REGISTRATION REPORT
Part A

Risk Management

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

Active Substances: (525 g/L Metamitron 40 g/L Quinmerac)

Central Zone
Zonal Rapporteur Member State: Germany

National Assessment: the Netherlands

Applicant: **Makhteshim-Agan Holland B.V.**

Date: **November 2013**

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of Goltix Queen (AG-QMM1-565 SC) 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.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 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.
Please note that the product name applied for the Netherlands is Goltix Queen and that the product name used by ZRMS Germany in the Core assessment is Goltix Titan.

Appendix 1 – Copy of the preliminary product label/instructions for use
Appendix 2 – Letter of Access - not required.
Appendix 3 – List of data submitted in support of the application

During the first risk assessment a combination long term risk to birds was identified for the aspect ecotoxicology. Based on the communication with the applicant it was decided to change the interval between applications from 5 days to 10 days. This interval will be taken into account only for the higher tier refinements in section IIIA 10.1.2. For the remaining aspects the risk assessment was performed considering the previous interval of 5 days which is considered worst-case.

1 Details of the application

1.1 Application background

This application was submitted by:

Makhteshim-Agan Holland B.V.
P.O. Box 355
3830 AK Leusden
The Netherlands

This application is for the approval of product Goltix Queen (AG-QMM1-565 SC), 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). 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.

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 notifier at whose request Metamitron has been included in this Annex provide such information to the Commission by 31 August 2011 at the latest. These data have been submitted in the meantime.

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.

Concerns that are relevant for this application have been addressed within this submission.

1.3 Regulatory approach

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 allow the first approval of this product/use in the 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
Authorization Number (for registration)	-
Function	Herbicide
Applicant	Makhteshim-Agan Holland 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

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 *:			
-			
Pictogram:	GHS09	Signal word:	Warning
H-statements:	H411	Toxic to aquatic life with long lasting effects.	
P-statements:	P273	Avoid release to the environment.	
	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)

2.2.2 R and S phrases under Directive 2003/82/EC (Annex IV and V)

none

2.2.3 Other phrases

none

2.3 Product uses – GAP for Goltix Queen, Active ingredients: 525 g/L Metamitron + 40 g/L Quinmerac

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Application**			**Application rate**			**PHI (days)**	**Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number (min. interval between applications) a) per use b) per crop/ season**	**kg, L product / ha a) max. rate per appl. [b) max. total rate per crop/season]**	**g, kg as/ha a) max. rate per appl. [b) max. total rate per crop/season]**	**Water L/ha min / max**		
001	BE DE NL	BEAVC Fodder beet, BEAVA Sugar beet	F	TTTDS Annual dicotyledonous weeds	spraying	10-19; Spring, after emergence	3 ; 3 10 days	a) 2 b) 6	Metamitron a) 1.05 b) 3.15 Quinmerac a) 0.08 b) 0.24	200-400		

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 (AG-QMM1-565 SC) is an off-white homogenous suspension, with characteristic odour. The expert statement revealed that it has no explosive and oxidising properties. Goltix Queen has a self-ignition temperature of 505°C and it is a surface formulation. The storage stability at ambient temperature over a period of 1 year and after 14 days at 54°C showed good stability in terms of active substance content and product characteristics. Results of the technical tests (spontaneity of dispersion, suspensibility, wet sieve test, pourability and particle size distribution) indicate that Goltix Queen can be adequately sprayed.

Implications for labelling: none

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

Compatibility of mixtures: For possible tank mixing, please refer to the country specific label.

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 in Goltix Queen was not evaluated as part of the EU review. Therefore all relevant data are provided and considered adequate.

A method was validated for the determination of the active substances Metamitron and Quinmerac in the formulation Metamitron 525 g/L and Quinmerac 40 g/L SC. The analysis was performed by HPLC with UV detection using an external standard technique.

Summary of the available method for the determination of Metamitron and Quinmerac in Goltix Queen

Reference no. Author (year) report no.	Active substance	Commodity	Single (S) /Multi (M) Method, Technique	GLP yes/ no	Pub–lished yes/ no	Anal. cali–bration yes/ no	LOQ [mg/kg]	No of Analyses	Mean recovery [%]	RSD [%]
IIIA 5.2.2/01 (Gorban, 2010) No. F10-03/4	Metamitron and Quinmerac	Formulation	HPLC-UV (280 nm)	Yes	No	Yes	n.a.	12	99.77 for Metamitronand 99.58 for Quinmerac	0.423 for Metamitron and 0.70 for Quinmerac

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

The following validated analytical methods for the determination of residues of Metamitron and Quinmerac and several metabolites have not previously been reviewed and are provided in support of this assessment.

Summary of the analytical methods for Metamitron and Quinmerac

Matrix	Analyte(s)	Method	LOQ	Reference
Metamitron				
Plant matrices (Wheat grain, orange pulp, rape seeds) IIIA 5.3.1/01	Metamitron	HPLC-MS/MS	0.01 mg/kg for wheat grain, orange pulp, rape seeds	Mende (2007a)
ILV Plant matrices: (Wheat grain, rape seeds) IIIA 5.3.1/02	Metamitron	LC-MS/MS	0.01 mg/kg for wheat grain, rape seeds	Bacher (2007a)
ILV Plant matrices: (Apples) IIIA 5.3.1/03	Metamitron	LC-MS/MS	0.01 mg/kg for apple	Meyer (2010a)
Animal Matrices (Milk, eggs, fat, kidney, liver, meat) IIIA 5.3.1/05	Metamitron	HPLC-MS/MS	0.05 mg/kg for milk, eggs, fat, kidney, liver, meat	Weber (2009)

Summary of the analytical methods for Metamitron and Quinmerac (continued)

Matrix	Analyte(s)	Method	LOQ	Reference
Metamitron				
ILV Animal Matrices (Milk, fat) IIIA 5.3.1/06	Metamitron	HPLC-MS/MS	0.05 mg/kg for milk, eggs, fat, kidney, liver, meat	Mende (2009)
Soil IIIA 5.4/01	Metamitron	LC-MS/MS	0.05 mg/kg	Bacher (2007b)
Water (Drinking and surface water) IIIA 5.6/01	Metamitron	HPLC-MS/MS	0.05 µg/L	Mende (2007b)
Air IIIA 5.7/01	Metamitron	LC-MS/MS	0.3 µg/m^3	Bacher (2007c)
Quinmerac				
Plant matrices (Oily, water containing, dry and acidic) IIIA 5.3.1/07	Quinmerac	LC-MS/MS	0.05 mg/kg for lettuce, oranges, wheat grain and rape seed	Meyer (2010b)
ILV Plant matrices (Lettuce and wheat grain) IIIA 5.3.1/08	Quinmerac	HPLC-MS/MS	0.05 mg/kg for lettuce and wheat grain	Mende (2010a)
Animal matrices (Bovine fat, egg, liver, kidney, muscle and milk) IIIA 5.3.1/10	Quinmerac	LC-MS/MS	0.02 mg/kg for bovine fat, egg, liver, kidney, muscle, milk	Meyer (2010c)
ILV Animal matrices IIIA 5.3.1/11	Quinmerac	LC-MS/MS	0.02 mg/kg for bovine muscle and bovine fat	Wiesner & Breyer (2011)
Soil IIIA 5.4/02	Quinmerac, BH 518-2 and BH 518-5	HPLC-MS/MS	0.01 mg/kg	Hamberger (2010a)
Water (Drinking and surface water) IIIA 5.6/02	Quinmerac, BH 518-2 and BH 518-5	HPLC-MS/MS	0.05 µg/L	Hamberger (2010b)
ILV Water (drinking water) IIIA 5.6/03	Quinmerac, BH 518-2 and BH 518-5	HPLC-MS/MS	0.05 µg/L	Mende (2010b)
Air IIIA 5.7/02	Quinmerac	HPLC-MS/MS	2.37 µg/m³	Witte (2009)

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 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

Goltix Queen has a low potential of toxicity following oral, dermal or inhalation exposure.

Goltix Queen was not irritating to the skin of the rabbit.

Goltix Queen was only mildly and reversibly irritating to the eyes of the rabbit.

Goltix Queen was not sensitizing to skin in a maximisation test in Guinea pigs.

Thus, no classification is required for the formulation 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)

Estimations of potential operator exposure have been undertaken for Goltix Queen using EUROPOEM.

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected operator after respiratory and dermal exposure to metamitron and quinmerac as a result of the application of Goltix Queen in sugar beet and fodder beet.

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

Bystanders may be exposed to the spray when present close to a field being treated with plant protection products. Estimation of potential bystander exposure have been undertaken using EUROPOEM II.

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected bystander due to exposure to metamitron and quinmerac during application of Goltix Queen in sugar beet and fodder beet.

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

Goltix Queen is applied as early post-emergence product in sugar- and fodder beets. Accordingly no cultivation work is performed. However, working in sugar or fodder beet fields where Goltix Queen is applied, may include procedures such as visible inspections of fields for effectiveness of plant protection measures. Daily work rate is considered to be 2 hours for scouting and inspection. Estimation of potential worker exposure have been undertaken using EUROPOEM II.

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected worker after respiratory and dermal exposure during re-entry activities in sugar beet and fodder beet due to exposure to metamitron and quinmerac after application of Goltix Queen.

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)

A sufficient number of supervised residue trials is presented within this dossier 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. Since these residue levels are far below the respective EU MRLs of 0.2 mg/kg for Metamitron and of 0.5 mg/kg for Quinmerac the critical GAP is considered to be covered by the critical EU GAP that was used for the MRL setting procedure. The currently existing MRLs for Metamitron are published in Regulation (EC) No 149/2008, which is amending the Regulation (EC) No 396/2005. The currently existing MRLs for Quinmerac are published in Regulation (EC) No 149/2008, which is amending the Regulation 396/2005.
The proposed uses of AG-QMM1-565 SC are within those supported for the EU MRL assessment, therefore, no further evaluation is required for national re-registration/registration. Application for additional crops or uses should be made by the appropriate process to establish an EU MRL and any additional risk assessment necessary to support additional uses should be submitted via relevant national label extension processes.

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

For the active substances Metamitron and Quinmerac, new dietary risk assessments were performed taking into account temporary EU MRLs of Metamitron and Quinmerac. The current EU MRLs exhibit a worst-case scenario compared to the residues of Metamitron and Quinmerac which were measured in sugar beet field trials. The chronic risk assessment was performed taking into account all the crops for which temporary EU MRLs of Metamitron and Quinmerac are available. For the calculation of the acute risk assessment only the intended use, i.e., sugar beet root, was evaluated. The assessment of the potential acute and chronic dietary consumer risk due to exposure to residues of Metamitron and Quinmerac were performed using the EFSA model rev 2.0 (“PRIMO” Pesticide Risk assessment Model, rev.2).

Metamitron

In the chronic risk assessment, the diet with the highest Theoretical Maximum Daily Intake (TMDI) is “UK toddler” with 26.5% of the Acceptable Daily Intake (ADI) of 0.03 mg/kg bw/day. The highest commodity contributors are sugar beet (root) with a maximum of 15.2% of ADI. For the acute dietary risk assessment, the calculated values for the International Estimated Short Term Intake (IESTI) are well below the Acute Reference Dose (ARfD) of 0.1 mg/kg bw for Metamitron.

Quinmerac

In the chronic risk assessment, the diet with the highest Theoretical Maximum Daily Intake (TMDI) is “UK toddler” with 18.4% of the Acceptable Daily Intake (ADI) of 0.08 mg/kg bw/day. The highest commodity contributors are sugar beet (root) with a maximum of 14.3% of ADI. For the acute dietary risk assessment, the calculated values for the International Estimated Short Term Intake (IESTI) are well below the Acute Reference Dose (ARfD) of 0.3 mg/kg bw for Quinmerac.

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 AG-QMM1-565 SC does not lead to unacceptable risk for consumer when applied according to the recommendations.

No risk for consumer has been identified resulting from the exposure to metabolites contaminating groundwater, which is used as drinking water, resulting from the representative use of Metamitron and Quinmerac in sugar beets.

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

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

A detailed description of PEC_S calculations, modelling inputs and results is given in Part B Section 5 IIIA 9.4 and IIIA 9.5 of the core assessment for the Central Zone, to which National Assessment for the Netherlands is referring to.

The PEC_S of Metamitron and Quinmerac and the relevant metabolite of Metamitron, i.e. Desamino-metamitron, and the metabolites of Quinmerac, i.e. BH 518-2 and BH 518-5 in soil has been assessed with the FOCUS guidance and approach and the FOCUS groundwater interception values and the DT_{50} values established in the EU review.

Based on uses proposed, Goltix Queen is to be applied to beets (sugar and fodder) 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) with an interval of 5 to 10 days. Therefore, crop interception of 20% for post-emergence applications was considered.

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. These values are considered acceptable according to the uniform principles.
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 following three cumulative post-emergence applications of Goltix Queen amounted to 0.123 and 0.095 mg/kg dry soil, respectively. These values are considered acceptable according to the uniform principles.

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

3.5.1.2 Predicted Environmental Concentration in Ground Water (PECGW) (Part B, Section 5, Point 9.6)

A detailed description of PEC_{GW} calculations, modelling inputs and results is given in Part B Section 5 IIIA 9.6 of the core assessment for the Central Zone and in the National Assessement for the Netherlands, which covers the national requirements.

The PEC_{GW} of Metamitron and Quinmerac and the relevant metabolite of Metamitron, i.e. Desamino-metamitron, and the metabolites of Quinmerac, i.e BH 518-2 and BH 518-5 in ground water has been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO 4.4.3 and FOCUS PEARL 4.4.4 models and the K_{OC} values established in the EU review. Furthermore, additional calculations were performed for Quinmerac and metabolites with adsorption endpoints established in the EU review along with new data submitted.

Based on uses proposed, Goltix Queen is to be applied to beets (sugar and fodder). The application scheme considers 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) with an interval of 5 to 10 days. Furthermore, it was assumed that sugar beet could be rotated with other crops and is typically grown every third year, therefore, calculations were preformed assuming consecutive yearly applications and applications every 3rd year onto the same area.

The concentrations were estimated for the FOCUS groundwater standard site scenario, Kremsmünster, pertinent to this crop covered in the models over a simulation period of up to 66 years.
For Metamitron, Quinmerac and Desamino-metamitron (metabolite of Metamitron) the PEC_{GW} were below 0.1 µg/L for all scenarios as well with a yearly as with a 3-yearly crop rotation sytem.

For BH 518-2 and BH 518-5 (metabolites of Quinmerac) the PECGW were above the trigger of 0.1 µg/L or 0.75 µg/L. However, it was concluded that these two metabolites are considered not to be relevant for groundwater, in the concentrations as predicted by the model after application of Goltix Queen according to he proposed GAP.
However, the predicted concentrations of M3 exceed 0.1 µg/L for all assessed uses. Furthermore, M3 has properties that in the Dutch decision scheme assessment of leaching potential trigger an assessment with GeoPEARL (DT50 < 10 days, Kom< 10 L/kg). As a higher tier the GeoPEARL 3.3.3 national model is used.

Input values are copied from the core for metamitron. Input parameters and application scheme are presented in table 9.6-1 and 9.6-2 respectively. The assessment is based on geomean values for degradation and median values for sorption (in line with recent Dutch authorisation assessments). Plant uptake factors were set to 0.5 for metamitron and 0 for the metabolite M3. A Q10 of 2.2 was used since metamitron data in the DAR were normalised using the Q10 of 2.2. The water solubility and vapour pressure used are at 25 °C as denoted in the LoEP physical chemical properties. For M3, DT_{50} values as derived in earlier assessments by Ctgb are used. As in the core assessment, the assessment was performed with a separate simulation where M3 is formed from metamitron (based on DT50 parent of 34.2 days). Desamino-metamitron is assessed in the core assessment and is not included in this simulation. Date of first application is April 1st, appropriate for beets at BBCH 10. Additional input is the crop (sugar beets) and the number of plots (minimum 250). As crop rotation is common practice for beets, a yearly, biannual and triannual crop rotation system is simulated. For results see Table 3.1.5.2-1. Please note that metabolite desamino-metamitron already meets the Dutch standards in the first tier for sugar beet. Therefore the higher tier assessment does not include desamino-metamitron.

Table 3.1.5.2-1 Leaching of a.s. metamitron and metabolites desamino-metamitron and M3 as predicted by GeoPEARL 3.3.3

Use	Substance	Rate a.s. [kg/ha]	Frequency	Interval [days]	Fraction Intercepted*	PEC groundwater [µg/L]
Beets (annual)	Metamitron M3	1.050 -**	3	5	0.20	0.0030 **0.1867**
Beets (biennial)	Metamitron M3	1.050 -**	3	5	0.20	< 0.001 0.084
Beets (triennial)	Metamitron M3	1.050 -**	3	5	0.20	<0.001 0.0571

* interception values derived from Table 1.6 in "generic guidance for FOCUS groundwater scenarios". For BBCH 10-18 in sugar beets, an interception of 20 % is appropriate.
** calculation via transformation scheme

For the metabolites M3, GeoPEARL modelling predicts that PEC_{GW} concentrations exceed the trigger of 0.1 µg/L, when a yearly crop rotation scheme is considered. However, when considering a 2-year or a 3-year crop-rotation system, concentrations are below the trigger of 0.1 µg/L. Therefore the following restriction will be included in the label:

Dit middel of een ander middel op basis van metamitron mag slechts 1 keer per 2 jaar, volgens bovenstaand gebruiksvoorschrift op een perceel worden toegepast.

Moreover, concentrations of metabolite M3 are above the additional trigger of 0.01 µg/L for protection of groundwater protection area's in the Netherlands. Therefore the following sentence will also be included in the label:

Om het grondwater te beschermen mag dit middel niet worden toegepast in grondwaterbeschermingsgebieden.

3.5.1.3 Predicted Environmental Concentration in Surface Water (PECSW) (Part B, Section 5, Points 9.7 and 9.8)

A detailed description of PEC_{SW} calculations, modelling inputs and results is given in Part B Section 5 IIIA 9.7 and IIIA 9.8 of the National Assessment for the Netherlands, which covers the national requirements.

The PEC_{SW} of Metamitron and Quinmerac and the relevant metabolite of Metamitron, i.e. Desamino-metamitron, and the metabolites of Quinmerac, i.e BH 518-2 and BH 518-5 in surface water and sediment (PEC_{SW} and PEC_{SED}) has 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 and the DT_{50} water/sediment values established in the EU review.

According to this guidance document, the TOXSWA model is used for determination of the concentration of a substance in a standard ditch (edge of field ditch) by emission via drift. All processes and process parameters considered in TOXSWA, including drift percentage, are based on research relevant for the Netherlands. Loading of surface water and sediment by agricultural use of plant protection products is for the time being only based on drift of spray mist (drift) while neglecting runoff, leaching and drainage. The loading of surface water and sediment is calculated on the basis of the drift percentage figures as laid down by the Board.

For a realistic worst-case scenario, it is assumed that Goltix Queen is applied in beets (sugar or fodder). In the application scheme 3 post-emergence applications (BBCH 10 to 19) are considered each at a rate of 2.0 L product/ha with an interval of 5 to 10 days.

Version 1.2 of TOXSWA was used for the calculations; this version is confined to simulate a constant flow velocity and a constant water depth in the water body. Pesticide inputs can occur once or repeatedly by pulse inputs or distributed inputs into the water layer. Results for active substances and metabolites are given in tables 3.5.1.3-1 to 3.5.1.3-4

Table 3.5.1.3-1: Overview of surface water concentrations for the active substance Metamitron, following applications of Goltix Queen SC to sugar and fodder beet in spring

Application rate [kg a.s./ha]	Drift [%]	Mass loading [g/m^2]	PIEC [a] [µg/L]	PEC_{twa} 21 days [µg/L]	PEC_{twa} 28 days [µg/L]	PEC_{sed} max [mg/kg]*
3 × 1.050	1.0	3 × 0.001050	12.65	11.79	9.478	0.155

a Maximum initial concentration after last application (= PECini)

* calculated as (PECsed in g/m^3 / 80 kg/m^3) (=TOXSWA output)*1000 (conversion of g/kg to mg/kg)

[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

Table 3.5.1.3-2: Overview of surface water concentrations for the active substance Quinmerac, following applications of Goltix Queen to sugar and fodder beet in spring

Application rate [kg a.s./ha]	Drift [%]	Mass loading [g/m^2]	PIEC [a] [µg/L]	PEC$_{twa}$ 21 days [µg/L]	PEC$_{twa}$ 28 days [µg/L]	PEC$_{sed}$ max [µg/kg]*
3 × 0.080	1.0	3 × 0.000080	1.09	1.071	0.9987	0.01338

a Maximum initial concentration after application (= PECini)

* calculated as (PECsed in g/m^3 / 80 kg/m^3) (=TOXSWA output)*1000 (conversion of g/kg to mg/kg)

Table 3.5.1.3-3: Overview of surface water concentrations for the metabolite Desamino-metamitron, following applications of Goltix Queen to sugar and fodder beet in spring

Application rate [kg a.s./ha]	Drift [%]	Mass loading [g/m^2]	PIEC [a] [µg/L]	PEC$_{twa}$ 21 days [µg/L]	PEC$_{twa}$ 28 days [µg/L]	PEC$_{sed}$ max [mg/kg] *
3 × 0.792	1.0	3 × 0.000525	7.152	7.033	6.599	0.1119

a Maximum initial concentration after application (= PECini)

* calculated as (PECsed in g/m^3 / 80 kg/m^3) (=TOXSWA output)*1000 (conversion of g/kg to mg/kg)

Table 3.5.1.3-4: Overview of surface water concentrations for the metabolite BH 518-2, following applications of Goltix Queen to sugar and fodder beet in spring

Application rate [kg a.s./ha]	Drift [%]	Mass loading [g/m^2]	PIEC [a] [µg/L]	PEC$_{twa}$ 21 days [µg/L]	PEC$_{twa}$ 28 days [µg/L]	PEC$_{sed}$ max [mg/kg] *
3 × 0.012	1.0	3 × 0.0000086	0.1183	0.1099	0.1022	0.0015

a Maximum initial concentration after application (= PECini)

* calculated as (PECsed in g/m^3 / 80 kg/m^3) (=TOXSWA output)*1000 (conversion of g/kg to mg/kg)

The PEC values, considering a first tier assessment for Metamitron, Quinmerac and their major water/sediment metabolites with the obligatory 50% drift reducing nozzles are sufficient to satisfactorily meet TER trigger values in the aquatic risk assessment. No further assessment or refinement was necessary for the active substances or their metabolites.

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

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

In consideration of the Annex I agreed endpoints for Metamitron and Quinmerac; relevant concentrations in air following use of Goltix Queen are unlikely to occur. Metamitron has a vapour pressure of 7.44×10^{-7} Pa at 25°C and a Henry's constant of 8.95×10^{-8} Pa m^3/mol. For Quinmerac a vapour pressure < 1.0×10^{-10} Pa at 20°C and a Henry's constant of < 1.0×10^{-10} Pa x m^3/mol is reported. Hence, for both compounds, no volatilisation is to be expected. However, if reaching the troposphere, Metamitron is degraded by photochemical processes (DT_{50} ≤ 19.8 hours). For Quinmerac, the photochemical oxidative degradation in air was estimated to < 39 hours.
Therefore, significant long-range transport and accumulation in the stratosphere is considered to be unlikely and no PEC calculations are necessary.

Implications for labelling resulting from environmental fate assessment: not readily biodegradable (Phrase **R51/53 -** Toxic to aquatic organisms, **may cause long-term adverse effects in the aquatic environment** – should be added to the label).

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

Note Ctgb:
During the first risk assessment a combination long term risk to birds was identified. Based on the communication with the applicant it was decided to change the interval between applications from 5 days to 10 days. This interval will be taken into account only for the higher tier refinements in section IIIA 10.1.2. For the remaining aspects the risk assessment was performed considering the previous interval of 5 days which is considered worst-case.

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

Birds

Effects of Goltix Queen on birds were not evaluated as part of the EU review of Metamitron and Quinmerac. However further data on Goltix Queen are not deemed necessary as active substance data on toxicity to birds is used and according to EU Regulation 1107/2009 data on the toxicity of the formulation are not considered essential. Therefore all relevant data were assessed in the EU review.
For the acute risk assessment to birds please refer to the Core assessment.

In the Core dossier, after conducting the long-term Tier 1 assessment the TERmix for small omnivorous bird was below (i.e. TER 4.29) the trigger of 5. ZRMS Germany refined the risk by using a PT of 0.5.
During the commenting round of the Core dRR, the Netherlands commented on the use of a PT of 0.5 in the refinement of long-term risk to birds. Ctgb does not agree with this approach as this is a German-specific refinement (according to Bundesanzeiger 2010, see Core dossier) and therefore, only applies to Germany. The scientific justification of the German working agreement is unclear to Ctgb.
In the view of the above, a long-term combination risk to omnivorous birds remains high. The applicant was informed of the issue raised above and in response; the applicant submitted the original dRR. However, combitox was not addressed in the original dRR, and it is the combitox that drives the risk in the Core Assessment (a combination risk (TER = 3.46) without the use of a PT of 0.5 (TERs for metamitron and quinmerac are 5.4 and 9.6, respectively)). Because the Core Assessment is based on an old risk envelope with a slightly higher application rate ("application scheme 2" was omitted), a new assessment was done for the long-term risk (Table 10.3.1.3-2).

Table 10.3.1.3-1: Long-term toxicity to birds

Species	Test substance	Endpoint	Reference
Bobwhite quail	Metamitron	NOAEL = 81.5 mg a.s/kg bw/d	EFSA (2008) *1* List of Endpoints
Japanese Quail	Quinmerac	NOEL = 1713mg /kg bw/d LOAEL = 111 mg /kg bw/d	EFSA Report (2010)*2* Hansen, B (2010)

Letters in bold were used for the risk assessment
1New study, submitted by the applicant (Hansen, B. (2010) Study on Reproduction in Birds (Japanese Quail) with Quinmerac Technical by Oral Administration via the Diet, LPT GmbH & Co. KG, Report No.: 25301).

Table 10.1.1.3-2: Long-term Tier 1 assessment for birds according to EFSA (2009)- applications BBCH 10-19

[1] EFSA Scientific Report (2008) 185, 1-95, Conclusion on the peer review of metamitron
[2] EFSA Scientific Report (2010) 8 (3): 1523, Conclusion on the peer review of quinmerac

Crop	Application rate	Scenario	Generic focal species	Shortcut valuea	MAFmean*	twab	DDDc	NOAEL [mg a.s/kg bw/d]	TERd (5)
	1.050 kg Metamitron /ha	BBCH 10 – 19	Small omnivorous bird (lark)	10.9	2.2	0.53	13.3	81.5	6.1
		BBCH 10 – 19	Small insectivorous bird (wagtail)	5.9	2.2	0.53	7.22	81.5	11.3
	0.080 kg Quinmerac /ha	BBCH 10 – 19	Small omnivorous bird (lark)	10.9	2.2	0.53	1.02	11	10.8
		BBCH 10 – 19	Small insectivorous bird (wagtail)	5.9	2.2	0.53	0.55	11	20.0
	TER Mix		Small omnivorous bird (lark)						3.90
			Small insectivorous bird (wagtail)						7.22

a mean percentile residues
b time-weighted average factor
c daily dietary dose
d Toxicity-to-exposure ratio (Trigger)
* MAFmean calculated by Ctgb using the formula from Appendix H of EFSA and by taking into account a DT50 of 10 days, 3 applications and 5 days interval.

The table above shows that a combination risk remains. Thus, the long-term risk to birds is high and not acceptable.

Further refinement omnivorous birds “lark”
Foliar residue studies are available in the DAR of metamitron. Based on these data a DT50 of 1.9 days was calculated for residue in beet leaves and accordingly a RUD of 48, based on mean residue values was calculated. As mentioned above in the “Note Ctgb” the agreed interval between applications is now 10 days and also by using the DT50 of 1.9 days the MAF and ftwa can be accordingly refined to 1.03 and 0.27, respectively. The RUDs for the ground arthropods and weeds seeds are as indicated in the Appendix F, EFSA GD (2009).

Table 10.1.1.3-2 Refinement of long-term risk assessment for lark exposed to Metamitron according to EFSA (2009)

Application rate	Food category	FIR/bw	PD	RUDa	MAFmean	ftwab	PT	DDDc	NOAEL [mg/kg bw/d]	TERd (5)
Sugar beets and fodder beets										
1.05 kg/ha	Ground arthropods	0.52	0.50	7.5	2.2	0.53	1	2.38	81.5	7.68
	Crop leaves	0.52	0.25	48	1.03	0.27		1.82		

	Weed seeds	0.52	0.25	40.2	2.2	0.53		6.39		
	Total							10.6		

a mean residues
b time-weighted average factor
c Daily dietary dose for multiple applications
d Toxicity-to-exposure ratio

Based on this new TER for metamitron and by taking into account the TER of quinmerac of 10.8 the resulting TERmix is 4.49. However, considering the worst-case assumption for PT of 1, and the RUDs, MAF and ftwa for seeds (n.b. given the fast dissipation it is expected that the DT50 on seeds should be comparable to the one on vegetation) the combination risk to birds is acceptable.

Drinking water assessments are not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger as set in the new EFSA GD (2009). The ratios do not exceed the value of 50 for metamitron (n.b. Koc of 122.3 L/kg) and quinmerac (n.b. Koc of 35.1 L/kg) Finally, an assessment of the risk from secondary poisoning is not required due to log P_{OW} values (i.e. 1.41 and 0.85 for quinmerac and metamitron, respectively) below the trigger of 3.

In conclusion, application of Goltix Queen in accordance with the proposed use patterns in pre- and early post-emergence in fodder and sugar beets does not pose a risk to birds.

Terrestrial Vertebrates other than Birds

The effects of Goltix Queen 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 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.

For the acute risk assessment to mammals, please refer to the Core dossier.

In the Core dossier, after conducting the long-term Tier 1 assessment the TERs metamitron and accordingly TERsmix were 1.45 and 4.19, and 1.42 and 4.08 for herbivorous and omnivorous mammals, respectively. In the refinement step of the long-term risk for a small omnivorous mammal “mouse” in the core assessment a trigger of ≥ 2 instead of ≥ 5 is used by the ZRMS. The ZRMS stated : “In cases where the relevant model species for the risk assessment is a mouse or a vole, the TER acceptability criterion may be modified. In terms of size and potential exposure, mice and voles already represent the ‘worst case’ for agricultural areas in Europes' central zone. Furthermore, the toxicological endpoints and effect values for the assessment are determined on phylogenetically closely related species. Hence, … a TER ≥ 2 in the long-term exposure scenario may be accepted as sufficient. It should additionally be noted that there are currently no indications for a significant impact of pesticides on the population dynamics of mice or voles in the agricultural landscape, which are apparently determined by other biological factors (e.g. periodical increases in vole populations creating the necessity for control measures)”.
Ctgb does not agree with the justification as this is a German-specific deviation of what is agreed upon in the EFSA GD (2009) (and the Uniform Principles), and therefore only applies to Germany. The scientific justification of the German working agreement is unclear to Ctgb (n.b. why the choice was made for a TER of 2 and not a different value). To the best of Ctgb’s knowledge, the lowering of the safety factor has never been accepted by the EU peer review (this was checked with EFSA). Also, it has never been agreed by risk managers across the EU. Therefore, Ctgb does not agree with altering the trigger values as used in the Core Assessment and will not use this for refinement of the risk for a small omnivorous mammal “mouse”. Therefore, the long-term risk to a small omnivorous mammal “mouse” is high and a combination risk remains.
In response to the issue raised the applicant submitted to Ctgb the original dRR (i.e. initially submitted to Germany). This dRR was used for the refinement of the risk to small omnivorous mammal “mouse”. The risk assessment is based on the 2009 EFSA guidance for birds and mammals (Journal 2009; 7(12):1483).
The effects of Metamitron and Quinmerac on the reproduction of mammals were examined. The results are summarized in the Table 10.3.1.3-1.

Table 10.3.1.3-1: Long-term toxicity to mammals

Species	Test substance	Endpoint	Reference
Rat	Metamitron	NOAEL = 36.4 mg a.s/kg bw/d (male) NOAEL = 53.8 mg a.s/kg bw/d (female)	EFSA (2008) *1* List of Endpoints
Rabbit	Quinmerac	NOEL = 100 mg /kg bw/d	EFSA Report (2010)*2*

Letters in bold were used for the risk assessment

Tier 1 assessment
As mentioned above, Ctgb does not agree with the change in the long-term trigger and will perform the risk assessment for the small omnivorous mammal "mouse".

Table 10.3.1.3-2: Long-term Tier 1 assessment for a small omnivorous mammal "mouse" according to EFSA (2009)

Crop	Application rate	Scenario	Generic focal species	Shortcut valuea	MAFmean	twab	DDDc	NOAEL [mg a.s/kg bw/d]	TERd (5)
	1.050 kg Metamitron /ha	BBCH 10 – 39	Small omnivorous mammal "mouse"	7.8	2.2	0.53	9.58	36.4	3.8
	0.080 kg Quinmerac /ha	BBCH 10 – 39	Small omnivorous mammal "mouse"	7.8	2.2	0.53	0.73	100	137
	TER Mix		Small omnivorous mammal "mouse"						3.71

a mean percentile residues
b time-weighted average factor
c daily dietary dose
d Toxicity-to-exposure ratio (Trigger)

The table above shows that a risk remains for a small omnivorous mammal "mouse". Therefore, a refinement is necessary.
Refinement of the long-term risk to a small omnivorous mammal "mouse"
The applicant submitted (in the original dRR) a refinement based on food types in the diet (PD), RUD, FIR/bw, PT and ftwa. The default representative Tier I species for small omnivorous mammals in sugar and fodder beets is the wood mouse (Apodemus sylvaticus).
PD
The applicant states the following in the dRR: "The wood mouse (Apodemus sylvaticus) is an omnivorous species with a varied diet. It feeds on grains and weeds, fruits, berries, roots, mushrooms and fruit of tress, and in spring and during summer the diet is also composed of animal components (e.g.: insects, worms, snails, spiders, etc.) (Ministerio de Agricultura, Pesca y Alimentación, 2001*3*). Although the diet of the wood mouse varies depending on the habitat and season of the year, the proportions of the principal

[1] EFSA Scientific Report (2008) 185, 1-95, Conclusion on the peer review of metamitron
[2] EFSA Scientific Report (2010) 8 (3): 1523, Conclusion on the peer review of quinmerac
[3] Ministerio de Agricultura, Pesca y Alimentación2001. Daños en la agricultura causados por vertebrados, Ministerio de Agricultura, Pesca y Alimentación, Spain, 41-45.

components of the food are maintained relatively stable throughout its geographic distribution (Tew et al., 2000*1*).
For the refinement of the diet, data obtained on an arable farmland during April and May was considered (Gurney et al., 1998*2*). Data on the volume of stomach content are given (%) over a 7 year period from 346 individuals. These data have been used to estimate the mixed diet of a wood mouse, and the different proportion of food items to reflect the potential exposure of wood mouse in the respective crops. Data collected over the entire year were considered for the use of AG-QMM1-565 SC.

Table 10.3.1.3-3: Percentage of food types in the diet for wood mouse (April-May)

	Insect larvae	Earthworms	Vegetation	Cereal seeds	Dicot seeds
Max. %a	55	66	40	35	4
Calc. %b	27.5	33	20	17.5	2
PD	0.28	0.33	0.2	0.18	0.02

a Maximum percentage of each food category. Individual food items, Pelz (1989) - cited in Gurney et al. (1998) - were combined. Data from all over the year were taken into consideration.
b Max. % of food category / (Sum of max. % of all food categories/100)

One of the food items mentioned above is cereal seeds. For the present crops, cereal seeds are not considered relevant because there is no cereal seed on the respective fields. However, the wood mouse can feed on different weed seeds that will be an alternative to the lack of cereal seeds. Thus, the proportion of cereal seeds is added to the weed seed consumption obtaining a final PD value for weed seeds of 0.2".

Reaction Ctgb

Ctgb agrees with the applicant regarding the diet composition of the wood mouse. Although the study is performed in Spain indeed the diet of the mouse will not change in different regions; although it might add some uncertainty.
Regarding the refinements the applicant refers to the study of Gurney et al., 1998. This study is a compendium containing data from multiple studies investigating the distribution of mammals in farmland, their feeding habitats, associations with crops, etc. The study the applicant refers to is Pelz, 1989 (see p. 200 of the Gurney et al., 1998). The study by Pelz, 1989 investigates the ecological damage to sugar beet seeds in the Rhineland, Germany.
The applicant states that data from the entire year were taken into consideration. According to the Danish EPA "Pesticide risk assessment for birds and mammals", p.49, the month April is the sowing and pre-emergence of the beets (BBCH 0-9) and in the months May-June the early growth stages will occur (BBCH 10-29). Given that the applications are intended in the spring (BBCH 10-19) Ctgb is of opinion that indeed the months April and May are relevant.
The diet of the wood mouse, according to Pelz 1989 during the spring months is as follows:

Table 10.3.1.3-4

	Diet composition (% of diet)					
Month	Insect larvae	Earthworms	Cereal grain	Vegetative plant tissue	Sugar beet seeds	Dicot seeds
April (n=49)	45	26	5	24	-	-
May (n=16)	10	40	30	16	-	4

[1] Tew, T.E., Todd, I.A. and Macdonald, D.W. 2000. Arable habitat use by wood mice (*Apodemus sylvaticus*). 1. Macrohabitat. The Zoological Society of London 250, 299-303.
[2] Gurney, J.E., Perrett, J., Crocker, D.R & Pascual, J.A. Mammals and farming: information for risk assessment. 1998 Update Contract PN0910/PN0919 Milestone Report. CSL Project No. M37

Average	27.5	33	17.5	20	-	2

As a next step the data from the Pelz, 1989 is classified according to EFSA GD (2009).

Given that in the cereal grain are not considered relevant in the sugar beet crops, Ctgb decided to pull the data of cereal grain and dicot seeds. This pulled data is considered to represent the worst-case weed seeds.

Regarding the data from earthworms and insect larvae, Ctgb decided to pull the data together. Although earthworms are not arthropods, the energy contents and moisture content is different, and considering that earthworms are not sprayed, the RUDs will be in principle different. However, considering the low logPow of metamitron (i.e. 0.85-0.96) and the BCF of 0.39 kg soil/kg worm it can be assumed that the substance will not bioaccumulate and therefore will not be taken up by the mammals. Therefore, taking the data together for the earthworms and arthropods can be considered a worst-case scenario.

Table 10.3.1.3-5

	Weeds	Weed seeds	Arthropods
Diet according to EFSA GD (2009)	20	19.5	60.5

FIR/bw
FIR/bw for each food type was estimated by the applicant according to Appendix G of EFSA GD, 2009. Daily energy expenditure (DEE) was calculated for the wood mouse (Table 10.3.1.3-6).

In the risk assessment of the applicant the following is stated:

“To obtain the specific equation for the wood mouse, log a and b have to be inserted. A body weight of 21.7 g was considered in the refined risk assessment.

Table 10.3.1.3-6: Daily energy expenditures (DEE) calculation for the wood mouse

Body weight [g]	log a	b	log bw	log DEE	DEE [kJ]
21.7	0.814	0.715	1.336	1.77	58.83

The FIR/bw was estimated for wood mouse considering the energy content of each food type, the moisture (%) and assimilation efficacy (%) values (Appendix G, EFSA Journal 2009).

Table 10.3.1.3-7: FIR/bw calculation for the wood mouse (acc. to Crocker et al., 2002, Appendix G EFSA 2009)

Food type	Energy content [kJ/g dw]	Moisture [%]	Assimilation efficacy [%]	FIR [g/d]	FIR/bw
terrestrial arthropods	22.7	68.8	87	9.55	0.44
Earthworms and slugs	19.4	84.3	87	22.20	1.02
non-grass herbs	17.8	88.1	76	36.54	1.68

Weed seeds	21.7	9.9	84	3.58	0.17

Reaction Ctgb
Ctgb calculated a FIR/bw according to Appendix G of the EFSA GD (2009), using the bw of a mouse of 21.7 g and the data as presented above in the Table 10.3.1.3-5. A total FIR/bw of for the months April-May was 0.374.
RUD
For the food category non-grass weeds, insects, and weed seeds, the mean RUD value of respectively 28.7, 7.5 and 40.2 were used by the applicant (Appendix F, EFSA GD (2009)).

Reaction Ctgb
As mentioned above the data for earthworms and arthropods will be taken together. Moreover no RUD for earthworms is available and therefore the data RUD for arthropods, without interception of 7.5 can be applied. Ctgb agrees with using the RUD for seeds. Regarding the residues on weeds, Ctgb will use the refined RUD of 48 which is derived from the foliar residue studies as mentioned in the DAR of metamitron, on which also proposed the DT50 values are derived (see below).
PT
Regarding the PT refinement, the applicant states as follows:

"Early stages of beet fields do not provide sufficient plant cover for small mammals. Studies estimating the reaction of wood mice to fields with sparse vegetation will help to estimate the exposure more realistically.
In the study conducted by Todd et al. (2000)1 23 wood mice were radio tracked in winter and spring (November – March) and 56 in summer (June – August) in arable habitat. The preferred macrohabitat of the wood mouse in arable land were hedgerows. In the study conducted by Tew et al. (2000)2 48 wood mice were radio tracked and microhabitats were recorded. In their study they found that wood mice avoided foraging in areas with a high abundance of bare earth. On such fields, predatory risk to feeding mice is high. This finding is also confirmed by Green (1979)3, who showed that fields with bare soil surface are not attractive feeding areas for mammals.
The predominant feeding habitats of a wood mouse are thick grass, woodland, arable land, heather and sand dunes (Mammals Bible4). They need cover protection for themselves and their offspring such as stone walls, hedgerows, gardens and even buildings if unoccupied. Beet fields at early BBCH stages do not provide such cover. Due to the absence of cover protections, it is unlikely that wood mouse will exclusively forage in beet fields in early BBCH stages. Thus a reduced PT value of 0.8 is much more realistic and will be considered in a refined risk assessment.
Even the PT value of 0.9 can be still regarded as conservative assumption with low uncertainty."

Reaction Ctgb
Ctgb does not completely agree with the applicant. Indeed the studies show that the mice will avoid bare soil, however the applications are intended from BBCH 10 (2 leaf stage) up to BBCH 19 (9 or more leaves are unfolded).
According to the CRD Mammals Bible citing the study by Tew (1994): the wood mouse is found on open arable land throughout the year. However, the suitability of arable fields for small mammals is seasonally variable and hedgerows are valuable resources for wood mice through the winter, providing both food and cover, although the open field is still exploited by some sections of the population. As the cover and food abundance in the fields increases during spring and summer, mice move out into the fields, nesting, mating and foraging entirely within the crop."

[1] Todd I.A., Tew T.E. and Macdonald D.W. (2000): Arable habitat use by wood mice (*Apodemus sylvaticus*). 1. MacrohabitatJ.Zoo., Lond. 250, 299-303
[2] Tew, T. E., Todd, I. A. & Macdonald, D. W. (2000): Arable habitat use by wood mice (*Apodemus sylvaticus*). 2. Microhabitat. Journal of Zoology (London), 250, 305-311.
[3] Green, R. 1979. The ecology of Wood mice (*Apodemus sylvaticus*) on arable farmland. Journal of Zoology, 188: 357–377.
[4] Gurney, J. E., Perett, J., Crocker, D. R. & Pascual, J. A. (1998): Mammal bible. Mammals and farming: information for risk assessment. Contract PN0910/PN0919. pp. 2-223. York: Central Science Laboratory; Project No. M37

According to the document “Pesticide risk assessment for birds and mammals” (2010) of Danish EPA: “The home ranges for individual mice are likely to be inside the area of a single field and it is therefore reasonable to assume that these mice spend their entire life cycle in a single field. This assumption is supported by other studies (Plesner-Jensen 1993; notifier study summarized in EFSA 2004)”.
Based on the above, it cannot be excluded that the mice will forage in the beet field and considering that the proposal of PT 0.8 is not fully supported by quantitative data, Ctgb will not accept this refinement and will still consider a PT of 1.

ftwa metamitron
The applicant has proposed a refined ftwa based on available residue data for metamitron:
“For a refined exposure assessment, initial residue levels on beets and their time-dependent decrease were calculated by use of measured residue levels determined in residue studies with Metamitron. A twa-value of 0.13 was considered in the following risk assessment which was calculated using a DT50 value of 1.9 days (based on residue decline studies; please refer to EFSA Report (2008) List of Endpoints*1*) for foliar residues. According to EFSA Report (2008) of Metamitron 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 measured residues of Metamitron were found to be reduced to non-significant level. The evidence is considered sufficient to support use of a DT50 of 1.9 days for foliar residues in the refined risk assessment”
Reaction Ctgb
According to the information available in the DAR of metamitron
“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)”.
The residue decline studies were performed on beet leaves and extrapolation to weeds is uncertain. Although the study was not performed with weeds and given the fast decline of the residue it is not expected that the dissipation in weeds will be much more different. Therefore, with the DT50 of 1.9 days the ftwa and MAF for weeds will be 0.46 and 1.19, respectively.
The refined long term risk for a small omnivorous mammals “mouse” is presented in tables 10.3.1.3-6 and 7.

Table 10.3.1.3-6: Refinement of long-term risk assessment for wood mouse exposed to Metamitron according to EFSA (2009)

Application rate	Food category	FIR/bw	PD	RUDa	MAFmean	ftwab	PT	DDDc	NOAEL [mg/kg bw/d]	TERd (5)
Sugar beets and fodder beets										
1.05 kg/ha	Ground arthropods	0.374	0.605	7.5	2.2	0.53	1	2.08	36.4	4.71
	Weeds	0.374	0.2	48	1.19	0.46		2.06		
	Weed seeds	0.374	0.195	40.2	2.2	0.53		3.59		
							Total	7.73		

a mean residues
b time-weighted average factor
c Daily dietary dose for multiple applications
d Toxicity-to-exposure ratio

1 EFSA Scientific Report (2008) 185, 1-95, Conclusion on the peer review of metamitron

Table 10.3.1.3-7: Refinement of long-term risk assessment for wood mouse exposed to Quinmerac according to EFSA (2009)

Application rate	Food category	FIR/bw	PD	RUDa	MAFmean	ftwab	PT	DDDc	NOAEL [mg/kg bw/d]	TERd (5)
Sugar beets and fodder beets										
0.08 kg/ga	Ground arthropods	0.27	0.25	7.5	2.2	0.53	1	0.05	100	136
	Weeds	0.27	0.25	28.7	2.2	0.53		0.18		
	Weed seeds	0.27	0.5	40.2	2.2	0.53		0.51		
							Total	0.73		

a mean residues
b time-weighted average factor
c Daily dietary dose for multiple applications
d Toxicity-to-exposure ratio

The combined risk taking into account the above TERs is 4.55. However, considering the worst-case assumption for PT of 1 and the RUDs, MAF and ftwa for seeds (n.b. given the fast dissipation it is expected that the DT50 on seeds should be comparable to the one on vegetation) the risk to wood mouse is acceptable.

Drinking water assessments are not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger as set in the new EFSA GD (2009). The ratios do not exceed the value of 50 for metamitron (n.b. Koc of 122.3 L/kg) and quinmerac (n.b. Koc of 35.1 L/kg) Finally, an assessment of the risk from secondary poisoning is not required due to log POW values (i.e. 1.41 and 0.85 for quinmerac and metamitron, respectively) below the trigger of 3.

In conclusion, application of Goltix Queen in accordance with the proposed use patterns in pre- and early post-emergence in fodder and sugar beets does not pose a 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.

As an analysis of the toxicity per fraction indicates, for most endpoints, the toxicity of the formulated product Goltix Queen is driven by the active substance Metamitron. Therefore, mixture toxicity has not to be considered. Nevertheless, assessments for Quinmerac are presented for completeness. In case of the acute and chronic exposure of fish, the toxicity of Quinmerac cannot be disregarded (in those cases the contribution of Quinmerac to the toxicity is marginally above 10%: 14.3 and 14.4%). The relevant toxicity endpoints are presented in the following Table.

Toxicity endpoints relevant for risk assessments

Test species	Active substance	Endpoint
Acute toxicity to fish		
Oncorhynchus mykiss	Quinmerac	LC_{50} = 86.8 mg/L
	BH 518-2	LC_{50} > 100 mg/L
	BH 518-5	LC_{50} > 100 mg/L
	Metamitron	LC_{50} > 190 mg/L
	Desamino-metamitron	EC_{50} > 1000 mg/L
Chronic toxicity to fish		
Oncorhynchus mykiss	Quinmerac	NOEC = 3.16 mg/L
	Metamitron	NOEC = 7 mg/L
	BH 518-2	NOEC = 0.32 mg/L (assumption)
	BH 518-5	NOEC = 5 mg/L
Acute toxicity to aquatic invertebrates		
Daphnia magna	Quinmerac	EC_{50} > 100 mg/L
	BH 518-2	EC_{50} > 100 mg/L
	BH 518-5	EC_{50} > 100 mg/L
	Metamitron	EC_{50} = 5.7 mg/L
	Desamino-metamitron	EC_{50} = 745 mg/L
Chronic toxicity to aquatic invertebrates		
Daphnia magna	Quinmerac	NOEC = 100 mg/L
	BH 518-2	NOEC = 25 mg/L
	BH 518-5	NOEC = 25 mg/L
	Metamitron	NOEC = 10 mg/L
Chronic toxicity to sediment dwelling organisms		
Chironomus riparius	Desamino-metamitron	NOEC = 100 mg/L
Chronic toxicity to algae		
Anabaena flos-aquae *Pseudokirchneriella subcapitata*	Quinmerac	E_bC_{50} > 100 mg /L
	BH 518-2	E_bC_{50} = 700 mg /L
	BH 518-5	E_bC_{50} = 160 mg /L
	Metamitron	E_bC_{50} = 0.4 mg /L
	Desamino-metamitron	E_bC_{50} = 25.1 mg /L
Chronic toxicity to higher plants		
Lemna gibba	Quinmerac	E_bC_{50} = 96 mg/L
	BH 518-2	E_bC_{50} > 100 mg/L
	BH 518-5	E_bC_{50} > 100 mg/L
Lemna minor	Metamitron	E_bC_{50} = 0.380 mg/L
Mesocosm		
Phytoplankton, zooplankton and macrophyte communities	Metamitron	NOAEC = 1.12 mg/L

Additional formulation data:

Active substance[1]	Test species	Ecotoxicological parameter	Value
AG-QMM1-565 SC	*Oncorynchus mykiss*	96 h LC_{50}	> 100 mg/L
AG-QMM1-565 SC	*Daphnia magna*	48 h EC_{50}	> 100 mg/L
AG-QMM1-565 SC	*Pseudokirchneriella subcapitata*	72 h E_rC_{50} 72 h E_bC_{50} 72 h E_yC_{50}	3.77 mg/L 2.09 mg/L 1.99 mg/L
AG-QMM1-565 SC	*Lemna gibba*	7 d E_yC_{50} E_rC_{50} E_fC_{50} E_aC_{50} $E_{ya}C_{50}$ $E_{ra}C_{50}$	 1.50 mg/L 4.27 mg/L 1.55 mg/L 0.86 mg/L 2.59 mg/L 3.66 mg/L

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. Loading of surface water by agricultural use of plant protection products is for the time being only based on drift of spray mist (drift) while neglecting runoff, leaching and drainage. The loading of surface water is calculated on the basis of the drift percentage figures as laid down by the Board.

In conclusion, the aquatic toxicity is mainly driven by the active ingredient Metamitron. With favourable TERs above the trigger for Metamitron, the acute and chronic risk to aquatic organisms following exposure to Goltix Queen according to intended worst-case use patterns is acceptable. For Quinmerac and the metabolites as well as for the major metabolite of Metamitron, Desamino-Metamitron, the PECs are sufficient to indicate low risk.

Based on the available formulation data the product is classified as H411, toxic to aquatic life with long lasting effects.

Use of Goltix Queen at the proposed label rates for sugar and fodder beets and according to good agricultural practice, poses an acceptable risk to all non-target aquatic species.

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

Bees

Not a Dutch specific aspect. For details regarding the risk assessment please refer to Section 6 of the Core dossier. The conclusion as stated in the Core is:

"It is concluded that AG-QMM1-565 SC (525 g/L metamitron; 40 g/L quinmerac) will not adversely affect bees or bee colonies when used as recommended".

Arthropods other than Bees

The in-field risk assessment is not a Dutch specific aspect. For details regarding the risk assessment please refer to Section 6 of the Core dossier.

[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 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 off-field exposure have been conducted based on the following endpoints for the formulated product Goltix Queen which are most relevant.

Goltix Queen (i.e. AG-QMM1-565 SC) - Toxicity to non-target arthropods

Species	Type of Test	LR_{50} / "$ER_{<50}$"* [mL product/ha]	Reference
Aphidius rhopalosiphi	Extended laboratory dose response test (3D test)	6000 / 6000	Stevens (2010), (see KIIIA 10.5.2/01)
Typhlodromus pyri	Extended laboratory dose response test (2D test)	6000 / 6000	Fallowfield (2010), (see KIIIA 10.5.2/02)

* $LR_{50}/ER_{<50}$ presents the test rate with ≤ 50 % effect on mortality and reproduction in extended laboratory test

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.

In-field and off-field hazard quotients based on extended laboratory data with the standard species are above the trigger and no unacceptable risk of treatment with Goltix Queen for non-target arthropods is indicated without any risk mitigation.

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

Not Dutch specific aspects. For details regarding the risk assessment please refer to Section 6 of the Core dossier.The conclusions of the Core assessment were as follows:

"All acute and chronic TERs for the active substances 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 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 – for details please see section 6 of the Core assessment.

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)

Not a Dutch specific aspect. For details regarding the risk assessment please refer to Section 6 of the Core dossier.**The conclusions of the Core assessment were as follows:**

"GOLTIX TITAN (Goltix Queen/AG-QMM1-565 SC) applied at the proposed worst-case use patterns does not pose
an unacceptable risk to soil microorganisms."

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

Given the off-field drift values for non-target plants are Dutch specific, the results of the risk assessment are presented below.

Ecotoxicological endpoints for the most sensitive tested species of non-target plants

Test substance	Endpoint	ER_{50}	Reference
AG-QMM1-565 SC	Vegetative Vigour	>1116 mL/ha	Minarski & Marquardt (2010a) (see KIIIA 10.8.1.2/01)
	Seedling Emergence	>1116 mL/ha	Minarski & Marquardt (2010b) (see KIIIA 10.8.1.3/01)

The risk assessment for non-target plants is based on an off-crop situation with a drift percentage of 4.7%. The exposure thus equals 0.047 * the application rate * MAF (in case of multiple application). MAF-values are taken from ESCORT 2.
The application rate according to Table 10-1 and Appendix 2 is 2000 ml Goltix Queen /ha with a maximum of 3 applications and 5 days interval. According to ESCORT2 the MAF value for the intended use is 2.3.
Table 10.8.1-2: Risk assessment for terrestrial non-target plants exposed to Goltix Queen (AG-QMM1-565 SC)

Effect endpoint	Dose [mL product/ha]	MAF	Drift% (off-field exposure)	Exposure [mL product/ha]	Effect rate [mL product/ha] (ER50)	TER
Vegetative vigour	2000	2.3	4.7	216.2	> 1116	> 5.16

The ratio between ER50 and the exposure concentration of the formulation is higher than the proposed Annex VI trigger of 5, indicating a low risk for non-target plants.

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

Information on the plant protection product

Goltix Queen is intended to become authorised as herbicide for weed control in fodder and sugar beets. Goltix Queen is formulated as suspension concentrate (SC) and contains the active ingredients metamitron (525 g/L) and quinmerac (40 g/L).
The field performance of Goltix Queen was investigated in a lot of field trials carried out in 2009, 2010 and 2011. The numbers of results available for the assessment of the different evaluation criteria are as follows:

Evaluation criteria	Use 001, Sugar and fodder beet 3x 2 l/ha, post emergence.	Use 002* LDS and pre emergence use in sugar and fodder beet.
Efficacy	20	18
- target rate	20	9
- minimum dose rate	17	-
Selectivity	31	9

- efficacy trials	20	9
- almost weed free conditions	11	-
- double rate	11	9
Yield	11	-
- almost weed free conditions	11	-
- double rate	11	-

Minimum effective dose Tests

The proposed dose rate for Use 001 in sugar and fodder beet 3x 2 l/ha, was shown to be the correct dose rate. The dose rate for use 002 was not supported by data.

Efficay tests

Goltix Queen (3 x 2 L/ha, POST emergence) provides a high level control of GALAP, clearly superior compared to the reference product. Against other annual broad-leaved weeds the performance of Goltix Queen is comparable to slightly superior to the reference product. For Use 002 (LDS) the effectiveness is not sufficiently described (not enough tests, effectiveness too low).

The core assessment concluded that efficacy of the product was acceptable for use 001, if the product was applied with an interval of 5-10 days. Based on the conclusions from the ecotox evaluation such an interval is not possible in the Netherlands, the minimum interval should be 10 days.
The original range for the interval was wider, a shorter interval can be important in situations with a high weed pressure or tougher weeds. Based on expert judgement and based on knowledge of the active substances and experiences with existing products the longer interval is found to be acceptable. Furthermore, in practice, metamitron based products are often used in tank mixes, which has a positive effect on efficacy.

Impact on the Quality of Plants and Plant Products

There are no indications for a negative impact on quality of plants and plant products in sugar or fodder beets if Goltix Queen is applied at the intended target dose rates of 6 L/ha in total and even at the double rate.

Effects on the Processing Procedure

Neither from trial experience nor from practical use of the active ingredients metamitron and quinmerac any cases were reported about negative influences on parameters influencing the processing procedure of sugar beets. Thus no special trials were carried out for the assessment of these criteria.

Effects on the Yield of treated Plants and Plant Products

There are no indications for a negative impact on quantity of yield in sugar or fodder beets if Goltix Queen is applied at the intended target dose rates of 6 L/ha in total and even at the double rate there is no substantial risk for an impact on yield quantity.

Phytotoxicity to Host Crop

When applied by 3 POST emergence splitting applications of 2 L/ha each or in a PRE-POST sequence (1 x 3 + 3 x 1 L/ha) Goltix Queen does not cause any substantial risk for the treated crop when applied up to the 9 leaf stage (BBCH 19). There is no unacceptable risk for the crop in overlapping areas and there are no indications for a variety dependent sensitivity of sugar beets to Goltix Queen. The selectivity of Goltix Queen is fully comparable to the reference products.

Impact on Succeeding Crops

There is no unacceptable risk for crops including catch and forage crops planted as succeeding crops in common crop rotations. They can be planted without any restrictions if Goltix Queen is applied in sugar or fodder beets with the intended use rates.
The applicant has placed the following sentence relating to replacement crops on the WG.

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.

Impact on other Plants, including Adjacent Crops

In none of the trials carried out, observations about impacts on adjacent crops or other plants were reported.

Information on the possible Occurrence of the Development of Resistance or Cross-Resistance
The evaluation of the inherent risk for resistance development of Goltix Queen shows that for the active ingredient metamitron there is a high risk for the development of weed resistance while the inherent risk of target weeds to develop resistance against quinmerac is considered low to medium. The applicant claims that the risk for the development of resistant weed biotypes in major sugar beet production areas is considered medium because despite many years of intensive use of metamitron only very occasional proven problems with weed resistance were reported in Europe. This conclusion cannot be followed as the number of biotypes of *Chenopodium album* with resistance to metamitron is high in Belgium and the Netherlands and has increased during the last years in Germany as well.
To further ensure the high level of activity on the target weeds, the applicant concluded that for the use of Goltix Queen in sugar or fodder beets measures for a resistance management should be established, especially with respect to the control of *Chenopodium album, Matricaria species, Senecio vulgaris, Solanum nigrum* and *Amaranthus retroflexus*. The following sentence should be placed on the label:

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**.**

Conclusions efficacy

The product complies with the Uniform Principles because it does in accordance with article 2.1 control: Annual broad leaved weeds in sugar and fodder beets, when applied as a post emergence herbicide at a dose rate of 2 l/ha.

The use in an LDS system, and the pre-emergence use in sugar and fodder beets can not be granted.

3.2 Conclusions

An acceptable risk to operators is estimated according to the German model for the application of Goltix Queen to field crops (tractor mounted spraying) when protective gloves and protective garment are worn by the operator during mixing/loading and during spray application.
According to the UK POEM exposure levels of operators are estimated to exceed the AOEL with regard to Metamitron exposure when protective gloves are worn during mixing/loading and during spraying

An acceptable risk to operators considering 90th percentile exposure values of a field study is estimated for the application of Goltix Queen to field crops (tractor mounted spraying) when protective gloves, standard coverall and sturdy foot wear are worn by the operator during mixing/loading and during spraying.
Bystanders and residents are considered to be at no risk if exposed to Metamitron- and Quinmerac-containing spray drift upon application of the product as intended.
There is no unacceptable risk anticipated for the worker upon re-entry for crop inspection wearing adequate work clothing (but no PPE), when re-entering crops treated with Goltix Queen.
In addition, 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 does not lead to unacceptable risk for consumer when applied according to the recommendations.
No risk for consumer has been identified resulting from the exposure to metabolites contaminating groundwater, which is used as drinking water, resulting from the representative use of Metamitron and Quinmerac in sugar beets.
No unacceptable risks are expected to environmental compartments following the use of the product in soil, groundwater, surface water and sediment for the active substances or their metabolites.
Use of Goltix Queen at the proposed label rates for sugar and fodder beets and according to good agricultural practice, poses low risk to all non-target species.

The use in an LDS system, and the pre-emergence use in sugar and fodder beets can not be granted as they are not supported by the efficacy dossier.

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 proposed product label/instructions for use

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

Toepassings-gebied	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per teeltcyclus	Minimum interval tussen toepassingen
Bieten	Eenjarige breedbladige onkruiden	2 L/ha	3	10 dagen

Toepassingsvoorwaarden

Dit middel of een ander middel op basis van metamitron mag slechts 1 keer per 2 jaar, volgens bovenstaand gebruiksvoorschrift op een perceel worden toegepast.

Om het grondwater te beschermen mag dit middel niet worden toegepast in grondwaterbeschermingsgebieden.

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.

<u>Resistentiemanagement</u>
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 application

Physical and chemical properties – Core assessment

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
IIIA 1.4.4/01	2011b	SAFETY DATA SHEET: METAMITRON TECHNICAL Agan Chemicals Manufacturers, Ltd Report-no. H-0182-23046 GLP/GEP: no Published: no	Y	N	Y	AGA
IIIA 1.4.4/02	2011c	SAFETY DATA SHEET: QUINMERAC TECHNICAL Agan Chemicals Manufacturers, Ltd Report-no. H-0303 GLP/GEP: no Published: no	Y	N	Y	AGA
IIIA 2.1/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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 (ONE-YEAR INTERIM REPORT) AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/5 GLP/GEP: no Published: no	Y	Y	Y	QPP
IIIA 2.2.1/01	2011	STATEMENT ON EXPLOSIVE AND OXIDIZING PROPERTIES Feinchemie Schwebda GmbH, Eschwege, Germany Feinchemie Schwebda GmbH Report-no. not stated GLP/GEP: no Published: no	Y	Y	Y	FSG

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
IIIA 2.2.2/01	2011	STATEMENT ON EXPLOSIVE AND OXIDIZING PROPERTIES Feinchemie Schwebda GmbH, Eschwege, Germany Feinchemie Schwebda GmbH Report-no. not stated GLP/GEP: no Published: no **Submitted in: IIIA 2.2.1/01**	Y	Y	Y	FSG
IIIA 2.3.1/01	2010a	FLASH POINT A.9 (OPPTS 830.6315) Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Quena Plant Protection N.V. Report-no. 20100231.02 GLP: yes Published: no	Y	Y	Y	QPP
IIIA 2.3.3/01	2010b	AUTO-FLAMMABILITY (DETERMINATION OF THE TEMPERATURE OF SELF-IGNITION OF VOLATILE LIQUIDS AND OF GASES) A.15 Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Quena Plant Protection N.V. Report-no. 20100231.03 GLP: yes Published: no	Y	Y	Y	QPP
IIIA 2.4.1/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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 (ONE-YEAR INTERIM REPORT) AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/5 GLP/GEP: no Published: no **Submitted in: KIIIA 2.1/01**	Y	Y	Y	QPP

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
IIIA 2.4.2/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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 (ONE-YEAR INTERIM REPORT) AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/5 GLP/GEP: no Published: no **Submitted in: KIIIA 2.1/01**	Y	Y	Y	QPP
IIIA 2.5.1/01	2010c	KINEMATIC VISCOSITY (OECD 114) Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Quena Plant Protection N.V. Report-no. 20100231.04 GLP: yes Published: no	Y	Y	Y	QPP
IIIA 2.5.2/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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 (ONE-YEAR INTERIM REPORT) AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/5 GLP/GEP: no Published: no **Submitted in: KIIIA 2.1/01**	Y	Y	Y	QPP

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
IIIA 2.5.3/01	2010d	SURFACE TENSION A.5 (OECD 115) Siemens AG, Prozess-Sicherheit, Frankfurt am Main, Germany Quena Plant Protection N.V. Report-no. 20100231.01 GLP: yes Published: no	Y	Y	Y	QPP
IIIA 2.6.1/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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 (ONE-YEAR INTERIM REPORT) AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/5 GLP/GEP: no Published: no **Submitted in: KIIIA 2.1/01**	Y	Y	Y	QPP
IIIA 2.7.1/01	2010	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF (QUINMERAC 40 G/L + METAMITRON 525 G/L) SC STORD AT 54°C FOR 14 DAYS AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/4 GLP: yes Published: no **Submitted in: IIIA 2.1/01**	Y	Y	Y	QPP

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
IIIA 2.7.4/01	2010	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF (QUINMERAC 40 G/L + METAMITRON 525 G/L) SC STORD AT 54°C FOR 14 DAYS AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/4 GLP: yes Published: no **Submitted in: IIIA 2.1/01**	Y	Y	Y	QPP
IIIA 2.7.5/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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 (ONE-YEAR INTERIM REPORT) AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/5 GLP/GEP: no Published: no **Submitted in: KIIIA 2.1/01**	Y	Y	Y	QPP

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
IIIA 2.8.2/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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. Report-no. F10-03/5 GLP/GEP: no Published: no **Submitted in: KIIIA 2.1/01**	Y	Y	Y	QPP
IIIA 2.8.3.1/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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 (ONE-YEAR INTERIM REPORT) AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/5 GLP/GEP: no Published: no **Submitted in: KIIIA 2.1/01**	Y	Y	Y	QPP

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
IIIA 2.8.3.2/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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 (ONE-YEAR INTERIM REPORT) AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/5 GLP/GEP: no Published: no **Submitted in: KIIIA 2.1/01**	Y	Y	Y	QPP
IIIA 2.8.5.2/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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 (ONE-YEAR INTERIM REPORT) AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/5 GLP/GEP: no Published: no **Submitted in: KIIIA 2.1/01**	Y	Y	Y	QPP

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
IIIA 2.8.8.2/01	2011	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC 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 (ONE-YEAR INTERIM REPORT) AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/5 GLP/GEP: no Published: no **Submitted in: KIIIA 2.1/01**	Y	Y	Y	QPP
IIIA 2.9.1/01	2010	EVALUATION OF PHYSICAL AND CHEMICAL COMPATIBILITY OF TANK MIXTURES OF FSG 02122 H BioChem Agrar, Gerichshain, Germany Feinchemie Schwebda GmbH Report-no. 10 10 35 750 GLP/GEP: no	Y	Y	Y	FSG
IIIA 2.9.2/01	2010	EVALUATION OF PHYSICAL AND CHEMICAL COMPATIBILITY OF TANK MIXTURES OF FSG 02122 H BioChem Agrar, Gerichshain, Germany Feinchemie Schwebda GmbH Report-no. 10 10 35 750 GLP/GEP: no Published: no **Submitted in: IIIA 2.9.1/01**	Y	Y	Y	FSG
IIIA 4.4.1/01	2007	HDPE 10 × 1 L PACKAGING INFORMATION The Standards Institution of Israel, Tel Aviv, Israel Amraz Ltd. Ashod Israel Report-no. not applicable GLP/GEP: no Published: no	Y	N	Y	AMZ

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
IIIA 4.4.1/02	2006	HDPE 4 × 5 L PACKAGING INFORMATION The Standards Institution of Israel, Tel Aviv, Israel Amraz Ltd. Ashod Israel Report-no. not applicable GLP/GEP: no Published: no	Y	N	Y	AMZ
IIIA 4.4.1/03	2003a	HDPE 2 × 10 L PACKAGING INFORMATION The Standards Institution of Israel, Tel Aviv, Israel Report-no. not applicable GLP/GEP: no Published: no	Y	N	Y	-
IIIA 4.4.1/04	2003b	HDPE 20 L PACKAGING INFORMATION The Standards Institution of Israel, Tel Aviv, Israel Report-no. not applicable GLP/GEP: no Published: no	Y	N	Y	-
IIIA 4.4/01	2011	SAFETY DATA SHEET, EU REGULATION NO. 1907/2006 – METAMITRON / QUINMERAC 525/40 SC Agan Chemicals Manufacturers, Ltd Report-no. H-0435 GLP/GEP: no Published: yes	-	N	Y	AGA

AGA = Agan Chemical Manufacturers
QPP = Quena Plant Protection
FSG = Feinchemie Schwebda GmbH
AMZ = Amraz Ltd. Israel

Methods of analysis – Core assessment

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
KIIIA 5.2.2/01	2010	(QUINMERAC 40 G/L + METAMITRON 525 G/L) SC DETERMINATION OF STORAGE STABILITY AND PHYS-CHEM PROPERTIES OF (QUINMERAC 40 G/L + METAMITRON 525 G/L) SC STORED AT 54°C FOR 14 DAYS AGAN Chemical Manufacturers, Ltd., Ashdod, Israel Quena Plant Protection N.V. Report-no. F10-03/4 GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 5.3.1/01	2007a	DEVELOPMENT AND VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF METAMITRON AND DESAMINO-METAMITRON ON PLANT MATERIAL (DRY, FATTY, ACIDIC) Eurofins Agroscience Services Chem GmbH Quena Plant Protection N.V. Report-no. 20071134/01-RVP GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 5.3.1/02	2007a	INDEPENDENT LABORATORY VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF METAMITRON AND DESAMINO-METAMITRON IN TWO PLANT MATRICES PTRL Europa, Ulm, Germany Quena Plant Protection N.V. Report-no. P 1346 G GLP: yes Published: no	yes	Y	Y	QPP

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
KIIIA 5.3.1/03	2010a	DETERMINATION OF RESIDUES OF METAMITRON AND ITS METABOLITE DESAMINO-METAMITRON IN APPLES-DEVELOPMENT AND VALIDATION OF THE METHOD. Institut Fresenius, Taunusstein, Germany Quena Plant Protection N.V. Report-no. IF-10/01618813 GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 5.3.1/04	2011	METAMITRON: EXPERT STATEMENT ON THE EFFICIENCY OF THE EXTRACTION METHOD – USED IN THE METHOD OF ANALYSIS FOR THE DETERMINATION OF RESIDUES IN PLANT MATERIALS – WITH RESPECT TO GROWN RESIDUES Feinchemie Schwebda, Germany GLP: no Published: no	yes	Y	Y	FSG
KIIIA 5.3.1/05	2009	VALIDATION OF MULTIRESIDUE METHOD DFG S19 FOR THE DETERMINATION OF RESIDUE OF METAMITRON IN FOOD OF ANIMAL ORIGIN AND AMENDMENT NR. 1 Eurofins Analytik GmbH, Dr. Specht Laboratorien, Hamburg, Germany Feinchemie Schwebda GmbH Report-no. FCS-0901V GLP: yes Published: no	yes	Y	Y	FSG

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
KIIIA 5.3.1/06	2009	INDEPENDENT LABORATORY VALIDATION (ILV) OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF METAMITRON IN FOOD ON ANIMAL ORIGIN Eurofins-GAB GmbH, Niefern-Öschelbronn, Germany Quena Plant Protection N.V. Report-no. S09-02830 GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 5.3.1/07	2010b	DETERMINATION OF RESIDUES OF QUINMERAC AND ITS METABOLITES BH 518-2 AND BH 518-4 IN PLANT MATRICES - DEVELOPMENT AND VALIDATION OF THE METHOD - SGS Institut Fresenius AGAN Chemical Manufacturers Ltd. Israel Report-no. IF-09/01249451 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 5.3.1/08	2010	INEPENDENT LABORATORY VALIDATION (ILV) OF AN ANALYTICAL METHOD FOR DETERMINATION OF RESIDUES OF QUINMERAC AND ITS METABOLITES BH 518-2 AND BH 518-4 IN PLANT MATRICES Eurofins Agroscience Service GmbH AGAN Chemical Manufacturers Ltd. Israel Report-no. S10-02256, 90013319 GLP: yes Published: no	yes	Y	Y	AGA

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
IIIA 5.3.1/09	2011	QUINMERAC AND METABOLITES: EXPERT STATEMENT ON THE EFFICIENCY OF THE EXTRACTION METHOD - USED IN THE METHOD OF ANALYSIS FOR DETERMINATION OF RESIDUES IN PLANT MATERIALS - WITH RESPECT TO GROWN RESIDUES Feinchemie Schwebda GmbH Report-no. - GLP/GEP: no Published: no	yes	Y	Y	FSG
IIIA 5.3.1/10	2010c	DETERMINATION OF RESIDUES OF QUINMERAC AND ITS METABOLITES BH 518-2 AND BH 518-4 IN ANIMAL MATRICES - DEVELOPMENT AND VALIDATION OF THE METHOD - SGS Institut Fresenius AGAN Chemical Manufacturers Ltd. Israel Report-no. IF-10/01572981 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 5.3.1/11	2011	INDEPENDENT LABORATORY VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF QUINMERAC AND ITS METABOLITES BH 518-2 AND BH 518-4 IN TWO ANIMAL MATRICES Eurofins Agroscience Services Chem GmbH AGAN Chemical Manufacturers Ltd. Israel Report-no. S11-02497 GLP: yes Published: no	yes	Y	Y	AGA

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
KIIIA 5.4/01	2007b	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF METAMITRON AND DESAMINO-METAMITRON IN SOIL PTRL Europe, Ulm, Germany Quena Plant Protection N.V. Report-no. P/B 1355 G GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 5.4/02	2010a	DEVELOPMENT AND VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF QUINMERAC AND ITS METABOLITES BH 518-2 AND BH 518-5 IN SOIL CIP Chemisches Institut Pforzheim GmbH, Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 09F02033-02-VMS GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 5.6/01	2007b	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF METAMITRON AND DESAMINO-METAMITRON IN DRINKING WATER AND SURFACE WATER Eurofins-GAB GmbH, Niefern-Öschelbronn, Germany Quena Plant Protection N.V. Report-no. 20071119/01-RVW GLP: yes Published: no	yes	Y	Y	QPP

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
KIIIA 5.6/02	2010b	DEVELOPMENT AND VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF RESIDUES OF QUINMERAC AND ITS METABOLITES BH 518-2 AND BH 518-5 IN DRINKING AND SURFACE WATER CIP Chemisches Institut Pforzheim GmbH, Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 09F02033-02-VMWA GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 5.6/03	2010b	INDEPENDENT LABORATORY VALIDATION OF AN ANALYTICAL METHOD FOR DETERMINATION OF QUINMERAC AND ITS METABOLITES BH 518-2 AND BH 518-5 IN DRINKING WATER Eurofins Agroscience Service GmbH AGAN Chemical Manufacturers Ltd. Israel Report-no. S10-03480 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 5.7/01	2007c	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF METAMITRON IN AIR PTRL Europe, Ulm, Germany Quena Plant Protection N.V. Report-no. P/B 1356 G GLP: yes Published: no	yes	Y	Y	QPP

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	Data protection granted Y/N	Used for evaluation Y/N	Owner
KIIIA 5.7/02	2009	VALIDATION OF AN ANALYTICAL METHOD FOR THE DETERMINATION OF QUINMERAC IN AIR CIP Chemisches Institut Pforzheim GmbH, Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 09A02033-01-VMAI, 90010980 GLP: yes Published: no	yes	Y	Y	AGA

AGA = AGAN CHEMICAL MANUFACTURERS
FSG = FEINCHEMIE SCHWEBDA GMBH
QPP = QUENA PLANT PROTECTION

Annex Point	Title	Year	Ref. App. Ref. JKI	Data protection granted y/n	Used for evaluation y/n
KIIIA1 6.1.2	GALAP und Dikotyle - Z.- Rüben 1.-3. NAK 2009	2009	FCS09-1211-E01 238161	Y	Y
KIIIA1 6.1.2	Unkrautbekämpfung in Zuckerrüben	2009	FCS09-1211-E02 238162	Y	Y
KIIIA1 6.1.2	Efficacy of FSG 02122 H against GALAP and dicotyledonous weeds in Fodder- and Sugarbeet	2009	FCS09-1211a-E02 238163	Y	Y
KIIIA1 6.1.2	An evaluation of the efficacy of FSG 02122 H vs. cleavers and other dicotyledonous weeds in fodder or sugar beets following three sequential post emergence applications	2009	FCS09-1211-E04 238164	Y	Y
KIIIA1 6.1.2	Efficacy of FSG 02122 H against Galium aparine and dicotyle weeds in fodder and sugar beets; split application (3 times) post-emergence in spring	2009	FCS09-1211-E06 238166	Y	Y
KIIIA1 6.1.4	Selectivity of FSG 02122 H on Fodder- and Sugarbeet at post-emergence application, split treatment	2010	FCS09-1212-S01 238167	Y	Y
KIIIA1 6.1.4	Selectivity of FSG 02122 H on Fodder- and Sugarbeet at post-emergence application, split treatment	2010	FCS09-1212-S02 238168	Y	Y
KIIIA1 6.1.4	Selectivity of FSG 02122 H in fodder and sugar beets after split post emergence application	2009	FCS09-1212-S03 238169	Y	Y
KIIIA1 6.1.4	Selectivity of FSG 02122 H in fodder and sugar beets after split post emergence application	2009	FCS09-1212-S04 238170	Y	Y
KIIIA1 6.1.4	An evaluation of the selectivity of FSG 02122 H to fodder or sugar beets following three sequential post emergence applications	2009	FCS09-1212-S05+FCS09-1212-S06 238171	Y	Y
KIIIA1 6.1.2	Unkrautbekämpfung in Zuckerrüben	2010	FCS10-1331-E02 238172	Y	Y

Annex Point	Title	Year	Ref. App. Ref. JKI	Data protection granted y/n	Used for evaluation y/n
KIIIA1 6.1.2	Efficacy of AG-QMM1-565 SC (FSG 02122 H) against GALAP and dicotyledonous weeds in fodder and sugarbeet (post emergence application)	2010	FCS10-1331-E04 238173	Y	Y
KIIIA1 6.1.2	Efficacy of AG-QMM1-565 SC (FSG 02122 H) against GALAP and dicotyledonous weeds in fodder- and sugar beets (post emergence application)	2010	FCS10-1331-E05 238174	Y	Y
KIIIA1 6.1.2	Efficacy of AG-QMM1-565 SC (FSG 02122 H) against Galium aparine and dicotyle weeds in Sugar Beets; split application post emergence	2010	FCS10-1331-E06 238175	Y	Y
KIIIA1 6.1.2	An evaluation of the efficacy of AG-QMM1-565 SC (FSG 02122 H) vs. GALAP and other dicotyledonous weeds following three sequential post emergence applications onto fodder or sugar beets	2010	FCS10-1331-E07 238176	Y	Y
KIIIA1 6.1.4	Selectivity of AG-QMM1-565 SC (FSG 02122 H) and Goltix Super in fodder- and sugar beets (post emergence application)	2010	FCS10-1332a-S01 238177	Y	Y
KIIIA1 6.1.4	Selectivity of AG-QMM1-565 SC(FSG 02122 H) and Goltix Super in fodder- and sugar beets (post emergence application)	2010	FCS10-1332a-S02 238180	Y	Y
KIIIA1 6.1.4	An evaluation of the selectivity of AG-QMM1-565 SC (FSG 02122 H) and Goltix Super to fodder or sugar beets following three sequential post emergence applications	2010	FCS10-1332a-S03 238182	Y	Y
KIIIA1 6.1.4	Selectivity of AG-QMM1-565 SC (FSG 02122 H) and Goltix Super in fodder- and sugar beet	2010	FCS10-1332a-S04 238184	Y	Yy
KIIIA1 6.1.4	Selectivity of AG-QMM1-565 SC (FSG 02122 H) in fodder- and sugar beets (post emergence)	2010	FCS10-1332b-S01 238186	Y	Y
KIIIA1 6.1.2	Evaluation of metamitron 525 + quinmerac 40 (FSG 02122 H / AG-QMM1-565 SC) on weeds in sugar beet	2010	R121-10H 238189	Y	Y
KIIIA1 6.1.2	Evaluation of metamitron 525 + quinmerac 40 (FSG 02122 H / AG-QMM1-565 SC) on weeds in sugar beet	2010	R122-10H 238192	Y	Y
KIIIA1 6.1.2	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 - THE NETHERLANDS	2011	H-10-2105-1 238194	Y	Y

Annex Point	Title	Year	Ref. App. Ref. JKI	Data protection granted y/n	Used for evaluation y/n
KIIIA1 6.1.2	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 THE NETHERLANDS	2011	H-10-2105-2 238197	Y	Y
KIIIA1 6.1.2	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 THE NETHERLANDS	2011	H-10-2105-3 238199	Y	Y
KIIIA1 6.1.2	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 THE NETHERLANDS	2011	H-10-2105-4 238201	Y	Y
KIIIA1 6.1.2	Efficacy of AGQMM1-565 SC (FSG 02122 H) and dicotyledonous weeds in fodder- and sugar beets (post emergence application)	2011	FCS-1331-E11 238203	Y	Y
KIIIA1 6.1.2	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND FIESTA NEW, 2011 - THE NETHERLANDS	2011	H-11-2101-1 238205	Y	Y
KIIIA1 6.1.2	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND FIESTA NEW, 2011 - THE NETHERLANDS	2011	H-11-2101-2 238207	Y	Y
KIIIA1 6.1.2	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND FIESTA NEW, 2011 - THE NETHERLANDS	2011	H-11-2101-3 238209	Y	Y
KIIIA1 6.1.3	GALAP und Dikotyle - Z.- Rüben 1.-3. NAK 2009	2009	FCS09-1211-E01 238211	Y	Y
KIIIA1 6.1.3	Unkrautbekämpfung in Zuckerrüben	2009	FCS09-1211-E02 238213	Y	Y
KIIIA1 6.1.3	Efficacy of FSG 02122 H against GALAP and dicotyledonous weeds in Fodder- and Sugarbeet	2009	FCS09-1211a-E02 238215	Y	Y
KIIIA1 6.1.3	An evaluation of the efficacy of FSG 02122 H vs. cleavers and other dicotyledonous weeds in fodder or sugar beets following three sequential post emergence applications	2009	FCS09-1211-E04 238217	Y	Y

Annex Point	Title	Year	Ref. App. Ref. JKI	Data protection granted y/n	Used for evaluation y/n
KIIIA1 6.1.3	Efficacy of FSG 02122 H against Galium aparine and dicotyle weeds in fodder and sugar beets; split application (3 times) post-emergence in spring	2009	FCS09-1211-E06 238220	Y	Y
KIIIA1 6.1.3	Unkrautbekämpfung in Zuckerrüben	2010	FCS10-1331-E02 238222	Y	Y
KIIIA1 6.1.3	Efficacy of AG-QMM1-565 SC (FSG 02122 H) against GALAP and dicotyledonous weeds in fodder and sugarbeet (post emergence application)	2010	FCS10-1331-E04 238224	Y	Y
KIIIA1 6.1.3	Efficacy of AG-QMM1-565 SC (FSG 02122 H) against GALAP and dicotyledonous weeds in fodder- and sugar beets (post emergence application)	2010	FCS10-1331-E05 238226	Y	Y
KIIIA1 6.1.3	Efficacy of AG-QMM1-565 SC (FSG 02122 H) against Galium aparine and dicotyle weeds in Sugar Beets; split application post emergence	2010	FCS10-1331-E06 238228	Y	Y
KIIIA1 6.1.3	An evaluation of the efficacy of AG-QMM1-565 SC (FSG 02122 H) vs. GALAP and other dicotyledonous weeds following three sequential post emergence applications onto fodder or sugar beets	2010	FCS10-1331-E07 238230	Y	Y
KIIIA1 6.1.3	Evaluation of metamitron 525 + quinmerac 40 (FSG 02122 H / AG-QMM1-565 SC) on weeds in sugar beet	2010	R121-10H 238232	Y	Y
KIIIA1 6.1.3	Evaluation of metamitron 525 + quinmerac 40 (FSG 02122 H / AG-QMM1-565 SC) on weeds in sugar beet	2010	R122-10H 238234	Y	Y
KIIIA1 6.1.3	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 - THE NETHERLANDS	2011	H-10-2105-1 238236	Y	Y
KIIIA1 6.1.3	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 THE NETHERLANDS	2011	H-10-2105-2 238238	Y	Y
KIIIA1 6.1.3	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 THE NETHERLANDS	2011	H-10-2105-3 238240	Y	Y

Annex Point	Title	Year	Ref. App. Ref. JKI	Data protection granted y/n	Used for evaluation y/n
KIIIA1 6.1.3	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 THE NETHERLANDS	2011	H-10-2105-4 238242	Y	Y
KIIIA1 6.1.3	Efficacy of AGQMM1-565 SC (FSG 02122 H) and dicotyledonous weeds in fodder- and sugar beets (post emergence application)	2011	FCS-1331-E11 238244	Y	Y
KIIIA1 6.1.3	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND FIESTA NEW, 2011 - THE NETHERLANDS	2011	H-11-2101-1 238246	Y	Y
KIIIA1 6.1.3	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND FIESTA NEW, 2011 - THE NETHERLANDS	2011	H-11-2101-2 238250	Y	Y
KIIIA1 6.1.3	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND FIESTA NEW, 2011 - THE NETHERLANDS	2011	H-11-2101-3 238252	Y	Y
KIIIA1 6.2.1	GALAP und Dikotyle - Z.- Rüben 1.-3. NAK 2009	2009	FCS09-1211-E01 238254	Y	Y
KIIIA1 6.2.1	Unkrautbekämpfung in Zuckerrüben	2009	FCS09-1211-E02 238256	Y	Y
KIIIA1 6.2.1	Efficacy of FSG 02122 H against GALAP and dicotyledonous weeds in Fodder- and Sugarbeet	2009	FCS09-1211a-E02 238258	Y	Yy
KIIIA1 6.2.1	An evaluation of the efficacy of FSG 02122 H vs. cleavers and other dicotyledonous weeds in fodder or sugar beets following three sequential post emergence applications	2009	FCS09-1211-E04 238259	Y	Y
KIIIA1 6.2.1	Efficacy of FSG 02122 H against Galium aparine and dicotyle weeds in fodder and sugar beets; split application (3 times) post-emergence in spring	2009	FCS09-1211-E06 238260	Y	Y
KIIIA1 6.2.1	Unkrautbekämpfung in Zuckerrüben	2010	FCS10-1331-E02 238261	Y	Y

Annex Point	Title	Year	Ref. App. Ref. JKI	Data protection granted y/n	Used for evaluation y/n
KIIIA1 6.2.1	Efficacy of AG-QMM1-565 SC (FSG 02122 H) against GALAP and dicotyledonous weeds in fodder and sugarbeet (post emergence application)	2010	FCS10-1331-E04 238262	Y	Y
KIIIA1 6.2.1	Efficacy of AG-QMM1-565 SC (FSG 02122 H) against GALAP and dicotyledonous weeds in fodder- and sugar beets (post emergence application)	2010	FCS10-1331-E05 238263	Y	Y
KIIIA1 6.2.1	Efficacy of AG-QMM1-565 SC (FSG 02122 H) against Galium aparine and dicotyle weeds in Sugar Beets; split application post emergence	2010	FCS10-1331-E06 238264	Y	Y
KIIIA1 6.2.1	An evaluation of the efficacy of AG-QMM1-565 SC (FSG 02122 H) vs. GALAP and other dicotyledonous weeds following three sequential post emergence applications onto fodder or sugar beets	2010	FCS10-1331-E07 238265	Y	Y
KIIIA1 6.2.1	Evaluation of metamitron 525 + quinmerac 40 (FSG 02122 H / AG-QMM1-565 SC) on weeds in sugar beet	2010	R121-10H 238267	Y	Yy
KIIIA1 6.2.1	Evaluation of metamitron 525 + quinmerac 40 (FSG 02122 H / AG-QMM1-565 SC) on weeds in sugar beet	2010	R122-10H 238268	Y	Y
KIIIA1 6.2.1	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 - THE NETHERLANDS	2011	H-10-2105-1 238269	Y	Y
KIIIA1 6.2.1	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 THE NETHERLANDS	2011	H-10-2105-2 238270	Y	Y
KIIIA1 6.2.1	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 THE NETHERLANDS	2011	H-10-2105-3 238271	Y	Y
KIIIA1 6.2.1	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND GOLTIX OF, 2010 THE NETHERLANDS	2011	H-10-2105-4 238272	Y	Y
KIIIA1 6.2.1	Efficacy of AGQMM1-565 SC (FSG 02122 H) and dicotyledonous weeds in fodder- and sugar beets (post emergence application)	2011	FCS-1331-E11 238273	Y	Y

Annex Point	Title	Year	Ref. App. Ref. JKI	Data protection granted y/n	Used for evaluation y/n
KIIIA1 6.2.1	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND FIESTA NEW, 2011 - THE NETHERLANDS	2011	H-11-2101-1 238274	Y	Y
KIIIA1 6.2.1	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND FIESTA NEW, 2011 - THE NETHERLANDS	2011	H-11-2101-2 238275	Y	Y
KIIIA1 6.2.1	CROP SAFETY AND CONTROL OF BROAD-LEAVED WEEDS IN SUGAR BEET BY AG-QMM1-565 SC AND FIESTA NEW, 2011 - THE NETHERLANDS	2011	H-11-2101-3 238284	Y	Y
KIIIA1 6.2.1	Selectivity of FSG 02122 H on Fodder- and Sugarbeet at post-emergence application, split treatment	2010	FCS09-1212-S01 238285	Y	Y
KIIIA1 6.2.1	Selectivity of FSG 02122 H on Fodder- and Sugarbeet at post-emergence application, split treatment	2010	FCS09-1212-S02 238286	Y	Y
KIIIA1 6.2.1	Selectivity of FSG 02122 H in fodder and sugar beets after split post emergence application	2009	FCS09-1212-S03 238287	Y	Y
KIIIA1 6.2.1	Selectivity of FSG 02122 H in fodder and sugar beets after split post emergence application	2009	FCS09-1212-S04 238288	Y	Y
KIIIA1 6.2.1	An evaluation of the selectivity of FSG 02122 H to fodder or sugar beets following three sequential post emergence applications	2009	FCS09-1212-S05+FCS09-1212-S06 238289	Y	Y
KIIIA1 6.2.1	Selectivity of AG-QMM1-565 SC (FSG 02122 H) and Goltix Super in fodder- and sugar beets (post emergence application)	2010	FCS10-1332a-S01 238292	Y	Y
KIIIA1 6.2.1	Selectivity of AG-QMM1-565 SC(FSG 02122 H) and Goltix Super in fodder- and sugar beets (post emergence application)	2010	FCS10-1332a-S02 238293	Y	Y
KIIIA1 6.2.1	An evaluation of the selectivity of AG-QMM1-565 SC (FSG 02122 H) and Goltix Super to fodder or sugar beets following three sequential post emergence applications	2010	FCS10-1332a-S03 238294	Y	Y

Annex Point	Title	Year	Ref. App. Ref. JKI	Data protection granted y/n	Used for evaluation y/n
KIIIA1 6.2.1	Selectivity of AG-QMM1-565 SC (FSG 02122 H) and Goltix Super in fodder- and sugar beet	2010	FCS10-1332a-S04 238295	Y	Y
KIIIA1 6.2.1	Selectivity of AG-QMM1-565 SC (FSG 02122 H) in fodder- and sugar beets (post emergence)	2010	FCS10-1332b-S01 238296	Y	Y
KIIIA1 6.1.1	AG-QMM1-565 SC (40 g/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	2010	238297	Y	Y
KIIIA1 6.2.6	AG-QMM1-565 SC (40 g/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	2010	238298	Y	Y
KIIIA1 6.2.7	Effect of AG-QMM1-565 SC (40 g/L quinmerac + 525 g/L metamitron)on the seedling emergence of terrestrial plants	2010	AS150 238299	Y	Y
KIIIA1 6.2.7	Effect of AG-QMM1-565 SC (40 g/L quinmerac + 525 g/L metamitron) on vegetative vigour of terrestrial plants	2010	AS151 238300	Y	Y
KIIIA1 6.2.8	Implementation of resistance risk analysis of plant protection products in the German authorisation procedure	2000	238301	Y	Y
KIIIA1 6.2.8	Ein neuer Gänsefuß-Biotyp mit Resistenz gegenüber Metribuzin und Metamitron	2010	238302	Y	Y
KIIIA1 6.2.8	Sensitivität verschiedener Herkünfte von Matricaria inodora und Matricaria chamomilla gegenüber Metamitron	2003	238303	Y	Yy
KIIIA1 6.2.8	Triazine resistance in Amaranthus tuberculatus (Moq) Sauer that is not site-of-action mediated	2003	238304	Y	Yy
KIIIA1 6.2.8	Cross-resistance profile of metamitron-resistant Chenopodium album L. biotypes from sugar beet	2006	238305	Y	Yy
KIIIA1 6.2.8	SENISTIVITÄTSANALYSE VERSCHIEDENER CHENOPODIUM ALBUM HERKÜNFTE GEGEN METAMITRON (GOLTIX GOLD)	2010	238306	Y	y

Annex point/ reference No	Year	Title Report-No. Authority registration No	Data protection claimed y/n	Data protection granted y/n	Studies relied on	Owner
OECD: KIIIA1 7.1.1	2010	Acute oral toxicity study of 40 g/l Quinmerac + 525 g/l Metamitron (AG-QMM1-565 SC) in rats 25392 BVL-2203484, ASB2011-14383	Yes	Yes	Yes	QPP
OECD: KIIIA1 7.1.2	2010	Acute dermal toxicity study of 40 g/l Quinmerac + 525 g/l Metamitron (AG-QMM1-565 SC) in CD rats 25393 BVL-2203490, ASB2011-14384	Yes	Yes	Yes	QPP
OECD: KIIIA1 7.1.3	2010	Acute inhalation toxicity study of 40 g/l Quinmerac + 525 g/l Metamitron (AG-QMM1-565 SC) in rats 25394 BVL-2203515, ASB2011-14385	Yes	Yes	Yes	QPP
OECD: KIIIA1 7.1.4	2010	Acute dermal irritation/corrosion test (patch test) of 40 g/l Quinmerac + 525 g/l Metamitron (AG-QMM1-565 SC) in rabbits 25395 BVL-2203518, ASB2011-14386	Yes	Yes	Yes	QPP
OECD: KIIIA1 7.1.5	2010	Acute eye irritation/corrosion test of 40 g/l Quinmerac + 525 g/l Metamitron (AG-QMM1-565 SC) in rabbits 25396 BVL-2203519, ASB2011-14387	Yes	Yes	Yes	QPP
OECD: KIIIA1 7.1.6	2010	Examination of 40 g/l Quinmerac + 525 g/l Metamitron (AG-QMM1-565 SC) in the skin sensitisation test in guinea pigs according to Magnusson and Kligman (maximisation test) 25397 BVL-2203578, ASB2011-14388	Yes	Yes	Yes	QPP

Annex point/ reference No	**Year**	**Title Report-No. Authority registration No**	**Data protection claimed y/n**	**Data protection granted y/n**	**Studies relied on**	**Owner**
OECD: KIIIA 1 7.6.2	2010	The in vitro percutaneous absorption of radiolabelled Quinmerac in the concentrate and a single in-use spray dilution through rat and human skin Dok-Nr. 788025, BVL-2203676, ASB2011-9378	Yes	Yes	Yes	AGA

Table A 1: List of data submitted in support of the evaluation

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
OECD: KIIA 6.1.1	2011	Determination of the storage stability of Quinmerac and metabolites in plant matrices IF-09/01173993 ASB2011-9249	yes	Y	y	FSC
OECD: KIIA 6.3	1995	Final report about testing the residual behaviour of AGH 211 (MAC 93 001 H) in sugar beet under field conditions /RP-H 94/MAC 93 001 H ASB2011-14415	yes	Y	y	FSC
OECD: KIIA 6.3	1996	Determination of the residues of metamitron and desamino-metamitron in sugar beets HVA 8/95 ASB2008-4378	yes	Y	y	FSC
OECD: KIIA 6.3	1996	Determination of the residues of Metamitron and Desomino-metamitron in sugar beets (4 trials in 1994) GER 94400/1 ASB2011-14416	yes	Y	y	FSC
OECD: KIIA 6.3	2011	Study on the magnitude of residue of Metamitron and its metabolite and Quimmerac and its metabolites in sugar beets after one application of Goltix WG 70 formulation or three applications of Quinmerac and Metamitron in Northern Europe 2010 IF-10/1539609 ASB2011-14418	yes	Y	y	FSC

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
OECD: KIIA 6.5.1	2010	Hydrolysis of Quinmerac at elevated temperatures – Simulated Processing FEI-025/7-32 ASB2011-9238	yes	Y	y	FSC
OECD: KIIA 6.6	2010	Confined rotational crops study with Quinmerac 30 days after treatment (DAT30) (incl. amendment no. 1 dated 20.05.2011) FEI-025/7-96A ASB2011-9239	yes	y	y	FSC
OECD: KIIA 6.6	2011	Confined rotational crops study with Quinmerac 120 and 365 days after treatment (DAT30) (incl. amendment no. 1 dated 03.05.2011) FEI-025/7-96B ASB2011-9240	yes	Y	Y	FSC
OECD: KIIA 6.6	2010	Study on the residue behaviour of Quinmerac and Metazachlor and their metabolites in the rotational crops: Winter cereal, carrots and spinach/lettuce after application of AG-QM2-500 SC-formulation (125 g/L Quinmerac + 375 g/L Metazachlor) to the soil 30 days before seeding/planting under field conditions in Germany, United Kingdom, Southern France and Spain, 2008/2010 IF-08/01172147 ASB2011-9246	yes	Y	Y	FSC
OECD: KIIA 6.6	2010	Study on the residue behaviour of Quinmerac and Metazachlor and their metabolites in the rotational crops: Spring cereal, carrots and spinach/lettuce after application of AG-QM2-500 SC-formulation (125 g/L Quinmerac + 375 g/L Metazachlor) to the soil 120/150 days before seeding/planting under field conditions in Germany,	yes	y	Y	FSC

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
		United Kingdom, Southern France and Spain, 2008 IF-08/01172345 ASB2011-9247				
OECD: KIIA 6.6	2010	Study on the residue behaviour of Quinmerac and Metazachlor and their metabolites in the rotational crops: Winter cereal after application of AG-QM2-500 SC-formulation (125 g/L Quinmerac + 375 g/L Metazachlor) to the soil 365 days before seeding under field conditions in Germany, Spain, Southern France and United Kingdom, 2008-2010 IF-08/01176226 ASB2011-9248	yes	y	Y	FSC

* 1 accepted (study valid and considered for evaluation)
2 not accepted (study not valid and not considered for evaluation)
3 not considered (study not relevant for evaluation)
4 not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5 supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Ecotoxicological studies: List of data submitted in support of the evaluation

OECD Annex point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protec-tion claimed yes/no	Data protect ion grante d Y/N	Studie s relied on	Owner
KIIIA 10.2.2.1/01	2010	Acute toxicity Testing of FSG 02122 H (40g/L Quinmerac + 525 g/L Metamitron) in Rainbow Trout (Oncorhynchus mykiss)(Teleostei, Salmonidae) eurofins-GAB GmbH, Niefern-Öschelbronn, Germany Quena Plant Protection N.V. Report-no. S10-00592 GLP: yes Published: no	yes	Y	Y	QPP

OECD Annex point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protec-tion claimed yes/no	Data protect ion grante d Y/N	Studie s relied on	Owner
KIIIA 10.2.2.2/01	2010a	Assessment of toxic Effects of FSG 02122 H (40g/L Quinmerac + 525 g/L Metamitron) on Daphnia magna using the 48 h Acute Immobilisation Test eurofins-GAB GmbH, Niefern-Öschelbronn, Germany Quena Plant Protection N.V. Report-no. S10-00593 GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 10.2.2.3/01	2010	Testing of Effects of FSG 02122 H (40g/L Quinmerac + 525 g/L Metamitron) on the Single Cell Green Alga Pseudokirchneriella subcapitata in a Static 3 Days Test eurofins-GAB GmbH, Niefern-Öschelbronn, Germany Quena Plant Protection N.V. Report-no. S10-00594 GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 10.4.2.1/01	2010	Acute Toxicity of FSG 02122 H (40 g/L Quinmerac + 525 g/L Metamitron) to the Honeybee Apis Mellifera L. under Laboratory Conditions BioChem Agrar, Gerichshain, Germany Quena Plant Protection N.V. Report-no. 10 10 48 006 B GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 10.5.2/01	2010	A rate-response extended laboratory test to determine the effects of FSG 02122 H (40g/L Quinmerac + 525 g/L Metamitron on the parasitic wasp, Aphidius rhopalosiphi (Hymenoptera, Braconidae) Mambo-Tox Ltd., Southampton, UK Quena Plant Protection N.V. Report-no. No. FSG-10-1 GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 10.5.2/02	2010	A rate-response extended laboratory test to determine the effects of FSG 02122 H (40g/L Quinmerac + 525 g/L Metamitron) on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) Mambo-Tox Ltd., Southampton, UK Quena Plant Protection N.V. Report-no. FSG-10-2 GLP: yes Published: no	yes	Y	Y	QPP

OECD Annex point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protec-tion claimed yes/no	Data protect ion grante d Y/N	Studie s relied on	Owner
KIIIA 10.6.2/01	2010a	Earthworm (Eisenia fedita), Acute Toxicity Test in Artificial Soil Dr. U. NOACK Lab. für angew. Biologie, Sarstedt, Germany Quena Plant Protection N.V. Report-no. No. 100202FW, RRA 13609 GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 10.6.3/01	2010b	Earthworm (Eisenia fetida), Effects on Reproduction Dr. U. NOACK Lab. für angew. Biologie, Sarstedt, Germany Quena Plant Protection N.V. Report-no. No. 100202FW, RBN13609 GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 10.7.1/01	2010	FSG 02122 H (40 g/L Quinmerac + 525 mg/L Metamitron) - Effects on the activity of soil microflora (Nitrogen and carbon transformation tests) BioChem Agrar, Gerichshain, Germany Quena Plant Protection N.V. Report-no. 10 10 48 022 C/N GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 10.8.1.2/01	2010a	Effect of AG-QMM 1-565 SC (40 g/L Quinmerac + 525 g/L Metamitron) on vegetative vigour of terrestrial plants RLP AgroScience GmbH Quena Plant Protection N.V. Report-no. AS151 GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 10.8.1.3/01	2010b	Effect of AG-QMM1-565 SC (40 g/L quinmarac + 525 g/L Metamitron) on the seedling emergence of terrestrial plants RLP AgroScience GmbH Quena Plant Protection N.V. Report-no. AS150 GLP: yes Published: no	yes	Y	Y	QPP

OECD Annex point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protec-tion claimed yes/no	Data protect ion grante d Y/N	Studie s relied on	Owner
KIIIA 10.8.2.1/01	2010b	FSG 02122 H - Assessment oN Toxic Effects on the Duckweed Lemna gibba in a Semi-Static Test eurofins-GAB GmbH, Niefern-Öschelbronn, Germany Quena Plant Protection N.V. Report-no. S10-00595 GLP: yes Published: no	yes	Y	Y	QPP
KIIIA 10.10.1/01	2010	Study on Reproduction in Birds(Japanese Quail) with Quinmerac Technical by oral Administration via the Diet LPT Lab. of Pharm. and Tox. GmbH & Co. KG, Hamburg, Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 25301 GLP/GEP: no Published: no	yes	Y	Y	AGA
KIIIA 10.10.1/02	2010a	Acute Toxicity of BH518-5 to Rainbow Trout (Oncorhynchus mykiss) in a 96-hour Static Test Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49704230 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 10.10.1/03	2009a	Acute Toxicity of Quinmerac Technical to Daphnia magna in a Static 48-hour Immobilisation Limit-Test Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49684220, 90010999 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 10.10.1/04	2010b	Influence of Quinmerac Technical to Daphnia magna in a Semi-Static Reproduction Test Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49686221, 90012516 GLP: yes Published: no	yes	Y	Y	AGA

OECD Annex point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protec-tion claimed yes/no	Data protect ion grante d Y/N	Studie s relied on	Owner
KIIIA 10.10.1/05	2010a	Toxicity of Quinmerac Technical to Anabaena flos-aquae in an Algal Growth Inhibition Test Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49682210 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 10.10.1/06	2009b	Toxicity of Quinmerac Technical to the Aquatic Plant Lemna gibba in a Staic Growth Inhibition Test Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49685240, 90011000 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 10.10.1/07	2010b	Toxicity of BH518-2 to the Aquatic Plant Lemna gibba in a Static Growth Inhibition Test Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49691240 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 10.10.1/08	2010c	Toxicity of BH518-5 to the Aquatic Plant Lemna gibba in a Static Growth Inhibition Test Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49702240 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 10.10.1/09	2009	Effects of Quinmerac Technical (Acute Contact and Oral) on Holney Bees (Apis mellifera L.) in the Laboratory AGAN Chemical Manufacturers Ltd. Israel Report-no. 49688035, 90010996 GLP: yes Published: no	yes	Y	Y	AGA

OECD Annex point/ reference number	Year	Title Testing Facility Owner / Source (where different from owner) Report No GLP or GEP status (where relevant) Published or not	Data protec-tion claimed yes/no	Data protect ion grante d Y/N	Studie s relied on	Owner
KIIIA 10.10.1/10	2009	Acute Toxicity (14 Days) of Quinmerac Technical to the Earthworm Eisenia fetida in Artificial Soil Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49689021, 90010995 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 10.10.1/11	2010a	Effects of BH518-5 on Reproduction and Growth of Earthworms Eisenia Fetida in Artificial Soil with 5% Peat Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49703022 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 10.10.1/12	2010b	Effects of BH518-5 on Reproduction of the Collembola Folsomia candida in Artificial Soil with 5% Peat Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49705016 GLP: yes Published: no	yes	Y	Y	AGA
KIIIA 10.10.1/13	2009	Toxicity of Quinmerac Technical to Activated Sludge in a Respiration Inhibition Test Institut für Biologische Analytik, Rossdorf Germany AGAN Chemical Manufacturers Ltd. Israel Report-no. 49680171, 90012513 GLP: yes Published: no	yes	Y	Y	AGA