-----Oorspronkelijk bericht-----
Van: art. 5.1.2.e Woo
Verzonden: dinsdag 13 juni 2017 13:15
Aan: art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Onderwerp: WG/GAP Ascernity voor CA

Hallo art. 5.1.2.e ,

Bijgesloten het WG en de GAP van Ascernity voor de Comparative Assessment.
Deze WG en GAP zijn nog niet definitief, maar ik verwacht geen grote wijzigingen.

Ik zal intern communiceren dat art. 5.1.2.e W niet langer bij het NVWA werkzaam is, bedankt voor de informatie.

Groeten,

art. 5.1.2.e V

Van: art. 5.1.2.e Woo
Verzonden: dinsdag 13 juni 2017 12:26
Aan: art. 5.1.2.e Woo
CC: art. 5.1.2.e Woo ing. art. 5.1.2.e Woo; art. 5.1.2.e Woo
Onderwerp: RE: Documenten uit OpenIMS DMS

Hallo art. 5.1.2.e V ,

Ik vervang art. 5.1.2.e Woo tijdens haar vakantie, dus de opdracht is bij mij aan het juiste adres en ik zal deze uitzetten. Inhoudelijk is voor CA, art. 5.1.2.e Woo degene die art. 5.1.2.e Woo vervangt.

Verder zag ik dat in de opdrachtbrief nog art. 5.1.2.e Woo wordt genoemd. artikel 5.1, lid werkt niet meer bij de NVWA, kunnen jullie dit wijzigen in ir. art. 5.1.2.e Woo ?

Ik begrijp uit het aanvraagformulier dat het gaat om een nog niet toegelaten middel. Zou je ons ook de GAP en het WG kunnen toesturen, dit hebben we nodig om de juiste alternatieven in kaart te kunnen brengen.

Alvast bedankt

Groet art. 5.1.2.e

art. 5.1.2.e Woo
Senior beleidsmedewerker, Coördinator Kleine Toepassingen en Advies Plantgezondheid / Senior Officer Plant Health, Manager Minor Uses, ...

Afdeling Beleid
Divisie Landbouw en Natuur /Division Agriculture and Nature Nederlandse Voedsel- en Warenautoriteit /Netherlands Food and Product Safety Authority Catharijnesingel 59 | 3511 GG | Utrecht, The Netherlands Postbox 43006 | 3540 AA | Utrecht, The Netherlands
.....
art. 5.1.2.e Woo

M art. 5.1.2.e Woo
email: art. 5.1.2.e Woo@nvwa.nl<mailto art. 5.1.2.e Woo@nvwa.nl>
.....
art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo
Verzonden: dinsdag 13 juni 2017 12:06
Aan: art. 5.1.2.e Woo
Onderwerp: Documenten uit OpenIMS DMS

Beste art. 5.1.2.e,

Ik wil graag een opdracht verstrekken aan de NVWA voor het uitvoeren van een Comparative Assessment.
De contactpersoon hiervoor is art. 5.1.2.e Woo. Zij is echter afwezig tot begin juli.
Zou jij kunnen zorgen dat deze e-mail bij de juiste persoon terecht komt, of kan je mij zeggen naar wie ik het kan sturen?
Ik heb het opdrachtformulier als bijlage toegevoegd, evenals een door de aanvrager ingevuld CA-formulier.
De opdracht zal ook per post worden verstuurd.

Bedankt en vriendelijke groeten,

art. 5.1.2.e Woo

Ir. art. 5.1.2.e Woo
Projectleider Gewasbescherming
Ctgb
College voor de toelating van gewasbeschermingsmiddelen en biociden Board for the Authorisation of Plant Protection Products and Biocides Bezoekadres / visiting address:
Bennekomseweg 41, NL6717 LL Ede
Type voor navigatie Hora park in
Postadres / postal address:
Postbus / P.O. box 8030, NL6710 AA Ede, The Netherlands art. 5.1.2.e Woo F art. 5.1.2.e Woo I www.ctgb.nl<http://www.ctgb.nl/> Niet aanwezig op woensdag Not at the office on Wednesday

ctgb

College voor de toelating van gewasbeschermingsmiddelen en biociden

NVWA
Ingekomen: 14 JUNI 2017
Registratienr. trcvwa/2017/5131
Behandelaar: art. 5.1.2.e. Woo
Afgedaan dd: 30/6 pa art. 5.1.2.e. Wo

NVWA Divisie Plant
T.a.v. de heer ir. art. 5.1 2 e. Woo ,
afdelingshoofd van de Afdeling Beleid
Postbus 9102
6700 HC WAGENINGEN

Briefnummer	201611240073
Behandeld door	art. 5.1 2.e. Woo;
Telefoonnummer	art. 5.1.2.e. Wo
Betreft	Opdracht voor landbouwkundige beoordeling Ascernity , aanvraagnummer 20170266 ZTG o.b.v. benzovindiflupyr en difenoconazole,opdrachtnummer 201611240073
Datum	13 juni 2017

ontv. dd -3 JUL 2017
no. CTB

Geachte heer art. 5.1.2.e. Woo ,

Het Ctgb en NVWA werken samen op het gebied de uitvoering van comparative assessments, conform Verordening (EG) nr. 1107/2009 art. 50.

Hierbij verleen ik u opdracht tot het verrichten van de werkzaamheden conform de offerte:
trcvwa /2016/1385.

Omschrijving van de werkzaamheden:
Bij de aanvraag voor het middel: Ascernity, 20170266 ZTG, . benzovindiflupyr en difenoconazole wordt een comparative assessment uitgevoerd.

De comparative assessment dient te worden uitgevoerd voor het volgende gebruik:
- Sportveld (exclusief golfterrein)

U wordt verzocht voor dit gebruik een landbouwkundige beoordeling uit te voeren.
Als bijlage bij deze brief is het formulier voor comparative assessment, ingevuld door de aanvrager, bijgevoegd.
Voor de beoordeling gelieve de template van de NVWA te gebruiken (Comparative Assessment Format LV 0.2).

De eindconclusie van de landbouwkundige beoordeling dient in een beknopte samenvatting duidelijk te worden aangegeven. Hierin is opgenomen welke alternatieven middelen zijn overwogen en waarom die al dan niet als volwaardig alternatief kunnen worden beschouwd.

Bennekomseweg 41
6717 LL Ede

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6710 AA Ede

t (0317) 471 810

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IBAN NL27RABO0397076053
SWIFT/BIC RABONL2U
KvK 092125700000

Wilt u aangegeven op welk moment (Step 6-11) gestopt kan worden met CA, omdat er geen alternatieve middelen gevonden zijn?

De projecturen bedragen maximaal 6 uur.

Het rapport ontvang ik uiterlijk 13 augustus, onder vermelding van bovengenoemd opdrachtnummer en aanvraagnummer.

Ter bevestiging van deze opdracht ontvang ik graag binnen een week na dagtekening een getekend exemplaar retour.

Als u inhoudelijke vragen heeft over deze opdracht, kunt u rechtstreeks met mij contact opnemen.

Akkoord,	Akkoord,
art. 5.1.2.e. Woo	art. 5.1.2.e. Woo
Projectleider	Naam opdrachtnemer
art. 5.1.2.e. Woo	art. 5.1.2.e. Woo

Met vriendelijke groet,

Het College voor de toelating van gewasbeschermingsmiddelen en biociden,
voor deze:
de secretaris/directeur,
voor deze:

art. 5.1.2.e. Woo
Projectleider

Annex I. Applicant information to support the process of comparative assessment

(no information is needed when the product doesn't contain a Candidate for Substitution)
(8 April 2016)

National addendum to the draft Registration Report (dRR)

Country	Netherlands
Product under evaluation	Ascernity (internal code A19188B)
Candidate for substitution (active substance name)	Difenoconazole and benzovindiflupyr
Reasons for approval as candidate for substitution (delete as appropriate).	Difenoconazole: persistent and toxic Benzovindiflupyr: persistent and toxic

Step 1. Is this application intended for a mutual recognition, derived authorisation or parallel trade permit?
If yes, no further information is needed > **stop CA.**
If no, go to step 2
No

Step 2. Is this product only destined for non-professional users ?
If yes, no further information is needed > **stop CA.**
If no, go to step 3
No

Step 3. Do you want to make use of the derogation in Article 50(3) for uses where it is necessary to acquire experience first through using that product in practice?
If yes, please state your reasons. Then > **stop CA.**
If no, go to step 4
No

Step 4. Is this product only destined or applied for minor use(s) according art 51 or NLKUG? (Minor Uses are defined in the list of Minor Uses).
If yes, no further information is needed > **stop CA.**
If no, go to step 5
No

Step 5. Does your application include a minor use?
If you apply for a minor use according art 51 or NLKUG or a minor use has been authorised (according art 51 or NLKUG) for the product, please indicate the minor uses (Minor Uses are defined in the list of Minor Uses).

If not, go to step 6

Yes, golf course (green & tees)

Step 6. What are the major uses of your product to be considered in a comparative assessment?
Please indicate the major uses in the tables under step 7, 8 and 9.

Disease control in sport fields excluding golf courses: Anthracnose, Fusarium patch, Dollarspot

Step 7. Alternative authorised plant protection products with the same mode of action:
Is there an alternative authorised product with the same mode of action available for the major uses?
If yes, go to step 10. If the conclusion of step 10 is: it's no alternative, then go further to step 8.
If no, go to step 8.

No

Ascernity is a combination product containing difenoconazole and benzovindiflupyr. Difeconazole belongs to the demethylation inhibitors (mode of action: demethylase in sterol biosynthesis, RAC group n°3). Benzovindiflupyr belongs to the succinate dehydrogenase inhibitors (mode of action: respiration, RAC group n° 7). In the Dutch market there is no product registration for the same uses combining these two mode of actions.
One solo product is registered belonging to the demethylation inhibitors (product name Caramba) but no solo product is registered belonging to the succinate dehydrogenase inhibitors. As consequence it is not possible to mix individual products having the same mode of actions in the tank in order to mimic the ready-to-use product Ascernity. Even if there is no ready to use product registered, mimicing it by combining the individual products with the same mode of actions is not possible either.

To conclude: no alternative authorised product with the same mode of actions are available in the Dutch market.

Step 8. Alternative authorised plant protection products with their mode of action:
Please indicate all alternative authorised products for the major uses and their modes of action, including the product under consideration in the table below.
Please, mention the number of modes of action per crop-pest combination.

Crop	Pest	Product	Active substance	Mode of Action	RAC-code	Total number of modes of actions per crop/pest combination
Sport fields	*Microdochium nivale* (MONGNI)	Signum	Boscalid	C: Respiration	7	4
			Pyraclostrobin	C: Respiration	11	
		Chipco Green	Iprodione	E: Signal transduction	2	
		Interface	Iprodione	E: Signal transduction	2	
			Trifloxystrobin	C: Respiration	11	

		Heritage	Azoxystrobin	C: Respiration	11	
		Caramba	Metconazole#	G1: C14-demethylase in sterol biosynthesis	3	
	Colletotrichum graminicola (COLLGR)	Signum	Boscalid	C: Respiration	7	2
			Pyraclostrobin	C: Respiration	11	
	Sclerotinia homoeocarpa (SCLEHO)	Signum	Boscalid	C: Respiration	7	3
			Pyraclostrobin	C: Respiration	11	
		Chipco Green	Iprodione	E: Signal transduction	2	
		Interface	Iprodione	E: Signal transduction	2	
			Trifloxystrobin	C: Respiration	11	

Active ingredient included on the list of Candidates for substitution

Step 9. What other options (non-chemical methods) are available for the proposed uses to be assessed?

For all uses, please consider non-chemical alternatives in general or use by use, as appropriate. Indicate chemical alternatives under step 6.

Crop	Pest	Alternative	description of method
There are currently no non-chemical alternatives available for the control of Fusarium patch (Microdochium nivale, MONGNI), Dollar spot (Sclerotinia homoeocarpa; SCLEHO) or Anthracnose (Colletotrichum graminicola, COLLGR) in sport fields other than cultural control methods.			

Are there 5 or more modes of action available for a use (including non-chemical methods)?

If yes, go to step 10

If no > **stop CA** No

Step 10. Can the alternative products with the same mode of application and/or control methods be used without significant economic and practical disadvantages to the user ?

Please indicate significant economic and practical disadvantages (including mode of application, or difference in mitigation measures or ....) of using the alternative controls identified under step 7 and 8.

Alternative	Describe disadvantages per alternative in general or per use	Conclusion; Yes or no

		alternative
Methods	n/a	
Products		
Chipco Green Signum Heritage Interface Caramba	The currently registered products have four mode of actions for the target disease MONGNI, 2 mode of actions for the target disease COLLGR and 3 mode of actions for the target disease SCLEHO. In order to have an optimized resistance management for all targeted diseases more mode of actions are needed for a sustainable resistance management.	No

Step 11. Consideration of consequences on minor uses (Art 50.1(d))
What would the consequences on the minor uses be if your product is replaced by a safer alternative product for any/some/all of those uses?
Examples of information that may be useful to consider here includes but is not limited to: the minor uses involved and the alternative products available for them; significance of the pest to the growing of those minor crops; usage data for both major and minor crops; marketing/sales/other commercial data of relevance to your product.

Step 12. Please indicate any other relevant information that will enable a comparison of risk.

Criteria low ADI/ARfD: see *Appendix I* of the Evaluation Manual, *General introduction and Generic aspects*, on how the comparative assessment will be conducted. This information can be used to provide a comparative assessment for this criteria.

Criteria low AOEL, classified Carcinogen 1A or 1B; classified as toxic for reproduction 1A or 1B; endocrine disruption; other reasons for concern: see *Appendix I* of the Evaluation Manual, *General introduction and Generic aspects* on how the comparative assessment will be conducted. This information can be used to provide a comparative assessment for this criteria.

Criteria PBT: see *Appendix I* of the Evaluation Manual, *General introduction and Generic aspects* on how the comparative assessment will be conducted. This information can be used to provide a comparative assessment for this criteria.

Evaluatieformulier evaluerende instantie

Opdrachtnummer	201611240073
Aanvraagnummer	20170266 ZTG
Middelnaam	Ascernity
Behandelaar	[redacted]

Offertevraag duidelijk ja □ nee □
Opmerking

Opdrachtstelling duidelijk ja □ nee □
Opmerking

Bijlage bij opdracht compleet ja □ nee □
Opmerking

Nazorg binnen gestelde termijn ja □ nee □
Opmerking

Wij verzoeken u dit formulier mee te zenden samen met de definitieve rapportage.

ctgb

Bijlage I.

	Omschrijving
1	Formulier CA Ascernity , ingevuld door de aanvrager

Van: art. 5.1.2.e Woo ing. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Verzonden: dinsdag 10 oktober 2017 11:16
Aan: art. 5.1.2.e Woo <art. 5.1.2.e Woo@ctgb.nl>
CC: art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Onderwerp: Oplevering CA Ascernity 201709110043 - 20170266ZTG

Beste art. 5.1.2.e W,

Hierbij de door de NVWA uitgevoerde landbouwkundige vergelijking voor Ascernity. Conform opdracht zullen 6 uur in rekening worden gebracht voor de uitgevoerde werkzaamheden.

Mochten er naar aanleiding van de landbouwkundige vergelijking nog vragen zijn dan hoor ik dat graag.

Met vriendelijke groeten,

art. 5.1.2.e Woo
Beleidsmedewerker plantgezondheid
……
Directie Handhaven
Divisie Regie & expertise
Afdeling Expertise
Nederlandse Voedsel- en Warenautoriteit
Catharijnesingel 59 | 3511 GG | Utrecht
Postbus 43006 | 3540 AA | Utrecht
……
T art. 5.1.2.e Woo
art. 5.1.2.e Woo@nvwa.nl
http://www.nvwa.nl

Agricultural aspects of Comparative assessment
National Plant Protection Organization the Netherlands

Subject	:	NPPO evaluation of the agricultural aspects of Comparative assessment of Ascernity
Document number	:	clv17Ascernity
Principal	:	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
Reference Ctgb	:	201709110043 - 20170266ZTG
Contact	:	art. 5.1.2.e Woo
Address	:	P.O. Box 8030 6710 AA Ede The Netherlands

Our reference	:	Ing. art. 5.1.2.e Woo
Telephone	:	art. 5.1.2.e Woo
Date	:	10-10-2017
Number of pages	:	6

The NPPO has compiled this Comparative Assessment of agricultural aspects with the greatest care and to the best of its current knowledge, acting in full conformity with the criteria and guidelines of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

The NPPO can accept no liability for any harmful consequences, whatever their nature, that may result from these evaluations or their application.

It should also be noted that the Ctgb is the sole body in the Netherlands qualified to decide on requests for the authorisation of pesticides.

NPPO evaluation of the agricultural aspects of Comparative assessment

National addendum to the draft Registration Report (dRR)

1. General information

Country	Netherlands
Name applicant	Syngenta Crop Protection BV
Product under evaluation	Ascernity (internal code A19188B)
Candidate for substitution (active substance name)	difenoconazole and benzovindiflupyr
Reasons for approval as candidate for substitution (delete as appropriate).	difenoconazole: two of PBT benzovindiflupyr: two of PBT
Formulation and content	SL (78.8 g/L difenoconazole, 23.6 g/L benzovindiflupyr)
Mode of action	difenoconazole: demethylase in sterol biosynthesis benzovindiflupyr: succinate-dehydro-genase inhibitor
FRAC-code	difenoconazole: 3 benzovindiflupyr: 7

2. Claim Major uses/minor uses

The proposed use of Ascernity is a fungicide for professional use applied as a foliar application in the following uses:

Major uses

Crop	Disease	Maximum number of applications per 12 months	Minimum interval between spray applications in days	Pre harvest interval in days
Golf courses: greens and tees	Fusarium patch (*Monographella nivalis*)	2	14	n.a.
	Dollar spot (*Sclerotinia homoeocarpa*)			
	Anthracnose (*Colletotrichum graminicola*)			

Proposed restrictions
Only apply on sports fields older than 1 year.
Apply with 125-500 litre water per ha.

To protect aquatic organisms application is only permitted under one of the following restrictions:

- minimal 50% drift reducing spray nozzles, considering a spray free zone of at least 1 metre;
- minimal 90% drift reducing spray nozzles, considering a spray free zone of at least 0.5 metre.

3. Characteristics of the product (PPP)

Ascernity is a fungicide containing difenoconazole and benzovindiflupyr. Difenoconazole belongs to the demethylation inhibitors (FRAC group 3) and benzovindiflupyr belongs to the succinate dehydrogenase inhibitors (FRAC group 7). Difenoconazole and benzovindiflupyr are transported systemically in the plant. Difenoconazole has preventive and curative action against fungal diseases. Benzovindiflupyr has preventive action against fungal diseases.

4. Comparative assessment of agricultural aspects

This assessment follows a step-wise approach which contains three area's (see chapters 4.1., 4.2. and 4.3.). As described in the EU Guidance document on comparative assessment the process may be terminated at any stage and it may not be necessary to continue through the whole scheme. In that case the CA-process can be finalized by filling in the final conclusions (chapter 5). If not, all steps have to be completed.

Where there are reasons to believe at the start of the comparative assessment that there might be a problem in a certain area, it may be useful to start the assessment in that particular area.

4.1. Conclusion alternatives available per use regarding limitations in the use (effectiveness, practical and/or economical disadvantages)

An assessment of the alternatives available per use was not considered because the CA-process was stopped in chapter 4.2.

4.2. Conclusion alternatives available per use regarding the risk of developing resistance (major uses)

An overview of all alternatives, both chemicals (date: 26-09-2017) and non-chemical methods, for the proposed major uses of Ascernity can be found in annexes I and II.

Table 1: Conclusions of availability of alternatives regarding resistance risk

Crop	Pest	Conclusion NPPO	Name(s) of alternative(s)
Golf courses: greens and tees	Anthracnose (*Colletotrichum graminicola*)	Ascernity is a component of the resistance management strategy for the control of Anthracnose. Although the number of mode of action groups with Ascernity increases from three to four, it is still less than five*: stop CA.	See Annex I
	Fusarium patch (*Monographella nivalis*)	CA was stopped because Ascernity is considered as a component of the resistance management strategy for the control of Anthracnose.	n.a.
	Dollar spot (*Sclerotinia homoeocarpa*)	CA was stopped because Ascernity is considered as a component of the resistance management strategy for the control of Anthracnose.	n.a.

* In The Netherlands it was decided that for a sustainable resistance management at least five mode of action groups are necessary.

4.3. Conclusions consequences for minor uses

Not applicable, because no minor uses are involved.

5. Overall NPPO conclusion on agriculture aspects

Substitution is not possible for the following uses of the CfS:

Crop	Pest	Conclusion NPPO
Golf courses: greens and tees	Anthracnose (*Colletotrichum graminicola*)	Substitution is not possible because Ascernity is a component of the resistance management strategy for the control of Anthracnose.
	Fusarium patch (*Monographella nivalis*)	CA was stopped because Ascernity is considered as a component of the resistance management strategy for the control of Anthracnose.
	Dollar spot (*Sclerotinia homoeocarpa*)	CA was stopped because Ascernity is considered as a component of the resistance management strategy for the control of Anthracnose.

Annex I: Alternative authorised plant protection products in the Netherlands
An overview of chemicals alternatives (date: 26-09-2017), for the proposed major uses of Ascernity.

Crop	Pest/ disease/ weed	Product	Active substance	FRAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
Golf greens	Anthracnose (*Colletotrichum graminicola*)	Signum (12630)	boscalid	7	n.a.*	n.a.*	Yes**
			pyraclostrobin	11			
Golf greens, fairways and tees	Anthracnose (*Colletotrichum graminicola*)	Chipco green (13818)	iprodion	2	n.a.*	n.a.*	Yes**
Golf courses: greens and tees	Fusarium patch (*Monographella nivalis*)	CA was stopped because Ascernity is considered as a component of the resistance management strategy for the control of Anthracnose.					
Golf courses: greens and tees	Dollar spot (*Sclerotinia homoeocarpa*)	CA was stopped because Ascernity is considered as a component of the resistance management strategy for the control of Anthracnose.					

* see conclusion chapter 4.1.
** Less than five different resistance groups are available against Anthracnose. See conclusion chapter 4.2.

Annex II: Alternative non-chemical methods

An overview of non-chemicals alternatives (date: 26-09-2017), for the proposed major uses of Ascernity. Each suitable alternative non-chemical method regarding resistance management counts as one resistance group.

Crop	Pest/ disease/ weed	alternative	description	Assessment NPPO regarding limits in the use	Alternative regarding limits in the use	Alternative regarding resistance management
Golf courses: greens and tees	Anthracnose (*Colletotrichum graminicola*)	Good drainage	Wet soil conditions can improve disease development of funguses. Good drainage can provide a good state of moisture in the soil preventing disease development of funguses.	This method is only beneficial.	No	No
		Low N and high K application	A low N and K application results in strong and vigorous plants with a low vulnerability for diseases.	This method is only beneficial.	No	No
		Resistant/ tolerant cultivars	Using resistant cultivars is an effective control measure. However, because most cultivars are grown for their specific characteristics, choosing resistant cultivars is not always feasible.	This method is not always feasible.	No	No
		Scarifying	Scarifying can result in more air and light between the grass resulting in less favourable conditions for fungal diseases.	This method is only beneficial.	No	No
		Sweeping	With a sweeping system the morning dew on greens and tees can be removed resulting in less favourable conditions for fungal diseases.	This method is only beneficial.	No	No
Golf courses: greens and tees	Fusarium patch (*Monographella nivalis*)	CA was stopped because Ascernity is considered as a component of the resistance management strategy for the control of Anthracnose.				
Golf courses: greens and tees	Dollar spot (*Sclerotinia homoeocarpa*)	CA was stopped because Ascernity is considered as a component of the resistance management strategy for the control of Anthracnose.				

NVWA
T.a.v. Dhr. ir. art. 5.1.2.e Woo
Postbus 43006
3540 AA UTRECHT

Datum 8 mei 2020

Behandeld door
Mr. drs. art. 5.1.2.e Woo

Telefoonnummer
art. 5.1.2.e Woo

E-mail
art. 5.1.2.e Woo @ctgb.nl

Kenmerk
202004030195

Betreft Opdracht voor comparative assessment LATIFAM EXTRA 20191104

Geachte heer art. 5.1.2.e Woo,

Het Ctgb en NVWA werken samen op het gebied de uitvoering van comparative assessments, conform Verordening (EG) nr. 1107/2009 art. 50.

Hierbij verleen ik u opdracht tot het verrichten van de werkzaamheden conform de offerte: trcvwa /2016/1385.

Omschrijving van de werkzaamheden:
Bij de aanvraag voor het middel: LATIFAM EXTRA, 20191104 NLTG, wordt een comparative assessment uitgevoerd.

De comparative assessment dient te worden uitgevoerd voor de volgende gebruiken:
- wintertarwe
- wintergerst
- triticale
- spelt
- zomertarwe
- zomergerst

U wordt verzocht voor deze zes gebruiken een landbouwkundige beoordeling uit te voeren. Als bijlage bij deze brief is het formulier voor comparative assessment en de template voor de beoordeling bijgevoegd.

De eindconclusie van de landbouwkundige beoordeling dient in een beknopte samenvatting duidelijk te worden aangegeven. Hierin is opgenomen welke

alternatieven middelen zijn overwogen en waarom die al dan niet als volwaardig alternatief kunnen worden beschouwd.

Wilt u per toepassing aangegeven op welk moment (Step 6-11) gestopt kan worden met CA, omdat er geen alternatieve middelen gevonden zijn?

De projecturen bedragen maximaal 36 uur.

Het rapport ontvang ik uiterlijk **11 juni 2020**, onder vermelding van bovengenoemd aanvraagnummer. Wilt u contact opnemen met de projectleider als deze datum niet haalbaar is?

Ter bevestiging van deze opdracht ontvang ik graag binnen een week na dagtekening een getekend exemplaar retour.

Als u inhoudelijke vragen heeft over deze opdracht, kunt u rechtstreeks met de projectleider, Mr. drs. art. 5.1.2.e Woo, contact opnemen.

Akkoord,
Het College voor de toelating van gewasbeschermingsmiddelen en biociden,
voor deze:
de secretaris,
voor deze:

art. 5.1.2.e Woo

dr. ir. art. 5.1.2.e Woo,
art. 5.1.2.e Woo

Akkoord,

Dhr. ir. art. 5.1.2.e Woo

Bijlagen:
- formulier comparative assessment voor dit middel;
- beoordelingstemplate comparative assessment
- WG
- GAP

Agricultural aspects of Comparative assessment
National Plant Protection Organization the Netherlands

Subject	:	NPPO evaluation of the agricultural aspects of Comparative assessment of
Document number	:	clv17…
Active substance	:	
Principal	:	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
Reference Ctgb	:	
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Address	:	P.O. Box 8030 6710 AA Ede the Netherlands
Our reference	:	
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Date	:	
Number of pages	:	

The NPPO has compiled this Comparative Assessment of agricultural aspects with the greatest care and to the best of its current knowledge, acting in full conformity with the criteria and guidelines of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

The NPPO can accept no liability for any harmful consequences, whatever their nature, that may result from these evaluations or their application.

It should also be noted that the Ctgb is the sole body in the Netherlands qualified to decide on requests for the authorisation of pesticides.

NPPO evaluation of the agricultural aspects of Comparative assessment

National addendum to the draft Registration Report (dRR)

1. General information

Country	
Name applicant	
Product under evaluation	
Candidate for substitution (active substance name)	
Reasons for approval as candidate for substitution (delete as appropriate)	low ADI, ARfD or AOEL; two of PBT; significant proportion of non-active isomers; classified Carcinogen 1A or 1B; classified as toxic for reproduction 1A or 1B; endocrine disruption; other reasons for concern
Formulation and content	
Mode of action	
IRAC-code	

2. Claim Major uses/minor uses

The proposed use of [CfS] is an [insecticide/herbicide/fungicide] for professional use applied as … application in the following uses:

Major uses

Crop	Pest/disease/weed	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days

Minor uses

Crop	Pest/disease/weed	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days

Proposed restrictions

……

3. Characteristics of the product (PPP)

Short written explanation of the PPP which contains the following info:

- Insecticide/fungicide/herbicide
- Working mechanism (e.g. contact, systemic, behaviour in/on plant)
- IRAC, HRAC, FRAC group
- Additional info which is helpful/necessary for the assessment (e.g. safe or not safe to bees, application restrictions)

4. Comparative assessment of agricultural aspects

This assessment follows a step-wise approach which contains three area's (see chapters 4.1., 4.2. and 4.3.). As described in the EU Guidance document on comparative assessment the process may be terminated at any stage and it may not be necessary to continue through the whole scheme. In that case the CA-process can be finalized by filling in the final conclusions (chapter 5). If not, all steps have to be completed.

Where there are reasons to believe at the start of the comparative assessment that there might be a problem in a certain area, it may be useful to start the assessment in that particular area.

4.1. Conclusion alternatives available per use regarding limitations in the use (effectiveness, practical and/or economical disadvantages)

An overview of all alternatives, both chemicals (date: [dd-mm-yyyy]) and non-chemical methods, for the proposed major uses of [CfS] can be found in annexes I and II.

Crop	Pest	Conclusion NPPO*

* Conclusion:
1. Alternatives available: [names of products]
2. No chemical alternatives with a comparable use available, and no comparable non-chemical alternatives: stop CA
3. Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
4. Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.3.

4.2. Conclusion alternatives available per use regarding the risk of developing resistance (major uses)

An overview of all alternatives, both chemicals (date: [dd-mm-yyyy]) and non-chemical methods, for the proposed major uses of [CfS] can be found in annexes I and II.

Crop	Pest	Conclusion NPPO*	Name(s) of alternative(s)**

* Conclusion:

1. There is an alternative with the same mode of action as the candidate.
2. The alternatives together have more than 5 different modes of action.
3. Insufficient alternatives available stop CA.
4. Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.
5. Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.3.

** When conclusion 1 is applicable provide the name of the alternative. When conclusion 2 is applicable provide the names of the alternatives. When conclusion 3, 4 or 5 is applicable this column can be left blank.

4.3. Conclusions consequences for minor uses

Option 1: Assessment regarding consequences for minor uses is not considered because substitution is not possible for any of the proposed major uses.

Option 2: Substitution is not possible for … of [CfS] because of the consequences for minor uses.

5. Overall NPPO conclusion on agriculture aspects

For the following uses [CfS] can be substituted by alternatives listed below.

Crop	Pest/disease	Alternative PPP	Registration number	Active substance

Substitution is not possible for the following uses of the CfS:

Crop	Pest/disease	Conclusion NPPO*

*Conclusion:

- Substitution is not possible for the following uses of the CfS because of lack of alternatives
- Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
- Substitution is not possible for the following uses of the CfS because of the consequences for minor uses

Annex I: Alternative authorised plant protection products in the Netherlands
An overview of chemicals alternatives (date: dd-mm-yyyy), for the proposed major uses of [CfS].

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management

Annex II: Alternative non-chemical methods

An overview of non-chemicals alternatives (date: dd-mm-yyyy), for the proposed major uses of [CfS].

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding limits in the use	Alternative regarding resistance management

Van: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Verzonden: maandag 25 mei 2020 11:07
Aan: art. 5.1.2.e Woo, drs. art. 5.1.2.e Woo <art. 5.1.2.e Woo@ctgb.nl>
CC: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Onderwerp: RE: Opdracht voor comparative assessment LATIFAM EXTRA 20191104

Beste art. 5.1.2.e Woo,
Zie bijgevoegd de getekende opdrachtbrief voor Latifam Extra.
Vriendelijke groet,
art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo
Verzonden: woensdag 13 mei 2020 15:31
Aan: art. 5.1.2.e Woo@ctgb.nl'
CC: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo
Onderwerp: Opdracht voor comparative assessment LATIFAM EXTRA 20191104
Beste art. 5.1.2.e Woo,
Bedankt voor de opdracht voor het uitvoeren van een CA voor LATIFAM EXTRA. In de opdrachtbrief wordt gevraagd de CA uit te voeren voor winter- en zomertarwe, winter- en zomergerst, triticale en spelt. Aangezien triticale en spelt kleine teelten zijn in Nederland zullen we hier, conform afspraak, geen CA beoordeling voor uitvoeren. Wel betreft het twee ziektes per gewas (Tarwehalmdoder en Fusarium) waarmee het aantal te beoordelen toepassingen op acht i.p.v. zes komt. Ik wil voorstellen om het aantal te besteden uren op maximaal 36 te laten staan.
Wij gaan ons best doen om voor de aangegeven deadline op te leveren.
Ter info: in de opdrachtbrief wordt verwezen naar offerte: trcvwa /2016/1385. Er is ondertussen een nieuwe overeenkomst tussen Ctgb en NVWA voor het uitvoeren van deze werkzaamheden (voor de periode 2020-2022) met referentie NVWATRC/20201895. Hier kan in het vervolg naar worden verwezen.
Ik hoop je hiermee voldoende geïnformeerd te hebben. I.v.m. vakantie wordt de opdrachtbrief volgende week door art. 5.1.2. ondertekend.
Met vriendelijke groet,
art. 5.1.2.e Woo
Beleidsmedewerker plantgezondheid

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Divisie Regie & expertise
Afdeling Expertise
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NVWA
T.a.v. Dhr. ir. art. 5.1.2.e Woo
Postbus 43006
3540 AA UTRECHT

Datum 8 mei 2020

Behandeld door
Mr. drs. art. 5.1.2.e Woo

Telefoonnummer
art. 5.1.2.e Woo

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art. 5.1.2.e Woo @ctgb.nl

Kenmerk
202004030195

Betreft Opdracht voor comparative assessment LATIFAM EXTRA 20191104

Geachte heer art. 5.1.2.e Woo,

Het Ctgb en NVWA werken samen op het gebied de uitvoering van comparative assessments, conform Verordening (EG) nr. 1107/2009 art. 50.

Hierbij verleen ik u opdracht tot het verrichten van de werkzaamheden conform de offerte: trcvwa /2016/1385.

Omschrijving van de werkzaamheden:
Bij de aanvraag voor het middel: LATIFAM EXTRA, 20191104 NLTG, wordt een comparative assessment uitgevoerd.

De comparative assessment dient te worden uitgevoerd voor de volgende gebruiken:
- wintertarwe
- wintergerst
- triticale
- spelt
- zomertarwe
- zomergerst

U wordt verzocht voor deze zes gebruiken een landbouwkundige beoordeling uit te voeren. Als bijlage bij deze brief is het formulier voor comparative assessment en de template voor de beoordeling bijgevoegd.

De eindconclusie van de landbouwkundige beoordeling dient in een beknopte samenvatting duidelijk te worden aangegeven. Hierin is opgenomen welke

alternatieven middelen zijn overwogen en waarom die al dan niet als volwaardig alternatief kunnen worden beschouwd.

Wilt u per toepassing aangegeven op welk moment (Step 6-11) gestopt kan worden met CA, omdat er geen alternatieve middelen gevonden zijn?

De projecturen bedragen maximaal 36 uur.

Het rapport ontvang ik uiterlijk **11 juni 2020**, onder vermelding van bovengenoemd aanvraagnummer. Wilt u contact opnemen met de projectleider als deze datum niet haalbaar is?

Ter bevestiging van deze opdracht ontvang ik graag binnen een week na dagtekening een getekend exemplaar retour.

Als u inhoudelijke vragen heeft over deze opdracht, kunt u rechtstreeks met de projectleider, Mr. drs. art. 5.1.2.e Woo, contact opnemen.

Akkoord,
Het College voor de toelating van gewasbeschermingsmiddelen en biociden,
voor deze:
de secretaris,
voor deze:

art. 5.1.2.e Woo

dr. ir. art. 5.1.2.e Woo ,

art. 5.1.2.e Woo

Akkoord,

art. 5.1.2.e Woo

Dhr. ir. art. 5.1.2.e Woo

Bijlagen:
- formulier comparative assessment voor dit middel;
- beoordelingstemplate comparative assessment
- WG
- GAP

Van: art. 5.1.2 e Woo, ir. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Verzonden: dinsdag 2 juni 2020 15:55
Aan: art. 5.1.2.e Woo, drs. art. 5.1.2.e Woo <art. 5.1.2.e Woo@ctgb.nl>
CC: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Onderwerp: Oplevering CA Latifam extra

Beste art. 5.1.2.e Woo,

Hierbij de door de NVWA uitgevoerde landbouwkundige vergelijking in het kader van Comparative Assessments voor Latifam extra

Mochten er naar aanleiding van de landbouwkundige vergelijking nog vragen zijn dan hoor ik dat graag.

Met vriendelijke groet,
art. 5.1.2.e Woo

art. 5.1.2.e Woo
Ir. art. 5.1.2.e Woo
Senior beleidsmedewerker plantgezondheid
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Netherlands Food and Consumer
Product Safety Authority
Ministry of Agriculture,
Nature and Food Quality

Agronomic aspects of Comparative assessment

National Plant Protection Organization the Netherlands

Subject	:	NPPO evaluation of the agronomic aspects of Comparative assessment of
Document number	:	Clv20_Latifam_Extra_def
Active substance	:	Fludioxonil, silthiofam
Principal	:	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
Reference Ctgb	:	
Contact	:	Hr. art. 5.1.2.e Woo
Address	:	P.O. Box 8030 6710 AA Ede the Netherlands
Date	:	2 June 2020
Number of pages	:	11

The NPPO has compiled this Comparative Assessment of agronomic aspects with the greatest care and to the best of its current knowledge, acting in full conformity with the criteria and guidelines of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

The NPPO can accept no liability for any harmful consequences, whatever their nature, that may result from these evaluations or their application.

It should also be noted that the Ctgb is the sole body in the Netherlands qualified to decide on requests for the authorisation of pesticides.

NPPO evaluation of the agronomic aspects of Comparative assessment

National addendum to the draft Registration Report (dRR)

1. General information

Country	The Netherlands
Product under evaluation	Latifam Extra
Candidate for substitution (active substance name)	fludioxonil
Formulation and content	FS, fludioxonil; 25 g/L, silthiofam; 125 g/L
Mode of action	Fludioxonil; signal transduction, silthiofam; respiration inhibition
FRAC-code	Fludioxonil; 12, silthiofam; 38

2. Claim Major uses/minor uses

The proposed use of Latifam Extra is an fungicide for professional use applied as seed treatment application in the following uses:

Table 1: Overview of major uses

Crop	Pest/disease/weed	Maximum number of applications per crop/season	Minimum interval between applications in days	Pre harvest interval in days
Winter wheat	Gaeumannomyces graminis var. tritici, Fusarium spp.	1	n.a.	n.a.
Spring wheat	Gaeumannomyces graminis var. tritici, Fusarium spp.	1	n.a.	n.a.
Winter barley	Gaeumannomyces graminis var. tritici, Fusarium spp.	1	n.a.	n.a.
Spring barley	Gaeumannomyces graminis var. tritici, Fusarium spp.	1	n.a.	n.a.

Table 2: Overview of minor uses

Crop	Pest/disease/weed	Maximum number of applications per crop/season	Minimum interval between applications in days	Pre harvest interval in days
Triticale	Gaeumannomyces graminis var. tritici, Fusarium spp.	1	n.a.	n.a.
Spelt	Gaeumannomyces graminis var. tritici, Fusarium spp.	1	n.a.	n.a.

Proposed legal restrictions
Treated seeds may not be used for human or animal consumption.

For treatment of winter wheat, spring wheat, winter barley, spring barley, triticale and spelt apply the product in 200-800 ml water per 100 kg sowing seed.

3. Characteristics of the product (PPP)

Latifam Extra is a fungicide, based on the active substances fludioxonil and silthiofam. It is used for seed treatment. Fludioxonil acts via signal transduction (not systemically) and has FRAC code 12. Silthiofam acts via respiration inhibition and has FRAC code 38.

4. Comparative assessment of agronomic aspects

This assessment follows a step-wise approach which contains three stages (see chapters 4.1., 4.2. and 4.3.). As described in EPPO PP 1/271 (2) on efficacy aspects of comparative assessment, the process may be terminated at any stage and it may not be necessary to continue through the whole scheme. In that case the CA-process can be finalised by filling in the final conclusions (chapter 5). If not, all steps have to be completed.

The order in which each stage is considered, is based on considering the key issues likely to stop CA early in the process.

4.1. Efficacy and practical and/or economical disadvantages of the available alternative(s)

An overview of all alternatives, both chemicals (date: 22-05-2020) and non-chemical methods, for the proposed major uses of Latifam Extra can be found in annexes I and II.

Table 3: Conclusion on efficacy and practical and/or economical disadvantages of the available alternative(s) for each use

Crop	Pest	Conclusion NPPO
Winter wheat	Gaeumannomyces graminis var. tritici	No chemical and/or non-chemical alternatives available: stop CA
Winter wheat	Fusarium spp.	No chemical and/or non-chemical alternatives available: stop CA
Spring wheat	Gaeumannomyces graminis var. tritici	No chemical and/or non-chemical alternatives available: stop CA
Spring wheat	Fusarium spp.	No chemical and/or non-chemical alternatives available: stop CA
Winter barley	Gaeumannomyces graminis var. tritici	No chemical and/or non-chemical alternatives available: stop CA
Winter barley	Fusarium spp.	No chemical and/or non-chemical alternatives available: stop CA
Spring barley	Gaeumannomyces graminis var. tritici	No chemical and/or non-chemical alternatives available: stop CA
Spring barley	Fusarium spp.	No chemical and/or non-chemical alternatives available: stop CA

4.2. Impact on resistance risks

An overview of all alternatives, both chemicals (date: 22-05-2020) and non-chemical methods, for the proposed major uses of Latifam Extra can be found in annexes I and II.Every suitable non-chemical method counts as one mode of action.

Table 4: Overview of alternatives regarding the risk of development of resistance

Crop	Pest	RAC code(s) of alternatives	Total number of available MoAs	Conclusion NPPO	Name(s) of alternative(s)
Winter wheat	Gaeumannomyces graminis var. tritici	n.a.	n.a.	Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.	n.a.
Winter wheat	Fusarium spp.	n.a.	n.a.	Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.	n.a.
Spring wheat	Gaeumannomyces graminis var. tritici	n.a.	n.a.	Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.	n.a.
Spring wheat	Fusarium spp.	n.a.	n.a.	Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.	n.a.
Winter barley	Gaeumannomyces graminis var. tritici	n.a.	n.a.	Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.	n.a.
Winter barley	Fusarium spp.	n.a.	n.a.	Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.	n.a.
Spring barley	Gaeumannomyces graminis var. tritici	n.a.	n.a.	Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.	n.a.
Spring barley	Fusarium spp.	n.a.	n.a.	Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.	n.a.

4.3. Impact on existing minor uses

Assessment regarding consequences for minor uses is not considered because substitution is not possible for any of the proposed major uses.

5. Overall NPPO conclusion on agronomic aspects

Substitution is not possible for the following uses: Winter wheat, winter barley, spring wheat and spring barley (table 5).

Table 5: Uses of Latifam Extra that cannot be substituted

Crop	Pest/disease/weed	Conclusion NPPO
Winter wheat	Gaeumannomyces graminis var. tritici	No chemical and/or non-chemical alternatives available.
Winter wheat	Fusarium spp.	No chemical and/or non-chemical alternatives available.
Spring wheat	Gaeumannomyces graminis var. tritici	No chemical and/or non-chemical alternatives available.
Spring wheat	Fusarium spp.	No chemical and/or non-chemical alternatives available.
Winter barley	Gaeumannomyces graminis var. tritici	No chemical and/or non-chemical alternatives available.
Winter barley	Fusarium spp.	No chemical and/or non-chemical alternatives available.
Spring barley	Gaeumannomyces graminis var. tritici	No chemical and/or non-chemical alternatives available.
Spring barley	Fusarium spp.	No chemical and/or non-chemical alternatives available.

Annex I: Alternative authorised plant protection products in the Netherlands

An overview of chemicals alternatives (date: 22-05-2020), for the proposed major uses of Latifam Extra.

					Practical and/or economical disadvantages		**Resistance risk**	
Crop	Pest/ Disease/ Weed	Active substance	MOA	Product	Practical and/or economical disadvantages (e.g. according to the label)	Alternative without practical and/or economical disadvantages (Y/N)	RAC-code	Alternative regarding resistance (Y/N)
winter wheat	Gaeumannomyces graminis var. Tritici	silthiofam	Respiration	Latitude XL	Not authorized in groundwater safe guard zones	N	n.a.	n.a.
winter wheat	Fusarium spp.	prochloraz, tebuconazool	Sterol biosynthesis in membranes	AMPERA	Candidate for substitution	-	-	-
		bixafen, fluopyram, prothioconazool	Respiration, sterol biosynthesis in membranes	Ascra Xpro	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		bixafen, prothioconazool	Respiration, sterol biosynthesis in membranes	Aviator Xpro	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		metconazool	Sterol biosynthesis in membranes	CARAMBA	Candidate for substitution	-	-	-
		prothioconazool	Sterol biosynthesis in membranes	Curbatur EC 250	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		prothioconazool, trifloxystrobin	Sterol biosynthesis in membranes	DELARO	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		Benzovindiflupyr, prothioconazool	Respiration, sterol biosynthesis in membranes	Elatus Era	Candidate for substitution	-	-	-
		fluoxastrobin, prothioconazool	Sterol biosynthesis in membranes	FANDANGO	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		isopyrazam, prothioconazool	Respiration, sterol biosynthesis in membranes	Gigant	Candidate for substitution	-	-	-
		epoxiconazool, metconazool	Sterol biosynthesis in membranes	Osiris	Candidate for substitution	-	-	-
		metconazool	Sterol biosynthesis in	PLEXEO 60	Candidate for substitution	-	-	-

					Practical and/or economical disadvantages		Resistance risk	
Crop	Pest/ Disease/ Weed	Active substance	MOA	Product	Practical and/or economical disadvantages (e.g. according to the label)	Alternative without practical and/or economical disadvantages (Y/N)	RAC-code	Alternative regarding resistance (Y/N)
			membranes					
		prothioconazool	Sterol biosynthesis in membranes	Proline	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		prothioconazool, tebuconazool	Sterol biosynthesis in membranes	PROSARO	Candidate for substitution	-	-	-
		prothioconazool, spiroxamine	Sterol biosynthesis in membranes	Prosaro Plus	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		metconazool	Sterol biosynthesis in membranes	SIRENA EC	Candidate for substitution	-	-	-
		bixafen, prothioconazool, tebuconazool	Respiration, sterol biosynthesis in membranes	Skyway Xpro	Candidate for substitution	-	-	-
		bromuconazool, tebuconazool	Sterol biosynthesis in membranes	Soleil	Candidate for substitution	-	-	-
		tebuconazool	Sterol biosynthesis in membranes	TEBUCUR 250 EW	Candidate for substitution	-	-	-
		tebuconazool	Sterol biosynthesis in membranes	Tebusha 250 EW	Candidate for substitution	-	-	-
		metconazool	Sterol biosynthesis in membranes	TURRET 60	Candidate for substitution	-	-	-
		fludioxonil	Signal transduction	BERET GOLD 025 FS	Candidate for substitution	-	-	-
		difenoconazool, fludioxonil	Sterol biosynthesis in membranes, signal transduction	DIFEND EXTRA	Candidate for substitution	-	-	-
		fludioxonil, tebuconazool	Signal transduction, sterol biosynthesis in membranes	Seedron	Candidate for substitution	-	-	-
		Sedaxaan, fludioxonil	Respiration, signal transduction	Vibrance Duo	Candidate for substitution	-	-	-

					Practical and/or economical disadvantages		Resistance risk	
Crop	Pest/ Disease/ Weed	Active substance	MOA	Product	Practical and/or economical disadvantages (e.g. according to the label)	Alternative without practical and/or economical disadvantages (Y/N)	RAC-code	Alternative regarding resistance (Y/N)
spring wheat	Gaeumannomyces graminis var. Tritici	silthiofam	Respiration	Latitude XL	Not authorized in groundwater safe guard zones	N	n.a.	n.a.
spring wheat	Fusarium spp.	prochloraz, tebuconazool	Sterol biosynthesis in membranes	AMPERA	Candidate for substitution	-	-	-
		bixafen, fluopyram, prothioconazool	Respiration, sterol biosynthesis in membranes	Ascra Xpro	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		bixafen, prothioconazool	Respiration, sterol biosynthesis in membranes	Aviator Xpro	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		metconazool	Sterol biosynthesis in membranes	CARAMBA	Candidate for substitution	-	-	-
		prothioconazool	Sterol biosynthesis in membranes	Curbatur EC 250	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		prothioconazool, trifloxystrobin	Sterol biosynthesis in membranes	DELARO	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		Benzovindiflupyr, prothioconazool	Respiration, sterol biosynthesis in membranes	Elatus Era	Candidate for substitution	-	-	-
		fluoxastrobin, prothioconazool	Sterol biosynthesis in membranes	FANDANGO	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		isopyrazam, prothioconazool	Respiration, sterol biosynthesis in membranes	Gigant	Candidate for substitution	-	-	-
		epoxiconazool, metconazool	Sterol biosynthesis in membranes	Osiris	Candidate for substitution	-	-	-
		metconazool	Sterol biosynthesis in membranes	PLEXEO 60	Candidate for substitution	-	-	-

					Practical and/or economical disadvantages		Resistance risk	
Crop	Pest/ Disease/ Weed	Active substance	MOA	Product	Practical and/or economical disadvantages (e.g. according to the label)	Alternative without practical and/or economical disadvantages (Y/N)	RAC-code	Alternative regarding resistance (Y/N)
		prothioconazool	Sterol biosynthesis in membranes	Proline	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		prothioconazool, tebuconazool	Sterol biosynthesis in membranes	PROSARO	Candidate for substitution	-	-	-
		prothioconazool, spiroxamine	Sterol biosynthesis in membranes	Prosaro Plus	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		metconazool	Sterol biosynthesis in membranes	SIRENA EC	Candidate for substitution	-	-	-
		bixafen, prothioconazool, tebuconazool	Respiration, sterol biosynthesis in membranes	Skyway Xpro	Candidate for substitution	-	-	-
		bromuconazool, tebuconazool	Sterol biosynthesis in membranes	Soleil	Candidate for substitution	-	-	-
		tebuconazool	Sterol biosynthesis in membranes	Tebusha 250 EW	Candidate for substitution	-	-	-
		metconazool	Sterol biosynthesis in membranes	TURRET 60	Candidate for substitution	-	-	-
		fludioxonil	Signal transduction	BERET GOLD 025 FS	Candidate for substitution	-	-	-
		fludioxonil, tebuconazool	Signal transduction, sterol biosynthesis in membranes	Seedron	Candidate for substitution	-	-	-
		Sedaxaan, fludioxonil	Respiration, signal transduction	Vibrance Duo	Candidate for substitution	-	-	-
winter barley	Gaeumannomyces graminis var. Tritici	silthiofam	Respiration	Latitude XL	Not authorized in groundwater safe guard zones	N	n.a.	n.a.
winter barley	Fusarium spp.	fludioxonil	Signal transduction	BERET GOLD 025 FS	Candidate for substitution	-	-	-
		difenoconazool, fludioxonil	Sterol biosynthesis in membranes, signal transduction	DIFEND EXTRA	Candidate for substitution	-	-	-

					Practical and/or economical disadvantages		Resistance risk	
Crop	Pest/ Disease/ Weed	Active substance	MOA	Product	Practical and/or economical disadvantages (e.g. according to the label)	Alternative without practical and/or economical disadvantages (Y/N)	RAC-code	Alternative regarding resistance (Y/N)
		kalium waterstofcarbonaat	Not classified	Karma	Broadcast spray treatment, different kind of treatment and application timing	N	n.a.	n.a.
		fludioxonil, tebuconazool	Signal transduction, sterol biosynthesis in membranes	Seedron	Candidate for substitution	-	-	-
		tebuconazool	Sterol biosynthesis in membranes	TEBUCUR 250 EW	Candidate for substitution	-	-	-
		tebuconazool	Sterol biosynthesis in membranes	Tebusha 250 EW	Candidate for substitution	-	-	-
		Sedaxaan, fludioxonil	Respiration, signal transduction	Vibrance Duo	Candidate for substitution	-	-	-
spring barley	Gaeumannomyces graminis var. Tritici	No alternatives available				-	-	-
spring barley	Fusarium spp.	fludioxonil	Signal transduction	BERET GOLD 025 FS	Candidate for substitution	-	-	-
		fludioxonil, tebuconazool	Signal transduction, sterol biosynthesis in membranes	Seedron	Candidate for substitution	-	-	-
		tebuconazool	Sterol biosynthesis in membranes	TEBUCUR 250 EW	Candidate for substitution	-	-	-
		tebuconazool	Sterol biosynthesis in membranes	Tebusha 250 EW	Candidate for substitution	-	-	-
		Sedaxaan, fludioxonil	Respiration, signal transduction	Vibrance Duo	Candidate for substitution	-	-	-

Annex II: Alternative non-chemical methods

An overview of non-chemicals alternatives (date: 22-05-2020), for the proposed major uses of Latifam Extra.

Crop	Pest/ disease/ weed	Name alternative	Description	Assessment NPPO of effectiveness and practical and/or economical disadvantages	Alternative without practical and/or economical disadvantages (Y/N)	Alternative regarding resistance risk (Y/N)
Winter wheat, Spring wheat, Winter barley, Spring barley	Gaeumannomyces graminis var. Tritici	Ploughing in crop residue	Burial of crop debris by ploughing can reduce inoculum for some necrotrophic pathogens which produce inoculum on plant debris. Cannot be applicated in combination with drilling method.	This method is only beneficial and not always feasible.	N	n.a.
		Seedbed quality	A good seedbed provides optimal growing conditions for a good germination of the crop. A poor seedbed quality gives poor growing conditions which results in more vulnerability of the crop to diseases.	This method is only beneficial.	N	n.a.
		Resistant varieties	Using resistant cultivars is an effective control measure. However, because most cultivars are grown for their specific characteristics, choosing resistant cultivars is not always feasible.	This method is not always feasible.	N	n.a.
		Drilling method	Method in which direct drilling is applied without cultivation such as ploughing. Crop debris such as straw residue may have a suppressive effect on some pathogens which can reduce disease pressure. Cannot be applicated in combination with ploughing in crop residue.	This method is only beneficial and not always feasible.	N	n.a.
		Control volunteers and weeds	Volunteers and weeds can be a source of fungicidal pathogens. Removing them contributes to disease control.	This method is only beneficial.	N	n.a.
		Delayed sowing	Sowing crops later than usual can reduce the severity of some diseases.	This method is only beneficial.	N	n.a.
		Nutrition	Good nutrition provides a better plant health which makes the plants less vulnerable to diseases.	This method is only beneficial.	N	n.a.
		Good drainage	High soil moisture provides optimal conditions for fungal disease development. Good drainage prevents high soil moisture.	This method is only beneficial.	N	n.a.
		Field history	Avoiding fields with a known history of disease to prevent high disease pressure.	This method is not always feasible	N	n.a.

Crop	Pest/ disease/ weed	Name alternative	Description	Assessment NPPO of effectiveness and practical and/or economical disadvantages	Alternative without practical and/or economical disadvantages (Y/N)	Alternative regarding resistance risk (Y/N)
		Rotation and break crops	Rotations of three or more years are essential to prevent build-up of most diseases that are capable of long term survival.	This method is only beneficial.	N	n.a.
Winter wheat, Spring wheat, Winter barley, Spring barley	Fusarium spp.	Ploughing in crop residue	Burial of crop debris by ploughing can reduce inoculum for some necrotrophic pathogens which produce inoculum on plant debris.	This method is only beneficial.	N	n.a.
		Steaming	Pressurised steam applied to the soil.	Effective method. This technique has high time and energy demands, drastic effects on other micro-organisms in the soil, and may pose a hazard to those operating the equipment.	N	n.a.
		Resistant varieties	Using resistant cultivars is an effective control measure. However, because most cultivars are grown for their specific characteristics, choosing resistant cultivars is not always feasible.	This method is not always feasible.	N	n.a.
		Control volunteers and weeds	Volunteers and weeds can be a source of fungicidal pathogens. Removing them contributes to disease control.	This method is only beneficial.	N	n.a.
		Seed testing	The use of certified seed is important for most crops to ensure that heavily infected seed stocks are not used, and can be an effective approach to reducing some diseases.	The use of certified seeds is common in the Netherlands. This method is only beneficial.	N	n.a.
		Rotation and break crops	Rotations of three or more years are essential to prevent build-up of most diseases that are capable of long term survival.	This method is only beneficial.	N	n.a.

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Betreft Opdracht voor comparative assessments Pitcher 20150428

Geachte heer art. 5.1.2.e Woo,

Het Ctgb en NVWA werken samen op het gebied de uitvoering van comparative assessments, conform Verordening (EG) nr. 1107/2009 art. 50.

Hierbij verleen ik u opdracht tot het verrichten van de werkzaamheden conform de offerte:
trcvwa /2016/1385.

Omschrijving van de werkzaamheden:
Bij de aanvraag voor het middel: Pitcher, 20150428 ZTG, op basis van de werkzame stoffen fludioxonil en folpet, wordt een comparative assessment uitgevoerd.

De comparative assessment dient te worden uitgevoerd voor de volgende gebruiken:

Toepassingsgebied	Type toepassing	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus
Gladiool (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1

Toepassingsgebied	Type toepassing	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus
Hyacint (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1
Lelie (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1
Narcis m.u.v. grofbollige narcis (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1
Tulp (onbedekte teelt)	Dompelbehandeling	Zuur1, Rhizoctonia 2	1% (1 L per 100 L water)	1
Iris (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1
Krokus (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1
Anemoon (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1

U wordt verzocht voor deze 8 gebruiken een landbouwkundige beoordeling uit te voeren.

De eindconclusie van de landbouwkundige beoordeling dient in een beknopte samenvatting duidelijk te worden aangegeven. Hierin is opgenomen welke alternatieven middelen zijn overwogen en waarom die al dan niet als volwaardig alternatief kunnen worden beschouwd.

Wilt u per toepassing aangegeven op welk moment (Step 6-11) gestopt kan worden met CA, omdat er geen alternatieve middelen gevonden zijn?

De projecturen bedragen maximaal 20 uur.
Het rapport ontvang ik uiterlijk 6 september 2019, onder vermelding van bovengenoemd aanvraagnummer.

Ter bevestiging van deze opdracht ontvang ik graag binnen een week na dagtekening een getekend exemplaar retour.

Als u inhoudelijke vragen heeft over deze opdracht, kunt u rechtstreeks met de projectleider art. 5.1.2.e Woo contact opnemen.

Akkoord, Het College voor de toelating van gewasbeschermingsmiddelen en biociden, voor deze: de secretaris, voor deze:	Akkoord, NVWA
art. 5.1.2.e Woo	
Mevrouw dr.ir. art. 5.1.2.e Woo art. 5.1.2.e Woo	De heer Ir. art. 5.1.2.e Woo

Bijlagen:

1 Formulier CA bij Pitcher, ingevuld door de aanvrager
2 Template comparative assessment
3 Evaluatieformulier evaluerende instantie

Annex I. Applicant information to support the process of comparative assessment

(no information is needed when the product doesn't contain a Candidate for Substitution)

(8 April 2016)

National addendum to the draft Registration Report (dRR)

Country	Netherlands
Product under evaluation	Pitcher (MCW-7695) 20150428 ZETG
Candidate for substitution (active substance name)	fludioxonil
Reasons for approval as candidate for substitution (delete as appropriate).	two of PBT

Step 1. Is this application intended for a mutual recognition, derived authorisation or parallel trade permit?

No.

Step 2. Is this product only destined for non-professional users?

No.

Step 3. Do you want to make use of the derogation in Article 50(3) for uses where it is necessary to acquire experience first through using that product in practice?

No.

Step 4. Is this product only destined or applied for minor use(s) according art 51 or NLKUG? (Minor Uses are defined in the list of Minor Uses).

No.

Step 5. Does your application include a minor use?

Yes.
The application concerns 8 regular new field uses of which 6 are **minor crops** as their crop area in NL is < 5000 ha, and 9 **minor uses** applied for according art. 51 of pesticide regulation 1107/2009.

The minor crops are determined by the latest figures of crop areas in NL published by CBS/Statline (July 2019; https://opendata.cbs.nl/statline/#/CBS/nl/dataset/81302ned/table?dl=DF60).

The uses according art. 51 of pesticide regulation 1107/2009, for floriculture, are based on the published guidance by the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) on their website (https://www.ctgb.nl/gewasbeschermingsmiddelen/documenten/toetsingskader-gewasbeschermingsmiddelen/2018/06/08/indeling-kleine-gewasgroepen-sierteelt) ,
where the minor uses are listed in collaboration with the NVWA (= Netherlands Food and Consumer Product Safety Authority).
Find in next table the minor uses intended for Pitcher.

Crop and/ or situation	F G or I	Pests or Group of pests controlled	Application			Application rate per treatment			PHI (days)	Minor or major crop
			Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	L product/ ha	kg as/ha	Water L/ha[1] min / max		
Gladiolus	I,F	*Fusarium oxysporum* (FUSAOX)	Dipping (immersion)	Short before planting; BBCH 00; Apr-Jun	1 / -	3.6	1.620 (fp); 0.216 (fd)	360	-	Minor as crop area is < 5000 Ha based on CBS figures
Iris	I,F	*Fusarium oxysporum* (FUSAOX)	Dipping (immersion)	Short before planting; BBCH 00; Sep-Nov	1 / -	4.9	2.205 (fp); 0.294 (fd)	490	-	Minor as crop area is < 5000 Ha based on CBS figures
Hyacinth	I,F	*Fusarium oxysporum* (FUSAOX)	Dipping (immersion)	Short before planting; BBCH 00; Sep-Nov	1 / -	7.15	3.218 (fp); 0.429 (fd)	715	-	Minor as crop area is < 5000 Ha based on CBS figures
Narcissus small	I,F	*Fusarium oxysporum* (FUSAOX)	Dipping (immersion)	Short before planting; BBCH 00; Sep-Nov	1 / -	6.5	2.925 (fp); 0.390 (fd)	650	-	Minor as crop area is < 5000 Ha based on CBS figures
Crocus	I,F	*Fusarium oxysporum* (FUSAOX)	Dipping (immersion)	Short before planting; BBCH 00; Sep-Nov	1/-	4.875	2.925 (fp); 0.390 (fd)	487.5	-	Minor as crop area is < 5000 Ha based on CBS figures
Anemone	I,F	*Fusarium oxysporum* (FUSAOX)	Dipping (immersion)	Short before planting; BBCH 00; Sep-Oct	1/-	5.6	2.520 (fp); 0.336 (fd)	560	-	Minor as crop area is < 5000 Ha based on CBS figures
Minor uses according to article 51										
Bulb flower and tuber flower, non-soil bound excluding large Narcissus and lily	I,G	*Fusarium oxysporum* (FUSAOX)	Dipping (immersion)	Short before planting; BBCH 00; Sep-Apr	1 / -	16.1	7.245 (fp); 0.966 (fd)	1610	-	Minor use acc. Art 51 based on guidance document of Ctgb
Tulip (soil-bound)	I,G	*Fusarium oxysporum* (FUSAOX)	Dipping (immersion)	Short before planting; BBCH 00; Sep-May	1 / -	6.5	2.925 (fp); 0.390 (fd)	650	-	Minor use acc. Art 51 based on guidance document of Ctgb
Iris (soil-bound)	I,G	*Fusarium oxysporum* (FUSAOX)	Dipping (immersion)	Short before planting; BBCH 00; Sep-May	1 / -	6.5	2.925 (fp); 0.390 (fd)	650	-	Minor use acc. Art 51 based on guidance document of Ctgb
Gladiolus (soil-bound)	I,G	*Fusarium oxysporum*	Dipping	Short before planting;	1 / -	3.6	1.62 (fp);	360	-	Minor use acc. Art 51 based on

[1] Water volume for bulb dipping is the amount of water absorbed by flower bulbs

		(FUSAOX)	(immersion)	BBCH 00; Sep-May			0.216 (fd)			guidance document of Ctgb
Floricultural crops (cut flowers and pot plants)	F	*Phoma* spp. (PHOMSP); *Septoria* spp. (SEPTSP); *Colletotrichum* spp. (COLLSP)	Foliar application	BBCH 10-89; Mar-Sep	1-3 / 7	1.5	0.675 (fp); 0.090 (fd)	200-400	-	Minor use acc. Art 51 based on guidance document of Ctgb
Buxus (< 50 cm)	F	*Cylindrocladium* spp. (CYLDSP)	Foliar application	BBCH 10-89; Mar- Sep	1-3 / 7	1.5	0.675 (fp); 0.090 (fd)	200-400	-	Minor use acc. Art 51 based on guidance document of Ctgb
Buxus (< 50 cm), non- soil bound	G	*Cylindrocladium* spp. (CYLDSP)	Foliar application	BBCH 10-89; Jan-Dec	1-3 / 7	1.5	0.675 (fp); 0.090 (fd)	200-400	-	Minor use acc. Art 51 based on guidance document of Ctgb
Perennial crops	F	*Phoma* spp. (PHOMSP); *Septoria* spp. (SEPTSP); *Colletotrichum* spp. (COLLSP)	Foliar application	BBCH 10-89; Mar- Sep	1-3 / 7	1.5	0.675 (fp); 0.090 (fd)	200-400	-	Minor use acc. Art 51 based on guidance document of Ctgb
Perennial crops, non- soil bound	G	*Phoma* spp. (PHOMSP); *Septoria* spp. (SEPTSP); *Colletotrichum* spp. (COLLSP)	Foliar application	BBCH 10-89; Jan-Dec	1-3 / 7	1.5	0.675 (fp); 0.090 (fd)	200-400	-	Minor use acc. Art 51 based on guidance document of Ctgb

Step 6. What are the major uses of your product to be considered in a comparative assessment?

The major uses to be considered in this comparative assessment are:
Find in next table the major uses intended for Pitcher.

Cropt	F G or I	Pests	Application			Application rate per treatment			PHI (days)	Remarks
			Method / Kind	Timing / Growth stage of crop & season	Number	L product / ha	kg as/ha	Water L/ha[2]		
Tulip	I,F	*Fusarium oxysporum* (FUSAOX); *Rhizoctonia solani* (RHIZSO)	Dipping (immersion)	Short before planting; BBCH 00; Sept-Nov	1	6.5	2.925 (fp); 0.390 (fd)	650	-	
Lily	I,F	*Fusarium oxysporum* (FUSAOX)	Dipping (immersion)	After harvest, before storage *or* short before planting; BBCH 00; April	1	7.0	3.150 (fp); 0.420 (fd)	700	-	

[2] Water volume for bulb dipping is the amount of water absorbed by flower bulbs

Step 7. Alternative authorised plant protection products with the same mode of action:

Pitcher (MCW-7695) is a two-way mixture, formulated as a suspension concentrate (SC), containing 450 g/L folpet and 60 g/L fludioxonil.

Pitcher is aimed to control Fusarium oxysporum (FUSAOX/FUSAGL/FUSANA) in flower bulb and bulb flower crops and Rhizoctonia solani (RHIZSO) in tulip by means of dipping plant material in an immersion bath before plating. The concentration of Pitcher in the immersion bath is 1% for all types of flower bulb and bulb flower crops. The major crops are tulips and lily to be planted in the field after dipping.

Pitcher is a non-systemic contact fungicide. Pitcher inhibits the cell division and the transport-associated phosphorylation of glucose as well as preventing glycerol synthesis within fungi due to the combination of 2 different active ingredients originating from 2 different classes of fungicides.
The active fludioxonil is classified by the Fungicide Resistance Action Committee (FRAC) in MAP/Histidine-Kinase in osmotic signal transduction (os-2, HOG1) with FRAC code 12. Resistance against actives from this FRAC group 12 is found sporadically and the mechanism is speculative. There is a low to medium risk for resistance and resistance management is required.
The active folpet is classified by the Fungicide Resistance Action Committee (FRAC) in 'multi-site contact activity' mode of action with FRAC code M4 and it belongs therefore to a low risk group without any signs of resistance developing to the fungicides.
As a consequence, Pitcher inhibits spore germination, germ tube elongation, mycelium formation and spread of spores of the respective fungi.
The two-way combination of active substances in Pitcher, that fits well in terms of resistance management is not present in the currently authorized products in NL.

<u>There are no alternative authorized products with the same mode of action available for the major uses.</u>

All authorized products for the major uses and their mode of action, can be found under Step 8.

Step 8. Alternative authorised plant protection products with their mode of action:

Please, find all authorized products for the major uses and their modes of action, including the product under consideration, in the tables below. Indicated is the number of modes of action per crop-pest combination.

***Fusarium oxysporum* in tulip and lily**

Key:

	Candidate for Substitution (CfS)	(One of) the ingredient(s) of the product is CfS (red, regular)
	Candidate for Substitution Active ingredient in Pitcher	**(One of) the ingredient(s) of the product is fludioxonil (bold/bold)**
	Approval of substance not (to be) renew by EU COM	

Crop	Pest	Product	Active substance	Mode of Action	RAC-code	Total number of modes of actions per crop/pest combination
Tulip / lily	*Fusarum oxysporum*	Thiophamet Extra (reg.nr. 15632), Topsin M Ultra (reg.nr. 7211), VSM thiofanaat 500 SC (15819)	thiophanate-methyl	MBC fungicides (Methyl Benzimidazole Carbamates)	1	RAC-code 1 and M05 will be discontinued -> 5 MoA (RAC-code M05 - chlorothalonil already voted for non-renewal; see final published renewal report SANTE/10186/2018 Rev 1 ; RAC-code 1 - thiophanate-methyl proposed by EU COM for non-renewal which is approved by NL; see letter from Minister to Parliament dated 11 July 2019 https://zoek.officielebekendmakingen.nl/kst-27858-482.html)
		Allure vloeibaar (reg.nr. 11585), Mirage Elan (reg.nr. 11824), Mirage Plus 570 SC (reg.nr. 11529), Sportak EW (reg.nr. 11567)	prochloraz	DMI-fungicides (DeMethylation Inhibitors) (SBI: Class I)	3	
		Rudis (reg.nr. 12970)	prothioconazole			
		Securo (reg.nr. 12955)	pyraclostrobin	QoI-fungicides (Quinone outside Inhibitors)	11	
		Pitcher (-)	fludioxonil	PP-fungicides (PhenylPyrroles)	12	
		Captor SC (reg.nr. 10331)	captan	phthalimides (electrophiles)	M04	
		Mirage Plus 570 SC (reg.nr. 11529), **Pitcher (-),** Securo (reg.nr. 12955), Solofol (reg.nr. 14507)	folpet			
		Allure vloeibaar (reg.nr. 11585)	chlorothalonil	chloronitriles (phthalonitriles) (unspecified mechanism)	M05	
		Trianum-G (reg.nr. 12841), Trianum-P (reg.nr. 12699)	*Trichoderma harzianum* Rifai stam T-22	Biologicals with multiple modes of action	BM	

We searched in August 2019, the Ctgb website on authorized, professional products with an authorization as a fungicide, applied in tulip for the control of *Fusarium oxysporum*, *Fusarium oxysporum* f.sp. *tulipae* and/or *Fusarium*. Authorized products for protected crops are excluded from the comparative assessment. The selection of products is checked by opening the label (WG) on the website. The label (WG) is leading.

The active substance fludioxonil is classified with FRAC code 12. No other authorized product against *Fusarium oxysporum*, *Fusarium oxysporum* f.sp. *tulipae* and/or *Fusarium* in tulip has the same mode of action.

The active folpet is classified with FRAC code M04. Within this FRAC code M4, we found 4 products authorized with either folpet or captan as active ingredient. The four authorized products are Captor SC (reg.nr. 10331), Mirage Plus (reg.nr. 10331), Securo (reg.nr. 12955) and Solofol (reg.nr. 14507).
The unique, two-way combination of active substances in Pitcher, that fits well in terms of resistance management, is not present in the authorized products with only one active ingredient i.e. Captor SC (reg.nr. 10331) and Solofol (reg.nr. 14507).
Mirage Plus (reg.nr. 10331) contains besides folpet also prochloraz. Prochloraz is a candidate for substitution. According to SANCO/11507/2013 rev.12, products containing no CfS should be preferred as substitutes. Due to the lack of information if the products containing Cfs will pass the re-evaluation process and thus will be available in the future, these products were excluded from further CA.
Securo (reg.nr. 12955) contains besides folpet also pyraclostrobin. The active ingredient pyraclostrobin belongs to the group of strobilurins for which the risk on resistance is high. Fludioxonil, besides folpet the other active ingredient in Pitcher, has a low to medium risk for resistance. Therefore, Securo (reg.nr. 12955) can not be seen as comparable product with regards to resistance strategy as it is a two way mixture and with one ingredient classified for high risk resistance.
Therefore, there are no comparable, authorized products for dipping against *Fusarium oxysporum*, *Fusarium oxysporum* f.sp. *tulipae* and/or *Fusarium* in tulip in this group with FRAC code M04.

The product Allure vloeibaar (reg.nr. 11585) is authorized. The product contains the active ingredients prochloraz and chlorothalonil, of which the former is candidate for substitution. The active ingredient chlorothalonil was voted for non-renewal of approval in March 2019. The authorizations should be withdrawn by 20 November 2019 with a maximum grace period till May 2020.
Pitcher is aimed for treatment of bulbs to be planted in the field after dipping. Allure vloeibaar (reg.nr. 11585) is intended against *Fusarium tulipea* for covered, non-soil bound crops.
For these reasons, the product Allure vloeibaar (reg.nr. 11585), the only product in the group of FRAC code M05, is no alternative for Pitcher.
The products Mirage Elan (reg.nr. 11824), Mirage Plus 570 SC (reg.nr. 11529) and Sportak EW (reg.nr.11567) contain also prochloraz (= CfS) and are no alternatives for Pitcher.

There is one authorized product in the group with FRAC code 3 with prothioconazole, i.e. Rudis (reg.nr. 12970) with only one active ingredient.
Pitcher, has a low to medium risk for resistance. The unique, two-way combination of active substances in Pitcher, that fits well in terms of resistance management, cannot be found in Rudis (reg.nr. 12970).
Prothioconazole belongs to the group of DMI-fungicides. There are big differences in the activity spectra of DMI fungicides. Resistance is known in various fungal species. Several resistance mechanisms are known incl. target site mutations in cyp51 (erg 11) gene, e.g. V136A, Y137F, A379G, I381V; cyp51 promotor; ABC transporters and others. It is generally wise to accept that cross resistance is present between DMI fungicides active against the same fungus. DMI fungicides are Sterol Biosynthesis Inhibitors (SBIs), but show no cross resistance to other SBI classes. There is a medium risk on resistance.
Therefore, Rudis (reg.nr. 12970) cannot be seen as an alternative product for Pitcher.

The group with FRAC code 1 contains only thiophanate-methyl. In the minutes of the SCOPAFF meeting of 16-17 July, Brussels it is mentioned that the commission proposal for renewal of the active ingredient

thiophanate-methyl is 'non-renewal', which is endorsed by NL as is stated by the Minister on 11 July 2019 to the Parliament. Therefore, all products based on the active ingredient thiophanate-methyl are no alternatives for Pitcher. It concerns Thiophamet Extra (reg.nr. 15632), Topsin M Ultra (reg.nr. 7211), and VSM thiofanaat 500 SC (reg.nr. 15819). The group with FRAC code 1 cannot be counted as an alternative MoA for Pitcher.

The active ingredient *Trichoderma harzianum* Rifai stam T-22 was included on 1 May 2009 in Annex I of Directive 91/414/EEC and subsequently approved under Regulation (EC) 1107/2009. The authorized products Trianum-G (reg.nr. 12841) and Trianum-P (reg.nr. 12699) are comparable products.
Regarding host specificity, according to the final review report SANCO/1839/08 – rev. 5 11 July 2014, *Trichoderma harzianum* T-22 does not have a specific host. It is a general saprophytic fungus occurring in soil, especially in the rhizosphere, but also on organic material. Also mycoparasitic activities are not limited to specific hosts, but rather occur on a wide range of fungi. *T. harzianum* has different mode of actions like competition with plant pathogens for space and substrates in the rhizosphere, mycoparasitism and the secretion of cell wall degrading enzymes, productions of antifungal substances, growth promotion, solubilisation of inorganic nutrients and induction of systemic resistance.
Until inclusion of the active ingredient *Trichoderma harzianum* Rifai stam T-22 in Annex I of Directive 91/414/EEC and subsequently approved under Regulation (EC) 1107/2009, Trianum-P and G were authorized as plant strengtheners. Both authorized products act as preventative biofungicides. The authorized products show a benefit (effectiveness) based on the fungicidal/suppressive effect. The efficacy was lower than for the chemical reference products used in the trials for *Fusarium oxysporum* and *Rhizoctonia solani*. (Ctgb decision, reg.nr. 12699, dated 4 Dec. 2015).
For this reason, the authorized products Trianum-G (reg.nr. 12841) and Trianum-P (reg.nr. 12699) are no alternatives for Pitcher.

Conclusion *Fusarium oxysporum* in tulip
In the Netherlands, 13 products are authorized for professional use against *Fusarium oxysporum, Fusarium oxysporum f.sp. tulipae and/or Fusarium* in tulip, none of them containing fludioxonil, 3 of them also containing folpet. 6 Mode of actions are available of which 2 (RAC-code 1 and M05) will be discontinued soon.
Chlorothalonil is voted for non-renewal of approval in March 2019. The commission proposal for thiophanate-methyl is 'non-renewal'. The efficacy of the products with *Trichoderma harzianum* Rifai strain T-22 is lower than for the chemical products.

Considering the non-renewal of chlorothalonil and thiophanate-methyl, there are four (4) MoA available to manage the risk of resistance for *Fusarium oxysporum, Fusarium oxysporum f.sp. tulipae and/or Fusarium* in tulip.
Pitcher will provide an essential benefit to the existing resistance management strategies.

Conclusion *Fusarium oxysporu*m in lily
After searching the database for professional products with an authorization as a fungicide, applied in lily for *Fusarium oxysporum*, *Fusarium oxysporum* f.sp. *lilli* and/or *Fusarium*, we found the same authorized products for lily as found for tulip. Therefore, above argumentation is comparable between tulip and lily and the conclusion is the same.

In the Netherlands, 13 products are authorized for professional use against *Fusarium oxysporum, Fusarium oxysporum f.sp. lilli and/or Fusarium* in lily, none of them containing fludioxonil, 3 of them also containing folpet. 6 Mode of actions are available of which 2 (RAC-code 1 and M05) will be discontinued soon.
Chlorothalonil is voted for non-renewal of approval in March 2019. The commission proposal for thiophanate-methyl is 'non-renewal'. The efficacy of the products with *Trichoderma harzianum* Rifai strain T-22 is lower than for the chemical products.

Considering the non-renewal of chlorothalonil and thiophanate-methyl, there are four (4) MoA available to manage the risk of resistance for *Fusarium oxysporum, Fusarium oxysporum f.sp. lilli and/or Fusarium* in lily.
Pitcher will provide an essential benefit to the existing resistance management strategies.

***Rhizoctonia solani* in tulip**

Key:

	On list of Candidates for Substitution	(One of) the ingredient(s) of the product is CfS (red, regular)
	Candidate for Substitution Active ingredient in Pitcher	**(One of) the ingredient(s) of the product is fludioxonil (bold/bold)**

Crop	Pest	Product	Active substance	Mode of Action	RAC-code	Total number of modes of actions per crop/pest combination
Tulip	*Rhizoctonia solani*	Monarch (reg.nr. 13144)	flutolanil	SDHI (Succinate dehydrogenase inhibitors)	7	8
		Amiplus azoxystrobin (reg.nr. 14812), Amistar (reg.nr. 11767), CropGuard Azoxystrobin (reg.nr. 14811), Mirador (reg.nr.13864)	azoxystrobin	QoI-fungicides (Quinone outside Inhibitors)	11	
		Pitcher (-)	**fludioxonil**	**PP-fungicides (PhenylPyrroles)**	**12**	
		Rizolex vloeibaar (reg.nr. 11098)	tolclofos-methyl	AH-fungicides (Aromatic Hydrocarbons) (chlorophenyls, nitroanilines)	14	
		Montego (reg.nr. 14926)	pencycuron	phenylureas	20	
		Dalimo (reg.nr. 15898), Ohayo (reg.nr. 10710), Santox (reg.nr. 12205)	fluazinam	Not available	29	
		Captor SC (reg.nr. 10331)	captan	phthalimides (electrophiles)	M04	
		Pitcher (-)	folpet			
		Trianum-G (reg.nr. 12841), Trianum-P (reg.nr. 12699)	*Trichoderma harzianum* Rifai stam T-22	Biologicals with multiple modes of action	BM	

***Rhizoctonia solani* in tulip**

We searched in August 2019, the Ctgb website for professional products with an authorization as a fungicide, applied in tulip for the control of *Rhizoctonia solani* and/or *Rhizoctonia*. Authorized products for indoor crops are excluded from the comparative assessment. The selection of products is checked by opening the label (WG) on the website. The label (WG) is leading.

The two products Topsin M Ultra (reg.nr. 7211), and VSM thiofanaat 500 SC (reg.nr. 15819) are authorized for *Rhizoctonia tuliparum* and therefore not taken into consideration.

The active substance fludioxonil in Pitcher is classified with FRAC code 12. No other authorized product for control of *Rhizoctonia solani* and/or *Rhizoctonia* in tulip has the same mode of action.

The active folpet in Pitcher is classified with FRAC code M04. Within this FRAC code M4, we found 1 product authorized with either folpet or captan as active ingredient. The authorized product is Captor SC (reg.nr. 10331). The unique, two-way combination of active substances in Pitcher, that fits well in terms of resistance management, is not present in the authorized products with only one active ingredient i.e. Captor SC (reg.nr. 10331).

The group with FRAC code 7 contains one registered product, i.e. Monarch (reg.nr. 13144) with the active ingredient flutolanil. Monarch is used as fungicide applied as a soil spray during planting in the furrow or broadcast followed by mixing through the topsoil before planting of flowerbulbs.
Flutolanil belongs to a group of fungicides known as the carboxamides, also referred to as the carboxanilides. Its mode of action is to inhibit electron transfer reactions through the succinate-ubiquinone oxidoreductase complex (Complex II) of the mitochondrial respiratory chain. Otherwise described as inhibition of cell respiration by inhibiting succinate oxidation (Ctgb decision Monarch (reg.nr. 13144), dated 6 november 2015).
There is resistance known for several fungal species in field populations and lab mutants. Target site mutations in sdh gene, e.g. H/Y (or H/L) at 257, 267, 272 or P225L, dependent on fungal species. Resistance management is required. There is a medium to high risk on resistance and resistance management is required.
Pitcher (MCW-7695) is a two-way mixture. The active fludioxonil is classified by the Fungicide Resistance Action Committee (FRAC) in a low to medium risk for resistance. The active folpet is classified by the Fungicide Resistance Action Committee (FRAC) to a low risk group without any signs of resistance developing to the fungicides. The two-way combination of active substances in Pitcher, that fits well in terms of resistance management is not present in the authorized products with only one active ingredient classified as medium to high risk on resistance as in Monarch (reg.nr. 13144).

The group with FRAC code 11 contains the active ingredient azoxystrobin. The authorized products in this group, i.e. Amiplus azoxystrobin (reg.nr. 14812), Amistar (reg.nr. 11767), CropGuard Azoxystrobin (reg.nr. 14811), and Mirador (reg.nr.13864), contain only this active ingredient.
Azoxystrobin is a systemic fungicide that is adsorbed quickly by the roots and translocated through the xylem to the stems and leaves, or through leaf surface to the leaf tips and growing edges. It inhibits spore germination, mycelial growth, and the spore production of fungi http://oxon.it/product/31/azoxystrobin).
According to FRAC, QoI-fungicides (FRAC Code 11) are classified as high risk fungicides for resistance development and are cross-resistant with each other. It is recommended by FRAC to use non-cross resistant mixture partners (e.g. SBI's) to control cereal pathogens and to ensure robust disease management. This will also help to delay resistance development in areas where no resistance cases were reported so far.
For this reason, Amiplus azoxystrobin (reg.nr. 14812), Amistar (reg.nr. 11767), CropGuard Azoxystrobin (reg.nr. 14811), and Mirador (reg.nr.13864) are not comparable products to Pitcher as they only contain one high risk resistance active ingredient.
Products that have a high risk of resistance even combined with one other medium resistant active ingredient are no alternative for Pitcher as the 2 active substances in Pitcher have low to medium risk to develop resistance. Therefore, Amiplus azoxystrobin (reg.nr. 14812), Amistar (reg.nr. 11767), CropGuard

Azoxystrobin (reg.nr. 14811), and Mirador (reg.nr.13864) are not suitable as alternatives for Pitcher. Additionally, all products must be applied by downward spraying (and subsequent mixing through the topsoil) and restrictions are in place on parcels bordering to surface water and use in groundwater protection zones is not allowed. Instead Pitcher can be applied as a dipping application, which is a different application timing and method without any restriction during planting of the treated crop in fields next to surface water or in groundwater protection zones.
For these reasons of resistance management, application timing/method and restriction in place, the products in FRAC group 11, i.e. Amiplus azoxystrobin (reg.nr. 14812), Amistar (reg.nr. 11767), CropGuard Azoxystrobin (reg.nr. 14811), and Mirador (reg.nr.13864), are no alternatives for Pitcher.
Therefore, in FRAC code 11 there are no comparable products against *Rhizoctonia solani* in tulip.

The group with FRAC code 14 contains the active ingredient tolclofos-methyl, with one authorized product i.e. Rizolex vloeibaar (reg.nr. 11098).
Tolclofos-methyl belongs to the AH-fungicides (Aromatic Hydrocarbons) (chlorophenyls, nitroanilines). There is resistance known in some fungi. Tolclofos-methyl has a low to medium risk for resistance.
The product must be applied before planting of the crop, by downward spraying and subsequent mixing trough the topsoil. Restrictions are in place on parcels bordered by surface water. Pitcher can be applied as a dipping application of the planting material before planting in the field, which is a different application method. No restrictions are in place during planting of the treated crop on parcels bordered by surface water.
The two-way combination of active substances in Pitcher, that fits well in terms of resistance management is not present in the authorized product with only one active ingredient classified as low to medium risk on resistance as in Rizolex vloeibaar (reg.nr. 11098).
For above mentioned reasons of resistance management, application timing/method and restrictions in place, the products in FRAC group 11, i.e. Rizolex vloeibaar (reg.nr. 11098) are no alternative for Pitcher.

The group with FRAC code 20 contains only the active ingredient pencyruron and the authorized product Montego (reg.nr. 14926) with one active ingredient.
Pencycuron is used as fungicide applied as a soil spray during planting in the furrow or broadcast followed by mixing through the topsoil before planting of flowerbulbs. The product cannot be used in groundwater protection zones. Instead, Pitcher can be applied as a dipping application, which is a different application method with no restriction during planting of the treated crop in the field.
Pencycuron belongs to the phenylureas and the resistance risk is not known. The only target pathogen of pencycuron, *Rhizoctonia solani,* is a fungus with a low capability to develop resistance against fungicides. However, the two-way combination of active substances in Pitcher, that fits well in terms of resistance management is not present in the authorized product with only one active ingredient as in Montego (reg.nr. 14926).
For above mentioned reasons of resistance management, difference in application method and restrictions in groundwater protection zones, the product Montego (reg.nr. 14926) in FRAC group 20 is no alternative for Pitcher.

The active substance fluazinam is classified with FRAC code 29. The three authorized products with fluazinam, i.e. Dalimo (reg.nr. 15898), Ohayo (reg.nr. 10710) and Santox (reg.nr. 12205), are identical products.
Fluazinam, a member of the chemical group of the 2,6-Dinitroanilines, is described as a fungicide with primarily protective action, showing mainly contact activity. Furthermore, the compound is characterised by a good residual activity. Fluazinam shows a single-site mode of action but unlike modern inhibitors of respiratory electron transport, where there is an interaction between the inhibitor and a specific binding site (e.g. QoI fungicides), the activity of uncouplers depend on physicochemical properties affecting the solubility of the inhibitor and its ability to carry protons through lipid layers. The uncoupling activity from fluazinam on the mitochondrial oxidative phosphorylation is exerted at several metabolic sites of the pathogen. This all makes the substance essentially a multi-site active one.
Regarding the uses in ornamentals, fluazinam can be considered as a low risk and no resistance problems

are expected for the near future if fluazinam is integrated in a well defined spray program. It seems reasonable to assume that the possibility of development of resistance is considered low under these practical agronomic conditions (Ctgb decision, reg.nr. 10710, dated 1 September 2014).
Dalimo (reg.nr. 15898), Ohayo (reg.nr. 10710) and Santox (reg.nr. 12205) cannot be used in groundwater protection areas.
Pitcher (MCW-7695) is a two-way mixture. Therefore, Pitcher inhibits spore germination, germ tube elongation, mycelium formation and spread of spores of the respective fungi. The two-way combination of active substances in Pitcher, that fits well in terms of resistance management is not present in the authorized products with only one active ingredient, i.e. Dalimo (reg.nr. 15898), Ohayo (reg.nr. 10710) and Santox (reg.nr. 12205).
For above mentioned reasons of resistance management and restrictions in groundwater protection zones, the products Dalimo (reg.nr. 15898), Ohayo (reg.nr. 10710) and Santox (reg.nr. 12205) in FRAC group 29 are no alternative for Pitcher.

Trichoderma harzianum Rifai stam T-22 is classified by FRAC as BM: Biologicals with multiple modes of action. The active ingredient was included on 1 May 2009 in Annex I of Directive 91/414/EEC and subsequently approved under Regulation (EC) 1107/2009. Authorized products are Trianum-G (reg.nr. 12841) and Trianum-P (reg.nr. 12699). The content of active substance in Trianum-G is a factor 10 lower that in Trianum-P.
Trianum-G is used by spreading the ready formulation in the furrow during planting. Trianum-P is sprayed broadcast or in the row after planting but before emergence of the crop and very high volumes of water are used (10-50 tonnes/ha) according to the approved GAP. Soil temperature during application must be > 8˚C.
The efficacy was lower than for the chemical reference products used in the trials for *Fusarium oxysporum* and *Rhizoctonia solani*. (Ctgb decision, reg.nr. 12699, dated 4 Dec. 2015).
Based on above information, the authorized products Trianum-G (reg.nr. 12841) and Trianum-P (reg.nr. 12699) are no alternatives for Pitcher.

Based on the above information, there are no comparable, authorized products against *Rhizoctonia solani* and/or *Rhizoctonia* in tulip.

Conclusion *Rhizoctonia solani* in tulip
In the Netherlands, 13 products are authorized for professional use against for *Rhizoctonia solani* and/or *Rhizoctonia* in tulip, none of them containing fludioxonil or folpet. Including the product under consideration (Pitcher) 8 Mode of actions are available of which 2 (RAC-No 7 & 11) have a high risk to develop risk resistance. All alternative products are based on 1 active substance in the formulation and therefore, pose a higher risk for resistance delevopment than Pitcher, a two way mixture of RAC. No M4 and 12.
Additionally:
The efficacy of the products with *Trichoderma harzianum* Rifai stam T-22 is lower than for the chemical products. For other practical disadvantages of the alternative products see in step 10.

Based on the above information, there are no comparable, authorized products against *Rhizoctonia solani* and/or *Rhizoctonia* in tulip.

Step 9. What other options (non-chemical methods) are available for the proposed uses to be assessed?
Varietal resistance plays a vital role in disease control, in both agricultural and horticultural crops. For cereals, oilseeds, sugar beet, potatoes and grasses, information on resistance is widely available from levy boards and breeders. In many horticultural crops, although resistance varieties are available, commercial pressures to provide products with particular characteristics, dictate that many susceptible varieties are still widely grown. Additionally, the ability of the pathogen to overcome resistance can reduce the commercial life of new resistant varieties. “In crop” disease control strategies in outdoor horticultural crops and arable

crops include preventing excessive N application, which promotes rusts and powdery mildews, however this is not likely to do any more than reduce disease severity and is unlikely to effectively replace chemical control methods.

Where a non-chemical control method is effective against a particular target, it may increase the prevalence of another pest, weed or disease; because making an ecological niche less favourable for one species often creates a niche favourable for another species.

A number of current and potential non-chemical control methods such as soil steaming, freezing, irradiation, use of lasers, electrocution, hand weeding, flame weeding, and diatomaceous earth were identified as potentially posing a threat to the health and safety of workers. They were also prohibitively expensive for use in many crops.

Across most crops the selection of more resistant or tolerant varieties can be an effective non-chemical crop protection measure. However, there is often some form of trade-off in terms of yield or quality (DEFRA report).

Therefore, for agricultural use, there are no non-chemical alternatives available.

Step 10. Can the alternative products with the same mode of application and/or control methods be used without significant economic and practical disadvantages to the user?

***Fusarium oxysporum* in tulip and lily**

The alternative products Trianum_P and Trianum -G have practical disadvantages:
Trianum-G is used by spreading the ready formulation in the furrow during planting. Trianum-P is sprayed broadcast or in the row after planting but before emergence of the crop and very high volumes of water are used (10-50 tonnes/ha) according to the approved GAP. Soil temperature during application must be > 8˚C. The efficacy was lower than for the chemical reference products used in the trials for *Fusarium oxysporum* and *Rhizoctonia solani*. (Ctgb decision, reg.nr. 12699, dated 4 Dec. 2015).

***Rhizoctonia solani* in tulip**

The following alternative products have practical disadvantages:
Amiplus azoxystrobin (reg.nr. 14812), Amistar (reg.nr. 11767), CropGuard Azoxystrobin (reg.nr. 14811), Mirador (reg.nr. 13864) Monarch (reg.nr. 13144) Montego (reg.nr. 14926), Rizolex vloeibaar (reg.nr. 11098) are authorized for soil treatment before, during or after planting. Details are given in step 9. This application technique increases cost as it is additional to the dipping of the plant material which is done by default. Also. restrictions are in place on parcels bordering to surface water and use in groundwater protection zones is not allowed.

Trianum-G is used by spreading the ready formulation in the furrow during planting and Trianum-P is sprayed broadcast or in the row after planting but before emergence of the crop and very high volumes of water are used (10-50 tonnes/ha) according to the approved GAP. Soil temperature during application must be > 8˚C. The efficacy was lower than for the chemical reference products used in the trials for *Fusarium oxysporum* and *Rhizoctonia solani*. (Ctgb decision, reg.nr. 12699, dated 4 Dec. 2015).

Rizolex vloeibaar (reg.nr. 11098) has restrictions on parcels bordering to surface water to protect water organisms, Montego (reg.nr. 14926), Dalimo (reg.nr. 15898), Ohayo (reg.nr. 10710) and Santox (reg.nr. 12205) have restrictions to protect groundwater. Details are given in step 9.

Step 11. Consideration of consequences on minor uses (Art 50.1(d))

As there are not enough alternatives for the use of Pitcher in the major uses, there is no consequence on minor uses.

Step 12. Please indicate any other relevant information that will enable a comparison of risk.

None.

References

- Ctgb website:
    - Indeling Kleine gewasgroepen: https://www.ctgb.nl/gewasbeschermingsmiddelen/documenten/toetsingskader-gewasbeschermingsmiddelen/2018/06/08/indeling-kleine-gewasgroepen-sierteelt
    - Ctgb decision Trianum-P (reg.nr. 12699), dated 4 Dec. 2015.
    - Ctgb decision Ohayo (reg.nr. 10710), dated 1 September 2014.
    - Ctgb decision Monarch (reg.nr. 13144), dated 6 november 2015.
- Statline: https://opendata.cbs.nl/statline/#/CBS/nl/dataset/81302ned/table?dl=DF60
- FRAC code list: https://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2019-final.xlsx?sfvrsn=3edc4b9a_2
- DEFRA report: Jonathan Blake, *et al*., January. 2013. Non-chemical pest control methods: A review of the literature to establish their efficacy and safety to workers, to inform the process of comparative assessment required by new pesticide legislation. Defra Project Code: PS2809/348656)

ADAMA, Leusden, 26 AUG. 2019

College voor de toelating van
gewasbeschermingsmiddelen en biociden
Bennekomseweg 41,
6717 LL Ede

t.a.v. art. 5.1.2.e Woo

Datum : 26 augustus 2019
Betreft : CA - aanvraag middel Pitcher 20150428 ZETG
Uw kenmerk :
Ons kenmerk : NL19_030

Geachte mevr. art. 5.1.2.e Woo,

Zoals toegezegd in onze brief nl19_027 d.d. 21 augustus j.l. zenden wij u hierbij de vergelijkende beoordeling van Pitcher als papieren versie. De digitale versie zal u per email worden toegestuurd.

Wij zien de rekening voor de additionele kosten van deze beoordeling tegemoet.

art. 5.1.2.e Woo

M t,

ar o

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Agricultural aspects of Comparative assessment
National Plant Protection Organization the Netherlands

Subject	:	NPPO evaluation of the agricultural aspects of Comparative assessment of
Document number	:	clv17…
Active substance	:	
Principal	:	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
Reference Ctgb	:	
Contact	:	
Address	:	P.O. Box 8030 6710 AA Ede the Netherlands
Our reference	:	
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Date	:	
Number of pages	:	

The NPPO has compiled this Comparative Assessment of agricultural aspects with the greatest care and to the best of its current knowledge, acting in full conformity with the criteria and guidelines of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

The NPPO can accept no liability for any harmful consequences, whatever their nature, that may result from these evaluations or their application.

It should also be noted that the Ctgb is the sole body in the Netherlands qualified to decide on requests for the authorisation of pesticides.

NPPO evaluation of the agricultural aspects of Comparative assessment

National addendum to the draft Registration Report (dRR)

1. General information

Country	
Name applicant	
Product under evaluation	
Candidate for substitution (active substance name)	
Reasons for approval as candidate for substitution (delete as appropriate)	low ADI, ARfD or AOEL; two of PBT; significant proportion of non-active isomers; classified Carcinogen 1A or 1B; classified as toxic for reproduction 1A or 1B; endocrine disruption; other reasons for concern
Formulation and content	
Mode of action	
IRAC-code	

2. Claim Major uses/minor uses

The proposed use of [CfS] is an [insecticide/herbicide/fungicide] for professional use applied as … application in the following uses:

Major uses

Crop	Pest/disease/weed	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days

Minor uses

Crop	Pest/disease/weed	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days

Proposed restrictions

……

3. Characteristics of the product (PPP)

Short written explanation of the PPP which contains the following info:

- Insecticide/fungicide/herbicide
- Working mechanism (e.g. contact, systemic, behaviour in/on plant)
- IRAC, HRAC, FRAC group
- Additional info which is helpful/necessary for the assessment (e.g. safe or not safe to bees, application restrictions)

4. Comparative assessment of agricultural aspects

This assessment follows a step-wise approach which contains three area's (see chapters 4.1., 4.2. and 4.3.). As described in the EU Guidance document on comparative assessment the process may be terminated at any stage and it may not be necessary to continue through the whole scheme. In that case the CA-process can be finalized by filling in the final conclusions (chapter 5). If not, all steps have to be completed.

Where there are reasons to believe at the start of the comparative assessment that there might be a problem in a certain area, it may be useful to start the assessment in that particular area.

4.1. Conclusion alternatives available per use regarding limitations in the use (effectiveness, practical and/or economical disadvantages)

An overview of all alternatives, both chemicals (date: [dd-mm-yyyy]) and non-chemical methods, for the proposed major uses of [CfS] can be found in annexes I and II.

Crop	Pest	Conclusion NPPO*

* Conclusion:
1. Alternatives available: [names of products]
2. No chemical alternatives with a comparable use available, and no comparable non-chemical alternatives: stop CA
3. Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
4. Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.3.

4.2. Conclusion alternatives available per use regarding the risk of developing resistance (major uses)

An overview of all alternatives, both chemicals (date: [dd-mm-yyyy]) and non-chemical methods, for the proposed major uses of [CfS] can be found in annexes I and II.

Crop	Pest	Conclusion NPPO*	Name(s) of alternative(s)**

* Conclusion:

1. There is an alternative with the same mode of action as the candidate.
2. The alternatives together have more than 5 different modes of action.
3. Insufficient alternatives available stop CA.
4. Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.
5. Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.3.

** When conclusion 1 is applicable provide the name of the alternative. When conclusion 2 is applicable provide the names of the alternatives. When conclusion 3, 4 or 5 is applicable this column can be left blank.

4.3. Conclusions consequences for minor uses

Option 1: Assessment regarding consequences for minor uses is not considered because substitution is not possible for any of the proposed major uses.

Option 2: Substitution is not possible for … of [CfS] because of the consequences for minor uses.

5. Overall NPPO conclusion on agriculture aspects

For the following uses [CfS] can be substituted by alternatives listed below.

Crop	Pest/disease	Alternative PPP	Registration number	Active substance

Substitution is not possible for the following uses of the CfS:

Crop	Pest/disease	Conclusion NPPO*

*Conclusion:

- Substitution is not possible for the following uses of the CfS because of lack of alternatives
- Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
- Substitution is not possible for the following uses of the CfS because of the consequences for minor uses

Annex I: Alternative authorised plant protection products in the Netherlands
An overview of chemicals alternatives (date: dd-mm-yyyy), for the proposed major uses of [CfS].

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management

Annex II: Alternative non-chemical methods

An overview of non-chemicals alternatives (date: dd-mm-yyyy), for the proposed major uses of [CfS].

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding limits in the use	Alternative regarding resistance management

Bijlage 3 Evaluatieformulier evaluerende instantie

Aanvraagnummer	20150428
Middelnaam	Pitcher
Behandelaar	Mevrouw art. 5.1.2.e Woo

Offertevraag duidelijk ja □ nee □
Opmerking

Opdrachtstelling duidelijk ja □ nee □
Opmerking

Bijlage bij opdracht compleet ja □ nee □
Opmerking

Nazorg binnen gestelde termijn ja □ nee □
Opmerking

Wij verzoeken u dit formulier mee te zenden samen met de definitieve rapportage.

Van: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Verzonden: dinsdag 27 augustus 2019 07:47
Aan: art. 5.1.2.e Woo ir. art. 5.1.2.e Woo <art. 5.1.2.e Woo@ctgb.nl>
Onderwerp: RE: opdracht_ca_pitcher

Hallo art. 5.1.2.e Woo,

We hebben de opdracht ontvangen en we gaan ons best doen om zo snel mogelijk op te leveren. Mochten we inderdaad eerder op kunnen leveren dan zullen we dat zeker doen.

We missen nog wel de GAP en WG. Zou je die vandaag nog willen sturen?

Met vriendelijke groet,
art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo
Verzonden: maandag 26 augustus 2019 16:41
Aan: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo
Onderwerp: RE: opdracht_ca_pitcher

Beste art. 5.1.2.e Woo,
Wij hebben zojuist de opdrachtbrief voor de CA voor Pitcher naar jullie verstuurd. Ik heb hier als opleverdatum 6 september aangehouden zoals je aangaf. Mocht je onverhoopt de landbouwkundige vergelijking eerder gereed hebben, wil je hem dan eerder sturen? Of misschien kun je iets eerder al een richting geven waar het heen gaat, dan kan ik bij mijn voorbereiding van de stukken voor het college hier al op voorsorteren.
In elk geval heel fijn dat jullie deze opdracht op zo'n korte termijn kunnen doen voor ons.
Vriendelijke groet,
art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo
Verzonden: donderdag 22 augustus 2019 17:08
Aan: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo
Onderwerp: RE: opdracht_ca_pitcher

Hallo art. 5.1.2.e Woo,

Dank voor je snelle reactie. De aanvrager heeft aangegeven het CA formulier uiterlijk maandag te zullen gaan leveren. Ik zal het dan onmiddellijk doorsturen naar jullie.
Wij zouden erg geholpen zijn als jullie een week eerder zouden kunnen opleveren. Ik moet de stukken voor besluitvorming van het middel uiterlijk 5 september aanleveren voor het College en ik heb ook nog wat tijd nodig om jullie uitkomst te verwerken.
Kun jij bespreken of dat mogelijk is. Zoals gezegd, het is echt een spoed geval voor ons.

Alvast bedankt,
art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo [mailto art. 5.1.2.e Woo@nvwa.nl]
Verzonden: donderdag 22 augustus 2019 16:13

Aan: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo
Onderwerp: RE: opdracht_ca_pitcher

Hallo art. 5.1.2.e Woo,
Als we de opdracht inderdaad maandag van jullie ontvangen dan kunnen wij 6 september opleveren.
In totaal denken we 20 uur nodig te hebben.

Je kunt de brief richten aan
Dhr. Ir. art. 5.1.2.e Woo
Postbus 43006
3540 AA UTRECHT

Met vriendelijke groet,
art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo <art. 5.1.2.e Woo@ctgb.nl>
Verzonden: donderdag 22 augustus 2019 12:33
Aan: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Onderwerp: opdracht_ca_pitcher

Hallo art. 5.1.2.e Woo,
Ik ben bezig met de voorbereidingen voor de opdracht voor de Comparative Assessment van het product Pitcher.
Omdat het voor het Ctgb zeer belangrijk is dat deze opdracht zo snel mogelijk wordt gedaan, stuur ik je alvast een eerste opzet van de opdrachtbrief, met de gebruiken die op het WG staan.
Zou jij alvast een inschatting kunnen maken van de uren die je nodig hebt, en nog belangrijker; de opleverdatum van deze opdracht. Verder ben ik niet zeker aan wie ik de brief moet richten.
Zoals gezegd, het is een zeer urgente opdracht voor ons; als het helpt dat onze directeur contact opneemt met jouw superieur, om te prioriteren, dan hoor ik dat graag.
We verwachten de aanvraag a.s. maandag en kunnen hem dan direct doorsturen naar de NVWA.
Ik hoor graag van je,
art. 5.1.2.e Woo

art. 5.1.2.e Woo **M.Sc.**
Project Manager

Ctgb
Board for the Authorisation of Plant Protection Products and Biocides

Bezoekadres / visiting address:
Bennekomseweg 41
6717 LL Ede
(type voor navigatie 'Hora park' in)

Postadres / postal address:
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The Netherlands

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Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is gezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen.
De Staat aanvaardt geen aansprakelijkheid voor schade, van welke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.

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Van: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Verzonden: maandag 2 september 2019 12:15
Aan: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo <art. 5.1.2.e Woo@ctgb.nl>
Onderwerp: RE: opdracht_ca_pitcher

Hallo art. 5.1.2.e Woo,

Hierbij de door de NVWA uitgevoerde landbouwkundige vergelijking in het kader van Comparative Assessments voor Pitcher.

Mochten er naar aanleiding van de landbouwkundige vergelijking nog vragen zijn dan hoor ik dat graag.

Met vriendelijke groet,

art. 5.1.2.e Woo
Beleidsmedewerker plantgezondheid
.....
Directie Handhaven
Divisie Regie & expertise
Afdeling Expertise
Nederlandse Voedsel- en Warenautoriteit
Catharijnesingel 59 | 3511 GG | Utrecht
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http://www.nvwa.nl

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievelijk aan u is toegezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. De Staat aanvaardt geen aansprakelijkheid voor schade, van we ke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.
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Agricultural aspects of Comparative assessment
National Plant Protection Organization the Netherlands

Subject	:	NPPO evaluation of the agricultural aspects of Comparative assessment of Pitcher
Document number	:	Clv19_Pitcher_def
Active substance	:	Fludioxonil, folpet
Principal	:	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
Reference Ctgb	:	20150428 ZETG
Contact	:	Mrs. art. 5.1.2.e Woo
Address	:	P.O. Box 8030 6710 AA Ede the Netherlands
Our reference	:	Netherlands Food and Consumer Product Safety Authority, Expertise department
Date	:	2 September 2019
Number of pages	:	11

The NPPO has compiled this Comparative Assessment of agricultural aspects with the greatest care and to the best of its current knowledge, acting in full conformity with the criteria and guidelines of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

The NPPO can accept no liability for any harmful consequences, whatever their nature, that may result from these evaluations or their application.

It should also be noted that the Ctgb is the sole body in the Netherlands qualified to decide on requests for the authorisation of pesticides.

NPPO evaluation of the agricultural aspects of Comparative assessment

National addendum to the draft Registration Report (dRR)

1. General information

Country	The Netherlands
Name applicant	Adama Northern Europe B.V.
Product under evaluation	Pitcher
Candidate for substitution (active substance name)	fludioxonil
Reasons for approval as candidate for substitution (delete as appropriate)	persistent and bioaccumulative
Formulation and content	SC, folpet 450 g/L + fludioxonil 60 g/L
Mode of action	Signal transduction
FRAC-code	12

2. Claim Major uses/minor uses

The proposed use of Pitcher is a fungicide for professional use applied as dip (immersion) application (in flower bulbs and tubers) or a foliar application (floriculture crops, Buxus and perennial crops) in the following uses:

Major uses

Crop	Disease	Maximum number of applications per crop	Minimum interval between spray applications in days	Pre harvest interval in days
Lily (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	1	n.a.	n.a.
Tulip (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	1	n.a.	n.a.
	Rhizoctonia solani (RHIZSO)	1	n.a.	n.a.

Minor uses

Crop	Disease	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days
Gladiolus (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	1 per crop	n.a.	n.a.
Hyacinth (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	1 per crop	n.a.	n.a.

Crop	Disease	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days
Narcissus, small (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	1 per crop	n.a.	n.a.
Iris (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	1 per crop	n.a.	n.a.
Crocus (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	1 per crop	n.a.	n.a.
Anemone (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	1 per crop	n.a.	n.a.
Bulb flowers and tuber flowers, excluding large Narcissus and lily (non-soil bound protected culture)	*Fusarium oxysporum* (FUSAOX)	1 per crop	n.a.	n.a.
Tulip (soil bound protected culture)	*Fusarium oxysporum* (FUSAOX)	1 per 12 months	n.a.	n.a.
Iris (soil bound protected culture)	*Fusarium oxysporum* (FUSAOX)	1 per 12 months	n.a.	n.a.
Gladiolus (soil bound protected culture)	*Fusarium oxysporum* (FUSAOX)	1 per 12 months	n.a.	n.a.
Floriculture crops (unprotected culture)	*Phoma* spp. (PHOMSP)	3 per 12 months	7	n.a.
	Septoria spp. (SEPTSP)	3 per 12 months	7	n.a.
	Colletotrichum spp. (COLLSP)	3 per 12 months	7	n.a.
Buxus (unprotected culture)	*Cylindrocladium* spp. (CYLDSP)	3 per 12 months	7	n.a.
Buxus (non-soil bound protected culture)	*Cylindrocladium* spp. (CYLDSP)	3 per crop, 12 per 12 months	7	n.a.
Perennial crops (non-soil bound unprotected culture)	*Phoma* spp. (PHOMSP)	3 per 12 months	7	n.a.
	Septoria spp. (SEPTSP)	3 per 12 months	7	n.a.

Crop	Disease	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days
	Colletotrichum spp. (COLLSP)	3 per 12 months	7	n.a.
Perennial crops (non-soil bound, protected culture)	*Phoma* spp. (PHOMSP)	3 per crop, 6 per 12 months	7	n.a.
	Septoria spp. (SEPTSP)	3 per crop, 6 per 12 months	7	n.a.
	Colletotrichum spp. (COLLSP)	3 per crop, 6 per 12 months	7	n.a.

Proposed restrictions
Wear suitable gloves when working on treated crops, including bulbs and/or tubers.

3. Characteristics of the product (PPP)

Pitcher is a non-systemic contact fungicide, based on the active substances fludioxonil and folpet. It is used for dip treatment and foliar treatment. Fludioxonil acts via signal transduction and has FRAC code 12. Folpet has a multi-site contact activity and has FRAC code M04. Pitcher inhibits spore germination, germ tube elongation, mycelium formation and spread of spores of the fungi.

4. Comparative assessment of agricultural aspects

This assessment follows a step-wise approach which contains three area's (see chapters 4.1., 4.2. and 4.3.). As described in the EU Guidance document on comparative assessment the process may be terminated at any stage and it may not be necessary to continue through the whole scheme. In that case the CA-process can be finalized by filling in the final conclusions (chapter 5). If not, all steps have to be completed.

Where there are reasons to believe at the start of the comparative assessment that there might be a problem in a certain area, it may be useful to start the assessment in that particular area.

4.1. Conclusion alternatives available per use regarding limitations in the use (effectiveness, practical and/or economical disadvantages)

An overview of all alternatives, both chemicals (date: 26-8-2019) and non-chemical methods, for the proposed major uses of Pitcher can be found in annexes I and II.

Crop	Pest	Conclusion NPPO
Lily (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
Tulip (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
	Rhizoctonia solani (RHIZSO)	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.

4.2. Conclusion alternatives available per use regarding the risk of developing resistance (major uses)

An overview of all alternatives, both chemicals (date: 26-08-2019) and non-chemical methods, for the proposed major uses of Pitcher can be found in annexes I and II.

Crop	Pest	Conclusion NPPO	Name(s) of alternative(s)
Lily (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	Insufficient alternatives available. Stop CA.	
Tulip (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	Insufficient alternatives available. Stop CA.	
	Rhizoctonia solani (RHIZSO)	Insufficient alternatives available. Stop CA.	

4.3. Conclusions consequences for minor uses

Assessment regarding consequences for minor uses is not considered because substitution is not possible for any of the proposed major uses.

5. Overall NPPO conclusion on agriculture aspects

Substitution is not possible for the following uses of the CfS:

Crop	Pest/disease	Conclusion NPPO
Lily (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
Tulip (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
	Rhizoctonia solani (RHIZSO)	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.

Annex I: Alternative authorised plant protection products in the Netherlands
An overview of chemicals alternatives (date: 26-08-2019), for the proposed major uses of Pitcher.

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
Lily (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	Captor SC	Captan	M04	Toxic to aquatic organisms, therefore apply in such a way that the PPP does not end up in surface water.		yes
		Solofol	Folpet	M04	To protect mammals, application in the cultivation of flower bulbs and tubers is only permitted before a ground cover of 25% has been reached.		yes
		Mirage Plus 570 SC	folpet, prochloraz	M04, 3	Candidate for substitution (prochloraz)		n.a.
		Securo	folpet, pyraclostrobin	M04, 11	To protect aquatic organisms, during and after dip application of flower bulbs, emission to the surface water should be prevented*.		yes
		Mirage Elan	prochloraz	3	Candidate for substitution		n.a.
		Sportak EW	prochloraz	3	Candidate for substitution		n.a.
		Rudis	prothioconazole	3	Apply from leaf development (BBCH 50) onwards.		yes
		Topsin M Ultra	thiophanate-methyl	1	To protect aquatic organisms, during and after dip application of flower bulbs, emission to the surface water should be prevented*.		yes
Tulip Unprotected culture)	*Fusarium oxysporum* (FUSAOX)	Captor SC	captan	M04	Toxic to aquatic organisms, therefore apply in such a way that the PPP does not end up in surface water.		yes
		Solofol	folpet	M04	To protect mammals, application in the cultivation of flower bulbs and tubers is only permitted before a ground cover of 25% has been reached.		yes

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
		Mirage Plus 570 SC	folpet, prochloraz	M04, 3	Candidate for substitution (prochloraz)		n.a.
		Securo	folpet, pyraclostrobin	M04, 11	To protect aquatic organisms, during and after dip application of flower bulbs, emission to the surface water should be prevented*.		yes
		Mirage Plus	prochloraz	3	Candidate for substitution		n.a.
		Sportak EW	prochloraz	3	Candidate for substitution		n.a.
		Rudis	prothioconazole	3	Apply from leaf development (BBCH 50) onwards.		yes
		Topsin M Ultra	thiophanate-methyl	1	To protect aquatic organisms, during and after dip application of flower bulbs, emission to the surface water should be prevented*.		yes
Tulip Unprotected culture)	*Rhizoctonia solani* (RHIZSO)	CAPTOR SC	captan	M04	Toxic to aquatic organisms, therefore apply in such a way that the PPP does not end up in surface water.		yes
		Ohayo	fluazinam	29	To protect aquatic organisms, during and after dip application of flower bulbs, emission to the surface water should be prevented*.		yes

*Application is only allowed if:
• dip treatments are conducted at a location where no rinsing or drainage on surface water or sewer is possible and where distribution of dip fluid via means of transport (e.g. forklift) is prevented
• After dipping the cask is blown dry and is left to drip for minimally 12 hours.
• Transport of treated bulbs to the field or another location is exclusively carried out in an emission-free transport trolley. E.g. a transport trolley with collection troughs and a collection container.
• Any leakage / residual fluids are reused, disposed of as chemical waste or processed via a purification system in accordance with legislation (e.g. PhytoBac of Heliosec).

Annex II: Alternative non-chemical methods

An overview of non-chemical alternatives (date: 26-08-2019), for the proposed major uses of Pitcher.

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding resistance management
Lily (unprotected culture), Tulip (unprotected culture)	*Fusarium oxysporum* (FUSAOX)	Warm water treatment	Bulbs are put into warm water for a period of time. Method is widely used to control nematodes and mites.	Not effective to fungi.	no
		Hot air treatment	Bulbs are treated with hot air for a period of time.	Meant to control nematodes and insects. Not ready to be used in practice Sufficient effectiveness against fungi not known.	no
		UV disinfection	Disinfection of flower bulbs in dip fluid.	Has fungicidal effect. Not widely used, because disinfection between deeper layers of the bulb is not sufficient. Because of soil particles in the dipping fluid, disinfection is hampered.	no
		CATT treatment	Controlled Atmosphere Temperature Treatment, a combination of an adjusted CO_2/O_2 balance in the air and a high temperature	Tested for nematodes and insects. Not ready to be used in practice. Sufficient effectiveness against fungi not known	no
		Resistant varieties	For most crops, resistant varieties are an important part of non-chemical disease control. Using resistant cultivars is an effective control	Because most cultivars are grown for their specific	no

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding resistance management
			measure.	characteristics, choosing resistant cultivars is not always feasible. Also resistance is seldom complete, so fungicide treatment is usually still required.	
Tulip (unprotected culture)	*Rhizoctonia solani* (RHIZSO)	Warm water treatment	Bulbs are put into warm water for a period of time. Method is widely used to control nematodes and mites.	Not effective to fungi.	no
		Hot air treatment	Bulbs are treated with hot air for a period of time.	Meant to control nematodes and insects. Not ready to be used in practice. Sufficient effectiveness against fungi not known	no
		UV disinfection	Disinfection of flower bulbs in dip fluid.	Has fungicidal effect. Not widely used, because disinfection between deeper layers of the bulb is not sufficient. Because of soil particles in the dipping fluid, disinfection is hampered.	no
		CATT treatment	Controlled Atmosphere Temperature Treatment, a combination of an adjusted CO_2/O_2 balance in the air and a high temperature	Tested for nematodes and insects. Not ready to be used in practice. Sufficient effectiveness against fungi not	no

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding resistance management
				known	
		Resistant varieties	For most crops, resistant varieties are an important part of non-chemical disease control. Using resistant cultivars is an effective control measure.	Because most cultivars are grown for their specific characteristics, choosing resistant cultivars is not always feasible. Also resistance is seldom complete, so fungicide treatment is usually still required.	no

ctgb

College voor de toelating van gewasbeschermingsmiddelen en biociden

NVWA
T.a.v. Dhr. Ir. art. 5.1.2.e Woo
Postbus 43006
3540 AA UTRECHT

Datum 26 augustus 2019

Behandeld door
Mrs. ir. art. 5.1.2.e Woo

Telefoonnummer
art. 5.1.2.e Woo

E-mail
art. 5.1.2.e Woo@ctgb.nl

Kenmerk
201908260199

Betreft Opdracht voor comparative assessments Pitcher 20150428

Geachte heer art. 5.1.2.e Woo,

Het Ctgb en NVWA werken samen op het gebied de uitvoering van comparative assessments, conform Verordening (EG) nr. 1107/2009 art. 50.

Hierbij verleen ik u opdracht tot het verrichten van de werkzaamheden conform de offerte:
trcvwa /2016/1385.

Omschrijving van de werkzaamheden:
Bij de aanvraag voor het middel: Pitcher, 20150428 ZTG, op basis van de werkzame stoffen fludioxonil en folpet, wordt een comparative assessment uitgevoerd.

De comparative assessment dient te worden uitgevoerd voor de volgende gebruiken:

Toepassingsgebied	Type toepassing	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus
Gladiool (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1

Toepassingsgebied	Type toepassing	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus
Hyacint (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1
Lelie (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1
Narcis m.u.v. grofbollige narcis (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1
Tulp (onbedekte teelt)	Dompelbehandeling	Zuur1, Rhizoctonia 2	1% (1 L per 100 L water)	1
Iris (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1
Krokus (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1
Anemoon (onbedekte teelt)	Dompelbehandeling	Zuur1	1% (1 L per 100 L water)	1

U wordt verzocht voor deze 8 gebruiken een landbouwkundige beoordeling uit te voeren.

De eindconclusie van de landbouwkundige beoordeling dient in een beknopte samenvatting duidelijk te worden aangegeven. Hierin is opgenomen welke alternatieven middelen zijn overwogen en waarom die al dan niet als volwaardig alternatief kunnen worden beschouwd.

Wilt u per toepassing aangegeven op welk moment (Step 6-11) gestopt kan worden met CA, omdat er geen alternatieve middelen gevonden zijn?

De projecturen bedragen maximaal 20 uur.
Het rapport ontvang ik uiterlijk 6 september 2019, onder vermelding van bovengenoemd aanvraagnummer.

Ter bevestiging van deze opdracht ontvang ik graag binnen een week na dagtekening een getekend exemplaar retour.

Als u inhoudelijke vragen heeft over deze opdracht, kunt u rechtstreeks met de projectleider art. 5.1.2.e Woo contact opnemen.

Akkoord, **Het College voor de toelating van gewasbeschermingsmiddelen en biociden,** **voor deze:** **de secretaris,** **voor deze:**	Akkoord, NVWA
art. 5.1.2.e Woo	art. 5.1.2.e Woo
Mevrouw dr.ir. art. 5.1.2.e Woo art. 5.1.2.e Woo	**De heer Ir.** art. 5.1.2.e Woo

Bijlagen:

1 Formulier CA bij Pitcher, ingevuld door de aanvrager
2 Template comparative assessment
3 Evaluatieformulier evaluerende instantie

ctgb

College voor de toelating van gewasbeschermingsmiddelen en biociden

NVWA
T.a.v. Dhr. Ir. art. 5.1.2.e Woo
Postbus 43006
3540 AA UTRECHT

Datum 27 mei 2019

Behandeld door
Mr. drs. art. 5.1.2.e Woo

Telefoonnummer
031 747 1893

E-mail
art. 5.1.2.e Woo@ctgb.nl

Kenmerk
201904160065

Betreft: Opdracht voor Comparitive assessment: PREPPER 20180714 NLTG

Geachte heer art. 5.1.2.e Woo,

Het Ctgb en NVWA werken samen op het gebied de uitvoering van comparative assessments, conform Verordening (EG) nr. 1107/2009 art. 50.

Hierbij verleen ik u opdracht tot het verrichten van de werkzaamheden conform de offerte trcvwa /2016/1385.

Omschrijving van de werkzaamheden:
Bij de aanvraag voor het middel: PREPPER 20180714 NLTG, op basis van de werkzame stof Fludioxonil wordt een comparative assessment uitgevoerd.

De comparative assessment dient te worden uitgevoerd voor de volgende gebruiken:
- Wintertarwe
- Wintergerst
- Winterrogge
- Triticale
- Zomertarwe
- Zomergerst
- Zomerrogge
- Haver

U wordt verzocht voor deze acht gebruiken een landbouwkundige beoordeling uit te voeren. Als bijlage bij deze brief is het formulier voor comparative assessment en de template voor de beoordeling bijgevoegd.

De eindconclusie van de landbouwkundige beoordeling dient in een beknopte samenvatting duidelijk te worden aangegeven. Hierin is opgenomen welke alternatieven middelen zijn overwogen en waarom die al dan niet als volwaardig alternatief kunnen worden beschouwd.

Wilt u per toepassing aangegeven op welk moment (Step 6-11) gestopt kan worden met CA, omdat er geen alternatieve middelen gevonden zijn?

De projecturen bedragen maximaal 54 uur.
Het rapport ontvang ik graag **uiterlijk 27 juni 2019**, onder vermelding van bovengenoemd opdrachtnummer en aanvraagnummer.

Ter bevestiging van deze opdracht ontvang ik graag binnen een week na dagtekening een getekend exemplaar retour.

Als u inhoudelijke vragen heeft over deze opdracht, kunt u rechtstreeks met de projectleider, de heer drs. art. 5.1.2.e Woo, contact opnemen.

Akkoord,
Het College voor de toelating van gewasbeschermingsmiddelen en biociden,
voor deze:
de secretaris,
voor deze:

art. 5.1.2.e Woo

art. 5.1.2.e Woo

Akkoord,
NVWA

Bijlagen:
1 Formulier comparitive assessment, ingevuld door de aanvrager
2 Beoordelingstemplate comparative assesment
3 Evaluatieformulier

Agricultural aspects of Comparative assessment
National Plant Protection Organization the Netherlands

Subject	:	NPPO evaluation of the agricultural aspects of Comparative assessment of
Document number	:	clv17…
Active substance	:	
Principal	:	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
Reference Ctgb	:	
Contact	:	
Address	:	P.O. Box 8030 6710 AA Ede the Netherlands
Our reference	:	
Telephone	:	+31
Date	:	
Number of pages	:	

The NPPO has compiled this Comparative Assessment of agricultural aspects with the greatest care and to the best of its current knowledge, acting in full conformity with the criteria and guidelines of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

The NPPO can accept no liability for any harmful consequences, whatever their nature, that may result from these evaluations or their application.

It should also be noted that the Ctgb is the sole body in the Netherlands qualified to decide on requests for the authorisation of pesticides.

NPPO evaluation of the agricultural aspects of Comparative assessment

National addendum to the draft Registration Report (dRR)

1. General information

Country	
Name applicant	
Product under evaluation	
Candidate for substitution (active substance name)	
Reasons for approval as candidate for substitution (delete as appropriate)	low ADI, ARfD or AOEL; two of PBT; significant proportion of non-active isomers; classified Carcinogen 1A or 1B; classified as toxic for reproduction 1A or 1B; endocrine disruption; other reasons for concern
Formulation and content	
Mode of action	
IRAC-code	

2. Claim Major uses/minor uses

The proposed use of [CfS] is an [insecticide/herbicide/fungicide] for professional use applied as … application in the following uses:

Major uses

Crop	Pest/disease/weed	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days

Minor uses

Crop	Pest/disease/weed	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days

Proposed restrictions

……

3. Characteristics of the product (PPP)

Short written explanation of the PPP which contains the following info:

- Insecticide/fungicide/herbicide
- Working mechanism (e.g. contact, systemic, behaviour in/on plant)
- IRAC, HRAC, FRAC group
- Additional info which is helpful/necessary for the assessment (e.g. safe or not safe to bees, application restrictions)

4. Comparative assessment of agricultural aspects

This assessment follows a step-wise approach which contains three area's (see chapters 4.1., 4.2. and 4.3.). As described in the EU Guidance document on comparative assessment the process may be terminated at any stage and it may not be necessary to continue through the whole scheme. In that case the CA-process can be finalized by filling in the final conclusions (chapter 5). If not, all steps have to be completed.

Where there are reasons to believe at the start of the comparative assessment that there might be a problem in a certain area, it may be useful to start the assessment in that particular area.

4.1. Conclusion alternatives available per use regarding limitations in the use (effectiveness, practical and/or economical disadvantages)

An overview of all alternatives, both chemicals (date: [dd-mm-yyyy]) and non-chemical methods, for the proposed major uses of [CfS] can be found in annexes I and II.

Crop	Pest	Conclusion NPPO*

* Conclusion:
1. Alternatives available: [names of products]
2. No chemical alternatives with a comparable use available, and no comparable non-chemical alternatives: stop CA
3. Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
4. Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.3.

4.2. Conclusion alternatives available per use regarding the risk of developing resistance (major uses)

An overview of all alternatives, both chemicals (date: [dd-mm-yyyy]) and non-chemical methods, for the proposed major uses of [CfS] can be found in annexes I and II.

Crop	Pest	Conclusion NPPO*	Name(s) of alternative(s)**

* Conclusion:

1. There is an alternative with the same mode of action as the candidate.
2. The alternatives together have more than 5 different modes of action.
3. Insufficient alternatives available stop CA.
4. Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.1.
5. Assessment regarding resistance management is not considered because the CA-process was stopped in chapter 4.3.

** When conclusion 1 is applicable provide the name of the alternative. When conclusion 2 is applicable provide the names of the alternatives. When conclusion 3, 4 or 5 is applicable this column can be left blank.

4.3. Conclusions consequences for minor uses

Option 1: Assessment regarding consequences for minor uses is not considered because substitution is not possible for any of the proposed major uses.

Option 2: Substitution is not possible for … of [CfS] because of the consequences for minor uses.

5. Overall NPPO conclusion on agriculture aspects

For the following uses [CfS] can be substituted by alternatives listed below.

Crop	Pest/disease	Alternative PPP	Registration number	Active substance

Substitution is not possible for the following uses of the CfS:

Crop	Pest/disease	Conclusion NPPO*

*Conclusion:

- Substitution is not possible for the following uses of the CfS because of lack of alternatives
- Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
- Substitution is not possible for the following uses of the CfS because of the consequences for minor uses

Annex I: Alternative authorised plant protection products in the Netherlands
An overview of chemicals alternatives (date: dd-mm-yyyy), for the proposed major uses of [CfS].

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management

Annex II: Alternative non-chemical methods

An overview of non-chemicals alternatives (date: dd-mm-yyyy), for the proposed major uses of [CfS].

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding limits in the use	Alternative regarding resistance management

Evaluatieformulier evaluerende instantie

Aanvraagnummer	20180714 NLTG
Middelnaam	Prepper
Behandelaar	art. 5.1.2.e Woo

Offertevraag duidelijk ja □ nee □
Opmerking

Opdrachtstelling duidelijk ja □ nee □
Opmerking

Bijlage bij opdracht compleet ja □ nee □
Opmerking

Nazorg binnen gestelde termijn ja □ nee □
Opmerking

Wij verzoeken u dit formulier mee te zenden samen met de definitieve rapportage.

20180714 NLTG

ontv. dd. 05 JUNI 2019
no. CTB /

ter behandeling		beantwoord	
aan:	dd	paraaf	dd
art. 5.1.2.e Woo			
copie verz. aan		paraaf	dd
dossier: PREPPER			

NVWA
T.a.v. Dhr. Ir. art. 5.1.2.e Woo
Postbus 43006
3540 AA UTRECHT

ctgb

College voor de toelating van gewasbeschermingsmiddelen en biociden

Datum 27 mei 2019

Behandeld door
Mr. drs. art. 5.1.2.e Woo

Telefoonnummer
031 747 1893

E-mail
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Kenmerk
201904160065

Betreft: Opdracht voor Comparitive assessment: PREPPER 20180714 NLTG

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Hierbij verleen ik u opdracht tot het verrichten van de werkzaamheden conform de offerte trcvwa /2016/1385.

Omschrijving van de werkzaamheden:
Bij de aanvraag voor het middel: PREPPER 20180714 NLTG, op basis van de werkzame stof Fludioxonil wordt een comparative assessment uitgevoerd.

De comparative assessment dient te worden uitgevoerd voor de volgende gebruiken:
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- Wintergerst
- Winterrogge
- Triticale
- Zomertarwe
- Zomergerst
- Zomerrogge
- Haver

U wordt verzocht voor deze acht gebruiken een landbouwkundige beoordeling uit te voeren. Als bijlage bij deze brief is het formulier voor comparative assessment en de template voor de beoordeling bijgevoegd.

De eindconclusie van de landbouwkundige beoordeling dient in een beknopte samenvatting duidelijk te worden aangegeven. Hierin is opgenomen welke alternatieven middelen zijn overwogen en waarom die al dan niet als volwaardig alternatief kunnen worden beschouwd.

Wilt u per toepassing aangegeven op welk moment (Step 6-11) gestopt kan worden met CA, omdat er geen alternatieve middelen gevonden zijn?

De projecturen bedragen maximaal 54 uur.
Het rapport ontvang ik graag **uiterlijk 27 juni 2019**, onder vermelding van bovengenoemd opdrachtnummer en aanvraagnummer.

Ter bevestiging van deze opdracht ontvang ik graag binnen een week na dagtekening een getekend exemplaar retour.

Als u inhoudelijke vragen heeft over deze opdracht, kunt u rechtstreeks met de projectleider, de heer drs. art. 5.1.2.e Woo, contact opnemen.

Akkoord,
Het College voor de toelating van gewasbeschermingsmiddelen en biociden,
voor deze:
de secretaris,
voor deze:

art. 5.1.2.e Woo

art. 5.1.2.e Woo

Akkoord,
NVWA

art. 5.1.2.e Woo

art. 5.1.2.e Woo

Bijlagen:
1 Formulier comparitive assessment, ingevuld door de aanvrager
2 Beoordelingstemplate comparative assesment
3 Evaluatieformulier

Van: art. 5.1.2 e Woo, ir. art. 5.1.2.e Woo <art. 5.1.2.e Woo @nvwa.nl>
Verzonden: dinsdag 25 juni 2019 09:19
Aan: art. 5.1.2.e Woo, drs. art. 5.1.2.e Woo <art. 5.1.2.e Woo @ctgb.nl>
CC: art. 5.1.2.e Woo, dr. ir. art. 5.1.2.e Woo <art. 5.1.2.e Woo @nvwa.nl>; art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo <art. 5.1.2.e Woo @nvwa.nl>
Onderwerp: Oplevering CA Prepper in granen

Hallo art. 5.1.2.e Woo,

Hierbij de door de NVWA uitgevoerde landbouwkundige vergelijking in het kader van Comparative Assessments voor Prepper in granen.

Mochten er naar aanleiding van de landbouwkundige vergelijking nog vragen zijn dan hoor ik dat graag.

Met vriendelijke groet,
art. 5.1.2.e Woo

art. 5.1.2.e Woo
Ir. art. 5.1.2.e Woo
Senior beleidsmedewerker plantgezondheid
.....
Team Natuur en Gewasbescherming
Divisie Regie & Expertise
Nederlandse Voedsel- en Warenautoriteit
Geertjesweg 15 | 6706 EA | Wageningen
Postbus 9102 | 6706 HC | Wageningen

.....
art. 5.1.2.e Woo
art. 5.1.2.e Woo

art. 5.1.2.e Woo
nvwa.nl
http://www.nvwa.nl

Agricultural aspects of Comparative assessment
National Plant Protection Organization the Netherlands

Subject	:	NPPO evaluation of the agricultural aspects of Comparative assessment of Prepper
Document number	:	Clv19_Prepper_granen_V1
Active substance	:	fludioxonil
Principal	:	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
Reference Ctgb	:	20180714 NLTG
Contact	:	Hr. art. 5.1.2.e Woo
Address	:	P.O. Box 8030 6710 AA Ede the Netherlands

Our reference	:	Mw. art. 5.1.2.e Woo
Telephone	:	art. 5.1.2.e Woo
Date	:	25 June 2019
Number of pages	:	19

The NPPO has compiled this Comparative Assessment of agricultural aspects with the greatest care and to the best of its current knowledge, acting in full conformity with the criteria and guidelines of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

The NPPO can accept no liability for any harmful consequences, whatever their nature, that may result from these evaluations or their application.

It should also be noted that the Ctgb is the sole body in the Netherlands qualified to decide on requests for the authorisation of pesticides.

NPPO evaluation of the agricultural aspects of Comparative assessment

National addendum to the draft Registration Report (dRR)

1. General information

Country	The Netherlands
Name applicant	Globachem NV
Product under evaluation	Prepper
Candidate for substitution (active substance name)	fludioxonil
Reasons for approval as candidate for substitution (delete as appropriate)	persistent and bioaccumulative
Formulation and content	FS, 25 g/L
Mode of action	signal transduction
FRAC-code	12

2. Claim Major uses/minor uses

The proposed use of Prepper is a fungicide for professional use applied as seed treatment application in the following uses:

Major uses

Crop	Disease	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days
Winter wheat	*Microdochium nivale / Monographella nivalis*	1	n.a.	n.a.
	Fusarium spp.	1	n.a.	n.a.
	Tilletia caries /Tilletia tritici	1	n.a.	n.a.
Spring wheat	*Microdochium nivale / Monographella nivalis*	1	n.a.	n.a.
	Fusarium spp.	1	n.a.	n.a.
	Tilletia caries /Tilletia tritici	1	n.a.	n.a.
Spring barley	*Microdochium nivale / Monographella nivalis*	1	n.a.	n.a.
	Fusarium spp.	1	n.a.	n.a.
	Ustilago hordei / Ustilago segetum var. hordei	1	n.a.	n.a.
	Pyrenophora graminea	1	n.a.	n.a.

Minor uses

Crop	Disease	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days
Winter barley	*Microdochium nivale / Monographella nivalis*	1	n.a.	n.a.
	Fusarium spp.	1	n.a.	n.a.
	Ustilago hordei / Ustilago segetum var. hordei	1	n.a.	n.a.
	Pyrenophora graminea	1	n.a.	n.a.
Winter rye	*Microdochium nivale / Monographella nivalis*	1	n.a.	n.a.
	Fusarium spp.	1	n.a.	n.a.
Spring rye	*Microdochium nivale / Monographella nivalis*	1	n.a.	n.a.
	Fusarium spp.	1	n.a.	n.a.
Triticale	*Microdochium nivale / Monographella nivalis*	1	n.a.	n.a.
	Fusarium spp.	1	n.a.	n.a.
	Tilletia caries /Tilletia tritici	1	n.a.	n.a.
Oats	*Fusarium* spp.	1	n.a.	n.a.

Proposed restrictions
Treated seeds may not be used for human or animal consumption.

3. Characteristics of the product (PPP)

Prepper is a fungicide, based on the active substance fludioxonil. It is used for seed treatment. Fludioxonil acts via signal transduction (not systemically) and has FRAC code 12.

4. Comparative assessment of agricultural aspects

This assessment follows a step-wise approach which contains three area's (see chapters 4.1., 4.2. and 4.3.). As described in the EU Guidance document on comparative assessment the process may be terminated at any stage and it may not be necessary to continue through the whole scheme. In that case the CA-process can be finalized by filling in the final conclusions (chapter 5). If not, all steps have to be completed.

Where there are reasons to believe at the start of the comparative assessment that there might be a problem in a certain area, it may be useful to start the assessment in that particular area.

4.1. Conclusion alternatives available per use regarding limitations in the use (effectiveness, practical and/or economical disadvantages)

An overview of all alternatives, both chemicals (date: 06-06-2019) and non-chemical methods, for the proposed major uses of Prepper can be found in annexes I and II.

Crop	Pest	Conclusion NPPO
Winter wheat	*Microdochium nivale / Monographella nivalis*	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
	Fusarium spp.	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
	Tilletia caries /Tilletia tritici	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
Spring wheat	*Microdochium nivale / Monographella nivalis*	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
	Fusarium spp.	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
	Tilletia caries /Tilletia tritici	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
Spring barley	*Microdochium nivale / Monographella nivalis*	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
	Fusarium spp.	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
	Ustilago hordei / Ustilago segetum var. hordei	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
	Pyrenophora graminea	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.

4.2. Conclusion alternatives available per use regarding the risk of developing resistance (major uses)

An overview of all alternatives, both chemicals (date: 06-06-2019) and non-chemical methods, for the proposed major uses of Prepper can be found in annexes I and II.

Crop	Pest	Conclusion NPPO	Name(s) of alternative(s)
Winter wheat	*Microdochium nivale / Monographella nivalis*	Insufficient alternatives available. Stop CA	
	Fusarium spp.	Insufficient alternatives available. Stop CA	
	Tilletia caries /Tilletia tritici	Insufficient alternatives available. Stop CA	
Spring wheat	*Microdochium nivale / Monographella nivalis*	Insufficient alternatives available. Stop CA	

	Fusarium spp.	Insufficient alternatives available. Stop CA	
	Tilletia caries /Tilletia tritici	Insufficient alternatives available. Stop CA	
Spring barley	*Microdochium nivale / Monographella nivalis*	Insufficient alternatives available. Stop CA	
	Fusarium spp.	Insufficient alternatives available. Stop CA	
	Ustilago hordei / Ustilago segetum var. hordei	Insufficient alternatives available. Stop CA	
	Pyrenophora graminea	Insufficient alternatives available. Stop CA	

4.3. Conclusions consequences for minor uses

Assessment regarding consequences for minor uses is not considered because substitution is not possible for any of the proposed major uses.

5. Overall NPPO conclusion on agriculture aspects

Substitution is not possible for the following uses of the CfS:

Crop	Pest/disease	Conclusion NPPO
Winter wheat	*Microdochium nivale / Monographella nivalis*	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
	Fusarium spp.	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
	Tilletia caries /Tilletia tritici	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
Spring wheat	*Microdochium nivale / Monographella nivalis*	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
	Fusarium spp.	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
	Tilletia caries /Tilletia tritici	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
Spring barley	*Microdochium nivale / Monographella nivalis*	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
	Fusarium spp.	Substitution is not possible for the following uses of the CfS because with the available alternatives there

		are less than 5 MoA, a good resistance management is not possible.
	Ustilago hordei / Ustilago segetum var. hordei	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
	Pyrenophora graminea	Substitution is not possible for the following uses of the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.

Annex I: Alternative authorised plant protection products in the Netherlands
An overview of chemical alternatives (date: 06-06-2019), for the proposed major uses of Prepper.

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
Winter wheat	*Microdochium nivale* / *Monographella nivalis*	Celest Extra	difenoconazole, fludioxonil	3, 12	Candidate for substitution (both a.s.)	n.a.	n.a.
		Beret Gold 025 FS	fludioxonil	12	Candidate for substitution	n.a.	n.a.
		Seedron	fludioxonil, tebuconazole	12, 3	Candidate for substitution (both a.s.)	n.a.	n.a.
		Redigo	prothioconazole	3	To protect birds and mammals, the product must be incorporated into the soil completely; take care that the product is incorporated in the whole field, also at the edges. To protect birds and mammals, spilled product must be removed.	no	yes
		Redigo Pro	prothioconazole, tebuconazole	3, 3	Candidate for substitution (tebuconazole)	n.a.	n.a.
		Cerall	*Pseudomonas chlororaphis* stam MA342	n.a.	-	yes	yes
		Vibrance Duo	sedaxane, fludioxonil	7, 12	Candidate for substitution (fludioxonil)	n.a.	n.a.
		Vibrance Star	sedaxane, fludioxonil, triticonazole	7, 12, 3	Candidate for substitution (fludioxonil)	n.a.	n.a.
Winter wheat	*Fusarium* spp.	Celest Extra	difenoconazole, fludioxonil	3, 12	Candidate for substitution (both a.s.)	n.a.	n.a.

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
		Difend Extra	difenoconazole, fludioxonil	3, 12	Candidate for substitution (both a.s.)	n.a.	n.a.
		Beret Gold 025 FS	fludioxonil	12	Candidate for substitution	n.a.	n.a.
		Seedron	fludioxonil, tebuconazole	12, 3	Candidate for substitution (both a.s.)	n.a.	n.a.
		Redigo	prothioconazole	3	To protect birds and mammals, the product must be incorporated into the soil completely; take care that the product is incorporated in the whole field, also at the edges. To protect birds and mammals, spilled product must be removed.	no	yes
		Redigo Pro	prothioconazole, tebuconazole	3, 3	Candidate for substitution (tebuconazole)	n.a.	n.a.
		Cerall	*Pseudomonas chlororaphis* stam MA342	n.a.	-	yes	yes
		Vibrance Duo	sedaxane, fludioxonil	7, 12	Candidate for substitution (fludioxonil)	n.a.	n.a.
		Vibrance Star	sedaxane, fludioxonil, triticonazole	7, 12, 3	Candidate for substitution (fludioxonil)	n.a.	n.a.
Winter wheat	*Tilletia caries /Tilletia tritici*	Difend	difenoconazole	3	Candidate for substitution	n.a.	n.a.
		Celest Extra	difenoconazole, fludioxonil	3, 12	Candidate for substitution (both a.s.)	n.a.	n.a.

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
		Difend Extra	difenoconazole, fludioxonil	3, 12	Candidate for substitution (both a.s.)	n.a.	n.a.
		Beret Gold 025 FS	fludioxonil	12	Candidate for substitution	n.a.	n.a.
		Seedron	fludioxonil, tebuconazole	12, 3	Candidate for substitution (both a.s.)	n.a.	n.a.
		Redigo	prothioconazole	3	To protect birds and mammals, the product must be incorporated into the soil completely; take care that the product is incorporated in the whole field, also at the edges. To protect birds and mammals, spilled product must be removed.	no	yes
		Redigo Pro	prothioconazole, tebuconazole	3, 3	Candidate for substitution (tebuconazole)	n.a.	n.a.
		Cerall	*Pseudomonas chlororaphis* stam MA342	n.a.	-	yes	yes
		Vibrance Duo	sedaxane, fludioxonil	7, 12	Candidate for substitution (fludioxonil)	n.a.	n.a.
		Vibrance Star	sedaxane, fludioxonil, triticonazole	7, 12, 3	Candidate for substitution (fludioxonil)	n.a.	n.a.
Spring wheat	*Microdochium nivale*	Beret Gold 025 FS	fludioxonil	12	Candidate for substitution	n.a.	n.a.

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
	/ *Monograp hella nivalis*	Seedron	fludioxonil, tebuconazole	12, 3	Candidate for substitution (both a.s.)	n.a.	n.a.
		Redigo	prothioconazole	3	To protect birds and mammals, the product must be incorporated into the soil completely; take care that the product is incorporated in the whole field, also at the edges. To protect birds and mammals, spilled product must be removed.	no	yes
		Redigo Pro	prothioconazole, tebuconazole	3, 3	Candidate for substitution (tebuconazole)	n.a.	n.a.
		Cerall	*Pseudomonas chlororaphis* stam MA342	n.a.	-	yes	yes
		Vibrance Duo	sedaxane, fludioxonil	7, 12	Candidate for substitution (fludioxonil)	n.a.	n.a.
		Vibrance Star	sedaxane, fludioxonil, triticonazole	7, 12, 3	Candidate for substitution (fludioxonil)	n.a.	n.a.
Spring wheat	*Fusarium* spp.	Beret Gold 025 FS	fludioxonil	12	Candidate for substitution	n.a.	n.a.
		Seedron	fludioxonil, tebuconazole	12, 3	Candidate for substitution (both a.s.)	n.a.	n.a.
		Redigo	prothioconazole	3	To protect birds and mammals, the product must be incorporated into the soil completely; take care that the product is incorporated in the whole field, also at the edges. To protect birds and mammals, spilled product must be removed.	no	yes

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
		Redigo Pro	prothioconazole, tebuconazole	3, 3	Candidate for substitution (tebuconazole)	n.a.	n.a.
		Cerall	*Pseudomonas chlororaphis* stam MA342	n.a.	-	yes	yes
		Vibrance Duo	sedaxane, fludioxonil	7, 12	Candidate for substitution (fludioxonil)	n.a.	n.a.
		Vibrance Star	sedaxane, fludioxonil, triticonazole	7, 12, 3	Candidate for substitution (fludioxonil)	n.a.	n.a.
Spring wheat	*Tilletia caries /Tilletia tritici*	Difend	difenoconazole	3	Candidate for substitution	n.a.	n.a.
		Beret Gold 025 FS	fludioxonil	12	Candidate for substitution	n.a.	n.a.
		Seedron	fludioxonil, tebuconazole	12, 3	Candidate for substitution (both a.s.)	n.a.	n.a.
		Redigo	prothioconazole	3	To protect birds and mammals, the product must be incorporated into the soil completely; take care that the product is incorporated in the whole field, also at the edges. To protect birds and mammals, spilled product must be removed.	no	yes
		Redigo Pro	prothioconazole, tebuconazole	3, 3	Candidate for substitution (tebuconazole)	n.a.	n.a.
		Cerall	*Pseudomonas chlororaphis* stam MA342	n.a.	-	yes	yes

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
		Vibrance Duo	sedaxane, fludioxonil	7, 12	Candidate for substitution (fludioxonil)	n.a.	n.a.
		Vibrance Star	sedaxane, fludioxonil, triticonazole	7, 12, 3	Candidate for substitution (fludioxonil)	n.a.	n.a.
Spring barley	*Microdochium nivale* / *Monographella nivalis*	Beret Gold 025 FS	fludioxonil	12	Candidate for substitution	n.a.	n.a.
		Seedron	fludioxonil, tebuconazole	12, 3	Candidate for substitution (both a.s.)	n.a.	n.a.
		Redigo	prothioconazole	3	To protect birds and mammals, the product must be incorporated into the soil completely; take care that the product is incorporated in the whole field, also at the edges. To protect birds and mammals, spilled product must be removed.	no	yes
		Redigo Pro	prothioconazole, tebuconazole	3, 3	Candidate for substitution (tebuconazole)	n.a.	n.a.
		Vibrance Duo	sedaxane, fludioxonil	7, 12	Candidate for substitution (fludioxonil)	n.a.	n.a.
		Vibrance Star	sedaxane, fludioxonil, triticonazole	7, 12, 3	Candidate for substitution (fludioxonil)	n.a.	n.a.
Spring barley	*Fusarium* spp.	Beret Gold 025 FS	fludioxonil	12	Candidate for substitution	n.a.	n.a.
		Seedron	fludioxonil, tebuconazole	12, 3	Candidate for substitution (both a.s.)	n.a.	n.a.

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
		Redigo	prothioconazole	3	To protect birds and mammals, the product must be incorporated into the soil completely; take care that the product is incorporated in the whole field, also at the edges. To protect birds and mammals, spilled product must be removed.	no	yes
		Redigo Pro	prothioconazole, tebuconazole	3, 3	Candidate for substitution (tebuconazole)	n.a.	n.a.
		Vibrance Duo	sedaxane, fludioxonil	7, 12	Candidate for substitution (fludioxonil)	n.a.	n.a.
Spring barley	*Ustilago hordei / Ustilago segetum var. Hordei*	Beret Gold 025 FS	fludioxonil	12	Candidate for substitution	n.a.	n.a.
		Seedron	fludioxonil, tebuconazole	12, 3	Candidate for substitution (both a.s.)	n.a.	n.a.
		Redigo	prothioconazole	3	To protect birds and mammals, the product must be incorporated into the soil completely; take care that the product is incorporated in the whole field, also at the edges. To protect birds and mammals, spilled product must be removed.	no	yes
		Redigo Pro	prothioconazole, tebuconazole	3, 3	Candidate for substitution (tebuconazole)	n.a.	n.a.
		Vibrance Duo	sedaxane, fludioxonil	7, 12	Candidate for substitution (fludioxonil)	n.a.	n.a.

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
		Vibrance Star	sedaxane, fludioxonil, triticonazole	7, 12, 3	Candidate for substitution (fludioxonil)	n.a.	n.a.
Spring barley	*Pyrenophora graminea*	Difo 3 FS	difenoconazole	3	Candidate for substitution	n.a.	n.a.
		Beret Gold 025 FS	fludioxonil	12	Candidate for substitution	n.a.	n.a.
		Seedron	fludioxonil, tebuconazole	12, 3	Candidate for substitution (both a.s.)	n.a.	n.a.
		Redigo	prothioconazole	3	To protect birds and mammals, the product must be incorporated into the soil completely; take care that the product is incorporated in the whole field, also at the edges.To protect birds and mammals, spilled product must be removed.	no	yes
		Vibrance Duo	sedaxane, fludioxonil	7, 12	Candidate for substitution (fludioxonil)	n.a.	n.a.
		Vibrance Star	sedaxane, fludioxonil, triticonazole	7, 12, 3	Candidate for substitution (fludioxonil)	n.a.	n.a.

Annex II: Alternative non-chemical methods

An overview of non-chemicals alternatives (date: 20-06-2019), for the proposed major uses of Prepper.

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding resistance management
Winter wheat, Spring wheat, Spring barley	*Microdochium nivale / Monographella nivalis*	Steaming	Pressurised steam applied to the soil.	Effective method. This technique has high time and energy demands, drastic effects on other micro-organisms in the soil, and may pose a hazard to those operating the equipment.	no
Winter wheat, Spring wheat, Spring barley	*Fusarium* spp.	Ploughing in crop residue	Burial of crop debris by ploughing can reduce inoculum for some necrotrophic pathogens which produce inoculum on plant debris.	This method is only beneficial.	no
		Steaming	Pressurised steam applied to the soil.	Effective method. This technique has high time and energy demands, drastic effects on other micro-organisms in the soil, and may pose a hazard to those operating the equipment.	no
		Resistant varieties	For most crops, resistant varieties are an important part of non-chemical disease control. Using resistant cultivars is an effective control measure.	Because most cultivars are grown for their specific characteristics, choosing resistant	no

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding resistance management
				cultivars is not always feasible. In wheat there is a trade off between yield and disease resistance, with the most resistant varieties yielding less. Also resistance is seldom complete, so fungicide treatment is usually still required.	
		Control volunteers and weeds	Volunteers and weeds can be a source of fungicidal pathogens. Removing them contributes to disease control.	This method is only beneficial.	no
		Seed testing	The use of certified seed is important for most crops to ensure that heavily infected seed stocks are not used, and can be an effective approach to reducing some diseases.	The use of certified seeds is common in the Netherlands. This method is only beneficial.	no
		Rotation and break crops	Rotations of three or more years are essential to prevent build-up of most diseases that are capable of long term survival.	This method is only beneficial.	no
		Phytosanitary regulation; grain quality	Imported plants and produce are inspected for quarantine pests, diseases and weeds. If a quarantine organism is detected, then the use of an eradication schedule will be required.	This is not effective for indigenous organisms.	no

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding resistance management
Winter wheat, Spring wheat,	*Tilletia caries /Tilletia tritici*	Hygiene	Hygiene measures to minimise spread of the diseases	This method is only beneficial	no
		Steaming	Pressurised steam applied to the soil.	Effective method. This technique has high time and energy demands, drastic effects on other micro-organisms in the soil, and may pose a hazard to those operating the equipment.	no
		Seed testing	The use of certified seed is important for most crops to ensure that heavily infected seed stocks are not used, and can be an effective approach to reducing some diseases.	The use of certified seeds is common in the Netherlands. This method is only beneficial.	no
		Field history	Knowing field history helps making the right choices for rotation.	This method is only beneficial.	no
		Rotation and break crops	Rotations of three or more years are essential to prevent build-up of most diseases that are capable of long term survival.	This method is only beneficial.	no
		Spatial seperation	Spatial separation of new crops from those of the previous year would decrease the risks of severe early infection.	This method is only beneficial.	no
Spring barley	*Ustilago hordei / Ustilago segetum*	Hygiene	Hygiene measures to minimise spread of the diseases	This method is only beneficial	no

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding resistance management
	var. hordei	Steaming	Pressurised steam applied to the soil.	Effective method. This technique has high time and energy demands, drastic effects on other micro-organisms in the soil, and may pose a hazard to those operating the equipment.	no
		Field history	Knowing field history helps making the right choices for rotation.	This method is only beneficial.	no
		Rotation and break crops	Rotations of three or more years are essential to prevent build-up of most diseases that are capable of long term survival.	This method is only beneficial.	no
		Spatial separation	Spatial separation of new crops from those of the previous year would decrease the risks of severe early infection.	This method is only beneficial.	no
		Select low-risk locations	Some regions have conditions where disease pressure is lower.	This method is only beneficial.	no
Spring barley	*Pyrenophora graminea*	Ploughing in crop residue	Burial of crop debris by ploughing can reduce inoculum for some necrotrophic pathogens which produce inoculum on plant debris.	This method is only beneficial.	no
		Steaming	Pressurised steam applied to the soil.	Effective method. This technique has high time and energy demands, drastic effects on other	no

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding resistance management
				micro-organisms in the soil, and may pose a hazard to those operating the equipment.	
		Control volunteers and weeds	Volunteers and weeds can be a source of fungicidal pathogens. Removing them contributes to disease control.	This method is only beneficial.	no
		Seed testing	The use of certified seed is important for most crops to ensure that heavily infected seed stocks are not used, and can be an effective approach to reducing some diseases.	The use of certified seeds is common in the Netherlands. This method is only beneficial.	no
		Rotation and break crops	Rotations of three or more years are essential to prevent build-up of most diseases that are capable of long term survival.	This method is only beneficial.	no
		Spatial separation	Spatial separation of new crops from those of the previous year would decrease the risks of severe early infection.	This method is only beneficial.	no
		Select low risk locations	Some regions have conditions where disease pressure is lower.	This method is only beneficial.	no

Van: art. 5.1.2.e Woo, drs. art. 5.1.2.e Woo < art. 5.1.2.e Woo @ctgb.nl>
Verzonden: vrijdag 20 september 2019 09:17
Aan: art. 5.1.2.e Woo, mr. art. 5.1.2.e Woo ; art. 5.1.2.e Woo mr. art. 5.1.2.e Woo
Onderwerp: FW: Oplevering CA Tavas

Hoi art. 5.1.2.e Woo,

Hierbij de door de NVWA uitgevoerde landbouwkundige vergelijking in het kader van Comparative Assessments voor Tavas in aardappel.

Groeten,
art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo [mailto: art. 5.1.2.e Woo @nvwa.nl]
Verzonden: vrijdag 20 september 2019 08:31
Aan: art. 5.1.2.e Woo, drs. art. 5.1.2.e Woo
CC: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo
Onderwerp: RE: Oplevering CA Tavas

Hallo artikel 5.1, lid 1 aa,

En hier de bijbehorende documenten.

Met vriendelijke groet,
art. 5.1.2.e W

Van: art. 5.1.2 e Woo, ir. art. 5.1.2.e Woo
Verzonden: vrijdag 20 september 2019 08:29
Aan: art. 5.1 2.e Woo, drs. art. 5.1.2.e Woo
CC: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo
Onderwerp: Oplevering CA Tavas

Hallo art. 5.1.2.e Woo,

Hierbij de door de NVWA uitgevoerde landbouwkundige vergelijking in het kader van Comparative Assessments voor Tavas in aardappel

Mochten er naar aanleiding van de landbouwkundige vergelijking nog vragen zijn dan hoor ik dat graag.

Met vriendelijke groet,

art. 5.1.2.e Woo
Ir. art. 5.1.2.e Woo
Senior beleidsmedewerker plantgezondheid
.....
Team Natuur en Gewasbescherming
Divisie Regie & Expertise
Nederlandse Voedsel- en Warenautoriteit
Geertjesweg 15 | 6706 EA | Wageningen
Postbus 9102 | 6706 HC | Wageningen
.....
art. 5.1.2.e Woo
art. 5.1.2.e Woo

art. 5.1.2.e Woo
art. 5.1.2.e Woo @nvwa.nl
http://www.nvwa.nl

Van: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Verzonden: vrijdag 8 maart 2019 13:26
Aan: art. 5.1.2.e Woo <art. 5.1.2.e Woo@ctgb.nl>
CC: art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Onderwerp: RE: Ctgb FileSender service: opdracht NVWA uitvoeren CA Vibrance Corn
Urgentie: Hoog

Hallo art. 5.1.2 e Woo,

Zie onderstaande mail. Zou je het gevraagde WG en de GAP ook aan art. 5.1.2.e Woo willen sturen. Ik ben volgende week afwezig.

Alvast bedankt!

Met vriendelijke groet,

art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo
Verzonden: woensdag 6 maart 2019 08:00
Aan: art. 5.1.2.e Woo@ctgb.nl'
CC: art. 5.1.2.e Woo ir. art. 5.1.2.e Woo
Onderwerp: FW: Ctgb FileSender service: opdracht NVWA uitvoeren CA Vibrance Corn

Hallo art. 5.1.2 e Woo,

Zou je ons nog het WG en de GAP van Vibrance corn kunnen sturen?

Bedankt.

Met vriendelijke groet,
art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo, dr. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Verzonden: donderdag 28 februari 2019 16:49
Aan: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>; art. 5.1.2.e Woo, ing. artikel 5.1, lid 1 aanh <art. 5.1.2.e Woo@nvwa.nl>
Onderwerp: FW: Ctgb FileSender service: opdracht NVWA uitvoeren CA Vibrance Corn

Zie hieronder en bijlage.

Van: art. 5.1.2.e Woo@ctgb.nl [mailto:art. 5.1.2.e Woo@ctgb.nl]
Verzonden: donderdag 28 februari 2019 13:45
Aan: art. 5.1.2.e Woo, dr. art. 5.1.2.e Woo
CC: art. 5.1.2.e Woo
Onderwerp: Ctgb FileSender service: opdracht NVWA uitvoeren CA Vibrance Corn

Dear Sir, Madam,

The file below has been uploaded to Ctgb FileSender service by art. 5.1.2.e Woo@ctgb.nl and you have been granted permission to download this file.

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Opdracht NVWA uitvoeren Comparitve assessement Vibrance Corn.pdf	1.03 MB	https://filesender.ctgb.nl/?vid=678caadc-8fa0-0829-52da-00003676a6e9	14-03-2019
Personal message from melinde.hilberink@ctgb.nl:			
Goedendag heer art. 5.1.2.e Woo, *In de bijlage treft u de opdrachtbrief en documenten aan tbv comparitive assessment voor Vibrance Corn. Graag ontvangen wij een ondertekend exemplaar retour.*			

Best regards,

Ctgb FileSender service

Dit bericht kan informatie bevatten die niet voor u is bestemd. Indien u niet de geadresseerde bent of dit bericht abusievel jk aan u is toegezonden, wordt u verzocht dat aan de afzender te melden en het bericht te verwijderen. De Staat aanvaardt geen aansprakelijkheid voor schade, van we ke aard ook, die verband houdt met risico's verbonden aan het elektronisch verzenden van berichten.
This message may contain information that is

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Verzonden: donderdag 21 maart 2019 16:56
Aan: art. 5.1.2.e Woo drs. art. 5.1.2.e Woo <art. 5.1.2.e Woo@ctgb.nl>
Onderwerp: FW: ondertekenen offerte CA Vibrance

Hoi art. 5.1.2.e Woo,
Hier de getekende opdracht. Ik zal dit bericht het in DSM uploaden.
Groet art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo [mailto:art. 5.1.2.e Woo@nvwa.nl]
Verzonden: donderdag 21 maart 2019 14:38
Aan: art. 5.1.2.e Woo
CC: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo; art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo
Onderwerp: RE: ondertekenen offerte CA Vibrance

Dag allen,

Bijgaand de getekende versie van het document.

Met vriendelijke groet,

art. 5.1.2.e Woo
Managementondersteuner

Directie Handhaven, divisie Regie & expertise
.....
Ministerie van Landbouw, Natuur en Voedselkwaliteit
Nederlandse Voedsel- en Warenautoriteit
Catharijnesingel 59 I 3511 GG I Utrecht
Postbus 43006 I 3540 AA I Utrecht
.....
M art. 5.1.2.e Woo
.....
art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo
Verzonden: woensdag 13 maart 2019 09:11
Aan: art. 5.1.2.e Woo
CC: art. 5.1.2.e Woo ing. art. 5.1.2.e Woo
Onderwerp: ondertekenen offerte CA Vibrance

Beste art. 5.1.2.e Woo,

In de bijlage vind je de offerte aanvraag voor een CA van Vibrance. Zou je deze offerte door art. 5.1.2. willen laten ondertekenen en terugsturen naar het Ctgb tav art. 5.1.2.e Woo (art. 5.1.2.e Woo@ctgb.nl)

Alvast bedankt,
art. 5.1.2.e Woo

Van: art. 5.1.2.e Woo@ctgb.nl [mailto:art. 5.1.2.e Woo@ctgb.nl]
Verzonden: maandag 11 maart 2019 16:57

Aan: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo
CC: art. 5.1.2.e Woo
Onderwerp: Ctgb FileSender service: nazending Vibrance Corn

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20170618 NLTG Vibrance XL WG en GAP.zip	616.61 kB	https://filesender.ctgb.nl/?vid=4bff156f-9b93-ada8-0b68-000032d15448	25-03-2019
Personal message from art. 5.1.2.e Woo@ctgb.nl:			
Goedendag, *Zoals met mw. Jilesen is afgesproken, zend ik de GAP en WG hierbij toe. Betreft de Comparitive assessment van Vibrance Corn*			

Best regards,

Ctgb FileSender service

ctgb

College voor de toelating van gewasbeschermingsmiddelen en biociden

NVWA
T.a.v. Dhr. Dr. art. 5.1.2.e Woo
Postbus 43006
3540 AA UTRECHT

Datum 28 februari 2019

Behandeld door
Mr. drs. art. 5.1.2.e Woo

Telefoonnummer
art. 5.1.2.e Woo

E-mail
art. 5.1.2.e Woo@ctgb.nl

Kenmerk
201902130140

Betreft Opdracht voor comparative assessment Vibrance Corn 20170618

Geachte heer art. 5.1.2.e Woo,

Het Ctgb en NVWA werken samen op het gebied de uitvoering van comparative assessments, conform Verordening (EG) nr. 1107/2009 art. 50.

Hierbij verleen ik u opdracht tot het verrichten van de werkzaamheden conform de offerte: trcvwa /2016/1385.

Omschrijving van de werkzaamheden:
Bij de aanvraag voor het middel: Vibrance Corn met aanvraagnummer 20170618 op basis van de werkzame stoffen fludioxonil, metalaxyl-M en sedaxaan wordt een comparative assessment uitgevoerd.

De comparative assessment dient te worden uitgevoerd voor de volgende gebruiken:

- mais - fungicide - Fusarium spp. [FUSASP]
- mais - fungicide - Pythium spp.[PYTHSP]
- mais - fungicide - Rhizoctonia solani

U wordt verzocht voor deze drie gebruiken een landbouwkundige beoordeling uit te voeren. Als bijlage bij deze brief is het formulier voor comparative assessment en de template voor de beoordeling bijgevoegd.

De eindconclusie van de landbouwkundige beoordeling dient in een beknopte samenvatting duidelijk te worden aangegeven. Hierin is opgenomen welke alternatieven middelen zijn overwogen en waarom die al dan niet als volwaardig alternatief kunnen worden beschouwd.

Wilt u per toepassing aangegeven op welk moment (Step 6-11) gestopt kan worden met CA, omdat er geen alternatieve middelen gevonden zijn?

De projecturen bedragen maximaal 24 uur.

Het rapport ontvang ik **uiterlijk 22 maart 2019**, onder vermelding van bovengenoemd aanvraagnummer.

Ter bevestiging van deze opdracht ontvang ik graag binnen een week na dagtekening een getekend exemplaar retour.

Als u inhoudelijke vragen heeft over deze opdracht, kunt u rechtstreeks met de projectleider, de heer drs. art. 5.1.2.e Woo.

Akkoord,
Het College voor de toelating van gewasbeschermingsmiddelen en biociden,
voor deze:
de secretaris,
voor deze:

art. 5.1.2.e Woo

art. 5.1.2.e Woo

Akkoord,
NVWA

art. 5.1.2.e Woo

art. 5.1.2.e Woo

art.art. 5.1.2.e Woo

art. 5.1.2.e Woo

Met vriendelijke groet,

Het College voor de toelating van gewasbeschermingsmiddelen en biociden,
voor deze:
de secretaris/directeur,
voor deze:

art. 5.1.2.e Woo

art. 5.1.2.e Woo

Bijlagen:
1 Formulier aanvrager Comparative Assessment Vibrance Corn
2 Template comparative assessment
3 Evaluatieformulier evaluerende instantie

Van: art. 5.1.2.e Woo, ing. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Verzonden: vrijdag 29 maart 2019 08:44
Aan: art. 5.1.2.e Woo, drs. art. 5.1.2.e Woo <art. 5.1.2.e Woo@ctgb.nl>
CC: art. 5.1.2.e Woo, ir. art. 5.1.2.e Woo <art. 5.1.2.e Woo@nvwa.nl>
Onderwerp: Oplevering CA Vibrance XL

Hallo art. 5.1.2.e Woo,

Hierbij de door de NVWA uitgevoerde landbouwkundige vergelijking in het kader van Comparative Assessments voor Vibrance XL. Door een misverstand is de CA na de deadline verzonden, hiervoor onze excuses.

Mochten er naar aanleiding van de landbouwkundige vergelijking nog vragen zijn dan hoor ik dat graag.

Met vriendelijke groet,

art. 5.1.2.e Woo
Beleidsmedewerker plantgezondheid
.....
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Agricultural aspects of Comparative assessment
National Plant Protection Organization the Netherlands

Subject	:	NPPO evaluation of the agricultural aspects of Comparative assessment of Vibrance XL
Document number	:	clv19_Vibrance_XL
Active substance	:	Fludioxonil
Principal	:	Board for the Authorisation of Plant Protection Products and Biocides (Ctgb)
Reference Ctgb	:	20170618
Contact	:	Mr. drs. artikel 5.1, lid 1 aanhef en onder sub d Woo
Address	:	P.O. Box 8030 6710 AA Ede the Netherlands

Our reference	:	artikel 5.1, lid 1 aanhef en onder sub d Woo
Telephone	:	artikel 5.1, lid 1 aanhef en onder sub d Woo
Date	:	21-03-2019
Number of pages	:	6

The NPPO has compiled this Comparative Assessment of agricultural aspects with the greatest care and to the best of its current knowledge, acting in full conformity with the criteria and guidelines of the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb).

The NPPO can accept no liability for any harmful consequences, whatever their nature, that may result from these evaluations or their application.

It should also be noted that the Ctgb is the sole body in the Netherlands qualified to decide on requests for the authorisation of pesticides.

NPPO evaluation of the agricultural aspects of Comparative assessment

National addendum to the draft Registration Report (dRR)

1. General information

Country	the Netherlands
Name applicant	Syngenta Crop Protection B.V.
Product under evaluation	Vibrance XL
Candidate for substitution (active substance name)	fludioxonil
Reasons for approval as candidate for substitution (delete as appropriate)	Two of PBT; toxicity and persistence
Formulation and content	fludioxonil, 88.3 grams per litre (g/L), metalaxyl-M, 34.3 grams per litre (g/L) and sedaxane, 176.4 grams per litre (g/L),
Mode of action	MAP/Histidine- Kinase in osmotic signal transduction
FRAC-code	12

2. Claim Major uses/minor uses

The proposed use of Vibrance XL is a fungicide for professional use applied as seed treatment application in the following uses:

Major uses

Crop	Pest/disease/weed	Maximum number of applications per crop/season	Minimum interval between spray applications in days	Pre harvest interval in days
Maize (ZEAMX)	*Fusarium spp.* (FUSASP)	1	N.a.	N.a.
	Pythium spp. (PYTHSP)	1	N.a.	N.a.
	Rhizoctonia solani (RHIZSO)	1	N.a.	N.a.

Minor uses
No Minor uses requested.

Proposed restrictions
Not yet available in the Netherlands

3. Characteristics of the product (PPP)

Vibrance XL is a fungicide containing three active substances. (fludioxonil, metalaxyl-M, and sedaxane) and is not yet authorised in the Netherlands. Fludioxonil is a non-systemic active substance with a long residual activity. It inhibits mainly the germination of conidia of fungi e.g. *Fusarium* spp. and *Rizoctonia* spp.. Metalaxyl-M is a systemic fungicide with protective and curative action to control air- and soil-borne Peronosporales. Sedaxane is a non-systemic fungicide and a SDHI effective against fungi like *Rizoctonia* spp. and *Fusarium* spp..

4. Comparative assessment of agricultural aspects

This assessment follows a step-wise approach which contains three area's (see chapters 4.1., 4.2. and 4.3.). As described in the EU Guidance document on comparative assessment the process may be terminated at any stage and it may not be necessary to continue through the whole scheme. In that case the CA-process can be finalized by filling in the final conclusions (chapter 5). If not, all steps have to be completed.

Where there are reasons to believe at the start of the comparative assessment that there might be a problem in a certain area, it may be useful to start the assessment in that particular area.

4.1. Conclusion alternatives available per use regarding limitations in the use (effectiveness, practical and/or economical disadvantages)

An overview of all alternatives, both chemicals (date: 18-03-2019) and non-chemical methods, for the proposed major uses of Vibrance XL can be found in annexes I and II.

Crop	Pest	Conclusion NPPO*
Maize (ZEAMX)	*Fusarium spp.* (FUSASP)	Assessment regarding limitations in the use is not considered because the CA-process was stopped in chapter 4.2.
	Pythium spp. (PYTHSP)	
	Rhizoctonia solani (RHIZSO)	

4.2. Conclusion alternatives available per use regarding the risk of developing resistance (major uses)

An overview of all alternatives, both chemicals (date: 18-03-2019) and non-chemical methods, for the proposed major uses of Vibrance XL can be found in annexes I and II.

Crop	Pest	Conclusion NPPO*	Name(s) of alternative(s)**
Maize (ZEAMX)	*Fusarium spp.* (FUSASP)	Insufficient alternatives available, stop CA.	
	Pythium spp. (PYTHSP)	Insufficient alternatives available, stop CA.	
	Rhizoctonia solani (RHIZSO)	Insufficient alternatives available, stop CA.	

4.3. Conclusions consequences for minor uses

No minor uses are included in the application.

5. Overall NPPO conclusion on agriculture aspects Substitution is not possible for the following uses of the CfS:

Crop	Pest/disease	Conclusion NPPO*
Maize (ZEAMX)	*Fusarium spp.* (FUSASP)	Substitution is not possible for the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
	Pythium spp. (PYTHSP)	Substitution is not possible for the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.
	Rhizoctonia solani (RHIZSO)	Substitution is not possible for the CfS because with the available alternatives there are less than 5 MoA, a good resistance management is not possible.

Annex I: Alternative authorised plant protection products in the Netherlands
An overview of chemicals alternatives (date: 18-03-2019), for the proposed major uses of Vibrance XL

Crop	Pest/ disease/ weed	Product	Active substance	RAC-code	Differences in limitations in the use of the alternative (e.g. according to the label)	Alternative regarding limits in the use	Alternative regarding resistance management
Maize (ZEAMX)	*Fusarium spp.* (FUSASP)	Maxim XL	fludioxonil, metalaxyl-M	12, 4	Candidate for substitution	N.a.	N.a.
		PROSARO	Prothioconazool, fluopyram	3, 7	No seed treatment. Efficacy only tested against *Fusarium* spp..	no	yes
	Pythium spp. (PYTHSP)	Maxim XL	fludioxonil, metalaxyl-M	12, 4	Candidate for substitution	N.a.	N.a.
	Rhizoctonia solani (RHIZSO)	Vibrance	Sedaxane	7	Efficacy only tested against *Rhizoctonia solani*.	no	yes

Annex II: Alternative non-chemical methods

An overview of non-chemicals alternatives (date: 18-03-2019), for the proposed major uses of Vibrance XL.

Crop	Pest/ disease/ weed	alternative	description	assessment NPPO regarding limits in the use	Alternative regarding limits in the use	Alternative regarding resistance management
Maize (ZEAMX)	all	Hot water treatment	Emerging seeds for some time in hot water to kill seed-born diseases.	Not effective against soil-born diseases.	no	no
		Crop rotation	Planting non-host crops in rotation helps preventing build-up of the diseases.	The host plant range of these diseases is quite extensive.	no	no
		Anaerobic soil disinfestation	Anaerobe decomposition of organic material in the ground.	Not effective against Oomycetes.	no	no