is expected.

DEEL 6 – Beoordeling Fate and behaviour [Ctgb]

Background

It concerns an application of the plant protection product Tracer for an emergency situation as an insecticide in the uses listed in Table M.0 based on the submitted GAP.

Table M.0 Overview of intended use

Use	Application rate [kg a.s./ha]	Frequency	Interval [days]	Time of application *
kers (F)	0.096	2	7	BBCH 77-89 (mei-august)
Buiten reikwijdte verzoek				

The following drift reducing sentences are submitted at the draft label:

Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van kersen in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van:
- een techniek uit tenminste de klasse DRT 97,5 in combinatie met een teeltvrije zone van 4,5 meter of
- een techniek uit tenminste de klasse DRT 99.

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

6 Environmental fate and behaviour

Risk assessment is done in accordance with Chapter 2 of the RGB published in the Government Gazette (Staatscourant) 188 of 28 September 2007, including the updates of 20 October 2009 (which came into effect on 1 January 2010) and 18 April 2011 (which came into effect on 23 April 2011).

The list of endpoints of a.s. spinosad is derived from the EFSA conclusion (EFSA Journal 2018;16(4):5252).

6.1 Fate and behaviour in soil

6.1.1 Persistence in soil

Article 2.8 of the *Plant Protection Products and Biocides Regulations* (RGB) describes the authorisation criterion persistence. 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 1107/2009 EG, the EU approach for persistence assessment is followed.

For the current application this means the following:

<u>Spinosyn A</u>
Laboratory DT_{50}-values are available for the active substance spinosyn A ranging 7.28-51.5 days (geomean 21.0 days). 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. Additionally, field soil dissipation values are available with DT_{50}-values ranging 4.9-100 days (geomean 27.4 days). In this way, the standards for persistence as laid down in the RGB are met.

<u>Spinosyn D</u>
Laboratory DT_{50}-values are available for the active substance spinosyn D ranging 8.3-113.8 days (geomean 35.0 days). 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. Additionally, field soil dissipation values are available with DT_{50}-values ranging 7.6-104 days (geomean 25.3 days). In this way, the standards for persistence as laid down in the RGB are met.

For the metabolite spinosyn B DT_{50}-values are available ranging 33.3-146 days (geomean 66.1 days). For the metabolite N-demethylated spinosyn D DT_{50}-values are available ranging 36.92-201 (geomean 72.8 days).

Due to the exceeding of the threshold value of 60 days for the geomean DT_{50} (lab) for metabolite spinosyn B and DT_{50} 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: spinosyn B 2.11 d and N-demethylated spinosyn D 3.77 d.

From the results it is shown that the mean field DT_{50} is < 90 days. Therefore, the standards for persistence as laid down in the RGB are met. Due to the fact that photolysis plays an important role in the dissipation of spinosad and 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 field study. There is no need to require more field studies for further confirmation.

PECsoil

[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'.

The concentration of the spinosad in soil is needed to assess the risk for soil organisms (earthworms, micro-organisms). The PECsoil for spray applications 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 (Log Pow at pH 7 is for spinosyn A: 4.01 and for spinosyn D: 4.53), a PEC_{21days} is needed for the assessment of secondary poisoning of birds and mammals through the consumption of earthworms.

PECsoil values are calculated for the field use in cherry and grapes.

The following input data are used for the calculation:

PEC soil:

Active substance spinosyn A:
Maximum field DT_{50} for degradation in soil (SFO): 100 days
Molecular mass: 731.98 g/mol

Active substance spinosyn D:
Maximum lab DT_{50} for degradation in soil (DFOP):
k1: 0.0734
k2: 0.0061
g: 0.488 days
Molecular mass: 746.00 g/mol

Metabolite spinosyn B (metabolite from spinosyn A):
Maximum lab DT_{50} for degradation in soil (SFO, 20°C): 146 days
Molecular mass: 717.93 g/mol
Correction factor: 67 (maximum observed percentage) * 0.98 (relative molar ratio = M metabolite/M parent) = 0.66

Metabolite N-demethylated spinosyn D (metabolite from spinosyn D):
Maximum lab DT_{50} for degradation in soil (SFO, 20°C): 201 days
Molecular mass: 731.98 g/mol
Correction factor: 68 (maximum observed percentage) * 0.98 (relative molar ratio = M metabolite/M parent) = 0.67

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

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

Use	Substance	Rate [kg a.s./ha]	Freq.	Interval [days]	Fraction intercepted *	$PIEC_{soil}$ [mg a.s./kg] (5 cm)	$PEC_{soil,21d}$ [mg a.s./kg] (5 cm)
Cherry	spinosyn A	0.0816	2	7	0.65	0.074	0.069
	spinosyn D	0.0144				0.012	0.009
	spinosyn B	0.0539				0.049	0.047
	N-demethylated spinosyn D	0.0096				0.009	0.009
Buiten reikwijdte verzoek							

* interception values derived from Table 1.4 in "generic guidance for FOCUS groundwater scenarios" (version 2.2, 2014). An interception of 0.65 is appropriate for cherry at growth stage BBCH 76-89 (based on apples). An interception of 0.75 is appropriate for grapes at growth stage BBCH 76-89 (based on vines).

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

6.1.2 Leaching to shallow groundwater

Article 2.9 of the *Plant Protection Products and Biocides Regulations* (RGB) describes the authorisation criterion leaching to groundwater.

The leaching potential of the active substance spinosad (spinosyn A and D) and metabolites spinosyn B and N-demethylated spinosyn 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 0.096 kg/ha (85% spinosyn A and 15% spinosyn D) for cherry and 0.0768 kg/ha (85% spinosyn A and 15% spinosyn D) for grapes, the crop (winter cereals, default for cherry, and vines for grapes) and an interception value appropriate to the crop of 0.65 for cherry and 0.75 for grapes. First date of yearly application is May 25th for the spring scenario regarding cherry, July 1st for the spring scenario regarding grapes and October 1st for the autumn scenario regarding grapes.

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 following input data are used for the calculation:

PEARL:

<u>Active substance spinosyn A:</u>
Geometric mean normalised DT_{50} for degradation in soil (20°C): 22.9 days
Geometric mean K_{om} (pH-independent): 1859 L/kg
Arithmetic meand 1/n: 0.86

Saturated vapour pressure: 1 x 10^{-5} Pa (25 ºC)
Solubility in water: 0.498 g/L (20 ºC)
Molecular weight: 732 g/mol

Plant uptake factor: 0
Q10: 2.58

Active substance spinosyn D:
Geometric mean normalised DT_{50} for degradation in soil (20°C): 31.2 days
Geometric mean K_{om} (pH-independent): 1727 L/kg
Arithmetic meand 1/n: 0.82

Saturated vapour pressure: 4 x 10^{-6} Pa (25ºC)
Solubility in water: 0.04 g/L (20ºC)
Molecular weight: 746 g/mol

Plant uptake factor: 0
Q10: 2.58

Metabolite spinosyn B from spinosyn A:
Geometric mean normalised DT_{50} for degradation in soil (20°C): 66.1 days
Geometric mean K_{om} (pH-independent): 1459 L/kg
Arithmetic mean 1/n: 0.83

Arithmetic mean formation fraction: 0.76

Saturated vapour pressure: 1 x 10^{-5} Pa (25ºC, parent value)
Solubility in water: 250 g/L (20ºC)
Molecular weight: 718 g/mol

Plant uptake factor: 0.0 (default for metabolites)
Q10: 2.58

Metabolite N-demethylated spinosyn D from spinosyn D:
Geometric mean DT_{50} for degradation in soil (20°C): 72.8 days
Geometric mean K_{om} (pH-independent): 1114 L/kg
Arithmetic mean 1/n: 0.76
Arithmetic mean formation fraction: 0.647

Saturated vapour pressure: 4 x 10^{-6} Pa (25ºC; parent value)
Solubility in water: 0.512 g/L (20ºC)
Molecular mass: 732 g/mol

Plant uptake factor: 0
Q10: 2.58

Other parameters: standard settings of PEARL 4.4.4

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

Table M.2 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

Use	Substance	Rate substance [kg/ha]	Frequency / Interval [days]	Fraction Intercepted *	PEC groundwater [µg/L]	
					Spring	autumn
Cherry	spinosyn A	0.0816	2 / 7	0.65	<0.001	-
	spinosyn B	**			0.001	-
	spinosyn D	0.0144			<0.001	-
	N-demethylated spinosyn D	**			0.004	-
Buiten reikwijdte verzoek						

* interception values derived from Table 1.4 in "generic guidance for FOCUS groundwater scenarios" (version 2.2, 2014). An interception of 0.65 is appropriate for cherry at growth stage BBCH 76-89 (based on apples). An interception of 0.75 is appropriate for grapes at growth stage BBCH 86-89 (based on vines).
** calculated with transformation scheme

Results of Pearl 4.4.4 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.2 it reads that the expected leaching based on the PEARL-model calculations for the active substance spinosad (85% spinosyn A and 15% spinosyn D) and for both metabolites 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.

Lysimeter/field leaching studies
No lysimeter studies standardized to NL conditions are presented in the RAR.

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

The active substance spinosad (sum of isomers) was observed in groundwater. Data are derived from the Groundwater Atlas for pesticides, version 1.1, d.d. 10-03-2022.
There are 246 results available in the groundwater atlas, from 94 sites (screen depth 1.93 to 180 meter below soil surface) sampled from 2009-2015. Descriptive statistics are presented in Table M.3.

Table M.3: Monitoring data in Dutch groundwater for spinosad (sum of isomers) from Ground Water Atlas (v. 1.1)

	<LOD	<LOQ	<LOR	≤ 0.1 µg/L	> 0.1 µg/L
Number of measurement result per category	0	246	0	0	0
Minimum value per category (µg/l)		0.05			
Maximum value per category (µg/l)		0.10			

Above data represent the sum of isomers spinosyn A and spinosyn D. The Ground Water Atlas also contains separate data for spinosyn A. There are 2 results available in the groundwater atlas, from 2 sites (screen depth 43.99 to 53.00 meter below soil surface) sampled in 2015. Descriptive statistics are presented in Table M.4. Regarding spinosyn D nor metabolites of spinosad, no data are available.

Table M.4: Monitoring data in Dutch groundwater for spinosyn A from Ground Water Atlas (v. 1.1)

	<LOD	<LOQ	<LOR	≤ 0.1 µg/L	> 0.1 µg/L
Number of measurement result per category	0	2	0	0	0
Minimum value per category (µg/l)		0.05			
Maximum value per category (µg/l)		0.05			

It must be noted that the quality of the data in the Ground Water Atlas version 1.1 still needs to be assessed (please refer to page 7 of the manual of the Ground Water Atlas). Work on establishing criteria to assess the quality and to set the values of the quality labels in the Ground Water Atlas is ongoing. In addition, a methodology for implementing the Ground Water Atlas in the national decision tree for leaching is lacking. A scientific working group has been assigned to derive such a methodology.
Therefore currently no consequences can be drawn for the proposed use of the product based on the data in the Ground Water Atlas.

Conclusions
The active substance spinosad and its metabolites comply with the requirements laid down in the RGB concerning persistence in soil.

The proposed applications of the product comply with the requirements laid down in the RGB concerning leaching in soil.

6.2 Fate and behaviour in water

6.2.1 Rate and route of degradation in surface water

Article 2.10c of the *Plant Protection Products and Biocides Regulations* (RGB) prescribes the use of Dutch specific drift percentages.

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.
From 2022 onwards, an updated drift dataset is to be used as included in the Wageningen Drift calculator (see Evaluation Manual Chapter 6, surface water and sediment, NL, part, version 2.6).

In addition, it is laid down in the Evaluation Manual that for woody soft fruit the crop free zone should always be specified on the label, since the minimum crop free zone of 3 meter is not explicitly stated in the Activity Decree, but is used as a basis for the drift deposition values used for the assessment of woody soft fruit.

The following drift reducing sentences are submitted, between brackets the corresponding updated drift deposition values are mentioned.

Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van kersen in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van:
- een techniek uit tenminste de klasse DRT 97,5 in combinatie met een teeltvrije zone van 4,5 meter (corresponding to 0.12 % spray drift) of
- een techniek uit tenminste de klasse DRT 99 (corresponding to 0.10 % spray drift).

Buiten reikwijdte verzoek

Calculations are performed using the appropriate drift deposition values for the requested mitigation options.

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

TOXSWA:
Active substance:
Geomean DT_{50} for degradation in water at 20°C: 1000 days (default, in line with EFSA conclusion).
DT_{50} for degradation in sediment at 20°C: 126 days (geomean of spinosyn A+D whole system DT_{50})

Geometric mean K_{om} for suspended organic matter: 1859 L/kg (value of spinosyn A)
Geometric mean K_{om} for sediment: 1859 L/kg
Arithmetic mean 1/n: 0.86

Saturated vapour pressure: 1 x 10^{-5} Pa (25°C; value of spinosyn A)
Solubility in water: 0.498 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 ($DegT_{50}$ values) are available for the water and sediment compartment (accepted level P-II values), the system degradation half-life ($DegT_{50}$-system, level P-I) is used as input for the degrading compartment and a default value of 1000 days is to be 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.

In Table M.5a, the drift percentages and calculated surface water concentrations for the active substance spinosad for each intended use are presented.

Table M.5a Overview of surface water concentrations for active substance spinosad in the edge-of-field ditch following spring application (original GAP)

Use	Rate a.s. [kg/ha]	Freq./ Interval [days]	Drift [%]	PIEC [µg/L] *	PEC21 [µg/L] *	PEC28 [µg/L] *
Cherry	0.096	2 / 7	0.12**	0.0916	0.0691	0.0642
			0.10***	0.0762	0.0573	0.0533
Buiten reikwijdte verzoek						

* calculated according to TOXSWA

** full leaf, DRT97.5 in combination with a crop free zone of 450 cm

*** full leaf, DRT99 in combination with a crop free zone of 300 cm

**** full leaf, DRT99 in combination with a crop free zone of 450 cm

After the initial assessment the applicant has refined the GAP (lower dose rate, larger interval) for grapes and proposes the following corresponding drift reducing measures (spray drift values added between brackets by Ctgb):

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

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

Monitoring data

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

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).

The Pesticide Atlas includes a statistical correlation analysis between concentrations, threshold exceedance and land use, which may indicate probable relationships.

Active substance spinosad

The active substance spinosad ('groepsstof' = sum of isomers) was measured in the surface water (most recent data from 2020). There are no separate data on spinosyn A or D.

In Table M.6 the number of observations in the surface water is 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 0.1*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.

Table M.6 Monitoring data in Dutch surface water for Spinosad (*groepsstof*) for 2020 (from www.pesticidesatlas.nl)

Total no of locations (2020)	***n* > authorisation threshold**	***n* > EQS**		
		MAC-EQS	**AA-EQS**	**MPC (ad-hoc/indicative)**
464*	14 (10 > 1-5 * threshold, 4 > 5 * threshold)	n.a.	n.a.	29 (15 > 1-5 * threshold, 14 > 5 * threshold)

*** the number of observations at each location varies between 1 and 30, total number of measurements is 3365 in 2020.**

**** n.a. not available**

The exceedance of the WFD water quality standards AA-EQS and MAC-EQS (and MPC in case no EQS have been derived), is from 2016 onwards addressed by the ERP (Emission Reduction Plan), which is carried out under responsibility of the Ministry of Infrastructure and Environment (I&M). Ctgb has no active role in this process. The outcome of the ERP may lead to label changes on request of the applicant.

[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.

However, Ctgb is the responsible authority to address exceedance of the authorisation threshold.

Several locations show an exceedance of the authorisation threshold.
Therefore it is assessed whether there is a correlation between the observed exceedance 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 2018 - 2020 are used to establish the relation.
A very strong significant correlation ($p < 0.001$) is observed between the exceedance of the authorisation threshold and the land use types asparagus, greenhouses, and leek. The correlation with tree nursery crops is significant ($0.01<p<0.05$).

The observed exceedance of the authorisation threshold is not significantly correlated to the proposed uses in cherry and grapes.

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

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

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 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.

[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

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 1 x 10^{-5} respectively 4x10^{-6} Pa at 25°C. The Henry constant is 1 x 10^{-3}, respectively 6.3 x 10^{-3} Pa.m^3.mol at 20°C (unbuffered). The half-life in air is 18 and 17 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 end-points relating to the product and approved uses
See List of End-points.

6.5 Data requirements
-

The following restriction sentences were proposed by the applicant:

Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van kersen in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van:
- een techniek uit tenminste de klasse DRT 97,5 in combinatie met een teeltvrije zone van 4,5 meter of
- een techniek uit tenminste de klasse DRT 99.

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use:
first assessment:
Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van kersen in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van:
- een techniek uit tenminste de klasse DRT 99, of
- een techniek uit tenminste de klasse DRT 97,5 in combinatie met een teeltvrije zone van 450 centimeter

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

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. the metabolites spinosyn B and N-demethylated spinosyn D meet the standards for persistence in soil as laid down in the RGB.
3. the proposed application of the active substance spinosad meets the standards for leaching to the shallow groundwater as laid down in the RGB.
4. the proposed application of metabolite spinosyn B and N-demethylated spinosyn D meets the standards for leaching to the shallow groundwater as laid down in the RGB.
5. all proposed applications of the active substance spinosad meet the standards for surface water destined for the production of drinking water.

DEEL 7 – Beoordeling Ecotoxiciteit [Ctgb]

Background

It concerns an application of the plant protection product Tracer for an emergency situation as an insecticide in the uses listed in Table M.0 based on the submitted GAP.

Table M.0 Overview of intended use

Use	Application rate [kg a.s./ha]	Frequency	Interval [days]	Time of application *
kers (F)	0.096	2	7	BBCH 77-89 (mei-augustus)

Buiten reikwijdte verzoek

The following drift reducing sentences are submitted by the applicant at the draft label:

Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van kersen in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van:
- een techniek uit tenminste de klasse DRT 97,5 in combinatie met een teeltvrije zone van 4,5 meter of
- een techniek uit tenminste de klasse DRT 99.

Buiten reikwijdte verzoek

Om niet tot de doelsoorten behorende geleedpotigen/insecten te beschermen is toepassing van het middel in de teelt van kersen en druiven in percelen die niet grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van een techniek uit tenminste de klasse DRT97,5.

Buiten reikwijdte verzoek

Gevaarlijk voor bijen. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen. Gebruik dit product niet op plaatsen waar bijen actief naar voedsel zoeken. Gebruik dit product niet in de buurt van in bloei staand onkruid. Verwijder onkruid voordat het bloeit.

Advies vrijstelling 2022/01 – Tracer (werkzame stof spinosad) in de teelt van kers en druif tegen suzukifruitvlieg

Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg deskundigen (uw leverancier van natuurlijke vijanden, de producent van dit middel, uw adviseur) over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden.
Because the emergency application is done after the 1st of January 2022, the drift values from the Wageningen Drift Calculator (WDC) will be applied in the risk assessment for aquatic organisms, bees, non-target arthropods and non-target plants.Furthermore a Vegetation Distribution Factor of 5 instead of 10 will be applied in the risk assessment for non-target arthropods. This applies to product dossiers submitted from the 1st of January 2020.

Because the emergency application is done after the 1st of January 2022, the drift values from the Wageningen Drift Calculator (WDC) will be applied in the risk assessment for aquatic organisms, bees, non-target arthropods and non-target plants.Furthermore a Vegetation Distribution Factor of 5 instead of 10 will be applied in the risk assessment for non-target arthropods. This applies to product dossiers submitted from the 1st of January 2020.

List of Endpoints Ecotoxicology
The list of endpoints of a.s. spinosad is derived from the EFSA conclusion (EFSA Journal 2018;16(4):5252).

List of Endpoints Ecotoxicology
- Spinosad = a.s. = mixture of 50-95% of Spinosyn A and 50-5% Spinosyn D.
- Tracer = NAF-85 = 480 g/L SC formulation. NAF 85 typically contains 85% spinosyn A and 15% spinosyn D

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw (per day))
Birds				
Colinus virginianus	XDE-105 (88% spinosyn A and D)	Acute	LD_{50}	> 2000*
Anas platyrhynchos	XDE-105 (88% spinosyn A and D)	Acute	LD_{50}	> 2000*
Both species	a.s.	Long-term	$LD_{50}/10$	200
Colinus virginianus	XDE-105 (88% spinosyn A and D)	Long-term	NOAEL EC_{10}	68.54[2] 116.15
Anas platyrhynchos	XDE-105 (88% spinosyn A and D)	Long-term	NOAEL $EC_{10,\ eggs/pen}$ Lower C.I. $EC_{10\ eggs/pen}$	78.06[3] 75.29 **44.8**
Mammals				
Rat	a.s.	Acute	LD_{50}	> 2000
Mus	Spinosyn B	Acute	LD_{50}	> 2000
Mus	Spinosyn K	Acute	LD_{50}	> 2000
Rat	a.s.	Long-term	NOAEL	10
Endocrine disrupting properties (Annex Part A, points 8.1.5) The available data were not sufficient to address the potential endocrine disrupting properties of spinosad for non-target organisms. Pending on the data gap in Section 2, further consideration of the endocrine potential of spinosad might be needed.				
Additional higher tier studies (Annex Part A, points 10.1.1.2): *Residues in turf were measured to determine a DT_{50} of 3.02 days to refine the chronic risk to mammals.* *Residues in fruits and fruiting vegetables from the residues section were used to calculate a DT_{50} of 3.75 days to refine the chronic risk to mammals-*				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): *No data was provided or available.*				

2 Converted to daily dose accounting for a mean body weight of 210.17 g and feed consumption of 26.19 g feed/bird/d of the birds exposed at the 550 mg/kg diet treatment.
3 Converted to daily dose accounting for a mean body weight of 1149.5 g and feed consumption of 162.9 g feed/bird/d of the birds exposed at the 550 mg/kg diet treatment.
* Maximum dose tested
Bold values used in risk assessment

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)

*This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
Rainbow trout (*Oncorhynchus* mykiss)	a.s.	Acute 96 hr (static)	Mortality, LC_{50}	27 mg a.s./$L_{(nom)}$
Bluegill sunfish (*Lepomis macrochirus*)	a.s.	Acute 96 hr (static)	Mortality, LC_{50}	5.8 mg a.s./$L_{(mm)}$
Common carp (*Cyprinus carpio*)	a.s.	Acute 96 hr (static)	Mortality, LC_{50}	5.3 mg a.s./$L_{(mm)}$
Common carp (*Cyprinus carpio*)	a.s.	Acute 96 hr (static)	Mortality, LC_{50}	4.0 mg a.s./$L_{(nom)}$
Sheepshead minnow (*Cyprinodon variegatus*)	a.s.	Acute 96 hr (static)	Mortality, LC_{50}	7.6 mg a.s./$L_{(nom)}$

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Common carp (*Cyprinus carpio*)	NAF-85	Acute 96 hr (static)	Mortality, LC_{50}	> 100 mg prep./L (> 49 mg a.s./$L_{(nom)}$)
Zebra fish (*Brachydanio rerio*	NAF-85	Acute 96 hr (static)	Mortality, LC_{50}	> 125 mg prep./L (> 56 mg a.s./$L_{(nom)}$)
Rainbow trout (*Oncorhynchus mykiss*)	a.s.	21 d Chronic (flow-through)	reproduction NOEC	1.2 mg a.s./$L_{(mm)}$
Rainbow trout (*Oncorhynchus mykiss*)	a.s.	80 d Chronic (flow-through)	reproduction NOEC	0.5 mg a.s./$L_{(nom)}$
Sheepshead minnow (*Cyprinodon variegatus*)	a.s.	35 d Chronic (flow-through)	reproduction NOEC	1.2 mg a.s./$L_{(nom)}$
Fathead minnow (Pimephales promelas)	a.s.	110 d Chronic (flow-through)	reproduction NOEC $EC_{10,\ F0\ fish\ standard\ length}$ $EC_{10,\ F0\ fish\ body\ weight}$	0.217 mg a.s./$L_{(mm)}$ 0.508 mg a.s./$L_{(mm)}$ 0.382 mg a.s./$L_{(mm)}$
Aquatic invertebrates				
Water flea (*Daphnia magna*)	a.s.	48 h (static)	Mortality, EC_{50}	> 1.10 mg a.s./$L_{(mm)}$
Water flea (*Daphnia magna*)	a.s.	48 h (semi-static)	Mortality, EC_{50}	7.3 mg a.s./$L_{(mm)}$
Midge (*Chironomus riparius*)	a.s.	48 h (static-renewal)	Mortality, EC_{50}	> 32 µg a.s./L (mm)
Grass shrimp (*Palaemonetes pugio*)	a.s.	96 h (semi-static)	Mortality, EC_{50}	> 9.7 mg a.s./$L_{(mm)}$
Eastern oyster (*Crassostrea virginica*)	a.s.	96 h (flow-through)	Shell deposition, EC_{50}	0. 295 mg a.s./$L_{(mm)}$
Water flea (*Daphnia magna*)	Spinosyn B	48 h (static)	Mortality, EC_{50}	6.5 mg ma/$L_{((mm)}$
Water flea (*Daphnia magna*)	Spinosyn B	48 h (semi-static)	Mortality, EC_{50}	6.9 mg ma/$L_{(mm)}$
Midge (*Chironomus riparius*)	Spinosyn B	48 h (static-renewal)	Mortality, EC_{50}	8.5 µg ma/L (mm)
Mysid shrimp (*Americamysis bahia*)	Spinosyn B	96 h (flow-through)	Mortality, EC_{50}	2.20 mg ma/$L_{(mm)}$
Water flea (*Daphnia magna*)	N-demethylated spinosyn D	48 h (static)	Mortality, EC_{50}	3.8 mg ma/$L_{(mm)}$

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Midge (*Chironomus riparius*)	N-demethylated spinosyn D	48 h (static-renewal)	Mortality, EC_{50}	34 µg ma/L $_{(nm)}$
Mysid shrimp (*Americamysis bahia*)	N-demethylated spinosyn D	96 h (flow-through)	Mortality, EC_{50}	1.4 mg ma/$L_{(mm)}$
Water flea (*Daphnia magna*)	β-13,14-dihydropseudoaglycone of spinosyn A	48 h (static)	Mortality, EC_{50}	> 197 mg ma/$L_{(mm)}$
Water flea (*Daphnia magna*)	β-13,14-dihydropseudoaglycone of spinosyn D	48 h (static)	Mortality, EC_{50}	65.8 mg ma/$L_{(nom)}$
Midge (*Chironomus riparius*)	β-13,14-dihydropseudoaglycone of spinosyn A	48 h (static-renewal)	Mortality, EC_{50}	> 100 mg ma/$L_{(nom)}$
Midge (*Chironomus riparius*)	β-13,14-dihydropseudoaglycone of spinosyn D	48 h (static-renewal)	Mortality, EC_{50}	2.2 mg ma/$L_{(nom)}$
Water flea (Daphnia magna)	NAF-85	48 h (static)	Mortality, EC_{50}	20 mg prep./L (9.1 mg a.s./$L_{(nom)}$)
Water flea (Daphnia magna)	GF-976	48 h (static renewal)	Mortality, EC_{50}	22 mg prep./L (9.64 mg a.s./$L_{(nom)}$)
Midge (*Chironomus riparius*)	GF-976	48 h (static renewal)	Mortality, EC_{50}	0.0013 mg prep./L (0.0057 mg a.s./$L_{(mm)}$)
Midge (*Chironomus riparius*)	GF-976	48 h (static renewal)	Mortality, EC_{50}	0.0017 mg prep./L (0.0074 mg a.s./$L_{(mm)}$)
Water flea (Daphnia magna)	a.s.	21 d (semi-static) # 21 d (flow-through)	Reproduction, NOEC Reproduction, NOEC $LC_{10,\ survival}$ $EC_{10,\ adult\ length}$	0.0068 mg a.s./$L_{(mm)}$ 0.0012 mg a.s./$L_{(m.m)}$ 0.00171 mg a.s./$L_{(mm)}$ 0.00168 mg a.s./$L_{(mm)}$
Water flea (Daphnia magna)	Spinosyn B	21 d (flow-through)	Development, NOEC	0.00095 mg ma/$L_{(mm)}$

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Water flea (Daphnia magna)	N-demethylated spinosyn D	21 d (flow-through)	Reproduction and development, NOEC $EC_{20,\ adult\ survival}$	0.001 mg ma/$L_{((mm)}$ 2.84 mg/$L_{((mm)}$
Water flea (Daphnia magna)	β-13,14-dihydropseudoaglycone of spinosyn A	21 d (semi-static)	Development, NOEC	1.25 mg ma/$L_{(nom)}$
Water flea (Daphnia magna)	β-13,14-dihydropseudoaglycone of spinosyn D	21 d (static renewal)	Development, NOEC	4.85 mg ma/$L_{(mm)}$
Midge (*Chironomus riparius*)	a.s	25 d (static)	NOEC	0.00062 mg a.s./$L_{(m.m.)}$
Mysid shrimp (*Mysidopsis bahia*)	Spinosad	28 d (flow-through)	Reproduction, NOEC $EC_{10,\ G1\ survival}$ $EC_{10,\ G1\ reproduction}$ $EC_{10\ G1\ growth}$	0.10 mg a.s./$L_{(nom)}$ 0.21 mg a.s./$L_{(nom)}$ 0.119 mg a.s./$L_{(nom)}$ 0.852 mg a.s./$L_{(nom)}$
Mysid shrimp (*Americamysis bahia*)	Spinosyn B	28 d (flow-through)	Reproduction, NOEC $EC_{10,\ G1\ reproduction}$	0.054 mg ma/$L_{(mm)}$ 0.42 mg ma/$L_{(mm)}$
Mysid shrimp (*Americamysis bahia*)	N-demethylated spinosyn D	28 d (flow-through)	Reproduction and survival, NOEC $EC_{10,\ G1\ juvenile\ survival}$ $EC_{10,\ G1\ adult\ survival}$ $EC_{10,\ G1\ reproduction\ (per\ reproductive\ day)}$ $EC_{10,\ G1\ reproduction\ (per\ reproductive\ day)}$	0.052 mg ma/$L_{(mm)}$ 0.17 mg ma/$L_{(mm)}$ 0.15 mg ma/$L_{(mm)}$ 0.030 mg ma/$L_{(mm)}$ 0.050 mg ma/$L_{(mm)}$
Sediment-dwelling organisms				
Midge (Chironomus riparius)	a.s.	28 d (static)	NOEC	0.0585 mg a.s./kg dry $sediment_{(mm)}$
Midge (Chironomus riparius)	Spinosyn B	28 d (static)	NOEC	0.0032 mg ma/$L_{(im)}$
Midge (Chironomus riparius)	N-demethylated spinosyn D	28 d (static)	NOEC	0.0024 mg ma/$L_{(im)}$
Midge (Chironomus riparius)	β-13,14-dihydropseudoaglycone of spinosyn A	28 d (static)	NOEC	1.12 mg ma/$L_{(mm)}$

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Midge (Chironomus riparius)	β-13,14-dihydropseudoaglycone of spinosyn D	28 d (static)	NOEC	0.731 mg ma/$L_{(mm)}$
Algae				
Marine diatom (Skeletonema costatum)	a.s.	120 h (static)	Growth rate: E_rC_{50} Biomass: E_bC_{50}	0.51 mg a.s./$L_{(mm)}$ 0.20 mg a.s./$L_{(mm)}$
Freshwater diatom (*Navicula pelliculosa*)	a.s.	72 h (static)	Growth rate: E_rC_{50} Biomass: E_yC_{50}	0.470 mg a.s./$L_{(mm)}$ 0.280 mg a.s./$L_{(mm)}$
Freshwater diatom (*Navicula pelliculosa*)	GF-976	72 h (static)	Growth rate: E_rC_{50} Yield: E_bC_{50}	0.69 mg prep./L (0.30 mg a.s./$L_{(mm)}$) 0.42 mg prep./L (0.18 mg a.s./$L_{(mm)}$)
Freshwater diatom (*Navicula pelliculosa*)	β-13,14-dihydropseudoaglycone of spinosyn D	96 h (static)	Growth rate: E_rC_{50} Biomass: E_bC_{50}	28 mg ma/$L_{(mm)}$ 40 mg ma/$L_{(mm)}$
Higher plant				
Duckweed (Lemna gibba)	a.s.	(static)	EC_{50}, frond yield, biomass yield, frond number growth rate, biomass growth rate	> 71 mg a.s./L (mm)
Further testing on aquatic organisms The exposure study by Kirk et al. 1995 (*D. magna* pulsed exposure study) could not be discussed as the notifier did not provide exposure profiles. Instead the notifier proposed to conduct additional modified exposure studies. Due to the changed chronic exposure endpoint for spinosad of *Chironomus riparius* as a result of the experts' teleconference (TC 159) additional studies should be performend with *C. riparius* instead.				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) The available data were not sufficient to address the potential endocrine disrupting properties of spinosad for non-target organisms. Pending on the data gap in Section 2, further consideration of the endocrine potential of spinosad might be needed.				

[1] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; prep.: preparation; a.s.: active substance
Pulse exposure study, not considered in the risk assessment in the absence of a comparison of the exposure profiles in this study with the FOCUS exposure predictions.

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Spinosyn A	Spinosyn D	-	-
$logP_{O/W}$	3.9	4.3		
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	114*	115*		
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)				
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				
Higher tier study				

* based on total ^{14}C or on specific compounds

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Apis mellifera	spinosad	Acute	Oral toxicity (LD_{50})	0.057 µg as/bee
Apis mellifera	preparation NAF-85 (similar to GF-976)	Acute	Oral toxicity (LD_{50})	0.11 µg/bee (0.049 µg as/bee)
Apis mellifera	spinosad	Acute	Contact toxicity (LD_{50})	0.0036 µg as/bee
Apis mellifera	preparation NAF-85 (similar to GF-976)	Acute	Contact toxicity (LD_{50})	0.12 µg/bee (0.050 µg as/bee)
Bombus terrestris	preparation NAF-85 (similar to GF-976)	Acute	Oral toxicity (LD_{50})	0.77 µg/bee (0.37 µg as/bee)
Bombus terrestris	preparation NAF-85 (similar to GF-976)	Acute	Contact toxicity (LD50)	36 µg/bee (17.2 µg as/bee)
	no study submitted	Chronic	10 d-LC50	µg/bee/day
	no study submitted	Bee brood development	NOEClarvae	µg/larva/developmental period
	no study submitted	Sub-lethal effects (behavioural and reproductive)	NOEC hypopharyngeal glands	

Potential for accumulative toxicity: no data available			
Semi-field test (Cage and tunnel test)			
Species	Test substance	Nature of the study	Results
Apis mellifera	NAF-85	Full-flowering Phacelia crop sprayed in early morning, before bee flight. Test rate 1x 144 g a.s./ha. Location: UK	7-d NOER = 144 g a.s./ha (mortality and foraging behaviour). 144 and 540 g a.s./ha in absence of bees (early morning) had no effects on mortality. At 540 g a.s./ha there was an effect on foraging behaviour and there were indications for effects on brood survival. These effects were not observed at the 144 g a.s./ha rate, however results for brood are inconclusive due to the short study duration.
Apis mellifera	NAF-85	Spray during bee flight on full-flowering Phacelia crop, in one	Increased mortality observed on day 1 after treatment in both treatments. Reduced foraging activity observed on 5.1.2.e 2 and up

		treatment preceded by three spraying events (33, 26 and 9 days earlier). Test rate 1x and 4x226 g a.s./ha. Location: UK	to Day 3 in the 1× and 4× treatments, respectively. No effects on brood were seen, but results for brood are inconclusive due to the short study duration.
Apis mellifera	NAF-85	Spray during bee flight on full-flowering Phacelia crop, in one treatment preceded by another spraying event (14 days earlier). Test rate 1x and 2x 216 g a.s./ha. Location: UK	Significant cumulative mortality on days 1-3 after application at both treatments. Reduced foraging activity for up to 4 days after treatment at both rates. No effects on brood were seen, but results for brood are inconclusive due to the short study duration.
Bombus terrestris	NAF-85	Spray in the late afternoon of the day before bee introduction on flowering tomato crop. Test rate 1x 542 g a.s./ha. Location: The Netherlands.	No significant effects on mortality after 7 days. Decrease in foraging activity (65%, 19 and 13% after 2, 4 and 6 days., respectively; not statistically significant but considered relevant). 27% reduction in brood development (not statistically significant but considered relevant).
Apis mellifera	GF-976	Spray either during bee flight on full-flowering Phacelia crop or in the evening after bee flight. Test rate 1x 76 and 1x 96 g a.s./ha. Location: Germany	Increased mortality and effects on behaviour might occur after daytime application, level and duration unclear due to bad weather conditions. Decreased foraging activity might occur after daytime application, level and duration unclear due to bad weather conditions. No increased mortality after evening application. Effect on behaviour, level and duration unknown. Effect on foraging activity unknown. Effects on brood and colony condition cannot be evaluated due to artifical feeding during the study.
Apis mellifera	GF-976	Spray on full-flowering Phacelia crop in the evening after bee flight. Test rate 1x 76 and 1x 96 g a.s./ha. Location: Germany	76 g a.s./ha sprayed in absence of bees caused no effects on mortality, flight intensity, behaviour, brood development and colony strength. 96 g a.s./ha sprayed in absence of bees caused no effects on flight intensity or behaviour, but caused increased mortality on the two days after evening application and a non-significant but clear decreased colony strength and delay in brood development.
Apis mellifera	GF-976	Spray on full-flowering Phacelia crop in the evening after bee flight. Test rate 1x 76 and 1x 96 g a.s./ha. Location: Germany	76 and 96 g a.s./ha sprayed in absence of bees caused no effects on mortality, flight intensity, behaviour, brood development and colony strength.
Apis mellifera	GF-976	Spray on full-flowering Phacelia crop during bee flight. Test rates: 48, 24, 12, 6 and 3 g a.s./ha	Rates from 3 to 48 g a.s./ha applied during bee flight caused no effects on mortality, brood, food storage and overall colony condition for 46 days. There was a reduction

		Location: South-West France	of flight intensity at 24 at 48 g a.s./ha.
Field tests : none			

Risk assessment: Hazard quotients for bees from GF-976 uses (all uses, rates range from 36 to 120 g a.s./ha)

Substance	Exposure pathway	Rate (g a.s./ha)	LD_{50} (µg/bee)	Q_{HO}/Q_{HC}	Trigger
Spinosad	Oral	36 120	0.057	**632** **2105**	50
	Contact	36 120	0.0036	**10000** **33333**	50
GF-976[1]	Oral	36 120	0.049	**735** **2449**	50
	Contact	36 120	0.050	**720** **2400**	50

[1] Based on data for NAF-85, a formulation similar to GF-976

Values in **bold** text exceed the Annex VI trigger value of 50

A risk assessment in line with EFSA (2013) was not provided (data gap)

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
Typhlodromus pyri	GF-976	Mortality, LR_{50}	8.54 g a.s./ha*
Typhlodromus pyri	NAF-85	Mortality, LR_{50}	<40 g a.s./ha
Aphidius rhopalosiphi	GF-976	Mortality, LR_{50}	0.371 g a.s./ha
Aphidius rhopalosiphi	NAF-85	Mortality, LR_{50}	<40 g a.s./ha
Additional species			
Coccinella septempunctata	NAF-85	Mortality, LR_{50}	>320 g a.s./ha

Species	Test Substance	End point	Toxicity
Coccinella septempunctata	12% EC formulation	Mortality, LR_{50}	>17 g a.s./ha
Episyrphus balteatus	12% EC formulation	Mortality, LR_{50} Reproduction, ER_{50}	<45 g a.s./ha <45 g a.s./ha
Episyrphus balteatus	480 g SC formulation	Mortality, LR_{50}	<96 g a.s./ha
Poecilus cupreus	NAF-85	Mortality, LR_{50}	>400 g a.s./ha

* It is noted that the number of replicates in the study was lower than that recommended in the test guideline.

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	L(E)R_{50}
Aphidius rhopalosiphi	Adults/pupa	NAF-85	48 h	4.8 9.6 19 38	Mortality Reproduction	13 40 67 80 No statisti-cally signifi-cant effects	LR_{50}(adults) = 18.48 g as/ha LR_{50} (pupa) = >38.4 g as/ha
Aphidius colemani	Adults	NAF-85	48 h	540 1080	Mortality	100 100	LR_{50} <540 g as/ha
Aphidius colemani	Adults	NAF-85	31 d	0.36 g as/L	Mortality	100	LR_{50} <0.36 g as/L (<39 g as/ha)
Typhlodromus pyri	Protonymphs	GF-976	14 d	0.156 0.3125 0.625 1.25 2.5 5	Mortality	21.1 47.8 66.7 93.3 95.6 100	LR_{50} = 0.3513 g as/ha NOER (fecundity) ≥ 0.625 g as/ha
Chrysoperla carnea	larvae	NAF-85	50 d	2 x 0.36 g as/L	Mortality fecundity	25 18	L(E)R_{50} >0.36 g as/L (>39 g as/ha)
Poecilus cupreus	adults	NAF-85	29 d	1 x 540 2 x 540 3 x 540 1 x 540 2 x 540 3 x 540	Mortality Food consumption	6.7 63 81 4 19 41	
Aleochara bilineata	adults	GF-976	28 d	300 g as/ha (soil incorporated)	Mortality Juvenile prod	17.5 5.63	LR_{50} > 300 g as/ha NOER ≥ 300 g as/ha

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	$L(E)R_{50}$
Phytoseiulus persimilis	Juveniles	NAF-85	7 d	2 x 0.36 g as/L	Mortality	93	LR_{50} <0.36 g as/L (based on 10% mortality and 84% missing mites) (<39 g as/ha)
Coccinella septempunctata	larvae	NAF-85	56 d	2 x 0.36 g as/L	Mortality	16	LR_{50} >0.36 g as/L (>39 g as/ha)

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation
[3] indicate if positive percentages relate to adverse effects or not

Field or semi-field tests						
Species	Test type	Test compound	Dose rate (g as/ha)	End point	Effect	Trigger
Typhlodromus pyri	Semi-field, test on leaf discs under outdoor conditions	GF-976	0.1, 0.39, 1.56 and 6.25	Mortality Fecundity	LR50 = 4.871 g as/ha NOER ≥ 6.25 g as/ha	N.A.
Typhlodromus pyri	Field, sprayed vineyard in France, ±7 weeks	NAF-85	24 and 48	abundance	<25	50
Typhlodromus pyri	Field, sprayed vineyard in France, ±7 weeks	NAF-85	96	abundance	43 after 7 d <25 from 16 d	50
Typhlodromus pyri	Field, sprayed vineyard, western part of Germany	NAF-85	4 applications 29-38-67-77	abundance	< 25%	50
Typhlodromus pyri	Field experiment, sprayed vineyard in Germany, 75 days	NAF-85	2 applications; 3.8[1] 3 applications; 3.2[2]	abundance	23.5 % (max.) after 35 d.	50
Typhlodromus pyri	Field experiment, sprayed vineyard in Germany, 75 days	NAF-85	2 applications; 58[1] 3 applications; 48[2]	abundance	31.6% (max.) after 14 d.	50
Typhlodromus pyri	Field sprayed vineyard, Freiburg	NAF-85	4 applications 29-39-68-78	abundance	24.6 (positive)	50
Macrolophus caliginosus	Semi-field, direct spray of bugs on plants, 14 days	NAF-85	0.096 g as/L (10.6 g as/ha), until run-off	abundance	23 (1-7 days) 0 (14 days)	50
Macrolophus caliginosus	Semi-field, direct spray of bugs on plants, 14 days	NAF-85	0.36 g as/L (39 g as/ha), until run-off	abundance	49 (1 day) 75 (3 days) 64 (7 days) 32 (14 days)	50
Chrysoperla carnea	Semi-field, potted apple trees, 75 d.	NAF-85	(2x26; 2x11) 4 x 109	mortality fecundity hatching success mortality fecundity hatching success	16.5 +30 +0.4 10.7 +1.8 0.1	50
Aphidius colemani	Semi-field, direct spray of aphids on sweet pepper 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	50

Aphidius colemani	Semi-field, residue on sweet pepper plants, 13 days	NAF-85	0.096 g as/L until run-off, aged 1 d	parasitism	98	50
Aphidius colemani	Semi-field, residue on sweet pepper plants, 19 days	NAF-85	0.096 g as/L until run-off, aged 7 d	parasitism	41	50
Aphidius colemani	Semi-field, residue on sweet pepper plants, 26 days	NAF-85	0.096 g as/L until run-off, aged 14 d	parasitism	46	50
Aphidius colemani	Semi-field, residue on sweet pepper plants, 13 days	NAF-85	0.36 g as/L until run-off, aged 1 d	parasitism	98	50
Aphidius colemani	Semi-field, residue on sweet pepper plants, 19 days	NAF-85	0.36 g as/L until run-off, aged 7 d	parasitism	36	50
Aphidius colemani	Semi-field, residue on sweet pepper plants, 26 days	NAF-85	0.36 g as/L until run-off, aged 14 d	parasitism	27	50
Aphidius colemani	Semi-field (greenhouse; potted apple trees);	NAF-85	-(4x109), 46 d, fresh residue -(4x109), 60 d., aged 14 d.	mortality	95% (max.) after 1 d. 0% after 14 d.	50
Aphidius colemani	Semi-field (greenhouse; potted apple trees);	NAF-85	-(2x26; 2x11), 46 d, fresh residue -(2x 26;2 x11), 60 d., aged 14 d.	mortality	45% (max.) after 1 d. 0% (max). after 14 d.	50
Aphidius colemani	Semi-field (greenhouse; pepper plants sprayed)	NAF-85	144 g as/ha 540 g as/ha	Parasitism Parasitism	85.2 (0 d) 39.7 (7 d) 9.9 (14 d) 99.4 (0 d) 43.2 (7 d) 3.5 (14 d)	50

[1] first and second application (interval 7 days)
[2] third, fourth and fifth application (interval 7 days), interval between second and third application was 14 days

Whole arthropod community field study
A non-target arthropod field study was submitted. 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.
Additional specific test

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity mg a.s or metabolite./kg d.w.soil
Earthworms					
Eisenia fetida	GF-976 (43.1% a.s.)	Soil incorporation 5% OM	Chronic	Growth and reproduction	NOEC = 127 $NOEC_{corrected}$ = 63.5*
Eisenia fetida	Spinosad	Soil incorporation 5% OM	Chronic	Growth and reproduction	NOEC = 35.2 $NOEC_{corrected}$ = 17.6*
Eisenia fetida	Spinosyn B	Soil incorporation 10% OM	Chronic	Growth and reproduction	NOEC = 3.58 $NOEC_{corrected}$ = 1.791
Eisenia fetida	N-demethylated Spinosyn D	Soil incorporation 10% OM	Chronic	Growth and reproduction	NOEC = 1.93 $NOEC_{corrected}$ = 0.964
Other soil macroorganisms					
Folsomia candida	GF-976 (43.1% a.s.)	Soil incorporation 5% OM	Chronic	Mortality, reproduction,	NOEC = 13.4 $NOEC_{corrected}$ = 6.7 $EC_{10, corrected}$ = 10.25
Folsomia candida	Spinosyn B	Soil incorporation 5% OM	Chronic	Mortality, reproduction	NOEC = 10 $NOEC_{corrected}$ = 5*
Folsomia candida	N-demethylated Spinosyn D	Soil incorporation 5% OM	Chronic	Reproduction	NOEC = 4.3 $NOEC_{corrected}$ = 2.15 $EC_{10, corrected}$ = 2.65
Hypoapsis aculeifer	GF-976 (43.1% a.s.)	Soil incorporation 5% OM	Chronic	Mortality, reproduction	NOEC= 4.32 $NOEC_{corrected}$ = 2.16
Hypoapsis aculeifer	GF-976 (43.8% a.s.)	Soil incorporation 5% OM	Chronic	Reproduction	NOEC =11 $NOEC_{corrected}$ = 5.5
Hypoapsis aculeifer	Spinosyn B	Soil incorporation 5% OM	Chronic	Mortality, reproduction	NOEC = 2 $NOEC_{corrected}$ = 1.0*

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity mg a.s or metabolite./kg d.w.soil
Hypoapsis aculeifer	N-demethylated spinosyn D	Soil incorporation 5% OM	Chronic	Reproduction	NOEC = 5 $NOEC_{corrected}$ = 2.5

[1]To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).
*highest tested dose

Higher tier testing (e.g. modelling or field studies)

Nitrogen transformation	Spinosyn B		<25% effect at day 28 at 3.582 mg a.s./kg d.w.soil
	N-demethylated Spinosyn D		<25% effect at day 28 at 1.928 mg a.s./kg d.w.soil
	GF-976 (43.8% a.s.)		<25% effects at (Day 40) 3.66 mg GF-976/kg soil (i.e. **1.60** mg a.s./kg soil)

Toxicity/exposure ratios for soil organisms

Leafy vegetables at 120 g a.s./ha x 3

Test organism	Test substance	Time scale	Soil PECmax	TER	Trigger
Earthworms					
Eisnenia fetida	a.s.	Chronic	0.312	56.4	5
Eisnenia fetida	Spinosyn B	Chronic	0.195	9.2	5
Eisnenia fetida	N-demethylated spinosyn D	Chronic	0.035	27.5	5
Eisnenia fetida	GF-976	Chronic	0.312 a.s.	204.2	5
Other soil macroorganisms					
Folsomia candida	GF-976	Chronic	0.312 a.s.	21.5	5
Folsomia candida	Spinosyn B	Chronic	0.195	25.6	5
Folsomia candida	N-demethylated spinosyn D	Chronic	0.035	61.4	5
Hypoaspis aculeifer	GF-976	Chronic	0.312 a.s.	17.6	5
Hypoaspis aculeifer	Spinosyn B	Chronic	0.195	5.1	5
Hypoaspis aculeifer	N-demethylated spinosyn D	Chronic	0.035	71.4	5

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not required for herbicides or plant growth regulators as ER_{50} tests should be provided

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Crop/Exposure[1] (g/ha)[2]	TER	Trigger
6 dicot and 4 monocot plant species	NAF-85	>579	>579	Leafy vegetables: 2.41 g as/ha	>240	5
				Vines: 6.90 g as/ha	>87	5
				Potatoes: 0.72 g as/ha	>804	5
Extended laboratory studies : Semi-field and field test:						

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	3 hour IC_{50} >100 mg/L

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s. Available monitoring data concerning effect of the PPP.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	Spinosad, sum of spinosyn A and spinosyn D
water	Spinosad, sum of spinosyn A and spinosyn D Spinosyn B
sediment	Spinosad, sum of spinosyn A and spinosyn D, pending N-demethylated spinosyn D and spinosyn B
groundwater	Spinosad, sum of spinosyn A and spinosyn D spinosyn B, pending N-demethylated spinosyn D

[1] metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	Spinosad
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][7]:	Aquatic Acute 1 H400 M=10 Aquatic Chronic 1 H410
Peer review proposal[8] for harmonised classification according to Regulation (EC) No 1272/2008:	Aquatic Acute 1 H400 M=10 Aquatic Chronic 1 H410 M=100

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.

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

	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	68.5 mg a.s./kg bw/d*

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

7.1.1 Natural food and drinking water

Sprayed products
For the current application, uses can be categorized as orchards and vineyards. Table E.2 shows which indicator species are relevant.

Table E.2 Indicator species per use

Use	Crop	Indicator species
Cherry	Orchard	Small insectivorous
Grapes	Vineyard	Small omnivorous bird

The risk assessment from the applicant is based on the revised guidance for birds and mammals (EFSA Journal 2009; 7(12):1483).

Table E.3 Acute risk for birds

Crop	Indicator species	LD_{50} [mg	DDD	DDD [mg	TER_A	Trigger

		a.s./kg bw]	Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}	a.s./ kg bw/d]		
Spinosad								
Orchard	Small insectivorous bird	>2000	0.096	46.8	1.3	5.8	>342	10
Buiten reikwijdte verzoek								

Table E.3 shows that the TER values is above the required trigger of 10 for acute exposure. Accordingly, the acute risk to birds from the use of the product according to the intended use pattern is considered acceptable.

Acute risk for birds through drinking water

Leaf scenario
The exposure of birds to drinking water from pools in leaf whorls is relevant for the use of tracer in leafy crops and orchards.

According to EFSA (2009) the leaf scenario is relevant for acute scenario only. Generic focal species is a small granivorous bird (body weight 15.3 g) with a DWR (daily drinking water rate) of 0.46 L/kg bw/d. According to EFSA (2009), the PEC_{pool} is calculated as follows:

$$PEC_{pool} = C_{spray} / 5 \text{ [mg/L]}$$

According to the GAP, the C_{spray} is 0.3 kg as/hL (equivalent to 3000 mg/L).Hence, the PEC_{pool} (= PEC_{dw}) is 3000/5 = 600 mg a.s./L. The calculation of DDD (here: daily drinking water dose) and TER are as follows:

$$DDD = DWR * PEC_{dw} \text{ [mg a.s./kg bw/d]}$$
$$TER_A = LD_{50} \text{ [mg as/kg bw/d] / DDD [mg a.s./kg bw/d]}$$

Table E.4 Acute risk for birds through drinking water from pools in leaf axils or on leaves

Exposure via	DWR [L/kg bw/d]	PEC_{dw} [mg a.s./L]	DDD [mg a.s./kg bw/d]	LD_{50} [mg a.s./kg bw]	$TERa_{, LEAF AXIL}$	Trigger
Pools in leaf axils	0.46	600	276	> 2000	**> 7.2**	10

Table E.4 shows that the TER_A value from exposure via leaf axils is possibly below the required trigger of 10 for acute exposure. However, only 17% mortality occurred at the dose of 2000 mg as/kg bw. Thus, the LD50 will be considerably higher than 2000 mg as/kg bw.

Therefore it is expected that the TER will be >10 at the real LD50 value. Hence, the risk is acceptable.

Puddle scenario:

The exposure of birds to drinking water from puddles formed on the field after rainfall is relevant for the proposed field use of Tracer.

According to EFSA (2009) the puddle scenario is relevant for the acute (this section) and reproduction scenario (see below). Generic focal species is a small granivorous bird (body weight 15.3 g) with a DWR (daily drinking water rate) of 0.46 L/kg bw/d.

According to EFSA Guidance Document for Birds and Mammals (2009), the PEC_{puddle} calculates as follows:

$$PEC_{puddle} = \frac{AR/10}{1000(w + Koc \times s)}$$

Where

AR = application rate in g/ha; divisor of 10 to achieve rate in mg/m²
w = 0.02 (pore water term: volume)
s = 0.0015 (soil term: volume, density, organic carbon content)

The PEC_{puddle} (= PEC_{dw}) is 0.14 mg a.s./L, based on the highest single application rate in cherry (screening PIEC) and a mean Koc of 35024 L/kg. The calculation of DDD (here: daily drinking water dose) and TER are as follows:

DDD = DWR * PEC_{dw} [mg a.s./kg bw/d]
TER_A = LD50 [mg as/kg bw] / DDD [mg a.s./kg bw/d]

Table E.5 Acute risk for birds through drinking water from puddles

Exposure via	DWR [L/kg bw/d]	PEC_{dw} [mg a.s./L]	DDD [mg a.s./kg bw/d]	LD50 [mg as/kg bw]	$TERa_{,puddle}$	Trigger
Puddles on soil	0.46	0.14	0.064	>2000	>31056	5

Table E.5 shows that the TER_A value from exposure via puddles is above the required trigger of 10 for acute exposure. Thus, the risk is acceptable.

Table E.6 Chronic risk for birds

Crop	Indicator species	NOEL [mg a.s./kg bw]	DDD			DDD [mg a.s./kg bw/d]	TER	Trigger
			Appl. rate [kg a.s./ha]	SV	MAF			
Spinosad								
Orchard	Small insectivorous bird	68.5	0.096	18.2	1.6	2.8	24.5	5

Buiten reikwijdte verzoek

Table E.6 shows that the TER values is above the required trigger of 5 for chronic exposure. Accordingly, the chronic risk to birds from the use of the product according to the intended use pattern is considered acceptable.

Chronic risk for birds through drinking water

Puddle scenario:
The exposure of birds to drinking water from puddles formed on the field after rainfall is relevant for all proposed field uses of Tracer.

According to EFSA (2009) the leaf scenario is relevant for the acute (see section above) and reproduction scenario (this section). Generic focal species is a small granivorous bird (body weight 15.3 g) with a DWR (daily drinking water rate) of 0.46 L/kg bw/d.

According to EFSA Guidance Document for Birds and Mammals (2009), the PEC_{puddle} calculates as follows:

$$PEC_{puddle} = \frac{AR/10}{1000(w + Koc \times s)}$$

Where

AR = application rate in g/ha; divisor of 10 to achieve rate in mg/m²
w = 0.02 (pore water term: volume)
s = 0.0015 (soil term: volume, density, organic carbon content)

The PEC_{puddle} (= PEC_{dw}) is 0.14 mg a.s./L, based on the highest single application rate in cherry (screening PIEC) and a mean Koc of 35024 L/kg. The calculation of DDD (here: daily drinking water dose) and TER are as follows:

DDD = DWR * PEC_{dw} [mg a.s./kg bw/d]
TER_{LT} = NO(A)EL [mg a.s./kg bw/d] / DDD [mg a.s./kg bw/d]

Table E.7 Chronic risk for birds through drinking water from puddles

Exposure via	DWR [L/kg bw/d]	PEC_{dw} [mg a.s./L]	DDD [mg a.s./kg bw/d]	NOEL[mg as/kg bw]	$TERlt_{,puddle}$	Trigger
Puddles on soil	0.46	0.14	0.064	68.5	1070	5

Table E.7 shows that the TER_{LT} value from exposure via puddles is above the required trigger of 5 for chronic exposure. Thus, 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 0.1042 µg/L = 0.000104 mg/L.
Indicator species is a 1000-g bird eating 159 g fresh fish per day.
The TER is then calculated as NOEL / ($PEC_{water(21)}$ * BCF_{fish} * (FIR/bw) = 68.5 / (0.000104 * 115 * 0.159) = >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) amounts 0.078 mg/kg soil (sum of spinosyn A and D).
Indicator species is a 100-g bird eating 104.6 g fresh worms per day.
The risk is then calculated as NOEL / $PEC_{soil(21)}$ * BCF_{worm} * (FIR/bw) = 68.5 / (0.078 * 0.344 * 1.05) = >1000. Since this is >> 5, the risk for birds as a result of consumption of contaminated worms is considered to be low.

Considering the large margin of safety that is calculated for the active substance, the risk from metabolites in soil and water is considered low as well.

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

Conclusions birds

The product complies with the RGB.

7.2 Effects on aquatic organisms

7.2.1 Aquatic organisms

The risk for aquatic organisms 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).
Toxicity data for aquatic organisms are presented in Table E.8. In the list of endpoints it can be seen that the formulation NAF-85 (=Tracer) is less toxic than the a.s. for all organism groups. Therefore, the risk assessment is based on the toxicity endpoints of spinosad.

Table E.8 Overview toxicity endpoints for aquatic organisms

Substance	Organism	Lowest	Toxicity value

		L(E)C_{50} [mg/L]	NOEC [mg/L]	[µg/L]
spinosad	*Acute*			
	Algae	0.14*		140
	Invertebrates	>0.032		>32
	Fish	4.0		4000
	Macrophytes	>71		>71000
	Chronic			
	Invertebrates		0.0012	1.2
	Fish		0.217	217
	Sediment org (*Chironomus riparius*)		0.00077	0.77
N-demethylated Spinosyn D	*Acute*			
	Algae	0.25		250
	Invertebrates	0.034		34
	Chronic			
	Daphnids		0.001	1
β-13,14-dihydropseudo-aglycone of Spinosyn A	*Acute*			
	Algae	38.8		38800
	Invertebrates	>100		>100000
	Chronic			
	Daphnids		1.25	1250
β-13,14-dihydropseudo-aglycone of Spinosyn D	*Acute*			
	Algae	28		28000
	Invertebrates	65.8		65800
	Chronic			
	Daphnids		4.85	4850

* ErC50-value

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. In table E.9a-b TER values for aquatic organisms are shown.

Table E.9a TER values for a.s. spinosad: acute

Use	PECsw [µg a.s./L]	TER_{st} (trigger 10)	TER_{st} (trigger 100)	TER_{st} (trigger 100)	TER_{st} (trigger 10)
		Algae	Daphnid	Fish	Macrophytes

		spring	spring	spring	spring
Cherry	0.0916*	>1000	>349	>1000	>1000
Buiten reikwijdte verzoek					

* full leaf, DRT97.5 in combination with a crop free zone of 450 cm
** full leaf, DRT99 in combination with a crop free zone of 300 cm

Table E.9b TER values for a.s. spinosad: chronic

Use	PECsw [µg a.s./L]	TER_{lt} (trigger 10) aquatic Invertebrates spring	TER_{lt} (trigger 10) Fish spring
Cherry	0.0916*	13.1	>1000
Buiten reikwijdte verzoek			

* full leaf, DRT97.5 in combination with a crop free zone of 450 cm
** full leaf, DRT99 in combination with a crop free zone of 300 cm

Taking the results in Table E.9a and b into account, all TERs are above the relevant Annex VI triggers, provided that the mentioned drift reduction measures are applied (cherry: DRT97.5 + 450 cm CFZ; Grape: DRT99 + 300 cm CFZ).

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 to the metabolite is expected to be lower than of the active substance, the risk from the metabolite N-demethylated Spinosyn D will be covered by the active substance.

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 114-115 L/kg is available (for spinosyn A and D resp.).
Since the BCF is above 100 L/kg and the substance spinosad is not ready biodegradable, the risk for bioconcentration should be further adressed.

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). However, an ELS study is available and based on this study the chronic risk to fish is acceptable (TER > 1000 for the use in cherry and grape).
Ad 2: from the risk assessment of secondary poisoning for birds and mammals a low risk is indicated.
Ad 3: When the BCF > 1000 and the elimination in the BCF study within 14 days is < 95% and the DT_{90} water or sediment > 100 days, a higher tier exposure assessment with regard to the potential for biomagnification in the aquatic food chain should be conducted. These triggers are not exceeded for spinosad.

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

The NOEC value for *Chironomus* is 0.77 µg/L. In Table E.10a, this value is examined against the highest refined PIEC in water.

Table E.10a TER values for a.s. spinosad for *Chironomus riparius*

Use	PECsw [µg a.s./L]	TER_{st} (trigger 10) Chironomus sp. spring
Cherry	0.0916*	**8.4**
Grape	0.1042**	**7.4**

* full leaf, DRT97.5 in combination with a crop free zone of 450 cm
** full leaf, DRT99 in combination with a crop free zone of 300 cm

The TER for *Chironomus* does not meet the trigger of 10. Hence, higher drift reduction is necessary. When for cherry measures from class DRT99 are chosen the drift is 0.10% and the PECsw for this use 0.0762. That is just beneath the RAC of 0.077 µg/L and thus the risk is acceptable (TER = 10.1).

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

The following restriction sentences are necessary:

Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van kersen in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van een techniek uit tenminste de klasse DRT99.

After the initial assessment the applicant has refined the GAP (lower dose rate, larger interval) for grapes and proposes the following corresponding drift reducing measures (spray drift values added between brackets by Ctgb):

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

5.1.2.e

Buiten reikwijdte verzoek

Overall conclusion
The risk for the use in cherries and grapes is acceptable, provided that a technique from class DRT99 is applied in combination with a crop-free zone of at least 300 cm.

7.3 Effects on terrestrial vertebrates other than birds

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

The threshold value for mammals is based on the trigger from the RGB. This means that the 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.11 presents an overview of toxicity data.

Table E.11 Overview of toxicity data for mammals

	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 #

daily dose value taken from DAR Spinosad (value not in LoEP).

7.3.1 Natural food and drinking water

The risk assessment from the applicant is based on the revised guidance for birds and mammals (EFSA Journal 2009; 7(12):1483).

- **Acute dietary risk assessment: screening step for sprayed products**

Table E.12 Acute risk for mammals

Crop	Generic focal species	LD_{50} [mg a.s./kg bw]	DDD			DDD [mg a.s./ kg bw/d]	TER_A	Trigger
			Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
Spinosad								
Orchard	Small herbivorous mammal	> 2000	0.096	136.4	1.4	18.3	>109	10

Buiten reikwijdte verzoek

Table E.12 shows that the TER value is above the required trigger of 10 for acute exposure. Accordingly, the acute risk to mammals from the use of the product according to the intended use pattern is considered acceptable.

Acute risk for mammals through drinking water

Leaf scenario
The exposure to drinking water from pools in leaf whorls is not relevant for mammals according to EFSA (2009).

Puddle scenario:
The exposure of mammals to drinking water from puddles formed on the field after rainfall is relevant for all proposed field of tracer

According to EFSA (2009) the leaf scenario is relevant for the acute (this section) and reproduction scenario (see below). Generic focal species is a small granivorous mammal (body weight 21.7 g) with a DWR (daily drinking water rate) of 0.24 L/kg bw/d..

$$PEC_{puddle} = \frac{AR/10}{1000(w + Koc \times s)}$$

According to EFSA Guidance Document for Birds and Mammals (2009), the PEC_{puddle} calculates as follows:

Where

AR = application rate in g/ha; divisor of 10 to achieve rate in mg/m²
w = 0.02 (pore water term: volume)
s = 0.0015 (soil term: volume, density, organic carbon content)

The PEC_{puddle} (= PEC_{dw}) is 0.14 mg a.s./L, based on the highest single application rate in cherry (screening PIEC) and a mean Koc of 35024 L/kg. The calculation of DDD (here: daily drinking water dose) and TER are as follows:

DDD = DWR * PEC_{dw} [mg a.s./kg bw/d]
TER_A = LD50 [mg as/kg bw] / DDD [mg a.s./kg bw/d]

Table E.13 Acute risk for mammals through drinking water from puddles

Exposure Via	DWR [L/kg bw/d]	PEC_{dw} [mg a.s./L]	DDD [mg a.s./kg bw/d]	LD50 [mg as/kg bw]	$TERa_{,puddle}$	Trigger
Puddles on soil	0.24	0.14	0.034	>2000	>59524	5

Table E.13 shows that the TER_A value from exposure via puddles is above the required trigger of 10 for acute exposure. Thus, the risk is acceptable.

- **Chronic dietary risk assessment: Tier 1 for sprayed products**

Table E.14 Chronic risk for mammals

Crop	Generic focal species	NOEL [mg	DDD	DDD [mg	TER	Trigger

		a.s./kg bw/d]	Appl. rate [kg a.s./ha]	SV	MAF	a.s./ kg bw/d]		
spinosad								
Orchard	Small herbivorous mammal	10	0.096	72.3	1.6	11.1	**0.9**	5

Buiten reikwijdte verzoek

Taking the results in Table E.14 into account, it appears that there is a chronic risk to mammals.

The following tier 1 assessement is preformed.

Table E.15a Chronic risk for mammals in orchards

Crop	Generic focal species	NOAEL [mg a.s./kg bw/d]	DDD				DDD [mg a.s./ kg bw/d]	TER_{LT}	Trigger
			Appl. rate [kg a.s./ha]	SV_{mean}	MAF mean	ftwa			
Spinosad									
Orchard	Small herbivorous mammal, “vole” (≥ 40)	10	0.096	21.7	1.6	0.53	1.77	5.7	5
	Large herbivorous mammal “lagomorph” (≥ 40)			4.3			0.35	28.6	
	Small omnivorous mammal “mouse” (≥ 40)			2.3			0.19	53.4	
	Frugivorous mammal ‘dormouse’			22.7			1.85	5.4	

From table E.15 it appears that the TER values are higher than 5 for all scenarios.

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

From table E.15b it appears that the TER values are higher than 5 for all scenarios.
Hence, the proposed use meets the standards for mammals as laid down in the RGB.

<u>Chronic risk for mammals through drinking water</u>

Puddle scenario:
The exposure of mammals to drinking water from puddles formed on the field after rainfall is relevant for all proposed field uses of Tracer.

According to EFSA (2009) the puddle scenario is relevant for the acute (see section above) and reproduction scenario (this section). Generic focal species is a small granivorous mammal (body weight 21.7 g) with a DWR (daily drinking water rate) of 0.24 L/kg bw/d..

$$PEC_{puddle} = \frac{AR/10}{1000(w + Koc \times s)}$$

According to EFSA Guidance Document for Birds and Mammals (2009), the PEC_{puddle} calculates as follows:

Where

AR = application rate in g/ha; divisor of 10 to achieve rate in mg/m²
w = 0.02 (pore water term: volume)
s = 0.0015 (soil term: volume, density, organic carbon content)

The PEC_{puddle} (= PEC_{dw}) is 0.14 mg a.s./L, based on the highest single application rate in cherry (screening PIEC) and a mean Koc of 35024 L/kg. The calculation of DDD (here: daily drinking water dose) and TER are as follows:

DDD = DWR * PEC_{dw} [mg a.s./kg bw/d]
TER_{LT} = NO(A)EL [mg a.s./kg bw/d] / DDD [mg a.s./kg bw/d]

Table E.16 Chronic risk for birds through drinking water from puddles

Exposure via	DWR [L/kg bw/d]	PEC_{dw} [mg a.s./L]	DDD [mg a.s./kg bw/d]	NOEL[mg as/kg bw]	$TERlt_{,puddle}$	Trigger
Puddles on soil	0.24	0.14	0.034	10	298	5

Table E.16 shows that the TER_{LT} value from exposure via puddles is above the required trigger of 5 for chronic exposure. Thus, 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 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 0.1042 µg/L = 0.000104 mg/L.
Indicator species is a 3000-g mammal eating 425 g fresh fish per day.
The TER is then calculated as NOEL / ($PEC_{water(21)}$ * BCF_{fish} * (FIR/bw) = 10 / (0.000104 * 115 * 0.142) = >1000. Since this is > 5, the risk for mammals 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) amounts 0.078 mg/kg soil (sum of spinosyn A and D).
Indicator species is a 10-g mammal eating 12.8 g fresh worms per day.
The risk is then calculated as NOEL / $PEC_{soil(21)}$ * BCF_{worm} * (FIR/bw) = 10 / (0.078 * 0.344 * 1.28) = 291. Since this is > 5, the risk for mammals as a result of consumption of contaminated worms is considered to be low.

Considering the large margin of safety that is calculated for the active substance, the risk from metabolites in soil and water is considered low as well.

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

Conclusions mammals

The product complies with the RGB.

7.4 Effects on bees

The risk assessment for bees is based on the ratio between the highest single application rate and toxicity endpoint (LD_{50} value).
An overview of the risk at the proposed uses is given in Table E.17.

Table E.17 Risk for bees

Use	Test substance	LD_{50}	Single application rate	Rate/LD_{50}	Trigger value
		[µg/bee]	[g a.s./ha]		
Cherry(worst-case use)	Tracer	0.049 (oral)	96	**1959**	50
	spinosad	0.0036 (contact)		**26667**	50

Since the ratio rate/LD_{50} is >> 50, there is a potentially high risk for bees.
Hence, the proposed use does not meet the standards for bees as laid down in the RGB.
Several higher tier studies (cage and semi-field) are available (see List of endpoints). These studies show that at the proposed application rates significant adverse effects on honey bees and bumble bees are to be expected.

About field uses the Dar (2001) says the following:

Field applications of NAF-85

The use of NAF-85 in field crops may pose a risk to bees and bumblebees.

- *NAF-85 is applied to wine and table grapes at a maximum rate of 9.6 g as/hL with a spraying volume of 200 – 1000 L/ha or at 0.12 g as/L with a spraying volume of 400 – 600 L/ha. The maximum application rate is thus 72 to 96 g as/ha (equivalent to 0.15 to 0.2 L NAF-85/ha), with a maximum of 5 applications being made at this rate.*
- *NAF-85 is applied to peppers in the field at a maximum rate of 9.6 g as/hL with a spraying volume of 400 – 1200 L/ha. The maximum application rate is thus 115 g as/ha (equivalent to 0.24 L NAF-85/ha), with a maximum of 3 applications being made at this rate.*
- *NAF-85 is applied to tomatoes and aubergines at a maximum rate of 9.6 g as/hL with a spraying volume of 400 – 1500 L/ha. The maximum application rate is thus 144 g as/ha (equivalent to 0.3 L NAF-85/ha), with a maximum of 3 applications being made at this rate.*

The lowest acute contact LD_{50} is reported to be 0.0036 µg as/bee and the lowest acute oral LD_{50}-value is reported to be 0.049 µg as/bee (when applied as NAF-85).
The hazard quotients for all the proposed uses, based on the above LD_{50} values are presented in Table B.9.4.3-2. For single applications at the maximum proposed dose for each crop, all hazard quotients (D/LD_{50}) are above the Annex VI trigger of 50, indicating that there is a potential risk to honeybees and bumblebees. In this calculation, repeated application was not taken into account.
To further refine the risk assessment, data have been submitted on the toxicity of NAF-85 to Apis mellifera in a cage trial. At the application rate of 144 g as/ha, no effects on survival, foraging or brood development were found. At the higher application rate of 540 g as/ha, survival was not affected, but foraging activity was significantly reduced. There were also qualitative indications that brood development was reduced. The application rate of 144 g as/ha exceeds the highest proposed field rate for grapes and peppers and is equal to the highest proposed rate for tomatoes and aubergines. However, the test substance was applied only once in the cage test, whereas up to 5 applications of NAF-85 may occur.
Additionally, data have been submitted on the toxicity of NAF-85 to Bombus terrestris in a semi field test at an application rate of 0.36 g as/L. No effect on survival was found in this test, but foraging activity and brood development were reduced by 65 and 16%, respectively. The tested application rate is 3 to 3.8 times higher than the proposed maximum field

application rates, but was applied only once. Multiple applications of NAF-85 may occur, and therefore an effect on Bombus terrestris cannot be excluded.
An adequate risk assessment for Apis mellifera and/or Bombus terrestris is considered necessary for all proposed field applications of NAF-85. The possibility of multiple applications and application when bees are flying should be taken into account.

In order to reduce the high risk for bees in the field, exposure must be kept to a minimum with the following restriction sentence:

Gevaarlijk voor bijen. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen. Gebruik dit product niet op plaatsen waar bijen actief naar voedsel zoeken. Gebruik dit product niet in de buurt van in bloei staand onkruid. Verwijder onkruid voordat het bloeit.

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 orchards and vineyards is 3.9% (DRT90 + 3 m) of the application rate.

Table E.18 Off-field risk to bees for spinosad

Use	Application rate	Drift fraction	Off-field rate	LD_{50}	HQ (off-field rate/LD_{50})	Trigger value
	(g a.s./ha)		(g a.s./ha)	(µg/bee)		
Cherry	96	0.039	3.74	0.0036	**1040**	50

Table E.18 shows that the HQ values are above 50, indicating that there is a potential risk to bees off-field.
For a recent application for minor uses, the applicant had submitted a semi-field cage study which 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 (for a summary and the endpoints see the LoEP). No effects on bee mortality, colony strength, food storage and brood development were recorded. There was a reduction of flight intensity at 24 and 48 g as/ha. Given that the current off-field dose (3.74 g as/ha) fall within the tested lower range of the field test, no off-field effects on bees is expected from the application of Tracer.
The actual state of the art is that semi-field tests are not used to draw a conclusion on brood and colonies, because the observation period is too short. However, the off-feld rate as presented in table E.18 will be much lower, taking into account the strict risk mitigation measures which are necessary for non-target arthropods and aquatic organisms. Techniques from class DRT99 must be applied and the drift% is then reduced to 0.36%. The off-field rate is then 0.35 g a.s./ha. This rate is about a factor of 10 below the lowest rate tested in the semi-field cage study. At this rate the risk the off-field risk to bees is considered acceptable.

Conclusions bees
The proposed uses of the product comply 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. See table E. 19a

Table E.19a HQ-values for *A. rhopalosiphi* and *T. pyri* in-field HQ-based on standard lab studies

	Application rate (kg a.s./ha)	MAF[1]	Drift factor/ Vegetation factor	Safety factor	LR_{50} (kg a.s./ha)	HQ
Grapes						
A. rhopalosiphi	0.0786	2.7	-	-	0.000371	**572**
T. pyri	0.0786	2.7	-	-	0.00854	**24.9**
Cherry						
A. rhopalosiphi	0.096	1.7	-	-	0.000371	**440**
T. pyri	0.096	1.7	-	-	0.00854	**19.1**

All HQ values exceed the trigger value of 2. Hence, a risk is expected.

Therefore a second tier assessment was carried out. In the second tier, lethal and sublethal effects should be < 50% at relevant applications, which means that the HQ should be < 1. The applicant has submitted two extended laboratory studies with *Typhlodromus pyri*. In one study the 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 the LR50 was 4.871 g a.s./ha. For *A. rhopalosiphi* an LR50 value of 18.48 g a.s./ha is available from an extended laboratory study. For both *A. rhopalosiphi* and *T. pyri* no effects were found on reproduction.

Table E.19b shows HQ-values.

Table E.19b HQ-values for *A. rhopalosiphi* and *T. pyri* in-field based on extended lab studies

	Application rate (kg a.s./ha)	MAF[1]	Drift factor/ Vegetation factor	Safety factor	LR_{50}* (kg a.s./ha)	HQ
Grapes						
A. rhopalosiphi	0.0786	2.7	-	-	0.01848	**11.5**
T. pyri	0.0786	2.7	-	-	0.0003513	**604**
					0.004871**	**43.6**
Cherry						
A. rhopalosiphi	0.096	1.7	-	-	0.01848	**8.8**
T. pyri	0.096	1.7	-	-	0.0003513	**465**
					0.004871**	**33.5**

*Reproduction was not affected.
**with photochemical degradation

[1]: Multiple Application Factor

Table E.20 HQ-values for *A. rhopalosiphi* and *T. pyri* off-field

	Application rate (kg a.s./ha)	MAF[1]	Drift factor/ Vegetation factor[2]	Safety factor[2]	LR_{50}* (kg a.s./ha)	HQ
Grapes						
A. rhopalosiphi	0.0786	2.7	0.069	5	0.01848	**4.0**
T. pyri	0.0786	2.7	0.069/5	5	0.0003513	**41.7**
					0.004871**	**3.0**
Cherry						
A. rhopalosiphi	0.096	1.7	0.039	5	0.01848	**1.7**
T. pyri	0.096	1.7	0.039/5	5	0.0003513	**18.1**
					0.004871**	**1.3**

*Reproduction was not affected.
**with photochemical degradation
[1]: Multiple Application Factor
[2]: off-field: drift factor = 3.9% for orchards (DRT90 + 3 m) and 6.9% for vineyards (DRT75 + 3 m), vegetation dilution factor = 5, not applicable at sprayed plants (i.e. for *A. rhopalosiphi*), safety factor = 5 (default value for extended lab)
"Note on VDF (vegetation distribution factor) for the off-field exposure calculation:
In the Pesticides Peer review Meeting on Recurring Issues on Ecotoxicology held in 2019 (EFSA Supporting publication 2019:EN-1673), the experts agreed that the VDF value should be changed as better data are now available. It was recommended that a VDF value of 5 is applied for all the tiers of the assessment as an interim solution. (This applies to EU active substance dossiers submitted from 7 July 2019 and national product assessment submitted from 1 january 2020.)"

As the above table shows, both in- and off-field HQ values are above the trigger value of 1, indicating a potentially high risk for non-target arthropods.

Refinement in-field

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. 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 a year.

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. The field studies in vineyards with *T. pyri* are not acceptable to address the off field risk.

Other arthropods

Information in the RAR 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 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.

Refinement off-field

Field study

For a recent application for minor uses the applicant submitted a non-target arthropod field study (for a summary and endpoints see the LoEP). 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 multiple times, higher than what was tested in the field study. Furthermore, Ctgb is of the opinion that for reaching a complete recovery in-crop it is very important to accept only no or very minimal effects off-crop. 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 is applied 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 maximum allowable rate off-crop is 0.75 g a.s./ha.
For the current application in grapes the off-field rate is 14.6 g a.s./ha. For the use in cherry the off-field rate is 6.4 g a.s./ha. Based on this it can be concluded that the exposure is 19.5 (grapes) respectively 8.5 times (cherry) higher than the maximum allowable rate.
Acceptable off-field rates can be obtained by applying drift mitigation measures. The drift has to be reduced to 6.9/19.5 = 0.35% for the use in grapes and 3.9/8.5 = 0.46% for the uses in cherry to reach an acceptable off-field risk.

Conclusion

Based on all information available, it appears that for in-field short-term effects are to be expected, but that recovery within an acceptable period is possible. However, to address the risk for natural enemies used in integrated pest management, the following warning sentence must be placed on the label:

Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg deskundigen (uw leverancier van natuurlijke vijanden, de producent van dit middel, uw adviseur) over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden.

To reach an acceptable off-field risk the following drift reduction measures should be applied:
- techniques from class DRT99 (drift = 0.36%); or
- techniques from at least class DRT97.5 in combination with a crop-free zone of 450 cm (drift = 0.22%).

Although the measure DRT99 reduces the drift to 0.36%, slightly higher than the acceptable percentage of 0.35% (grapes), it is considered sufficiently protective taking into account that

the MAF calculation is worst-case, because it is acknowledged that spinosad will dissipate from leaves more quickly than assumed in default values (see argumentation above).

Hence, the following restriction sentence is necessary:

Om niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing van het middel in de teelt van kersen en druiven uitsluitend toegestaan indien op het gehele perceel gebruik wordt gemaakt van:
- een techniek uit tenminste de klasse DRT99; of
- een techniek uit tenminste de klasse DRT97,5 in combinatie met een teeltvrije zone van tenminste 450 cm gemeten vanaf het midden van de laatste bomenrij of de laatste boom in de rij tot aan de perceelgrens.

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

5.1.2.e

7.5.2 Soil macro-organisms

Earthworms

The acute risk for earthworms is calculated as TER-value (trigger value 10). Since the logPow of the active substance is > 2, a correction to the reference soil containing 4.7 % organic matter is necessary. Exposure is expressed as the initial PEC soil. PEC soil is calculated in section 6.1.1. Table E.21 presents endpoints, PECsoil and TER values for the use with the highest PIECsoil. Only the risk assessment for use in grapes is shown as it covers all other uses.

Table E.21 Overview of soil concentrations and acute TERs for earthworms

Use	Substance	$LC50_{corr}$ [mg/kg]	PIEC soil [mg/kg]	TER	Trigger value
Grapes (worst-case use)	Spinosad (sum spinosyn A and D)	>431	0.092	>1000	10
	Spinosyn B	>470	0.054	>1000	
	N-demethylated spinosyn D	>470	0.010	>1000	

In view of the results presented in Table E.22 a low acute risk for earthworms is expected.

In the subchronic risk assessment for earthworms, a long-term TER-value is calculated. Examination of the PIEC takes place against the trigger of 0.2*NOEC. See Table E.22.

Table E.22 Overview of soil concentrations and chronic TERs for earthworms

Use	Substance	$NOEC_{corr}$ [mg/kg]	PIEC soil [mg/kg]	TER	Trigger value
Grapes (worst-case use)	Spinosad (sum spinosyn A and D)	3.6	0.092	39.1	5
	Spinosyn B	1.68	0.054	31.1	
	N-demethylated spinosyn D	0.91	0.01	91	

The TER value for earthworms resulting from exposure to the spinosad (sum of spinosyn A and D), spinosyn B and N-nemethylated spinosyn D meets the trigger. The proposed applications of the product therefore meet the standards as laid down in the RGB.

Other soil macro-organisms

In chronic risk assessment for other soil macro-organisms (*Folsomia candida* and *Hypoaspis aculeifer*), a long-term TER-value is calculated. Examination of the PIEC takes place against the trigger of 0.2*NOEC. See Table E.23.

Table E.23 Overview of soil concentrations and chronic TERs for earthworms for *Folsomia candida* and *Hypoaspis aculeifer*

Use	Substance	$NOEC_{corr}$ [mg/kg]	PIEC soil [mg/kg]	TER	Trigger value
		Folsomia candida			

Grapes	Spinosad (sum spinosyn A and D)	6.7	0.092	72.8	5
	Spinosyn B	5	0.054	92.6	
	N-demethylated spinosyn D	2.15	0.01	215	
	Hypoaspis aculeifer				
Grapes	Spinosad (sum spinosyn A and D)	2.16	0.092	23.5	5
	Spinosyn B	1.0	0.054	18.5	
	N-demethylated spinosyn D	2.5	0.01	250	

The TER values for *Folsomia candida* and *Hypoaspis aculeifer* resulting from exposure to the spinosad (sum of spinosyn A and D), spinosyn B and N-nemethylated spinosyn D meet the trigger. The proposed applications of the product therefore meet the standards as laid down in the RGB.

7.5.3 Effects on soil micro-organisms

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

Article 2.10a of the Plant Protection Products and Biocides Regulations (RGB) describes the authorisation criterion STP.
An IC_{50} value of >100 mg/L is available. The trigger is set to 0.1* EC_{50} corresponding to 10000 µg/L.

For the proposed use no exposure of activated sludge is expected.

Based on the above, the proposed application complies with the standards for activated sludge as laid down in the RGB.

7.5.5 Effects on non target-plants

For field-uses two studies are available, which are also considered in the RAR (2018):
Given the proposed use of NAF-85 in the field, exposure of non-target flora may be expected.
Two tests are available for a number of species, one with the active substance (at a rate of 227 g XDE-105/ha), and one with the formulation NAF-85 (at a rate of 579 g as/ha). All data concern crop species. Non-crop data were not available. The rate used in the study with NAF-85 is similar to a single maximum dose in the field. All effects (emergence, shoot length and shoot weight) were <25%, so potential risk of spinosad is considered to be low. No further data are required.

Ctgb agrees.

Conclusions any other organisms

The product does comply with the RGB for the aspects earthworms, soil micro-organisms, activated sludge and non-target plants. The product does comply with the aspect non-target arthropods, provided that risk mitigation measures are applied.

7.6 Appropriate ecotoxicological end-points relating to the product and approved uses

See List of End-points.

7.7 Data requirements

-

7.8 Classification and Labelling

-

Restriction sentences, proposed by the applicant:

Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van kersen in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van:
- een techniek uit tenminste de klasse DRT 97,5 in combinatie met een teeltvrije zone van 4,5 meter of
- een techniek uit tenminste de klasse DRT 99.

Buiten reikwijdte verzoek

Om niet tot de doelsoorten behorende geleedpotigen/insecten te beschermen is toepassing van het middel in de teelt van kersen en druiven in percelen die niet grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van een techniek uit tenminste de klasse DRT97,5.

Gevaarlijk voor bijen. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen. Gebruik dit product niet op plaatsen waar bijen actief naar voedsel zoeken. Gebruik dit product niet in de buurt van in bloei staand onkruid. Verwijder onkruid voordat het bloeit.

Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg deskundigen (uw leverancier van natuurlijke vijanden, de producent van dit middel, uw adviseur) over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden.

Buiten reikwijdte verzoek

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use:

In the WG (legal instructions):

Advies vrijstelling 2022/01 – Tracer (werkzame stof spinosad) in de teelt van kers en druif tegen suzukifruitvlieg

Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van kersen in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van een techniek uit tenminste de klasse DRT99.

*Om niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing van het middel in de teelt van kersen in percelen die **niet** grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik wordt gemaakt van:*
- een techniek uit tenminste de klasse DRT99; of
- een techniek uit tenminste de klasse DRT97,5 in combinatie met een teeltvrije zone van tenminste 450 cm gemeten vanaf het midden van de laatste bomenrij of de laatste boom in de rij tot aan de perceelgrens.

Buiten reikwijdte verzoek

Gevaarlijk voor bijen. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen. Gebruik dit product niet op plaatsen waar bijen actief naar voedsel zoeken. Gebruik dit product niet in de buurt van in bloei staand onkruid. Verwijder onkruid voordat het bloeit.

Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg deskundigen (uw leverancier van natuurlijke vijanden, de producent van dit middel, uw adviseur) over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden.

Buiten reikwijdte verzoek

Buiten reikwijdte verzoek

7.9 Overall conclusions regarding ecotoxicology

It can be concluded that:

1. the proposed applications of the active substance spinosad meet the standards for persistence as laid down in the RGB.
2. the proposed applications of the active substance spinosad meet the standards for birds as laid down in the RGB.
3. the proposed applications of the active substance spinosad in cherries and grapes meet the standards for aquatic organisms as laid down in the RGB, provided that risk mitigation measures are applied.
4. the proposed applications of the active substance spinosad in cherries and grapes meet the standards for sediment organisms as laid down in the RGB, provided that risk mitigation measures are applied.
5. the active substance spinosad meets the standards for bioconcentration as laid down in the RGB.
6. the proposed applications of the active substance spinosad meet the standards for mammals as laid down in the RGB.
7. the proposed applications of the active substance spinosad meet the standards for bees as laid down in the RGB.
8. the proposed applications of the active substance spinosad meet the standards for non-target arthropods as laid down in the RGB, provided that risk mitigation measures are applied.
9. the proposed applications of the active substance spinosad meet the standards for earthworms as laid down in the RGB.
10. the proposed applications of the active substance spinosad meet the standards for soil micro-organisms as laid down in the RGB.
11. the proposed applications of the active substance spinosad meet the standards for activated sludge.
12. the proposed applications of the active substance spinosad meet the standards for non-target plants as laid down in the RGB.

<u>Conclusies vrijstelling</u>

Het risico voor vogels, zoogdieren, bodemmacro- en micro-organismen, en niet-doelwit planten is acceptabel.

Het risico voor waterorganismen is acceptabel met de volgende restrictiezin:

Om in het water levende organismen te beschermen is toepassing van het middel in de teelt van kersen en druiven in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik gemaakt wordt van een techniek uit tenminste de

klasse DRT99 in combinatie met een teeltvrije zone van tenminste 300 centimeter gemeten vanaf het midden van de laatste bomenrij of de laatste boom in de rij tot aan de insteek van de sloot / perceelgrens.

Het risico voor bijen is acceptabel, mits de volgende restrictiezin op het etiket wordt geplaatst:

Gevaarlijk voor bijen. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen. Gebruik dit product niet op plaatsen waar bijen actief naar voedsel zoeken. Gebruik dit product niet in de buurt van in bloei staand onkruid. Verwijder onkruid voordat het bloeit.

Het risico voor niet-doelwit arthropoden is acceptabel, mits de volgende restrictiezinnen en waarschuwingszin op het etiket worden geplaatst:

Om niet tot de doelsoorten behorende geleedpotigen/ insecten te beschermen is toepassing van het middel in de teelt van kersen in percelen die niet grenzen aan watergangen uitsluitend toegestaan indien op het gehele perceel gebruik wordt gemaakt van:
- een techniek uit tenminste de klasse DRT99; of
- een techniek uit tenminste de klasse DRT97,5 in combinatie met een teeltvrije zone van tenminste 450 cm gemeten vanaf het midden van de laatste bomenrij of de laatste boom in de rij tot aan de perceelgrens.

Buiten reikwijdte verzoek

Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg deskundigen (uw leverancier van natuurlijke vijanden, de producent van dit middel, uw adviseur) over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden.