ctgb

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 WEDERZIJDSE ERKENNING

Gelet op de aanvraag d.d. 13 januari 2014 (20140099 NLWERG) van

BASF Nederland B.V.
Groningensingel 1
6835 EA ARNHEM

tot verkrijging van een wederzijdse erkenning van de toelating in Denemarken van het gewasbeschermingsmiddel op basis van de werkzame stoffen epoxiconazool en pyraclostrobine,

Retengo Plust

gelet op artikel 40, lid 1 van de Verordening (EG) 1107/2009,

BESLUIT HET COLLEGE als volgt:

1.1 Toelating

1. Het middel Retengo Plust is toegelaten voor de in bijlage I genoemde toepassingen onder nummer 14454 N met ingang van datum dezes. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.

2. De toelating geldt tot 31 december 2015.

1.2 Samenstelling, vorm en verpakking

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

1.3 Gebruik

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

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

Dit leidt tot de volgende voorschriften:

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

aard van het preparaat: Suspo-emulsie

werkzame stof:	*gehalte:*
Epoxiconazool	50 g/l
Pyraclostrobine	133 g/l

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

PICTOGRAM(MEN)

pictogram:
GHS07-schadelijk
GHS08-gezondheidsrisico's
GHS09-milieu

SIGNAALWOORD

Gevaar

Gevarenaanduidingen

H302	Schadelijk bij inslikken.
H332	Schadelijk bij inademing.
H351	Verdacht van het veroorzaken van kanker.
H360Df	Kan het ongeboren kind schaden. Wordt ervan verdacht de vruchtbaarheid te schaden.
H410	Zeer giftig voor in het water levende organismen, met langdurige gevolgen.

Voorzorgsmaatregelen

SP 1	-Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
P201	Alvorens te gebruiken de speciale aanwijzingen raadplegen.
P261	Inademing van stof/rook/gas/nevel/damp/spuitnevel vermijden.
P280	Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen.
P308 + P313	NA (mogelijke) blootstelling: een arts raadplegen.
P391	Gelekte/gemorste stof opruimen.
P501	Inhoud/verpakking afvoeren naar inzamelpunt voor gevaarlijk of bijzonder afval.

Aanvullende etiketelementen

EUH205	Bevat epoxyverbindingen. Kan een allergische reactie veroorzaken.
EUH401	Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.

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

a. letterlijk en zonder enige aanvulling:
het wettelijk gebruiksvoorschrift
De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I.

2 DETAILS VAN DE AANVRAAG

Het betreft een aanvraag tot verkrijging van een toelating van het middel Retengo Plust (14454 N), een middel op basis van de werkzame stoffen epoxiconazool en pyraclostrobine. Het middel wordt aangevraagd als schimmelbestrijdingsmiddel in de teelt van:
a. wintertarwe
b. wintergerst
c. triticale
d. zomertarwe
e. zomergerst
f. haver
g. maïs
h. suikerbiet

2.2 Informatie met betrekking tot de stof

Er zijn in Nederland reeds andere middelen op basis van de werkzame stoffen epoxiconazool en pyraclostrobine toegelaten.

De stof epoxiconazool is per 1 mei 2009 geplaatst op Annex I van Richtlijn 91/414/EEG (Dir 2008/107/EG d.d. 25 november 2008) en is goedgekeurd krachtens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) No 540/2011 d.d. 25 mei 2011) en geplaatst op bijlage I (nummer 211).

De stof pyraclosytrobine is per 1 juni 2004 geplaatst op Annex I van Richtlijn 91/414/EEG (Dir 2004/30/EG d.d. 10 maart 2004 en 2009/25/EG d.d. 2 april 2009) en is goedgekeurd krachtens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) No 540/2011 d.d. 25 mei 2011) en geplaatst op bijlage I (nummer 81).

2.3 Karakterisering van het middel

Retengo Plust bevat de werkzame stoffen epoxiconazool.en pyraclostrobine. Epoxiconazool is een triazool. Epoxiconazool is een systemisch en selectief fungicide met een preventieve en curatieve werking. Het werkingsmechanisme berust op ergosterol biosynthese remming. De triazolen vallen wat betreft het werkingsmechanisme onder de zogenaamde DMI fungiciden. De combinatie werkt op aanwezige sporen en groeiend mycelium.
Pyraclostrobine behoort tot de groep van de strobilurines. Enkele werkzame stoffen binnen deze groep zijn o.a. kresoxim-methyl, azoxystrobin, famoxadone en trifloxystrobine. Pyraclostrobine remt de mitochondrische ademhaling. Het middel remt de kieming van schimmelsporen en de groei van de kiembuis op het bladoppervlak. Pyraclostrobine is niet systemisch.

2.4 Voorgeschiedenis
De aanvraag is op 15 januari 2014 ontvangen; op 17 januari 2014 zijn de verschuldigde aanvraagkosten ontvangen. Bij brief d.d. 7 maart 2014 is de aanvraag in behandeling genomen.

3 RISICOBEOORDELINGEN
De beoordeling van deze aanvraag is conform Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual Zonaal uitgevoerd.

3.1 Inleiding
De onderhavige aanvraag betreft een verzoek tot wederzijdse erkenning van de toelating in Denemarken van het gewasbeschermingsmiddel Opera (19-144).
Gezien de aard van de wederzijdse erkenning wordt ervan uitgegaan dat de beoordeling door Denemarken is uitgevoerd conform de Uniforme Beginselen (annex VI bij richtlijn 91/414/EEG). Voor de beoordeling van de aspecten fysische en chemische eigenschappen, analysemethoden, werkzaamheid en delen van de aspecten risico voor de mens en risico voor het milieu refereert het Ctgb aan het toelatingsbesluit in Denemarken. Op een aantal hieronder weergegeven voor de Nederlandse situatie specifieke punten, toetst het Ctgb zelf inhoudelijk.

3.2 Risico voor de mens
De volgende aspecten worden nationaal ingevuld:
- Arbeidsomstandigheden - nationale modellen en arbeidshygiënische strategie
- Volksgezondheid - de criteria voor residuen in volggewassen.

Het middel voldoet aan de voorwaarde dat het, rekening houdend met alle normale omstandigheden waaronder het middel kan worden gebruikt en de gevolgen van het gebruik, geen directe of indirecte schadelijke uitwerking heeft op de gezondheid van de mens. De beoordeling van het risico voor de toepasser staat beschreven in Hoofdstuk 4 Mammalian Toxicology, van Bijlage II bij dit besluit.

3.3 Risico voor het milieu
De volgende aspecten worden nationaal ingevuld:
- Uitspoeling naar grondwater
- Drift naar oppervlaktewater; van toepassing op : Waterorganismen, vogels, zoogdieren, niet-doelwitplanten, niet-doelwitarthropoden en oppervlaktewater bestemd voor de bereiding van drinkwater
- Drinkwatercriterium oppervlaktewater.

Het middel voldoet aan de voorwaarde dat het, rekening houdend met alle normale omstandigheden waaronder het middel kan worden gebruikt en de gevolgen van het gebruik, geen voor het milieu onaanvaardbaar effect heeft, waarbij in het bijzonder rekening wordt gehouden met de volgende aspecten:
- de plaats waar het middel in het milieu terechtkomt en wordt verspreid, met name voor wat betreft besmetting van het water, waaronder drinkwater en grondwater,
- de gevolgen voor niet-doelsoorten.

(artikel 28, eerste lid, sub b, onderdeel 4 en 5, Wet gewasbeschermingsmiddelen en biociden).
De beoordeling van het risico voor het milieu staat beschreven in Hoofdstuk 6, Environmental Fate and Behaviour, en Hoofdstuk 7, Ecotoxicology, in Bijlage II bij dit besluit.

3.4 Eindconclusie

Bij gebruik volgens het Wettelijk Gebruiksvoorschrift is het middel Retengo Plust op basis van de werkzame stoffen epoxiconazool en pyraclostrobine voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu.

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

Wageningen, 9 mei 2014

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

ir. J.F. de Leeuw
voorzitter

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I bij het besluit d.d. 9 mei 2014 tot wederzijdse erkenning van het middel Retengo Plust, toelatingnummer 14454 N

Wettelijk Gebruiksvoorschrift

Toegestaan is uitsluitend het professionele gebruik als schimmelbestrijdingsmiddel door middel van een gewasbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.0, Ctgb juni 2011) onder de vermelde toepassingsvoorwaarden.

Toepassings gebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Maximaal aantal liter middel per ha per teeltcyclus	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen
Wintertarwe	Roest [1,2] Bladvlekkenziekte [4]	0,75 – 1,5 L/ha	1	1,5 L/ha	-	35
Wintergerst	Roest [2,3] Netvlekkenziekte [5] Bladvlekkenziekte [6]	0,75 – 1,5 L/ha	1	1,5 L/ha	-	42
Triticale	Roest [1,2] Bladvlekkenziekte [4]	0,75 – 1,5 L/ha	1	1,5 L/ha	-	42
Zomertarwe	Roest [1,2] Bladvlekkenziekte [4]	0,75 – 1,5 L/ha	1	1,5 L/ha	-	35
Zomergerst	Roest [2,3] Netvlekkenziekte [5] Bladvlekkenziekte [6]	0,75 – 1,5 L/ha	1	1,5 L/ha	-	42
Haver	Roest [7]	0,75 – 1,5 L/ha	1	1,5 L/ha	-	42
Maïs	Bladvlekkenziekte [8] Oogvlekkenziekte [9]	0,75 – 1,5 L/ha	2	1,5 L/ha	14	60
Suikerbiet	Echte meeldauw [10] Roest [11] Bladvlekkenziekte [12,13]	0,5 – 1 L/ha	1	1 L/ha	-	28

[1] Bruine roest (*Puccinia recondita*),
[2] Gele roest (*Puccinia striiformis*),
[3] Dwergroest (*Puccinia hordei*),
[4] Bladvlekkenziekte (*Septoria tritici*),

[5] Netvlekkenziekte (*Pyrenophora teres*),
[6] Bladvlekkenziekte (*Rynchosporium secalis*),
[7] Kroonroest (*Puccinia coronata*),
[8] Bladvlekkenziekte (*Helmintosporium* spp),
[9] Oogvlekkenziekte (*Kabatiella zeae*),
[10] Echte meeldauw (*Erysiphe beate*),
[11] Bietenroest (*Uromyces betae*),
[12] Bladvlekkenziekte (*Cercospora beticola*),
[13] Bladvlekkenziekte (*Ramularia beticola*).

Toepassingsvoorwaarden

Draag geschikte handschoenen en beschermende kleding, ook bij werkzaamheden aan behandeld gewas.

Om in het water levende organismen te beschermen is de toepassing in de teelt van wintertarwe, wintergerst, triticale, zomertarwe, zomergerst, haver, maïs en suikerbiet uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater gebruik wordt gemaakt van minimaal 75 % driftreducerende spuitdoppen.

Resistentiemanagement
Dit middel bevat de werkzame stof epoxiconazool en pyraclostrobine. Epoxiconazool behoort tot de triazolen/DMI fungiciden. De Frac code is 3. Pyraclostrobine behoort tot de strobulirinen/methoxycarbamaten, De FRAC code is 11.
Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 9 mei 2014 tot wederzijdse erkenning van het middel Retengo Plust, toelatingnummer 14454 N

RISKMANAGEMENT

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1. Identity of the plant protection product

1.1 Applicant

BASF Nederland B.V.
Groningensingel 1
6835 EA Arnhem

1.2 Identity of the active substance

Common name	Epoxiconazole
Name in Dutch	Epoxiconazool
Chemical name	(2*RS*, 3*SR*)-1-[3-(2-chlorophenyl)-2,3-epoxy-2-(4-fluorophenyl)propyl]-1*H*-1,2,4-triazole
CAS no	135319-73-2
EC no	406-850-2

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

Common name	Pyraclostrobin
Name in Dutch	Pyraclostrobine
Chemical name	methyl N-(2-{[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl}phenyl) N-methoxy carbamate
CAS no	175013-18-0
EC no	not assigned

The active substance was included in Annex I of Directive 91/414/EEC on 1 June 2004. From 14 June 2011 forward, according to Reg. (EU) No 540/2011 the substance is approved under Reg. (EC) No 1107/2009, repealing Directive 91/414/EEC.

1.3 Identity of the plant protection product

Name	Retengo Plust
Formulation type	SE
Content active substance	Epoxiconazole: 50 g/L Pyraclostrobin: 133 g/L

For the assessment of the formulation and its proposed use we refer to the member state of the original authorisation (Denmark).

1.4 Function

Fungicide

1.5 Uses applied for

See GAP (Appendix I).

1.6 Background to the application

It concerns an application for mutual recognition based on the authorization (19-144) in Denmark for Opera.

1.7 Packaging details

1.7.1 Packaging description

Material:	PE/PA (COEX)
Capacity:	1L, 5L or 10L
Type of closure and size of opening:	42mm or 54 mm polyethylene screw cap
Other information	UN/ADR compliant.

1.7.2 Detailed instructions for safe disposal

No particular recommendations

2. Physical and chemical properties

For the assessment of the physical and chemical properties of Retengo Plust we refer to the member state of the original authorisation (Denmark).

In the GAP/instructions for use the following has to be stated:

-

3. Methods of analysis

For the assessment of the methods of analysis required for Retengo Plust we refer to the member state of the original authorisation (Denmark).

4. Mammalian toxicology

4.1 Toxicity of the formulated product (IIIA 7.1)

For the evaluation of the toxicity of the formulated product Retengo Plust, we refer to the member state of the original authorisation (Denmark).

4.2 Dermal absorption (IIIA 7.3)

Denmark used a value of 4% for epoxiconazole and 1% for pyraclostrobin for dermal absorption in the risk assessment.

Epoxiconazole: For epoxiconazole, a 4% dermal absorption value was used by Denmark with the explanation that it was based on *in vivo* and *in vitro* studies on the product Opus. The studies itself were not provided in the original authorisation. It can therefore not be evaluated on which basis the conclusion of a dermal absorption value of 4% for both the concentrate and the formulation was made.

In the DAR of epoxiconazole an *in vivo* study in rat for the formulation Opus (SC) is described, which resulted in dermal absorption values of 3% for the concentrate and 18% for the dilution.
An application for the mutual recognition of the formulation Opus EC (83.0 g/L epoxiconazole, RMS: United Kingdom) has been previously evaluated by the Ctgb (13823N). In the original authorization by the United Kingdom the dermal absorption for epoxiconazole in the formulation Opus EC was set at 0.8% for the concentrate and 21% for the dilution on the basis of *in vivo* and *in vitro* studies. These dermal absorption values have previously been used for the mutual recognition request of Retengo Plus (13947N) on which the EFSA guidance on dermal absorption was not applicable.

As the support for the use of a dermal absorption value by Denmark was not sufficiently described and considering the formulation of Opus differs too much from the formulation of Retengo Plust, according to the EFSA guidance on dermal absorption (EFSA Journal 2012; 10(4): 2665), for epoxiconazole a default dermal absorption value of 25% (for products containing > 5% active substance) is used for the concentrate, and a value of 50% for the field dilution based on the value for oral bioavailability.

Pyraclostrobin: According to original authorisation of Denmark the 1% dermal absorption value for pyraclostrobin was based on *in vivo* and *in vitro* studies on the agent Comet, corresponding with the List of Endpoints of pyraclostrobin (in an EC formulation). However, as the EFSA guidance on dermal absorption (EFSA Journal 2012; 10(4): 2665) is applicable to this application, and the formulation of Comet differs too much from the formulation of Retengo Plust, the values suggested by Denmark cannot be used in the current risk assessment.

However, the applicant submitted an additional human in vitro dermal absorption study for pyraclostrobin with BAS 512 04 F, a product similar to Retengo Plust (=BAS 512 16 F), only differing in the quality of one of the co-formulants. The study was evaluated according to the EFSA guidance on dermal absorption and dermal absorption values were derived of 0.1% for the concentrate and 8.1% for a 1:800 spray dilution. These values can be used for the dermal absorption of the Retengo Plust concentrate and field dilution (the maximum dilution of 1:533 for Retengo Plust is covered by the 1:800 spray dilution in the in vitro study), respectively.

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

For toxicological data relating to non-active substances we refer to the registration report written by Denmark

4.4 Exposure/risk assessments *(Dutch specific aspect)*

Overview of the intended uses

An application (request for mutual recognition) has been submitted for the authorisation of the plant protection product Retengo Plust, a fungicide based on the active substances epoxiconazole and pyraclostrobin.

Retengo Plust is a SE formulation and contains 50 g/L epoxiconazole and 133 g/L pyraclostrobin.

The formulation Retengo Plust is applied once or twice during the period April-September. Therefore, a semi-chronic exposure duration is applicable for the operator (including contract workers).

4.4.1 Operator exposure/risk

Calculation of the EU-AOEL / Tolerable Limit Value (TLV)

<u>Epoxiconazole</u>

Denmark calculated a different AOEL from the EU-AOEL stated in the List of Endpoints using the following argument: "*In the carcinogenicity study of epoxiconazole on rats, a NOAEL of 8 mg/kg b.w./day was found. In the second-generation study of epoxiconazole on rats, a NOAEL of 2.3 mg/kg b.w./day was found. As carcinogenic effects and damage to reproduction are considered serious, the Environmental Protection Agency is of the opinion that additional safety factors of 10 for carcinogenic effects and 3 for damage to reproduction are necessary. Thus the overall safety factors will be 1000 and 300 respectively. The Environmental Protection Agency is of the opinion that AOEL should be based on the NOAEL where the AOEL is lowest. The*

applicant has stated that oral absorption is around 70%. The AOEL calculated from the carcinogenicity study is therefore 0.0056 mg/kg b.w./day, equivalent to 0.39 mg/person/day. The AOEL calculated from the second generation study is therefore 0.0054 mg/kg b.w./day, equivalent to 0.38 mg/person/day. Thus the lowest AOEL is based on the NOAEL from the reproduction study."

In the Netherlands the agreed upon EU-AOEL is generally used as the reference value. In addition, Denmark uses an oral absorption correction factor of 70% while in the list of endpoints it is stated to be 50%.

Since the formulation is applied once or twice during the period April-September, a semi-chronic exposure duration is applicable for the operator (including contract workers). A semi-chronic AOEL is therefore derived.

For epoxiconazole the semi-chronic EU-AOEL of 0.008 mg/kg bw/day (= 0.56 mg/day for a 70-kg operator), based on the 1-year study in dog is used for the risk assessment (see List of Endpoints).

Exposure/risk
Exposure to epoxiconazole during mixing and loading and application of Retengo Plust is estimated with models. The exposure is estimated for the unprotected operator. In general, mixing and loading and application is performed by the same person. Therefore, for the total exposure, the respiratory and dermal exposure during mixing/loading and application have to be combined.
In the Table below the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.1 Internal operator exposure to epoxiconazole and risk assessment for the use of Retengo Plust

	Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Mechanical downward spraying on wheat, barley, oats, rye, triticale, maize, and sugar beet (uncovered, 0.075 kg a.s./ha)				
Mixing/ Loading[c]	Respiratory	0.01	0.56	0.01
	Dermal	3.75	0.56	6.69
Application[c]	Respiratory	0.01	0.56	0.01
	Dermal	0.86	0.56	1.54
	Total	4.62	0.56	8.25

a Internal exposure was calculated with:
- biological availability via the dermal route: 25% (concentrate) and 50% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
c External exposure is estimated with EUROPOEM.

Since the EU-AOEL is exceeded, a risk assessment with the use of PPE has to be performed.

Table T.2 Internal operator exposure to epoxiconazole and risk assessment for the use of Retengo Plust

	Route	Estimated internal exposure [a] (mg /day)		Systemic EU-AOEL (mg/day)	Risk-index [b]	
		without PPE	with PPE		without PPE	with PPE
Mechanical downward spraying on wheat, barley, oats, rye, triticale, maize, and sugar beet (uncovered, 0.075 kg a.s./ha)						
Mixing/ Loading[c]	Respiratory	0.01	(0.01)	0.56	0.01	(0.01)
	Dermal	3.75	0.38	0.56	6.69	0.67
Application[d]	Respiratory	0.01	(0.01)	0.56	0.01	(0.01)
	Dermal	0.86	0.10	0.56	1.54	0.17
	Total	4.62	0.48 [d]	0.56	8.25	0.86 [d]

a Internal exposure was calculated with:
- biological availability via the dermal route: 25% (concentrate) and 50% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
c External exposure is estimated with EUROPOEM.
d PPE: gloves during mixing/loading and application

For the unprotected operator, adverse health effects after dermal/respiratory exposure to epoxiconazole as a result of the application of Retengo Plust in the intended uses cannot be excluded, however, correct use of personal protective equipment (gloves during mixing/loading and application) will reduce the dermal exposure and results in a sufficient reduction of the exposure to epoxiconazole for the application of Retengo Plust in the intended uses.

Pyraclostrobin

For pyraclostrobin the semi-chronic EU-AOEL of 0.015 mg/kg bw/day (= 1.05 mg/day for a 70-kg operator), based on the developmental toxicity study in rabbit is used for the risk assessment (see List of Endpoints).

Exposure/risk

Exposure to pyraclostrobin during mixing and loading and application of Retengo Plust is estimated with models. The exposure is estimated for the unprotected operator. In general, mixing and loading and application is performed by the same person. Therefore, for the total exposure, the respiratory and dermal exposure during mixing/loading and application have to be combined.
In the Table below the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.3 Internal operator exposure to pyraclostrobin and risk assessment for the use of Retengo Plust

	Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Mechanical downward spraying on wheat, barley, oats, rye, triticale, maize, and sugar beet (uncovered, 0.200 kg a.s./ha)				
Mixing/ Loading[c]	Respiratory	0.01	1.05	0.01
	Dermal	0.04	1.05	0.04
Application[c]	Respiratory	0.02	1.05	0.02
	Dermal	0.37	1.05	0.35
	Total	0.44	1.05	0.42

a Internal exposure was calculated with:
- biological availability via the dermal route: 0.1% (concentrate) and 8.1% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
c External exposure is estimated with EUROPOEM.

Although the EU-AOEL is not exceeded, a risk assessment with the use of PPE has to be performed in order to calculate the combination toxicology.

Table T.4 Internal operator exposure to pyraclostrobin and risk assessment for the use of Retengo Plust

	Route	Estimated internal exposure [a] (mg /day)		Systemic EU-AOEL (mg/day)	Risk-index [b]	
		without PPE	with PPE		without PPE	with PPE
Mechanical downward spraying on wheat, barley, oats, rye, triticale, maize, and sugar beet (uncovered, 0.200 kg a.s./ha)						
Mixing/ Loading[c]	Respiratory	0.01	(0.01)	1.05	0.01	(0.01)
	Dermal	0.04	<0.01	1.05	0.04	<0.01
Application[d]	Respiratory	0.02	(0.02)	1.05	0.02	(0.02)
	Dermal	0.37	0.04	1.05	0.35	0.04
	Total	0.44	0.07 [d]	1.05	0.42	0.07 [d]

a Internal exposure was calculated with:
- biological availability via the dermal route: 0.1% (concentrate) and 8.1% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

b The risk-index is calculated by dividing the internal exposure by the systemic AOEL.
c External exposure is estimated with EUROPOEM.
d PPE: gloves during mixing/loading and application

4.4.2 Bystander exposure/risk

Epoxiconazole

The exposure is estimated for the unprotected bystander. In Table T.5 the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.5 Internal bystander exposure to epoxiconazole and risk assessment during application of Retengo Plust

Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Mechanical downward spraying on wheat, barley, oats, rye, triticale, maize and sugar beet (uncovered, 0.075 kg a.s./ha, 150 L/ha)			
Respiratory	0.02	0.56	0.03
Dermal	0.04	0.56	0.07
Total	0.06	0.56	0.10

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 50% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

Bystanders and residents may be exposed via the dermal route to spray drift deposits or by inhalation of vapour drift within or directly adjacent to an application area (bystander), or in the vicinity of the application (resident). The internal bystander and resident exposure is calculated in addition to the internal bystander exposure and risk assessment calculated with EUROPOEM II above, which is intended to estimate the work-related bystander exposure. Two different methods are used: 1) the German model which calculates the total exposure for adults, and children, and considers for the latter also the oral exposure via hand-to-mouth or object-to-mouth transfer; and 2) the United Kingdom method which calculates the total bystander exposure for adults, and separately the respiratory and dermal/oral route for resident children. In the table below the estimated internal exposure values from these methods are compared with the systemic AEL.

Table T.6 Internal bystander and resident exposure to epoxiconazole and risk assessment for the application of Retengo Plust

	Route	Estimated internal exposure [a] (mg /day)	Systemic AEL (mg/day)[b]	Risk-index [c]
Bystander exposure during application in representative uses according to the German model				
Child	Total	0.02	0.13	0.17
Adult	Total	0.10	0.48	0.22
Resident exposure during application in all representative uses according to the German model				
Child	Total	0.01	0.13	0.09
Adult	Total	0.02	0.48	0.05
Bystander exposure during application in representative uses according to the UK method				
Adult	Total	0.03	0.48	0.06
Resident exposure during application in representative uses according to the UK method				
Child	Respiratory	0.01	0.12	0.07
	Dermal+Oral	<0.01	0.12	0.02

a External exposure was estimated according to 1) the German guidance paper for exposure and risk assessment for bystanders and residents (Martin *et al.* 2008, *J. Verbr. Lebensm.* 3: 272-281), and 2) the UK method. Internal exposure was calculated with:
- biological availability via the respiratory route: 100% (worst case)
- biological availability via the dermal route: 50% (see 4.2)
- biological availability via the oral route: 50% (see List of EndPoints)

b From the systemic AOEL of 0.008 mg/kg bw/day a specific AEL is derived assuming a body weight of 16.15 or 15 kg for children in the German model or UK method, respectively, and of 60 kg for adults.
c The risk-index is calculated by dividing the internal exposure by the systemic AEL.

Based on the calculated risk indexes for epoxiconazole, the resident exposure of children and adults living next to a field treated with Retengo Plust is considered to be safe.

Pyraclostrobin

The exposure is estimated for the unprotected bystander. In Table T.7 the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.7 Internal bystander exposure to pyraclostrobin and risk assessment during application of Retengo Plust

Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Mechanical downward spraying on wheat, barley, oats, rye, triticale, maize and sugar beet (uncovered, 0.200 kg a.s./ha, 150 L/ha)			
Respiratory	0.05	1.05	0.05
Dermal	0.02	1.05	0.02
Total	0.07	1.05	0.06

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 8.1% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

Bystanders and residents may be exposed via the dermal route to spray drift deposits or by inhalation of vapour drift within or directly adjacent to an application area (bystander), or in the vicinity of the application (resident). The internal bystander and resident exposure is calculated in addition to the internal bystander exposure and risk assessment calculated with EUROPOEM II above, which is intended to estimate the work-related bystander exposure. Two different methods are used: 1) the German model which calculates the total exposure for adults, and children, and considers for the latter also the oral exposure via hand-to-mouth or object-to-mouth transfer; and 2) the UNITED KINGDOM method which calculates the total bystander exposure for adults, and separately the respiratory and dermal/oral route for resident children. In the table below the estimated internal exposure values from these methods are compared with the systemic AEL.

Table T.8 Internal bystander and resident exposure to pyraclostrobin and risk assessment for the application of Retengo Plust

	Route	Estimated internal exposure [a] (mg /day)	Systemic AEL (mg/day)[b]	Risk-index [c]
Bystander exposure during application in representative uses according to the German model				
Child	Total	0.01	0.24	0.04
Adult	Total	0.04	0.90	0.05
Resident exposure during application in all representative uses according to the German model				
Child	Total	0.01	0.24	0.04
Adult	Total	0.02	0.90	0.02
Bystander exposure during application in representative uses according to the UK method				
Adult	Total	0.01	0.90	0.01
Resident exposure during application in representative uses according to the UK method				
Child	Respiratory	0.01	0.23	0.04
	Dermal+Oral	<0.01	0.23	0.01

a External exposure was estimated according to 1) the German guidance paper for exposure and risk assessment for bystanders and residents (Martin *et al.* 2008, *J. Verbr. Lebensm.* 3: 272-281), and 2) the UK method. Internal exposure was calculated with:
- biological availability via the respiratory route: 100% (worst case)
- biological availability via the dermal route: 8.1% (see 4.2)
- biological availability via the oral route: 100% (worst case)

b From the systemic AOEL of 0.015 mg/kg bw/day a specific AEL is derived assuming a body weight of 16.15 or 15 kg for children in the German model or UK method, respectively, and of 60 kg for adults.

c The risk-index is calculated by dividing the internal exposure by the systemic AEL.

Based on the calculated risk indexes for pyraclostrobin, the resident exposure of children and adults living next to a field treated with Retengo Plust is considered to be safe.

4.4.3 Worker exposure/risk

Crop inspection tasks may occur shortly after application of Retengo Plust. Therefore, worker exposure is calculated.

Epoxiconazole

The exposure is estimated for the unprotected worker. In Table T.9 the estimated internal exposure is compared with the systemic EU-AOEL. A work period of 2 hours/day is considered appropriate and a TC value for hand harvesting ornament flowers is used since ornamental flowers in terms of morphology, leaf area index and work tasks are considered as a suitable worst case surrogate for inspection activities in maize.

Table T.9 Internal worker exposure to epoxiconazole and risk assessment after application of Retengo Plust

Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Mechanical downward spraying on wheat, barley, oats, rye, triticale, maize and sugar beet (uncovered, 0.075 kg a.s./ha)			
Respiratory	-	0.56	-
Dermal	1.13	0.56	2.01
Total	1.13	0.56	2.01

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 50% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

Since the EU-AOEL is exceeded, a risk assessment with the use of PPE has to be performed. The exposure is estimated for the unprotected and protected worker. In Table T.10 the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.10 Internal worker exposure to epoxiconazole and risk assessment after application of Retengo Plust

Route	Estimated internal exposure [a] (mg /day)		Systemic EU-AOEL (mg/day)	Risk-index [b]	
	without PPE	with PPE		without PPE	with PPE
Mechanical downward spraying on wheat, barley, oats, rye, triticale, maize and sugar beet (uncovered, 0.075 kg a.s./ha)					
Respiratory	-	(-)	0.56	-	(-)
Dermal	1.13	0.23	0.56	2.01	0.40
Total	1.13	0.23 [c]	0.56	2.01	0.40 [c]

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 50% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

c PPE: gloves.

Pyraclostrobin

The exposure is estimated for the unprotected worker. In Table T.11 the estimated internal exposure is compared with the systemic EU-AOEL. A work period of 2 hours/day is considered appropriate and a TC value for hand harvesting ornament flowers is used since ornamental flowers in terms of morphology, leaf area index and work tasks are considered as a suitable worst case surrogate for inspection activities in maize.

Table T.11 Internal worker exposure to pyraclostrobin and risk assessment after application of Retengo Plust

Route	Estimated internal exposure [a] (mg /day)	Systemic EU-AOEL (mg/day)	Risk-index [b]
Mechanical downward spraying on wheat, barley, oats, rye, triticale, maize and sugar beet (uncovered, 0.200 kg a.s./ha)			
Respiratory	-	1.05	-
Dermal	0.49	1.05	0.46
Total	0.49	1.05	0.46

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 8.1% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

Although the EU-AOEL is not exceeded, a risk assessment with the use of PPE has to be performed in order to calculate the combination toxicology.

Table T.12 Internal worker exposure to pyraclostrobin and risk assessment after application of Retengo Plust

Route	Estimated internal exposure [a] (mg /day)		Systemic EU-AOEL (mg/day)	Risk-index [b]	
	without PPE	with PPE		without PPE	with PPE
Mechanical downward spraying on wheat, barley, oats, rye, triticale, maize and sugar beet (uncovered, 0.075 kg a.s./ha)					
Respiratory	-	(-)	1.05	-	(-)
Dermal	0.49	0.10	1.05	0.46	0.09
Total	0.49	0.10 [c]	1.05	0.46	0.09 [c]

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 8.1% (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

c PPE: gloves.

4.4.4 Re-entry

See 4.4.3 Worker exposure/risk.

Overall conclusion of the exposure/risk assessments of operator, bystander, and worker

The product complies with the Uniform Principles.

Operator exposure

Epoxiconazole: For the unprotected operator, adverse health effects after dermal/respiratory exposure to epoxiconazole as a result of the application of Retengo Plust in wheat, barley, oats, rye, triticale, maize and sugar beet cannot be excluded. Correct use of personal protective equipment (gloves and coverall during mixing/loading and application) will reduce the dermal exposure and results in a sufficient reduction of the exposure to epoxiconazole for the application of Retengo Plust in wheat, barley, oats, rye, triticale, maize and sugar beet.

Pyraclostrobin: Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected operator after dermal and respiratory exposure to pyraclostrobin as a result of the application of Retengo Plust in wheat, barley, oats, rye, triticale, maize and sugar beet.

Bystander exposure

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected bystander, nor for nearby non-work related bystanders and residents, due to exposure to epoxiconazole and pyraclostrobin during application of Retengo Plust in wheat, barley, oats, rye, triticale, maize and sugar beet.

Worker exposure

Epoxiconazole: For the unprotected worker, adverse health effects after dermal/respiratory exposure during re-entry activities in wheat, barley, oats, rye, triticale, maize and sugar beet due to exposure to epoxiconazole after application of Retengo Plust cannot be excluded. Correct use of personal protective equipment will reduce the dermal exposure and results in a sufficient reduction of the exposure for the re-entry activities after application of Retengo Plust in wheat, barley, oats, rye, triticale, maize and sugar beet.

Pyraclostrobin: Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected worker after dermal and respiratory exposure during re-entry activities in wheat, barley, oats, rye, triticale, maize and sugar beet due to exposure to pyraclostrobin after application of Retengo Plust.

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use:
“Draag geschikte handschoenen en beschermende kleding, ook bij werkzaamheden aan behandeld gewas.”

These conclusions are also valid for the simultaneous exposure to epoxiconazole and pyraclostrobin.

4.5 Appropriate mammalian toxicology and operator exposure end-points relating to the product and approved uses

See List of Endpoints.

4.6 Data requirements

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

4.7 Combination toxicology

The formulation Retengo Plust is a mixture of 2 active substances. The combined toxicological effect of these 2 active substances has not been investigated with regard to repeated dose toxicity. Possibly, the combined exposure to these active substances may lead to a different toxicological profile than the profiles based on the individual substances.

Pyraclostrobin and epoxiconazole both induce effects on the liver and blood cells. The liver effects could possibly be correlated to the induction of biotransformation enzymes. In that case, these substances could in principle influence the toxicological effects on each other (induce or inhibit). The combined estimated operator exposure of epoxiconazole and pyraclostrobin with the use of PPE is below the EU-AOEL with a combined risk index of 0.93 (0.86 + 0.07, for epoxiconazole and pyraclostrobin, respectively). Also the combined estimated worker exposure with the use of PPE is below the EU-AOEL with a combined risk index of 0.49 (0.40 + 0.09). Also the estimated bystander and resident scenarios have a

combined risk index below 1. Therefore, no risks are expected even if an additive effect is induced by the simultaneous exposure to both substances.

5. Residues

For the aspect 'Residues' and risk for consumers we refer to the member state of the original authorisation (Denmark). The Guidelines for the generation of data concerning residue data Appendix C 7524/VI/95 rev.2 require that the residue situation in rotational crops must always be considered if, after the treated crop has been harvested (or in the event of early ploughing), it is possible to sow or plant a crop which can be used as a foodstuff and/or feed. Since the product was assessed according to the Uniform Principles by the member state of the original authorisation, residues in succeeding crops need no further consideration.
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6. Environmental fate and behaviour

Risk assessment is done in accordance with Chapter 4 of the BGB published in the Bulletin of Acts and Decrees (Staatsblad) 594 of November 30th 2011 and Chapter 2 of the Rgb published in the Government Gazette (Staatscourant) 22280 of December 2nd 2011.

The underlying risk assessment regarding epoxiconazole is based on the final list of endpoints from the EFSA Conclusion for epoxiconazole (26 March 2008). Additional information is given in *italics*. For epoxiconazole metabolite CGA 71079 (1,2,4-triazole), the new endpoints based on confirmatory data submitted by the Triazole Derivative Metabolite Group (TDMG) have been added in *italics* to the LoEP (Triazole Derived Metabolite: 1,2,4-Triazole - Proposed revision to DT50, version January 2013 (evaluated by RMS UNITED KINGDOM and revised after commenting of the Member Stated; noted on 13 December 2013)). These new endpoints have already been published in the LoEP for active substance epoxiconazole (EFSA Conclusion, April 2013) and tebuconazole (EFSA Conclusion, January 2014).

For the risk assessment the final list of endpoints of pyraclostrobin from the review report is used, where necessary amended with information from the LoEP on Circa (October 2003).

The underlying risk assessment is furthermore based on the Danish authorisation for the product Opera. For the Dutch specific aspects, data from the Retengo Plus (13947 N) assessment is used.

List of Endpoints Fate/behaviour

Epoxiconazole (March 2008, EFSA conclusion)

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralisation after 100 days ‡	- Oxirane ^{14}C-labelled epoxiconazole: Clay/clay loam: 5.5 % CO_2 after 84 days 10.3 % CO_2 after 336 days (study end) Sand: 7.2 % CO_2 after 84 days 38.3 % CO_2 after 336 days (study end) - Metabolite [3,5-^{14}C] 1,2,4-triazole (rate study): Sandy loam 20/11 % CO_2 after 120 days (study end) Loamy sand: 1.4/1.6 % CO_2 after 120 days (study end)

	Silt loam: 34/32 % CO_2 after 120 days (study end) (higher mineralisation rates can be expected in soils pre-adapted to azole fungicides)
Non-extractable residues after 100 days ‡	- Oxirane ^{14}C-labelled epoxiconazole: Clay/clay loam: 8.9 % after 84 days 23.2 % after 336 days (study end) Sand: 12.1 % after 84 days 15.1 % after 336 days (study end) - Metabolite [3,5-^{14}C] 1,2,4-triazole (rate study): Sandy loam 63/66 % after 120 d (study end) Loamy sand: 54/65 % after 120 d (study end) Silt loam: 38/42 % after 120 d (study end)
Relevant metabolites - name and/or code, % of applied (range and maximum) ‡	Oxirane ^{14}C-labelled epoxiconazole: - Unknown fraction M2/M3 (only partly resolved, fraction M2 consisting of at least 4 further fractions) Clay/clay loam: max. 4.0 % after 84 d 2.3 % after 336 days (study end) Sand: max. 3.6 % after 28 d 1.1 % after 336 days (study end) Triazole ^{14}C-labelled epoxiconazole: Loamy sand: 5% 1,2,4-triazole after 343 days (only analysed after 343d) Triazole ^{14}C-labelled epoxiconazole: Sandy loam: 6,6% 1,2,4-triazole after 175 days (only analysed after 175d)

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

Anaerobic degradation ‡	Investigated: fluorophenyl ^{14}C-labelled epoxiconazole - loamy sand = silty sand Recoveries in % of total applied radioactivity (TAR): active substance 55.3 % after 120 days (study end) metab. BF 480-entriazol: max. 8.6 % after 120 days 5.7 % after 91 d metab. BF 480-alcohol: max. 1.2 % after 63/91/120 days each mineralisation: 1.6 % CO_2 after 120 d bound residues: 18.4/24.2 % after 120 d DT_{50} 154 days (1st order, nonlinear fit)
Soil photolysis ‡	Investigated: fluorophenyl ^{14}C-epoxiconazole in sandy loam, 40 % WHC, 22 °C. Continuous irradiation (Xe-lamp, SUNTEST apparatus 3 mW/cm²) for 15 d. Recoveries in % of total applied radioactivity: active substance 84.1 % after 15 days (study end) CO_2 1.9 % after 15 days bound residues 10.1 % after 15 days metabolites max 1 % after 15 days DT_{50} 67 days, continuous irridation

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

Laboratory studies ‡

Parent	Aerobic conditions						
Soil type	X1[3] mg/kg	pH	t. oC / % MWHC	DT50 /DT90 (d)	DT50 (d) 20 °C pF2/10kPa	St. (r2)	Method of calculation
Itingen, clay	-	6.9	20.5/ 40	673	384	0.73	SFO
Collombey, sand	-	7.1	20.5/ 40	254	264	0.94	SFO
Speyer 2.2, loamy sand	-	6.0	20.7/ 20	1064	431	0.88	SFO
Speyer 2.2, loamy sand	-	6.0	20.7/ 60	408	978 (649*)	0.84	SFO
Les Ecouvette, sandy loam	-	4.8	20.7/ 60	502	531	0.92	SFO
Bruch West, sandy loam	0.05	7.4	20/ 40	127	86	0.91	SFO
Bruch West, sandy loam	0.5	7.4	20/ 40	354	238 (143*)	0.75	SFO
Broom`s Barn, sandy loam	-	6.99	10/ 40	453	139	0.74	SFO
Broom`s Barn, sandy loam	-	6.99	15/ 60	206	124	0.76	SFO
Broom`s Barn, sandy loam	-	6.99	10/ 60	180	73 (108*)	0.91	SFO
Shuttleworth, clay loam	-	6.37	15/ 60	281	145	0.94	SFO
Shuttleworth, clay loam (application rate: 1 mg/kg)	-	6.37	10/ 60	221	77	0.76	SFO
Shuttleworth, clay loam	-	6.37	10/ 80	327	140	0.80	SFO
Shuttleworth, clay loam (application rate: 0.05 mg/kg)	-	6.37	10/ 60	170	59 (98*)	0.71	SFO
Woburn, loamy sand	-	5.7	15/ 60	192	129	0.83	SFO
Geometric mean/median					226 / 204		

* geometric mean of different soil treatments in one soil

Met.: 1,2,4-triazole	Aerobic conditions

Soil type	X[1]	pH	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_{dp}/k_f	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Laacher Hof AXXa, sandy loam		6.4	20/ 40	6	-	5	-	SFO
BBA 2.2, loamy sand		5.8	20/ 40	10	-	10	-	SFO
Laacher Hof A III, silt loam		6.7	20/ 40	12	-	9	-	SFO
Geometric mean/median						8		

Added by Ctgb:
Agreed endpoint for 1,2 4- triazole (PRAPeR 12)

1,2,4-triazole	*Aerobic conditions*							
Soil type (USDA)		*pH ($CaCl_2$)*	*t. °C / % MWHC*	*DT_{50}/ DT_{90} (d)*	*f. f. k_{dp}/k_f*	*DT_{50} (d) 20 °C pF2/10kPa*	*St. (r^2)*	*Method of calculation*
Sandy loam		*6.4*	*20°C / 40 % MWHC*	*6.32 / 21.0*		*5.0*	*0.75*	*SFO*
Loamy sand		*5.8*	*20°C / 40 % MWHC*	*9.91 / 33.0*		*9.9*	*0.81*	*SFO*
Silt loam		*6.7*	*20°C / 40 % MWHC*	*12.27 / 40.8*		*8.2*	*0.95*	*SFO*
Geometric mean						*7.4*		

Agreed End-point for calculating PEC soil for EU assessments 12 days (Not normalised).

Field studies ‡ soils with r^2 > 0,7 (considered models: SFO, DFOP, FOMC)

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country) : :	X1	pH	Depth (cm)	DT50 (d) actual	DT90(d) actual	St. (r2)	DT50 (d) Norm.	Method of calculation
Silty clay	Achtum (Germany)		7.5		52	174	0.89	-	SFO
Loamy silt	Boehl (Germany)		7.5		120	>5000	0.72	-	DFOP**
Loamy sand	Bothkamp (Germany)		4.6		216 111 137	719 - 1180	0.72 0.91 0.90	-	SFO FOMC* DFOP**
Sandy loam	Havixbeck (Germany)		6.3		112 82 79	372 1077 >5000	0.88 0.97 0.98	-	SFO FOMC* DFOP**
loam	Stetten (Germany)		6.9		74 56 58	247 1016 >5000	0.82 0.94 0.97	-	SFO FOMC* DFOP**
Sandy loam	Oberding (Germany)		6.6		150 128	499 1026	0.84 0.89	-	SFO FOMC*

					103	>5000	0.86		DFOP**
Loamy sand	Birkenheide (Germany)		4.9		226 184 190	752 >5000 >5000	0.86 0.91 0.93	-	SFO FOMC* DFOP**
Sandy silt	Manzanilla (Spain)		7.7		141	$2x10^6$ 170	0.93 0.97	-	FOMC* DFOP**
sand	Utrera (Spain)		7.2		1	313	0.99	-	FOMC*
Geometric mean/median					-	-		-	

*) FOMC Parameters (soils with r^2>0,7)			
Test site	Co	Alpha	Beta
Bothkamp	0.2084	0.2584	8.1822
Havixbeck	0.3941	0.7619	55.1166
Stetten	0.3116	0.6410	28.7590
Oberding	0.2463	1.0199	131.4887
Birkenheide	0.2525	0.5347	69.4095
Manzanilla*	0.274	0.169	0.426
Utrera*	0.263	0.270	15.909

**) DFOP Parameters (soils with r^2>0,7)				
Test site	Co	K1	K2	Dist
Böhl	0.02794	0.010186	1*10-11	0.725
Bothkamp	0.20581	0.001542	0.05340	0.617
Havixbeck	0.38759	1*10-10	0.01261	0.208
Stetten	0.30188	0.017393	1*10-11	0.784
Oberding	0.24636	1*10-10	0.00804	0.114
Birkenheide	0.25811	0.001887	0.02987	0.714
Manzanilla	0.27562	0.000516	0.06665	0.546

Added by Ctgb:

Normalised field DT50 values for epoxiconazole (taken from DAR II A 7.1.1.2.2/5)

Site	***DT_{50} Best Fit not standardised [d]***	***DT_{50} First Order Kinetic Temperature standardised [d]***	***DT_{50} First Order Kinetic Temperature standardised + Moisture standardised [d]***
Boehl	*104*	*124*	-
Achtum	*62*	*44*	-
Holzen	*not given*	*49*	-
Havixbeck	*74*	*74*	-
Bothkamp	*109*	*122*	-
Stetten	*69*	*65*	-
Oberding	*98*	*82*	-
Birkenheide	*226*	-.	*71*
Geometric mean		*74**	
Median		*73*	
max		*124*	

**geomean value used for PECgw calculations in the DAR.*

Revised endpoints for the aerobic degradation of 1,2,4-triazole in the lab (Triazole Derived Metabolite: 1,2,4-Triazole - Proposed revision to DT50, version January 2013 (evaluated by RMS UNITED KINGDOM and revised after commenting of the Member Stated; noted by the Standing Committee on the Food Chain and Animal Health (SCFCAH) on 13 December 2013):

Laboratory studies – modelling kinetic parameters

1,2,4-triazole (applied as parent)	*Aerobic conditions*					
Soil type	*pH*	*t. °C / % MWHC*	*DT_{50} fast phase/DT_{50} slow phase(d)/g*	*DT_{50} (d) 20 °C pF2/10kPa*	*St. (r^2)*	*Method of calculation*
Sandy loam	*6.4*	*20 °C / 40 %*	*0.9/59.2/ 0.683*			*DFOP*
Loamy sand	*5.8*	*20 °C / 40 %*	*1.5/247.6/0.5 80*			*DFOP*
Silt loam	*6.7*	*20 °C / 40 %*	*0.8/20.6/ 0.443*			*DFOP*
Geometric mean/median			*1.0/67.1/ 0.569*			*DFOP*

Revised endpoints for the field dissipation of soil metabolite 1,2,4-triazole (Triazole Derived Metabolite: 1,2,4-Triazole - Proposed revision to DT50, version January 2013 (evaluated by RMS UNITED KINGDOM and revised after commenting of the Member Stated; noted by the Standing Committee on the Food Chain and Animal Health (SCFCAH) on 13 December 2013):

Field studies ‡

1,2,4-triazole (applied as parent)	*Aerobic conditions, kinetics calculated for **ambient conditions**. Bare soil with grass sown immediately after application (with exception of Spain site where no grass sown).*								
Soil type (indicate if bare or cropped soil was used).	*Location (country or USA state).*	*X^1*	*pH*	*Depth (cm)*	*DT_{50} (d) actual*	*DT_{90}(d) actual*	*St. (χ^2)*	*DT_{50} (d) Norm.*	*Method of calculation*
Silt loam	*Germany*		*6.4*	*0-30*	*7.8*	*366.7*	*15.2*		*FOMC*
Silty clay loam	*Italy*		*7.6*	*0-40*	*21.2*	*207.4*	*10.7*		*DFOP*
Sandy loam	*United Kingdom*		*7.4*	*0-40*	*6.8*	*109.3*	*17.8*		*DFOP*
Loam	*Spain*		*5.8*	*0-30*	*28.1*	*717.6*	*13.3*		*DFOP*
Geometric mean/median									
1,2,4-triazole (applied as parent)	*Aerobic conditions, kinetics calculated timestep **normalised to 20°C and pF2 moisture**. Bare soil with grass sown immediately after application (with exception of Spain site where no grass sown).*								
Soil type	*Location*		*pH*	*Depth (cm)*	*DT_{50} (d) Fast phase*	*DT_{50} (d) Slow phase*	*'g'*	*St. (χ2)*	*Method of calculation*
Silt loam	*Germany*		*6.4*	*0-30*	*2.5*	*70.7*	*0.655*	*18.8*	*DFOP*
Silty clay loam	*Italy*		*7.6*	*0-40*	*1.4*	*59.8*	*0.364*	*10.6*	*DFOP*
Sandy loam	*United Kingdom*		*7.4*	*0-40*	*0.5*	*25.1*	*0.458*	*18.1*	*DFOP*

Loam	*Spain*		*5.8*	*0-30*	*4.6*	*126.0*	*0.489*	*12.7*	*DFOP*
Geometric mean ('g' value is arithmetic mean)					*1.68*	*60.5*	*0.489*		*DFOP*

In the evaluation of the new data by RMS United Kingdom the following is stated regarding the use of the revised endpoints in pesticide leaching models:
If 1,2,4-triazole is being considered as a terminal metabolite in a leaching assessment, it is appropriate to simulate degradation of this metabolite using two compartments, one for the rapid degradation phase and the other for the slow degradation phase. The separate flows from the precursor to the rapid and slow phases should be specified along a similar scheme as shown in chapter 8.3.3.2.2 and Box 8-2 of the FOCUS Degradation Kinetics guidance. Specifically, the proportion of flow to the rapid phase of degradation would be specified by ffM x g (i.e. formation fraction for precursor to 1,2,4-triazole multiplied by the DFOP 'g' parameter) and the proportion of flow from precursor to the slow phase would be specified by ffM x (1-g) (i.e. formation fraction for precursor to 1,2,4-triazole multiplied by 1-'g'). Given that this method divides the formation fraction for the metabolite between fast and slowly degrading compartments using the 'g' parameter as part of the simulation, it is considered unnecessary to run the model twice as specified in FOCUS degradation kinetics (i.e. it is unnecessary to run the fast and slow compartments separately and add the results together). However, due to the 1/n value for 1,2,4-triazole being less than 1, the recommendation that the application rate in the simulation is doubled and the resulting leaching concentrations divided by 2 is supported.

The proposed method is in line with the recommendations in section 7.1.2.2.2. of FOCUS Kinetics (2006), for the implementation of bi-exponential kinetics (DFOP) into pesticide leaching models. These recommendations apply to a parent compound, but can similarly be applied to a metabolite for which the degradation is best described by DFOP. In the case that the 1/n value of the metabolite is 1, than a single run can be performed in which both the fast and the slow degrading compartment is formed from the precursor. However, if the 1/n value of the metabolite is not one, than the application rate should be doubled. In the opinion of the Ctgb the only true way to achieve this, is to model the metabolite as parent and double the application rate, corrected for the molecular weight and the maximum percentage observed/fraction formed. However, this kind of modelling, disregarding the transformation scheme, may lead to an underestimation of the leaching. Therefore Ctgb will perform both simulations in a risk assessment in order to establish which method calculates the highest concentrations for 1,2,4-triazole on a case-by-case basis.

For the leaching assessment of 1,2,4,-triazole as metabolite of epoxiconazole, the following revised endpoints should be used:
Fast compartment: DT50 of 1.68 days, formation fraction of 0.489;
Slow compartment DT50 of 60.5 days, formation fraction of 0.511.
For the calculation of the formation fractions the 'g' parameter value of 0.489 was used in combination with a formation fraction of 1 (worst-case assumption conform EU).

Laboratory studies ‡

Parent	Anaerobic conditions						
Soil type	X[2][4]	pH	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa	St. (r^2)	Method of calculation
Bruch West, silty sand*	-	7.5	20 /44.5	154			SFO
Geometric mean/median				-			

* epoxiconazole in soil was 55% of TAR after 120 d

Soil accumulation and plateau concentration ‡	Two field accumulation (Germany) studies with 6 to 9 years duration: Study 1: Niederhofen, Germany, 6 years duration, loamy sand/sandy loam, 437 g a.s./ha/year measured residues after last application (mg/kg soil) in 0 to 25 cm min. /max. trial 1 (cereals; no biomass withdrawal) 0.062 /0.114 trial 2 (cereals; grain/ straw harvested) 0.056 /0.108 Calculated degradation rates (TOPFIT modelling, SFO): $DT_{50, trial\ 1}$: 420 d $DT_{50, trial\ 2}$: 387 d Geometric mean DT50: 403 d Study 2: Boehl, Germany, 9 years duration, sandy loam, 312 g a.s./ha/year measured residues after last application (mg/kg) in 0 to 25 cm min. / max. trial 1 (bare soil) 0.09 / 0.19 trial 2 (cereals; grain harvested) 0.05 / 0.13 trial 3 (cereals; grain and straw harvested) 0.06 / 0.12 Calculated degradation rates (TOPFIT modelling, SFO): $DT_{50, trial\ 1}$: 343 d $DT_{50, trial\ 2}$: 251 d $DT_{50, trial\ 3}$: 389 d Geometric mean DT_{50}: 322 d Soil accumulation modelling with ModelMaker 3 2 x 125 g a.s./ha every year for 26 year, interval 21 days, 1.5 kg/L bulk density, with interception (FOCUS) for cereal scenario f = 0.5 (BBCH 25) and 0.7 (BBCH 61), DT_{50} 403 days (geometric mean from study 1 in Niederhofen) Max. residue in top 5 cm: PECsoil, accu overall: 0.167 mg kg-1

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_f /K_{oc} ‡ [L/kg]	Epoxiconazole: Koc 280 – 2647 (2 studies), arithmetic mean 1073 (n=5): soil pH Koc Kf 1/n 2.1, sand 6.0 957 4.79 0.766 (90,9 % sand, 3.8 % silt, 5.3 % clay, 0.5 % org.C.) Les.EV, 4.75 2647 19.59 0.813 sandy loam (53,7 % sand, 29.3 % silt, 17 % clay, 0.74 % org.C.) Itingen, 6.87 1100 21.78 0.808

pH dependence (yes / no) (if yes type of dependence) ‡	clay/clay loam (33.6 % sand, 24.8 % silt, 41.6 % clay, 1.98 % org.C.) Sandy 7.1 280 7.25 0.882 silty loam (40.4 % sand, 43 % silt, 16.9 % clay, 2.6 % org.C.) Clayey loam 6.8 380 7.50 0.910 (19.1 % sand, 40.2 % silt, 41 % clay, 2.0 % org.C.) *Mean 1/n: 0.836* no correlation of kf with parameters oc, clay and pH was observed metabolite 1,2,4-triazole Koc: 43-120, arithmetic mean 89 (n=4) soil pH Koc Kf 1/n Sandy loam 6.9 89 0.720 1.016 (62 % sand, 21 % silt, 17 % clay, 1.4 % org. matter, Corg 0.812 %.) Clay loam 6.9 43 0.748 0.827 (26 % sand, 46 % silt, 28 % clay, 3.0 % org. matter, Corg 1.74 %.) Silty clay 8.8 120 0.833 0.897 (11 % sand, 44 % silt, 45 % clay, 1.2 % org.C matter, Corg 0.696) Silty clay loam 7.0 104 0.722 0.922 (9 % sand, 62 % silt, 29 % clay, 1.2 % org. matter, Corg 0.696) no (for 1,2,4-triazole agreed by PRAPeR 12).

Added by Ctgb:

Additional adsorption/desorption study for epoxiconazole:
For a recent assessment an additional adsorption/desorption study with epoxiconazole was submitted by the (same) applicant:
Zirnstein, 2005. Adsorption/desorption-study of BAS 480 F (Reg.No. 205 259) on five European soils. BASF DocID 2005/1012874.

Results:

Soil	***Soil Type (USDA)***	***TOC (%)***	***pH ($CaCl_2$)***	***K_f (mL g^{-1})***	***1/n***	***K_{foc} (mL g^{-1})***	***K_d (mL g^{-1})***	***K_{oc} (mL g^{-1})***
Utrera	*sand / loamy sand*	*0.42*	*5.9*	*8.24*	*0.846*	*1962*	*10.3*	*2451*
Li 10 (1680)	*loamy sand*	*0.87*	*6.6*	*9.27*	*0.859*	*1065*	*11.3*	*1304*
Forst H6	*sandy loam / loam*	*1.61*	*7.1*	*14.8*	*0.882*	*922*	*18.2*	*1130*
LUFA 3A	*loam*	*2.54*	*7.3*	*17.8*	*0.839*	*702*	*24.0*	*945*
LUFA 5M	*sandy loam*	*1.46*	*7.3*	*13.5*	*0.849*	*928*	*17.8*	*1217*

For the preliminary test (Tier 1) and the screening test (Tier 2) results were used from the study by Seher (2002; Adsorption/Desorption - Study of BAS 480 F (Epoxiconazol) on two german soils), which was evaluated in the DAR. An isotherm test (Tier 3) was performed on five soils. Results are within the range of the agreed EU endpoints.

The study is considered acceptable by Ctgb. In combination with the results presented in the LoEP this gives a mean Kfoc value and a mean 1/n for epoxiconazole of 1094 L/kg (median is 942.5 L/kg) and 0.85 respectively (n=10).

Added by Ctgb:
Agreed end point (from PRAPeR 12)

Metabolite 1,2-4 triazole ‡							
Soil Type(USDA)	*OC %*	*Soil pH ($CaCl_2$)*	*Kd (mL/g)*	*Koc (mL/g)*	*Kf (mL/g)*	*Kfoc (mL/g)*	*1/n*
Silty clay	*0.70*	*8.8*			*0.833*	*120*	*0.897*
Clay loam	*1.74*	*6.9*			*0.748*	*43*	*0.827*
Sand	*0.12*	*4.8*			*0.234*	*202*	*0.885*[1]
Silty clay loam	*0.70*	*7.0*			*0.722*	*104*	*0.922*
Sandy loam	*0.81*	*6.9*			*0.720*	*89*	*1.016*
Arithmetic mean (of 4 values excluding the very low OC sand that was considered not representative of agricultural soils)					*0.756*	*89*	*0.9155*
pH dependence (yes or no)			*No*				

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

Column leaching ‡	Guideline: BBA IV 4-2. Three studies with 3 LUFA soils each: German standard soils LUFA 2.1, 2.2 (loamy sand), 2.3 (sandy loam), saturated soil moisture, room temp. Applied: 1 L BAS 480 13 F or BAS480 03 F or BAS 483 00 F/ha = 125 g as/ha in 2 studies, 3rd study 187 g as/ha, 200 mm irrigation. Concentrations in leachate: Epoxiconazole conc. were < 0.05 µg/L in all leachates of the two studies (< 0.2 % of applied amount).
Aged residues leaching ‡	(1) Guideline: BBA IV 30 day ageing in the dark, 22 °C, 21.1 % WHC, 10.2 % field capacity. Application rate 1 mg as/kg (509 g as/ha), 14C-labelled. Soil: LUFA 2.1 (90 % sand, 3.8 % silt, 5.3 % clay, 0.48 % org. C., pH 6.0) Very low radioactive residues in the 4 percolates (about 100 ml each): 0.1 - 0.4 % of applied radioactivity, sum 0.8 % (0.8 µg total). Epoxiconazole: in soil segments 1, 2 and 3: 16.6, 74.8 and 1.5 % of applied radioactivity. (2) Guideline EPA 163-1 Test conditions as described above. 10 percolate fraction of 100 mL but 205 g as/ha. Very low radioactive residues in percolates: 0.0 - 0.2 % of applied radioactivity, sum 0.7 % (0.352 µg total). Epoxiconazole: in soil segments 1, 2 and 3: 68.5, 21.0 and 0.4 % of applied radioactivity. (3) Guideline: BBA IV 4-2 and EPA 163-1 175 day ageing in the dark, 22 °C, application rate 0.5 mg as/kg, triazole-14C labelled = 255 g as/ha. Soil: Sand, LUFA 2.1 (93.3 % sand, 4.7 % silt, 2.0 % clay, 0.74% org. C., pH 5.4) Sandy loam (74 % sand, 10 % silt, 16 % clay, 0.9 % org. C., pH 7.2) : Very low radioactive residues in the 4 percolates: BBA guideline evaluation 1.3 % of applied radioactivity, epoxiconazole: in segments 1, 2 and 3: 82.2, 17.9 and 0.5 % of applied radioactivity. EPA evaluation 1.1 % = 0.226 µg total). epoxiconazole: in segments 1, 2 and 3: 57.8, 35.6 and 3.9 % of applied radioactivity.

	(4) Guideline: BBA IV 4-2 343 day ageing in the dark, 22 °C, application rate 0.5 mg as/kg oxirane- and triazole-14C labelled. Soil: Sandy loam (81 % sand, 12 % silt, 7 % clay, 1.0 % org. C., pH 6.3). Very low radioactive residues in the 5 percolates: oxirane-labelled: < 0.01-0.6 % of applied radioactivity, sum 0.72 % (0.311 µg total). Epoxiconazole: in segments 1, 2 and 3: 64.6, 28.6, 0.5 % of applied radioactivity. triazole-labelled: sum in percolate 1.3 % TAR, Epoxiconazole: in soil segments 1, 2 and 3: 61.4, 33.5, 0.6 % of applied radioactivity. Metabolite 1,2,4-triazole 31 day ageing in the dark, application rate 1 mg triazole = 215 g/ha. Soil: Sandy loam and silt loam, 31 d ageing. 520 mm irrigation throughout 91 d. 42 - 46 % of applied radioactivity in the leachates, 54 - 58 % remained in soil, one half of it in the upper 5 cm. No triazole was identified in the leachates.
Lysimeter/ field leaching studies ‡	not performed, not required

PEC (soil) (Annex IIIA, point 9.1.3)

Parent

Method of calculation	SFO kinetic Worst case of non-standardised DT50field out of 8 studies: 226 days ("Birkenheide") 5 cm soil layer, 1.5 kg/L bulk density with interception (FOCUS) for cereal scenario f = 0.5 (BBCH 25) and 0.7 (BBCH 61) Interval between applications 21 d.
Application rate	2 × 0.125 kg active substance /ha

Metabolite 1,2,4-triazole

Method of calculation	PEC: 1st order kinetic, DT50Lab worst case standardised to 15 °C of 3 studies: 18 d, 5 cm soil layer, 1.5 kg/L bulk density, with interception (FOCUS) for cereal scenario f = 0.5 (BBCH 25) and 0.7 (BBCH 61). Interval between applications 21 d. ModelMaker, k1_deg = 1st order rate constant for BAS 480 F to metabolite 1,2,4-triazole 0.0038/d, k2_deg = 1st order rate constant for elimination of metabolite 1,2,4-triazole 0.039/d, molar mass correction BAS 480 F to metabolite 1,2,4-triazole 0.211 (69.1 g/mol/329.8g/mol).
Application rate	2 x 0.125 kg active substance /ha

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

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature) ‡	pH 3: parent: 65 % decrease at 70 °C after 20 d
	pH 5: parent: stable at 25 °C, stable at 75 °C for 29 d, 20 % decrease at 90 °C after 29 d 1,2,4-triazole: stable at 25 °
	pH 7: parent: stable at 25 °C, 75 °C, 90°C 1,2,4-triazole: stable at 25 °

	pH 9: parent: stable at 25 °C, 75 °C, 12 % decrease at 90 °C 1,2,4-triazole: stable at 25 °
Photolytic degradation of active substance and relevant metabolites ‡	Active substance - absorption coefficient < 10 L/mol x cm. - no photolysis in sterile buffer solution after 31 days, 3 mg as/L, pH 7, 25 °C, natural sunlight mimic, 1800 µEinstein (SUN-TEST apparatus), 12 h cycle light/dark. ^{14}C-labelled a.s. - 20 % degradation in natural water after 15 days, 3.3 mg as/L, pH 8.2, DOC 11.7, TOC 11.2 mg/L; nitrate 0.84 mg/L. 22 °C, natural sunlight mimic, 3 mW/cm² (SUNTEST-apparatus), constant light. A.s. not labelled. Epoxiconazole: slow photolysis, DT_{50} 52 d, 1st order. No metabolites investigated Metabolite: 1,2,4-triazole, 14C-labelled - 80 mg/L triazole in distilled water containing humic acid (Fluka). No photochemical loss after 30 days (natural sun light). absorption coefficient < 10 L/mol x cm
Readily biodegradable (yes/no) ‡	no (OECD 301F)
Dissipation in water/sediment	Water/sediment, 2 systems, ^{14}C-U-chlorophenyl and ^{14}C-U-fluorophenyl labelled epoxiconazole, application rate 125 g as/ha. 2 systems (A = Millstream Pond, sediment: clayey loam; B = Swiss lake, sediment: sand)
Active substance	Epoxiconazole as: (ModelMaker 3.0.4, 1st order) system A system B DT50,water 38.4 d 93.1 d DT90,water 127.6 d 309.4 d r² 0.987 0.975 DT50,system 172 d 67.5 d DT90,system 573 d 224 d r² 0.997 0.989 DT50,sediment - 61.4 d DT90,sediment - 204 d r² - 0.975
Degradation in water/sediment - DT_{50} water ‡ - DT_{90} water ‡ - DT_{50} whole system ‡ - DT_{90} whole system ‡ - DT_{50} sediment ‡ - DT_{90} sediment ‡	
Dissipation - DT_{50} water ‡	ModelMaker 4.0 system A system B DT50,water degradation 2.8 d 6.4 d best fit
Metabolite	Metabolite: BAS 480-entriazole system A system B DT50,sediment -/-* 65.2 d DT90,sediment -/-* 216 d r² 0.987 0.975 * no reliable fit in ModelMaker calculations
Degradation in water/sediment - DT_{50} sediment ‡ - DT_{90} sediment ‡	
Mineralisation	after 100 days (study end) in % TAR: ^{14}C-U-chlorophenyl / ^{14}C-U-fluorophenyl labelled epoxiconazole system A: 4.2 / 3.3 system B: 3.8 / 3.2
Non-extractable residues	after 100 days (study end) in % TAR: ^{14}C-U-chlorophenyl / ^{14}C-U-fluorophenyl labelled epoxiconazole

	system A: 21.9 / 21.6 system B: 19.7 / 19.2
Distribution in water / sediment systems (active substance) ‡	Maximum values: (as in % TAR) epoxiconazole, ^{14}C-U-chlorophenyl / ^{14}C-U-fluorophenyl label System A: 71.0/67.7 % in sediment after 30 days System B: 48.3/50.0 % in sediment after 13 days

BAS 480 F in % total applied radioactivity (TAR)

days after applicat.	(A) water	(B)	(A) sediment	(B)
0	93.6/91.1	93.4/91.1	< LOD/3.2	2.0/2.7
1	66.7/67.5	76.8/78.1	26.9/26.0	18.1/15.8
3	49.4/43.0	64.4/62.5	45.4/48.6	31.2/30.3
7	24.9/25.7	47.8/49.9	65.7/62.2	42.8/41.0
13	12.9/22.7	37.7/32.3	69.9/60.3	48.3/50.0
30	8.0/9.6	21.6/15.2	71.0//67.7	36.4/40.7
59	4.5/4.7	12.8/12.8	66.4/63.8	38.5/35.0
100	3.6/4.5	6.3/6.6	64.0/58.5	33.6/37.2

Distribution in water / sediment systems (metabolites) ‡

Maximum values: (BAS 480 entriazole in % TAR)
System A: 6.1/6.6 % in sediment after 30/59 days
System B: 32.7/34.0 % in sediment after 100/59 days

BAS 480 entriazole in % TAR

days after applicat.	(A) water	(B)	(A) sediment	(B)
0	< LOD/1.4	< LOD/1.7	< LOD	< LOD
1	< LOD/0.7	< LOD/0.9	< LOD/0.4	< LOD
3	< LOD	< LOD/0.8	< LOD/0.8	< LOD/0.9
7	< LOD	< LOD	1.3/2.6	2.5/2.4
13	< LOD	< LOD	3.9/5.7	6.4/7.0
30	< LOD	< LOD	6.1/5.6	27.0/27.4
59	< LOD	< LOD	3.1/6.6	30.6/34.0
100	< LOD	< LOD	3.7/5.7	32.7/28.1

other unknown metabolites:
water A: max. 0.8/1.7 %TAR at day 0
water B: max. 1.4/1.3 %TAR at day 0
sediment A: max. 2.3/2.5 %TAR after 30 resp. 100 d
sediment B: max. 2.1/1.8 % TAR after 100 d

PEC (surface water) (Annex IIIA, point 9.2.3)

Parent

Method of calculation	FOCUS surface water Step 3, 9 different FOCUS locations with 9 scenarios. Input parameters: $DT_{50,water}$ from water/sediment study 59.8 d, $DT_{50,sediment}$ 149.7 d (geometric means). Median of standardised $DT_{50,soil}$ 73 d.; Koc 1073 L/kg *; 1/n 0.836. Vapour pressure < $1 \cdot 10^{-5}$ Pa 20°C, molar enthalpy of vaporisation 95000 J/mol, water solubility 7.05 mg/L at pH 7, molar enthalpy of dissolution 27000 J/mol, diffusion coefficient in water 4.3×10^{-5} m²/d, diffusion coefficient in air 0.43 m²/d. Scenario: spring [2)]cereals, BBCH code 25 and 69
Application rate	2 x 125 g as/ha with an interval of 21 days.
Main routes of entry	Run off and Spray drift

* arithm. mean of 5 Koc and 1/n values (broad range of individual values)

[2)] crop scenario with worst case max. concentrations

PEC (ground water) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	FOCUS-PELMO 2.2.2 and FOCUS-Macro 3.3.1 Epoxiconazole: Interception (FOCUS) for cereal scenario f=0.5 (BBCH 25) and 0.7 (BBCH 61). $DT_{50\ field}$, 74 (20°C standardised geom. mean). K_{oc} 280 L/kg, 1/n 0.882, water sol. 7.1 mg/L, pH independent, TSCF (crop uptake default 0.5. Metabolite 1,2,4-triazole: $DT_{50\ lab}$ 8 d (20°C, pF2 standardised). K_{oc} 43 L/kg, 1/n 0.827, water sol. 700 mg/L,pH independent, TSCF (crop uptake default 0.5
Application rate	2 x 0.125 g as/ha with an interval of 21 d days, BBCH growth stage 25-61

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

Direct photolysis in air ‡	no calculation performed, not studied, not required
Quantum yield of direct photo transformation	criteria for the determination not reached (A > 10 L/mol x cm), determination is not necessary.
Photochemical oxidative degradation in air ‡	DT_{50} = 4 days , indicating a potential for long range aerial transport. (calculation according to Atkinson 1987, considering a hydroxyl radical concentration of 5 × 105 cm-3) A re-calculation with a newer version (v. 1.91) of AOPWIN is available in section 4.3, but not peer reviewed.
Volatilization ‡	(circulation chamber, air flow 1 m/s, 21 ± 1 °C, rel. humidity 45 %.). from plant surfaces: < 5 % within 24 h after application
	from soil: ‡ < 5 % within 24 h after application

Definition of the Residue (Annex IIA, point 7.3)

Relevant to the environment for quantitation	Soil : epoxiconazole Water : epoxiconazole Sediment: epoxiconazole metabolite BF 480 entriazole [1)] Groundwater : epoxiconazole (by default) Air : epoxiconazole (by default)

1) 1-[(2Z)-3-(2-chlorophenyl)-2-(4-fluorophenyl)-2 propenyl]-1H-1,2,4-triazole

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

Soil (indicate location and type of study)	USA, California. Soil survey of naturally occurring 1,2,4-triazole. 68 non-agricultural and agricultural samples. 45 % contained 1,2,4-triazole between 1.5 - 4.68 µg/kg. Intensity and frequency independent from agricultural practice.
Surface water (indicate location and type of study)	not available
Ground water (indicate location and type of study)	Germany, groundwater monitoring programme Data from 4 Federal States number

total	< LOQ	≤ 0.1	> 0.1-1.0		> 1.0µg/L
2000	102	102	0	0	0
2001	114	114	0	0	0
2002	411	409	2	0	0
total	627	625	2	0	

Air (indicate location and type of study)	not available, data required to assess the long range atmospheric transport

Classification and proposed labelling (Annex IIA, point 10)

With regards to fate and behaviour data

Dir. 67/548/EEC	N; R51/53
According to Reg. 1272/2008	Aquatic Chronic 2 - H411

List of Endpoints pyraclostrobin (in line with LoEP of September 2004 as included in final review report, where needed amended with LoEP on Circa, October 2003)

Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)	
Mineralisation after 100 days	4 % after 87 d (tolyl-label, route study) 5 % after 91 d (chlorophenyl-label, route study)
Non-extractable residues after 100 days	54.3 % after 87 d (tolyl-label, route study) 56.1 % after 91 d (chlorophenyl-label, route study)
Major metabolites - name and/or code, % of applied (range and maximum)	BF 500-6, max. 31 % after 120 days (rate studies) BF 500-7, max. 13 % after 62 days (rate studies)

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)	
Anaerobic degradation	no residues of the parent after 120 days, bound residues: 61 % (tolyl-label), 37 % (chlorophenyl-label). Major metabolite BF 500-3: max 95.8 % after 14 d (tolyl-label), 80 % after 14 d (chlorophenyl-label)

Soil photolysis	after 15 days: 64-74 % parent, 12 % bound residues, 2 % CO_2, no major metabolites (> 10 %)

Remarks	Degradation in soil is mainly depending on microbial activity

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)	
Laboratory studies DT50lab (20 °C, aerobic):	DT_{50lab} **as** (20 °C, aerobic): 12-101 days (5 soils) DT_{50lab} BF 500-6 (tolyl-label, route study): 129 d DT_{50lab} BF 500-6 (chlorphenyl-label, route study): 166 d DT_{50lab} BF 500-7 (tolyl-label, route study): 112 d DT_{50lab} BF 500-7 (chlorphenyl-label, route study): 159 d
DT90lab (20 °C, aerobic):	DT_{90lab} **as** (20 °C, aerobic): 143-163 days (5 soils)

	DT_{90lab} BF 500-6 (tolyl-label, route study): 428 d DT_{90lab} BF 500-6 (chlorphenyl-label, route study): 552 d DT_{90lab} BF 500-7 (tolyl-label, route study): 372 d DT_{90lab} BF 500-7 (chlorphenyl-label, route study): 529 d
DT50lab (10 °C, aerobic):	DT_{50lab} (5 °C, aerobic): > 120 days
DT50lab (20 °C, anaerobic):	DT_{50lab} (20 °C, anaerobic): 3 days

Field studies (country or region) DT50f from soil dissipation studies:	DT_{50f} : 2 – 37 days, 6 locations (3 Germany, 2 Spain, 1 Sweden)
DT90f from soil dissipation studies:	DT_{90f} : 83-230 days
Soil accumulation studies:	Not required
Soil residue studies:	Not required

Soil adsorption/desorption (Annex IIA, point 7.1.2)	
K_f /K_{oc} K_d pH dependence	**Active substance** (^{14}C-Chlorphenol-ring) soils: 3 German, 2 US, 1 Canadian Koc 6000 – 16000 (no average value calculated because of extremely high range) Kd 30 – 368 1/n = 0.861 – 1.025 *Ctgb: arithmetic mean: 0.95 (calculated from DAR)* None **BF 500-6** Koc = 3160 – 71300 Kd = 79 - 610 1/n not available.Due to low water solubility only one concentration considered. **BF 500-7** Koc = 4020 – 149900 1/n not available. Due to low water solubility only one concentration considered.

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)	
Column leaching	0 % in leachate, all radioactivity in top soil layer
Aged residues leaching	0 % in leachate, all radioactivity in top soil layer
Lysimeter/ field leaching studies	based on K_{oc} and DT_{50} values, no leaching expected Studies are not required.

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

Hydrolysis of active substance and major metabolites (DT_{50}) (state pH and temperature)	pH 5-9, 25 °C: stable
Photolytic degradation of active substance and major metabolites	DT_{50} parent : 1-2 days *From LoEP circa (not included in review report):* *BF 500-11:max. 45 % after 21 days* *BF 500-13:max. 17 % after 6 days*

	BF 500-14:max. 21 % after 3 hours *BF 500-15:max. 27 % after 1 day* *500M58:max. 23 % after 1 day*
Readily biodegradable (yes/no)	Not readily biodegradable
Degradation in water/sediment - DT_{50} water - DT_{90} water - DT_{50} whole system - DT_{90} whole system	**Best fit** pond system: 3 days; river system: 1 day pond system: 41 days; river system: 9 days pond system: 27 days; river system: 29 days** pond system: 89 days; river system: 96 days** ** = low r^2 value (0.5593)
Degradation in water/sediment - DT_{50} water - DT_{50} whole system - DT_{90} whole system -DT_{50} sediment -DT_{90} sediment	**1st-order (Timme and Frehse)** pond system: 8.7 days; river system: 1 day pond system: 26.8 days; river system: 29 days** pond system: 89 days; river system: 96 days** ** = low r^2 value (0.5593) pond system: 33 days; river system: 9 days pond system: 105 days; river system: no calc.possible *NB: Ctgb cannot retrieve the system values from the DAR or the addenda. A first order fit on the total of a.s. in water and sediment was performed using the FOCUS kinetics excel sheet (using Solver)* *Whole system (SFO):* *-pond system (A): DT_{50} 25.6 d; DT_{90} 85.0 d (chi2 6.5, M0 91.6, k 0.027))* *-river system (B): DT_{50} 7.4 d; DT_{90} 24.6 d (chi2 10.0, M0 98.9, k 0.094)* *geomean $DT_{50system}$ of 13.8 days used for Risk assessment*

Distribution in water / sediment systems (active substance)	pond system: sediment max. 53 % after 14 days, decreasing to 7 % after 100 days river system: sediment max. 62 % after 2 days, decreasing to 10 % after 100 days
Distribution in water / sediment systems (metabolites)	BF 500-3: in water: max. 2 %, in sediment: max. 12 % (pond system) after 100 days; max. 66 % (river system) after 14 days, decreasing to 29 % after 100 days BF 500-6: (only in pond system) in sediment max. 7 % after 61 days BF 500-7: (only in pond system) in sediment max. 6 % after 61 days
Mineralisation	0.7 – 7.5 % in 100 days
Bound residues	51 - 66.2 % in 100 days
Accumulation in water and/or sediment:	not expected, only bound residues
Metabolites from additional water/sediment study with irradiation:	BF 500-11: max. 11% after 21 days BF 500-13: max. 16% after 62 days BF 500-14: max. 11% after 10 days
Degradation in the saturated zone	not relevant

remarks	results from water/sediment study with irradiation

	only useful as additional information concerning possible metabolites, not accepted as higher tier study for the determination of degradation rates

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

Vapour pressure	2.6 x 10^{-8} Pa, 20°C
Henry's law constant	5.307 x 10^{-6} Pa m^3 mol^{-1}
Direct photolysis in air	see photochemical oxidative degradation
Quantum yield of direct phototransformation	2.17 x 10^{-1}
Photochemical oxidative degradation in air (DT_{50})	< 2 hours (24- hours day, according to Atkinson, AOP)
Volatilisation	from plant surfaces: about 3 % in 24 hours
	From LoEP circa: from soil: < 1 % in 24 hours

remarks	No short or long range transport in air expected

Not in review report, taken from LoEP on circa:

***Definition of the Residue** (Annex IIA, point 7.3)*

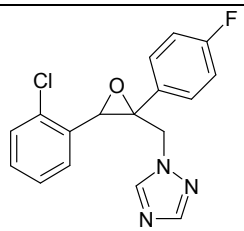
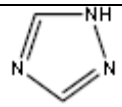
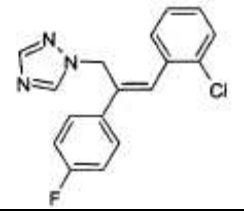
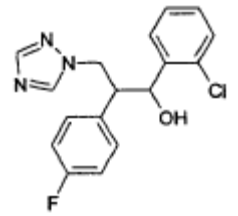
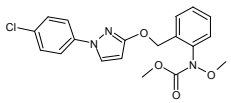
Relevant to the environment	***Soil**: parent, BF500-6, BF500-7* ***Groundwater**: parent, BF500-6, BF500-7* ***Surface water including sediment:** parent, BF500-3, BF 500-11, BF 500-13*

***Monitoring data, if available** (Annex IIA, point 7.4)*	
Soil (indicate location and type of study)	*none*
Surface water (indicate location and type of study)	*none*
Ground water (indicate location and type of study)	*none*
Air (indicate location and type of study)	*None*

Appendix A: Metabolite names, codes and other relevant information of the plant protection product Retengo Plust with active substances epoxiconazole and pyraclostrobin.

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

Compound name	Code number(s)	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (% of occurrence/ formation)

Compound name	Code number(s)	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (% of occurrence/ formation)
Epoxiconazole	135319-73-2 (formerly 106325-08-0)	(2*RS*, 3*SR*)-1-[3-(2-chlorophenyl)-2,3-epoxy-2-(4-fluorophenyl)propyl]-1*H*-1,2,4-triazole	$C_{17}H_{13}ClFN_3O$		329.76	Parent, all compart-ments
1,2,4-triazole (BF 480-16)	CGA 71019	1,2,4-triazole			69.1	Minor in soil (6.6 % after 175 days, one observation)
BF 480-entriazol		1-[(2Z)-3-(2-chlorophenyl)-2-(4-fluorophenyl)-2 propenyl]-1H-1,2,4-triazole			313.76	34 % in sediment
BF 480 - alcohol		1-(2-chlorophenyl)-2-(4-fluorophenyl)-1-hydroxy-3-(1H-1,2,4-triazol-1-yl)propane			330.76	Minor
Pyraclo-strobin	175013-18-0 (CAS no)	methyl N-(2-{[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxymethyl}phenyl) N-methoxycarbamate	C19H18ClN3O4		387.82	Parent, all compart-ments
BF500-6					641.55	31 % in soil
BF500-7					625.55	13 % in soil
BF500-3						66 % in sediment
BF500-11						Aqueous photolysis
BF500-13						Aqueous photolysis
BF500-14						aqueous photolysis
BF500-15						Aqueous photolysis
500M58						Aqueous photolysis

6.1 Fate and behaviour in soil

6.1.1 Persistence in soil

The risk assessment of persistence in soil is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorization (Denmark).

6.1.2 Leaching to shallow groundwater *(Dutch specific aspect)*

Leaching to shallow ground water is a Dutch specific aspect. For the current application for mutual recognition this means that the Danish risk assessment for leaching to ground water cannot be used for mutual recognition and a national risk assessment has to be performed.

Article 8e of the Plant Protection Products and Biocides Decree (BGB) describes the authorisation criterion for leaching to groundwater.
The leaching potential of the active substances epoxiconazole and pyraclostrobin (and metabolites 1,2,4-triazole, BF500-6 and BF500-7 is calculated in the first tier using Pearl 4.4.4 and the FOCUS Kremsmünster scenario. Input variables are the actual worst-case application rate (0.075 kg/ha for epoxiconazole and 0.200 kg/ha for pyraclostrobin), the crops KREM-Wcereals (for winter wheat, winter barley, oats, rye and triticale), KREM-Scereals (for spring wheat and spring barley) sugar beet and maize, and an interception value appropriate to the crop stage (see Table M.2a). The (first) date of yearly application is May 25th, except for sugar beet, for which in addition an application on September 1st is modelled in line with the GAP. For maize, both a single application of the maximum application rate at May 25th, and split applications of the minimum application rate at May 25th and June 8th, were calculated. For metabolites, all available data concerning substance properties are taken into account. Epoxiconazole metabolite 1,2,4-triazole and major pyraclostrobin metabolites BF500-6 and BF500-7 are included in the calculations. No other metabolites occurred in soil above > 10 % of AR, > 5 % of AR at two consecutive sample points or had an increasing tendency. The following input data are used for the calculation:

PEARL:

Active substance epoxiconazole:
Median normalized field DT_{50} for degradation in soil (20°C): 73 days (n=7)
Median K_{om} (pH-independent): 547 L/kg (n=10)
Arithmetic mean 1/n: 0.85 (n=10)

Saturated vapour pressure: 3.5 x 10^{-7} Pa (20 °C) (Addendum 7, April 2005)
Solubility in water: 7.1 mg/L at 20°C
Molecular weight: 329.76 g/mol

Plant uptake factor: 0.5 (systemic mode of action)
Q10: 2.2

Metabolite 1,2,4-triazole:
Geometric mean field DT_{50} for degradation in soil (20°C):
1.68 days (fast degrading compartment)
60.5 days (slow degrading compartment)
Arithmetic mean K_{om} (pH-independent): 51.6 L/kg (n=4) (agreed at PRAPeR 12)
Arithmetic mean 1/n: 0.916 (n=4) (agreed at PRAPeR 12)

Formation fraction:
0.489 (fast degrading compartment)
0.511 (slow degrading compartment)

Saturated vapour pressure: 0.22 Pa (20°C)
Solubility in water: 730000 mg/L (agreed at PRAPeR 12)
Molecular mass: 69.1 g/mol

Plant uptake factor: 0.0
Q10: 2.58

1,2,4-triazole is modelled in two ways (see addition to the LoEP):
1) using the transformation scheme: doubling the application rate of the parent and dividing the sum of the calculated concentration for the slow and the fast degrading compartment by two;
2) modelling 1,2,4-triazole as parent: a separate run is performed for both compartments in which the application rate (corrected for the molecular weight and the fraction formed) is doubled and the resulting PECgw is divided by two. The results for both compartments are summed to give the overall PECgw for 1,2,4-triazole.

Active substance pyraclostrobin:
Geometric mean lab DT_{50} for degradation in soil (20°C): 45.6 days (n=5)
Median K_{om} (pH-independent): 4898 L/kg. (n=6)
Arithmetic mean 1/n: 0.95 (n=6)

Saturated vapour pressure: 2.6 E^{-8} Pa (20°C)
Solubility in water: 19 g/L (at 20 °C in deionised water (pH of 5.8))
Molecular weight: 387.82 g/mol

Plant uptake factor: 0
Q10: 2.2

Metabolite BF 500-6:
Lab DT_{50} for degradation in soil (20°C): 146.3 days (n=1)
K_{om} (pH-independent): 22324 L/kg. (n=1)
1/n: 1 (default for metabolites in absence of data)

Saturated vapour pressure: 2.6 E^{-8} Pa (20°C)
Solubility in water: 19 g/L (at 20 °C in deionised water (pH of 5.8))
Molecular weight: 641.55 g/mol
Formation fraction: 0.31 (based on % maximum observed)

Plant uptake factor: 0
Q10: 2.2

Metabolite BF 500-7:
Lab DT_{50} for degradation in soil (20°C): 133.4 days (n=1)
K_{om} (pH-independent): 36630 L/kg. (n=1)
1/n: 1 (default for metabolites in absence of data)

Saturated vapour pressure: 2.6 E^{-8} Pa (20°C)
Solubility in water: 19 g/L (at 20 °C in deionised water (pH of 5.8))
Molecular weight: 626.55 g/mol
Formation fraction: 0.13 (based on % maximum observed)

Plant uptake factor: 0
Q10: 2.2

Other parameters: standard settings of PEARL 4.4.4

1,2,4-triazole was modelled both as parent and as the metabolite of epoxiconazole. The worst case PECgw is presented in Table M.1a. The application rate was corrected for the relative molar ratio and the formation fraction (i.e. 1 as worst case assumption conform EU). In the calculation a fast and a slow degrading compartment was modelled (see input box) with a DT_{50} value corresponding to the degradation rate of the fast and slow phase of the DFOP kinetic fit. The application rate for both compartments is determined by the DFOP “g”

parameter. Due to the fact that the 1/n value for 1,2,4-triazole is not one, the application rate of both compartments was doubled and the resulting predicted leaching concentrations were divided by two, conform FOCUS Kinetics section 7.1.2.2.2. The concentrations presented in Table M.1a are the sum of the predicted leachate concentrations of both compartments. The following concentrations are predicted for the active substances epoxiconazole and pyraclostrobin and the metabolites 1,2,4-triazole, BF500-6 and BF500-7 following the realistic worst case GAP, see Table M.1a.

Table M.1a Leaching of active substances epoxiconazole and pyraclostrobin and metabolites 1,2,4-triazole, BF500-6 and BF500-7 as predicted by PEARL 4.4.4

Use	Substance	Rate substance [g/ha]	Frequency / Interval [days]	Fraction Intercepted*	PEC groundwater [µg/L]	
					Spring	Autumn
Winter wheat, winter barley, oats, triticale	Epoxiconazole	75	1 / -	0.7	< 0.001	
	1,2,4-triazole	-**			0.0093	
	Pyraclostrobin	200			< 0.001	n.a.
	BF500-6	-**			< 0.001	
	BF500-7	-**			< 0.001	
Spring wheat, spring barley	Epoxiconazole	75	1 / -	0.7	< 0.001	
	1,2,4-triazole	-**			0.0097	n.a.
	Pyraclostrobin	200			< 0.001	
	BF500-6	-**			< 0.001	
	BF500-7	-**			< 0.001	
Rye	Epoxiconazole	75	1 / -	0.5	< 0.001	
	1,2,4-triazole	-**			0.016	n.a.
	Pyraclostrobin	200			< 0.001	
	BF500-6	-**			< 0.001	
	BF500-7	-**			< 0.001	
Sugar beet	Epoxiconazole	50	1 / -	0.7	< 0.001	< 0.001
	1,2,4-triazole	-**			0.0052	0.0053
	Pyraclostrobin	133			< 0.001	< 0.001
	BF500-6	-**			< 0.001	< 0.001
	BF500-7	-**			< 0.001	< 0.001
Maize (single application)	Epoxiconazole	75	1 / -	0.5	< 0.001	
	1,2,4-triazole	-**			0.017	
	Pyraclostrobin	200			< 0.001	n.a.
	BF500-6	-**			< 0.001	
	BF500-7	-**			< 0.001	
Maize (split application)	Epoxiconazole	37.5	2 / 14	0.5	< 0.001	
	1,2,4-triazole	-**			0.017	
	Pyraclostrobin	100			< 0.001	n.a.
	BF500-6	-**			< 0.001	
	BF500-7	-**			< 0.001	

* interception values derived from Table 1.5 in “generic guidance for FOCUS groundwater scenarios v.2.1”, by crossreferencing to the BBCH values from the GAP. For most cereals, application is requested from BBCH 30 onwards, which corresponds to an interception of 70% (elongation). For rye specifically application is from BBCH 29 onwards, corresponding to an interception of 50 % (tillering). For maize BBCH 30 corresponds to an interception of 50%. For sugar beet, BBCH 39 corresponds to 70% interception.
** calculated via transformation scheme

Results of Pearl 4.4.4 using the Kremsmünster scenario are examined against the standard of 0.01 µg/L. This is the standard of 0.1 µg/L with an additional safety factor of 10 for vulnerable groundwater protection areas (NL-specific situation).

From Table M.1a it reads that the expected leaching based on the PEARL-model calculations for the active substances epoxiconazole and pyraclostrobin and their metabolites is smaller than 0.01 µg/L for all proposed applications, except for metabolite 1,2,4-triazole in the maize and rye applications.
Therefore, further study into the leaching behaviour was done.

GeoPEARL
The leaching potential of substances to the shallow groundwater in the potential area of use within The Netherlands is calculated using the GeoPEARL model. 1,2,4-triazole was modelled both as parent and as the metabolite of epoxiconazole and the worst case PECgw is presented in Table M.1b The same input data as used in the first tier with Pearl 4.4.4 is employed. The selected crop for rye is cereals and the crop for maize is maize. The number of plots is set at 250 (minimum). For results see Table M.2b.

Table M.1b Leaching of metabolite 1,2,4-triazole as predicted by GeoPEARL 3.3.3

Use	Substance	Rate a.s. [g/ha]	Frequency / Interval [days]	Fraction Intercepted*	PEC groundwater [µg/L]	
					spring	autumn
Rye	Epoxiconazole	75	1 / -	0.5	0.014	n.a.
	1,2,4-triazole	-**				
Maize (single application)	Epoxiconazole	75	1 / -	0.5	0.0074	n.a.
	1,2,4-triazole	-**				
Maize (split application)	Epoxiconazole	37.5	2 / 14	0.5	0.0075	n.a.
	1,2,4-triazole	-**				

* interception values derived from Table 1.5 in "generic guidance for FOCUS groundwater scenarios v.2.1", by crossreferencing to the BBCH values from the GAP. See Table M.1a for details.
** calculated via transformation scheme

When applied at maize, GeoPEARL calculations show that the predicted leachate concentrations for the metabolite 1,2,4-triazole are smaller than 0.01 µg/L. Hence, the metabolite 1,2,4-triazole meets the standards laid down in the BGB for the proposed application.

However, for rye, the predicted concentration for metabolite 1,2,4-triazole is larger than 0.01 µg/L, and a restriction on the use in groundwater protection areas should be placed on the label:
Om het grondwater te beschermen mag dit product niet worden gebruikt in grondwaterbeschermingsgebieden.

Based on further discussion with the applicant, the applicant proposed to withdraw the proposed use in rye. Therefore the restriction sentence is no longer required. All remaining proposed applications meet the standards for leaching to groundwater without restriction.

Monitoring data
Epoxiconazole
There are no recent Dutch data available regarding the presence of the substance epoxiconazole in groundwater. In the LoEP reference is made to German studies of the early '00 years. Only a few exceedings were observed.

Pyraclostrobin

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

Regarding the presence of metabolites BF500-6 and BF500-7, no monitoring data are available

Hence, the applications meet the standards for leaching as laid down in the BGB.

Conclusions
The proposed applications of the product Retengo Plust complies with the requirements laid down in the BGB concerning leaching to groundwater.

6.2 Fate and behaviour in water

6.2.1 Rate and route of degradation in surface water *(Dutch specific aspect)*

The Netherlands has its own national drift percentages, as described in Article 8f of the BGB. The exposure concentrations of the active substances epoxiconazole, pyraclostrobin and their metabolites in surface water have been estimated for the various proposed uses, using calculations of surface water concentrations (in a ditch of 30 cm depth), which originate from spray drift during application of the active substance. The spray drift percentage depends on the use.
The applicant proposed the use of 75% drift reducing nozzles for all uses.

For epoxiconazole, one metabolite appeared in major quantities in one system: BAS 480-entriazole, 34 %. This metabolite was only observed in sediment. Not all substance properties are known. Only a dissipation half-life for sediment is available. As the metabolite is only found in sediment, the use of this sediment dissipation half-life is considered acceptable in combination with a default DT_{50} of 1000 for the water phase. No K_{om} is available. For the calculation, a high default value of 1000 L/kg is assumed. As the ecotoxicology endpoint is based on a water-spiked study, only PEC surface water is calculated.

The system value for pyraclostrobin was recalculated by Ctgb since it was unclear which value from the LoEP was to be used, and the kinetics methods used for deriving the endpoint were outdated.

In the aqueous photolysis study, the following metabolites of pyraclostrobin were found: BF 500-11 (max. 45 % after 21 days), BF 500-13 (max. 17 % after 6 days), BF 500-14 (max. 21 % after 3 hours), BF 500-15 (max. 27 % after 1 day, transient) and 500M58 (max. 23 % after 1 day, transient). Metabolites BF 500-15 and 500M58 are formed within 1 day. It is assumed that the toxicity of these metabolites are included in the mesocosm tests for the parent pyraclostrobin; this study will be discussed in Chapter 7 (ecotoxicology).

Pyraclostrobin metabolite BF500-3 is observed in a maximum percentage of 66 % of A.R. in river sediment). However it is not mentioned in the ecotox LoEP and no substance properties are available. The parent pyraclostrobin is assessed for the risk to sediment organisms, which is expected to cover the risk for BF500-3. Therefore, no PEC values are calculated. Major soil metabolites BF500-6 and –7 are found in minor quantities in the water-sediment study and do not need an aquatic risk assessment under the present Dutch assessment framework (only drift entry).

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

TOXSWA:
Active substance epoxiconazole:

Geomean DT_{50} for degradation in water at 20°C: 107.7 days (*n*=2)
DT_{50} for degradation in sediment at 20°C: 1000 days (default)

Median K_{om} for suspended organic matter: 547 L/kg (n=10)
Arithmetic mean K_{om} for sediment: 547 L/kg (n=10)
Arithmetic mean 1/n: 0.85 (n=10)

Saturated vapour pressure: < $1x10^{-5}$ Pa at 20°C (extrapolated from 70 °C)
Solubility in water: 0.0071 g/L at 20°C
Molecular mass: 329.76 g/mol
Q10: 2.2

Metabolite BAS 480-entriazole:
DT_{50} for degradation in water at 20°C: 1000 days (default)
DT_{50} for degradation in sediment at 20°C: 65.2 days (*n*=1, as the metabolite is only found in sediment, the use of this sediment dissipation half-life is considered acceptable)

K_{om} for suspended organic matter: 1000 L/kg (estimation)
K_{om} for sediment: 1000 L/kg (estimation)
1/n: 1.0 (default for metabolites)

Saturated vapour pressure: 3.5 x 10^{-7} Pa (20 °C) (parent value)
Solubility in water: 7.1 mg/L at 20 °C (parent value
Molecular mass: 313.76 g/mol
Correction factor: maximum observed (34 %) * relative molecular mass (313.76/329.76)=0.32
Q10: 2.2

Active substance pyraclostrobin:
Geomean DT_{50} for degradation in water at 20°C: 13.8 days (recalculated by Ctgb on the basis of the study in the DAR)
DT_{50} for degradation in sediment at 20°C: 1000 days (default)

Median K_{om} for suspended organic matter: 4898 L/kg (n=6)
Median K_{om} for sediment: 4898 L/kg (n=6)
Arithmetic mean 1/n: 0.95 (n=6)

Saturated vapour pressure: 2.6 x 10^{-8} Pa (20°C)
Solubility in water: 19 g/L (at 20 °C in deionised water (pH of 5.8))
Molecular weight: 387.82 g/mol
Q10: 2.2

Other parameters: standard settings TOXSWA

When no separate degradation half-lives ($DegT_{50}$ values) are available for the water and sediment compartment (accepted level P-II values), the system degradation half-life ($DegT_{50}$-system, level P-I) is used as input for the degrading compartment and a default value of 1000 days is to be used for the compartment in which no degradation is assumed. This is in line with the recommendations in the FOCUS Guidance Document on Degradation Kinetics.

For metabolites, the level M-I values are used (system $DegT_{50}$ value) only, since level M-II criteria have not been fully developed under FOCUS Degradation Kinetics.

In Table M.2a, the drift percentages and calculated surface water concentrations for the active substances epoxiconazole and pyraclostrobin and its metabolite BAS 480-entriazole for each intended use are presented. The metabolite is modelled as parent.

Table M.2a Overview of surface water concentrations for active substances epoxiconazole and pyraclostrobin and metabolite BAS 480-entriazole in the edge-of-field ditch following spring application

Use	Substance	Rate [g/ha]	Freq./ Inter-val [days]	Drift [%]	PIEC [µg/L]*	PEC21 [µg/L] *	PEC28 [µg/L] *
winter wheat, winter barley, oats, triticale, spring wheat, spring barley, rye	Epoxiconazole BAS 480-entriazole Pyraclostrobin	75 24 200	1 / -	0.5**	0.178 0.057 0.459	0.135 0.044 0.242	0.129 0.042 0.217
Sugar beet	Epoxiconazole BAS 480-entriazole Pyraclostrobin	50 16 133	1 / -	0.5**	0.118 0.038 0.305	0.090 0.030 0.160	0.085 0.028 0.144
Maize (single application)	Epoxiconazole BAS 480-entriazole Pyraclostrobin	75 24 200	1 / -	0.5**	0.178 0.057 0.459	0.135 0.044 0.242	0.129 0.042 0.217
Maize (split application)	Epoxiconazole BAS 480-entriazole Pyraclostrobin	37.5 12 100	2 / 14	0.5**	0.151 0.049 0.327	0.118 0.039 0.192	0.106 0.035 0.177

* calculated according to TOXSWA
** drift reducing nozzles class 75 %

$PEC_{sediment}$
To address the risk to sediment organisms, a $PEC_{sediment}$ value is needed for the active substance epoxiconazole. The $PEC_{sediment}$ values calculated with TOXSWA are expressed in g a.s./m^3 sediment. This $PEC_{sediment}$ has to be converted to mg a.s./kg sed dw by dividing it by the dry bulk density. It is assumed that the substance will be present mainly in the top 1 cm layer. This layer has a density of 80 kg/m^3. The maximum PEC value in sediment in the top 1 cm of sediment is reached at 22 - 26 days after application, depending on the loading. See Table M.2b for calculation of PECsediment.

Table M.2b Maximum sediment concentration for active substance epoxiconazole following spring application (worst-case)

Use	Substance	Rate a.s. [kg/ha]	Drift [%]	$PEC_{sediment}$ [g a.s./m^3 sediment] *	$PEC_{sediment}$ [mg a.s./kg sediment dw]**
winter wheat, winter barley, oats, triticale, spring wheat, spring barley, rye	Epoxiconazole	75	0.5***	0.145E-02 (after 24 days)	1.81E-02
Sugar beet	Epoxiconazole	50	0.5***	0.100E-02 (after 25 days)	1.25E-02
Maize (single application)	Epoxiconazole	75	0.5***	0.100E-02 (after 25 days)	1.25E-02
Maize (split application)	Epoxiconazole	75	0.5***	0.138E-02 (after 28 days)	1.73E-02

* TOXSWA output
** calculated as (PECsed in g/m3 / 80 kg/m3) x 1000 (conversion of g/kg to mg/kg)
*** drift reducing nozzles class 75 %

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

Monitoring data
Article 8g of the Plant Protection Products and Biocides Decree (BGB) describes the use of the 90th percentile.

The Pesticide Atlas on internet (www.pesticidesatlas.nl, www.bestrijdingsmiddelenatlas.nl) is used to evaluate measured concentrations of plant protection products and biocides in Dutch surface water, and to assess whether the observed concentrations exceed threshold values. Dutch water boards have a well-established programme for monitoring surface waters. In the Pesticide Atlas, these monitoring data are processed into a graphic format accessible on-line and aiming to provide an insight into measured concentrations of Dutch surface waters against environmental standards.
The current version 2.0 of the Pesticide Atlas does not contain a land use correlation analysis, which may indicate probable or causal relationships with land use. Instead a link to the land use analysis performed in version 1.0 is made, in which the analysis is made on the basis of data aggregation based on grid cells of either 5 x 5 km or 1 x 1 km.

Data from the Pesticide Atlas are used to evaluate potential exceeding of the authorisation threshold and the MPC (*ad-hoc* or according to INS) threshold.
For examination against the drinking water criterion, another database (VEWIN) is used, since the drinking water criterion is only examined at drinking water abstraction points. For the assessment of the proposed applications regarding the drinking water criterion, see next section.

<u>epoxiconazole</u>
The active substance epoxiconazole was observed in the surface water (most recent data from 2012). In Table M.3a the number of observations in the surface water are presented. In the Pesticide Atlas, surface water concentrations are compared to the authorisation threshold value of 0.43 µg/L (07-09-2012, consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case 0.1*NOEC lemna) and to the indicative Maximum Permissible Concentration (MPC) of 1.2 µg/L as presented in the Pesticide Atlas.

For the substance epoxiconazole, an MPC-INS value of 0.19 µg/L is available (RIVM report 12415A00, January 2010). This value is presented in the Pesticide Atlas as AA-EQS. Therefore, if threshold exceedings are correlated to the proposed use, this may have consequences for the authorisation.

Table M.3a Monitoring data in Dutch surface water for epoxiconazole (from www.pesticidesatlas.nl, version 2.0)

Total no of locations (2012)	***n* > authorisation threshold**	***n* > indicative/ad hoc MPC threshold**	***n* > MPC-INS threshold**
131*	3 (2 locations exceeding the threshold with a factor between 1-2, 1 location exceeding the threshold with a factor 2-5)	0	0

* the number of observations at each location varies between 1 and 30, total number of measurements is 817 in 2012.

On three locations in the upper part of Friesland, the authorisation threshold is exceeded. The correlation of exceeding of the authorisation threshold with land use is derived from the 1.0 version of the Pesticide Atlas. Hence, the correlation is not based on the exact same monitoring data (in 2005 11 locations with 55 samples, in 2006 43 locations with 172 samples monitored). However, this is the best available information and therefore it is used in this assessment.

The observed exceeding could not be correlated to any use since there are too few exceeding data to perform the correlation analysis. At this moment no information on relation with land use is available. Therefore, no consequences for the current application for authorisation can be drawn.

pyraclostrobin

The active substance pyraclostrobin was observed in the surface water (most recent data from 2012). In Table M.3b the number of observations in the surface water are presented. In the Pesticide Atlas, surface water concentrations are compared to the authorisation threshold value of 1.75 µg/L (01-07-2011, consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case HC5 for fish) and to the indicative Maximum Permissible Concentration (MPC) of 0.023 µg/L as presented in the Pesticide Atlas.

For substance pyraclostrobin, an MPC-INS value of 0.023 µg/L is available (RIVM report 11925, November 2009, see section 7.2 for details).
This value is identical to the ad hoc MPC presented in the Pesticide Atlas. Therefore, if threshold exceedings are correlated to the proposed use, this may have consequences for the authorisation. However, it should be noted that for the examination of an exceedance, the indicative MPC is examined against the 90th percentile of the monthly averages, while the AA-EQS is examined against the mean of the monthly averages (which is less conservative).

Table M.3b Monitoring data in Dutch surface water for pyraclostrobin (from www.pesticidesatlas.nl, version 2.0)

Total no of locations (2012)	***n* > authorisation threshold**	***n* > indicative/ad hoc MPC threshold**	***n* > MPC-INS threshold ***
145**	0	13 (1 exceeding the MPC with a factor > 5, 4 exceeding with a factor 2-5, 8 with a factor 1-2)	<

* < : exceeding expected to be lower than with indicative/ad hoc MPC value;

** the number of observations at each location varies between 1 and 30, total number of measurements is 961 in 2012.

At several locations in Overijssel, Noord-Holland, Zeeland and in the Noordoostpolder, the ad-hoc MPC (equalling the MPC-INS) is exceeded. The correlation of exceeding of the MPC with land use is derived from the 1.0 version of the Pesticide Atlas. Hence, the correlation is not based on the exact same monitoring data (in 2005 18 locations with 66 samples, in 2006 43 locations with 172 samples were monitored). However, this is the best available information and therefore it is used in this assessment.

The observed exceeding (in 2005-2006) could not be correlated to any use since there are too few exceeding data to perform the correlation analysis. It is noted however that in some regions not monitored yet in 2005-2006, several exceedings occur. At this moment no

information on relation with land use is available. The locations with exceeding are typically cereal growing areas. Still, no consequences for the current application for authorisation can be drawn.

Drinking water criterion
Assessment of the drinking water criterion is in principle not a Dutch specific aspect however the interpretation is done in a Dutch specific way.

Article 8g of the *Plant Protection Products and Biocides Regulations* (BGB) describes the use of the 90th percentile.

It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, the Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion 'surface water intended for drinking water production'.
The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635[3].

Substances are categorized as new substances on the Dutch market (less than 3 years authorisation) or existing substances on the Dutch market (authorised for more than 3 years).
- For new substances, a preregistration calculation is performed.
- For existing substances, the assessment is based on monitoring data of VEWIN (drinking water board).
    - If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.
    - If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90th percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

<u>Epoxiconazole</u>
Epoxiconazole has been on the Dutch market for > 3 years (authorised since 07-04-1994). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water as laid down in the BGB are met.

<u>Pyraclostrobin</u>
Pyraclostrobin has been on the Dutch market for > 3 years (authorised since 12-12-2003). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water as laid down in the BGB are met.

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

6.3 Fate and behaviour in air

Route and rate of degradation in air
Assessment of fate and behaviour in air is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorization (Denmark).

At present there is no framework to assess fate and behaviour in air of plant protection products.

6.4 Appropriate fate and behaviour end-points relating to the product and approved uses

See List of End-points.

6.5 Data requirements

-

The following restriction sentences were proposed by the applicant:
Om in het water levende organismen te beschermen is toepassing uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use (WG):
Om in het water levende organismen te beschermen is toepassing uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater gebruik wordt gemaakt van minimaal 75 % driftreducerende spuitdoppen.

6.6 Overall conclusions fate and behaviour

It can be concluded that:

1. all proposed applications of the active substances epoxiconazole and pyraclostrobin, epoxiconazole metabolite 1,2,4-triazole and pyraclostrobin metabolites BF500-6 and BF500-7 meet the standards for leaching to the shallow groundwater as laid down in the BGB.
2. Denmark did not assess the product with regard to the standards for surface water destined for the production of drinking water, however, the proposed application of the product complies with the BGB with regard to the standards for surface water destined for the production of drinking water.

7. Ecotoxicology

For the current application of mutual recognition of Retengo Plust, risk assessment is done in accordance with Chapter 2 of the RGB.

The underlying risk assessment is based on the final list of endpoints for epoxiconazole (EFSA conclusion, 2008, 138) and pyraclostrobin (Final review report, 8 September 2004) and on the Danish authorisation for Opera. For the Dutch specific aspects data from previous assessment is used (C249.II.1.3). For formulation data reference is made to the data submitted for Opera (12509 N, dd. 09/01/2004).

Additional studies evaluated by RIVM (report 12405a00 and 12396a00) and NOTOX (report 204488/501755) were taken into account. Comments and additions by Ctgb are given in italics.

The most recent risk assessment of Retengo Plus was also taken into account.

The following is mentioned in the risk assessment of Denmark:

"In connection with its application dated 2 September 2008 concerning renewal of the approval concerning epoxiconazole (where a request was made to process Opera instead of Opera N), the company has reported that no new studies have been submitted. Therefore, processing will take place on the basis of documentation already submitted, plus the EU material. In addition, risk assessments will take place based on additive toxicity in the two active substances included.
As no new studies have been submitted, the Environmental Protection Agency will refer to:

- *Approval of Opera dated 27 February 2004 with Annex 1a (actually 2a)*
- *Approval of Comet (containing pyraclostrobin) dated 24 April 2002 with Annex 1a of pyraclostrobin dated 18 April 2002*
- *Approval of Opus (containing epoxiconazole) dated 18 February 2003 with Annex 1.2 dated 12 March 1998".*

List of Endpoints Ecotoxicology

Epoxiconazole

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

Acute toxicity to mammals ‡	rat LD_{50} = 3160 mg as/kg bw
Long-term toxicity to mammals ‡	rat NOAEL = 25 mg as/kg diet (2 gen. reproduction) 2.3 mg as/kg bw
Acute toxicity to birds ‡	*Colinus virginianus* LD_{50} = > 2000 mg as/kg bw
Short term dietary toxicity to birds ‡	*Colinus virginianus* LD_{50} = > 907 mg as/kg bw > 5000 mg as/kg diet
Reproductive toxicity to birds ‡	*Colinus virginianus* NOEL = 10 mg as/kg diet 1.0 mg as/kg bw

Additional information *(summarized and evaluated by RIVM (Report 12405a00)*
Maximum residue on arthropods (*Poecilus cupreus) :29.9 mg a.s./kg (4) replicates per sampling time). DT50 was 2.65 h (FOMC), equivalent to 0.11 days.*

Toxicity data for aquatic species (most sensitive species of each group or relevant for risk assessment, respectively) (Annex IIA, point 8.2, Annex IIIA, point 10.2)‡

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l) *
Pseudokirchneriella subcapitata	Epoxiconazole	72 h acute	E_bC_{50} biomass E_rC_{50} growth rate NOEC biomass NOEC growth rate	1.19 > 10 0.0078 -
Daphnia magna	Epoxiconazole	48 h acute	EC_{50} immobilisation	8.69
Oncorhynchus mykiss	Epoxiconazole	96 h acute	LC_{50}	3.14
Lemna gibba	Epoxiconazole	7 d	E_bC_{50} biomass	0.0043**

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l) *
			E_rC_{50} growth rate E_bC_{10} biomass E_rC_{10} growth rate	0.0138** 0.00098** 0.0019**
Daphnia magna	Epoxiconazole	21 d	NOEC reproduction	0.63
Oncorhynchus mykiss	Epoxiconazole	28 d	NOEC juvenile growth	0.01
P. promelas	Epoxiconazole	FLC	NOEAEC growth F2	0.01
Danio rerio, *3 different life stages, with sediment, static*	Epoxiconazole	FLC	NOEAEC (EC_{10}) sex ratio	0.030
Danio rerio	Epoxiconazole	FLC	NOEAEC reproduction F1	0.012
Chironomus riparius	Epoxiconazole	28 d	NOEC emergence LC_{50} emergence	0.0625 > 0.0625
Pseudokirchneriella subcapitata	formulated product	72 h	E_bC_{50} biomass E_rC_{50} growth rate NOEC biomass NOEC growth rate	0.81 (0.1 as) - 0.02 (0.0024 as) -
Daphnia magna	formulated product	48 h	EC_{50} immobilisation	1.8 (0.22 as)
Daphnia magna	formulated product	21 d	NOEC reproduction	0.625 (0.08 as)
Oncorhynchus mykiss	formulated product	96 h	LC_{50}	0.50 (0.059 as)
Oncorhynchus mykiss	formulated product	28 d	NOEC feed consumption	0.1 (0.012 as)
Pseudokirchneriella subcapitata	metabolite 1,2,4-triazole	72 h	E_bC_{50} biomass E_rC_{50} growth rate NOEC biomass NOEC growth rate	14 31 3.1 6.8
Daphnia magna	metabolite 1,2,4-triazole	48 h	EC_{50} immobilisation	> 100
Oncorhynchus mykiss	metabolite 1,2,4-triazole	96 h	LC_{50}	760
Oncorhynchus mykiss	metabolite 1,2,4-triazole	28 d	NOEC juvenile growth	3.2
Chironomus riparius	metabolite BF480-entriazole	28 d	NOEC emergence LC_{50} emergence	0.03 1.55

* nominal concentrations, confirmed by chemical analyses
** initial measured concentrations

From DAR vol.1: Studies on the acute toxicity to fish, daphnia and green algae and chronic toxicity on fish and Daphnia were performed using the formulation BAS 480 13 (*121 g a.s./L*), which is only a minor change to BAS 480 27 F (*125 g a.s./L*) and also contained the same amount of active substance.

Sediment organisms *(summarized and evaluated by RIVM (12396a00)*

Substance	***Species***	***Method***	***Duration [d]***	***Criterion***	***Value [µg a.s./kg dwt]***
Epoxiconazole	*Chironomus riparius*	*Static spiked sediment*	*28*	*NOEC*	*≥ 674.5*

Microcosm or mesocosm tests
not required

Bioconcentration

Bioconcentration factor (BCF) ‡	whole fish (trout): highest mean value 70 (steady state)
Annex VI Trigger for the bioconcentration factor	100
Clearance time (CT_{50})	whole fish: 0.72 days
(CT_{90})	whole fish: 1.6 days
Level of residues (%) in organisms after the 14 day depuration phase	after 7 days depuration phase: 5 µg/L 5.7 % TAR in whole fish, 4.8 % in inedible tissue, 11.3 % in edible tissue 1 µg/L: 6.8 % TAR in whole fish, 5.4 % in inedible tissue, 11.5 % in edible tissue

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

Acute oral toxicity ‡	LD_{50} > 83 µg as/bee (active substance) LD_{50} > 69.9 µg as/bee (formulation)
Acute contact toxicity ‡	LD_{50} > 100 µg as/bee (active substance) LD_{50} > 59.7 µg as/bee (formulation)

Field or semi-field tests
not required

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

Species	Stage	Test substance	Dose (kg as/ha)	Endpoint	Effect	Trigger
Laboratory tests with inert substrate						
Typhlodromus pyri	proto-nymphs	formulation BAS 480 27 F		mortality	LR_{50} 2.1 L product/ha 258 g as/ha	30 % *
			0.086 0.123 0.185 0.283 0.431	mortality and reproduction	mortality / repro. 10 % / 44.4 % 10 % / 41.3 % 17.6 % / 31.7 % 57.9 % / - 82.8 % / -	
Aphidius rhopalosiphi	adults			mortality	LR_{50} > 2 L product/ha > 246 g as/ha	30 % *
			0.246	mortality	40.8 %	
			0.246	reproduction	18.2 %	
C. septempuncta	adult	BAS 480 13 F	0.188	mortality	2.0 %	30 % *
				reproduction	- 4.3 %	30 % *
P. cupreus	adult	BAS 480 13	0.188	mortality	0 %	30 % *

		F		food cons.	- 2.4 %	30 % *
Extended laboratory tests with natural substrate						
Aphidius rhopalosiphi	adults	BAS 480 27 F	0.246	mortality	0 %	50 % **
		BAS 480 27 F	0.246	reproduction	not valid	

* Trigger according to Annex VI 91/414/EEC ** Trigger at field rate according to Sanco/10329/2002

Field or semi-field tests
No field tests were triggered on basis of the intended field uses and data available

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

Acute toxicity ‡	techn. as: LC_{50} > 1000 mg as/kg soil dw LC_{50} corrected > 500 mg as/kg soil dw Formulation (related to as): LC_{50} > 125 mg as/kg soil dw LC_{50} corrected > 62,5 mg as/kg soil dw Metabolite 1,2,4-triazole: LC_{50} > 1000 mg /kg soil dw
Reproductive toxicity ‡	NOEC 1 L product/ha = 0.167 mg as/kg soil dw (depth 5 cm) NOEC corrected 0.084 mg as/kg soil dw Terrestrial Model Ecosystem (TME): NOEC 2 x 1.0 L product/ha (125 g as/ha; Enchytraeidae) Metabolite 1,2,4-triazole: NOEC 0.0708 mg/kg soil dw
Field study	Monitoring study: NOEC 3 x 1.0 L product/ha (125 g as/ha; adapted earthworm populations of an arable field site)

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

Reproductive toxicity with collembolan species *Folsomia candida*	Metabolite 1,2,4-triazole: 28 day reproduction test mortality: LC_{50} 214 mg/kg soil dw reproduction: NOEC 1.8 mg/kg soil dw
Terrestrial Model Ecosystem (TME)	Effects on total, species or group abundance, dominances and species composition of Collembola, Enchytraeida, Acari, Nematoda. NOER: 2 x 1.0 L BAS 480 28 F/ha (2 x 125 g as/ha) for Collembola NOER: 2 x 1.0 L BAS 480 F/ha for Enchytraeidae
Field study: Decomposition of organic matter (litter bag test) and monitoring of soil dwelling macro-organisms (Collembola species)	Arable land site, Dannstadt/Rheinland-Pfalz, Germany; Plant protection products (i.e. herbicides) according to conventional standards for the region were applied on both the control and all treatment plots. Historic test site with $PEC_{plateau}$ level after multi-year use since 1992. Plots were spray-treated with 1, 2 or 3 applications of the formulation BAS 480 21 F.

Application rate (kg as/ha)	Crop	Test level (kg as/ha)	Time-scale	Effects
2 x 0.125	cereals	1, 2, or 3 x 0.125	around 11 months	Decomposition of organic matter (litter bag test): no significant impairment on organic matter degradation by repeated treatments neither in winter wheat nor in oilseed rape plots up to highest application rate of 3 L product/ha.
				Collembola: monitoring study on arable land was performed, might be used for the on-crop risk assessment NOEC 3 x 1.0 L product/ha (3 x 125 g as/ha; adapted Collembola populations of an arable field site)

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

Nitrogen mineralisation ‡	in loamy sand and sandy loam: no effects at 1.5 L or 15 L product/ha (0.188 kg or 1.88 kg as/ha = (2 µL or 20 µL formulation/kg soil dw)
Carbon mineralisation ‡	in loamy sand and sandy loam: no effects at 1.5 L or 15 L product/ha (0.188 kg or 1.88 kg as/ha = (2 µL or 20 µL formulation/kg soil dw)
Terrestrial Model Ecosystem (TME)	Effects of 1 x and 2 x 1.0 L/ha BAS 480 28 F on microbial biomass, nitrogen transformation, enzyme activity. NOER: 2.0 L BAS 480 28 F/ha (0.334 g as/kg soil dw)
Field study	Additional information: Arable land site, Dannstadt/Rheinland-Pfalz, Germany; Plant protection products (i.e. herbicides) according to conventional standards for the region were applied on both the control and all treatment plots. Historic test site with $PEC_{plateau}$ level after multi-year use since 1992. Plots were spray-treated with 1, 2 or 3 applications of the formulation BAS 480 21 F. No reference substance. No indication of a clear trend of epoxiconazole related influences on microbial turnover rates (N-transformation, microbial biomass) up to 3 x 1.0 L/ha application of BAS 480 27 F (= 3 x 0.167 mg as/kg soil dw)

Impact on water treatment procedures (Annex IIA, point 8.7)

Oxygen consumption by activated sludge ‡	EC_{20} respiration: > 1014 mg as/L (highest test conc.)
Oxygen consumption by *Pseudomonas putida*	NOEC respiration: > 1000 mg as/L (highest test conc.)

Effects on other non-target organisms (flora and fauna) (Annex IIA, point 8.6)

Species	Parameter	Test Substance	Dose (kg as/ha)	Effect plant weight visible damage	Trigger*
Limit test, 14 days, application: spraying, post-emergence BBCH code 13-14					
Avena sativa	mean plant	formulation BAS 480 27	0.250	4 % reduction n.s. 0 %	50 %
Allium cepa				3 % increase n.s. 0 %	

Beta vulgaris	weight and visible damage	F		16 % reduction [n.s]	20 %
Brassica oleracea				5 % reduction [n.s]	0 %
Cucumis sativus				1 % reduction [n.s.]	0 %
Daucus carota				2 % increase [n.s]	0 %
Helianthus annuus				7 % reduction [n.s]	0 %
Pisum sativum				36 % increase [n.s]	0 %

* Trigger at field rate according to Sanco/10329/2002
n.s. not significant different from control

Classification and proposed labelling (Annex IIA, point 10)

with regard to ecotoxicological data	R 50/53, N, dangerous for the environment

Metabolites 1,2,4-triazole, triazolyl alanine and triazole acetic acid
In PRAPeR 13, endpoints of 1,2,4-triazole, tiazolyl alanine and tiazole acetic acid were discussed. For the risk assessment of these metabolites, endpoints agreed upon are used (updated after PRAPeR 43, 06/2008).

Birds	**Mammals**	**Fish**	**Daphnia**	**Algae**	**Earthworms**	**Collembola**	**Micro-org.**
1,2,4-triazole							
LD_{50}>316 mg/kg bw*	LD_{50}=500 mg/kg bw NOAEL=37.9 mg/kg bw (90-day rat) $NOAEL_p$=30 mg/kg bw/d $NOAEL_r$=100 mg/kg bw/d $NOAEL_d$=10 mg/kg bw/d	LC_{50}=498 mg/L; LC_{50}>100 mg/L; NOE_rC=100 mg/L; NOEC=3.20 mg/L; NOAEL	EC_{50}>100 mg/L (48h); LC_{50} = 800 mg/L	E_rC_{50}>31 mg/L; E_bC_{50}=13 mg/L ErC_{50}=22,5 mg/L; E_bC_{50}=8.2 mg/L	LC_{50} >1000 mg/kg soil LC_{50} >1000 mg/kg soil LC_{50} >1000 mg/kg soil LC_{50} >1000 mg/kg soil NOEC=0.0708 mg/kg soil NOEC=1.0 mg/kg soil	NOEC=1.8 mg/kg soil	<25% effect at 0.353 mg/kg soil <25% effect at 0.333 mg/kg soil
Triazolyl alanine							
Birds	**Mammals**						
LC_{50}>1410, >1404, >1368 mg/kg bw/d (bobwhite quail); LC_{50} >1354, >1342 , >1309 mg/kg bw/d (bobwhite quail) mallard	LD_{50}>2000 mg/kg bw (rat) LD_{50}>5000 mg/kg bw (rat, mouse) NOEC= 10000 mg/kg diet (rat) $NOAEL_{par.I}$ = 10000mg as/kg diet $NOAEL_{par.I}$ =						

duck	500 mg as/kg bw/day *) $NOAEL_{rep./dev.}$ = 2000mg as/kg diet $NOAEL_{rep./dev.}$ = 100 mg as/kg bw/day *)						
Triazolyl acetic acid							
Birds	**Mammals**	**Fish**	**Daphnia**	**Algae**		**Collembola**	**Micro-org.**
LD_{50}>2000 mg/kg bw/d	LD_{50} > 5000 mg as/kg bw LD_{50} > 5000 mg as/kg bw (rat) $NOAEL_p$=30 mg/kg bw/d $NOAEL_r$=100 mg/kg bw/d $NOAEL_d$=10 mg/kg bw/d	NOE_rC=100 mg/L; NOEC=3.20 mg/L;	EC_{50} > 100 mg/L	ErC_{50}=22,5 mg/L; E_bC_{50}=8.2 mg/L EbC_{50}= 12.2 ErC_{50} =135.1 mg/L		$NORC_{mortality}$=125 mg/kg soil $NOEC_{repr}$=15.6 mg/kg soil	<25% effect at 0.08043 mg/kg soil

*public literature, gives indication of the toxicity

Note on endocrine disruption
Epoxiconazole has endocrine properties (see EFSA note in EFSA conclusions). This does not change the endpoints on mammals. For fish endocrine disruption is considered in the ELS and FLC test and is thus taken into account in the risk assessment.

Pyraclostrobin

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

Acute toxicity to mammals	LD50 > 5000 mg/kg bw (rat)
Long-term toxicity to mammals	NOAEL 75 ppm (rat multi-generation study) *(DAR: This is equal to 8.2 mg/kg bw/d)*
Acute toxicity to birds	LD50 > 2000 mg/kg bw (bobwhite quail)
Dietary toxicity to birds	LC50 > 5000 ppm (bobwhite quail and mallard duck) LC50 > 1176 mg/kg bw/d (bobwhite quail) LC50 > 1320 mg/kg bw/d (mallard duck)
Reproductive toxicity to birds	NOEL 1000 ppm (bobwhite quail and mallard duck) NOEL: 105 mg/kg bw/d (bobwhite quail) NOEL: 128 mg/kg bw/d (mallard duck)NOEL 1000 ppm

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

Group	Test substance	Time-scale	Endpoint	Toxicity (mg as/L)
Laboratory tests				
O. mykiss	BAS 500 F	static - 96 h	LC_{50}	0.006

Group	Test substance	Time-scale	Endpoint	Toxicity (mg as/L)
	(pyraclostrobin)			
O. mykiss		flow-through - 28 d	NOEC	0.005
O. mykiss		ELS - 98 d	NOEC	0.002
D. magna		static – 48 h	EC_{50}	0.016
D. magna		semi-static – 21 d	NOEC	0.011
C. riparius		static – 28 d	NOEC	0.04
P. subcapitata		static – 96 h	E_bC_{50}	0.152
Activated sludge		Static – 0.5 h	EC_{20}	> 1000
O. mykiss	BAS 500 00 F (formulated product)	Static - 96 h	LC_{50}	0.014
D. magna		Static - 48 h	EC_{50}	0.065
P. subcapitata		Static - 72 h	E_bC_{50}	1370
O. mykiss	BF 500-11 (metabolite)	Static - 96 h	LC_{50}	≥100
D. magna		Static – 48 h	EC_{50}	> 100
S. subspicatus		Static – 72 h	E_rC_{50}	> 100
O. mykiss	BF 500-13 (metabolite)	Static - 96 h	LC_{50}	≥100
D. magna		Static – 48 h	EC_{50}	> 100
S. subspicatus		Static – 72 h	E_bC_{50}	66
O. mykiss	BF 500-14 (metabolite)	Static - 96 h	LC_{50}	> 100
D. magna		Static – 48 h	EC_{50}	> 100
S. subspicatus		Static – 72 h	E_bC_{50}	46
Microcosm or mesocosm tests				
A mesocosm study was conducted with the formulated product BAS 500 00 F. Four concentration levels ranging from 0.9 µg as/L to 24 µg as/L simulating a vineyard situation with 8 applications in 14 d intervals were investigated. Approximately 260 different taxa of aquatic invertebrates were determined in the study. In most cases only insignifcant transient effects were observed. Affected populations usually recovered until the end of the study. For the mollusc species *Bithynia tentaculata* and *Valvata* spec and the mussel species *Dreissena polymorpha* treatment related effects were observed in the highest treatment level. The NOEC was determined to be 8 µg as/L.				

Bioconcentration (Log P_{OW} : 3.99)

Bioconcentration factor (BCF)	675 (whole fish, chlorophenyl label) 736 (whole fish tolyl label)
Annex VI Trigger for the bioconcentration factor	> 100 for non readily biodegradable substances
Clearance time (CT_{50})	< 1 d
(CT_{90})	2.3 – 3.2 d
Level of residues (%) in organisms after the 14 day depuration phase	

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

Acute oral toxicity (as)	LD_{50} > 73.1 µg/bee
Acute contact toxicity (as)	LD_{50} > 100 µg/bee

Multiple Dose Test

Acute oral toxicity (formulation)	LD_{50} = 76.9 µg as/ bee
Acute contact toxicity (formulation)	LD_{50} > 100 µg as/bee

Field or semi-field tests
Not required

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

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Adverse effects %[1]	Annex VI Trigger %
Laboratory tests						
T. pyri	Protonymphs	BAS 500 00 F	0.320	Mortality Fertility	47 99	30 30
A. rhopalosiphi	Adults	BAS 500 00 F	0.320	Mortality Fertility	30 80	30 30
C. carnea	Larvae	BAS 500 00 F	0.320	Mortality Fertility	79 0	30 30
C. septem-punctata	Larvae	BAS 500 00 F	0.320	Mortality	100	30
P. cupreus	Adults	BAS 500 00 F	0.320	Mortality Food uptake	0 11	30 30
Pardosa spp	Adults	BAS 500 00 F	0.320	Mortality Food uptake	0 9.9	30 30
Extended laboratory tests						
A. rhopalosiphi	Adults	BAS 500 00 F	0.320	Mortality Fertility	0 0	acceptable
C. carnea	Adult/LC	BAS 500 00 F	0.160	Mortality Fertility	27 80	acceptable
C. septem-punctata	Adults/LC	BAS 500 00 F	0.064	Mortality Fertility	0 3.1	acceptable

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

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

Field tests with BAS 500 00 F

Predatory mites

Species	Details of uses	Dosage per application	Total dosage	Effects
T. pyri	8 applications	0.16-0.4 kg product/ha	2.64 kg product/ha/year	0.0 / 0.0
T. pyri	8 applications	0.16-0.6 kg product/ha	3.14 kg product/ha/year	0.0 / 12
T. pyri	8 applications	0.24-0.6 kg product/ha	3.12 kg product/ha/year	58.1/ 0.0

Summary:
Three field tests with *T. pyri* clearly demonstrated recovery of affected populations within at latest 8 weeks.

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

Acute toxicity	LC50 = 567 mg a.s./kg
Acute toxicity (formulation BAS 500 00 F)	LC50 = 282 mg form./kg
Reproductive toxicity (formulation BAS 500 00 F)	NOEC = 1 L product/ha *(=0,357 mg w.s./kg)*
Acute toxicity (metabolite BF 500-6)	LC50 > 1000 mg/kg soil
Acute toxicity (metabolite BF 500-7)	LC50 > 1000 mg/kg soil

Field tests with BAS 500 00 F and BAS 500 01 F
Two field tests were conducted with BAS 500 00 F 0.03 and 0.06 kg as/ha. In one field test there was no adverse effect on number and biomass of earthworms, on feeding activity (bait-lamina) and on overall abundance of collembola. In the second field test a slight effect with the full application rate was observed, but is regarded acceptable. One field test was conducted with BAS 500 01 F with an application rata of 2 x 0.25 kg as/ha. No long lasting effects on earthworm populations were observed.

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

Nitrogen mineralisation	No effects up to 10 L product/ha (respective 2.5 kg as/ha)
	BAS 500-6: No effect up to 750 g/ha BAS 500-7: No effect up to 375 g/ha
Carbon mineralisation	No effects up to 10 L product/ha (respective 2.5 kg as/ha)
	BAS 500-6: No effect up to 750 g/ha BAS 500-7: No effect up to 375 g/ha

Formulation studies submitted for Retengo Plus (studies summarized and evaluated by NOTOX (nr. 204488/501755) in November 2012)

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

Species	Stage	Test Substance*	Dose (kg total as/ha)	Endpoint	Toxicity (kg total a.s./ha)
Laboratory tests					
T. pyri	Protonymphs	BAS 512 04 F	0.034 - 0.549	LR50	0.177
A. rhopalosiphi	Adults	BAS 512 04 F	0.034 – 0.549	LR50	0.100

* BAS 512 04 F = Retengo Plus = pyraclostrobin (BAS 500 F) : 133.4 g/L (nominal 133 g/L) and epoxiconazole (BAS 480 F): 50.9 g/L (nominal 50.0 g/L)

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

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Adverse effects %[1]
Extended laboratory tests					
T. pyri	Protonymphs	BAS 512 04 F	0. 549	Mortality	7 DAI

		(dry residues on bean leaves)	0..823	0 DAT Reproduction 0 DAT	9.2 21 7-14 DAI +4.4 +1.7
A. rhopalosiphi	Adults	BAS 512 04 F (dry residues on barley seedlings)	0.034 0.183 0.275 0.366 0.549	Mortality Fertility	0 16.7 10 13 16.67 - - 11 15.8 15.8

* BAS 512 04 F = Retengo Plus = pyraclostrobin (BAS 500 F) : 133.4 g/L (nominal 133 g/L) and epoxiconazole (BAS 480 F): 50.9 g/L (nominal 50.0 g/L)

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

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

Effects on other non-target organisms (flora and fauna) (Annex IIA, point 8.6)

One vegetative vigour test with the formulation BAS 512 04F was submitted. This study was considered unreliable for the following reasons:

1) The method of watering was not reported, except that it was stated that first watering was performed over the top of the plants 24 hours after application of the test item.. Bottom watering or watering under the foliage is recommended (OECD 227), to avoid leaching of residues through the soil and residues being washed off the foliage.
(2) Contrary to OECD 227 requirements, the content of BAS 651 00 F in the spray solutions was not analytically confirmed.

The study was performed in 2007 and was reported to be based on OECD 227 (2006). Because of the deviations from OECD 227 described above, the study result is not accepted.

For this aspect reference will be made to the Comet (12411 N, dd. 21/02/2003) and Comet Duo (12921 N, dd. 25/05/2007).

Formulation studies submitted for Opera, formulation similar to Retengo Plust, containing 50 g/L epoxiconazole and 133 g/L pyraclostrobin

Toxicity aquatic organisms

Algae

Substance	Species	72-h NOE_rC [mg form./L]	Remarks
Opera	*Pseudokirchneriella subcapitata*	0,48 (*0.087 mg total a.s./L*)	E_rC_{10}

Invertebrates

Substance	Species	48-h EC_{50} [mg form./L]	Remarks
Opera	*Daphnia magna*	0,099 (*0.0181 mg total a.s./L)*	none

There is no data on the chronic toxicity of Opera to invertebrates.

Fish

Substance	Species	96-h LC_{50} [mg form./L]	Remarks
Opera	*Oncorhynchus mykiss*	0,054 (*0.0098 mg total a.s./L)*	Nominal

There is no data on the chronic toxicity of Opera to fish.

Sediment organisms
There is no data on the toxicity of Opera to sediment organisms.

Toxicity terrestrial organisms

(Bumble)bees

Substance	Species	LD_{50} [µg form./bee]	Remarks
Opera	*Apis mellifera*	>170 (oral) >200 (contact)	none

Non-target arthropods

Substance	Species	Dosage	Adverse effect [%]	Remarks
Opera	*Poecilus cupreus*	4 L/ha	-3%	none
Opera	*Aleochara bilineata*	4 L/ha	39%	reduction of parasitism
Opera	*Aleochara bilineata (natural substrate)*	2 x 2 L/ha	-12%	reduction of parasitism
Opera	*Pardosa spec.*	4 L/ha	Mortality –3,3%	none
Opera	*Aphidius rhopalosiphi (Lab. Study)*	4 L/ha	Mortality 95%	none
Opera	*Aphidius rhopalosiphi (Ext. Lab. Study)*	4 L/ha	E *= -15 %	none
Opera	*Chrysoperla carnea*	4 L/ha	Mortality = 100%	none
Opera	*Chrysoperla carnea (Ext. Lab. Study)*	0,175 L/ha	Mortality = 4%	
Opera	*Chrysoperla carnea (Ext. Lab. Study)*	1,75 L/ha	Mortality = 56%	no negative effect on reproduction
Opera	*Chrysoperla carnea*	3,5 L/ha	Mortality = 60%	

	(Ext. Lab. Study)		E = 45%	
Opera	*Typhlodromus pyri*	4 L/ha	E = 97%	none
	Typhlodromus pyri *(Ext. Lab. Study)*	2x2 L/ha	E = 7,7%	none

* E = over-all effect

Extended laboratory study with Opera: *Chrysoperla carnea*, residues on leaves (additional information (09/2004))

Substance	Dosage (L/ha)	Aged (d)	Exposure duration (d)	Parameter	Adverse effect[1] (%)
	2 x 0.21	0	20	Mortality	26.5
				Reproduction	21
		7	20	Mortality	4.1
				Reproduction	+3.8
		14	25	Mortality	-2.1
				Reproduction	+19
	1.5	0	25	Mortality	67.3
		7	18	Mortality	6.1
				Reproduction	25
		14	25	Mortality	6.4
				Reproduction	37
	2 x 1.5	0	20	Mortality	85.7
		7	18	Mortality	20.4
				Reproduction	+7.9
		14	22	Mortality	8.5
				Reproduction	0.3

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

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

Earthworms

Substance	Species	14-d LC_{50} [mg form./kg]	Remarks
Opera	*Eisenia fetida*	262	Corrected for 4,8% o.c.

Micro-organisms

At a concentration of 2,9 mg form./kg (equivalent to 2 L/ha) and 29 mg form./kg (equivalent to 20 L/ha) Opera had a small effect (-9%) on the SIR soil respiration after 28 days in loamy sand and sandy loam.
At a concentration of 2,9 mg form./kg (equivalent to 2 L/ha) Opera had an effect of +5% on the formation of ammonium and nitrate from alfalfa flour in loamy sand after 28 days and an effect of -5% in sandy loam after 28 days.
At a concentration of 29 mg form./kg (equivalent to 20 L/ha) Opera had an effect van +10% on the formation of ammonium and nitrate form alfalfa flour in loamy sand and 56 days and an effect of –0,5% in sandy loam after 28 days.

Combination toxicology

Combination toxicology is assessed for formulations containing more than one active substance, and for combinations of products, which are made according to the Instructions for Use as a tank mixture. Based on the precautionary principle, concentration-addition is assumed.
For pesticides the TER (Toxicity-Exposure Ratio) is used as a standard in the risk assessment (except for bees and other non-target arthropods, where HQ-values are calculated). The TER must be higher than a trigger value to comply with the standards.
The combination risk of formulations containing more than one active substance and for tank mixtures is calculated as follows:

When for each substance the trigger values are equal, the combined TER value can be calculated according to:

- TER_{combi} = trigger/((trigger/$TER_{substance\ 1}$)+(trigger/$TER_{substance\ 2}$)+(trigger/$TER_{substance\ 3}$))

An acceptable risk is expected when TER_{combi} > trigger.

In case of unequal triggers, the combined TER value can be calculated using the following formula:

- $Trigger_{combi}$ = $trigger_{substance\ 1}$/$trigger_{substance\ 2}$/$trigger_{substance\ i}$
- TER_{combi} = $trigger_{combi}$ /(($trigger_{substance\ 1}$ /$TER_{substance\ 1}$)+($trigger_{substance\ 2}$ /$TER_{substance\ 2}$)+($trigger_{substance\ i}$ /$TER_{substance\ i}$))

An acceptable risk is expected when TER_{combi} > $trigger_{combi}$.

In this formula, 'triggers' are the trigger values as mentioned in the corresponding chapter of the HTB (v1.0).
In case toxicity of the formulation has been measured, the TER-value of the formulation is calculated with the PEC of the formulation and the toxicity value of the formulation. The PEC of the formulation is the sum of the PECs of the individual active substances. The toxicity value of the formulation is expressed in total amount active substance. Trigger/TER must be smaller than 1.
In the risk assessment, the risk of combination toxicology is assessed using the highest trigger/TER-value from the one based on the sum of the individual substances and the one based on formulation studies. When the standard of 1 is breached, the product is not permissable, unless an adequate risk assessment shows that there are no unacceptable effects under field conditions after application of the product according to the proposed GAP.

Exception to the above is the acute risk to birds and mammals, where the formula as indicated in the b&m guidance from EFSA (2009) will be used.

7.1 Effects on birds (*Dutch specific aspect)*

The risk assessment for birds from exposure via sprayed natural food and secondary poisoning via earthworms is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (Denmark).

The risk assessment for birds via surface water (drinking water and secondary poisoning via fish) is a Dutch specific aspect, since surface water concentrations are calculated based on national drift values.

drinking water

The risk from exposure through drinking surface water is calculated for a small bird with body weight 10 g and a DWI (daily water intake) of 2.7 g/d. Surface water concentrations are

calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account.

Epoxiconazole
The highest $PIEC_{water}$ is 0.178 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (>2000 * 0.010) / (0.000178 * 0.0027) = >1000.
Since TER ≥ 10, the risk is acceptable.

Pyraclostrobin
The highest $PIEC_{water}$ is 0.459 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (>2000 * 0.010) / (0.000459 * 0.0027) = >1000.
Since TER ≥ 10, the risk is acceptable.

Given the high values for the individual TERs, no combination risk is expected.

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

Fish
Epoxiconazole
For epoxiconazole a BCF of 70 L/kg is available. The highest $PEC_{water(21)}$ (taken from paragraph 6.2.1.) amounts 0.135 µg/L = 0.000135 mg/L.
Indicator species is a 1000-g bird eating 206 g fresh fish per day.
The TER is then calculated as NOEL / ($PEC_{water(21)}$ * BCF_{fish} * (FIR/bw) = 105 / (0.000135 * 70 * 0.21) = >1000. Since this is > 5, the risk for birds as a result of consumption of contaminated fish is considered to be small.

Pyraclostribin
For pyraclostrobin a BCF of 736 L/kg is available. The highest $PEC_{water(21)}$ (taken from paragraph 6.2.1.) amounts 0.242 µg/L = 0.000242 mg/L.
Indicator species is a 1000-g bird eating 206 g fresh fish per day.
The TER is then calculated as NOEL / ($PEC_{water(21)}$ * BCF_{fish} * (FIR/bw) = 1 / (0.000242 * 736 * 0.21) = 504. Since this is > 5, the risk for birds as a result of consumption of contaminated fish is considered to be small.

Combination
Given the high values for the individual TERs, no combination risk is expected.

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

Conclusions birds
The application for mutual recognition of the product complies with the RGB for exposure of birds via surface water and secondary poisoning.

7.2 Effects on aquatic organisms *(Dutch specific aspect)*

7.2.1 Aquatic organisms
Since the Netherlands have their own national drift values, the exposure concentrations in surface water have been estimated based on these drift values (see PECsw in section 6.2).

The risk for aquatic organisms is assessed by comparing toxicity values with surface water exposure concentrations from section 6.2. Risk assessment is based on toxicity-exposure ratio's (TERs).
Toxicity data for aquatic organisms are presented in Table E.1

Table E.1 Overview toxicity endpoints for aquatic organisms

Substance	Organism	Lowest		Toxicity value
		L(E)C_{50} [mg/L]	NOEC [mg/L]	[µg/L]
epoxiconazole	*Acute*			
	Algae	1.19		1190
	Invertebrates	8.69		8690
	Fish	3.14		3140
	Macrophytes	0.0043		4.3
	Chronic			
	Invertebrates		0.63	630
	Fish		0.01	10
pyraclostrobin	*Acute*			
	Algae	0.152		152
	Invertebrates	0.016		16
	Fish	0.006		6
	Chronic			
	Invertebrates		0.011	11
	Fish		0.002	2
formulation*	*Acute*			
	Algae		0.087	87
	Invertebrates	0.0181		18
	Fish	0.0098		9.8

* Opera = 133 g/L pyraclostrobin and 50 g/L epoxiconazole. Data expressed as mg total a.s./ha.

These toxicity values are compared to the surface water concentrations calculated in section 6.2. Trigger values for acute exposure are 100 for invertebrates and fish (0.01 times the lowest L(E)C_{50}-value) and 10 for algae and macrophytes (0.1 times the lowest EC_{50}-value). Trigger values for chronic exposure are 10 for invertebrates and fish (0.1 times the lowest NOEC-values).
For acute and chronic risk, the initial concentration is used (PIEC).
In table E.2 TER values for aquatic organisms are shown.

Table E.2a TER values: acute

Table E.2a TER values: acute

Use	Substance	PECsw [µg a.s./L]	TER_{st} (trigger 10)	TER_{st} (trigger 100)	TER_{st} (trigger 100)	TER_{st} (trigger 10)
			Algae	Invertebrates	Fish	Macrophytes
Maize, winter wheat, winter barley, oats, triticale,	epoxiconazole	0.178	>1000	>1000	>1000	24.2
	pyraclostrobin	0.459	332	**34.9**	**13.1**	-
	combination		317	**34.9**	**13.1**	-
	formulation*	0.637	137	**28.3**	**15.4**	

spring wheat, spring barley, rye											

* Opera = 133 g/L pyraclostrobin and 50 g/L epoxiconazole. Data expressed as mg total a.s./ha.

Taking the results in Table E2a and b into account, the acute TERs for fish and invertebrates are above the relevant Annex VI triggers of 100 for epoxiconazole, but not for pyraclostrobin, combination risk and the formulation. The acute TERs for algae and *Lemna* (epoxiconazole) are above the relevant Annex VI triggers of 10. The chronic TERs for invertebrates are above the relevant Annex VI triggers of 10 and for fish for epoxiconazole, but not for pyraclostrobin and combination risk. Thus, it appears that a risk for aquatic organisms cannot be excluded.

Epoxiconazole belongs to the group of trizole fungicides known to have some potential for effects on aromatase activity. Aromatase is an enzyme playing a key role in the biosynthesis of estrogens.
As mentioned in the DAR of epoxiconazole, "*a number of complex fish full life cycle studies has been performed with two different species, using standard flow-through conditions as well as an extended test reflecting more realistic exposure. The variety of studies and results allows a clear and conclusive picture of potential chronic and endocrine effects of epoxiconazole to fish".* The population relevant endpoints selected in the DAR for the risk assessment were 10 µg as/L (flow-through study) and 30 µg as/L (static exposure including sediment). For the current risk assessment the lowest value was used. The endocrine disruptive effects of epoxiconazole are considered to be covered during the chronic risk assessment of the substance (see Table E. 2b).

Higher tier risk assessment (refinement of the risk assessment)
A mesocosm study was conducted with the formulated product BAS 500 00 F, containing only pyraclostrobin. Four concentration levels ranging from 0.9 µg as/L to 24 µg as/L simulating a vineyard situation with 8 applications in 14 d intervals were investigated. Approximately 260 different taxa of aquatic invertebrates were determined in the study. In most cases only insignifcant transient effects were observed. Affected populations usually recovered before the end of the study. For the mollusc species *Bithynia tentaculata* and *Valvata* spec and the mussel species *Dreissena polymorpha* treatment related effects were observed in the highest treatment level. The NOEC was determined to be 8 µg as/L.

Because only one micro-/mesocosm study is available, conducted on only one site during one time period, the spatio-temporal variation must be taken into account. From research done by Alterra, it became clear that this variation depends on the toxicity endpoint which is used for risk assessment. If the NOEC-value is taken as the relevant endpoint, the variation in space and time is in general not large. However, if recovery is taken into account and a NOEAEC-value is established, the spatio-temporal variation is much greater. In that case a safety factor is necessary. Based on available data from Alterra a safety factor of 3 has to be applied to the NOEAEC-value.

Fish were not included in the mesocosm, but they were included in a parallel pond study. Only 1 species was tested (*C. caprio*), which is not the most sensitive fish species. Therefore a final safety factor (trigger) of 10 is used on the NOEC of 8 µg/L.

In C-190.3.1 (02/2008), the applicant proposed a statement in order to come to a higher endpoint.

Statement applicant
The applicant does not agree with the final endpoint of 0.8 µg/L for fish.

In the monograph of pyraclostrobin, acute toxicity laboratory studies of seven different fish species are available. From this data it appears that the rainbow trout is the most sensitive species, but the carp (species tested in the mesocosm) is not the least sensitive species. From these studies also appears that pyraclostrobin shows a very steep concentration response relationship for all species. Furthermore, the difference in endpoints of acute toxicity tests is close to the endpoints from chronic tests (i.e. 6.2 µg/L v.s. 2 µg/L for rainbow trout (98 d ELS study)).
The applicant proposes an endpoint based on the HC_5 or HC_1 value, calculated from the NOEC values from acute toxicity studies described in the monograph.

Table E.3: Available LC_{50} values (fish) for pyraclostrobin

Species	**LC_{50} [µg/L]**	**Acute NOEC [µg/L]**
Oncorhynchus mykiss	6.16	4.5
Lepomis macrochirus	25.4	10.9
Cyprinus carpio	17.7	12.1
Pimephales promelas	16.1	7.0
Oryzias latipes	53.3	16.5
Brachydanio rerio	61.9	23.4
Leuciscus idus melanotus	19.1	13.5
HC_5 HC_1	5.9 2.8	4.2 2.4

Since the acute to chronic toxicity rate is quite narrow and pyraclostrobin is not stable in water, the NOEC from acute toxicity tests should also cover the chronic risk.

For the reasons mentioned above, the applicant proposes an endpoint of 2.4 µg/L for fish.

Reaction Ctgb
Ctgb agrees that since more fish species were tested, the safety factor of 10 is too conservative. The difference in sensitivity between *Oncorhynchus mykiss* (the most sensitive test species) and *Cyprinus carpio* (used in the mesocosm) is about a factor 3 and a sensitivity factor of about 5 is considered protective enough. This leads to an endpoint of 1.6 µg/L.
Using the HC_5 method is an acceptable refinement method in the Dutch assessment. However, still the small differences between acute endpoints and chronic endpoints should be taken into account. It is therefore proposed to use the lower limit of the HC_5 value, based on the NOEC values.
After recalculation of the endpoints available, a HC_5 of 4.34 µg/L is calculated, with a lower limit of 1.75 µg/L.

Comparing the endpoint based on the mesocosm study and based on the lower limit of the HC_5 calculation, it appears that these values are close together. Therefore the endpoint of 1.75 µg/L for fish is acceptable and can be used for risk assessment.
For the other aquatic organisms the derived NOEC value of 8 µg/L from the mesocosm study can be used for risk assessment. No safety factor is required.

Conclusion
The most critical endpoint (pyraclostrobin) for aquatic organisms is 1.75 µg/L, based on the HC5 for fish.

In Table E. 4a an b the refined TERs for pyraclostrobine and the combined TERs with epoxiconazole are calculated.

Table E. 4 Refined TER values pyraclostrobin: acute and chronic

Substance	PECsw (µg a.s./L)	TER (trigger 1) Mesocosm (8 µg/L)	TER (trigger 1) HC 5 fish (1.75 µg/L)
Pyraclostrobin	0.459	17.4	3.81

Table E. 4b: Refined TER values - chronic

Substance	PECsw (µg a.s./L)	TER (trigger 10)
Epoxiconazole	0.178	56.2
Pyraclostrobin	0.459	38.1
Combination		22.7

The table above shows that the acute (invertebrates and fish) and chronic (fish) risk of pyraclostrobin is acceptable, and for combination risk also. In the case of the formulation the TERs are similar with the TERs of the combination of individual substances, therefore the risk for the formulation can be refined through the refinement of the risk of the individual substances.

Thus, the active substance epoxiconazole and pyraclostrobin meet the standards for bioconcentration as laid down in the RGB.

7.2.2 Risk assessment for bioconcentration

Epoxiconazole

For the active substance epoxiconazole a BCF-value of 70 L/kg is available. Since this value is below 100 L/kg, the risk for bioconcentration is small. Therefore the active substance epoxiconazole meets the standards for bioconcentration as laid down in the RGB.

Pyraclostrobin

For the active substance pyraclostrobin a BCF-value of 736 L/kg is available.
Since the BCF is above 100 L/kg and the substance is not ready biodegradable, there is a risk for bioconcentration.
According to the guidance document on aquatic ecotoxicology the following points should be checked:

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

Ad 1) An ELS study should be available if 100 < BCF < 1000 and EC_{50} a.s. < 0.1 mg/L. These triggers are exceeded for pyraclostrobin and an ELS study is available. The long term NOEC is 2 µg/L. The risk assessment in section 7.2.1 above showed a chronic risk to fish based on first-tier assessment. In the refinement an acceptable risk for fish was expected (see higher tier risk assessment for aquatic organisms in section 7.2.1.).
Ad 2) From the assessment of birds and mammals it should appear that there is no risk on secondary poisoning through fish, which is the case for the proposed uses.
Ad 3) When the BCF > 1000 and the elimination in the BCF study within 14 days is < 95% and the DT_{90} water or sediment > 100 days, a higher tier exposure assessment with regard to the potential for biomagnification in the aquatic food chain should be conducted. These triggers are not exceeded for pyraclostrobin.

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

7.2.3 Risk assessment for sediment organisms

Epoxiconazole

The NOEC value for *Chironomus* is 0.0625 mg a.s./L. When this value is examined against the highest PIEC in water of 0.000178 mg/L, the TER value is 351 which is above the trigger value of 10.
Additionally a sediment spiked test is available. The NOEC value for *Chironomus* is ≥ 0.6745 mg a.s./kg. When this value is examined against the highest PIEC in sediment of 0.0181 mg a.s./kg, the TER value is ≥ 37.3, which is above the trigger value of 10.

Metabolite BAS 480-entriazole is relevant in sediment. The NOEC value for *Chironomus* is 0.03 mg a.s./L. When this value is examined against the highest PIEC in water of 0.000057 mg/L, the TER value is 526 which is above the trigger value of 10.

Therefore, the active substance epoxiconazole and metabolite BAS 480-entriazole meets the standards for sediment organisms as laid down in the RGB.

Pyraclostrobin

The NOEC value for *Chironomus* is 0.04 mg a.s./L. When this value is examined against the highest PIEC in water of 0.000459 mg/L, the TER value is 87.1 and the trigger value of 10 is met.

The combined risk for sediment dwelling organisms based on water-spiked tests is 69.8, which is above the trigger of 10. Therefore the risk for sediment organisms is acceptable.

Conclusions aquatic organisms
The proposed applications meet the standards for aquatic organisms.

7.3 Effects on terrestrial vertebrates other than birds (*Dutch specific aspect)*
The risk assessment for mammals via natural food and secondary poisoning via earthworms is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (Denmark).

The risk assessment for mammals via surface water (drinking water and secondary poisoning via fish) is a Dutch specific aspect, since surface water concentrations are calculated based on national drift values.

drinking water
The risk from exposure through drinking from surface water is calculated for a small mammal with body weight 10 g and a DWI (daily water intake) of 1.57 g/d. Surface water concentrations are calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account.

Epoxiconazole
The highest $PIEC_{water}$ is 0.178 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (3160 * 0.010) / (0.000178 * 0.00157) = > 1000.
Since TER > 10, the risk is acceptable.

Pyraclostrobin
The highest $PIEC_{water}$ is 0.459 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (>5000 * 0.010) / (0.000459 * 0.00157) = > 1000.
Since TER > 10, the risk is acceptable.

Given the high values for the individual TERs, no combination risk is expected.

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

Fish
Epoxiconazole
For epoxiconazole a BCF of 70 L/kg is available. The highest $PEC_{water(21)}$ (taken from paragraph 6.2.1.) amounts 0.135 µg/L = 0.000135 mg/L.
Indicator species is a 3000-g mammal eating 390 g fresh fish per day.
The TER is then calculated as NOEL / ($PEC_{water(21)}$ * BCF_{fish} * (FIR/bw) = 2.3 / (0.000135 * 70 * 0.13) >1000. Since this is > 5, the risk for mammals as a result of consumption of contaminated fish is considered to be small.

Pyraclostrobin
For pyraclostrobin a BCF of 736 L/kg is available. The highest $PEC_{water(21)}$ (taken from paragraph 6.2.1.) amounts 0.242 µg/L = 0.000242 mg/L.
Indicator species is a 3000-g mammal eating 390 g fresh fish per day.
The TER is then calculated as NOEL / ($PEC_{water(21)}$ * BCF_{fish} * (FIR/bw) = 8.2 / (0.000242 * 736 * 0.13) = 354. Since this is > 5, the risk for mammals as a result of consumption of contaminated fish is considered to be small.

Combination
Given the high values for the individual TERs, no combination risk is expected.

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

Conclusions mammals
The application for mutual recognition of the product complies with the RGB for exposure of mammals via surface water and secondary poisoning.

7.4 Effects on bees
The risk assessment for bees is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorization (Denmark).

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

7.5.1 Effects on non-target arthropods (*Dutch specific aspect)*
In-field
The in-field risk assessment for non-target arthropods in accordance with ESCORT2 is not based on drift values and is therefore not a Dutch specific aspect.

No in-field risk assessment is available in the Danish dossier. Reference is made to the registration of Opera. Therefore, for the purpose of this application, the in-field risk assessment will be performed (see below).

Off-field *(Dutch specific aspect)*
For the off-field risk assessment on non-target arthropods in accordance with ESCORT2, drift values are used to estimate the off-crop risk for the two standard species *A. rhopalosiphi* and *T. pyri.* Since the Netherlands have their own national drift values, the off-field risk assessment is a national specific aspect.

The risk for non-target arthropods is assessed by calculating Hazard Quotients. For this, Lethal Rate values (LR_{50}) are needed. Based on LR_{50}-values from studies with the two standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* an off-field Hazard Quotient (HQ) can be calculated according to the assessment method established in the SETAC/ESCORT 2 workshop and described in the Evaluation Manual. Hazard Quotients should be below the trigger value of 2 to meet the standards. The resulting Hazard Quotients are presented in Table E.3a.

Table E.3a HQ-values for *A. rhopalosiphi* and *T. pyri*

	Application rate (kg a.s./ha)	MAF[1]	Drift fraction / Vegetation factor[2]	Safety factor[2]	LR_{50} (kg a.s./ha)	HQ
In-field						
A. rhopalosiphi	0.275	1.7	-	-	0.100	**4.7**
T. pyri	0.275	1.7	-	-	0.177	**2.6**
Off-field						
A. rhopalosiphi	0.275	1.7	0.1/10	10	0.100	0.47
T. pyri	0.275	1.7	0.1/10	10	0.177	0.26

[1]: Multiple Application Factor
[2]: off-field: drift fraction = [0.1], vegetation distribution factor = 10, safety factor = 10 (default values)

As the above table shows, off-field HQ values are below the trigger of 2 while the in-field HQ values are above the trigger of 2. Therefore a further refinement of the in-field risk is required.

Second tier assessment

In the second tier lethal and sublethal effects should be lower than 50% at proposed application rates in extended laboratory tests. This means that the HQ should be below 1. Additionally at least two extra species should be tested.

Standard species : *A. rhopalosiphi* and *T. pyri.*
Extended laboratory tests are available for the two standard species exposed to BAS 512 04 (formulation containing 50.9 g/L epoxiconazole and 133.4 g/L pyraclostrobin).

In the case of *A. rhopalosiphi,* 16.7% effects on mortality occurred at application rates of 3 L/ha (i.e 0.546 kg total a.s./ha). At this dose, the decrease in reproduction as compared to the control was 15.8%. The L(E)R50 is > 0.546 kg total a.s./ha.

In the case of *T. pyri* the effects on mortality were clearly less than 30% (although the effects of 9.2 and 21.4% at at 3 and 4.5 L product/ha, respectively, were statistically significant), and no effects on reproduction were recorded, hence L(E)R50 > 0.819 kg total a.s./ha.

Table E.3b Refined HQ-values for *A. rhopalosiphi* and *T. pyri*

	Application rate (kg total a.s./ha)	MAF[1]	Drift fraction / Vegetation factor[2]	Safety factor[2]	LR_{50} (kg total a.s./ha)	HQ
In-field						
A. rhopalosiphi	0.275	1.7	-	-	> 0.546	<0.85
T. pyri	0.275	1.7	-	-	> 0.819	<0.57

Based on the results form the extended laboratory studies, the in-field risk to the standard test species is considered acceptable.

Additional species

Since in the first tier only an effect on the in-field situation is expected, information of just one additional species is required. Data on the toxicity of the formulation Opera to soil inhabitant species (*Poecilus cupreus, Aleochara bilineata, Pardosa spec.)* and to leaf inhabitant species (*Chrysoperla carnea)* are available.

In a laboratory test with *Chrysoperla carnea* 100% mortality occurred at 4 L/ha. In 2 extended lab studies and at application rates of 1.75 and 3.5 L/ha the effects on mortality were 56 and 60%, respectively. No effect on reproduction were recorded at 1.75 L/ha while at 3.5 L/ha the overall effect was 45%. Given these it can be concluded that effects > 50% (approximately 58%) will occur on mortality at the current application rates of 2x1.5L/ha.
One extended laboratory study with *Chrysoperla carnea* exposed to aged residue of Opera is available. Exposure of *Chrysoperla carnea* to 2x1.5 L/ha fresh residue resulted in 86% mortality. However, exposure to the 7 d and 14 d aged residue resulted in effects on mortality of 20% and 8.5%, respectively, while the effect on reproduction were of 7.9% (increase) and 0.3%, respectively. These results suggest that the effects on mortality and reproduction decrease with increased aging of the product and that there is a potential recovery of *Chrysoperla carnea* before the next spraying season.

No effects were recorded on *Poecilus cupreus* and *Pardosa spec* at application rates of 4L/ha. In case of *Aleochara bilineata* 39% on parasitism were recorded at 4L/ha. No effects were measured in an extended lab test.
Based on the above results it can be concluded that, the standards for non-target arthropods as laid down in the RGB are met.

7.5.2 Earthworms
The risk assessment for earthworms is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (Denmark).

7.5.3 Effects on soil micro-organisms
The risk assessment for soil micro-organisms is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (Denmark).

7.5.4 Effects on activated sludge
The risk assessment for activated sludge is not a Dutch specific aspect. For the risk assessment we refer to the member state of the original authorisation (Denmark).

7.5.5 Effects on non target-plants *(Dutch specific aspect)*
According to the Terrestrial guidance document (Sanco/10329/2002) spray drift is considered to be the key exposure route for non-target plants in the off-field area. Since the Netherlands have their own national drift values, the risk assessment for non-target plants is a national specific aspect. The risk assessment for non-target plants is performed below.

The applicant submitted one vegetative vigour study. The study was considered not acceptable by Ctgb for the following reasons:
1) The method of watering was not reported, except that it was stated that first watering was performed over the top of the plants 24 hours after application of the test item. Bottom watering or watering under the foliage is recommended (OECD 227), to avoid leaching of residues through the soil and residues being washed off the foliage.
(2) Contrary to OECD 227 requirements, the content of BAS 651 00 F in the spray solutions was not analytically confirmed.

The study was performed in 2007 and was reported to be based on OECD 227 (2006). Because of the deviations from OECD 227 described above, the study result is not accepted.

Regarding epoxiconazole, the data from the Annex I agreed endpoints for non-target terrestrial plants will be used.
The EFSA conclusion for epoxiconazole (EFSA, 2008, 138, 1-80) reported no statistically significant effect on the vegetative vigour of eight plant species up to and including 0.250 kg epoxiconazole/ha. The ER_{50} for epoxiconazole on vegetative vigiour was > 0.25 kg a.s./ha.

Regarding pyraclostrobine, formulation data are available from the authorization of Comet (250 g/L pyraclostrobin) (12411N, dd. 21/02/2003). According to the this risk assessment the effect of BAS 500 01 F (i.e. pyraclostrobine 250 g/L) on six plant species at doses of 0.250 and 0.750 kg a.s./ha were investigated. No effects more than 25% were found.

Data from the authorization of Comet Duo (62.5 g/L epoxiconazole and 85 g/L pyraclostrobin) (12921 N, dd. 25/05/2007) indicate that no effects on seedling emergence occur at doses higher than 0.596 kg total a.s./ha. Regarding vegetative vigour, phytotoxicity effects occurred in Helianthus annuus and Pisum sativum at doses of 0.149 and 0.298 kg total a.s./ha. Since the phytotoxicity scores cannot be used directly for the estimating of an ER (the % effects does not refer to a number of plants affected and thus no statisctics can be employed), the fresh weight were considered more reliable. Based on these the ER50 > 0.596 kg total a.s./ha.

The risk assessment for non-target plants (Table E.4) is based on an off-crop situation with a drift percentage of 4.7%. The exposure thus equals 0.047 * the application rate * MAF (in case of multiple application). MAF-values are taken from ESCORT 2.

Table E.4 Overview of exposure concentrations and TERs for non target plants

Use	Substance	Dose [kg a.s. /ha]	MAF	Drift% (off-field exposure)	Exposure (kg a.s./ha)	EC_{50} [kg a.s./ha]	TER	Trigger value
Maize	epoxiconazole	0.075	1.7	4.7	$5.99*10^{-3}$	>0.250	>42	5
	pyraclostrobin	0.200	1.7	4.7	0.0159	>0.596	>38	5
	combination						>20	5

The ratio between EC_{50} and the exposure concentration is > 5 for epoxiconazole, pyraclostrobin and their combination. Therefore, the risk for non-target plants is considered to be low.

Conclusions any other organisms
The proposed application of the product Retengo Plust complies with the RGB for the aspects activated sludge, non-target arthropods (off-field) and terrestrial non-target plants.

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

See List of End-points.

7.7 Data requirements

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7.8 Restriction sentences

The following restriction sentences were proposed by the applicant:

Om in het water levende organismen te beschermen is toepassing uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

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

In the WG (legal instructions):

Om in het water levende organismen te beschermen is de toepassing in de teelt van wintertarwe, wintergerst, rogge, triticale, zomertarwe, zomergerst, haver, maïs en suikerbiet uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater gebruik wordt gemaakt van minimaal 75 % driftreducerende spuitdoppen.

7.9 Overall conclusions regarding the environment

It can be concluded that:

1. for the risk assessment for birds via natural food and secondary poisoning via earthworms, Ctgb refers to the member state of the original authorisation (Denmark).
2. all proposed applications of the active substance epoxiconazole and pyraclostrobin meet the standards for birds (exposure via surface water; secondary poisoning via fish) as laid down in the RGB.
3. all proposed applications of the active substance epoxiconazole and pyraclostrobin meet the standards for aquatic organisms as laid down in the RGB, provided that drift reduction measures are applied.
4. the active substances epoxiconazole and pyraclostrobin meet the standards for bioconcentration as laid down in the RGB.

5. for the risk assessment for mammals via natural food and secondary poisoning via earthworms, Ctgb refers to the member state of the original authorisation (Denmark)
6. all proposed applications of the active substances epoxiconazole and pyraclostrobin meet the standards for mammals (exposure via surface water; secondary poisoning via fish) as laid down in the RGB.
7. for the risk assessment for bees, Ctgb refers to the member state of the original authorisation (Denmark).
8. for the risk assessment for non-target arthropods in-field, Ctgb could not refer to the member state of the original authorisation (Denmark) because no in-field risk assessment for Retengo Plust was available. Denmark did refer to the authorization of Opera. Therefore, Ctgb did perform the in-field risk assessment. All proposed applications of epoxiconazole and pyraclostrobin meet the in-field standards as laid down in RGB.
9. all proposed applications of the active substances epoxiconazole and pyraclostrobin meet the standards for non-target arthropods (off-field) as laid down in the RGB.
10. for the risk assessment for earthworms, Ctgb refers to the member state of the original authorisation (Denmark).
11. for the risk assessment for soil micro-organisms, Ctgb refers to the member state of the original authorisation (Denmark)
12. for the risk assessment for activated sludge, Ctgb refers to the member state of the original authorisation (Denmark)
13. all proposed applications of the active substances epoxiconazole and pyraclostrobin meet the standards for non-target plants as laid down in the RGB

8. Efficacy

The product is authorised in Denmark for the use in cereals, maize and sugar beet. Climatological and environmental circumstances relevant for the aspect efficacy in the claimed uses in The Netherlands are comparable to those in Denmark. The cultivation method in cereals, maize and sugar beet is similar in both countries and there are no country-specific situations for the use of Retengo Plust as a fungicide in the claimed uses.

8.1 Efficacy evaluation

For the evaluation of the aspect ‘Efficacy’ we refer to the evaluation of the member state of the original authorisation (Denmark).

8.2 Harmful effects

For the evaluation of the aspect ‘Harmful effects’ we refer to the evaluation of the member state of the original authorisation (Denmark).

8.3 Resistance

Retengo Plust is based on the active ingredients pyraclostrobin and epoxiconazole. Resistance development is known for these active ingredients. Therefore a standard resistance management sentence is added to the label:

Resistentiemanagement
Dit middel bevat de werkzame stof epoxiconazool en pyraclostrobin. Epoxiconazool behoort tot de triazolen/DMI fungiciden. De Frac code is 3. Pyraclostrobin behoort tot de strobilurinen/methoxycarbamaten, De FRAC code is 11.
Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

8.4 For vertebrate control agents: impact on target vertebrates

Because no vertebrates are controlled, this point is not relevant.

8.5 Any other relevant data / information

None.

9. Conclusion

The authorisation of the product is based on mutual recognition of the authorisation in Denmark of the product Opera (19-144). For the evaluation is referred to the original authorisation, as Denmark has adopted the Uniform Principles.

Rye is withdrawn by the applicant.

The evaluation is in accordance with the Uniform Principles laid down in appendix VI of Directive 91/414/EEC. The evaluation has been carried out on basis of a dossier that meets the criteria of appendix III of the Directive.

The product is considered to comply with the Uniform Principles.

10. Classification and labelling

Proposal for the classification and labelling of the formulation

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment for the operator, as mentioned above, the following labeling of the preparation is proposed:

The identity of all substances in the mixture that contribute to the classification of the mixture *:		
-		
Pictogram:	GHS07 GHS08 GHS09	Signal word: Danger
H-statements:	H302	Harmful if swallowed.
	H332	Harmful if inhaled.
	H351	Suspected of causing cancer.
	H360Df	May damage the unborn child. Suspected of damaging fertility.
	H410	Very toxic to aquatic life with long lasting effects.
P-statements:	P201	Obtain special instructions before use.
	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P308+P313	IF exposed or concerned: Get medical advice/attention.
	P391	Collect spillage.
	P501	Dispose of contents/container to hazardous or special waste collection point.
Supplemental Hazard information:	EUH205	Contains epoxy constituents. May produce an allergic reaction.
	EUH401	To avoid risks to human health and the environment, comply with the instructions for

		use.
	SP 1	Do not contaminate water with the product or its container.
Child-resistant fastening obligatory?		Not applicable
Tactile warning of danger obligatory?		Not applicable

Explanation:	
Pictogram:	-
H-statements:	H360Df instead of H361df because of RAC opinion for epoxiconazole. H315 does not need to be applied on the basis of CLP classification. H400 not necessary because of H410 .
P-statements:	P201, P280 and P308+P313 are highly recommended and follow from H360Df. P391 and P501 are proposed by the applicant. The applicant suggests much more P-statements which can be applied when the space on the label allows (no more than 6 P-statements), of which the following would make most sense to be contributed: P261 is recommended, therefore applied. P271 is highly recommended for general public, however, Retengo Plust is a PPP for professional use, therefore not applied. P264, P270 are recommended for general public, however, Retengo Plust is a PPP for professional use, therefore not applied.
Other:	EUH205 is assigned because the product contains epoxiconazole.

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

Draag geschikte handschoenen en beschermende kleding, ook bij werkzaamheden aan behandeld gewas.

Om in het water levende organismen te beschermen is de toepassing in de teelt van wintertarwe, wintergerst, triticale, zomertarwe, zomergerst, haver, maïs en suikerbiet uitsluitend toegestaan wanneer in percelen die grenzen aan oppervlaktewater gebruik wordt gemaakt van minimaal 75 % driftreducerende spuitdoppen.

<u>Resistentiemanagement</u>
Dit middel bevat de werkzame stof epoxiconazool en pyraclostrobine. Epoxiconazool behoort tot de triazolen/DMI fungiciden. De Frac code is 3. Pyraclostrobine behoort tot de strobilurinen/methoxycarbamaten, De FRAC code is 11.

Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

Appendix 1 Table of authorised uses

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation**	**F G or I**	**Pests or Group of pests controlled**	**Application**			**Application rate per treatment**			**PHI** (days)	**Remarks:** a) max. no. of applications per crop and season b) Maximum product rate per season c) additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	kg, L product / ha	g as/ha	Water L/ha min / max		
1	NL	Wheat, winter	F	Puccinia recondita, Puccunia striiformis, Septoria tritici	spray	BBCH 30-71 (April-June)	1/-	0.75 - 1.5	Pyraclostrobin: 100 - 200 Epoxiconazole: 38 - 75	150-250	35	Maximal dose 1.5 L/ha per season
2	NL	Wheat, spring	F	Puccinia recondita, Puccunia striiformis, Septoria tritici	spray	BBCH 30-71 (April-June)	1/-	0.75 - 1.5	Pyraclostrobin: 100 - 200 Epoxiconazole: 38 - 75	150-250	35	Maximal dose 1.5 L/ha per season
3	NL	Barley, winter	F	Puccinia striiformis, Puccinia hordei, Pyrenophora teres, Rhynchosporium secalis	spray	BBCH 30-65 (April-June)	1/-	0.75 - 1.5	Pyraclostrobin: 100 - 200 Epoxiconazole: 38 - 75	150-250	42	Maximal dose 1.5 L/ha per season
4	NL	Barley, spring	F	Puccinia striiformis, Puccinia hordei Pyrenophora teres, Rhynchosporium secalis	spray	BBCH 30-65 (April-June)	1/-	0.75 - 1.5	Pyraclostrobin: 100 - 200 Epoxiconazole: 38 - 75	150-250	42	Maximal dose 1.5 L/ha per season
5	NL	Oats	F	Puccinia coronata	spray	BBCH 30-65 (April-June)	1/-	0.75 - 1.5	Pyraclostrobin: 100 - 200 Epoxiconazole: 38 - 75	150-250	42	Maximal dose 1.5 L/ha per season
6	NL	Triticale	F	Puccinia recondita, Puccunia striiformis, Septoria tritici	spray	BBCH 30-71 (may-august)	1/-	0.75 - 1.5	Pyraclostrobin: 100 - 200 Epoxiconazole: 38 - 75	150-250	42	Maximal dose 1.5 L/ha per season
7	NL	Maize	F	Helminthosporium spp., Kabatiella zeae	spray	BBCH 30-51 (May-August)	2/14	0.75 - 1.5	Pyraclostrobin: 100 - 200	200-400	60	Maximal dose 1.5 L/ha per season

									Epoxiconazole: 38 - 75			
8	NL	Sugar beet	F	Erysiphe betae, Uromyces betae, Cercospora beticola, Ramularia beticola	spray	BBCH 39-49 (July-September)	1/-	0.5-1.0	Pyraclostrobin: 66,7-133 Epoxiconazool: 25-50	150-250	28	Maximal dose 1.0 L/ha per season

Appendix 2 Reference list

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

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Owner	Application number*	Date of submission*
KIIIA 7.6.1/1	2009	^{14}C-BAS 500 (Pyraclostrobin) in BAS 512 04 F. Study of penetration through human skin in vitro. BASF SE, Ludwigshafen, Germany 2009/1041556 Yes Unpublished	BASF		
KIIIA 9.6/2 - 10.9.2/2	2014	Evaluation risk analyses Retengo plus: mutual recognition from Denmark (BAS 512 16 F) BASF Nederland BV; Arnhem; The Netherlands. - No Unpublished	BASF	20140099 WERG	05-02-2014
KIIIA 9.6/2 - 10.9.2/2	2014	Evaluation risk analyses Retengo plus: mutual recognition from Denmark (BAS 512 16 F) BASF Nederland BV; Arnhem; The Netherlands. - No Unpublished	BASF	20140099 WERG	05-02-2014

* in case of an earlier submission (for an earlier application)