HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. BESLUIT

Op 14 april 2014 is van

ADAMA Registrations B.V.
Postbus 355
3830 AK LEUSDEN

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

Goltix Queen

op basis van de werkzame stoffen metamitron en quinmerac. Nederland is in deze een betrokken lidstaat, als bedoeld in artikel 36, tweede lid; de beoordelend lidstaat is Duitsland.

HET COLLEGE BESLUIT tot uitbreiding en wijziging van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A en deel B, vormen een onlosmakelijk onderdeel van dit besluit.

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

1.3 Classificatie en etikettering

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

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder "verpakkingsinformatie" in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.
- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in hoofdstuk 2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

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

2. WETTELIJKE GRONDSLAG

Besluit	artikel 33 en artikel 36, derde lid, Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Conform Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual Zonaal.

3. BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Voor nadere onderbouwing van de beoordelingen verwijzen wij u naar deel A en B van het Registration Report als toegevoegd aan de bijlagen van dit besluit overeenkomstig Besluit beleidsregel bekendmaken delen A en B van het Registration Report.

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

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

Aanvraagnummer:	20131475 NLWTG
Type aanvraag:	Aanvraag tot uitbreiding en wijziging van toelating gewasbeschermingsmiddel (NL is CMS)
Middelnaam:	Goltix Queen
Verzenddatum aanvraag:	23 oktober 2013
*Formele registratiedatum: **	15 april 2014
Datum in behandeling name:	20 december 2016
Datum compliance check:	nvt

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

2.2 Stofinformatie

Werkzame stof	Gehalte
metamitron	525G/L
quinmerac	40G/L

- De stof metamitron is per 1 september 2009 geplaatst op Annex I van Richtlijn 91/414/EEG ((Dir 2008/125/EC d.d. 19 december 2008) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd) De goedkeuring van deze werkzame stof expireert op 31 augustus 2019.
- De stof quinmerac is per 1 mei 2011 geplaatst op Annex I van Richtlijn 91/414/EEG ((Dir 2010/89/EC d.d. 6 november 2010) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd) . De goedkeuring van deze werkzame stof expireert op 30 april 2021.

2.3 Toelatingsinformatie

Toelatingsnummer:	14298 N
Expiratiedatum:	30 november 2020
Afgeleide parallel of origineel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

- *W-codering professioneel gebruik:* 3
- *Vorige w-codering professioneel gebruik:* 2
- *Aflevertermijn professioneel gebruik:* niet van toepassing
- *Opgebruiktermijn professioneel gebruik:* niet van toepassing

2.4 Verpakkingsinformatie

Aard van het preparaat:
Suspensie concentraat

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel Goltix Queen

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

Pictogram	GHS09
Signaalwoord	-
Gevarenaanduidingen	H411 Giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P102 Buiten het bereik van kinderen houden. 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	EUH208 Bevat 1,2-benzisothiazol-3(2H)-on. Kan een allergische reactie veroorzaken. EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

REGISTRATION REPORT
Part A

Risk Management

Product name (code): **Goltix Queen**
(AG-QMM1-565 SC)

Active Substances: **525 g/L Metamitron**
40 g/L Quinmerac

COUNTRY: the Netherlands

Central Zone
Zonal Rapporteur Member State: Germany

National Assessment: the Netherlands

Applicant: **ADAMA Registrations B.V.**
Date: **July 2017**

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PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of Goltix Queen containing the active substances Metamitron and Quinmerac in the Netherlands. This evaluation is required subsequent to the inclusion of Quinmerac and Metamitron in Annex I.

In particular, this document describes the acceptable use conditions of the first original submission which led to authorisation of the product Goltix Queen in the Netherlands (reg. No. 14298N) as well as new information to support the current application of a label extension (3 L/ha pre-emergence + 3 x 1 L/ha post-emergence) in the central zone. Only new and/or necessary documents are attached to this submission. In addition the applicant applied for a change in the interval between the applications for the current use (2 L/ha).
This evaluation is required subsequent to the first registration of Goltix Queen to support a label extension.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-8 and Part C and, where appropriate, the addenda for the Netherlands. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to Goltix Queen where that data has not been considered in the EU review. Otherwise assessments for the safe use of Goltix Queen have been made using endpoints agreed in the EU review of Metamitron and Quinmerac.

This document describes the specific conditions of use and labelling required for the Netherlands for the registration of Goltix Queen.

Appendix 1 – Copy of the product label
Appendix 2 – Letter of Access.
Appendix 3 – List of data in support of the evaluation.

1 Details of the application

1.1 Application background

This application was submitted by:

ADAMA Registrations B.V.
P.O. Box 355
3830 AK Leusden
The Netherlands

This application is for the label extension of product Goltix Queen (reg. No. 14298N), a suspension concentrate containing 525 g/L Metamitron and 40 g/L Quinmerac, for use against annual monocotyledonous weeds, GALAP and other annual dicotyledonous weed species.

1.2 Annex I inclusion

Metamitron
The active substance Metamitron was listed on Annex I of Directive 91/414 with effect date 1 September 2009 (Commission Directive 2008/125/EC) and implemented under Regulation (EU) No 540/2011. MAK-FSG was main notifier (see SANCO/208/08 final – 06/01/2009).

For the implementation of the uniform principles of Annex VI, the conclusions of the review report on the active substance Metamitron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account. In this overall assessment:

In this overall assessment Member States must pay particular attention to:
- operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate,
- the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions,
- the risk to birds and mammals, and non-target terrestrial plants

Conditions of authorisation shall include risk mitigation measures, where appropriate.

The Member States concerned shall request the submission of further information on the impact of soil metabolite M3 on groundwater, on residues in rotational crops, on the long-term risk to insectivorous birds and the specific risk to birds and mammals that may be contaminated by the intake of water in field.
They shall ensure that the notifiers at whose request Metamitron has been included in the Annex provide such information to the Commission by 31 August 2011 at the latest. These data have been submitted in the meantime and were evaluated recently.
The evaluation report is now available on CIRCA.
Conclusion of CRD (zRMS UK) concerning the M 3 metabolite: *Regarding further information on soil metabolite M3 in relation to impact on groundwater; The UK RMS agrees with the Applicant assessment that M3 is a likely artefact of the reaction of metamitron with acetone as an extraction solvent, especially under higher temperature conditions. Overall the RMS considers the GW modelling in the original DAR that cover metamitron and its main metabolite desamino-metamitron to be sufficient. No further information is considered necessary with respect to the risk to groundwater*.

Quinmerac
The active substance Quinmerac was listed on Annex I of Directive 91/414 with effect date 1 May 2011 (Commission Directive 2010/89/EU).
MAK-FSG has submitted data to support their own source of Quinmerac to the RMS UK for equivalence evaluation. The RMS UK has assessed the active substance source of MAK-FSG as being equivalent to the notified source of Quinmerac. The decision was taken on 16 December 2010 and is published on CIRCA for the other Member States.
Further to this MAK-FSG owns an Annex II data compensation dossier, to match protected data according to the published "List of Annex II studies which were considered as relied upon for the evaluation with a view to Annex I inclusion and for which the main data submitter has claimed data protection, version 2, February 2011, RMS UK", which has been submitted on 19 April 2011 to RMS UK.
On 13 September 2011 the RMS UK confirmed that they considered the MAK-FSG Annex II data package to be complete. The evaluation of the RMS UK is available for other MS on CIRCA.
The Annex II compensation data for Quinmerac however already have been summarised and are submitted with this dossier.

For the implementation of the Uniform Principles of Annex VI, the conclusions of the review report on Quinmerac, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account.

In this overall assessment Member States must pay particular attention to:

- the protection of groundwater when the active substance is applied in regions with vulnerable soil and/or climatic conditions;
- the dietary exposure of consumers to residues of Quinmerac (and its metabolites) in succeeding rotational crops;
- the risk to aquatic organisms and the long term risk for earthworms

Conditions of use shall include risk mitigation measures, where appropriate.

The Member States concerned shall request the submission of information as regards:

- the potential of plant metabolism to result in an opening of the quinoline ring;
- residues in rotational crops and the long term risk for earthworms due to the metabolite BH 518-5.

They shall ensure that the applicant provides such confirmatory data and information to the Commission by 30 April 2013.

These concerns have been addressed within the current submission in the respective sections.

1.3 Regulatory approach

This application was submitted to support a label extension of the product Goltix Queen already authorised in Germany (reg. No. 007529-00), Belgium (reg. No. 10238P/B) and the Netherlands (reg. No. 14298N). For the sake of clarity, information related to the first original submission as well as the new information to support the current application are reported. However, only new and/or necessary documents are attached to this submission.

To obtain approval, the product Goltix Queen must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to extend the uses of this product in Netherlands in accordance with the above.

The dossier is submitted in parallel to the following member states of the central zone: Germany (DE) and Belgium (BE).

Germany is acting as zonal rapporteur here.

1.4 Data protection claims

For all data in this submission data protection is claimed.

1.5 Letters of Access

No Letters of Access are required as protected data were matched with equivalent studies.

2 Details of the authorisation

2.1 Product identity

Product Name	Goltix Queen (AG-QMM1-565 SC)
Authorization Number (for registration)	Currently registered with authorisation No. 14298N
Function	Herbicide
Applicant	ADAMA Registrations B.V.
Composition	525 g/L Metamitron + 40 g/L Quinmerac
Formulation type	Suspension concentrate [Code: SC]
Packaging	1, 5, 10 and 20 L HDPE bottle or canister

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

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

The identity of all substances in the mixture that contribute to the classification of the mixture *:

-

Pictogram:	GHS09	Signal word: -
H-statements:	H411	Toxic to aquatic life with long lasting effects.
P-statements:	P102	Keep out of reach of children
	P280c	Wear protective gloves and protective clothing.
	P501	Dispose of contents/container to hazardous or special waste collection point.
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.
	EUH208	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.
	SP1	Do not contaminate water with the product or its container.
Child-resistant fastening obligatory?		not applicable
Tactile warning of danger obligatory?		not applicable

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

2.2.3 Other phrases

See Appendix 1

2.3 Product uses

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	Member state(s)	Crop and/or situation	F G Or I	Pests or Group of pests controlled	Application			Application rate per treatment			PHI (days)	Remarks: 1. max. no. of applications per crop and season 2. Maximum product rate per season 3. additional remarks
					Method / Kind	Timing / Growth stage of crop & season	Number / (min. Interval between applications)	kg, L product / ha	g as/ha	Water L/ha min / max		
1	NL, BE, DE	Sugar beet, fodder beet	F	Annual dicotyledonous weeds	Spraying	Post-emergence (BBCH 10-19) (Mar-Jul)	3 / (7)	2 L/ha	M: 1050 Q: 80	200 – 400	-	1. 3 2. 6 L/ha in total for all beet applications
2	NL, BE, DE	Sugar beet, fodder beet	F	Annual dicotyledonous weeds	Spraying	Pre-emergence (BBCH 00-09) (Mar-may)	1	3 L/ha	M: 1575 Q: 120	200 – 400	-	1. 1 2. 6 L/ha in total for all beet applications Minimum 10 days interval between the l application before emergence and the 1st application after emergence
						Post-emergence (BBCH 10-19) (Mar-Jul	3 / (5)	1 L/ha	M: 525 Q: 40	200 - 400	-	1. 3 2. 6 L/ha in total for all beet applications 3. Only as LDS application Minimum 10 days interval between the l application before emergence and the 1st application after emergence

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary: Goltix Queen is an off-white homogenous suspension, characteristic odour. It has no explosive and oxidising properties. Goltix Queen has a self-ignition temperature of 505°C and has no flash-point up to vaporizing point of 99˚C. The pH of the neat formulation is 4.4 and a 1% aqueous dilution is 3.7. The kinematic viscosity is 825 mm^2/s with a hydrocarbon content <<10%. The surface tension at 25˚C is 46.9 mN/m for 1% dilution and it is considered a surface active mixture. The density is 1.163 g/mL. The storage stability at accelerated, low and ambient temperature showed good stability in terms of active substance content and product characteristics and therefore a shelf-life of 2 years at ambient temperature in HDPE is granted. Its technical characteristics are acceptable for a SC formulation.

Implications for labelling: none

Compliance with FAO specifications: The product Goltix Queen complies with FAO specifications.

Compatibility of mixtures: Not applicable.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment: Information regarding the required protective clothing and equipment for the safe handling of Goltix Queen has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

Analytical method for determination of Metamitron and Quinmerac and relevant impurities and relevance of CIPAC methods in Goltix Queen were not evaluated as part of the EU review. Therefore all relevant data are provided and considered adequate.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Point 5.3 – 5.8)

All analytical methods are active substance data and were provided in the EU review of metamitron and quinmerac or provided in the original zonal application of Goltix Queen and were considered adequate.

The analytical method for the determination of metamitron and desamino-metamitron in surface water is compliant with Dutch national requirements (LOQ $\leq$ 0.1 µg/L for metamitron and desamino-metamitron).

The analytical method for determination for quinmerac, BH815-2 and BH815-5 in surface water is compliant with Dutch national requirements (LOQ ≤ 0.1 µg/L for quinmerac, BH815 2 and BH815 5)

3.1.3 Mammalian Toxicology (Part B, Section 3, Point 7)

3.1.3.1 Acute Toxicity (Part B, Section 3, Point 7.1)

The following tests were performed on Goltix Queen (AG-QMM1-565 SC). For details of the formulation please refer to dRR Part C. The results of these toxicological studies are summarised in **Table 3.1.3.1-1** and individual study summaries are provided in Part B, Section 3 (Points IIIA 7.1.1 to 7.1.6).

Acute toxicological data obtained with AG-QMM1-565 SC

Parameter [Reference]	**Species**	**Result mg/kg or mg/L or effect**	**Classification**
Oral route IIIA 7.1.1/01 (Haferkorn, 2010a)	Rat	LD_{50} > 2000 mg/kg 2/6 animals died prematurely	None
Percutaneous route IIIA 7.1.2/01 (Haferkorn, 2010b)	Rat	LD_{50} > 2000 mg/kg No mortality	None
Inhalation route IIIA 7.1.3/01 (Haferkorn, 2010c)	Rat	LC_{50} > 5.57 mg/L (4 h) No mortality	None
Skin irritation IIIA 7.1.4/01 (Leuschner, 2010a)	Rabbit	Non-irritating	None
Eye irritation IIIA 7.1.5/01 (Leuschner, 2010b)	Rabbit	Non-irritating	None
Skin sensitisation IIIA 7.1.6/01: (Haferkorn, 2010d)	Guinea pig	Not sensitising	None

AG-QMM1-565 SC has a low potential of toxicity following oral, dermal or inhalation exposure.

AG-QMM1-565 SC was not irritating to the skin of the rabbit.

AG-QMM1-565 SC was only mildly and reversibly irritating to the eyes of the rabbit.

AG-QMM1-565 SC was not sensitizing to skin in a maximisation test in Guinea pigs.

Thus, no classification is required for the formulation Goltix Queen (AG-QMM1-565 SC) according to the classification criteria of Council Directive 67/548/EEC and subsequent regulations.

3.1.3.2 Operator Exposure (Part B, Section 3, Point 7.3)

According to the model calculations in the Core, it is concluded that there is no unacceptable risk anticipated from metamitron and quinmerac for the operator wearing gloves in case gloves are worn during mixing and loading and application and protective clothing during application.

3.1.3.3 Bystander Exposure (Part B, Section 3, Point 7.4)

According to the model calculations, bystander exposure, resident exposure of children and adults living next to a field treated with Goltix Queen is considered to be safe.

3.1.3.4 Worker Exposure (Part B, Section 3, Point 7.5)

According to the model calculations in the Core, it is concluded that there is no unacceptable risk anticipated from metamitron and quinmerac for the worker wearing gloves, when re-entering crops treated with Goltix Queen. Thus, the application of Goltix Queen is acceptable provided that the following measure is included on the label:

Draag geschikte handschoenen bij werkzaamheden aan behandeld gewas

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

For the evaluation of the active substances, reference is made to the original application of Goltix Titan®.

To support the intended cGAP on/in sugar beet within the framework of this application, reference is made to the studies evaluated in the RR for the original registration of the product Goltix Queen (zRMS Germany).

In this application, the product will be evaluated for zonal as well as national authorisation whereby an application is made to adjust the interval between treatments from 5 days to 7 days in the case of zonal authorization and from 10 days to 7 days in the case of national authorisation. An application interval of 5 days is already evaluated and accepted during the original authorization of the product (zRMS Germany).

A sufficient number of supervised residue trials is presented within the RR to cover the intended use of Metamitron and Quinmerac. No residues of Metamitron and its metabolite Desamino-metamitron and Quinmerac and its metabolites BH 518-2 and BH 518-4 at or above the respective limit of quantification were found in sugar beet leaves and roots at harvest in any residues trial.

Considering this in to account, an exceedance of the current EU MRL of 0.2 mg/kg for metamitron (Reg. (EC) No 149/2008) and 0.5 mg/kg for quinmerac (Reg. (EC) No 14972009) in sugar beets is not expected.

Sugar beet might be fed to livestock. However, due to the residue levels below the respective limit of quantification for Metamitron and Quinmerac and its metabolites in sugar beet roots and leaves at harvest time in supervised residue trials, significant intake of residues by livestock is not expected. Thus, supplementary livestock feeding studies were considered to be not required.

According to Annex II of Metamitron, no studies on residues in succeeding crops after application of Metamitron are considered to be required as no residues are expected in succeeding crops. For Quinmerac, new confined rotational crop study and field rotational crop study were evaluated in the DAR by zRMS UK. Based on those studies, it was concluded that the use of AG-QMM1-565 SC under usual agricultural rotation practices with sugar and fodder beets will not lead to measurable residue levels of Quinmerac above the analytical limit of quantification in food commodities from rotational crops.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

For the active substances Metamitron and Quinmerac, dietary risk assessments were performed taking into account the EU MRLs of Metamitron and Quinmerac as set in Reg. (EC) No 149/2008. The consumer risk assessments were performed with revision 2 of the EFSA PRIMo. Result shows that the long-term and the short-term intake of residues of metamitron and quinmerac residues is unlikely to present a public health concern.

Based on the different calculations made to estimate the risk for consumer through diet and other means it can be concluded that the use of the product Goltix Queen (AG-QMM1-565 SC) does not lead to unacceptable risk for consumer when applied according to the recommendations.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

No new studies are presented. Appropriate endpoints from the EU reviews of metamitron and quinmerac were used to calculate PECs for the active substances and their metabolites in soil, surface water, groundwater, and air for the intended use patterns.

Based on uses proposed, Goltix Queen (AG-QMM1-565 SC) is to be applied to beets (sugar and fodder) considering two application schemes. The first application scheme (application scheme A) concerns a modification of an already authorised use in the Netherlands. It consists of up to three post-emergence applications (BBCH 10-19) each at rates of 2.0 L product/ha (equivalent to 1.050 kg metamitron/ha and 0.080 kg quinmerac/ha). The application interval for this use is changed from 10 to 7 days. The second application scheme (application scheme B) concerns an extension of uses. It consists of up to four applications, with one pre-emergence application (BBCH 00-09) at rate of 3.0 L product/ha (equivalent to 1.575 kg metamitron/ha and 0.120 kg quinmerac/ha), followed by three post-emergence applications (BBCH 10-19) each at a rate of 1.0 L product/ha (equivalent to 0.525 kg metamitron/ha and 0.040 kg quinmerac/ha) with a minimum interval of 5 days.

3.1.5.1 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)

National modification of authorised use

The PECs relevant for the modification of the authorised use in the Netherlands (i.e., application interval change from 10 to 7 days; Application Scheme A in Table 9.1) are covered by the core assessment of Goltix Titan June 2012, for which an application interval of five days is used (see also Part A of the Dutch assessment of Goltix Queen, 14298N, Decision of the Board d.d. 06-12-2013):
The maximum $PEC_{S,\ ini}$ for Metamitron and Quinmerac following 3 applications to beets amounted to 2.894 mg/kg dry soil and 0.241 mg/kg dry soil, respectively. The maximum $PEC_{S,\ ini}$ for metabolite Desamino-metamitron following three post-emergence applications of Goltix Queen amounted to 0.489 mg/kg dry soil.
The maximum $PEC_{S,\ ini}$ for metabolites BH 518-2 and BH 518-5 (including plateau concentration, persistent metabolite) following three cumulative postemergence applications of Goltix Queen amounted to 0.123 and 0.095 mg/kg dry soil, respectively.

Zonal extension of use

The maximum initial PEC_S upon application of 1x 1575 and 3x 420 g/ha metamitron is 2.756 mg/kg. The corresponding maximum PEC_S of the metabolite desamino-metamitron (using a formation fraction = 0.5) is 0.840 mg/kg.

No calculation of PEC_{soil} for quinmerac and its soil metabolites is necessary, as the risk is covered by the assessment of metamitron and the formulation (based on extrapolation of the risk assessment of the original authorisation of Goltix Queen).

The results for PEC_S for the active substances and metabolites were used for the eco-toxicological risk assessment.

3.5.1.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

The leaching potential of metamitron and quinmerac and their major soil metabolites is determined using the FOCUS PEARL model (version 4.4.4) with the FOCUS Kremsmünster-SUGARBEET scenario and EU-agreed endpoints in the first tier of the assessment.

For quinmerac, the national decision tree with regard to the derivation of an appropriate endpoint for pH dependent sorption was taken into account.

The PEC_{GW} of metamitron and the metabolite desamino-metamitron are below both the regulatory threshold of 0.1 µg/L and the Dutch specific threshold of 0.01 µg/L for groundwater protection areas.

Quinmerac and its metabolites BH518-2 and BH518-5 are predicted to occur in groundwater at concentrations above both the regulatory threshold of 0.1 µg/L, thereby triggering tier 2 of the assessment. In Tier 2, the leaching potential of substances to shallow groundwater is evaluated for the potential area of use within the Netherlands using the spatial distribution model GeoPEARL version 3.3.3. The PEC_{GW} of the active substance quinmerac is below the regulatory threshold of 0.1 µg/L, but above the Dutch specific threshold of 0.01 µg/L for groundwater protection areas. Therefore, the following restriction on the use in groundwater protection areas should be placed on the label:

Om het grondwater te beschermen mag dit product in de teelt van bieten niet worden gebruikt in grondwaterbeschermingsgebieden.

The quinmerac metabolites BH518-2 and BH518-5 are predicted to occur in groundwater at concentrations above 0.1 µg/L. An assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is therefore required.

The Acceptable Daily Intake (ADI) for quinmerac (0.08 mg/kg bw) was considered applicable to BH518-2 and BH518-5 during the EU peer review. At maximal PEC_{GW} concentrations of 0.835 and 7.125 µg/L for BH518-2 and BH518-5, the highest estimated exposure via drinking water is 0.1% and 0.6% of the Acceptable Daily Intake, respectively. This means that the individual and combined exposure of metabolites BH518-2 and 518-5 is below the allocation factor of 20% set in the WHO Guidance for drinking-water quality and is considered acceptable.

Monitoring data ground water.

Active substance metamitron and metabolite desamino-metamitron

Most recent data are presented in RIVM Rapport 607310001/2007. The mean concentration of metamitron was <0.02 µg/L. These monitoring results indicate that the substance metamitron was detected on some occasions. After evaluation of the data in RIVM Rapport 607310001/2007, the 90th percentile concentrations did not exceed the limit of 0.1 µg/L on several locations. Hence, the monitoring data are in line with the predicted concentrations.

Regarding the presence of metabolite desamino-metamitron no monitoring data are available.

Active substance quinmerac

There are no data available regarding the presence of quinmerac, BH518-2 and BH518-5 in groundwater.

Based on the assessment, the use of Goltix Queen is not expected to lead to unacceptable leaching levels when applied according to the recommended use pattern.

3.5.1.3 Predicted Environmental Concentration in Surface Water (PECSW) (Part B,

Section 5, Points 9.7 and 9.8)

The predicted environmental concentrations of the active substances metamitron and its metabolite desamino-metamitron, and of the active substance quinmerac and its metabolite BH518-2 have been determined using the TOXSWA-NL model (version 1.2; GUI 1.0) with the standard spring scenario, Dutch specific drift figures and the EU agreed endpoints.

The results for PEC surface water for the two active substances and their metabolites (see table below) were used for the eco-toxicological risk assessment.

Application Scheme	Drift value (%)	Max PEC_{SW} (µg/L)	21 d-PECsw,twa (µg/L)	28 d-PECsw,twa (µg/L)	Max PEC_{SED} (µg/kg)**
Metamitron					
A	1*	14.32	13.15	12.24	186
B	1*	13.9	12.43	11.61	185
Desamino-metamitron					
A 81.5% observed percentage (water-sediment)	1*	10.8	9.982	9.287	163
B 81.5% observed percentage (water-sediment)	1*	10.5	9.439	8.817	163
A 92.4% observed percentage (photolysis)	1*	14.33	13.24	12.32	211
B 92.4% observed percentage (photolysis	1*	11.93	10.71	10.01	182
Quinmerac					
A	1*	1.091	1.002	0.933	13.36
B	1*	1.058	0.947	0.885	13.25
BH518-2					
A	1*	0.1646	0.1531	0.1423	2.04
B	1*	0.159	0.143	0.134	2.01

* corresponding to the use of (standard) 50% drift-reducing nozzles.
** calculated as (PECsed in g/m^3 / 80 kg/m^3)*1000

Monitoring data in surface water

The Pesticide Atlas on internet (www.pesticidesatlas.nl, www.bestrijdingsmiddelenatlas.nl) is used to evaluate measured concentrations of pesticides in Dutch surface water, and to assess whether the observed concentrations exceed threshold values.

<u>metamitron</u>

The relevant EQS for metamitron is the MPC, which is 10 µg/L. The authorisation threshold equals 56 µg a.s./L (consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case second tier 0.1*NOECmesocosm).

Metamitron was monitored in surface water (at 912 locations; data from 2015); there was no exceedance of the above thresholds. Therefore, the monitoring data have no consequences for the proposed uses of the product.

quinmerac

The relevant EQS for quinmerac is the MPC, which is 100 µg/L. The authorisation threshold equals 316 µg a.s./L (consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case 0.1*NOECfish).

Metamitron was monitored in surface water (at 71 locations; data from 2015); there was no exceedance of the above thresholds. Therefore, the monitoring data have no consequences for the proposed uses of the product.

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

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

Metamitron and quinmerac have been on the Dutch market for > 3 years (authorised since before 1995). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

3.5.1.4 Predicted Environmental Concentration in Air (PECAir) (Part B, Section 5, Point 9.9)

The fate and behaviour of metamitron and quinmerac in air were evaluated during the Annex I inclusion. No additional studies have been performed.

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Birds

Effects of Goltix Queen (AG-QMM1-565 SC) on birds were not evaluated as part of the EU review of Metamitron and Quinmerac. However further data on Goltix Queen (AG-QMM1-565 SC) are not deemed necessary as active substance data on toxicity to birds is used and according to EU Directive 91/414/EEC data on the toxicity of the formulation are not considered essential. Therefore all relevant data were assessed in the EU review. Risk assessments Goltix Queen (AG-QMM1-565 SC) with the proposed use pattern are provided here and are considered adequate.

Long-term risk to birds resulting from the interval change for existing label (application interval 7 days) was considered acceptable,.

With regard to the extension of use (application Scheme B), the refinement of long-term risk to small omnivourous bird “lark” provided by the applicant (multiplying pre-emergence application rate by dissipation factor of 0.35) was not considered correct.

Ctgb refined risk to lark considering the difference in composition of pre- and post-emergence diets. TER combi fot the two active substances was still below 5 (4.2). It should be noted that the assessment above is a worst-case situation. Dissipation between pre- and post-emergence applications is not taken into account, however with an interval of 5 days this will probably only be relevant for metamitron. PT of 1 also represents a worst-case scenario. Weed seeds proportion of diet makes the highest contribution to exposure for both metamitron and quinmenrac (which makes up to 50% of pre-emergence). For metamitron it can be suggested that a lower DT50 value on seeds might be expected (due to low DT50 on leaves) which will increase TER. However it should be noted that this is not always the case and further information on DT50 for metamitron on seeds is not available. Considering uncertainties discussed above, acceptable long-term risk to birds could not be concluded.
To address long-term risk to birds, the applicant proposed a GAP change. The new proposed GAP for application scheme B gets a minimum spray interval of 10 days between the pre- and first post-emergence application. The interval between the post-emergence applications stays the same at 5 days.

Based on the new GAP (pre-emergence followed by post-emergence applications, interval between pre-emergence and the first post-emergence application 10 days, interval between post-emergence applications 5 days), the applicant calculated time-weighted average concentrations (TWA) for metamitron and quinmerac, which were considered acceptable by Ctgb.

TWA concentrations were used to refine exposure. The applicant calculated two scenario’s, one with the proposed dose rates, but only assuming it to be applied pre-emergence; and a second scenario with the proposed dose rates, but only assuming it to be applied post-emergence (which is slightly more worst-case). When considering the risk for omnivorous birds, the actual exposure indeed lies somewhere between the exposure for pre-emergence and post emergence diets. Therefore also the relevant TER will be between the calculated TER for pre-emergence and for post-emergence, meaning between 4.8 (4.5 if worst-case RUD of 48 is used for metamitron)- and 5.3 (trigger=5).There might be some uncertainty if the TER would be exactly a mean value (as suggested by the applicant), but as no PT refinements are given and as metamitron is expected to also have a higher dissipation from other diet items than the default value, the combined risk is considered to be acceptable.

The following sentence should be mentioned on the label:

Minimaal 10 dagen tussen voor opkomst en de 1e na opkomst behandeling

Drinking water assessments are not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Finally, an assessment of the risk from secondary poisoning is not required due to log P_{OW} values below the trigger.

Terrestrial Vertebrates other than Birds

The effects of Goltix Queen (AG-QMM1-565 SC) on terrestrial vertebrates other than birds were not evaluated as part of the EU review of Metamitron and Quinmerac. However, further data on Goltix Queen (AG-QMM1-565 SC) are not deemed necessary as active substance data on toxicity to small mammals is used and additional formulation data are reported in Section 3. Therefore, all relevant data were assessed in the EU review. Risk assessments for Goltix Queen (AG-QMM1-565 SC) with the proposed use pattern are provided here and are considered adequate. The risk assessment was based on the toxicity endpoints for Metamitron and Quinmerac. Mixture toxicity was also assessed.

For the long-term risk to mammals, only metamitron was considered in the refinement, as the contribution of quinmetac is considered to be negligible. Long-term risk to small omnivorous mammal “mouse” following application Scheme B was refined by the applicant based on time weighted average concentrations. However this was not considered acceptable due to the difference in mouse diet before and after emergence, while the dissipation refinement is only relevant for crop leaves. Ctgb refined risk to mouse considering the difference in composition of pre- and post-emergence diets, and FIR/bw values. Resulting TER was 4.7. Based on weight-of-evidence this was considered acceptable.

Drinking water assessments are not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Finally, an assessment of the risk from secondary poisoning is not required due to log P_{OW} values below the trigger.

In conclusion, application of Goltix Queen (AG-QMM1-565 SC) in accordance with the proposed use patterns in pre- and early post-emergence in fodder and sugar beets poses an acceptable risk to mammals.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

Risk assessments for aquatic organisms were conducted based on the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001 rev. 4 final) and under consideration of the Netherlands national requirements. Predicted environmental concentrations in surface water have been assessed with the TOXSWA 1.2 model following the currently agreed approaches described in the CTGB Manual for the Authorisation of Pesticides [1] in the Netherlands. The risk to aquatic organisms was shown to be acceptable.

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Point 10.4 and 10.5)

Bees

[1] Evaluation manual for the authorisation of plant protection products and biocides. NL part. Plant protection products. Chapter 6 Fate and behaviour in the environment: behaviour in surface water, sediment and sewage treatment plants (STP) version 1.0; January 2010

Risk assessments for bees, conducted following the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final) for acute oral and contact exposure have been conducted based on the following endpoints for the active substances and the formulated product Goltix Queen (AG-QMM1-565 SC) which are most relevant. The risk to bees was shown to be acceptable.

Arthropods other than Bees

Risk assessments for non-target arthropods other than bees, conducted following the Guidance Document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods (ESCORT 2) for in- and off-field exposure have been conducted based on the following endpoints for the formulated product Goltix Queen (AG-QMM1-565 SC) which are most relevant.

No standard laboratory tests are available with the formulated product. Therefore it cannot be checked if information on additional species is required. However, since formulations with both separate a.s. showed a very low toxicity to non-target arthropods in standard laboratory tests (no effects at concentration rates much higher than the expected in-field exposure), it is not expected that standard laboratory tests with the formulated products would lead to the trigger of additional species.

The off-field HQ values for exposure to maximum residues for the representative species A. rhopalosiphi and T. pyri are less than the ESCORT 2 trigger value of 1. Thus, the results indicate that Goltix Queen poses low risk to off-field non-target arthropods following application according to the proposed use patterns.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms (Part B, Section 6, Point 10.6)

Risk assessments for earthworms and other soil non-target macroorganisms were conducted following the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final). The assessments for acute and chronic exposure have been conducted based on the following endpoints for the formulated product Goltix Queen (AG-QMM1-565 SC), active substances and relevant soil metabolites.

All acute and chronic TERs for the active substances (also tested as formulated product) and the major soil degradation products are above the respective trigger values indicating that the acute and chronic risk to earthworms and other soil non-target macroorganisms following treatment with Goltix Queen (AG-QMM1-565 SC) is low and acceptable at the intended worst-case uses.

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

An assessment of the risk for organic matter breakdown is not required.

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7) (Part B, Section 6, Point 10.8)

The risk assessment for soil microflora functions was conducted following the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final) based on data for the formulated product Goltix Queen (AG-QMM1-565 SC), active substances and relevant

soil degrades of both active substances. Soil microflora functions (carbon respiration and nitrogen transformation) are not at risk from the proposed uses of Goltix Queen (AG-QMM1-565 SC).

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

Terrestrial Non-Target Plants

Risk assessments for non-target plants were conducted following the Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final) for the off-field exposure scenario. The endpoints for the formulated product Goltix Queen (AG-QMM1-565 SC), which are most relevant, have been used for the risk assessment.

An acceptable risk to non-target plants can be achieved by prescribing low drift nozzles. Thus, the application of Goltix Queen on sugar beet is acceptable provided that the following measures are included on the label:

Om de niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 50% driftreducerende spuitdoppen

3.1.7 Efficacy (Part B, Section 7, Point 6)

Goltix Queen (AG-QMM1-565 SC, metamitron 525 g/L) is authorised in the Netherlands 14298N as a herbicide for the control of annual broadleaved weeds in beets, lilly (propagation, field), gladiolus (propagation, field) and peonies (cut flowers, field). The control in beets has a dose rate of 2 L/ha with a maximum of 3 applications per year and a minimum interval of 10 days. A label extension is requested for 3 L/ha pre-emergence and/or 3 treatments of 1 L/ha for post-emergence in beets. The maximum amount per year is 6 L/ha and mimimum interval of 5 days. This evaluation is based on the evaluation of the zRMS Germany.
On a national level the applicant requests an interval of 7 days for 2 L/ha due to the risk for birds.

Minimum effective dose
The dose response results against some target weed species show that there is a trend that for most of the weed species the efficacy is reduced and the variability of the level of control is inreased, if rates lower than 3+3x1 L/ha of AG-QMM1-565 SC are applied. According to zRMS a minimum dose rate of 3 L/ha for the first application and 1 L/ha for the following applications is acceptable. This is not in agreement with the WG/GAP that was agreed with the applicant. According to concerted WG it is possible to use 3 L/ha and/or 3 times 1 L/ha. Therefore the addition LDS is mentioned for the application of 1 L/ha.

Efficacy
Efficacy was assessed in 17 trials (the Netherlands 11) in fodder- and sugar beet. AG-QMM1-565 SC was applied at a dose rate of 3 L/ha before emergence followed by up to 3 post-emergence splitting applications of 1 L/ha each. Based on the results it can be concluded AG-QMM1-565 SC provides sufficient control of a number of annual broadleaved weed species in fodder and sugar beets. According to the zRMS member States should consider the levels of control achieved according to National conventions. Efficacy was high enough for the Netherlands. For 13 annual broadleaved weed species the efficacy was higher than 80%. A claim for efficacy is acceptable for the Netherlands.
A label extension is requested for 3 L/ha and/or 3 times 1 L/ha. Efficacy was assessed at a dose rate of 3 L/ha before emergence followed by up to 3 post-emergence splitting applications of 1 L/ha each. It can be

expected that an user will only apply LDS on a field that was clean at the start or clean after using 3 L/ha. Therefore it is acceptable to use LDS together or without an application of 3 L/ha.
According to the zRMS a minimum time interval of 5 days between applications is acceptable. Because of the impact on the environment an interval of 5 days is not acceptable for the Netherlands for a dose rate of 2 L/ha. A minimum time interval of 7 days for 2 L/ha is proposed by the applicant for the Netherlands. Due to the fact that the current authorised WG/label has a minimum interval of 10 days for 2 L/ha and the zRMS agrees with 5 days for 2 L/ha a minimum interval of 7 days between applications is acceptable for the Netherlands.

Impact on the quality of plants and plant products
Based on the results of 8 trials carried out in sugar beets in Germany and the Netherlands during the cropping season 2013 it can be concluded that there are no indications for a negative impact on quality of plants and plant products in sugar or fodder beets if AG-QMM1-565 SC is applied at the intended target application rates. Even at the double rates there is no substantial risk for an impact on plant or plant products.

Effects on the yield of treated plants and plant products
The results demonstrate that there are no indications for a negative impact on quantity of yield in sugar- or fodder beets if AG-QMM1-565 SC is applied at the intended target application rates. Even at the double rate there is no substantial risk for an impact on yield quantity.

Phytotoxicity
The results show that AG-QMM1-565 SC is tolerated well by sugar beets. For this indication only one year results are available from trials carried out with the double rate included under almost weed free conditions (2013). According to the EPPO PP 1/226(2) 'Number of efficacy trials' usually the trials should be done in a period over 2 years. Therefore the zRMS mentions the possibility of a warning sentence on the label. Because AG-QMM1-565 SC was already found safe for 3 applications with 2 L/ha for the current authorised WG/label, the 8 trials with a dose rate of 2N within year is sufficient for a claim that there is no unacceptable risk for phytotoxicity.

Succeeding crops
According to the zRMS there is no unacceptable risk for all succeeding crops in common crop rotation. However the current authorised WG/label mentions a restriction sentence in case of crop failure. This restriction sentence will remain on the WG/label.

Mislukt een bietengewas door welke oorzaak dan ook (bijv. vorstschade of insectenvraat) en is Goltix Queen 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;
- na ploegen en een wachttijd van 2 maanden na de laatste toepassing kunnen raaigras en klaver worden geteeld.

Adjacent crops
According to a risk assessment with 10 plant species no indication was found that there is a risk of spray drift damage for the tested crops. Following the principles of good agriculture practice during the application, no effects on adjacent crops are expected.

Resistance
The current authorised WG/label mentions a restriction sentence for resistance. This restriction sentence will remain on the WG/label.

Dit middel bevat de werkzame stoffen metamitron en quinmerac.
Metamitron behoort tot de triazinonen de Hrac code is C1, Quinmerac behoort tot de quinolinecarboxylic-zuren de Hrac code is O.
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.

3.2 Conclusions

The assessment conducted for the label extension of Goltix Queen as well as the assessment conducted for the change in the interval between the applications for the current use of 2 L/ha were in accordance with Uniform Principles and demonstrate an acceptable risk to human health and the environment. An authorisation can therefore be granted.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

No further data required.

Appendix 1 – Copy of the product label

Wettelijk Gebruiksvoorschrift

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

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Minimum interval tussen toepassingen in dagen	Maximaal aantal liter middel per ha per teeltcyclus
Bieten	Na opkomst	Eenjarige breedbladige onkruiden	2 L/ha	3	7 dagen	6 L/ha
	Voor opkomst	Eenjarige breedbladige onkruiden	3 L/ha	1	5 dagen[2]	
	Na opkomst		1 L/ha[1]	3		

[1] in LDS-systeem
[2] Minimaal 10 dagen tussen voor opkomst en de 1e na opkomst behandeling

Het gebruik in de teelt van lelie, gladiool en pioen is beoordeeld conform artikel 51 EC 1107/2009. Er is voor deze toepassingen geen werkzaamheids- en fytotoxiciteitonderzoek 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 toepassingen per teeltcyclus	Minimum interval tussen toepassingen
Lelie (vermeerderingsteelt, onbedekt)	Na-opkomst	Eenjarige breedbladige onkruiden	0,7 – 1 L/ha	6	5 dagen
Gladiool (vermeerderingsteelt,onbedekt)	Na-opkomst	Eenjarige breedbladige onkruiden	0,7 – 1 L/ha	6	5 dagen

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Minimum interval tussen toepassingen
Pioen (snijbloemen, onbedekt)	Na-opkomst, onder het gewas	Eenjarige breedbladige onkruiden	1,5 L/ha	3	5 dagen

Toepassingsvoorwaarden

Draag geschikte handschoenen bij werkzaamheden aan behandeld gewas.

Mislukt een bietengewas door welke oorzaak dan ook (bijv. vorstschade of insectenvraat) en is Goltix Queen 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;
- na ploegen en een wachttijd van 2 maanden na de laatste toepassing kunnen raaigras en klaver worden geteeld.

Om de niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 50% driftreducerende spuitdoppen

Om het grondwater te beschermen mag dit product in de teelt van bieten niet worden gebruikt in grondwaterbeschermingsgebieden.

Om het grondwater te beschermen mag dit product in de teelt van lelie en gladiolen in de periode 1 september tot 1 maart niet worden gebruikt in grondwaterbeschermingsgebieden

Resistentiemanagement
Dit middel bevat de werkzame stoffen metamitron en quinmerac.
Metamitron behoort tot de triazinonen de Hrac code is C1, Quinmerac behoort tot de quinolinecarboxylic-zuren de Hrac code is O.
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 2 – Letter of Access

Not required.

Appendix 3 - List of data submitted in support of the evaluation

Physical and chemical properties and analytical methods

Annex point/ reference No	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant)	Data protection claimed	Data protection granted Y/N	Studies relied on Y/N	Owner	How considered in dRR Study-Status / Usage*
KIIIA 2.7.5	2012	Determination of storage stability and phys-chem properties of (quinmerac 40 g/l + metamitron 525 g/l) SC stored at ambient temperature for two years AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V., F10-03/5, GLP: Yes Published: No	yes	Y	Y	ADM	1 accepted (study valid and considered for evaluation)

Toxicology

No new studies submitted

Metabolism and Residue

Annex point/ reference No	Year	Title Report-No. Authority registration No	Data protection claimed	Data protection granted	Studies relied on Y/N	Owner	How considered in dRR *
KIIA 6.3	2009	Determination of Quinmerac and Metamitron residues in Sugar Beet (RAC) following treatment with the formulated product MAF0617 under field conditions in Northern France in 2007 R A7091 ! FR-qut-07-1 GLP: Yes Published: No BVL-2757382, ASB2015-1088	Y	Y	Y	ADM*	The study is not evaluated previously

Environmental fate and behaviour

Annex point/reference No	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Data protection granted Y/N	Studies relied on Y/N	Owner	How considered in dRR Study-Status/Usage*
OECD: KIIA 7.1.1 / KIIA	2010a	Aerobic and anaerobic transformation of Quinmerac	Y	Y	Y	ADM*	1) accepted (study valid

7.1.2OECD: KIIA		in soils according to OECD 307 Fraunhofer IME Report No.: FEI-025/7-90 GLP, unpublished					and considered for evaluation)
OECD: KIIA 7.4.1	2011	Determination of Adsorption/desorption of Quinmerac according to OECD 106 and EU 91/414/EEC Fraunhofer IME Report No.: FEI-025/7-13 and 2nd Amendment 11 June 2011 GLP, unpublished	Y	Y	Y	ADM*	1) accepted (study valid and considered for evaluation)
OECD: KIIA 7.8.3	2010e	Aerobic transformation of Quinmerac in aquatic sediment systems according to OECD 308 Fraunhofer IME Report No.: FEI-025/7-92 GLP, unpublished	Y	Y	Y	ADM*	1) accepted (study valid and considered for evaluation)

Ecotoxicology

No new studies submitted

Efficacy

Annex Point	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Data protection granted	Studies relied on	Owner
KIIIA1 6.1.1	2010	AG-QMM1-565SC (40g/L Quinmerac+525 g/L Metamitron) standardized bioassay for the determination of EC10-(NOEC) and EC50-values for herbicides and selected following crops in soil AG-QMM1-565SC N/J N 2594007/349305	J	J	J	ADM*
KIIIA1 6.1.2	2013	Evaluate the efficacy of AG-QMM1-565 SC for the control of dicotyledonous weeds and Poa annua in sugar beet 11200612 N/J N 2594008/349307	J	J	J	ADM*

Annex Point	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Data protection granted	Studies relied on	Owner
KIIIA1 6.1.2	2012	An evaluation of the efficacy of AG-QMM1-565 SC against ACETY, GALAP and dicotyle weeds after splitting application in sugar beets FCS12-1621-E01 N/J N 2594009/349309	J	J	J	ADM*
KIIIA1 6.1.2	2012	ACETY, GALAP, LAMPU-Z.-Rüben VA, NA 2012 FCS12-1621-E03 N/J N 2594010/349311	J	J	J	ADM*
KIIIA1 6.1.2	2012	An evaluation of the efficacy of AG-QMM1-565 SC against ACETY, GALAP and dicotyle weeds after splitting application in sugar beets FCS12-1621-E04 N/J N 2594098/349314	J	J	J	ADM*
KIIIA1 6.1.2	2012	An evaluation of the efficacy of AG-QMM1-565 SC against ACETY, GALAP and dicotyle weeds after splitting application in sugar beets FCS12-1621-E05 N/J N 2594100/349317	J	J	J	ADM*
KIIIA1 6.1.2	2013	Sugarbeet-Efficacy of AG-QMM1-565 SC R090-12H N/J N 2594104/349320	J	J	J	ADM*
KIIIA1 6.1.2	2013	Sugarbeet-Efficacy of AG-QMM1-565 SC R091-12H N/J N 2594105/349322	J	J	J	ADM*
KIIIA1 6.1.3	2011	Crop safety and control of dicotyledonous weeds in sugar beet by AG-QMM1-565 SC and Goltix of 2010-the Netherlands H-10-2105 N/J N 2594108/349325	J	J	J	ADM*

Annex Point	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Data protection granted	Studies relied on	Owner
KIIIA1 6.1.3	2011	Crop safety and control of dicotyledonous weeds in sugar beet by AG-QMM1-565 SC and Fiesta new of 2011-the Netherlands H-11-2101 N/J N 2594114/349328	J	J	J	ADM*
KIIIA1 6.1.3	2013	Evaluate the efficacy of AG-QMM1-565 SC for the control of dicotyledonous weeds and Poa annua in sugar beet 11200612 N/J N 2594134/349332	J	J	J	ADM*
KIIIA1 6.1.3	2012	An evaluation of the efficacy of AG-QMM1-565 SC against ACETY, GALAP and dicotyle weeds after splitting application in sugar beets FCS12-1621-E01 N/J N 2594137/349335	J	J	J	ADM*
KIIIA1 6.1.3	2012	ACETY, GALAP, LAMPU-Z.-Rüben VA, NA 2012 FCS12-1621-E03 N/J N 2594138/349337	J	J	J	ADM*
KIIIA1 6.1.3	2012	An evaluation of the efficacy of AG-QMM1-565 SC against ACETY, GALAP and dicotyle weeds after splitting application in sugar beets FCS12-1621-E04 N/J N 2594140/349340	J	J	J	ADM*
KIIIA1 6.1.3	2012	An evaluation of the efficacy of AG-QMM1-565 SC against ACETY, GALAP and dicotyle weeds after splitting application in sugar beets FCS12-1621-E05 N/J N 2594150/349343	J	J	J	ADM*
KIIIA1 6.1.3	2013	Sugarbeet-Efficacy of AG-QMM1-565 SC R090-12H N/J N 2594155/349346	J	J	J	ADM*

Annex Point	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Data protection granted	Studies relied on	Owner
KIIIA1 6.1.3	2013	Sugarbeet-Efficacy of AG-QMM1-565 SC R091-12H N/J N 2594160/349349	J	J	J	ADM*
KIIIA1 6.1.4	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in Germany 2013 DE13HSBEAVA550B N/J N 2594162/349352	J	J	J	ADM*
KIIIA1 6.1.4	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in Germany 2013 DE13HSBEAVA550A N/J N 2594164/349355	J	J	J	ADM*
KIIIA1 6.1.4	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in Germany 2013 DE13HSBEAVA550C N/J N 2594166/349358	J	J	J	ADM*
KIIIA1 6.1.4	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in Germany 2013 DE13HSBEAVA550D N/J N 2594167/349360	J	J	J	ADM*
KIIIA1 6.1.4	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in Germany 2013 DE13HSBEAVA550E N/J N 2594168/349363	J	J	J	ADM*
KIIIA1 6.1.4	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in 2013 NL13HSBEAVA001 N/J N 2594169/349366	J	J	J	ADM*

Annex Point	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Data protection granted	Studies relied on	Owner
KIIIA1 6.2.1	2011	Crop safety and control of dicotyledonous weeds in sugar beet by AG-QMM1-565 SC and Goltix of 2010-the Netherlands H-10-2105 N/J N 2594173/349368	J	J	J	ADM*
KIIIA1 6.2.1	2011	Crop safety and control of dicotyledonous weeds in sugar beet by AG-QMM1-565 SC and Fiesta new of 2011-the Netherlands H-11-2101 N/J N 2594174/349371	J	J	J	ADM*
KIIIA1 6.2.1	2013	Evaluate the efficacy of AG-QMM1-565 SC for the control of dicotyledonous weeds and Poa annua in sugar beet 11200612 N/J N 2594176/349373	J	J	J	ADM*
KIIIA1 6.2.1	2012	An evaluation of the efficacy of AG-QMM1-565 SC against ACETY, GALAP and dicotyle weeds after splitting application in sugar beets FCS12-1621-E01 N/J N 2594177/349376	J	J	J	ADM*
KIIIA1 6.2.1	2012	ACETY, GALAP, LAMPU-Z.-Rüben VA, NA 2012 FCS12-1621-E03 N/J N 2594178/349379	J	J	J	ADM*
KIIIA1 6.2.1	2012	An evaluation of the efficacy of AG-QMM1-565 SC against ACETY, GALAP and dicotyle weeds after splitting application in sugar beets FCS12-1621-E04 N/J N 2594180/349382	J	J	J	ADM*

Annex Point	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Data protection granted	Studies relied on	Owner
KIIIA1 6.2.1	2012	An evaluation of the efficacy of AG-QMM1-565 SC against ACETY, GALAP and dicotyle weeds after splitting application in sugar beets FCS12-1621-E05 N/J N 2594181/349385	J	J	J	ADM*
KIIIA1 6.2.1	2013	Sugarbeet-Efficacy of AG-QMM1-565 SC R090-12H N/J N 2594183/349389	J	J	J	ADM*
KIIIA1 6.2.1	2013	Sugarbeet-Efficacy of AG-QMM1-565 SC R091-12H N/J N 2594184/349392	J	J	J	ADM*
KIIIA1 6.2.1	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in Germany 2013 DE13HSBEAVA550B N/J N 2594185/349394	J	J	J	ADM*
KIIIA1 6.2.1	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in Germany 2013 DE13HSBEAVA550A N/J N 2594186/349397	J	J	J	ADM*
KIIIA1 6.2.1	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in Germany 2013 DE13HSBEAVA550C N/J N 2594187/349399	J	J	J	ADM*
KIIIA1 6.2.1	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in Germany 2013 DE13HSBEAVA550D N/J N 2594189/349402	J	J	J	ADM*

Annex Point	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Data protection granted	Studies relied on	Owner
KIIIA1 6.2.1	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in Germany 2013 DE13HSBEAVA550E N/J N 2594192/349404	J	J	J	ADM*
KIIIA1 6.2.1	2013	An evaluation of the selectivity of AG-QMM1-565 SC in sugar beet (pre- and post emergence) in 2013 NL13HSBEAVA001 N/J N 2594193/349407	J	J	J	ADM*
KIIIA1 6.2.6	2010	AG-QMM1-565SC (40g/L Quinmerac+525 g/L Metamitron) standardized bioassay for the determination of EC10-(NOEC) and EC50-values for herbicides and selected following crops in soil AG-QMM1-565SC N/J N 2594198/349410	J	J	J	ADM*
KIIIA1 6.2.7	2010	Effect of AG-QMM1-565SC (40g/L Quinmerac+525 g/L Metamitron) on vegetative vigour of terrestrial plants AS150 N/J N 2594199/349413	J	J	J	ADM*
KIIIA1 6.2.7	2010	Effect of AG-QMM1-565SC (40g/L Quinmerac+525 g/L Metamitron) on vegetative vigour of terrestrial plants AS151 N/J N 2594202/349416	J	J	J	ADM*
KIIIA1 3.9	2014	Gebrauchsanleitung N/N N 2594255/349438	J	J	J	ADM*

* The study owner (sponsor) of the studies is ADAMA Maktheshim Ltd., a member of Agriculturual Solutions Ltd. (ADM)