HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

Het besluit van 5 juni 2015 komt te vervallen. Bjilage I is als volgt gewijzigd: de expiratiedatum is gewijzigd van 31 december 2015 naar 31 december 2016.

1 HERSTELBESLUIT WEDERZIJDSE ERKENNING

Op 24 december 2013 is van
Certiplant NV
Lichtenberglaan 2045
B-3800 SINT-TRUIDEN
BELGIE

een aanvraag ontvangen tot uitbreiding van een toelating ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

Dragoon

op basis van de werkzame stof diquatdibromide, uitgedrukt als diquat.

HET COLLEGE BESLUIT tot uitbreiding van de toelating van bovenstaand middel.

Voor nadere gegevens over deze toelating wordt verwezen naar de bijlagen:
- Bijlage I voor details van de aanvraag en toelating;
- Bijlage II voor de etikettering;
- Bijlage III voor wettelijk gebruik;
- Bijlage IV voor de onderbouwing.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen op de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
- Het toelatingsnummer met een cirkel met daarin de aanduiding van de w-codering zoals vermeld onder “toelatingsinformatie” in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in bijlage III.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. De te hanteren w-coderingen en aflever- en opgebruiktermijnen voor oude verpakkingen staan vermeld onder “toelatingsinformatie” in bijlage I.

2 WETTELIJKE GRONDSLAG

Besluit	artikel 40 van de Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual Zonaal 2.0

3 BEOORDELINGEN

3.1 Inleiding

Gezien de aard van de wederzijdse erkenning wordt ervan uitgegaan dat de beoordeling door het Verenigd Koninkrijk 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 het Verenigd Koninkrijk. 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 IV 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 IV bij dit besluit.

Bezwaarmogelijkheid
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.

Ede, 20 november 2015

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

13849 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20140020 NLWERGU
Type aanvraag:	NLWERGU
Middelnaam:	Dragoon
Verzenddatum aanvraag:	23 december 2013
Formele registratiedatum: *	25 februari 2014
Datum in behandeling name:	3 december 2014

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

2 Stofinformatie

Werkzame stof	Gehalte
diquatdibromide	374 g/L
uitgedrukt als diquat	200 g/L

De stof is per 1 januari 2002 geplaatst op Annex I van richtlijn 91/414 (Richtlijn 2001/21/EG, 5 maart 2001), met expiratiedatum 31 december 2015 (Richtlijn 2010/77/EG), en vervolgens goedgekeurd krachtens Verordening (EG) No 1107/2009 (Uitvoeringsverordening (EU) No 540/2011 d.d. 25 mei 2011).

3 Toelatingsinformatie

Toelatingsnummer:	13849 N
Expiratiedatum:	31 december 2016
Afgeleide parallel of origineel:	N.v.t
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel
W-codering professioneel gebruik:	W.1

4 Aflever- en opgebruiktermijnen voor oude etiket

Vorige W-codering professioneel gebruik:	W.0
Aflevertermijn professioneel gebruik:	N.v.t.
Opgebruiktermijn professioneel gebruik:	N.v.t.

5 Verpakkingsinformatie

Aard van het preparaat: Met water mengbaar concentraat.

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HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel Dragoon

Professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel: diquatdibromide, uitgedrukt als diquat

Pictogram	GHS05 GHS06 GHS08 GHS09
Signaalwoord	GEVAAR
Gevarenaanduidingen	H290 Kan bijtend zijn voor metalen. H302 Schadelijk bij inslikken. H315 Veroorzaakt huidirritatie. H317 Kan een allergische huidreactie veroorzaken. H319 Veroorzaakt ernstige oogirritatie. H331 Giftig bij inademing. H335 Kan irritatie van de luchtwegen veroorzaken. H372 Veroorzaakt schade aan organen <of alle betrokken organen vermelden indien bekend> bij langdurige of herhaalde blootstelling. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P102 Buiten het bereik van kinderen houden. P261 Inademing van stof/rook/gas/nevel/damp/spuitnevel vermijden. P270 Niet eten, drinken of roken tijdens het gebruik van dit product. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P284 Adembescherming dragen. P301 + P310 NA INSLIKKEN: Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. P304 + P340 NA INADEMING: de persoon in de frisse lucht brengen en ervoor zorgen dat deze gemakkelijk kan ademen. P314 Bij onwel voelen een arts raadplegen. P391 Gelekte/gemorste stof opruimen. P501 Inhoud/verpakking afvoeren naar .... SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt. SPe 3 Om [in het water levende organismen/niet tot de doelsoorten behorende planten en dieren/niet tot de doelsoorten behorende geleedpotigen/ insecten] te beschermen mag u in een bufferzone van (geef de afstand aan) rond [niet-landbouwgrond/oppervlaktewater] niet spuiten. SPo 2 Was alle beschermende kleding na gebruik.
Aanvullende etiketelementen	EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE III WG van het middel

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

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal l middel per ha	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Veiligheidstermijn in dagen
Aardappelen	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per teeltcyclus	-
	doodspuiten	aardappelloof	4 l/ha	4 l/ha	1 per teeltcyclus	-
Bieten	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per teeltcyclus	-
Bladgroenten (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per 12 maanden	-
Peulgroenten (onbedekt)	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per teeltcyclus	-
Vruchtgroenten (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per teeltcyclus	-
Koolgewassen (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per 12 maanden	-
Wortel- en knolgewassen (onbedekt)	voor opkomst	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per 12 maanden	-
Ui-achtigen	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5 l/ha	1,5 l/ha	1 per 12 maanden	-
Stengelgroenten (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per 12 maanden	-

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal l middel per ha	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Veiligheidstermijn in dagen
Bloembol- en bloemknolgewassen (onbedekt)	voor opkomst of voor uitplanten	Eenjarige breedbladige onkruiden	1,5-2 l/ha	2 l/ha	1 per 12 maanden	-

Toepassingsvoorwaarden
In ui-achtigen Dragoon toepassen in 500 l water per ha. In de overige toepassingen Dragoon toepassen in 200-500 l water per ha.

In de teelt van ui-achtigen kan de werking onvoldoende zijn.

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een bufferzone van 1,5 m.

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn.

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HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE IV

RISKMANAGEMENT

Contents

1 Identity of the plant protection product

1.1 Applicant

Certiplant NV
Lichtenberglaan 2045
B-3800 Sint-Truiden
Belgium

1.2 Identity of the active substance

Common name	Diquat
Name in Dutch	Diquat
Chemical name	9,10-dihydro-8a,10a-diazoniaphenanthrene ion (diquat) [IUPAC]
CAS no	2764-72-9 (diquat), 85-00-7 (diquat dibromide)
EC no	220-433-0 (diquat), 201-579-4 (diquat dibromide)

The active substance was included in Annex I of Directive 91/414/EEC on 1 January 2002. 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	Dragoon
Formulation type	SL, soluble concentrate
Content active substance	200 g/L pure diquat, equivalent to 374 g/L pure diquat dibromide

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

1.4 Function

Herbicide.

1.5 Uses applied for

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation**	**F G or I**	**Pests or Group of pests controlled**	**Application**			**Application rate per treatment**			**PHI** (days)	**Remarks:** a) max. no. of applications per crop and season b) Maximum product rate per season c) additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	L product / ha	kg as/ha	Water L/ha min / max		
New uses												
WEED CONTROL – OVERALL												
19	NL	Onion family	F	Annual dicotylodonous weeds	Overall spraying	Pre-emergence // Pre-planting, february – june BBCH 0 - 9	1	1.5 – 2 L product/ha	0.3 – 0.4 kg as/ha	200 – 500L/ha		

During the application, applicant lowered the dose to 0.3 kg as/ha and limited the water volume to 500 L/ha.

1.6 Background to the application
Extension of the approval of the plant protection product Dragoon, approval number 13849 N.

1.7 Packaging details

1.7.1 Packaging description

Material:	HDPE container
Capacity:	1, 5 or 10 L
Type of closure and size of opening:	Screw cap with induction seal. Resp. 45 mm, 63 mm, 63 mm
Other information	ADR/UN 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 Dragoon we refer to the member state of the original authorisation (United Kingdom).

3 Methods of analysis

For the assessment of the methods of analysis required for Dragoon we refer to the member state of the original authorisation (United Kingdom).

4 Mammalian toxicology

4.1 Toxicity of the formulated product (IIIA 7.1)
For the evaluation of the toxicity of the formulated product Dragoon, we refer to the member state of the original authorisation (United Kingdom).

4.2 Dermal absorption (IIIA 7.3)
The United Kingdom used a value of 1% for dermal absorption for both the concentrate and spray dilution in the risk assessment and since this application is a request for mutual recognition the value of 1% is also used in this risk assessment.

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 the United Kingdom.

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

Overview of the intended uses
An application (request for mutual recognition) has been submitted for the extension of the authorisation of the plant protection product Dragoon, a herbicide based on the active substance diquat.

Dragoon is a SL (soluble concentrate) formulation and contains 200 g/L diquat.

The formulation Dragoon is applied once during the cultivation period. 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)
For diquat no TLV has been set. The AOEL will be used for the risk assessment.

Since diquat is included in Annex I of 91/414/EEC and subsequently approved under Regulation (EC) 1107/2009, the semi-chronic EU-AOEL of 0.001 mg/kg bw/day (= 0.07 mg/day for a 70-kg operator), based on the 2-year study in rat (90-day endpoint), is used in the risk assessment. This AOEL has also been used in the risk assessment performed by the United Kingdom.

Exposure/risk
Exposure to diquat during mixing and loading and application of Dragoon 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 diquat and risk assessment for the use of Dragoon

	Route	Estimated internal exposure [a] (mg/day)	Systemic EU-AOEL (mg/day)	% AOEL [b]
Mechanical downward spraying on onions (uncovered, 1.5 L/ha)				
Mixing/ Loading[c]	Respiratory	0.02	0.07	21
	Dermal	0.60	0.07	**857**
Application[c]	Respiratory	0.02	0.07	34
	Dermal	0.07	0.07	99
	Total	0.71	0.07	**1011**

a Internal exposure was calculated with:
- biological availability via the dermal route: 1% (concentrate) and 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.

Since the EU-AOEL is exceeded without the use of PPE, an assessment using PPE has to be performed.

Table T.2 Internal operator exposure to diquat and risk assessment for the use of Dragoon

	Route	Estimated internal exposure [a] (mg/day)		Systemic EU-AOEL (mg/day)	% AOEL [b]	
		without PPE	with PPE		without PPE	with PPE
Mechanical downward spraying on onions (uncovered, 1.5 L/ha)						
Mixing/ Loading[c]	Respiratory	0.02	<0.01	0.07	21	2
	Dermal	0.60	0.06	0.07	**857**	**86**
Application[c]	Respiratory	0.02	<0.01	0.07	34	3
	Dermal	0.07	0.01	0.07	99	11

	Route	Estimated internal exposure [a] (mg/day)		Systemic EU-AOEL (mg/day)	% AOEL [b]	
		without PPE	with PPE		without PPE	with PPE
	Total	0.71	0.07	0.07	**1011**	**102**[d]

a Internal exposure was calculated with:
- biological availability via the dermal route: 1% (concentrate) and 1% (spray dilution) (see 4.2)
- biological availability via the respiratory route: 100% (worst case)

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

c External exposure is estimated with EUROPOEM.

d PPE: respiratory protective equipment and gloves during mixing/loading and respiratory protective equipment, gloves and coverall during application.

The % AOEL with PPE (respiratory protective equipment and gloves during mixing/loading and respiratory protective equipment, gloves and coverall during application) is just slightly exceeded (102%). Based on the combination of the following considerations it is not expected that in this specific case an unacceptable risk occurs for operators due to exposure to diquat as the result of the application of Dragoon in onions:

1. The use of exposure models is expected to result in an overestimation of the exposure and considering the uncertainty factors already taken into account in the risk assessment, no adverse health effects are expected after respiratory and dermal exposure to diquat for the operator as a result of the application of Dragoon in onions in case personal protective equipment (respiratory protective equipment and gloves during mixing/loading and respiratory protective equipment, gloves and coverall during application) is worn;
2. The use extension in onions is covered by the risk envelop of the current authorisation regarding Dragoon in the Netherlands. However, for the current authorisation a refinement using the NL-AOEL was used, while this refinement step is not part of the assessment framework for the use extension;
3. In the UK the same GAP for onions has been authorised.

4.4.2 Bystander exposure/risk

The exposure is estimated for the unprotected bystander. In Table T.3 the estimated internal exposure is compared with the systemic EU-AOEL.

Table T.3 Internal bystander exposure to diquat and risk assessment during application of Dragoon

Route	Estimated internal exposure [a] (mg/day)	Systemic EU-AOEL (mg/day)	% AOEL [b]
Bystander exposure during application on onions			
Respiratory	0.02	0.07	32
Dermal	<0.01	0.07	4
Total	0.03	0.07	36

a External exposure was estimated with EUROPOEM II. Internal exposure was calculated with:
- biological availability via the dermal route: 1% (spray dilution)
- biological availability via the respiratory route: 100% (worst case)

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

Non-professional 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 UK 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 EU-AOEL.

Table T.4 Internal bystander and resident exposure to diquat and risk assessment for the application of Dragoon

	Route	Estimated internal exposure [a] (mg/day)	Systemic AEL (mg/day) [b]	% AOEL [c]
Bystander exposure during application in intended uses according to the German model				
Child	Total	<0.01	0.02	11
Adult	Total	0.01	0.06	14
Resident exposure during application in intended uses according to the German model				
Child	Total	0.01	0.02	54
Adult	Total	0.02	0.06	29
Bystander exposure during application in intended uses according to the UK method				
Adult	Total	<0.01	0.06	1
Resident exposure during application in intended uses according to the UK method				
Child	Respiratory	0.01	0.02	55
	Dermal+Oral	<0.01	0.02	2

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: 1% (spray dilution)
- biological availability via the oral route: 10% (see List of Endpoints)

b From the systemic AOEL of 0.001 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 % AOEL is calculated by dividing the internal exposure by the systemic AOEL and multiplying this by 100%.

4.4.3 Worker exposure/risk

Shortly after application it is not necessary to perform any re-entry activities during which intensive contact with the treated crop will occur. Therefore no worker exposure is calculated.

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

The % AOEL with PPE (respiratory protective equipment and gloves during mixing/loading and respiratory protective equipment, gloves and coverall during application) is just slightly exceeded (102%). Based on the combination of the following considerations it is not expected that in this specific case an unacceptable risk occurs for operators due to exposure to diquat as the result of the application of Dragoon in onions:

1. The use of exposure models is expected to result in an overestimation of the exposure and considering the uncertainty factors already taken into account in the risk assessment, no adverse health effects are expected after respiratory and dermal exposure to diquat for the operator as a result of the application of Dragoon in onions in case personal protective equipment (respiratory protective equipment and gloves during mixing/loading and respiratory protective equipment, gloves and coverall during application) is worn;
2. The use extension in onions is covered by the risk envelop of the current authorisation regarding Dragoon in the Netherlands. However, for the current authorisation a refinement using the NL-AOEL was used, while this refinement step is not part of the assessment framework for the use extension;
3. In the UK the same GAP for onions has been authorised.

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 diquat during application of Dragoon in onions.

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

The current classification and labelling of the formulation can be maintained.

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

4.6 Data requirements
None.

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

5 Residues
For the aspect ‘Residues’ and risk for consumers we refer to the member state of the original authorisation (United Kingdom). 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.

6 Environmental fate and behaviour

List of Endpoints Fate/behaviour
The LoEP is taken from the final registration report 2001/21/EC OJ L69; d.d. 10/03/2001.

Fate and behaviour in soil

Route of degradation

Aerobic:	
Mineralization after 100 days:	Microbial degradation has been demonstrated only in isolation due to strong adsorption to soil.
Non-extractable residues after 100 days:	Not relevant. See comment above.
Relevant metabolites above 10 % of applied active substance: name and/or code % of applied rate (range and maximum)	Not relevant. See comment above.
Supplemental studies Anaerobic:	Relatively stable, withstands degradation
Soil photolysis:	No significant degradation in 32 d
Remarks:	Standard requirements are not applicable due to strong adsorption to soil.

Rate of degradation

Laboratory studies DT_{50}lab (20 °C, aerobic):	No measurable degradation in soil under laboratory conditions after one year.
DT_{90}lab (20 °C, aerobic):	Not relevant. See comment above.
DT_{50}lab (10 °C, aerobic):	Not relevant. See comment above.
DT_{50}lab (20 °C, anaerobic):	Not relevant. See comment above.
Field studies (country or region) DT_{50f} from soil dissipation studies:	DT_{50} = 10 - 20 y (UK), 1.2 - 3.6 y (US)
DT_{90f} from soil dissipation studies:	DT_{90} values were never reached
Soil accumulation studies:	Performed as part of US soil dissipation study - refer to detailed results. (16% of diquat applied remained in the soil after 11 years of annual application to the soil at 1 kg diquat/ha/yr)
Soil residue studies:	< 0.05 - 2.3 mg/kg (Denmark 32 sites) 0.11 mg/kg (maximum), 0.03 mg/kg (average) for various Western European Countries
Remarks e.g. effect of soil pH on degradation rate	The strong adsorption of diquat to soil precludes diquat degradation in soil being studied effectively by standard guideline methods. The strong adsorption also greatly reduces the rate of formation of degradation products to amounts that would not be detectable using standard methods. Soil microbial studies fulfil the scientific intent of demonstrating the intrinsic degradability of diquat.

Adsorption/desorption

	Following end points based on the results obtained from a soil residue study performed at 32 sites in Denmark. (Bewick *et al*, 1984)
K_f / K_{OC}	Koc values (32 soils in study) ranged from 32,000 to 7,900,000 (very strong adsorption in

	all the soils tested - with 31 of the soils having Koc values at least one order of magnitude greater than 5,000). Mean Koc value = 2,184,750 Median Koc value = 1,600,000
K_d	Kd values (32 soils in study) ranged from 1,200 to 92,000 (very strong adsorption in all the soils tested) Mean Kd value = 27,100 Median Kd value = 23,500
ph dependence	Not relevant

Mobility

Laboratory studies:

Column leaching:	Not relevant as all studies indicate that diquat is immobile.
Aged residue leaching:	Not relevant as all studies indicate that diquat is immobile.

Field studies:

Lysimeter/Field leaching studies:	Not relevant as all studies indicate that diquat is immobile.

Remarks:	Adsorption is correlated to clay content. Adsorption capacity is quantified by wheat bioasssay (SAC-WB). Most soils have a large excess in adsorption capacity. For very sandy soil exceedance may be a possibility following repeated high application rates.

Fate and behaviour in water

Abiotic degradation

Hydrolytic degradation:	No sterile hydrolysis at environmental pHs.
Relevant metabolites:	None
Photolytic degradation:	DT_{50} < 7 d (UK summer conditions)
Relevant metabolites:	None

Biological degradation

Ready biological degradability:	No, due to rapid adsorption by sediment or suspended solids.
Water/sediment study:	DT_{50} = 12 - 24 hours.
DT_{50} water: DT_{90} water: DT_{50} whole system: DT_{90} whole system:	Aquatic biodegradation studies, (two water/sediment studies performed in the laboratory under aerobic or anaerobic conditions, and a field study performed in natural ponds in the US) show similar results.
Distribution in water / sediment systems (active substance)	The primary route of dissipation of diquat from natural water is through very rapid adsorption onto sediment, or by adsorption onto plant material and/or suspended particulate matter which ultimately settle to the bottom of the pond
Distribution in water / sediment systems (metabolites)	

	or water course. The field study in natural ponds shows that diquat dispersion within and dissipation from water are both extremely rapid with difficulties in measuring these accurately. Substantial dissipation occurs after a few hours, with estimates of the DT50 for the partition to sediment ranging from <8 to 34 hours, with a mean of 12 to 24 hours. Diquat was stable withstanding degradation under the conditions of the aerobic and anerobic studies conducted in pond water and sand sediment.
Accumulation in water and/or sediment:	Not relevant as diquat dissipates very rapidly by adsorption onto sediment; plant material and/or suspended particulate matter which settle to the bottom of the pond or water course. There is no evidence of desorption of diquat back into the water in the relevant studies.
Degradation in the saturated zone	See above remarks.
Remarks:	None

Fate and behaviour in air

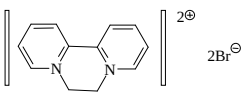
Volatility	
Vapour pressure:	$< 10^{-8}$ kPa at 25 °C
Henry's law constant:	$5 \cdot 10^{-12}$ Pa·m^3·mol^{-1}

Photolytic degradation

Direct photolysis in air:	Not relevant, due to low vapour pressure.
Photochemical oxidative degradation in air DT_{50}:	Not relevant, due to low vapour pressure.
Volatilisation:	Not relevant, due to low vapour pressure.
Remarks:	None

Appendix A: Metabolite names, codes and other relevant information of the plant protection product Dragoon with active substanc diquat (as diquat dibromide).

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

Compound name	Code number(s)	IUPAC name	Structural formula	Structure	Molecular Weight [g/mol]	Observed in study (% of occurrence/ formation)
diquat (ion), diquat dibromide		9,10-dihydro-8a,10a-diazoniaphenanthrene ion (dibromide)	$C_{12}H_{12}N_2$, $C_{12}H_{12}Br_2N_2$		184.2 (diquat)	Parent substance

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 the Ctgb refers to the member state of the original authorisation in the UK.

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 UK 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 substance diquat (as diquat dibromide) 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 0.4 kg/ha, the crop onion and an interception value appropriate to the crop stage of 0. Date of yearly application is 1st of February for autumn application and 25th of May for spring application.

PEARL:

Active substance: diquat (as diquat dibromide

DT_{50} for degradation in soil (20°C): 3650 days (UK soil dissipation study)
Median K_{om} (pH-independent): 928,074 L/kg (n=32)
1/n: 0.9 (default)

Saturated vapour pressure: 1 x 10^{-5} Pa (25 ºC)
Solubility in water: 718 g/L (20 ºC)
Molecular weight: 184.2 g/mol
Q10: 2.2
Plant uptake factor: 0.0

Other parameters: standard settings of PEARL 4.4.4

The following concentrations are predicted for the active substance diquat dibromide following the realistic worst case GAP, see Table M.1.

Table M.1 Leaching of active substance diquat dibromide as predicted by PEARL 4.4.4. Values ≥0.1 µg/L are indicated in bold, values ≥0.01-<0.1 µg/L are underlined

Use	Sub-stance	Rate substance [kg/ha]	Frequency / Interval [days]	Fraction Inter-cepted	PEC groundwater [µg/L]	
					spring	autumn
Onion family	diquat	0.4	1	0	<0.001	<0.001

* interception values derived from Table 1.4 and/or 1.5 in Generic Guidance for Tier 1 FOCUS Ground Water Assessments. (FOCUS, 2011).For pre-emergence application an interception value of 0 is used.

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

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

Monitoring data

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

Conclusions
The proposed application of the product Dragoon 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)*

Article 8f of the *Plant Protection Products and Biocides Decree* (BGB) prescribes the use of Dutch specific drift percentages.

Since the Netherlands has its own national drift values, the exposure concentrations of the active substance diquat (as diquat dibromide) 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. A default of 1% drift has been used for TOXSWA calculations.

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

TOXSWA:

Active substance diquat:
DT_{50} for degradation in water at 20°C: 1000 days (no degradation in the total system)
DT_{50} for degradation in sediment at 20°C: 1000 days (default).

Median K_{om} for suspended organic matter: 928,074 L/kg
Median K_{om} for sediment: 928,074 L/kg
1/n: 0.9 (default)

Saturated vapour pressure: 1 x 10^{-5} Pa (25 ºC)
Solubility in water: 718 g/L (20 ºC)
Molecular weight: 184.2 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 substance diquat (as diquat dibromide) for each intended use are presented.

Table M.2a Overview of surface water concentrations for active substance diquat (as diquat dibromide) in the edge-of-field ditch following spring/autumn application

Use	Substance	Rate a.s. [kg/ha]	Freq./ Inter-val [days]	Drift [%]	PIEC [µg/L] *		PEC21 [µg/L] *		PEC28 [µg/L] *	
					spring	autumn	spring	autumn	spring	autumn
Onion family	Diquat	0.4	1 / n.a.	1	0.208	0.208	0.168	0.029	0.156	0.021

***** calculated according to TOXSWA

$PEC_{sediment}$

To address the risk to sediment organisms, a $PEC_{sediment}$ value is needed for active substance diquat (as diquat dibromide). 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 day 33 after application. See Table M.2b for calculation of $PEC_{sediment}$.

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

Use	Sub-stance	Rate a.s. [kg/ha]	Drift [%]	$PEC_{sediment}$ [g a.s./m^3 sediment] *	$PEC_{sediment}$ [mg a.s./kg sediment dw]**
				spring	spring
Onion family	diquat	0.4	1	0.237×10^{-1}	0.296

* TOXSWA output

** calculated as (PECsed in g/m3 / 80 kg/m3) x 1000 (conversion of g/kg to mg/kg)

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

Monitoring data

In 2014, version 3 of the Pesticide Atlas was launched, which includes a statistical correlation analysis between concentrations, threshold exceedance and land use, which may indicate probable relationships. In this version also the correlation analysis of land use with the environmental quality standards (EQS) of the Water Framework Directive (WFD) is included.

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards (MKN in Dutch, data source http://www.rivm.nl/rvs/Normen). These environmental quality standards consist either of the harmonised WFD thresholds derived according to the Fraunhofer methodology[1] (AA-EQS and MAC-EQS) or of an MPC value (which is usually derived on the basis of outdated guidance). When EQS values according to the Water Framework Directive are available, the MPC value is not used further in the analysis of monitoring data for the purpose of the registration.

For examination against the drinking water criterion, another database (VEWIN) is used, since the drinking water criterion is only examined at drinking water abstraction points. For

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

the assessment of the proposed applications regarding the drinking water criterion, see next section.

Active substance diquat (as diquat dibromide)
The active substance diquat (as diquat dibromide) was not observed in the surface water (most recent data from 2013). In Table M.3 the number of observations in the surface water from 2012 are presented. (Only measurements in Zeeland are reported in the Pesticide Atlas for 2012.)

The authorisation threshold equals 0.84 µg a.s./L (consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case 0.1*NOEC for Lemna). The relevant environmental quality standards (EQS) for this substance are not available.

Table M4 Monitoring data in Dutch surface water for diquat dibromide (from www.pesticidesatlas.nl, version 3.0)

Total no of locations (2012)	***n* > authorisation threshold**	***n* > EQS**		
		MAC-EQS	**AA-EQS**	**MPC (ad-hoc/indicative)**
21	2 (1 > authorisation threshold; 1 > 5 x authorisation threshold)	n.a.	n.a.	n.a.

*** the number of observations at each location varies between 1 and 10, total number of measurements is 83 in 2012.**
**** n.a. not available**

Two locations show an exceedance of the authorisation threshold.

Therefore it is assessed whether there is a correlation between the observed exceedances and land use types. The correlation analysis as included in the Pesticide Atlas uses a progressive three-year period to assess whether there is a relation. The last three available years, in this case 2011-2013 are used to establish the relation.

The observed exceedance of the water quality standard authorisation threshold is not significantly correlated to the proposed use.

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

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 Decree* (BGB) describes the Assessment of the drinking water criterion.

It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, the Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion ‘surface water intended for drinking water production’. The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635[2].

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

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

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

Active substance diquat (as diquat dibromide) has been on the Dutch market for > 3 years (authorised since 30/09/1994). 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.

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 authorisation (UK).

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 Endpoints.

6.5 Data requirements

None.

The following restriction sentences were proposed by the applicant:
None.

Based on the current assessment, the following has to be stated in the GAP/legal instructions for use (WG):
None.

6.6 Overall conclusions fate and behaviour

It can be concluded that:

1. the proposed application of the active substance diquat (as diquat dibromide) meets the standards for leaching to the shallow groundwater as laid down in the BGB.
2. the proposed application of the active substance diquat (as diquat dibromide) meets the standards for surface water destined for the production of drinking water as laid down in the BGB.

7 Ecotoxicology

For the extension of the current application of mutual recognition of Dragoon, risk assessment is done in accordance with the RGB d.d. 16 December 2011 and the Ctgb Evaluation Manual 1107, version 2.0 (2014).

The underlying risk assessment is based on the final list of endpoints for diquat (EU Review Report, 1688/VI/97-final, 2001/21/EC OJ L69, d.d. 22 March 2001) and on the UK authorisation for Dragoon. For the Dutch specific aspects data from the previous assessment is used (13849 N, d.d. 9 November 2012).

List of Endpoints Ecotoxicology
Diquat is placed on Annex I since 2002. For the risk assessment the List of Endpoints from the final registration report (d.d. 10/03/2001) is used, complemented with additional studies submitted during and after EU peer review of the active substance, as stated in the Dutch authorisation from 2012 (13849 N).

Dragoon (Diquat (200 g/L) (diquat bromide (374 g/L)) is a water soluble concentrate (SL).

Terrestrial Vertebrates

Acute toxicity to mammals:	LD50 (diquat ion - rat)= 214 - 222 mg/kg bw
Short term oral toxicity to mammals:	NOAEL 8.9mg /kg bw/d, 90 day rat (diquat ion) NOAEL 0.5 mg/kg bw/d, 1 y dog - (diquat ion)
Acute toxicity to birds:	LD_{50} = 83 mg /kg bw (diquat ion) *Anas platyrhynchos*
Dietary toxicity to birds:	LC_{50} = 721 ppm, 5 d study (diquat ion) *Coturnix japonica (162 mg a.s./kg bw/d, recalculated by applicant)*
Reproductive toxicity to birds:	NOEC = 5 mg/kg (diquat ion) (= *0.6 mg a.s./kg bw/d based on FIR/bw 0.121* [1]) *28 d NOEC = 100 ppm = 21.7 mg a.s./kg bw/d (Mallard ducklings, 1 d old)* [2] *9 w NOEC = 40 ppm = 6.6 mg a.s./kg bw/d (Mallard duck)* [a] *12 w NOEC = <80 ppm (Mallard duck), quick recovery – see discussion below*[2]

[1] based on FIR/bw = (146/1205 =) 0.121 (data provided by notifier)
[2] *evaluated in RIVM-report 12465A00*

Relevant long-term toxicity value
(Statement provided by the notifier for their own product; and repeated by the applicant. The applicant has a LoA from the notifier for the essential studies)
The above risk assessment is based on the lowest reproduction NOEC given in the LoE. However, more reproduction studies were done. Below an overview is given of the available chronic bird studies with a.s. diquat.

Long-term toxicity of diquat to birds

Study type	Species	Endpoint	Value (expressed as diquat ion)	Reference
Studies submitted during EU Peer Review:				
Effects on reproduction (18 weeks exposure)	*Colinus virginianus* (Bobwhite quail)	NOEC (NOEL)	100 mg/kg diet (9.4 mg/kg bw/d)	**Beavers and Fink, 1982b**
Effects on reproduction (18 weeks exposure, including poor layers)	*Anas platyrhynchos* (Mallard duck)		5 mg/kg diet according to LoE (0.6 mg/ a.s.kg bw/d[1])	**Beavers and Fink, 1982c**
Effects on duckling growth (2 and 4 weeks exposure)	*Anas platyrhynchos* (Mallard duck)	NOEC (NOEL)	100 mg/kg diet (21.7 mg/kg bw/day)	**Frey et al., 1995**
New studies, submitted to Ctgb after EU Peer Review:				
Effect on reproduction (3 weeks pre-egg laying plus 6 weeks post-egg laying exposure, including poor layers) Only egg production and egg weight measured	*Anas platyrhynchos* (Mallard duck)	NOEC (NOEL)	40 mg/kg diet (6.6 mg/kg bw/day for males + females; 10.0 mg/kg bw/d for females only)	**Temple et al., 2004a PP901/1436**
Effect on reproduction (6 weeks post-egg laying exposure, normal layers) Only egg production and egg weight measured	*Anas platyrhynchos* (Mallard duck)		80 mg/kg diet (11.1 mg/kg bw/day)	**Temple et al., 2004b PP901/1437**
Effect on reproduction (6 weeks post-egg laying exposure, late layers) Only egg production and egg weight measured	*Anas platyrhynchos* (Mallard duck)		>20 mg/kg diet (2.7 mg/kg bw/day)	
Reproduction Study to Evaluate Reversibilty oin Effects (6 weeks exposure during egg laying, and 6 weeks recovery)	*Anas platyrhynchos* (Mallard duck)	LOEC = 80 mg/kg diet (11.1 mg/kg bw/day), but complete recovery seen after 1 week at this rate. Recovery seen after 2 weeks at 160 mg/kg diet (19.7 mg/kg bw/day)		**Temple et al., 2009 (PP901/10751)**

[1] based on FIR/bw = (146/1205 =) 0.121 (data provided by notifier)

Besides these studies in which the effects of diquat on birds were studied, the applicant also performed a feeding regime study without active substance (Temple, 2006). The purpose of this study was to investigate the differences in food consumption between male and female mallard ducks and to consider how this might affect the estimate of the LOEL and NOEL for sex specific endpoints. This study demonstrates that following the onset of egg-laying, female exposure may double through increased food consumption, while in the male it remains relatively constant. Thus the NOED based on the daily dose per bird for female specific endpoints tends to be underestimated when the calculation from the NOEL to the NOED is based on the mean feed consumption for both sexes.
Based on this study, female feed consumption can be calculated as follows:

$$\text{Female feed consumption at plateau} = Feed_{week1} + 2 * (Feed_{week5\text{-}9} - Feed_{week1})$$

This approach can be considered as a generic method for calculating female feed consumption and therefore be applied to mallard reproduction studies, unless food avoidance behaviour is noticed.
Based on the above formula, the NOEC of 40 ppm from the Temple&Martin study of 2004a is recalculated to 10 mg a.s./kg bw/d for females only.

13849 N

The lowest available NOEC is 5 mg/kg diet, which is equivalent to a NOEL of 0.6 mg/kg bw/d, based on effects on the number of viable embryo's, the number of live 3 weeks embryo's, the number of hatchlings and the number of 14 day old survivors (Fink&Beavers, 1982b). These parameters were also measured in the new study by Temple et al. of 2009 and they were found not to be affected at 80 and 160 ppm. The Temple study is considered more relevant in exposure duration (diquat is applied only once per season and availability for birds is expected to be much shorter than the 18 weeks exposure used in the old study) and furthermore of better quality (higher statistical power because more replicates were used). Therefore, it is considered that the EU-endpoint of 0.6 mg a.s./kg bw/d based on the Fink&Beavers study of 1982b can be superseded. The relevant endpoints for use in the egg-laying period are the NOEL of 10 mg a.s./kg bw/d for mallard duck and 9.4 mg as/kg bw/d for bobwhite quail (the underlying studies are based on exposure of parents (and eggs) in the egg-laying period). Thus, the NOEL to be used for risk assessment during the egg-laying season is 9.4 mg a.s./kg bw/d.

The Temple et al. study of 2009 was furthermore initiated to give an answer to the question whether outside the breeding period a NOEC of 21.7 mg/kg bw/d for adult birds could be used instead of a NOEC of 9.4 mg/kg bw/d which is the applicable NOEC for the reproductive phase of the birds.
Clinical observations of adults did not show overt signs of toxicity and gross pathology did not show treatment related abnormalities. Feed consumption was significantly reduced during week 1 in the 80 mg diquat cation per kg food (~ 11.1 mg/kg bw/d) but not in the 5 following weeks of exposure. Feed consumption was significantly reduced during week 1, 3, 4, 5 and 6 in the 160 mg diquat cation per kg food (~ 19.7 mg/kg bw/d). Feed consumption after the exposure period was comparable to the control group.
No significant changes in body weight were noticed in any of the two exposure levels.
There was a marked reduction of number of eggs laid during the 6 weeks exposure period in both treatment groups. During the withdrawal phase the 80 mg diquat per kg food treatment group (11.1 mg/kg bw/d) recovered quickly. Egg production in the 160 mg diquat per kg food treatment group (19.7 mg/kg bw/d) remained depressed in the first week of the withdrawal phase, increased during the second week and was comparable to the control during the third and following weeks of the experiment. No other reproductive effects were noticed. If the application of Reglone is during the egg-laying season, the NOEL of 10 mg as/kg bw/d can be used for mallard. For quail a slightly lower NOEL of 9.4 mg as/kg bw/d is available. Therefore, the relevant endpoint during the egg-laying season is 9.4 mg as/kg bw/d.
From the Temple et al. study of 2009 it could be concluded that the use of diquat will not influence the breeding success in the following breeding period. It is evident that birds do not like diquat and probably will look for other types of food. No other effects have been noticed that are relevant for the survival of birds outside the breeding period. Therefore, if the application of Reglone is outside the egg-laying season, the NOEL for duckling development can be used, which is 21.7 mg/kg bw/d based on the Frey et al study from 1995.

Aquatic Organisms

Acute toxicity fish:	LC_{50} = 21 mg /l, 96 h static study (diquat ion) *Oncorhynchus mykiss* LC_{50} = 6.1 mg /l, 96 h flow through study (diquat ion) *Oncorhynchus mykiss*
Long term toxicity fish:	*Pimephales promelas* 34 day study on embryos/larvae - NOEC (larval weight) considered to be 0.12 mg diquat/litre based on mean measured concentration
Bioaccumulation fish:	Low risk of bioaccumulation

Acute toxicity invertebrate:	EC_{50} = 1.2 mg/l, 48 h study *Daphnia magna* (diquat ion)
Chronic toxicity invertebrate:	21-day LC50 was 0.16 mg/l based on nominal concentration *Daphnia magna* (diquat ion). 21-day NOEC = 0.125 mg/l based on nominal concentration.
Acute toxicity algae:	EC_{50} = 0.011 - 1.0 mg/l, 96 h study (diquat ion) *Psuedokirchneriella subcapitata (syn. Rhapidocellis subcapitata and Selenastrum capricornutum)*
Acute toxicity algae - study in presence of sediment	NOEC biomass = 320 µg/l with EbC50 of >320 µg/l. 72 hours (diquat ion).. NOEC growth rate = 320 µg/l with ErC50 of >320 µg/l. 72 hours (diquat ion). *Psuedokirchneriella subcapitata (syn. Rhapidocellis subcapitata and Selenastrum capricornutum)*
Chronic toxicity sediment dwelling organism:	NOEC > 100 mg diquat ion/kg^{-1} sediment (diquat ion). *Chironomus riparius*
Acute toxicity aquatic plants:	No data requirement set at time of review.

Honeybees

Acute oral toxicity:	LD_{50} = 13 µg /bee (diquat ion)
Acute contact toxicity:	LD_{50} = 60 µg /bee (diquat ion)

Other arthropod species

Test species	% Effect
Aphidius rhopalosiphi	An extended laboratory study. At full field rate (i.e. 5 l/ha) there was significant mortality of wasps in the treatment compared to the control. No adverse effects were noted on either fecundity or behaviour.
Coccinella septumpunctata.	Extended laboratory study. Bean plants treated with 'Reglone' at 5 l/ha (1000 g /ha) - equivalent to the maximum field rate. Larvae of *Coccinella septumpunctata* exposed to residues of the test substance. Corrected pre-imaginal mortality of *Coccinella septumpunctata* was 58%, mortality for the positive control was 78.9%. The reproduction rate was: • 640.9 eggs/female in the treatment • 255.3 eggs/female in the control. R value 151.0%.

	Results within the range of historical control variability. IOBC classification : slightly harmful
Trichogramma cacocecie	Laboratory study: exposed to 'Reglone' at 1000 g diquat ion/ha - equivalent to maximum field rate. Parisitisation capacity reduced by 58 %. Exposed adults reduced by 98%.
Chrysoperla carnea	Laboratory study: exposed to 'Reglone' at 1600 g diquat ion/ha. 96% mortality recorded in exposed larvae.
Pterosticus melanarius	Exposed to 'Reglone' at 1600g diquat ion/ha on loamy sand. No lethal or sublethal effects.
Pardosa spp.	Exposed to 'Reglone' at 1600g diquat ion/ha on loamy sand. No lethal or sublethal effects.

Earthworms

Acute toxicity:	LC_{50} = 130 mg as/kg soil 14 day (diquat ion) NOEC > 18 mg as/kg soil 14 day (diquat ion)

Soil micro-organisms

Nitrogen mineralization:	No significant effects up to 50.0 kg diquat/ha
Carbon mineralization:	No significant effects up to 720 kg as/ha

Dragoon (200 g/L diquat)
Additional studies were summarized and evaluated by EPP consultancy (report 120603, 06/2012)

Aquatic Organisms

Acute toxicity aquatic plants (*Lemna minor*):	7-d E_rC_{50} 357 µg form*./L (62.5 µg a.s./L) 7-d E_bC_{50} 173µg form./L (30.2 µg a.s./L) 7-d $NOE_{r,b}C$ 33.7 µg form./L (5.9 µg a.s./L)

* SL formulation containing 203.5 g diquat/L (174.9 g diquat/kg)

Other arthropod species

Test species	Organism stage/Type of test	Value/ Adverse effect
Typhlodromus pyri	Protonymphs 2-3 days old/Dried residues on sprayed sweet-pepper leaves	Mortality: LR_{50} 23.4 mL form*./ha (4.75 g a.s./ha) Reproduction: ER_{50} >64.0 mL form./ha (>13.0 g a.s./ha)
Chrysoperla carnea	Larvae 2-4 days old/Dried residues on sprayed bean plants	Mortality: LR_{50} 4.46 L form./ha (0.90 kg a.s./ha) Reproduction (viable eggs/female/d): 2.0 L form./ha (0.41 kg a.s./ha) +16%**

	4.0 L form/ha (0.81 kg a.s./ha) 18%

* SL formulation containing 202.9 g diquat/L
** + means increase compared to control

Earthworms

Reproduction toxicity (*Eisenia fetida*):	NOEC 248 mg form./kg dw (43.3 mg a.s./kg dw)

Other soil non-target macro-organisms

Reproduction toxicity (*Folsomia candida*):	Mortality: LR_{50} 29.1 mg form./kg dw (5.08 mg a.s./kg dw) Reproduction: EC_{50} 20.4 mg form./kg dw (3.56 mg a.s./kg dw) NOEC 5.6 mg form./kg dw (0.98 mg a.s./kg dw)

Effects on non-target plants

Test substance	Test type	Species	Endpoint	Value
Diquat 200 g/L SL*	Vegetative vigour	*Zea mays*	21-d NOER	<0.0512 L form./ha
			21-d ER_{50}	1.16 L form./ha
		Allium cepa	21-d NOER	0.32 L form./ha
			21-d ER_{50}	1.94 L form./ha
		Beta vulgaris	21-d NOER	0.0102 L form./ha
			21-d ER_{50}	0.153 L form./ha
		Brassica napus	21-d NOER	<0.0512 L form./ha
			21-d ER_{50}	0.242 L form./ha
		Daucus carota	21-d NOER	0.0512 L form./ha
			21-d ER_{50}	0.240 L form./ha
		Glycine max	21-d NOER	0.128 L form./ha
			21-d ER_{50}	0.512 L form./ha

* SL formulation containing 202.9 g diquat/L

Based on the results of the vegetative vigour, the applicant has submitted a resulted HC5 of 0.081154 L form/ha calculated using ETX 2.0.

The applicant has submitted a letter report on " Assessment of the effect of Diquat 200 g/L SL on the emergence of non-target terrestrial plants" . This is a screening test performed with doses of 4-36 L formulation/ha in 9 plant species: *Allium cepa, Avena sativa, Brassica napus, Linum usitatissium, Helianthus annuus, Lycopersicon esculentum, Pisum sp., Daucus carota subsp. Sativus, Lactuca sativa.* In this letter it was concluded that at doses up to 36 L form/ha the emergence and plant weights are not affected. The report was not evaluated for reliability by Ctgb.

Additional studies

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Measured residues of diquat in a Canadian field study (for bird and mammal risk assessment) (evaluated in RIVM-report 11162A00, also available in EU-monograph (Edwards et al. 1991))

A study has been conducted in Canada to assess the potential effect of accidental overspray application on plant cover (bird nesting habitat) and on exposure to residues on their food. Six sites, each comprising a field, slough (prairie pond) and upland, were deliberately sprayed with diquat both on- and off-crop from the air at a rate of 550 g diquat/ha in July and August. Resulting residue values and residue degradation are shown in the Table below.

Diet	**n=**	**Initial residue value, 90thile or max, at 0.55 kg/ha (mg/kg fresh weight)**	**Initial residue value, 90thile or max, RUD for 1.0 kg/ha (mg/kg fresh weight)**	**Initial mean residue value at 0.55 kg/ha (mg/kg fresh weight)**	**Initial mean residue value, RUD at 1.0 kg/ha (mg/kg fresh weight)**	**DT_{50} value (days)**	**21-day TWA residue (mg/kg)**	**f_{twa}**	**r^2**	**Ri[c]**
Terrestrial vegetation	12	60.3 (90th percentile)[a]	110	36.8	66.9	1.59	4.07	0.11	0.85	1
Terrestrial invertebrates (pitfall traps)	2	6.9 (maximum) [a]	12.5	4.80	8.73	1.23	0.40	0.084	0.76	1
Whole seeds	5	42 (maximum) [a]	76	22	40	13.4	14.2	0.61	0.15	3
Seeds without husk	5	64 (maximum) [a]	116	21	38	13.7	9.44	0.62	0.16	3
Crop seed	nd	nd[b]		0.521	nd[b]	4.62	0.155	0.31	0.24	3
Aquatic vegetation	nd	nd[b]		5.23	nd[b]	2.96	1.06	0.20	0.20	3
Aquatic invertebrates	nd	nd[b]		1.61	nd[b]	1.58	0.11	0.068	0.56	3
Aquatic tubers	nd	nd[b]		0.583	nd[b]	7.53	0.256	0.45	0.50	3
Aquatic seeds	nd	nd[b]		1.07	nd[b]	17.5	0.625	0.68	0.16	3

[a] According to SANCO/4145/2000, 90th percentile residue values can be used for acute risk assessment. However, this is only acceptable when the sample size is sufficiently large. In this case, maximum values are given when n<10 and 90th percentile values when n≥10.

[b] Not given, because not relevant for the risk assessment.

[c] Ri = Risk index. Ri 1: acceptable; Ri 3: not acceptable. Ri values refer only to degradation, not to initial values.

Remarks:
The study is considered relevant for spray application of diquat in the Netherlands.
All initial residue values can be used for risk assessment. The recalculated DT_{50} values, 21-day TWA residues and f_{twa} for terrestrial vegetation and invertebrates can also be used for long-term risk assessment. For the other feed substances the fit was not good enough resulting in unreliable DT_{50} values, 21-day TWA and f_{twa} (Ri = 3).

The residue data from the Canadian field study are based on invertebrates sampled with pitfall traps. Thus, foliar dwelling invertebrates are not included, whilst it cannot be excluded that these will be exposed as well, and may be exposed to a higher degree because no crop interception takes place. However, two field studies with paraquat in which residues on invertebrates were measured after application of 1.1 kg paraquat/ha in an apple orchard and

melon field in Spain (Bakker (2004 and 2005), evaluated in RIVM-report 10994A01), show a mean (over different invertebrate groups) maximum (in time) residue value of 6.43 mg a/s/kg for foliar dwelling/flying invertebrates. Considering the similarities in physico-chemical and fate/behaviour properties of paraquat and diquat, which makes a comparison of residue data acceptable, it can be concluded that the RUD value of 8.73 mg a.s./kg for diquat based on pitfall samples only, is not likely to result in an underestimation of exposure, and is therefore acceptable.

Metabolites of diquat

Diquat is considered immobile in the environment due to its strong binding affinity to soil and sediment. Hydrolytic degradation in water has not been reported to occur at environmentally relevant pH. Photolytic degradation DT50 was <7 d (UK summer conditions) but no relevant metabolites were identified. In general, no relevant metabolites above 10% have been identified in water, soil or sediment. Therefore metabolites will not be considered in this risk assessment.

Note to the dose rate use in risk assessment:
The applicant lowered the application rate. Therefore this risk assessment can be considered as very worst case. Thus, the risk remains acceptable.

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 current application for extension of mutual recognition this means that the UK risk assessment should be used.

However, it is known that diquat can cause problems in birds (evaluation of Reglone, C164.3.8, 01/2006). A refined risk assessment was required.
In a later stage, from protected studies in birds, it was shown that diquat can cause problems in the egg-laying period (evaluation of Reglone, C187.3.14, 11/2007). This has lead to a discussion about the egg-laying period for birds. Finally, for the use of Reglone as dessicant in potatoes the following was concluded:

… *the standards for birds are met for the desiccation use of Reglone in potatoes, under the condition that the application takes place after the 15th of July and that within 2 years the applicant has to demonstrate that no unacceptable effects for birds will result from this application after 15 July.'*

The currently proposed extension of uses concerns the application of Dragoon as weed control in the onion family (pre-emergence/pre-planting of the crop (February - June), BBCH 00-09), and not as a desiccant. Even though such pre-emergence use, after refinements, was found to be acceptable in the initial application of mutual recognition (2012), in view of new data requirements the current risk assessment of Dragoon in the proposed use as weed control in the onion family has been performed according to the EFSA Guidance Document for Birds and Mammals (2009) and is given below.

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

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

Table E.1 Overview of toxicity data for birds for substance Diquat

	Endpoint	Value
Acute toxicity to birds:	LD_{50}	83 mg a.s./kg bw
Reproductive toxicity to birds:	NOEL	5 ppm mg a.s./kg bw/d = 0.6 mg/kg bw/d

Toxicity endpoints in Tabel E.1are both derived from tests in Mallard duck.

Additionally to the acute toxicity value in the LoEP of the review report, in the DAR (March 1996) another acute toxicity study with diquat was presented:
- test species: Partridge
- endpoint: LD_{50} = 158 mg a.s./kg bw.

Also, another reproductive toxicity study with diquat was presented in the DAR (March 1996):
- test species: Bobwhite quail
- endpoint: NOEL = 9.4 mg a.s./kg bw/d.

7.1.1 Natural food and drinking water

Sprayed products
The risk assessment for birds is carried out following the latest guidance document by EFSA (*Anonymous 2009: Guidance Document on risk assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. European Food Safety Authority*), hereafter cited as EFSA/2009/1438.
According to this guidance document the short term exposure scenario is not required anymore. Therefore only the acute and long-term risks are estimated below.

Acute dietary risk assessment: screening step and Tier 1 for sprayed products according to EFSA/2009/1438

According to the GD (EFSA 2009) it is recommended to calculate a geometric mean if acute toxicity studies from more than one species are available. The geometric mean from the available studies is 115 mg a.s./kg, which will be used for the acute risk assessment.

The proposed use of the product is as weed contol in the onion family at BBCH 00-09. This corresponds with a bare soil scenario.
For the application in bare soils (and hop), the indicator species is a small granivorous bird.
For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. In this case however, a single application is proposed, thus MAF is 1.

The DDD_m is calculated as application rate * shortcut value * MAF_{90}. The DDD_m is compared to the relevant toxicity figure. TER should be above the trigger (10) for an acceptable risk.
The screening assessment is shown in Table E.2a.

Table E.2a Acute risk for birds (screening assessment)

Crop	Substance	Indicator species	LD_{50} [mg a.s./ kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_A	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
Bare soils and hop	Diquat	Small granivorous bird	115	0.4	24.7	1	9.88	11.6	10

The result in Table E.2a shows that the screening assessment TER value is above the required trigger of 10 for acute exposure to diquat, so the proposed use meets the standards laid down in the RGB. Therefore a Tier 1 assessment is not conducted.

Chronic risk assessment: screening step and Tier 1 for sprayed products according to

For the application in bare soils (and hop), the indicator species is a small granivorous bird. For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. In this case however, a single application is proposed, thus MAF is 1.

The DDD_m is calculated as application rate * shortcut value * MAF_{90} * TWA. The DDD_m is compared to the relevant toxicity figure. TER should be above the trigger (5) for an acceptable risk. Chronic TER values are presented in Tables 3a and 3b.

Table E.3a Chronic risk for birds (screening assessment)

Crop	Substance	Indicator species	NOEL [mg a.s./kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_{LT}	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	TWA			
Bare soils and hop	Diquat	Small granivorous bird	0.6	0.4	11.4	0.53	2.42	**0.25**	5

The result in Table E.3a shows that the screening assessment TER value is below the required trigger of 5 for chronic exposure to diquat, so the proposed use does not meet the standards laid down in the RGB. Therefore a Tier 1 assessment is conducted.

In the Tier 1 assessment, indicator species for the application in bare soils and hop (BBCH <10) are a small granivorous bird (finch), a small omnivorous bird (lark) and a small insectivourous bird (wagtail). For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. In this case however, a single application is proposed, thus MAF is 1.

Table E.3b Chronic risk for birds (Tier 1 assessment) for bare soil applications in the onion family (BBCH 00-09)

Substance	Generic focal species	NOEL [mg a.s./kg bw]	DDD			DDD [mg a.s./ kg bw/d]	TER_{LT}	Trigger
			Appl. rate [kg a.s./ha]	SV_{90}	TWA			
Diquat	Small granivorous bird “finch”	0.6	0.4	11.4	0.53	2.42	**0.25**	5
Diquat	Small omnivorous bird “lark”	0.6	0.4	8.2	0.53	1.74	**0.35**	5
Diquat	Small insectivorous bird “wagtail”	0.6	0.4	5.9	0.53	1.25	**0.48**	5

Table E.3b shows that all Tier 1 assessment TER values are below the required trigger of 5 for chronic exposure to diquat, thus a high risk to birds is expected. Further refinement of the risk is needed.

Refined risk assessment

Relevant endpoints

For the chronic risk, the applicant has a LoA for the additional studies from Syngenta. The applicant proposes to use the NOEC of 9.4 kg/kg bw/d based on the new studies, also for the risk outside the breeding season, for which a NOEC of 21.7 mg a.s./kg /d was previously accepted. According to EFSA 2009, the risk assessment should be performed either with the lowest from the relevant chronic endpoints or the LD50/10, which is 11.5 mg/kg bw/d. Since the lowest NOEC for the reproduction studies is below this value, namely 9.4 mg/kg bw/d,

this value will be used in risk assessment, as proposed by the applicant.

Table E.3c Chronic risk for birds (Tier 1 assessment) for bare soil applications in the onion family (BBCH 00-09)

Substance	Generic focal species	NOEL [mg a.s./kg bw]	DDD			DDD [mg a.s./ kg bw/d]	TER_{LT}	Trigger
			Appl. rate [kg a.s./ha]	SV_{90}	TWA			
Diquat	Small granivorous bird "finch"	9.4	0.4	11.4	0.53	2.42	**3.89**	5
Diquat	Small omnivorous bird "lark"	9.4	0.4	8.2	0.53	1.74	5.41	5
Diquat	Small insectivorous bird "wagtail"	9.4	0.4	5.9	0.53	1.25	7.52	5

Table E.3c shows that refined Tier 1 assessment TER values for small omnivorous and small insectivorous birds are above the required trigger of 5 for chronic exposure to diquat, whereas the TER value is below the trigger of 5 for small granivorous birds. Thus, a risk to birds cannot be excluded. Further refinement of the risk to small granivorous birds is needed.

Follow up
After the first risk assessment, the applicant lowered the maximum dose rate to 0.3 kg a.s./ha. The adapted risk assessment is given in Table E.3d.

Table E.3d Chronic risk for birds (Tier 1 assessment) for bare soil applications in the onion family (BBCH 00-09)

Substance	Generic focal species	NOEL [mg a.s./kg bw]	DDD			DDD [mg a.s./ kg bw/d]	TER_{LT}	Trigger
			Appl. rate [kg a.s./ha]	SV_{90}	TWA			
Diquat	Small granivorous bird "finch"	9.4	0.3	11.4	0.53	1.81	5.2	5
Diquat	Small omnivorous bird "lark"	9.4	0.3	8.2	0.53	1.30	7.2	5
Diquat	Small insectivorous bird "wagtail"	9.4	0.3	5.9	0.53	0.94	10	5

Based on the calculations presented in table E.3d, an acceptable risk to birds is expected.

Risk for birds through drinking water
Leaf scenario
The leaf scenario is not relevant for any of the proposed applications, and is therefore not assessed.

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

According to EFSA/2009/1438 the puddle scenario is relevant for the acute (this section) and reproduction scenario (see below). Generic focal species is a small granivorous bird (body weight 15.3 g) with a DWR (daily drinking water rate) of 0.46 L/kg bw/d.
According to EFSA Guidance Document for Birds and Mammals (2009), no specific calculations are necessary when the ratio of effective application rate (in g a.s./ha) to

relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc <500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥500 L/kg). The mean Koc of diquat is 2184750 L/kg. The ratio of application rate to acute endpoint is 400 g a.s./ha / 83 mg a.s./kg bw = 4.8, and the ratio of application rate to chronic endpoint is 400 g a.s./ha / 0.6 mg a.s./kg bw/d = 667. Neither ratio exceeds the trigger of 3000. The risk due to exposure to drinking water from puddles is concluded to be acceptable.

7.1.2 Secondary poisoning

The risk as a result of secondary poisoning is assessed based on bioconcentration in fish. Since the log Kow of diquat < 3 (-4.6), the potential for bioaccumulation is considered low and no further assessment is deemed necessary.

Conclusions birds

The application for extension of the mutual recognition of the product complies with the RGB for exposure of birds via natural food, 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 of the active substance diquat 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.4. Because the application for authorisation concerns a herbicide, also the effects on macrophytes (aquatic plants) are evaluated.

Table E.4. Overview toxicity endpoints for aquatic organisms

Substance	Organism	Lowest		Toxicity value
		$L(E)C_{50}$ [mg/L]	NOEC [mg/L]	[µg/L]
diquat	*Acute*			
	Algae	0.011		11
	Daphnids	1.2		1200
	Fish	6.1		6100
	Macrophytes	0.0302*		30.2
	Chronic			
	Daphnids		0.125	125
	Fish		0.12	120

*no information in the DAR. Endpoint derived from a study with the formulated product, submitted by AgriChem for the current application.

No information on macrophytes is available in the DAR. However according to current guidance (SANCO/3268/2001 rev. 4), a test on macrophytes is required for herbicides. For the current request, the study on *Lemna minor* was provided by the applicant. The resulting TERs for macrophytes are included in the table below.

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 tables E.5a and E.5b TER values for aquatic organisms are shown.

Table E.5a TER values: acute

use	Substance	PIEC [µg a.s./L]	TER_{st} (trigger 10) Algae	TER_{st} (trigger 100) Daphnid	TER_{st} (trigger 100) Fish	TER_{st} (trigger 10) Macrophytes
Weed control	diquat	0.208	52.9	5769	29327	145

Table E.5b TER values : chronic

use	Substance	TER_{lt} (trigger 10) Daphnid	TER_{lt} (trigger 10) Fish
Weed control	diquat	601	577

Taking the results in Tables E.5a and E.5b into account, the acute TERs for algae and macrophytes are above the relevant Annex VI trigger of 10, the acute TERs for fish and *Daphnia magna* are above the relevant Annex VI triggers of 100. The chronic TERs for fish and *Daphnia magna* are above the relevant Annex VI triggers of 10.

Therefore, the proposed uses of the active substance diquat meet the standards for aquatic organisms as laid down in the RGB.

7.2.2 Risk assessment for bioconcentration

Since logKow of diquat is < 3 (-4.6), experimental data are not required. Considering the low log Kow, the risk for bioconcentration is small. Therefore the active substance diquat meets the standards for bioconcentration as laid down in the RGB.

7.2.3 Risk assessment for sediment organisms

The water–sediment study indicates that over 10% of diquat is found in the sediment after 14 days, however the the NOEC for daphnids is above 0.1 mg/L, therefore a low risk is expected for sediment organisms. This is confirmed by toxicity data on *Chironomus.*

The NOEC value for *Chironomus* is ≥ 100 mg/kg sediment. When this value is examined against the highest PIEC in sediment of 0.1, the TER value is >1000, which is above the trigger of 10. Therefore, the active substance diquat meets the standards for sediment organisms as laid down in the RGB.

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 sprayed food (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 (UK).

However, it is known that diquat can cause problems in mammals (evaluation of Reglone, C164.3.8, 01/2006). A refined risk assessment is required. To indicate the risk for Dragoon in the proposed use as weed control in the onion family, risk assessment according to the EFSA Guidance Document for Birds and Mammals (2009) has been performed and is given below.

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

The threshold value for mammals is based on the trigger from the RGB. This means that the Toxicity-Exposure Ratio (TER) for acute exposure should be ≥ 10 and TER for chronic exposure should be ≥ 5. Dietary toxicity is not taken into account for mammals.

Table E.6 presents an overview of toxicity data.

Table E.6 Overview of toxicity data for mammals for substance Diquat

	Endpoint	Value
Acute toxicity to mammals:	LD_{50}	214 mg a.s./kg bw
Reproductive toxicity to mammals:	NOEL	8.9 mg a.s./kg bw/d

7.1.1 Natural food and drinking water

Sprayed products
The risk assessment for mammals is carried out following the latest guidance document by EFSA (*Anonymous 2009: Guidance Document on risk assessment for Birds & Mammals on request from EFSA. EFSA Journal 2009; 7(12):1438. European Food Safety Authority*), hereafter cited as EFSA/2009/1438.
According to this guidance document the short term exposure scenario is not required anymore. Therefore only the acute and long-term risks are estimated below.

Acute dietary risk assessment: screening step for sprayed products according to EFSA/2009/1438

The proposed use of the product is as weed contol in the onion family at BBCH 0-9. This corresponds with a bare soil scenario.
For the application in bare soils (and hop), the indicator species is a small granivorous mammal. For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. In this case however, a single application is proposed, thus MAF is 1.

The DDD_m is calculated as application rate * shortcut value * MAF_{90}. The DDD_m is compared to the relevant toxicity figure. TER should be above the trigger (10) for an acceptable risk.
The screening assessment is shown in Table E.7.

Table E.7 Acute risk for mammals (screening assessment)

Crop	Substance	Indicator species	LD_{50} [mg a.s./ kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_A	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	MAF_{90}			
Bare soils and hop	Diquat	Small granivorous mammal	214	0.4	14.4	1	5.76	37	10

As the TER for the screening assessment is above the trigger of 10, the acute risk to mammals is acceptable.

Chronic risk assessment: screening step for sprayed products according to EFSA/2009/1438

For the application in bare soils (and hop), the indicator species is a small granivorous mammal. For uses with frequency > 1, a MAF (Multiple Application Factor) may be applicable. In this case however, a single application is proposed, thus MAF is 1.

The DDD_m is calculated as application rate * shortcut value * MAF_{90} * TWA. The DDD_m is compared to the relevant toxicity figure. TER should be above the trigger (5) for an acceptable risk. The screening assessment is shown in Table E.8.

Table E.8 Chronic risk for mammals (screening assessment)

Crop	Substance	Indicator species	NOEL [mg a.s./kg bw]	DDD			DDD_m [mg a.s./ kg bw/d]	TER_{LT}	Trigger
				Appl. rate [kg a.s./ha]	SV_{90}	TWA			
Bare soils and hop	Diquat	Small granivorous mammal	8.9	0.4	6.6	0.53	1.40	6.4	5

As the TER for the screening assessment is above the trigger of 10, the acute risk to mammals is acceptable.

Risk for mammals through drinking water

Puddle scenario

The exposure of mammals to drinking water from puddles formed on the field after rainfall is relevant for the proposed field uses of diquat.

According to EFSA/2009/1438 the puddle scenario is relevant for the acute and reproduction scenario. Generic focal species is a small granivorous mammals (body weight 21.7 g) with a DWR (daily drinking water rate) of 0.24 L/kg bw/d.
According to EFSA Guidance Document for Birds and Mammals (2009), no specific calculations are necessary when the ratio of effective application rate (in g a.s./ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc <500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥500 L/kg). The mean Koc of diquat is 2184750 L/kg. The ratio of application rate to acute endpoint is 400 g a.s./ha / 214 mg a.s./kg bw = 1.9, and the ratio of application rate to chronic endpoint is 400 g a.s./ha / 8.9 mg a.s./kg bw/d = 44.9. Neither ratio exceeds the trigger of 3000. The risk due to exposure to drinking water from puddles is concluded to be acceptable.

7.3.2 Secondary poisoning

The risk as a result of secondary poisoning is assessed based on bioconcentration in fish. Since the log Kow of diquat < 3 (-4.6), the potential for bioaccumulation is considered low and no further assessment is deemed necessary.

Conclusions mammals

The application for extension of the mutual recognition of the product complies with the RGB for exposure of mammals via natural food, 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 (UK).

However, a bee incident was reported in potatoes after use of Reglone. Therefore it was concluded that for the product Reglone, the following restriction sentence should be placed on the label:

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik

dit product niet wanneer bloeiende onkruiden aanwezig zijn.

Although the proposed concentration rates for Dragoon are lower than for Reglone, the HQ for the use in desiccation in potatoes and cereals is 61.5, which is above the trigger of 50. Therefore this restriction sentence should also be placed on the label for Dragoon.

Conclusions bees
The application for mutual recognition of the product complies with the RGB, if the following warning sentence is place on the label:

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn.

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. For the risk assessment we refer to the member state of the original authorisation (UK).

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 arthopods 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 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.

However, no Tier 1 data for *T. pyri* or other mites are available. For *A. rhopalosiphi* an extended laboratory test showed 58% effect on mortality at 1 kg a.s./ha, no effects on reproduction were found. Although the effects are > 50 % at the lowest rate tested, it can be assumed that the effects will be < 50% at the maximum rate of 0.8 kg a.s./ha (see also table E.9). Since the current application for extension of the mutual recognition of the product concerns the use as weed control in the onion family at an application rate of 0.4 kg a.s./ha, effects are also expected to be <50%. The risk was assessed for this application rate and is presented below.

The applicant has submitted two extended lab studies conducted with the formulation Diquat 200 g/L SL and *T. pyri* and *Chrysoperla carnea*. The results of theses studies are discussed below.

Table E.9 HQ-values for *A. rhopalosiphi* and *T. pyri*

	Application rate (kg a.s./ha)	MAF[1]	Drift factor/ Vegetation factor[2]	Safety factor[2]	LR_{50} (kg a.s./ha)	HQ
Off-field						
A. rhopalosiphi	0.4	1	0.1	5	<1.0	>0.2

13849 N						
T.pyri	0.4	1	0.1/10	5	0.00475 (lethal) > 0.013 (sub-lethal)	**4.2** <1.5

[1]: Multiple Application Factor

[2]: off-field: default drift = 10%, thus drift factor =10/100, vegetation dilution factor = 10 (not applicable for *A. rhopalosipohi* since whole plants were sprayed), safety factor = 5 (default value for second tier assessment)

The results presented in Table E.9 show that the off-field risk to *A.rhopalosiphi* can be considered acceptable for the use as weed control in the onion family at the proposed application rate. In the case of *T.pyri*, however, there is an off-field risk from diquat.

Also some additional species were tested. For *Coccinella septempuntata,* at concentrations of 1 kg diquat ion/ha, corrected pre-imaginal mortality was 58%. The reproduction rate was 640.9 eggs/female. In the case of *Pterostichus melanarius* and *Pardosa* spp.no lethal and sub-lethal effects were measured at 1.6 kg diquat ion/ha. For *Trichogramma cacocecie* a risk could be expected based on a standard laboratory study, however in the DAR it was concluded (and accepted) that the data for *A. rhopalosiphi* was more applicable and it was more appropriate to use this species.

For *Crysoperla carnea* 96% mortality occurred at 1.6 kg a.s./ha. In the extended lab study submitted by the applicant, the LR50 is 0.9 kg a.s./ha and at 0.81 kg a.s./ha the resulting effect was 18% reduction of viable eggs/female/day. Since the effects are below 50% at relevant application rates, it can be concluded that the risk to *Crysoperla* carnea are low.

Overall the results show that *T.pyri* is the most sensitive species. Therefore, drift reducing measures are required in order to demonstrate a low off-field risk to *T. pyri*.

On the label, the following restriction sentences is included:

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een bufferzone van 1,5 m.

With this sentence, the drift will be lowered with more than a factor of 5, meaning that the off-field HQ is also below 2. Thus this restriction sentences is also protective for this extension.

However, for clarity reasons, the restriction sentence needs to be updated:

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een teeltvrije zone van 1.5 m (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens).

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 (UK).

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 (UK).

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 (UK).

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 risk assessment for non-target plants 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.

The applicant has submitted a vegetative vigour test and a statement for the effects on seedling emergence. The lowest EC50 of 0.031 kg a.s./ha from the vegetative vigour test was recorded for sugar beet. Based on the results of the vegetative vigour, the applicant has submitted a resulted HC5 of 0.081154 L form/ha (0.0162 kg a.s./ha) calculated using ETX 2.0. From the seedling emergence statement it was concluded by the applicant that no effects were seen up to the maximum test dose of 36 L form/ha (7.2 kg a.s./ha).

A TER is calculated with the lowest EC_{50} value from a laboratory test with higher plants and the exposure concentration. See table E.10. for TER calculation.

Table E.10: 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
Weed control	diquat	0.4	-	4.7	0.019	0.031	**1.65**	5

* For the Netherlands, the amount of drift for field crops is currently set at 4.7%. This is based by taking into account a total distance of the evaluation zone of 1.5-2.5 m from the centre of the last crop row. The standard position of the last spraying nozzle is assumed to be above the centre of the last crop row.

As it can be seen from the Table E.10 the TER is below the trigger of 5. Next, a probabilistic approach will be employed. Therefore, the risk can be determined by using the HC5 data. As this is considered Tier II assessment, the trigger value is set to 1.

Table E.11: 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)	HC_5 [kg a.s./ha]	TER	Trigger value
Weed control	diquat	0.4	-	4.7	0.019	0.0162	**0.86**	1

The result presented in Table. E11 shows that the TER is below the trigger of 1, thus a risk to non-target plants from the proposed use as weed control in the onion family cannot be excluded.

In the letter submitted by the applicant on 10/03/2011, drift reducing measures such as 50% drift reducing nozzles are proposed. This means that the drift will be reduced to 1.7% resulting in a TER value of 2.38 for the use as weed control.

The applicant proposes the following restriction sentence to be placed on the label:

"*Om niet tot de doelsoorten behorende planten te beschermen is toepassing op perceelsranden uitsluitend toegestaan indien gebruikt wordt gemaakt van driftarme spuitdoppen*".

Given that the restriction measures proposed for the non-target arthropods are more strict, a new restriction sentence is proposed by Ctgb (see below).

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een teeltvrije zone van 1.5 m (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens).

The product does comply with RGB provided that a restriction sentence is placed on the label.

Conclusions any other organisms

The application for mutual recognition of the product complies with the RGB for the aspects earthworms, soil micro-organisms and activated sludge.
The proposed application of the product complies with the RGB for the aspects non-target arthropods (off-field) and terrestrial non-target plants provided that a restriction sentence is placed on the label.

7.6 Appropriate ecotoxicological endpoints relating to the product and approved uses

See List of Endpoints.

7.7 Data requirements

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7.8 Restriction sentences

The following restriction sentences were proposed by the applicant:

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een bufferzone van 1,5 m.

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn.

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

In the WG (legal instructions):

Om niet tot de doelsoorten behorende geleedpotigen / insecten en niet tot de doelsoorten behorende planten te beschermen is de toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met een kantdop en een teeltvrije zone van 1.5 m (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens).

Gevaarlijk voor bijen en hommels. Om de bijen en andere bestuivende insecten te beschermen mag u dit product niet gebruiken op in bloei staande gewassen of op niet-bloeiende gewassen wanneer deze actief bezocht worden door bijen en hommels. Gebruik dit product niet wanneer bloeiende onkruiden aanwezig zijn.

7.9 Overall conclusions regarding the environment

It can be concluded that:

1. all proposed applications of the active substance diquat meet the standards for birds as laid down in the RGB.
2. all proposed applications of the active substance diquat meet the standards for aquatic organisms as laid down in the RGB.
3. the active substance diquat meets the standards for bioconcentration as laid down in the RGB.
4. all proposed applications of the active substance diquat meet the standards for mammals as laid down in the RGB.
5. for the risk assessment for bees, Ctgb refers to the member state of the original authorisation (UK).
6. for the risk assessment for non-target arthropods in-field, Ctgb refers to the member state of the original authorisation (UK).
7. all proposed applications of the active substance diquat meet the standards for non-target arthropods (off-field) as laid down in the RGB provided that drift reducing measures are taken.
8. for the risk assessment for earthworms, Ctgb refers to the member state of the original authorisation (UK).
9. for the risk assessment for soil micro-organisms, Ctgb refers to the member state of the original authorisation (UK).
10. for the risk assessment for activated sludge, Ctgb refers to the member state of the original authorisation (UK).
11. all proposed applications of the active substance diquat meet the standards for non-target plants as laid down in the RGB, provided that drift reducing measures are taken.

8 Efficacy

The applicant has claimed a label extension; the application against annual broadleaved weeds in onion family at 1,5-2 l/ha.

The product is authorised in United Kingdom for the professional use in edible crops at 1,5 – 2 l/ha. Climatological and environmental circumstances relevant for the aspect efficacy in the claimed uses in The Netherlands are comparable to those in the United Kingdom. The cultivation method in edible crops is similar in both countries and there are no country-specific situations for the use of Dragoon as a herbicide and desiccant 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 (United Kingdom).

For other reasons than the efficacy evaluation the dose rate has to be reduced to 1,5 l/ha. As 1,5-2 l/ha was evaluated as the effective dose rate for a good and consistent weed control in different situations, applied at 1,5 l/ha it is expected that weed control is not sufficient in all situations. Therefore a warning sentence is placed on the label:
In de teelt van ui-achtigen kan de werking onvoldoende zijn.

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 (United Kingdom).

8.3 Resistance

A resistance management sentence is not necessary.

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 the United Kingdom of the product Dragoon, authorisation number MAPP 13927. For the evaluation is referred to the original authorisation as the United Kingdom has adopted the Uniform Principles.

The evaluation of the Dutch specific aspects 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

The current label can be maintained.

The following restriction sentences have to be included in the legal instructions:
In de teelt van ui-achtigen kan de werking onvoldoende zijn.

In ui-achtigen Dragoon toepassen in 500 l water per ha. In de overige toepassingen Dragoon toepassen in 200-500 l water per ha.

Voor toepassing in aardappelen die worden opgeslagen dient een periode van 14 dagen te worden aangehouden tussen toepassing en oogst om de aardappelen voldoende te laten afharden.

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, kg as/ha	Water L/ha min / max		
New uses												
WEED CONTROL - OVERALL												
11	NL	Onion family	F	Annual dicotylodonous weeds	Overall spraying	Pre-emergence // Pre-planting, february – june BBCH 0 - 9	1	1.5 L product/ha	0.3 kg as/ha	500		

Existing uses

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pest controlled ©	Formulation		Application					Application rate per treatment						PHI days (days)	Remarks:
(a)	(NL)	(a)	(b)		Type (d-f)	Conc. Of as g/L (i)	method kind (f-h)	growth stage & season (j)	number (k)		interval between applications (days)	kg as/hL		water L/ha		kg as/ha		(l)	(m)
									min	max		min	max	min	max	min	max		
WEED CONTROL - OVERALL																			
Potatoes	NL	Dragoon	F	Chickweed, cleavers, knotgrass and annual nettle	SL	200	Overall spraying	Pre-emergence, spring	1	1		0,06	0,2	200	500	0,3	0,4		
Beetroot	NL	Dragoon	F	Chickweed, cleavers, knotgrass and annual nettle	SL	200	Overall spraying	Pre-emergence, spring	1	1		0,06	0,2	200	500	0,3	0,4		
Leafy vegetables	NL	Dragoon	F	Chickweed, cleavers, knotgrass and annual nettle	SL	200	Overall spraying	Pre-emergence // Pre-planting, spring // summer	1	1		0,06	0,2	200	500	0,3	0,4		
Pulses	NL	Dragoon	F	Chickweed, cleavers, knotgrass and annual nettle	SL	200	Overall spraying	Pre-emergence // Pre-planting, spring	1	1		0,06	0,2	200	500	0,3	0,4		
Fruiting vegetables	NL	Dragoon	F	Chickweed, cleavers, knotgrass and annual nettle	SL	200	Overall spraying	Pre-emergence // Pre-planting, spring // summer	1	1		0,06	0,2	200	500	0,3	0,4		
Cabbages	NL	Dragoon	F	Chickweed, cleavers, knotgrass and annual nettle	SL	200	Overall spraying	Pre-emergence // Pre-planting, spring // summer	1	1		0,06	0,2	200	500	0,3	0,4		
Root vegetables and tubers	NL	Dragoon	F	Chickweed, cleavers, knotgrass and annual nettle	SL	200	Overall spraying	Pre-emergence // Pre-planting, spring // summer	1	1		0,06	0,2	200	500	0,3	0,4		
stalk vegetables	NL	Dragoon	F	Chickweed, cleavers, knotgrass and annual nettle	SL	200	Overall spraying	Pre-emergence // Pre-planting, spring // summer	1	1		0,06	0,2	200	500	0,3	0,4		
Flower bulb and Flower corm crops	NL	Dragoon	F	Chickweed, cleavers, knotgrass and annual nettle	SL	200	Overall spraying	Pre-emergence // Pre-planting, spring // summer	1	1		0,06	0,2	200	500	0,3	0,4		

DESSICATION																			
Potatoes	NL	Dragoon	F	Dessication	SL	200	Overall spraying	late summer // autumn, BBCH 91-97	1	1		0,16	0,4	200	500	0,8	0,8	14 for stored potatoes	

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

Appendix 2 Reference list

No studies submitted.

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.