8629 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 BESLUIT

Op 8 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 WG

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 BBCH 65 (volledige bloei, of koppen van het gewas).
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 kg 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 W8 naar W.9.

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 kg product/ha. Vanwege die beperking moeten respijttermijnen worden vastgesteld voor afleveren en opgebruik van verpakkingen met volgnummer W.8. 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 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.

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

8629 N

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I DETAILS VAN DE AANVRAAG EN AFWIJZING

1 Aanvraaginformatie

Aanvraagnummer:	20170244 NLWG
Type aanvraag:	aanvraag tot wijziging van het Wettelijk Gebruiksvoorschrift
Middelnaam:	Goltix WG
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	70%

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:	8629 N
Expiratiedatum:	1 september 2026
Afgeleide of parallel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel
W-codering professioneel gebruik:	W.9

4 Aflever- en opgebruiktermijnen voor oude etiket

Vorige W-codering professioneel gebruik:	W.8
Aflevertermijn professioneel gebruik:	1 februari 2018
Opgebruiktermijn professioneel gebruik:	1 februari 2019

5 Verpakkingsinformatie

Aard van het preparaat:	water dispergeerbaar granulaat

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BIJLAGE II Etikettering van het middel Goltix WG

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 toepas-singen per teeltcyclus	Maximaal aantal kg middel per ha per jaar	Minimum interval tussen toepassingen in dagen
Bieten	voor opkomst	eenjarige breedbladige onkruiden en straatgras[1]	1,5 - 3 kg/ha[2]	1	5 kg/ha	-
	rond opkomst	eenjarige breedbladige onkruiden en straatgras[1]	2 kg/ha[3]	1		-
	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5 - 2 kg/ha[4]	6		5
Rode biet	voor opkomst	eenjarige breedbladige onkruiden en straatgras[1]	1,5 - 3 kg/ha[2]	1	5 kg/ha	-
	rond opkomst	eenjarige breedbladige onkruiden en straatgras[1]	2 kg/ha[3]	1		-
	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5 - 2 kg/ha[4]	6		5
Bloembol- en bloemknolgewassen (onbedekte teelt)	rond opkomst en na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	2 - 4 kg/ha[2]	2	5 kg/ha	7
Lelies (onbedekte teelt)	rond opkomst en na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	2 - 4 kg/ha[2]	2	5 kg/ha	7
	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5 kg/ha[5]	10		7

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepas-singen per teeltcyclus	Maximaal aantal kg middel per ha per jaar	Minimum interval tussen toepassingen in dagen
Bloembol- en bloemknolgewassen (bedekte teelt)	rond opkomst en na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	1 - 2 kg/ha[6]	2	4 kg/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 olie.
[5] LDS in combinatie met 5 liter per ha minerale of plantaardige olie.
[6] De lage dosering in combinatie met toegelaten middelen.

Het gebruik in de teelt van tagetes, aardbei, oregano voor etherische oliën, zomerbloemen (onbedekte teelt), de vaste plantenteelt (onbedekt) en de bloemenzaadteelt (onbedekt) is beoordeeld conform artikel 51 EG 1107/2009. Er is voor uitbreiding geen werkzaamheid- en fytotoxiciteitsonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren voordat het middel gebruikt wordt. Gebruik van dit middel in deze toepassingsgebieden komt voor risico en verantwoordelijkheid van de gebruiker.

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepas-singen per teeltcyclus	Maximaal aantal kg middel per ha per teeltcyclus	Minimum interval tussen toepassingen in dagen
Tagetes (groenbemester)	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5 - 2 kg/ha[2]	5	5 kg/ha	7
Aardbei (onbedekte teelt)	na uitplanten	eenjarige breedbladige onkruiden en straatgras[1]	0,5 - 1 kg/ha	3	3 kg/ha	10
Oregano voor etherische oliën (onbedekte teelt)	na opkomst of na planten	eenjarige breedbladige onkruiden en straatgras[1]	0,5 - 2 kg/ha[2]	3	5 kg/ha	10

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepas-singen per teeltcyclus	Maximaal aantal kg middel per ha per teeltcyclus	Minimum interval tussen toepassingen in dagen
Zomerbloemen (onbedekte teelt)	voor opkomst	eenjarige breedbladige onkruiden en straatgras[1]	3 kg/ha[3]	1	5 kg/ha	-
	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5 kg/ha[3]	9		7
Vaste plantenteelt (onbedekte teelt)	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5 - 2 kg/ha	10	5 kg/ha	7
Bloemenzaadteelt (onbedekte teelt)	voor opkomst	eenjarige breedbladige onkruiden en straatgras[1]	3 kg/ha[3]	1	5 kg/ha	-
	na opkomst	eenjarige breedbladige onkruiden en straatgras[1]	0,5 kg/ha[3]	9		7

[1] Straatgras (*Poa annua*)
[2] Dosering afhankelijk van de grondsoort.
[3] Eventueel in combinatie met toegelaten middelen.

Toepassingsvoorwaarden

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in de onbedekte teelten van bieten, rode biet, bloembol- en bloemknolgewassen, lelies, *Tagetes*, *Oregano*, zomerbloemen, vaste plantenteelt en bloemenzaadteelt uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen en een kantdop.

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in de onbedekte teelt van aardbei uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 50% driftreducerende spuitdoppen en een kantdop, of minimaal 75% drift reducerende spuitdoppen.

Mislukt een bietengewas door welke oorzaak dan ook (bijv. vorstschade of insectenvraat) en is Goltix WG 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**.**

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BIJLAGE II

RISKMANAGEMENT

Contents

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 WG
Formulation type	WG
Content active substance	70%w/w metamitron

The formulation was not part of the assessment of the active substance for inclusion in Annex I of Directive 91/414/EEC.

1.4 Function

Herbicide

1.5 Uses applied for

See GAP 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 kg product per hectare per application to 0.5 kg 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 kg 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 kg/ha, as described in section 1.5. As the proposed dose rate of 0.5 kg/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:** Polyethylene
Capacity:	**Professional use:**

	1kg, 5kg, 15kg
Type of closure and size of opening:	Heat seal
Other information	UN/ADR compliant 1kg and 5kg bags are packed in cartons. 1kg bags are packed per 10 (10kg total pack size) 5kg bags are packed per 4 (20kg total pack size)

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 Conclusion issued on 09/29/2008 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)
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)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s. /L unless indicated otherwise)
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)
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)

Group	Test substance	Time-scale (Test type)	End point	Toxicity (mg a.s. /L unless indicated otherwise)
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

Test substance	Acute oral toxicity (48h LD_{50} µg a.s. /bee)	Acute contact toxicity (48h LD_{50} µg a.s./bee)
'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]

Test organism	Test substance	Time scale	End point
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

Most sensitive species	Test substance	ER_{50} Post-emergence exposure	ER_{50} Pre-emergence Exposure
			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

Ecotoxicologically relevant compounds

Compartment	
soil	Metamitron, desamino-metamitron
water	Metamitron.
sediment	Desamino-metamitron
groundwater	-

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	R50, R53.

	RMS/peer review proposal
Preparation	R50, R53.

Formulation
Additional studies with a formulation. Submitted for this assessment. Taken from the RR of the Northern Zone (FI) and Southern Zone (FR).

Non-target arthropods

Substance	***Species***	***Method***	***Dose [g/ha]***	***Parameter***	***Adverse effects[2] [%]***	***L(E)R_{50} [g a.s./ha]***
*Goltix 70 WG**	*Aphidius rhopalosiphi*	*extended lab test using barley plants, (fresh residue test)*	*625 – 5000 g prod./ha*	*Mortality and reproduction*	*$Mortality_{corr}$ = 0 to 10% Red. in repro = -15.8 to -3.0%*	*LR_{50}/ER_{50} > 5000 g prod./ha (> 3500 ga.s./ha)*
*Goltix 70 WG**	*Typhlodromus pyri*	*extended lab test using barley plants, (fresh residue test)*	*625 – 5000 g prod./ha*	*Mortality and reproduction*	*$Mortality_{corr}$ = 0% Red. in repro = -29.9 to 23.9%*	*LR_{50}/ER_{50} > 5000 g prod./ha (> 3500 ga.s./ha)*

** a formulation containing metamitron: 70.6 % w/w*

Additional studies with a formulation. Submitted for this assessment. Summarized and evaluated by the Ctgb (12-2014)

Aquatic organisms

Substance	***Species***	***Method***	***Duration [h]***	***Criterion***	***Value formulation [mg /L]***	***Value [mg total a.s. /L]***
*Goltix WG 70**	*Pseudokirchneriella subcapitata*	*static*	*72*	*E_rC_{50}*	*2.90 mg prod./L (geometric mean)*	*2.05 mg a.s./L (geometric mean)*
				E_bC_{50}	*0.58 mg prod./L (geometric mean)*	*= 0.41 mg a.s./L (geometric mean)*

** a formulation containing 697 g/L metamitron (analysed)*

Non-target arthropods

Substance	***Species***	***Method***	***Dose [g/ha]***	***Dose [g a.s./ha]***	***Parameter***	***Adverse effects[2] [%]***	***L(E)R_{50} [g a.s./ha]***
*Metamitron SC 700**	*Typhlodromus pyri*	*Laboratory, glass, 7 d (mortality), 14 d (fecundity)*	*0 425.3 2430 6075 8505 17010 25515*	*0 246.4 1408 3520 4928 9856 14784*	*Mortality and reproduction*	*Mortalitycorr: 0 - 8 % Sublethal effects: 4.8 – 33.8 %*	*LR50 > 21 L prod./ha (14784 g a.s./ha, analysed)*

** a formulation containing 704 g/L metamitron (analysed)*

Earthworms

Substance	***Species***	***Soil type***	***OM [%]***	***Duration [d]***	***Criterion***	***Dose product [mg/kg]***	***Dose [mg total a.s./kg]***
*Metamitron SC 700**	*Eisenia fetida*	*artificial*	*10*	*14*	*LC_{50}*	*> 1000 (nominal)*	*> 700 (nominal)*
*Goltix WG 70 ***	*Eisenia fetida*	*artificial*	*10*	*56*	*NOEC*	*389 (nominal)*	*272 (nominal)*

** a formulation containing 700 g/L metamitron (nominal)*
*** a formulation containing 70 % w/w metamitron (nominal)*

Micro-organisms

Substance	***Soil type***	***Dose product [mg/kg]***	***Dose [mg total a.s./kg]***	***Duration [d]***	***Process***	***Effect at test end < 25% (after 28 days) [Y/N]***
*Goltix WG 70**	*loamy sand*	*13.33*	*9.4*	*28*	*Nitrogen transformation*	*Y*
		133.3	*94*	*28*	*Nitrogen transformation*	*Y*

** a formulation containing 70.6% w/w metamitron (analysed)*

Terrestrial plants

Test substance	*Species*	*Exposure*	*Duration*	*Criterion*	*ER_{50} [g a.s./ha]*
*Goltix WG 70**	*Sugar beet (Beta vulgaris)* *Oilseed rape (Brassica napus)* *Carrot (Daucus carota)* *Soybean (Glycine max)* *Tomato (Solanum lycopersicum)* *Lettuce (Lactuca sativa)* *Oat (Avena sativa)* *Onion (Allium cepa)* *Rye grass (Lolium multiflorum)* *Corn (Zea mays)*	*Sprayed on plant foliage*	*21 days*	*Vegetative vigour*	*ER_{50} = 133.7 g a.s./ha (nominal)* *(lowest ER_{50} for effects on fresh weight of lettuce)*
*Goltix WG 70**	*Sugar beet (Beta vulgaris)* *Oilseed rape (Brassica napus)* *Carrot (Daucus carota)* *Soybean (Glycine max)* *Tomato (Solanum lycopersicum)* *Lettuce (Lactuca sativa)* *Oat (Avena sativa)* *Onion (Allium cepa)* *Rye grass (Lolium multiflorum)* *Corn (Zea mays)*	*Sprayed on soil surface*	*21 days*	*Seedling emergence*	*ER_{50} = 133.7 g a.s./ha (nominal)* *(lowest ER_{50} for effects on fresh weight of lettuce)*

** a formulation containing 706 g/kg metamitron (analysed)*

Additional studies with a formulation. Submitted for this assessment. Summarized and evaluated by the RIVM (12-2014)

Aquatic organisms

Substance	Species	Method	T [°C]	pH	Duration [d]	Criterion		Value [mg as/L[1]]
GOLTIX WG 70*	Lemna gibba	semi-static	23-23.8	7.5-8.3	7	ErC_{50}	frond numbers	1.12
						ErC_{50}	biomass	1.02
						EyC_{50}	frond numbers	0.35
						EyC_{50}	biomass	0.55
						ErC_{10}	frond numbers	0.09
						ErC_{10}	biomass	0.36
						EyC_{10}	frond numbers	0.02
						EyC_{10}	biomass	0.14
						NOErC	frond numbers	0.02
						NOErC	biomass	0.21
						NOEyC	frond numbers	0.02
						NOEyC	biomass	0.21

1: based on mean measured values, lowest endpoints are in bold
** metamitron 70 % w/w (nominal), 70.6 w/w (analysed)*

Biological effects and fate of metamitron SC 700 in outdoor microcosm enclosures. Heimbach, Brock and Deneer (1999). This is the study of the DAR.

Conclusion
The authors of the study report conclude that the overall NOEAEC is 1120 µg as/L. Significant effects were observed at the two highest concentrations for community metabolism endpoints (1120 and 4480 µg as/)L. For phytoplankton the author considered the overall NOEC to be ≥ 4480 µg as/L. This was based on univariate and multivariate analysis. The species Volvox aureus however showed a significant effect at 4480 µg as/L (). This significant effect is possibly inherent to the unstability of the enclosure. For periphyton and macrophytes significant effects could not be demonstrated. Densities of the major zooplankton groups also appeared to be unaffected. The effects of metamitron on pH and oxygen level were considered to be slight and transient at the 1120 µg as/L level as a significant was only observed at one sampling date after treatment. The effects at the highest concentration were more pronounced in magnitude and duration but showed a recovery within 15 days. This is in accordance with the short half-life of metamitron in this study (1.94 and 2.12 days).

Evaluation of the results of the study
Some of the endpoints that were tested showed a clear decrease after treatment, including the control. This concerned the phytoplankton, pH, oxygen level and temperature. At two days after application, the temperature had decreased to its lowest value with approximately 3 °C within 12 days. This decrease and its effects on the development of the community in the enclosure has not been discussed by the author. The lower temperature may have decreased the growth rate of the phytoplankton. It is uncertain how this decrease of growth rate affects the sensitivity of the test. With little growth it is difficult to demonstrate differences in growth caused by the metamitron application. Moreover, the zooplankton feeding on the phytoplankton may have further decreased the phytoplankton community, giving little opportunity for the phytoplankton to recover. Little growth was also reflected in the Shannon Weaver Index () which shows a slight decrease of the number of species until day 15 after application. A dose response relationship was however not very clear. Only the highest concentration had fewer species than the control at all sampling point apart from day 7 after application. The difference was not found to be significant. The Principle Response Curve of Figure 7 showed a decrease relative to the control, of all concentrations. Again, the highest concentration more or less showed the largest decrease, but differences were not significant. It is well possible that the densities of the phytoplankton were in general too low, making this endpoint not sensitive enough. This was demonstrated for the species Volvox and Gomphonema as described above. Fewer species, such as Anabaena had large and increasing densities, showing a negative weight in Figure 7. This demonstrates that most species showed a decline of densities, questioning the sensitivity of the phytoplankton endpoint. Furthermore, the results show a large variation especially in the untreated control over time. This makes it more difficult to detect effects of the applications. For these reasons the study is judged Ri2, less reliable.

Apart from pH, oxygen and temperature in the enclosure, the general environmental conditions were not monitored. It can be assumed that the decrease of phytoplankton can be explained by the decrease of temperature or oxygen. The development of each enclosure very much depends on the initial colonization and the weather conditions. It was shown for many parameters that the variation after treatment was larger than before treatment, but this is most likely caused by the natural development of the community within the enclosures.

It is concluded that the enclosure study can be used for the ecological risk assessment of the test compound regarding phytoplankton, zooplankton, periphyton and macrophytes. For the macrophytes it appeared that the bioassay with M. spicatum in the same system, that M. spicatum growth was relatively low between days 14 and 28 (Table 15). According to study description dry weights were also measured on day 0 but the data were not found in the report. It however seems that there was little development of this species in the parallel bioassay and for that reason the study is assigned Ri 2, less reliable. Also, very few macrophyte species were present in the microcosm. For instance Lemna gibba and L. minor were absent. These two species have a low EbC50 for biomass of 0.4 mg as/L according to the EFFSA scientific report (2008). It is unclear whether the species in the microcosms are more or less sensitive.

When recovery within 8 weeks after first application is taken as endpoint (effect class 3A) for determining the NOEAEC, the NOEAEC based on effects of metamitron and desamino-metamitron can be set at the 1120 µg as/L. This NOEAEC is based on community effects that are seen at the two highest Therefore, the evaluator can agree with the overall NOEAEC of 1120 µg as/L as proposed by the authors of the report. However, the sensitivity of the phytoplankton endpoint is questionable because of lack of growth. Effects, although not significant, were only observed at the highest concentration. If a stronger growth had occurred, the test could have been more sensitive, possibly demonstrating effects at the two highest concentrations. For this reason the study is considered to be less reliable.

Residues in invertebrates (Rossbach and Wilkens 2008)

Substance	***Crop***	***Dose [L/ha]***	***Dose [g as/ha]***	***Species***	***Sampling method***	***Exposure Duration [d]***	***Maximum residue [mg as/kg fw] based on 1000 g as/ha***	***Time after application [d]***	***DT_{50} [d]***
Goltix 700 SC	*Sugar beet, Beta vulgaris*	*2 L/ha in first appl; 1.5 L/ha[1] In second application*	*1050-1400*	*Ground-dwelling*	*Pitfall trap*	*35*	*2.63 (Metamitron)*	*1 d after 2nd appl.*	*nd*
							0.92 (Desamino-metamitron)	*1 d after 2nd appl.*	*nd*

Nd: not determined
1: by mistake 2 L/ha instead of 1.5 L/ha in the second application in one of the three subplots

Remarks of the evaluator
EFSA guidance recommends at least one test site and "Each test site will represent an individual residue value/time course, i.e. an individual study. Nevertheless, within each site it is desirable to have at least three replicates available to have information on intra-site variability of the residue values. The minimum size of each replicate within the test site should be approximately 1 ha". In this study one field (test site) was available with three replicates. The three subplots were flanking each other. According to EFSA guidance at least three samples from each strata/sample method should be planned for each sampling date (n ≥ 3). Exactly three samples were taken from the test site (one in each subplot) and the sampling can be qualified as sufficient. According to (EFSA 2009) determination of the DT50 with first order kinetic is not preferred for arthropods, because several processes are interfering (e.g. a rapid decline of surface residues by abrasion / renewal of the wax layer of the cuticle of individuals with direct contamination during the application vs. systemic uptake via food and residue decline via metabolisation and excretion, which is often much slower as well as immigration and emigration and population turnover).

It seems that the applications of Goltix on 15 and 26 May in the field adjacent to the test plots were a deviation in the study plan. This problem was solved by not sampling the traps in the rows adjacing the field. Although a margin of 30 m was effectuated it is not unlikely that ground-dwelling arthropods have migrated into the test plots. A small peak in Figure 15 at DAT17 may be the result of the Goltix application at DAT14 (15 May). In Figure 16 small peaks were seen at DAT 14 and 28. Only the peak at DAT 28 could be caused by arthropods immigration into the test plots as applications of Goltix took place in the main field at DAT 25. These effects, if really existent, can lead to a slight overestimation of the TWAs. TWA values clearly demonstrate that residues of metamitron decrease during the time course of 35 days. Maximum levels of 2.63 mg metamitron/kg fw in ground-dwelling arthropods and 0.92 mg desamino-metamitron/kg fw, and TWA values as given in Figure 17 can be used for risk assessment. These values are based on an application rate of 1000 g as/ha.

Investigations of the population ecology of brown hares in the Upper Rhine Plain. Späth 1989.

Description

Investigations of the population ecology of brown hares in the Upper Rhine Plain. This summary is based on an English translation by the applicant of the original report. The authors first summarize the studies that have been performed to explain fluctuating population densities in all German states. Studies on the effects of weather conditions and agricultural methods were shortly mentioned in the introduction.
The aim of the original study is to investigate the extent to which hare densities in the Upper Rhine Plain correlate with various structural parameters in the landscape, and how far a causal model can be developed to explain observed hare population densities. However, the current gaps in knowledge of hare ecology pose obstacles to an evaluation of agricultural methods in relation to the development of brown hare stocks. This study therefore serves to establish foraging and sheltering preferences as well as the condition of hare populations studied.

Methods

The Upper Rhine Plain between Neuenburg and Karlsruhe was selected to be the study area. This area is regarded as a 'home range' for brown hares. An investigation of hare populations, their habitats and population dynamics, was carried out at 23 selected sample sites distributed across the study area. The investigation took place between late winter 1984 and spring 1986. Radio telemetry was used to observe and monitor a total of 21 brown hares. These hares were fitted with transmitter collars with built-in motion sensors. In addition each hare was fitted with a fluorescent orange ear tag, in order to better distinguish the hares in the field. Observation and monitoring of the hares was performed with binoculars (after locating the hares using the tracking receiver equipment).

Location was recorded on 1:5,000 scale maps on which the soil use of the areas studied had already been marked before the investigation began. The hares' behaviour was also recorded in a diary with the exact time of observation. Thus results were obtained, not only about the size of the hares' area of activity, but also about rhythms of activity and browsing behaviour. This was especially simple to achieve when there was visual contact.
The motion sensors were used to recognize particular behaviour such as browsing, sitting, lying and running.

From the reports, following has been calculated (note: only PT presented under point 3 will be used for the applicant's conclusion for the risk assessment):
1. Distribution of browsing time over individual crop types.
2. Seasonal sequence of crops chosen for cover.
3. Proportion of browsing time spent in field margin areas for 5 hares.
4. Size of seasonal core ranges as polygon areas obtained by joining the outermost observation locations of hares during set periods of time. However, boundary structures respected by hares (such as tracks, watercourses and woods) were also taken into account when drawing range areas. This resulted at times in concave boundary lines.
5. Habitat area during total observation time as total of seasonal core areas.

Out of a total of 23 individuals observed by telemetry, it was possible to observe 13 hares for more than 100 days (some for more than 200 days), three times a week, for up to 10 months from March until December. Results from intensive observation of 9 individuals during the 1985 observation year were presented in particular in this study.

Results

The results in the English translation focused on the proportion of time spent in the treated area (PT) that is relevant for the risk assessment. The relevant application time-frame of several metamitron containing products in which exposure of brown hares is possible, is early post-emergence of sugar and fodder beets (at BBCH 10-39), approximately in April until the end of June. Sugar beet fields were available in the home ranges of five individuals, which visited this crop to varying degrees during the course of the year. In Table 1 only comprises those individuals with access to sugar beet fields during the application period of several metamitron containing products, i.e. April to June. The month April was excluded as no time was spent in these fields.According to the authors these field were not yet available. This possibly means that the fields were not sown yet.

Table 1. Time spent foraging [%] by radio-tracked brown hares in sugar beet fields in Germany

Hare	Percentage of sugarbeet in total home range during May-June	20 May	30 May	10 June	20 June	30 June
Willi	2	0.0	0.0	0.0	10.0	14.0
Seppl	3	23.0	27.0	17.0	8.0	3.0
Annie	12	25.0	11.0	23.0	26.0	25.0
Dollie	15	0.0	14.0	56.0	70.0	48.0
Egon	3	0.0	0.0	17.0	11.0	3.0
Mean	7	9.6	10.0	23.0	25.0	19.0
Overall mean May-June		17.2				
Overall 90th percentile May-June		39.6				

The radio-tracked brown hares spent 3.0-70.0% of their foraging time during May to June in sugar beets (mean 17.2%, 90th percentile 39.6).
The period May-June was considered for PT calculation, excluding the April when PT was Zero. This value is regarded particularly representative for the application period of several metamitron containing products in sugar and fodder beet fields. In addition, the study was conducted in a typical sugar beet growing area and the hares show a slight preference for root crops during this time of the year.

Remarks

Mean PT in sugar beet growing area as calculated by the applicant was 17.2%. This mean value does however not reflect the percentage of sugar beet in the total home range. Table 1 clearly shows a relation between the percentage of sugar beet and the PT. The data were therefore presented in Figure 1 to more clearly show this relationship.

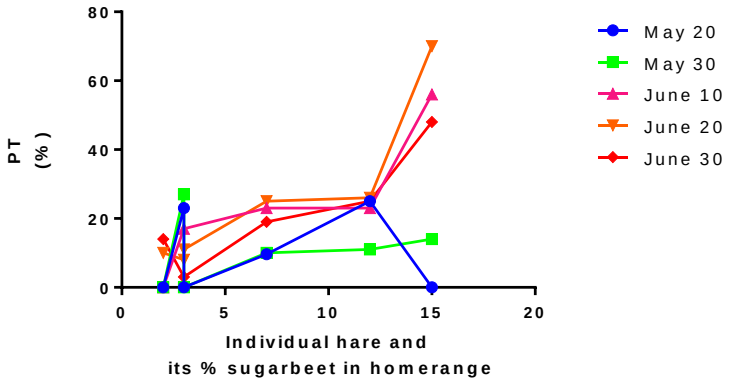

Figure 1. PT values for individual hares with home ranges containing 2, 3, 3, 7, 12 and 15% sugar beet

Figure 1 shows a correlation between the % sugar beet in the hares' homerange and PT for the surveying data in June. Clearly, PTs become higher when sugar beet is a more frequent crop in the home range of the hare. Also this figure shows that the PT is relatively low at the two surveying data in May. This is probably best explained by the use of herbicides as a pre-emergence herbicide and as a result the absence of attractive weeds in those

treated fields. Also, other more attractive crops may be present in the neighbouring fields. In figures presented in the translated document (similar to Figure 2 presented below) more preferred crops are meadows, verges of the road and spring and winter cereal ("sommer- und wintergetreide").

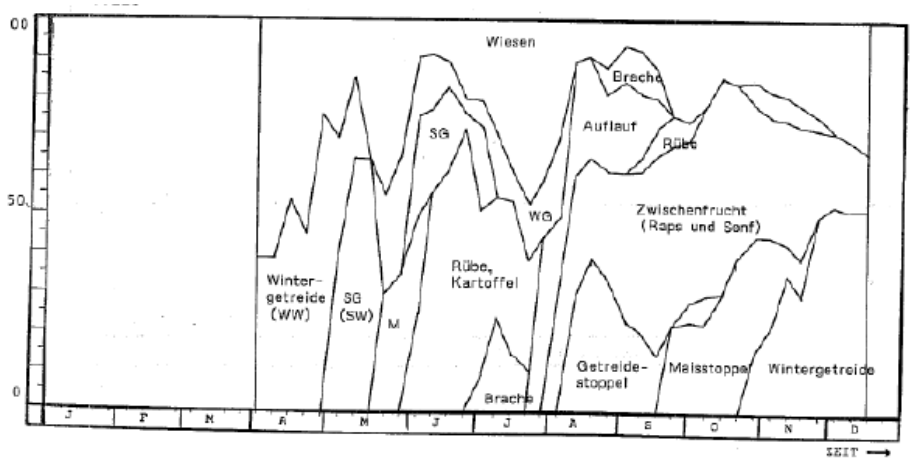

Figure 2 Distribution (%) of time spent in different habitats (%) in the course of the year, for hare "Dollie" (Remark: Dollie lived in the home range with 15% sugar beet; "Rübe" = sugar beet)

Figure 2 is included as an example of the distribution of time (time in percentage on the y-axis) of the hare that lived in an area with the highest percentage of sugar beet (15%). This figure shows that the high presence of this hare in sugar beet was restricted to the months June and July. The other four hares also visited sugar beet in the same months. According the applicant, the relevant application time-frame of several metamitron containing products in which exposure of brown hares is possible is early post-emergence of sugar and fodder beets (at BBCH 10-39), approximately in April until the end of June. As Table 1 and Figure 2 show that sugar beet is frequented most often in June, the risk assessment should be based on the PT that was obtained in this month. Also, the risk assessment should take the percentage of sugar beet in the region into consideration. In the present study, this percentage was maximum 15%. Because there is a clear correlation between the percentage sugar beet in the region and PT, the overall mean PT of 17.2% would underestimate the PT for regions with high sugar beet presence. For those areas mean PTs of 56% and 70% are probably more representative. However, a 90th percentile should be used in risk assessment rather than a mean.
Evidently, the scope of the original study was much broader than calculation of the PT for sugar beet. Therefore it is doubted that the study area was chosen because of its high production of sugar beets. This cannot be checked in the original document. The important producing areas are Schleswig-Holstein, Saarland, Lower Saxony, North Rhine-Westphalia, Hessen, Hamburg, Bremen, Bavaria, Rhineland and Palotinate. The Middle Elbe valley is also a leading sugar beet-producing area of the Germany (http://www.yourarticlelibrary.com/essay/country-wise-production-and-distribution-of-sugar-beet-around-the-world/25531/). The area of the study is situated in Baden-Württemberg. This area is not specifically mentioned for the production of sugar beet. Therefore, the percentage of sugar beet in this area is probably not representative. It can be concluded that the PTs derived from the 5 hares is probably an underestimation. Moreover, a number of five hare is extremely small for the derivation of a PT. The results of this study are therefore not reliable.

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 20170244 NLWG** page 25) 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

Acute risk to mammals

The screening step for the current application uses is presented in table E.14a.

Table E.14a Indicator species and default values for the acute risk assessment

Use	Crop / crop group	Indicator species (screening step)	Shortcut value	MAF_{90}
Beet pre-emergence and during emergence, beetroot pre-emergence and during emergence, summer flowers and flower seed production	Bare soil	small granivorous	14.4	1
Beet post emergence	Sugarbeet	small herbivorous	118.4	1
Beetroot post emergence	Root and stem vegetables	small herbivorous	118.4	1
Strawberies	Strawberries	small herbivorous	118.4	1
Bulb flowers/flower bulbs, Lily	Bulbs and onion like crops	small herbivorous	118.4	1
Perennial ornamental crops, tagetes, summer flowers, flower seed production	Ornamentals/nursery	small herbivorous	136.4	1
Oregano for essential oils	Oilseed rape*	small herbivorous	118.4	1

* Consulted with efficacy, for the use of oregano for essential oils fall within the group of oilseed rape

Depending on the crop category, different indicator species are chosen. Shortcut values (based on 90th percentile residues) according to Table 8 of the Birds and Mammals Guidance document (2009) were considered for the screening assessment. “Daily dietary dose” (DDD) values were calculated by multiplying respective “shortcut values” with the corresponding highest single application rates in kg/ha. “Multiple application factors” for 90th percentile residue data (MAF90) were selected from Table 9 of the guidance document. The DDD values were calculated according to the following equation: DDD = application rate [kg /ha] × shortcut value × MAF90. The TER value = LD50 / DDD. TER values for mammals for the worst-case uses, considering default values, are shown in Table E.14b.

Table E.14b Screening assessment, TER_A calculation

Acute exposure			
Indicator species	Small granivorous	Small herbivorous	Small herbivorous
Max. single application rate [kg a.s./ha]	3.5	3.5	3.5
Shortcut value	14.4	118.4	136.4
frequency	1	1	1
Interval [d]	-	-	-
Multiple application factor for 90th percentile residue data (DT_{50} = 10	1	1	1
Daily dietary dose	50.4	414	477
Endpoint (LD_{50}) [mg a.s./kg b.w.]	644	644	644
TER	12.8	**1.55**	**1.35**
Trigger value [TER]	10	10	10
Refinement required	No	Yes	Yes

Taking the results in Table E.14b into account, it appears that the acute risk to mammals is only acceptable for the bare soil uses, and not for the other uses. A Tier 1 assessment is performed with the generic focal species with the highest shortcut value for each crop group. Only the wosrt case shortcut values per crop group are used. If there is a risk the next scenario/shortcut value is also assessed. In addition the maximum total amount product per season is 2.1 kg a.s./ha for strawberries instead of 3.5 kg a.s./ha for the other field uses.

Table E.14c First Tier risk assessment, TER_A calculation

Crop group	**Scenario, BBCH**	**Generic focal species**	**Short cut value**	**DDD**	**TER**
Sugar beet	10-39	“lagomorph”	35.1	122.9	**5.24**

	10-29	"mouse"	17.2	60.2	10.7
Root and stem vegetables	10-39	"mouse"	17.2	60.2	10.7
Strawberries	≥40	"vole"	54.6	115	**5.6**
	10-39	"lagomorph"	35.1	73.7	**8.74**
	10-29	"mouse"	17.2	36.1	17.8
Bulbs and onion like crops	≥40	"vole"	81.9	287	**2.25**
	10-39	"mouse"	17.2	60.2	10.7
Ornamentals/ nursery	applic. to plant – exp. to underlying ground (downward spraying)	"shrew"	5.4	18.9	34.1
Oilseed rape	all season	"lagomorph"	35.1	122.9	**5.24**
	10-29	"mouse"	17.2	60.2	10.7

From the table above it is clear that all scenarios are above the trigger of 10 for the use in root and stem vegetables (beetroot) and the acute risk for mammals is acceptable for these uses. However, for the use in sugar beet there is a risk for the "lagomorph", for strawberries for the "vole"(BBCH ≥40) and the "lagomorph", for bulbs and onion like crops (Lily) for for the "vole"(BBCH ≥40) and for oilseed rape for the "lagomorph". Refinement of the risk is required.

The above risks were calculated with the maximum dose per season. Therefore, Ctgb will use the highest single rate in combination with the number of applications and interval days.

For sugar beet the proposed frequency of 2, an interval of 5 days and an application rate of 2.1 kg a.s./ha (highest application rate in the GAP) results in a DDD value of 103. Therefore the TER will not meet the trigger of 10 (**6.2**) for the risk for a "lagomorph". Thus the risk has to be refined.

For strawberries the proposed frequency of 3, an interval of 10 days and an application rate of 0.7 kg a.s./ha (highest application rate in the GAP) are used.

Table E.14d First Tier risk assessment for the use in strawberries, TER_A calculation

Crop group	Scenario, BBCH	Generic focal species	App. rate kg (a.s./ha)	MAF	Shortcut value	DDD	TER
strawberries	≥40	"vole"	0.7	1.5	54.6	57.3	11.2
	10-39	"lagomorph"	0.7	1.5	35.1	36.9	17.5

The table above shows that the risk for strawberries is acceptable.

For bulb and onion like crops the proposed frequency of 10, an interval of 7 days and a maximum application rate of 0.7 kg a.s./ha for lily was used, as the vole is only relevant for this scenario (BBCH 9-79).

Table E.14e First Tier risk assessment for the use in bulb and onion like crops, TER_A calculation

Crop group	Scenario, BBCH	Generic focal species	App. rate kg (a.s./ha)	MAF	Shortcut value	DDD	TER
lily	≥40	"vole"	0.7	2.0	81.9	115	**5.6**
lily	≥40	"vole"	0.7	1.9	81.9	109	**5.9**

The table above shows that the risk for lilies is unacceptable with a worst case total amount of 7 kg a.s./ha. However, the risk is also unacceptalbe with a frequency of 5, an interval of 7 days and a maximum application rate of 0.7 kg a.s./ha. Therefore, a risk remains.

For oregano (oilseed rape scenario) the proposed frequency of 3, an interval of 10 days and an application rate of 1.4 kg a.s./ha (highest application rate in the GAP) are used as a very worst case (total amount is 4.2 kg a.s./ha).

Table E.14f First Tier risk assessment for the use in oregano, TER_A calculation

Crop group	Scenario, BBCH	Generic focal species	App. rate kg (a.s./ha)	MAF	Shortcut value	DDD	TER
Oregano (Oilseed rape)	all season	"lagomorph"	1.4	1.5	35.1	73.7	**8.74**

The table above shows that the risk for oregano is not acceptable. Thus the risk has to be refined.

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Refinement of the risk for a small herbivorous mammal "vole"

Focal species

Approach applicant

"For the purpose of a refined risk assessment (Tier-2), the initial exposure assumptions were improved based on the selection of the wood mouse (Apodemus sylvaticus) as relevant focal species. The wood mouse was deemed most appropriate, since it is widespread in whole Europe and it is well known that it is foraging in a wide range of habitats including arable land.

In addition, for the use on lily (GAP no. 02b) and strawberries (GAP no. 03) in consideration of growth stages above BBCH 40, small herbivores should be used. This guild is represented by the common vole as focal species. However, common voles are not considered relevant in an ecological context for the following reasons:

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 availibilty 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 also covering the risk for small herbivorous mammals."

Reaction Ctgb

The Ctgb does not agree with dissmissing the vole as a focal species and selecting the wood mous instead.

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

The 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 woodmouse 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.

Thus, the applicant is requested to provide a risk assessment for the vole for the use bulb and onion like crops (lily).

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 and oregano, 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 if 1.9 days has only be established for beets. It is therefore quiestionable 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 usd 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 & oregano (oilseed rape) 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									
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 radiotracking study in flowerbulbs. (see full summary and evaluation below). From the study, it canbe concluded that the vole is not relevant in bulbflowers up to BBCH 65. Please note tha ta PT refinement is usually not acceted for the acute risk; however as the study give clear results about the presense 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, risk to large herbivorous mammals is considerd to be acceptable, as the TER is cleary above the trigger. For the small herbivorous mammal, the rsik assessment is still considerd 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 trigge 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.15 and the uncertainty analyses in table E.16, 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 BBCH 65 (volledige bloei, of koppen van het gewas).

Refined risk assessment applicant 20170244 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 kg/ha (0.700 kg a.s. /ha) to 0.5 kg/ha (0.350 kg a.s. /ha). The adjusted table 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.15a: 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.

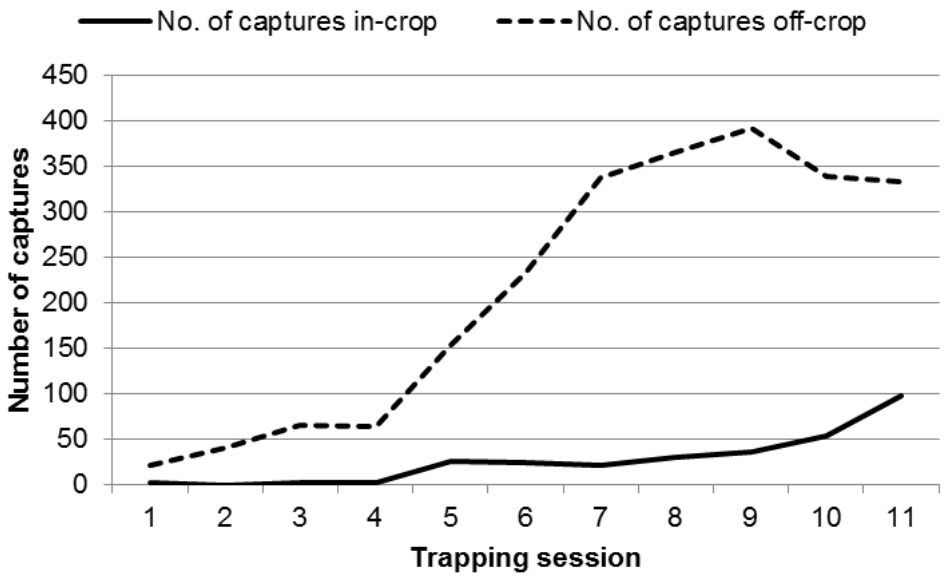

Figure 10- 1: Total number of captures in-crop and off-crop per trapping session for all study fields (numbers were corrected to the same trapping effort, i.e. actual numbers off-crop were multiplied with 2 to account for the double amount of traps set in-crop).

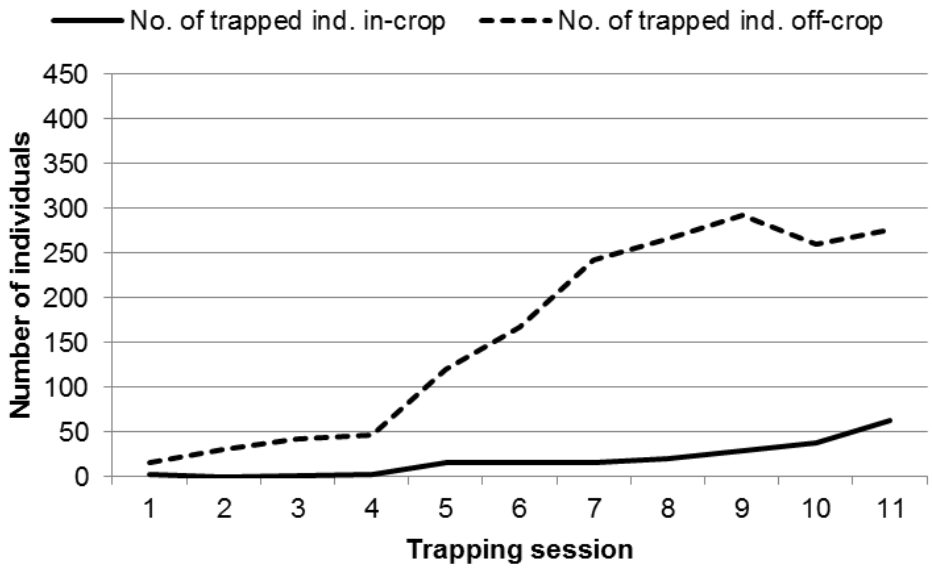

Figure 10- 2: Total number of trapped individuals (=ind.) in-crop and off-crop per trapping session for all study fields (numbers were corrected to the same trapping effort, i.e. actual numbers off-crop were multiplied with 2 to account for the double amount of traps set in-crop).

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.

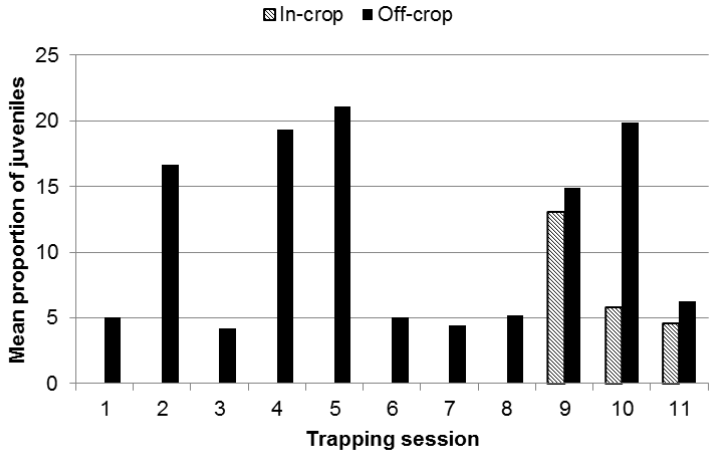

Figure 10- 3: Proportion of juveniles during each trapping session for in- and off-crop, given as mean for all study fields

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 15.5 µg/L. It follows that the risk of drinking water is (LD50 * bw) / (PIEC*DWI) = (644 * 0.010) / (0.0155 * 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 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.

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 onbedekte teelt van lelies uitsluitend toegestaan voor BBCH 65 (volledige bloei, of koppen van het gewas).*

The following restrictions remain unchanged:

➔ *Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in bieten, rode biet, bloembol- en bloemknolgewassen, lelies, tagetes, oregano, zomerbloemen, vaste plantenteelt en bloemenzaadteelt uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen in combinatie en een kantdop.*

➔ *Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in aardbeien uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 50% driftreducerende spuitdoppen en een kantdop, of minimaal 75% drift reducerende spuitdoppen.*

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. the proposed applications of the active substance metamitron 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 meet the standards for activated sludge as laid down in the RGB for field uses or cannot be examined against the standards as laid down in the RGB; for the time being this issue is not taken into consideration for glasshouse use.
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.

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

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.	
SP 1-statement: (gewas)	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 based on the operator exposure risk assessment.
Other:	As metamitron is responsible for the classification of the product with H302 it needs to be identified according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b).

* 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 BBCH 65 (volledige bloei, of koppen van het gewas).

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

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in de onbedekte teelten van bieten, rode biet, bloembol- en bloemknolgewassen, lelies, afrikaantjes (tagetes als groenbemester) , oregano, zomerbloemen, vaste plantenteelt en bloemenzaadteelt uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen in combinatie en een kantdop.

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in de onbedekte teelt van aardbei uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 50% driftreducerende spuitdoppen en een kantdop, of minimaal 75% drift reducerende spuitdoppen.

Mislukt een bietengewas door welke oorzaak dan ook (bijv. vorstschade of insectenvraat) en is Goltix WG 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 WG – metamitron 700 g/kg ;

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			Rate per treatment			PHI (days)	Remarks: 1. max. no. of applications per crop and season 2. Maximum product rate per season 3. additional remarks
	NL	Lily	F	Annual dicot weeds and annual meadow grass	Downward spraying	During and/or post-emergence (BBCH 09-19; February until with July)	2 (7)	2.0 – 4.0	1.40 – 2.80	200 – 500	-	Max total amount of product per season 5 kg/ha
						During and/or post-emergence (BBCH 09-79; April until with September)	10 (7)	0.5 ~~– 1.0~~	0.35 ~~– 0.70~~	200 – 500	-	LDS; combination with 5L oil/ha. Max total amount of product per season 5 kg/ha

Appendix 2 Reference list

No new studies were submitted for this application