12629 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 9 februari 2017 is van

ADAMA Registrations B.V.
Arnhemseweg 87
3832 GK LEUSDEN

een aanvraag tot wijziging van het Wettelijk Gebruiksvoorschrift (WG) ontvangen voor het middel

Goltix SC

op basis van de werkzame stof metamitron.

De aangevraagde wijziging betreft het wegnemen van de volgende restrictiezin opgelegd bij de herregistratie (Collegebesluit van 31 augustus 2016) om tot een acceptabel risico voor kleine herbivore zoogdieren te komen :
Om de zoogdieren te beschermen is toepassing in de onbedekte teelt van lelies uitsluitend toegestaan voor het koppen van het gewas of voor volledige bloei (uiterlijk tot BBCH 65).
Aanvrager heeft hiertoe voor het na-opkomst LDS gebruik in de onbedekte teelt van lelie een verlaging van de dosering van 0,5-1,0 naar 0,5 l product/ha aangevraagd. Deze dosisverlaging is bedoeld als (verdere) verfijning voor het acute risico voor kleine herbivore zoogdieren.

HET COLLEGE BESLUIT tot toelating van de aangevraagde wijziging van het Wettelijk Gebruiksvoorschrift.

Alle bijlagen vormen een onlosmakelijk onderdeel van dit besluit.

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.

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

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Als gevolg van dit besluit wordt het WG aangepast. Daarom wordt het volgnummer van het etiket verhoogd van W4 naar W.5.

De restrictie die het gebruik in lelie beperkt tot gewasstadia kleiner of gelijk aan BBCH 65 vervalt, maar tegelijkertijd wordt de maximale dosering van het na-opkomst LDS gebruik in de onbedekte teelt van lelie beperkt tot 0,5 l product/ha. Vanwege die beperking moeten respijttermijnen worden vastgesteld voor afleveren en opgebruik van verpakkingen met volgnummer W.4. Omdat geen risico’s zijn verbonden aan opgebruik volgens de voorschriften op het oude etiket kunnen de maximale respijttermijnen worden toegekend, conform het verzoek van de aanvrager.

Het nieuwe gebruiksvoorschrift en de nieuwe etikettering dienen bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. Voor details over W-coderingen en respijttermijnen vastgesteld volgens het besluit beleidsregel respijttermijnen voor gewasbeschermingsmiddelen (Staatscourant 31 augustus 2016), wordt verwezen naar bijlage I; onder **4 Aflever- en opgebruiktermijnen voor oude etiket.**

2 WETTELIJKE GRONDSLAG

Besluit	artikel 45 van de Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Rgb d.d. 13 juni 2011 en Evaluation Manual 1.1

3 BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

Niet beoordeeld. De aangevraagde wijziging van GAP en WG zijn een beperking ten opzichte van hetgeen beoordeeld en acceptabel bevonden is in de herregistratie, Collegebesluit van 31 augustus 2016, en valt daarmee onder de risico enveloppe.

3.2 Analysemethoden

Niet beoordeeld. De aangevraagde wijziging van GAP en WG zijn een beperking ten opzichte van hetgeen beoordeeld en acceptabel bevonden is in de herregistratie, Collegebesluit van 31 augustus 2016, en valt daarmee onder de risico enveloppe.

3.3 Risico voor de mens

Niet beoordeeld. De aangevraagde wijziging van GAP en WG zijn een beperking ten opzichte van hetgeen beoordeeld en acceptabel bevonden is in de herregistratie, Collegebesluit van 31 augustus 2016, en valt daarmee onder de risico enveloppe.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor zoogdieren verwacht. De overige deelaspecten zijn niet beoordeeld, omdat de aangevraagde wijziging van GAP en WG een beperking is ten opzichte van hetgeen beoordeeld en acceptabel bevonden is in de herregistratie, Collegebesluit van 31 augustus 2016 en de eerdere aanpassing van het WG, Collegebesluit 30 december 2016, en daarmee valt onder de risico enveloppe .

3.5 Werkzaamheid

Niet beoordeeld. De aangevraagde dosering van de LDS toepassing in lelie (onbedekte teelt) is reeds beoordeeld en acceptabel bevonden in de herregistratie, Collegebesluit van 31 augustus 2016 en de eerdere aanpassing van het WG, Collegebesluit 30 december 2016.

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 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Ede, 4 augustus 2017

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

12629 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

1 Aanvraaginformatie

Aanvraagnummer:	20170246 NLWG
Type aanvraag:	aanvraag tot wijziging van het Wettelijk Gebruiksvoorschrift
Middelnaam:	Goltix SC
Formele registratiedatum: *	28 februari 2017
Datum in behandeling name:	7 juni 2017

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

2 Stofinformatie

Werkzame stof	Gehalte
metamitron	700G/L

De stof metamitron is per 1 september 2009 geplaatst op Annex I van Richtlijn 91/414/EEG (Dir 2008/125/EC d.d. 19 december 2008) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 augustus 2019.

3 Toelatingsinformatie

Toelatingsnummer:	12629 N
Expiratiedatum:	1 september 2026
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel
W-codering professioneel gebruik:	W.5
Toelatingsnummer:	12629 N

4 Aflever- en opgebruiktermijnen voor oude etiket

Vorige W-codering professioneel gebruik:	W.4
Aflevertermijn professioneel gebruik:	1 februari 2018
Opgebruiktermijn professioneel gebruik:	1 februari 2019

5 Verpakkingsinformatie

Aard van het preparaat:	Suspensie concentraat

12629 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel Goltix SC

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

Pictogram	GHS07 GHS09
Signaalwoord	WAARSCHUWING
Gevarenaanduidingen	H302 Schadelijk bij inslikken. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P102 Buiten het bereik van kinderen houden. P270 Niet eten, drinken of roken tijdens het gebruik van dit product. P280C Beschermende handschoenen en beschermende kleding dragen. P501 Inhoud/verpakking afvoeren naar .... SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.

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BIJLAGE III WG van het middel

WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het professionele gebruik als onkruidbestrijdingsmiddel 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 toepassingen per teeltcyclus of per 12 maanden	Maximaal aantal liter middel per ha per teeltcyclus	Minimum interval tussen toepassingen in dagen.
Bieten	voor opkomst	eenjarige breedbladige onkruiden en straatgras[1]	1,5-3 L/ha[2]	1 per teeltcyclus	5 L/ha	-
	rond opkomst	eenjarige breedbladige onkruiden en straatgras[1]	2 L/ha[3]	1 per teeltcyclus		14[7]
	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5-1 L/ha[4]	6 per teeltcyclus		5[8]
Afrikaantjes (*Tagetes*) als groenbemester	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5-2 L/ha[2]	5 per teeltcyclus	5 L/ha	7
Rode biet	voor opkomst	eenjarige breedbladige onkruiden en straatgras[1]	1,5-3 L/ha[2]	1 per teeltcyclus	5 L/ha	-
	rond opkomst	eenjarige breedbladige onkruiden en straatgras[1]	2 L/ha[3]	1 per teeltcyclus		14[7]
	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5-1 L/ha[4]	6 per teeltcyclus		5[8]
Bloembol- en bloemknolgewassen m.u.v. lelie (onbedekte teelt)	rond opkomst en na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	2 L/ha	2 per teeltcyclus	4 L/ha	7

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus of per 12 maanden	Maximaal aantal liter middel per ha per teeltcyclus	Minimum interval tussen toepassingen in dagen.
Lelie (onbedekte teelt)	rond opkomst of na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	2 L/ha	1 per teeltcyclus	5 L/ha	7
	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5 L/ha[5]	10 per teeltcyclus		
Lelie (bedekte teelt)	rond opkomst en na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	1-2 L/ha[6]	2 per 12 maanden	4 L/ha	7

[1] Straatgras (*Poa annua*)
[2] Dosering afhankelijk van de grondsoort.
[3] In combinatie met 2 liter per ha minerale of plantaardige olie.
[4] LDS in combinatie met toegelaten middelen
[5] LDS in combinatie met 5 liter per ha minerale of plantaardige olie.
[6] De lage dosering in combinatie met toegelaten middelen.
[7] Het minimum interval tussen de rond opkomst behandeling en de voorgaande voor opkomst behandeling is 14 dagen.
[8] Het minimum interval tussen de eerste na opkomst behandeling en de voorgaande rond opkomst behandeling en tussen na opkomst behandelingen onderling is 5 dagen.

Toepassingsvoorwaarden

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in onbedekte teelten uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen en kantdoppen.

Mislukt een bietengewas door welke oorzaak dan ook (bijv. vorstschade of insectenvraat) en is Goltix SC toegepast dan zijn de mogelijkheden voor een volggewas beperkt:
- zonder grondbewerking kunnen bieten of kroten worden gezaaid;
- na ploegen kunnen maïs en aardappelen worden geteeld;

Resistentiemanagement

Dit middel bevat de werkzame stof metamitron. Metamitron behoort tot de triazonen. De Hrac code is C1.
Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen**.**

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE IV

RISKMANAGEMENT

Contents **Page**

1. Identity of the plant protection product

1.1 Applicant

ADAMA Registrations B.V.
Arnhemseweg 87
3832 GK LEUSDEN

1.2 Identity of the active substance

Common name	Metamitron
Name in Dutch	Metamitron
Chemical name	4-amino-4,5-dihydro-3-methyl-6-phenyl-1,2,4-triazin-5-one
CAS no	41394-05-2
EC no	255-349-3

The active substance was included in Annex I of Directive 91/414/EEC on 1 September 2009.
From 14 June 2011 onwards, 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	Goltix SC
Formulation type	SC
Content active substance	700 g/L metamitron

The formulation is comparable to that assessed for the inclusion in Annex I of Directive 91/414/EEC / approval under Reg. (EC) No 1107/2009.

1.4 Function

herbicide

1.5 Amendments applied for

See GAP (Appendix I). For the post emergence LDS use in lily (open field) the applicant proposes to reduce the dose from 0.5-1 l product per hectare per application to 0.5 l product per hectare per application.

1.6 Background to the application

With the Board decision on the reregistration of 31 August 2016, it was concluded that the post emergence LDS use in lily with a dose rate of 0.5-1 l product per hectare per application should be limited to crop stages of BBCH 65 or lower. This restriction was needed to achieve an acceptable acute risk for the small herbivorous mammal (vole) scenario.
With the current application the applicant applies for removing the above-mentioned restriction from the Legal Instructions for Use (WG). In order to achieve an acceptable risk without the restriction, the applicant proposes a refinement by limitation of the dose to 0.5 l/ha, as described in section 1.5. As the proposed dose rate of 0.5 l/ha was included in the reregistration , it was already assessed and concluded to be acceptable for all other aspects. Therefore, only the aspect triggering the restriction – i.e. the acute risk for the small herbivorous mammal under EFSA GD Birds and Mammals 2009 - was re-assessed for this application.

1.7 Packaging details

1.7.1 Packaging description

Material:	**Professional use:** HDPE/EVOH (1L), HDPE (5L), co-extruded HDPE (10L), HDHMWPE (20L)
Capacity:	**Professional use:** 1L, 5L, 10L, 20L
Type of closure and size of opening:	46 mm-63 mm Screw cap or K60+gasket+security ring
Other information	UN/ADR compliant

1.7.2 Detailed instructions for safe disposal

No particular recommendations.

2. Physical and chemical properties

No changes. Please refer to the assessment of the reregistration as confirmed by Board decision 31 August 2016.

3. Methods of analysis

No changes. Please refer to the assessment of the reregistration as confirmed by Board decision 31 August 2016.

4. Mammalian toxicology

No changes. Please refer to the assessment of the reregistration as confirmed by Board decision 31 August 2016.

5. Residues

No changes. Please refer to the assessment of the reregistration as confirmed by Board decision 31 August 2016.

6. Environmental fate and behaviour

No changes. Please refer to the assessment of the reregistration as confirmed by Board decision 31 August 2016.

7. Ecotoxicology

List of Endpoints Ecotoxicology

Metamitron is an existing substance that has been placed on Annex I per 09/01/2008 (2008/125/EC. For the risk assessment, the final list of endpoints (LoEP d.d. 09/29/2008) as given in the EFSA Scientific Report on metamitron (2008) 185; 1-95 (d.d. 29 September 2008) is used.

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

Species	Test substance	Time scale	End point (mg a.s. or metabolite /kg bw /day)	End point (mg a.s. /kg feed)
Birds ‡				
Japanese quail (*Coturnix coturnix japonica*)	Technical metamitron	Acute	LD50 (male) = 1358 LD50 (female) = 1302	-
Bobwhite quail (*Colinus virginianus*)	Technical metamitron	Short-term	LD50 = >904	LC50 >5000 mg a.s. /kg diet
Mallard duck (*Anas platyrhynchos*)	Technical metamitron	Short-term	LD50 = >1586	LC50 >5000 mg a.s. /kg diet
Bobwhite quail (*Colinus virginianus*)	Technical metamitron	Long-term	NOAEL = 81.5	NOAEC 1000
Mammals ‡				
Rat	Technical metamitron	Acute	LD50 (male) = 1183 LD50 (female) = 1482	-
Mouse	Technical metamitron	Acute	LD50 (male) = 691 LD50 (female) = 644	-
Rat	'Goltix SC 700'	Acute	LD50 = 200-2000 (precise value not calculable)	-
Rat	Desaminometamitron	Acute	LD50 = 4325	-
Rat	Technical metamitron	Long-term	Ecological NOAEL = 36..4 (male) & 53.8 (female)	Ecological NOAEC = 500

Additional higher tier studies ‡
Foliar residue studies: Details for a UK foliar residue decline field study indicate that following a spray application of 'Goltix SC 700' metamitron residues declined rapidly. The apparent short foliar half-life of metamitron is also supported by the results of four German residue field studies in which, following spray applications of formulated metamitron, the high initial (day 0) measured residues of metamitron were found to be reduced to non-significant levels (i.e. ≤ 0.1 mg/kg) at the subsequent analysis made in each trial 14-16 days after treatment. The evidence is considered sufficient to support use of a DT50 of 1.9 days in the refined risk assessment (in place of a default '1st tier' value of 10 days). Based on the available 'day 0' (initial) metamitron foliar residue data from one UK site and from five sites in Germany, the generic acute and long-term residue per unit dose values (RUDs) used in the first tier risk assessment can also be refined. Using these data, the 'refined' acute RUD is 74 (based on maximum residue levels) and the long-term RUD is 48 (based on mean residue levels). The 21 day time averaged C_{res} level is calculated to be 21.53 mg a.s./kg foliage. The long term risk assessment for herbivorous birds and mammals can be refined using this refined exposure value. Various published studies on bird behaviour and feeding preferences: The evidence is sufficient to support the assumption that in relation to the long-term consumption of invertebrates, the invertebrate component of the diet for the skylark and yellowhammer will consist (by weight) of approximately 75% 'large' invertebrates (>4mm body length) and 25% 'small' invertebrates (≤4mm body length). For the yellow wagtail, the evidence supports a long-term consumption estimate of 50% (by weight) of 'large' invertebrates and 50% of 'small' invertebrates.

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

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s. /L unless indicated otherwise)
Laboratory tests ‡				
Fish				
Oncorhynchus mykiss (rainbow trout)	Technical metamitron (>98% purity)	96 hr (static), acute.	Mortality, EC_{50}	>190 (nominal)
Oncorhynchus mykiss (rainbow trout)	Technical metamitron (>98% purity)	21 d (semi-static with daily renewal), prolonged toxicity test.	Growth NOEC	7.0 (nominal)
Oncorhynchus mykiss *(rainbow trout)*	'Goltix SC 700' (690g /l metamitron)	96 hr (static)	Mortality, EC_{50}	>200 mg product /l ≡ >114 a.s. /l (nominal)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s. /L unless indicated otherwise)
Oncorhynchus mykiss *(rainbow trout)*	Desamino-metamitron (99.5% purity)	96 hr (static)	Mortality, EC_{50}	>1000 mg (nominal)
Aquatic invertebrates				
Daphnia magna	Technical metamitron (99% purity)	48 h (static)	Immobilisation, EC_{50}	5.7 (mean measured)
Daphnia magna	Technical metamitron (99% purity)	21 d (semi-static, renewal 3 times per week), reproductive toxicity test	Reproduction, NOEC	10 (nominal)
Daphnia magna	Goltix SC 700 (57.4 w/w metamitron)	48 h (static)	Immobilisation, EC_{50}	170 mg product /l ≡ 97.6 mg a.s./l (nominal)
Daphnia magna	Desamino-metamitron (99% purity)	48 h (static)	Mortality, EC_{50}	745 mg metabolite / l (nominal)
Sediment dwelling organisms				
Chironomus riparius (dipteran midge)	Desamino-metamitron (99.5% purity)	28 d (static spiked water) emergence & development study.	NOEC	100 mg metabolite /l (initial nominal)
Algae				
Pseudokirchneriella subcapitata formerly *Selanastrum capricornutum* (green alga)	Metamitron (technical: purity 99.3%)	72 h (static) Growth inhibition	Biomass E_bC_{50} Growth rate E_rC_{50}	0.4 (initial measured) 1.8 (initial measured)
Pseudokirchneriella subcapitata formerly *Selanastrum capricornutum* (green alga)	'Goltix SC 700' (724.1 g/l metamitron)	72 h (static) Growth inhibition	Biomass E_bC_{50} Growth rate E_rC_{50}	0.82 mg product/l ≡ 0.49 mg a.s./l (nom.) 3.38 mg product/l ≡ 2.01 mg a.s./l (nom.)
Pseudokirchneriella subcapitata formerly *Selanastrum capricornutum* (green alga)	Desamino-metamitron (99% purity)	72 h (static) Growth inhibition	Biomass E_bC_{50} Growth rate E_rC_{50}	25.1 mg metabolite /l (nominal) 73.5 mg metabolite /l (nominal)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s. /L unless indicated otherwise)
Higher plant				
Lemna gibba	a.s. (technical: purity 98.8%)	7 day (semi-static with renewal on days 3 & 5) Growth inhibition	Biomass E_bC_{50} Growth rate E_rC_{50}	0.4 mg a.s./l (mean measured) 0.8 mg a.s./l (mean measured)
Lemna minor	a.s. (technical: purity 98.6%)	14 day (semi-static with renewal on days 2, 5, 7, 9, & 12) Growth inhibition	Biomass E_bC_{50} Frond no. EC_{50}	0.38 mg a.s./l (mean measured) 0.45 mg a.s./l (mean measured)

Microcosm or mesocosm tests:

After a single application of 'Goltix SC 700' to outdoor mesocosm enclosures containing phytoplankton, zooplankton and macrophyte communities, significant treatment related effects were observed at the 2 highest test concentrations (i.e. 1120 and 4480 µg a.s./L), but only for physical-chemical endpoints related to the community metabolism (pH and dissolved oxygen concentration), with these effects at 1120 µg a.s./L being slight and transient (day 2 reductions of 0.5 in pH & of 30% in oxygen levels, with no effects when next assessed on day 5). No consistent treatment-related effects on structural endpoints of phytoplankton (species composition, densities, chlorophyll-a level), periphyton (chlorophyll-a level) and macrophytes (% cover, final biomass, growth of *Myriophyllum spicatum* in *in situ* bioassays) were obtained at up to the highest test concentration. In addition, densities of the major zooplankton groups appeared to be unaffected. Only the more pronounced effects on oxygen and pH levels at 4480 ug a.s. /L (i.e. reductions on day 2 compared with day 0 in oxygen levels by 80% and a pH drop from 9.2. to 7.5, with recovery by day 15) are considered to be ecologically relevant, and on this basis the **study NOAEC** (no observed ecologically adverse effect concentration) is 1120 µg a.s. /L or **1.12 mg a.s. /l (nominal)**.

It is noted that exposure in the study differs from the proposed use in not including repeat exposure. However, given the low level and rapid reversibility of effects at the NOAEC, the effects of metamitron exposure at or below this concentration are considered unlikely to be significant increased by repeat exposure. Although effects on a wide range of aquatic invertebrates and algae species were assessed in the study, effects on only three species of higher aquatic plants were assessed – which may not be fully representative of the range of sensitivity of higher aquatic plants to metamitron. To take account of the uncertainty involved in extrapolating the results of the mesocosm study to the field situation, an uncertainty factor of 3 has been applied by the RMS to the study NOAEC.

Bioconcentration		
	Metamitron	Desamino-metamitron
$logP_{OW}$	0.85-0.96	1.43-2.46
Bioconcentration factor (BCF)[1]	-	-

[1] only required if log P_{OW} >3.

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

Test substance	Acute oral toxicity (48h LD_{50} µg a.s. /bee)	Acute contact toxicity (48h LD_{50} µg a.s./bee)
Metamitron ‡	>97.2	> 100.0
'Goltix SC 700' (690g a.s./l) ‡ #	123.3	> 200.0

Toxicity of 'Goltix 700 SC' expressed in terms of levels of active substance exposure

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

Laboratory tests with standard sensitive species:

Species	Test Substance	End point	Effect (LR_{50})
Typhlodromus pyri ‡	'Goltix SC 700'	Mortality	LR50 = > 21 litres product /ha (≡ > 14383 g a.s./ha)
Aphidius rhopalosiphi ‡	'Goltix SC 700'	Mortality	LR50 = > 21 litres product /ha (≡ > 14383 g a.s./ha)

Further laboratory and extended laboratory studies ‡

Species	Life stage	Test substance, substrate and duration	Dose (g/ha)	End point	% effect	ESCORT 2 Trigger value
Pardosa spp	Adult	'Goltix SC 700'; quartz sand; 14 day exposure.	5 litres product /ha (exposure to initial residues)	Corrected mortality (%) Feeding activity (% reduction)	0% mortality 8% reduction	50 % (at in-field exposure rate)
Coccinella septempunctata	Larvae	'Goltix SC 700'# glass plate substrate, exposure up to adult emergence	2.0-6.1 litres product /ha (exposure to initial residues)	% corrected mortality (M) & % reduction in reproduction (R) 2.0 l product /ha 5.1 l product /ha 6.1 l product /ha	12(M), 32(R) 5(M), 33(R) 10(M), 68(R)	50 % (at in-field exposure rate)

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7):

Test organism	Test substance	Time scale	End point
Earthworms			
Eisenia fetida	Technical metamitron (99% purity) ‡	Acute, 14 days	LC_{50} 914 mg a.s./kg d.w. soil
Eisenia fetida	Desamino-metamitron (99.4% purity) ‡	Acute, 14 days	$LC_{50corrected}$ > 500 mg a.s. /kg d.w. soil [1]
Eisenia fetida	'Goltix SC 700' (690.2 g metamitron / litre) ‡	Chronic, 8 weeks (reproductive toxicity study)	NOEC 28 mg a.s. /kg d.w. soil[2]
Other soil macro-organisms			
Folsomia candida, (Collembola)	Desamino-metamitron (99.4% purity) ‡	Chronic, 28 days (reproductive toxicity study)	NOEC 100
Soil micro-organisms			
Nitrogen mineralisation	'Goltix SC 700' (690 g/L metamitron)‡	28 day study	Effects on nitrogen transformation processes by day 28 at 19.5 mg a.s./kg d.w. soil < ±25% of the control [3]
Nitrogen mineralisation	Desamino-metamitron (99.4% purity). ‡	56 day study	Effects by day 42 on nitrogen transformation at 21.73 mg metabolite /kg dw soil <±25% of the control [3]
Carbon mineralisation	'Goltix SC 700' (690 g/L metamitron)‡	28 day study	Effects on soil respiration at 19.5 mg a.s./kg d.w. soil throughout the study < ±25% of the control [3]
Field studies			
Not required			

[1] Since the maximum estimated Log P_{OW} values of desamino-metamitron is above 2 and testing was conducted in an artificial soil containing 10% organic matter, an EPPO correction factor of 2 was applied to the toxicity endpoint

[2] Calculated from the applied rate per unit area - considering a soil depth of 5 cm and a density of 1.5 g/cm^3

[3] Test doses compares with maximum soil PECs from the proposed use of 3.74 mg a.s. /kg dw soil and 0.62 mg desamino-metamitron /kg dw soil.

Effects on non-target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data:

Not required for herbicides

Laboratory dose response tests:

Most sensitive species	Test substance	ER_{50} Post-emergence exposure	ER_{50} Pre-emergence Exposure
Lettuce (based on post-emergence exposure effects in vegetative vigour test) ‡	'Goltix 700 SC'	171.6 g a.s./ha (effects on shoot fresh weight – the most sensitive measured effect)	-
Rape (based on pre-emergence exposure effects in seedling emergence & growth test) ‡	'Goltix 700 SC'	-	54.9 g a.s./ha (effects on shoot fresh weight – the most sensitive measured effect)

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	End point
Activated sludge bacterial respiratory inhibition study with technical metamitron (98.4% purity)	EC50 6400 mg a.s. /litre

The following data is taken from the core assessment of AG-MA-700 SC (Goltix SC) from the zonal RR evaluated by CRD (UK) November 2012

Effects on aquatic organisms

AG-M4-700 SC #	*Daphnia magna*	48 h (static)	EC50	>136.1 (prod.) > 77.4 (a.s.) [Nominal]	Ref. IIIA 10.2.2.2/02: Juckeland, D. (2011)
AG-M4-700 SC #	*P. subcapitata*	72 h (static)	EyC50 ErC50	0.231 (a.s.) 0.886 (a.s.) [Mean measured]	Ref. IIIA 10.2.2.3/02: Juckeland, D. (2011)
AG-M4-700 SC #	*Lemna minor*	7 d (semi-static)	ErC50 EyC50	1.03 (a.s.) 0.491 (a.s.) [Mean measured]	Ref. IIIA 10.8.2.1/01: Juckeland, D. (2011)

Effects on earthworms

AG-M4-700 SC	*Eisenia fetida*	14 d	LC_{50}	**> 575**	Ref. IIIA 10.6.2/01: Meisner, P. (2001)
AG-M4-700 SC	*Eisenia fetida*	56 d	NOEC	**28**	Ref. IIIA 10.6.3/01: Heimbach, F. (1999) [EU agreed endpoint: EFSA

					Review Report (2008) 185]

Effects on non-target plants

Reference	IIA 8.6.1/01; Fiebig, S. (2000)[1] IIA 8.6.1/02; Spatz, B.; Wever, B. (2002)[2]	IIA 8.6.1/03; Spatz, B.; Schmitzer, S. (2002)
Test system:	Vegetative vigour test (post-emergence); Single spray application on the plant and leaf surfaces (GS = 2-4 leaf stage) Test rates: 35 - 3520 g a.s./ha Exposure period: 14 days	Seedling emergence and growth test (pre-emergence); Single spray application onto the soil surface following seed sowing Test rates: 14.33 - 3500 g a.s./ha Exposure period: 21 days
Test substance:	GOLTIX SC 700	GOLTIX SC 700
Test method:	OEDC 208 B (draft 2000)	OEDC 208 A (draft 2000)
	Rate and parameter used for establishing the endpoint	
Species	ER_{50} [g a.s./ha]	ER_{50} [g a.s./ha]
Oat	2323 B	427.6 C
Onion	> 3520 a, b	272.6 c
Maize	> 3520 a, b	469.3 c
Rape	1035 B	**54.9** c
Carrot	725 B	63.0 c
Soya bean	> 3520 a, b	3428.0 c
Lettuce	**171.6** C	66.8 c

[1] tests in oat, onion, maize, rape, carrot, Soya bean; [2] test in lettuce

Bold letters: most sensitive ER_{50}
a = shoot height; b = dry weight; c = fresh weight

Risk assessment

During reregistration, an unacceptable acute risk was identified for voles for application in lily after BBCH 65. Therefore this use was restricted. The applicant now proposed a lower dose for those late applications. Since the other parts of the risk assessment already passed with the higher dose rate, these sections have not been re-assessed. A reference is made to the re-registration. Thus only the acute risk to mammals has been taken into account.

7.1 Effects on birds

No changes. Please refer to the assessment of the reregistration as confirmed by Board decision 31 August 2016.

7.2 Effects on aquatic organisms

No changes. Please refer to the assessment of the reregistration as confirmed by Board decision 31 August 2016.

7.3 Effects on terrestrial vertebrates other than birds

The original assessment of the reregistration as confirmed by Board decision 31 August 2016 is copied for consistency and adjusted in section 7.3.1 (Refinement of the acute risk assessment for the small herbivorous mammal (**Refined risk assessment applicant 20170246 NLWG** page 18) and the final conclusion of section 7.3.

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

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

Table E.10 Overview of toxicity data for mammals

	Endpoint	Value
Acute toxicity to mammals:	LD_{50}	644 mg a.s./kg bw
Reproductive toxicity to mammals:	NOEL	36.4 mg a.s./kg bw/d

7.3.1 Natural food and drinking water

Sprayed products

Procedures for risk assessment for mammals comply with the recommendations in the Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (Sanco/4145/2000).
For the current application, uses can be categorized as leafy crops. Depending on the crop category different indicator species are chosen. Table E.11 shows which indicator species are relevant for which uses.

Table E.11 Indicator species per use

Use	Crop	Indicator species
All	Leafy crops	Medium herbivorous mammal

Table E.12a-b show the estimated daily uptake values (ETE, Estimated Theoretical Exposure) for acute and long-term exposure, using the Food Intake Rate of the indicator species (FIR) divided by the body weight of the indicator species (bw), the Residue per Unit Dose (RUD), a time-weighted-average factor (f_{TWA}, only for long term) and the application rate. For uses with frequency of > 1, a MAF (Multiple Application Factor) may be applicable. The ETE is calculated as application rate * (FIR/bw) * RUD * MAF [* $f_{TWA,}$ only for long term]. The ETE is compared to the relevant toxicity figure. TER should be above the trigger for an acceptable risk.

Table E12a Acute risk for mammals

Substance	FIR / bw	RUD	Application rate (kg a.s./ha)	MAF	Acute ETE (mg/kg bw/d)	LD50 (mg/kg bw/d)	TER (trigger 10)
Medium herbivorous mammal							
Metamitron	0.28	87	3.5	n.a.	85.3	644	**7.5**

Table E.12b Long-term risk for mammals

Substance	FIR / bw	RUD	Application rate (kg a.s./ha)	MAF	ftwa	Long-term ETE (mg/kg bw/d)	NOEL (mg/kg bw/d)	TER (trigger 5)
Medium **herbivorous mammal**								
Metamitron	0.28	40	3.5	n.a.	0.53	20.8	36.4	**1.7**

Taking the results in Table E.12 into account, it appears that a risk to mammals for the proposed uses cannot be excluded. Hence, for those uses that pose a risk it must be demonstrated by means of an adequate risk assessment that there are no unacceptable effects under field conditions after application of the plant protection product according to the proposed GAP.

As already discussed for birds, a refined DT50 of 1.9 d is accepted to refine the f_{twa} for foliage. Since this is only applicable to long-term exposure, Therefore, the refined long-term risk assessment is given in the table below.

Table E.13 Refined long-term risk for mammals

Substance	FIR / bw	RUD	Application rate (kg a.s./ha)	MAF	ftwa	Long-term ETE (mg/kg bw/d)	NOEL (mg/kg bw/d)	TER (trigger 5)
Medium **herbivorous mammal**								
Metamitron	0.28	40	3.5	n.a.	0.13	5.1	36.4	7.1

As shown in Table E.13 the long-term risk for mammals is acceptable for all uses considering a maximum of 3.5 kg a.i./ha per year.

Higher tier risk assessment according to EFSA 2009

Table E.12a shows that the SANCO GD indicates an acute risk. Ctgb has decided to perform a first tier risk assessment based on the new GD (EFSA Journal 2009; 7(12):1483) which is the state of the art in the risk assessment guidance. The generic focal species for the different crops are presented in the table below:

GAP no.	Crop	Worst-case application scenario	EFSA crop group/s	EFSA Tier-1 scenario	Generic focal species	Shortcut value for TER_A
01a	Sugar beet, fodder beet, beetroot, mangels*	1x 3500 g a.i./ha	Bare soil	BBCH < 10	Small omnivore	14.3
01b	Sugar beet, fodder beet, beetroot, mangels*		Sugar beet(1, Root & stem vegetables(2	BBCH 10-19(1,2	**Small insectivore**	**7.6**
				BBCH ≥ 20(1,2	Small insectivore	5.4
				BBCH 10-39(1	**Large herbivore**	**35.1**
				BBCH 10-39(1,2	**Small omnivore**	**17.2**
02a	Ornamental flowers: Bulbflowers, flowerbulbs, iris, narcissus, tulip, lily, tagetes etc		Bare soil, Bulbs & onion like crops(1, Ornamentals & nursery(2	BBCH < 10(1,2	Small omnivore	14.3
				BBCH 10-19(1 BBCH ≥ 20(1	Small insectivore	7.6#
				BBCH 10-39(1 BBCH 10-49(2	Small omnivore	17.2
				Application to plant – exposure to underlying ground(2	Small insectivore	5.4
02b	Lily		Bulbs & onion like crops(1 ##	BBCH 10-19(1	Small insectivore	7.6
				BBCH ≥ 20(1/	Small insectivore	5.4
				BBCH ≥ 40(1	**Small herbivore**	**81.9**
				BBCH 10-39(1/	Small omnivore	17.2

GAP no.	Crop	Worst-case application scenario	EFSA crop group/s	EFSA Tier-1 scenario	Generic focal species	Shortcut value for TER_A
				BBCH ≥ 40(1	Small omnivore	10.3#

* According to EFSA Journal 2009; 7(12): 1438, beetroots and mangels are classified as "root & stem vegetables", whereas sugar and fodder beets are classified as "sugar beet"

Highest Shortcut Value for the specified timeframes

In first instance, only the acute risk assessment will be performed for the generic focal species with the highest (worst case) shortcut values.

The results are presented in the table below:

Table E.14 Acute risk for mammals – first tier risk assessment according to EFSA 2009 GD for bird and mammal risk assessment

Generic focal species	LD50 [mg a.s./kg bw/d]	Application rate [kg a.s./ha]	SV_{mean}	MAF_m	DDD [mg a.s./kg bw/d]	TER	trigger
Large herbivorous mammal "lagomorph"	644	3.5	**35.1**	1	122.8	**5.2**	10
Small insectivorous mammal "shrew"	644	3.5	**7.6**	1	26.6	24.2	10
Small omnivorous mammal "mouse"	644	3.5	**17.2**	1	60.2	10.7	10
Small herbivorous mammal "vole"	644	3.5	**81.9**	1	287	**2.2**	10

As can be seen in table E.11a, for the scenarios that did not breach the trigger, the maximum application rate per season has been assessed for these scenarios as well. The scenarios still did not breach the trigger of 10.

As can be seen in table E.14 an acute risk is found for Large herbivorous mammal "lagomorph" and the small herbivorous mammals ''vole'. (BBCH ≥ 40).

Therefore, refinement is necessary for the large herbivorous mammal and the small herbivorous mammal.

Tier 2 small herbivorous mammal

The applicant selected the wood mouse (*Apodemus sylvaticus*) as relevant focal species for the small omnivorous mammals. This is accepted by Ctgb. However, the risk for the small herbivorous mammal was not refined for the common vole, since they are not considered relevant in an ecological context by the applicant:

Firstly, the height and density of ground vegetation is the central point for spatial common vole population dynamics and is considered a main factor determining the habitat quality. However, weed control is a common practice and leads to reduction of ground cover. Less dense and low vegetation cover itself leads to vole population decline since in habitats with low vegetation cover, the common vole perceives an increased predation risk compared to habitats with dense vegetation cover present in the off-field area. In addition, such treatments reduce the availability of potential food items and thus, it is concluded that common voles considered as strictly herbivores satisfy their food demand in the untreated off-crop area.

Secondly, it should be noted that voles are regarded as pest organisms in fields planted with ornamental flowers. It is well noted that the vole erodes bulbs and roots resulting in irreversible crop damages that would not be tolerated by farmers, especially in this case of onions/flower bulbs also planted for ornamental purposes. Consequently, voles are actively controlled by intense culturing, catching or by use of biocides. In consideration of this, from an ecological point of view, it is obvious that it is not possible to apply the same protection goal to the vole as to the other indicator species. Instead, it is more appropriate to focus on the wood mouse as relevant representative (for which an acceptable risk is already indicated at Tier-1) also covering the risk for small herbivorous mammals.

Ctgb:
CTGb does not agree with excluding the common vole based on the following statement:
"It is often argued that voles are pest organisms. That statement in itself does not mean that no risk assessment should be performed. The fact that 'the vole' is considered a pest organism by farmers does not mean that the protection goal for pesticide risk assessment changes. In addition to the need to protect this species group in itself, voles are also part of the food chain (e.g. an important food source for predators). Most small herbivorous mammals (including the common vole), have a protected status in the Netherlands (Flora- en Fauna wet: beschermde soort), and pest control is only allowed in very specific cases. Additionally, there are reports that vole populations are declining (Cornulier et al, 2013)[1]. An additional argument which is often mentioned by applicants is that damage control is done by farmers by creating an unfavourable habitat for voles. However; this is not under control of Ctgb and not compulsory for every user (currently this cannot be enforced by some kind of restriction sentence)).
Conclusion: for pesticide risk assessment, the fact that voles are considered a pest by some groups of people is no reason not to perform a risk assessment.

Solutions
Ctgb does not see any generic solutions to 'solve the problem' with voles for the different scenarios. If the relevance of small herbivorous mammals in a scenario is questioned, this should be reconsidered by EFSA to maintain harmonisation at the EU level. For some specific uses, Ctgb agrees that small herbivorous mammals are less relevant in the Netherlands; for instance in some scenarios of strawberries, when those are placed on tables (but outdoors); or for applications on the bare soil strips around orchard trees. In those cases an off-field risk assessment is performed. For other scenarios, the relevance of small herbivorous mammals can only be confirmed or rejected by field monitoring studies/radiotracking studies. However it should be considered that low numbers of voles compared to the numbers of for instance the wood mouse is not enough evidence on its own to disregard the small herbivorous mammals. Only complete absence or incidental presence can be used as argumentation. Unfortunately this is a difficult approach for small scale uses or uses with a high variety of crops, such as tree nurseries and ornamentals.
Substance specific refinements such as DT50 and RUD and refinements of the GAP (e.g. increasing the interval) are of course acceptable. Also, as the protection goal concerns populations, population modelling could be used. However, it should be noted that the use of population modelling in risk assessment is a relatively new approach and requires much scrutiny and input from modelling experts. It should be kept in mind that with any of these refinements it should be clear that the risk assessment still covers the whole group of small herbivorous mammals.

[1]*Cornulier et al, 2013; Europe-Wide Dampening of Population Cycles in Keystone Herbivores, Science 5Vol 40, April 2013, p63-66*

Therefore, the refined risk assessment for the wood mouse is not sufficient to cover the risk of the small herbivorous mammal, the vole. The applicant is requested to provide a risk assessment for the common vole.

Refined risk assessment applicant

Higher-Tier acute dietary risk assessment for small and large herbivorous mammals

The evaluation of the acute risk for herbivorous mammals at Tier-1 was performed in accordance with the recommendations of the current "Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA" (EFSA Journal 2009; 7(12): 1438).

For the initial Tier-1 risk assessment, “generic focal species” and exposure scenarios were selected as recommended in EFSA Journal 2009; 7(12): 1438. According to this current guidance document, the large herbivorous mammal was selected for the post-emergence use in beets (GAP no. 01b), and the small herbivorous mammals was selected for the post-emergence use (BBCH ≥ 40) in lilies (GAP no. 02b).

Multiple Application Factors (MAF) were taken into account for uses with more than one application. Where different rates are applied to the crop (relevant in the case of post-emergence treatment of sugar beet etc. with a worst-case multiple application scenario of 1× 700 + 2× 1400 g a.s./ha), each rate was adjusted separately.

Furthermore, as outlined in the DAR (2007) and the EFSA Scientific Report (2008) for metamitron, a fast foliar residue decline (significantly below the Tier-1 DT_{50} of 10 d) was determined indicated by a foliar DT_{50} of 1.9 days. It is deemed acceptable to use this refined DT_{50} for the recalculation of MAF_{acute} (considering the standard equation for MAF_{acute} calculations) in all kind of foliage contaminated with metamitron and potentially fed by terrestrial vertebrates. Accordingly, based on a foliar DT_{50} of 1.9 days the refined A_{MAF} was calculated and an adjusted application rate as follows:

Application rates in beets, timing:	1st application: 700 g a.s./ha, 10 days before last application 2nd application: 1400 g a.s./ha, 5 days before last application 3rd application: 1400 g a.s./ha	
MAF_{90th}:	1st-3rd application: 1.01	(i = 10 d, DT_{50} = 1.9 d)
	2nd-3rd application: 1.09	(i = 5 d, DT_{50} = 1.9 d)

MAF adjusted application rate:
for acute assessments (1.01-1)× 700 + (1.09-1)× 1400 + 1× 1400 g a.s./ha = **1533 g a.s./ha**

Ctgb response:
The reported DT50 of 1.9 days has only be established for beets. It is therefore questionable if this DT50 can be extrapolated to all kind of foliage. As the ‘lagomorphs’ in sugar beet reported in the Guidance document are mainly consuming ‘crop leaves’ this DT50 value can be used for the refinement for the large herbivorous mammal.
However it is not correct to also assume the same dissipation from grass like crops, based on such a small dataset. Therefore this refinement cannot be used for the small herbivorous mammal.

The acute risk for herbivorous mammals was assessed by calculating Toxicity Exposure Ratios (TER) considering the toxicity endpoints already used and exposure expressed as Daily Dietary Dose (DDD). The results are presented in the table below.

Table E.15: DDD and TER_A values for herbivorous mammals (Tier-1)

Generic focal species, scenario	Exposure	A_{MAF} adjusted appl rate [kg a.s./ha]	SV	f_{twa}	DDD [mg/kg bw/d]	Endpoint [mg/kg bw/d]		TER	TER trigger
GAP no 01b: Sugar beet etc. supported in the Netherlands: 1× 700 + 2× 1400 g a.s./ha, post-emergence (BBCH 10-39), i = 5 d, DT_{50} = 1.9									
Large herbivore, BBCH 10-39	acute	1.533	35.1	1	54	LD_{50}	644	12	10
GAP no 02b: Lily supported in the Netherlands: 5× 700 g a.s./ha, post-emergence (BBCH 10-79), i = 7 d, DT_{50} = 1.9									
Small herbivore, BBCH ≥ 40	acute	1.33	81.9	1	109	LD_{50}	644	**5.91**	10

bold: below the respective trigger

In summary, based on the Tier-1 TER calculations presented above, an acceptable acute risk can be concluded for large herbivorous mammals, but not for small herbivorous mammals.

Field study voles

The applicant submitted a monitoring and radio tracking study in flower bulbs. (see full summary and evaluation below). From the study, it can be concluded that the vole is not relevant in flower bulbs up to BBCH 65. Please note that a PT refinement is usually not accepted for the acute risk; however as the study gives clear results about the presence or absence of small herbivorous mammals, the study can be used for the acute risk assessment. Therefore the risk to small herbivorous mammals is acceptable is the applications takes place before BBCH 65 (before full flowering/or heading)

Uncertainty analysis

Table E.16: Uncertainties and conservativeness of the refined risk assessment / Weight of evidence analysis

Uncertainty description	Effect on uncertainty in the RA*	Effect on conservativeness of RA*	Conclusions
Refined DT50 (lagomorph)	-	unknown	DT50 was determined in beets, which is reported to be the diet in this case
Refined DT50 (small herbivorous)	-	+	Proposed DT50 was not used in risk assessment, as extrapolation from data from beets to grasses and cereals is not allowed. Therefore default values are used. Due to the low DT50 established for beets, it is expected that the DT50 from grasses would be lower than 10 days
Refined interception	+	+	In relation to the RA of Small herbivorous mammal "vole" the interception is slightly underestimated, later in the growth stadium the interception is slighty higher than 0.4 from the Appendix one of GD B&M.
Overall conclusions	Despite of the uncertainties of the DT50 refinements, the risk to large herbivorous mammals is considerd to be acceptable, as the TER is cleary above the trigger. For the small herbivorous mammal, the risk assessment is still considered to be worst case, as no DT50 is used and effects of interception at late stages might be underestimated. However, the TER is considerable below the trigger for appliaciton after BBCH 65. Therfore a restriction sentence is proposed for the use in Lily.		

* A'+' sign means that the parameter is still considered worst-case for risk assessment, while a '-'sign means that there are still some uncertainties not considered.

Based on the calculations presented in table E.16 and the uncertainty analyses, the risk to mammals is acceptable, provided that the following restriction sentence is placed on the label:

Om de zoogdieren te beschermen is toepassing in de onbedekte teelt van lelies uitsluitend toegestaan voor het koppen van het gewas of voor volledige bloei (uiterlijk tot BBCH 65).

Refined risk assessment applicant 20170246 NLWG:
In order to remove the need for a restriction sentence as stated above, the applicant applied for a GAP change. The maximum application on Lily is changed from 1 L/ha (0.700 kg a.s. /ha) tot 0.5 L/ha (0.350 kg a.s. /ha). The adjusted tabel E.15 is shown below in Table E15a only for GAP 02b.

Acute MAF for 10 application with interval of 7 days is 2.0.

Table E.5: DDD and TER_A values for herbivorous mammals (Tier-1)

Generic focal species, scenario	Exposure	A_{MAF} adjusted appl rate [kg a.s./ha]	SV	f_{twa}	DDD [mg/kg bw/d]	Endpoint [mg/kg bw/d]		TER	TER trigger
GAP no 02b: Lily supported in the Netherlands: 10× 350 g a.s./ha, post-emergence (BBCH 10-79), i = 7 d DT_{50} = 10 (default) resulting in MAF_{90} = 2.0									
Small herbivore, BBCH ≥ 40	acute	0.7	81.9	1	57	LD_{50}	644	11.2	10

bold: below the respective trigger

Conclusion: Based on the calculations presented in table E.15a the acute risk to mammals is acceptable without the restriction to limit the application in lily (open field) to crops stages of BBCH 65 or lower.

IIIA 10.3.3 Supervised cage or field trials or other appropriate studies

Report:	KIIIA 10.3.3/01, Grimm, T., Görlitz, A., 2015
Title:	Generic field monitoring study on common voles in bulbs and onion like crops in the Netherlands in spring/summer 2015 (DRAFT)
Testing facility:	RIFCon GmbH, Heidelberg, Germany
Document No:	R1440045
Guidelines:	No official test guideline(s) available at present
GLP:	Yes

Executive summary

The present study aimed at obtaining generic monitoring data of common voles in bulbs and onion like crops (tulip fields) during BBCH stages ≥ 40 and in adjacent habitats (selected as favourable habitats for the common vole) in the Netherlands (Central Europe) based on live trapping and radio tracking.

This generic field study demonstrated that in-crop areas of bulbs and onion like crops at growth stages of BBCH ≥ 40 are not attractive habitats for common voles. This leads to the conclusion that the vole scenario for bulb and onion like crops at BBCH stage ≥40 is rather irrelevant with regard to protect the population and that off-crop risk assessments would be more relevant than standard in-crop risk assessment for the common vole. This conclusion is supported by various ecological

parameters (number of captures, trapping efficiency, the minimum number alive (MNA) and proportion of juveniles trapped) resulting from live trapping data:

- In total 1175 captures were recorded off-crop, whereas only 297 captures were made in-crop bearing in mind that the number of traps set within the fields was twice as high as off-crop.
- The mean trapping efficiency for all study fields was 8 times higher in the off-crop habitats.
- MNA analysis indicated that the vast majority of long-followed and stationary common voles was recorded off-crop.
- No juveniles at all were trapped within the fields up to approx. mid of June. Later on numbers were continuously lower than in the off-crop habitats.

I. Materials and methods

A. Study characteristics

Study type:	Generic field study
Location:	Two different areas in the Netherlands (Noordoostpolder and Noord-Holland), both typical areas for the growing of tulips
Timing:	Spring/summer 2015 covering post-emergence growth stages of bulbs and onion like crops
Test organisms:	Natural common vole community
Experimental phase:	April 15 to June 27, 2015

B. Study design and method

The study was conducted in two different areas in the Netherlands (Noordoostpolder and Noord-Holland), both typical areas for the growing of tulips. Ten tulip fields per area were used as study fields, representing the common size and basic structure of tulip fields in the regions. Common vole monitoring included live trapping with individual marking and radio tracking.

Live trapping was conducted in order to obtain information on the occurrence of common voles within the tulip fields (which were located adjacent to favourable habitats for common voles) and additionally the presence of this species in these suitable adjacent habitats. For this purpose live trapping was conducted from 16 April 2015 until 27 June 2015 with a total trapping effort of 25,920 trapnights. On each study field 33% of traps were set in the adjacent off-crop habitat.

For live trapping ‘Ugglan’ multiple capture live traps were used. In each study field and its adjacent habitat 60 traps were set up. The majority of traps (40) was installed within the study field and the remaining 20 traps in the adjacent habitat. The traps in the surrounding habitat were arranged according to the shape and size of the habitat at distances of approximately 5-10 m. The traps in the study field were arranged in a trapping grid, also at distances of approximately 5-10 m. Each trap was baited with rolled oats which served as food for captured animals. Traps were activated for trapping in the evening and checked in the morning.

Live trapping followed a Capture-Mark-Recapture (CMR) design, allowing identification of individually marked animals upon recapture. Common vole individuals were marked via fur cuts as described in Gurnell & Flowerdew (2006). The fur was clipped from different parts of the body (e.g. left hind leg, right shoulder) and combinations of the markings gave a number of individual patterns. The same marking code was applied to individuals of each study field, whereas it was ensured that there was no exchange of individuals between the different study fields.

In order to obtain more detailed information on the use of tulip fields during developmental BBCH stages ≥ 40 by common voles, individual common voles were radio tracked for at least one whole

activity period. A PT (portion of diet obtained from the treated area) value was determined for all complete radio tracking sessions.

II. Results and discussion

As outlined in the table below, the vast majority of captures was made in the surrounding habitats (off-crop habitats). In total 1175 captures were recorded off-crop, whereas only 297 captures were made in-crop; and on eight study fields no single common vole was trapped during the entire study within the fields. In this context it has to be noted that these absolute values are not directly comparable since the number of traps set within the fields was twice as high as off-crop (800 traps in total compared to 400 off-crop traps in total).

For direct comparison, the trapping efficiency (as captures per 100 trap nights) was calculated. The mean trapping efficiency for all study fields was 8 times higher in the off-crop habitats (13.47 compared to 1.69), i.e. only 12.5% of the number of common voles trapped off-crop could be trapped within the tulip fields. The trapping efficiency for the single study fields (only to be calculated for the study fields on which common voles were trapped in both habitats, i.e. for eight study fields without in-crop captures these numbers cannot be given) was up to 31 times higher off-crop than within the tulip fields.

From 467 individuals trapped off-crop 437 (93.6%) were solely trapped in off-crop traps (79.2% of all trapped individuals (N=552)). 30 individuals (5.4%) were recorded also within the tulip fields at least once. 85 common voles (15.4% of all trapped individuals) could be recorded in the tulip fields only. Again it has to be noted that the number of traps in-crop was twice as high as off-crop.

Number of captures and individuals and resulting trapping efficiencies are summarised in the table below.

Table 10- 1: Captures and trapping efficiency of common voles in in-crop and off-crop habitats

Study field	In-crop			Off-crop		
	Captures	Individuals	Trapping efficiency	Captures	Individuals	Trapping efficiency
1	-	-	0.00	12	4	2.73
2	-	-	0.00	30	9	6.82
3	-	-	0.00	20	6	4.55
4	-	-	0.00	25	9	6.94
5	-	-	0.00	21	11	5.83
6	12	3	1.36	28	16	6.36
7	1	1	0.11	14	7	3.18
8	-	-	0.00	40	12	9.09
9	20	7	2.27	4	2	0.91
10	3	1	0.34	32	14	7.27
11	50	25	5.68	83	34	18.86
12	8	6	0.91	124	56	28.18
13	69	20	7.84	265	91	60.09
14	48	20	5.45	304	117	69.32
15	13	8	1.48	72	28	16.36
16	-	-	0.00	38	13	8.64
17	24	9	2.73	13	9	2.95

18	3	2	0.34	8	8	1.82
19	-	-	0.00	13	11	2.95
20	46	13	5.23	29	10	6.59
	Total: 297	**Total: 115**	**Mean: 1.69**	**Total: 1175**	**Total: 467**	**Mean: 13.47**

From the temporal perspective the number of captured common voles was quite low up to mid of May, but increased with proceeding season afterwards. Within the tulip fields only single captures on single study fields were made up to mid of May. At this time the tulip heads on most of the study fields had already been cut, indicating BBCH development > 65 (see figure below). This shows that common voles enter tulip fields much later than defined by EFSA (2009) for the crop group 'bulb and onion like crops' (which includes tulips).

Using a measurement generally used to assess population densities (MNA), an approach was additionally made to determine the habitat type (in-crop versus off-crop) in which animals proven to be alive over a long period could be detected. The vast majority of these long-followed and stationary common voles was recorded off-crop. During the entire study only single individuals were recorded exclusively in traps within the respective study field, which therefore seems to be exceptional.

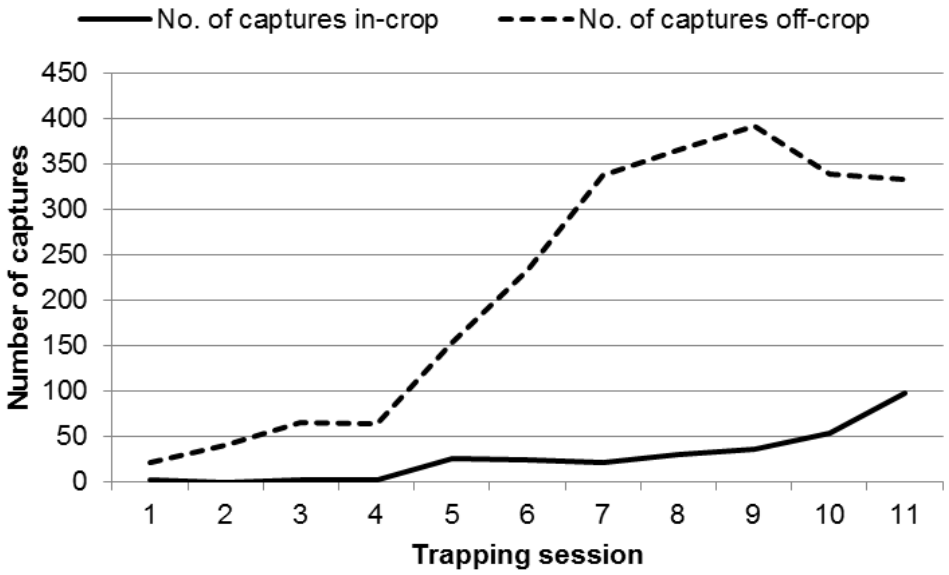

Figure 10- 1: Total number of captures in-crop and off-crop per trapping session for all study fields (numbers were corrected to the same trapping effort, i.e. actual numbers off-crop were multiplied with 2 to account for the double amount of traps set in-crop).

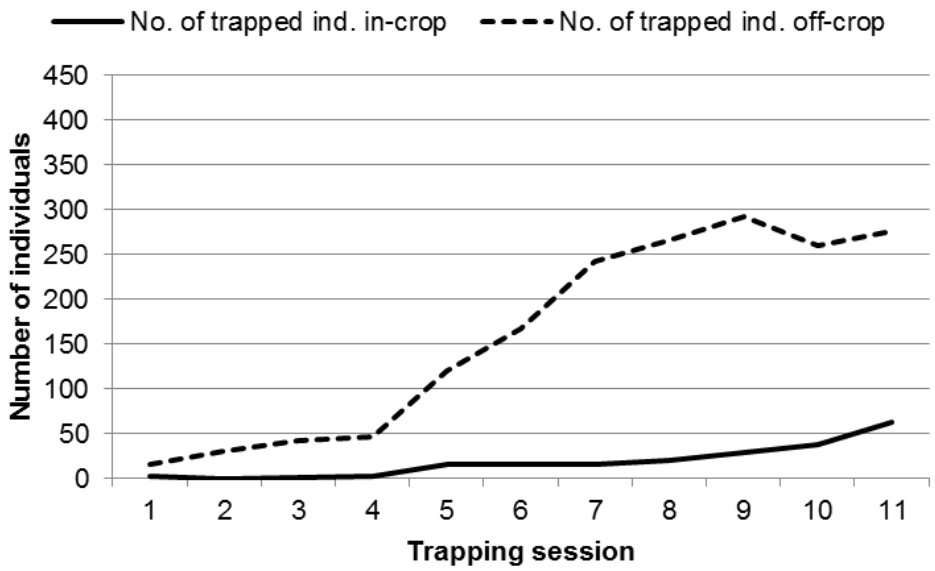

Figure 10- 2: Total number of trapped individuals (=ind.) in-crop and off-crop per trapping session for all study fields (numbers were corrected to the same trapping effort, i.e. actual numbers off-crop were multiplied with 2 to account for the double amount of traps set in-crop).

In order to determine the importance of tulip fields as a habitat in which common voles reproduce, the proportion of juveniles was evaluated as well. No juveniles at all were trapped within the tulip fields up to approx. mid of June. Later on numbers were continuously lower than in the off-crop habitats. This leads to the same conclusion that probably after reaching the carrying capacity in favourable habitats directly adjacent, tulip fields are colonised by individuals urged to emigrate or immigrate into tulip fields, respectively, and the tulip fields are no preferred habitat for reproduction.

Proportion of juveniles during each trapping session for in- and off-crop is displayed in the figure below.

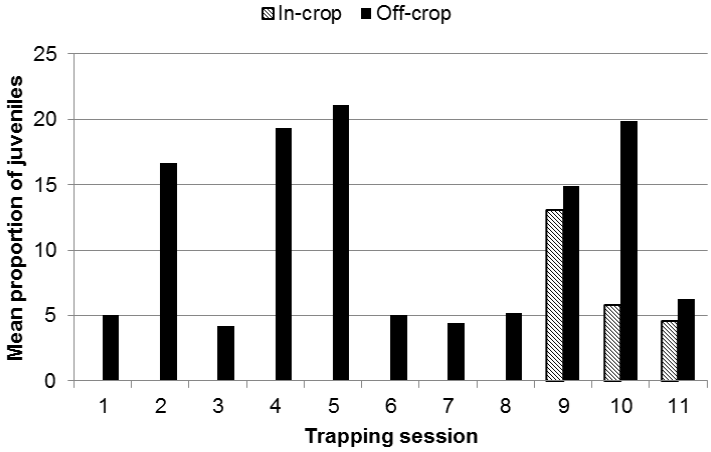

Figure 10- 3: Proportion of juveniles during each trapping session for in- and off-crop, given as mean for all study fields

The development of BBCH growth stages were recorded on each study field. As the common farming practice in the study areas includes the growing of several different tulip varieties on the same field, the BBCH development was not homogenous for the whole study field due to the fact that different varieties grow within different time spans. Therefore an approach was made to give percentage values for each study field and trapping session. For clarity reasons this was summarized in ranges for each field (see table below). In general this information can be condensed to the following:

	Trapping season				
	1	**2**	**3**	**4**	**5-11**
BBCH	> 40	> 40 - 65	> 50 - > 65	65 - > 65	> 65

This implies the following:
>40: development of harvestable vegetative plant parts
>50: inflorescence emergence
>60: flowering
65: full flowering
>65: flower heads cut, further development of fruits

III. Conclusions

This generic field study demonstrated that in-crop areas of bulbs and onion like crops at growth stages of BBCH ≥ 40 are not attractive habitats for common voles. This leads to the conclusion that the vole scenario for bulb and onion like crops at BBCH stage ≥40 is rather irrelevant with regard to protect the population and that off-crop risk assessments would be more relevant than standard in-crop risk assessment for the common vole. This conclusion is supported by various ecological parameters (number of captures, trapping efficiency, the minimum number alive (MNA) and proportion of juveniles trapped) resulting from live trapping data:

- In total 1175 captures were recorded off-crop, whereas only 297 captures were made in-crop bearing in mind that the number of traps set within the fields was twice as high as off-crop.
- The mean trapping efficiency for all study fields was 8 times higher in the off-crop habitats.
- MNA analysis indicated that the vast majority of long-followed and stationary common voles was recorded off-crop.
- No juveniles at all were trapped within the fields up to approx. mid of June. Later on numbers were continuously lower than in the off-crop habitats.

Study comments: IIIA 10.3.3/01

Evaluation by reviewer

- The mean and 90th percentile PT was 0.76 and 1.00, based on data for all radiotracked individuals. One of 13 radiotracked individuals was caught off-crop and did not use the tulip fields as foraging habitat at all during the tracking session. When excluding the data from this individual ("consumer only"-approach), the mean and 90th percentile PT is 0.81 and 1.00.
- The number of individuals trapped in-crop on all study fields was very low (0-2) up to and including session 4 (growth stage >40 up to 65), but thereafter gradually increased from 15-16 individuals during session 5-7 (representing 6-12% of the total number of common voles caught) to 63 individuals at the last session (representing 19% of the total number of common voles caught). Therefore the reported conclusion that the vole scenario for bulbs and onion like crops at BBCH growth stage ≥40 is irrelevant with regard to protecting the population, and that off-crop risk assessments would be more relevant than standard in-crop risk assessment for the common vole, is not accepted. An in-crop assessment is still considered relevant for BBCH >65, taking into consideration that at BBCH >65 the in-crop numbers of common vole represent a non-negligible proportion of the overall common vole population (up to 19%).
- The report did not present an analysis of FOfield and FOsurvey. These two parameters are recommended in Appendix M of EFSA Guidance (2009) to determine the focal species. According to the EFSA Guidance (2009), species with a frequency of occurrence >20% might be considered to be of high priority especially if they have high dominance. The Table below summarises the FOfield and FOsurvey values determined by the reviewer based on the reported raw data (report Table A5), for the entire study period, and separately for growth stage 40-65 (session 1-4) and >65 (session 5-11). This analysis confirms the position taken above: FOfield and FOsurvey are <20% for BBCH 40-65, indicating that at these growth stages the common vole is not a relevant focal species in tulip fields, but FOfield and FOsurvey are >20% for BBCH 40-65, indicating that an in-field assessment for the common vole is relevant at these growth stages.

Table 8: PT values for 15 radio tracking sessions of common voles

Crop stage	total number of fields	number of fields with in-field captures	Fofield (%)	total number of surveys	number of surveys with captures	Fosurvey (%)
40-65	20	3	15	80	5	6
>65	20	12	60	140	51	36
40->65 (entire study period)	20	12	60	220	56	25

- Please note that during the study only the omnivorous wood mouse and the seed and insect eating harvest mouse were caught in-crop in significant numbers, but these do not belong to the feeding guild of the common vole, which is herbivorous. Hence at BBCH 40-65 no small herbivorous mammals at all were found in-crop in the 20 tulip fields, apart from very low numbers of common voles (0-2 individuals).

Agreed endpoint/s: IIIA 10.3.3/01	Field monitoring study on common vole in The Netherlands in tulip fields at BBCH >40: • In tulip fields at BBCH 40-65 the contribution of in-crop individuals to the overall common vole population is negligible (FOfield and FOsurvey <20%, in-crop assessment not required); • In tulip fields at BBCH >65 an in-crop assessment for common vole is considered relevant, taking into consideration that at BBCH >65 the in-crop numbers of common vole represent a non-negligible proportion (up to 19%) of the overall common vole population, with FOfield and FOsurvey values of 60% and 36%, respectively; • The 90th percentile PT value for all individuals and for "consumers only" is 1.00.

Plant metabolites

In the DAR of metamitron (2007) it was stated that: "*Metamitron is metabolised in plants with the formation of a major metabolite 'desaminometamitron' Given that desaminometamitron is formed as a major primary metabolite in laboratory mammals, the toxicity of this principle metabolite was intrinsically assessed as part of the toxicity testing of the active substance in laboratory animals. Therefore, the risk potentially arising from this metabolite is covered by the risk assessment for the parent compound."*

Drinking water

The risk from exposure through drinking from surface water is calculated for a small mammal with body weight 10 g and a DWI (daily water intake) of 1.57 g/d. Surface water concentrations are calculated using TOXSWA (see paragraph 6.2.1). In the first instance, acute exposure is taken into account. The highest $PIEC_{water}$ is 15.15 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (644 * 0.010) / (0.01515 * 0.00157) = >1000.
Since TER > 10, the risk is acceptable.

7.3.2 Secondary poisoning

The risk as a result of secondary poisoning is assessed based on bioconcentration in fish and worms. Since the log Kow of the active substance metamitron and the metabolite desamino-metamitron < 3 (0.85-0.96 and 1.43-2.46, respectively), the potential for bioaccumulation is considered low and no further assessment is deemed necessary.
Taking the results for secondary poisoning through fish and earthworms into account, the proposed uses meet the standards for secondary poisoning as laid down in the RGB.

Conclusions mammals

The product complies with the RGB.

7.4 Effects on bees

No changes. Please refer to the assessment of the reregistration as confirmed by Board decision 31 August 2016.

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

No changes. Please refer to the assessment of the reregistration as confirmed by Board decision 31 August 2016, and the amendment of the Legal Instructions for Use (WG) as decided on by the Board on 30 December 2016 (risk to non-target plants).

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

See List of End-points.

7.7 Data requirements

None.

7.8 Restriction sentences

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

The following restriction can be removed from the label:

➔ *Om de zoogdieren te beschermen is toepassing in de teelt van lelies uitsluitend toegestaan voor het koppen van het gewas of voor volledige bloei (uiterlijk tot BBCH 65).*

The following restriction remains unchanged:

➔ *Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met luchtondersteuning en kantdoppen.*

7.9 Overall conclusions regarding ecotoxicology

It can be concluded that:

1. all proposed applications of the active substance metamitron meet the standards for birds as laid down in the RGB.
2. all proposed applications of the active substance metamitron meet the standards for aquatic organisms as laid down in the RGB.
3. the active substance metamitron meets the standards for bioconcentration as laid down in the RGB.
4. all proposed applications of the active substance metamitron in meet the standards for mammals as laid down in the RGB.
5. all proposed applications of the active substance metamitron meet the standards for bees as laid down in the RGB.
6. all proposed applications of the active substance metamitron meet the standards for non-target arthropods as laid down in the RGB.
7. all proposed applications of the active substance metamitron meet the standards for earthworms as laid down in the RGB.
8. all proposed applications of the active substance metamitron meet the standards for soil micro-organisms as laid down in the RGB.
9. all proposed applications of the active substance metamitron cannot be examined against the standards as laid down in the RGB; for the time being this issue is not taken into consideration.
10. all proposed applications of the active substance metamitron meet the standards for non-target plants as laid down in the RGB, provided drift mitigating measures are applied.

8. Efficacy

No changes. Please refer to the assessment of the reregistration as confirmed by Board decision 31 August 2016, and the amendment of the Legal Instructions for Use (WG) as decided on by the Board on 30 December 2016.

9. Conclusion

The product complies with the Uniform Principles.
With the applied for limitation of the dose rate to 0.5 kg/ha for the LDS use in lily (open field), the acute risk to mammals is acceptable for application in all crop stages BBCH 10-79. Therefore , the restriction that application in lily should be limited to crop stages of BBCH 65 or below can be removed from the Legal Instructions for Use.

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

10. Classification and labelling

No changes. Copied for completeness from the assessment of the reregistration as confirmed by Board decision 31 August 2016.

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

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
Metamitron			
Pictogram:	GHS07 GHS09	Signal word:	Warning
H-statements:	H302	Harmful if swallowed.	
	H410	Very toxic to aquatic life with long lasting effects.	
P-statements:	P102	Keep out of reach of children.	
	P270	Do not eat, drink or smoke when using this product.	
	P280c	Wear protective gloves and protective clothing.	
	P501	Dispose of contents/container to …	
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.	
	SP1	Do not contaminate water with the product or its container.	
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable

Explanation:	
Pictogram:	-
H-statements:	-
P-statements:	P280c is assigned based on operator exposure assessment. Other P-statements were proposed by the applicant and are accepted.
Other:	-

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

The following restriction and warning sentences need to be included in the Legal Instructions for Use:

The following restriction sentence is no longer needed as a result from the assessment of the current application:

Om de zoogdieren te beschermen is toepassing in de onbedekte teelt van lelies uitsluitend toegestaan voor het koppen van het gewas of voor volledige bloei (uiterlijk tot BBCH 65).

The other restriction and warning sentences as confirmed by Board decision of 31 August 2016 and Board decision of 30 December 2016 remain on the label:

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in onbedekte teelten uitsluitend toegestaan wanneer gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen met luchtondersteuning en kantdoppen.

Mislukt een bietengewas door welke oorzaak dan ook (bijv. vorstschade of insectenvraat) en is Goltix SC toegepast dan zijn de mogelijkheden voor een volggewas beperkt:
- *zonder grondbewerking kunnen bieten of kroten worden gezaaid;*
- *na ploegen kunnen maïs en aardappelen worden geteeld;*

<u>Resistentiemanagement</u>
Dit middel bevat de werkzame stof metamitron. Metamitron behoort tot de triazonen. De Hrac code is C1.
*Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen***.**

Appendix 1; Table of changed uses applied for and authorized; Goltix SC – metamitron 700 g/l ;

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: 1. max. no. of applications per crop and season 2. Maximum product rate per season 3. additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	kg, L product / ha	kg as/ha	Water L/ha min / max		
5	NL	Lily	F	annual broadleaved weeds and Poa annua	Downward spraying	During and/or post-emergence (BBCH 09 - 19) Feb- Jul	1	2 L/ha	1.4	200-500	-	2. Max. 5 L product/ha/season
					Downward spraying	LDS post emergence (BBCH 10 - 79) Apr - Sep	1-10 (7 days)	0.5 ~~– 1~~ L/ha	0.35 ~~– 0.7~~	200-500	-	2. Max. 5 L product/ha/season 3. In combination with 5 l/ha mineral or vegetable oil

Appendix 2 Reference list

No new studies were submitted for this application