HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. BESLUIT

Op 16 juli 2015 is van

Bayer CropScience SA-N.V.
Energieweg 1
3641 RT MIJDRECHT

een aanvraag tot wederzijdse erkenning van een gewasbeschermingsmiddel ontvangen voor het middel

Betanal Elite

op basis van de werkzame stoffen desmedifam, ethofumesaat en fenmedifam.

HET COLLEGE BESLUIT tot toelating van bovenstaand middel.

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

1.1 Samenstelling, vorm en verpakking

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

1.2 Gebruik

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

1.3 Classificatie en etikettering

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

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.

- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in paragraaf 2.2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Niet van toepassing. Het betreft een nieuwe toelating.

2. WETTELIJKE GRONDSLAG

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

3. BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

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

3.2 Analysemethoden

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

3.3 Risico voor de mens

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

3.4 Risico voor het milieu

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

3.5 Werkzaamheid

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

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

Bezwaarmogelijkheid

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 8030, 6710 AA, EDE. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Ede, 1 april 2016

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

Aanvraagnummer:	20151306 NLWERGZ
Type aanvraag:	aanvraag tot toelating van een gewasbeschermingsmiddel op basis van wederzijdse erkenning
Middelnaam:	Betanal Elite
Verzenddatum aanvraag:	14 juli 2015
*Formele registratiedatum: **	10 augustus 2015
Datum in behandeling name:	28 oktober 2015
Datum compliance check:	n.v.t.

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

2.2 Stofinformatie

Werkzame stof	Gehalte
desmedifam	71 g/L
ethofumesaat	112 g/L
fenmedifam	91 g/L

- De stof desmedifam is per 1 maart 2005 geplaatst op Annex I van Richtlijn 91/414/EEG (2004/58/EG d.d. 23 april 2004) en vervolgens bij Uitvoeringsverordening (EG) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 juli 2017 (de expiratiedatum is verlengd middels Uitvoeringsverordening (EG) 1197/2012/EG d.d. 13 december 2012).

- De stof ethofumesaat is per 1 maart 2003 geplaatst op Annex I van Richtlijn 91/414/EEG (2002/37/EG d.d. 3 mei 2002) en vervolgens bij Uitvoeringsverordening (EG) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 juli 2016 (de expiratiedatum is verlengd middels Uitvoeringsverordening (EG) 823/2012/EG d.d. 14 september 2012).

- De stof fenmedifam is per 1 maart 2005 geplaatst op Annex I van Richtlijn 91/414/EEG (2004/58/EG d.d. 23 april 2004) en vervolgens bij Uitvoeringsverordening (EG) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 juli 2017 (de expiratiedatum is verlengd middels Uitvoeringsverordening (EG) 1197/2012/EG d.d. 13 december 2012).

2.3 Toelatingsinformatie

Toelatingsnummer:	15080 N
Expiratiedatum:	31 juli 2017
Afgeleide parallel of origineel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

2.4 Verpakkingsinformatie

Aard van het preparaat:
Emulgeerbaar Concentraat

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel Betanal Elite

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

Pictogram	GHS09
Signaalwoord	WAARSCHUWING
Gevarenaanduidingen	H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P280A Beschermende handschoenen dragen. P501 Inhoud/verpakking afvoeren naar .... SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

REGISTRATION REPORT
Part A

Risk Management

Trade name: Betanal Elite

Product code: 102000000606

Active Substance: Desmedipham + Ethofumesate + Phenmedipham EC 274 (71+112+91) G

Country: The Netherlands

Central Zone

Zonal Rapporteur Member State: Czech Republic

NATIONAL ASSESSMENT

Applicant: Bayer CropScience

Date: March 2016

OECD Statement on Confidentiality

The summaries and evaluations contained in this monograph or review report may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this Monograph or review report unless they have received the data on which the summaries and evaluation are based, either:

- From the owner of the data; or
- From a second party that has obtained permission from the owner of the data for this purpose or, alternatively, the applicant has received permission from the data owner that the summaries and evaluation contained in this Monograph or review report may be used in lieu of the data; or
- Following expiry of any period of exclusive use, by offering – in certain jurisdictions – mandatory compensation;

unless the period of protection of the proprietary data concerned has expired.

Applicants wishing to avail of information in this Monograph or review report should seek advice from the regulatory authority to which application is made concerning the requirements in their country.

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PART A – Risk Management

The authorisation of Betanal Elite is based on mutual recognition of the authorisation of the product BETANAL EXPERT in the Czech Republic (authorisation number: 4155-4).

This document describes the acceptable use conditions required for the registration of DMP+ETO+PMP EC 274 (71+112+91 g/L) G (also referred to as Betanal Elite), specification number 102000000606, which contains the active substances desmedipham, ethofumesate and phenmedipham, in the Netherlands.

In the scope of 'mutual recognition', reference is made for substance and formulation related studies as well as for non-country specific assessments to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

This document describes the specific conditions of use and labelling required for the Netherlands for the registration of DMP+ETO+PMP EC 274 (71+112+91 g/L) G.

Appendix 1 of this document is a copy of the proposed product label for the Netherlands.

Appendix 2 of this document contains copies of letters of access to protected data / third party data if required for the evaluation of the formulation.

Appendix 3 contains the reference list.

Details of the application

1.1 Application background

This application was submitted by Bayer CropScience SA-NV. in July 2015.

The application is for approval of DMP+ETO+PMP EC 274, an emulsifiable concentrate formulation containing desmedipham, 71 g/l, ethofumesate, 112 g/l and phenmedipham 91 g/l for the use as post-emergence herbicide in sugar beet and fodder beet.

1.2 Annex I inclusion

Desmedipham
Desmedipham was included into Annex I of Directive 91/414 in 2004 (Directive 2004/58/EC, dated 23rd of April 2004, Entry into Force 1st of March 2005).

For the implementation of the Uniform Principles of Annex VI, the conclusions of the Review Report on desmedipham and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on the 13th of February 2004 shall be taken into account.

In the Annex I Inclusion directive for desmedipham, there are specific provisions under Part B which need to be considered related to the ecotoxicological studies.
In this overall assessment Member States should pay particular attention to

- the protection of aquatic organisms and earthworms.

Risk mitigation measures should be applied if appropriate.
These concerns have been addressed within the current submission.

The Review Report (SANCO/4061/2001-final) for desmedipham is considered to provide the relevant scientific information for the review of the product.

Annex I renewal submission of desmedipham was performed in January 2015 to the rapporteur member state Finland. As the data submitted with the Annex I renewal dossier are not evaluated on an EU-Level this new information is in general not considered within this dossier. No studies resulted in lower endpoints and hence no change of the risk assessment needed to be considered for this dossier.

Ethofumesate
Ethofumesate was included into Annex I of Directive 91/414 in 2002 (Directive 2002/37/EC, dated 3rd of May 2002, Entry into Force 1st of March 2003).

For the implementation of the Uniform Principles of Annex VI, the conclusions of the Review Report on ethofumesate and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on the 26th of February 2002 shall be taken into account.

In the Annex I Inclusion directive for ethofumesate, there are no specific provisions under Part B which need to be considered related to the ecotoxicological studies.
In this overall statement Member States may pay particular attention to

- the protection of the groundwater, when the active substance is applied in regions with vulnerable soil and/or climatic conditions and must apply risk mitigation measures, where appropriate.

These concerns have been addressed within the current submission.

The Review Report (SANCO/6503/VI/99-final) for ethofumesate is considered to provide the relevant scientific information for the review of the product.

Annex I renewal submission of ethofumesate was performed in January 2014 to the rapporteur member state Austria. As the data submitted with the Annex I renewal dossier are not evaluated on an EU-Level this new information are in general not considered within this dossier. Only studies which resulted in lower endpoint and hence resulted in a change of the risk assessment were considered for this dossier. This was the case for the Fish Full Life Cycle test as well as for a test performed on a second aquatic macrophyte species (*Myriophyllum*).

Phenmedipham
Phenmedipham was included into Annex I of Directive 91/414 in 2004 (Directive 2004/58/EC, dated 23rd of April 2004, Entry into Force 1st of March 2005).

For the implementation of the Uniform Principles of Annex VI, the conclusions of the Review Report on phenmedipham and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on the 13th of February 2004 shall be taken into account.

In the Annex I Inclusion directive for phenmedipham, there are specific provisions under Part B which need to be considered related to the ecotoxicological studies.
In this overall assessment Member states should pay particular attention to

- the protection of aquatic organisms

Conditions of authorization should include risk mitigation measures, where appropriate
These concerns have been addressed within the current submission.

The Review Report (SANCO/4060/2001-final) for phenmedipham is considered to provide the relevant scientific information for the review of the product.

Annex I renewal submission of phenmedipham was performed in January 2015 to the rapporteur member state Finland. As the data submitted with the Annex I renewal dossier are not evaluated on an EU-Level this new information is in general not considered within this dossier. No studies resulted in lower endpoints and hence no change of the risk assessment needed to be considered for this dossier.

1.3 Regulatory approach

To obtain approval, the product DMP+ETO+PMP EC 274 (71+112+91 g/L) G 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.
In the scope of 'mutual recognition', reference is made for substance and formulation related studies as well as for non-country specific assessments to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

The formulation details provided in the Czech Republic draft Registration Report and approved within the reregistration of Betanal EXPERT by the Czech Authorities in 2010 (specification number: 102000000606-03) do not reflect the currently approved Czech Republic formulation details. A minor formulation change was notified to the Czech Republic Authorities in May 2013, however, a registration report or authorisation documents detailing this change are not available (the Czech Republic Authority does not issue amended documentation for notifications of minor formulation change).

The proposed formulation for DMP+ETO+PMP EC 274 for the Netherlands is identical to that notified to the Czech Republic in May 2013 (spec.nr. 102000000606-04) which includes the May 2013 application proposed minor formulation change to introduce a frame to the ethoxylated castor oil formulation component. No change to the amount of this ingredient was proposed.

1.4 Data protection claims

The reference list included in the dossier defines the list of studies and reports, submitted with the application, for which a claim for data protection was made. This claim for protection was made as the studies and reports were submitted and used as the basis for approval for the first time in the Netherlands. Based on Article 59 of Regulation 1107/2009 Bayer S.A.S. (Bayer CropScience) claims 10 years protection for these studies and reports.

1.5 Letters of Access

Bayer CropScience is the owner of most of the studies. For these studies no Letter of Access is required.

However, a general Letter of Access has been submitted to Ctgb in which it is stated that all studies and reports belonging to Bayer CropScience AG and/or any other Bayer affiliate can be used by any interested affiliate within the Bayer Group, including but not limited to, Bayer CropScience SA-NV.

In addition, a Letter of Access from UPL is submitted for a report referred to in Section 6.

2 Details of the authorisation

2.1 Product identity

Product Name	Betanal Elite DMP + ETO + PMP EC 274 *Specification number: 102000000606-04*
Authorisation Number (for re-registration)	Not applicable, first submission
Function	Herbicide

Applicant	Bayer CropScience SA-NV
Composition	71.0 g/L desmedipham 91.0 g/L phenmedipham, 112 g/L ethofumesate,
Formulation type	EC
Packaging	Type: jerry can Material: HDPE/PA Capacity: 5 litres Type: jerry can Material: HDPE/PA Capacity: 10 litres Type: jerry can Material: HDPE/PA Capacity: 15 litres Type: barrel Material: COEX Capacity: 200 litres

2.2 Classification and labelling

2.2.1 Classification and labelling according to Regulation (EC) No 1272/2008

Based on the profile of the substances, 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:	H410	Very toxic to aquatic life with long lasting effects.	
P-statements:	P280a	Wear protective gloves.	
	P501	Dispose of contents/container to	
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.	
	SP1	Do not contaminate water with the product or its container.	
Child-resistant fastening obligatory?			not applicable
Tactile warning of danger obligatory?			not applicable

Explanation:	
Pictogram:	-
H-statements:	-
P-statements:	P280a is assigned based on the operator risk assessment. P501 was proposed by the applicant and is accepted.
Other:	-

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

2.3 Product uses

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(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		
1	Netherlands	Sugar beet	F	Annual grasses and annual broadleaved weeds	Spraying/ Broadcast, overall	BBCH 10-18 April-June	a) 4 (6) b) as in a	a) 1.5 L/ha b) 4.5 L/ha	a) 106.5 g/ha (1) 168 g/ha (2) 136.5 g/ha (3) b) 319.5 g/ha (1) 504 g/ha (2) 409.5 g/ha (3)	200	-	Dose rate: 1-1.5 L/ha (max. 4.5 L/ha/ season), Low dosage system Number of applications: 1-4
2	Netherlands	Fodder beet	F	Annual grasses and annual broadleaved weeds	Spraying/ Broadcast, overall	BBCH 12-18 April-June	a) 4 (6) b) as in a	a) 1.5 L/ha b) 4.5 L/ha	a) 106.5 g/ha (1) 168 g/ha (2) 136.5 g/ha (3) b) 319.5 g/ha (1) 504 g/ha (2) 409.5 g/ha (3)	200	-	Dose rate: 1-1.5 L/ha (max. 4.5 L/ha/ season, Low dosage system) Number of applications: 1-4

Note: (1) desmedipham, (2) ethofumesate, (3) phenmedipham

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)

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).
The minor formulation change (compared to that presented in the Czech Republic RR) is an extension of the ethoxylated castor oil frame. Formulation details of this minor formulation change are submitted in the Netherlands, along with up to date MSDS.

Implications for labelling: None.

Nature and characteristics of the protective clothing and equipment: Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

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)

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

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

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

The analytical methods for residues in water were evaluated and considered acceptable in the EU review of the active substances and meet the Dutch specific required (LOQ $\leq$0.1µg/L).

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

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

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

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

Operator exposure to DMP+ETO+PMP EC 274 was not evaluated as part of the EU review of ethofumesate, phenmedipham or desmedipham for this proposed used pattern. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.

Operator exposure to DMP+ETO+PMP EC 274 is estimated using the EUROPOEM I (national requirement for The Netherlands).

The following dermal absorption values for ethofumesate, phenmedipham and desmedipham are used in the present risk assessment.

Ethofumesate: 25% for the concentrate and 75% for the spray dilution
Phenmedipham: 25% for the concentrate and 75% for the spray dilution
Desmedipham: 1% for the concentrate and spray dilution

Ethofumesate: AOEL = 2.5 mg/kg bw/day
Phenmedipham: AOEL = 0.13 mg/kg bw/day
Desmedipham: AOEL = 0.04 mg/kg bw/day

Exposure of unprotected operators is below the ethofumesate and desmedipham AOEL, but slightly above the phenmedipham AOEL (101%). Exposure of operators wearing protective gloves during mixing/loading (in addition to work wear) is below all the substance specific AOELs.

In the Netherlands, applications for products based on more than one active substance must include an evaluation of the potential combined toxicity[1]. The sum of the fractions (percentages) of the estimated systemic exposures for the three active substances is well below 100% (38%) when using PPE.

According to the model calculations, it can be concluded that the risk for the operator using DMP+ETO+PMP EC 274 on sugar- and fodder beets is acceptable if adequate work clothing is worn and, in addition, protective gloves during mixing/loading and when handling contaminated surfaces are used.

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

Bystander and resident exposure has been calculated according to EUROPOEM II, the German model and the UK method.
It is concluded that there is no undue risk to any bystander and residents after accidental short-term exposure to DMP+ETO+PMP EC 274. This has no labelling implications. An evaluation of the potential combined toxicity was carried and the sum of the fractions (percentages) of the estimated systemic exposures for the three active substances is well below 100% (4%).

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

According to the application parameters of DMP+ETO+PMP EC 274 the intended use is spray application in sugar beet and fodder beet during the growth stage BBCH 10-18. At this growth stage only few leaves of the plants are unfolded and re-entry activities are not necessary immediately after application of the product. However, in the present risk assessment scouting activities of beet crops after the intended use is estimated using the EUROPOEM II approach.

Exposure of operators entering treated crops for scouting/inspection activities is within acceptable levels. Calculations reflect standard work clothing worn by adult workers (shoes, socks, long-legged pants, and long sleeves) working with bare hands. No personal protective equipment is considered to mitigate the exposure.

Potential combined toxicity is assessed considering the tier one approach, i.e. no unacceptable risk is to be expected if the sum of AOEL exhaustions (% of AOEL) is <100%. For the unprotected worker exposure the value is well below 100% (19%).

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

For the aspect ‘Residues’ and risk for consumers we refer to the member state of the original authorisation (Czech Republic). The Guidelines for the generation of data concerning residue data Appendix C 7524/VI/95 rev.2 require that the residue situation in rotational crops must always be

[1] Evaluation Manual for the Authorisation of Plant protection products and Biocides; NL part; Plant protection products; Chapter 4; Human toxicology; risk operator, worker and bystander; version 2.0; January 2014.

considered if, after the treated crop has been harvested (or in the event of early ploughing), it is possible to sow or plant a crop which can be used as a foodstuff and/or feed. Since the product was assessed according to the Uniform Principles by the member state of the original authorisation, residues in succeeding crops need no further consideration.

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

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

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

The European standard calculation for the scenario 'Kremsmünster' (relevant for the Netherlands), according to FOCUS PEARL 4.4.4. has been provided in the national addendum, complying with the request of the Ctgb.

No Tier 2 (GeoPEARL simulation) calculations were triggered or presented for refinement purposes.

In national evaluation for the Netherlands, an extra safety factor of 10 to the European trigger value of 0.1 µg/L is applied for assessment of possible product use in groundwater protection zones.

There are no concerns for groundwater from the use of DMP+ETO+PMP EC 274 on sugar / fodder beets in accordance with the use pattern for the current formulation. The model(s) predicts that the active ingredients and metabolites (where appropriate) will not be found in ground water at concentrations greater than 0.1µg/L (EU trigger) nor 0.01 µg/L (trigger for use in groundwater protected areas in the Netherlands). Based on the assessment, the use of DMP+ETO+PMP EC 274 is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern and the product can be used also in groundwater protected areas.

Monitoring data: No data are currently available regarding the presence of the active substances desmedipham and phenmedipham in groundwater.
For ethofumesate monitoring data from 2006 indicate a certain occurrence of ethofumesate in ground water. However, as stated by Ctgb in a recent evaluation, no check was performed on the presented measurements as is required for use of data in registration assessment and for this reason the presented values cannot be used in registration procedures.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4) for general information.

Calculations of predicted environmental concentrations in surface water (PEC_{sw}) were performed according to specific national data requirements for the Netherlands.

The PEC of desmedipham, ethofumesate and phenmedipham in surface water (PEC_{sw} and PEC_{sed}) has been assessed with the TOXSWA simulation drift model for the Dutch standard scenario (spring and autumn, even when the use is only in spring) and the DT_{50} water/sediment values established in the EU review or agreed in the assessment based on new data provided. The drift rate used in this assessment was based on the starting point value of 1% for field crops, which includes a 50 % drift-mitigation nozzle plus end nozzle in the last 14 m of the field. For the purpose of refined risk assessments, PEC values are also derived for the situation of 75 % drift reducing nozzles (relative drift factor = 0.5 %) and for the situation of 90 % drift reducing nozzles (relative drift factor = 0.2 %)

Based on the recommended use rate of 3 applications x a maximum dose rate of 106.5 g desmedipham/ha, 168 g ethofumesate/ha and 136.5 g phenmedipham/ha, the maximum PEC values for surface water and sediment have been calculated according to TOXSWA for the active substances and its metabolites.

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

Monitoring data:
The active substances desmedipham, ethofumesate and phenmedipham were observed in surface water (most recent data from 2014). As there are no exceeding of the thresholds, the monitoring data has no consequence for the proposed uses of the product.

Regarding drinking water, the active substances desmedipham and phenmedipham have not been identified as substances of concern by VEWIN. No exceeding of the drinking water criterion is expected. The standards for surface water destined for the production of drinking water are met.

Active substance ethofumesate is included in the list of substances of concern due to its presence in surface water at drinking water abstraction points as established by VEWIN/Ctgb. Therefore, an adequate risk assessment was needed based on the highest tier data. The relevant monitoring data (data set VEWIN, 2009-2013) indicate that the application of the product is not expected to exceed the drinking water criterion (0.1 µg/L). The standards for surface water destined for the production of drinking water as laid down in the RGB are met.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation nr: 4155-4), for general information.

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

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

Birds
Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4), for general information.

The acute and chronic risk assessments in the core dossier were conducted according to the SANCO/4145/2000 guidance document. For the present assessment, Tier 1 acute and chronic risk assessments are conducted following the EFSA GD (2009).

The combined toxicity via dietary intake has been assessed taking into account the acute and chronic exposure of birds. A low risk was concluded.

The risk of secondary poisoning for birds was assessed for the active substances phenmedipham and desmedipham as the log P_{OW} > 3.0. The combined toxicity assessment is also presented.

In addition the risk assessment for birds drinking contaminated water was also assessed, according to the new guidance EFSA GD (2009).

It can be concluded that the risk of use of the product according to the proposed use pattern is acceptable.

Terrestrial vertebrates (other than birds)
Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation nr: 4155-4), for general information.

The acute and chronic risk assessments in the core dossier were conducted according to the SANCO/4145/2000 guidance document. For the present assessment, Tier 1 acute and chronic risk assessments are conducted following the EFSA GD (2009). A reproductive risk was identified for the generic focal species large herbivorous mammal "lagomorph" and the small omnivorous mammal "mouse" from exposure to desmedipham. The risk was concluded low after a refinement of a DT_{50} was applied.

The combined toxicity via dietary intake has been assessed taking into account the acute and chronic exposure of mammals. A low risk was concluded.

The risk of secondary poisoning for mammals was assessed for the active substances phenmedipham and desmedipham as the log P_{OW} > 3.0. The combined toxicity assessment is also presented.

In addition the risk assessment for mammals drinking contaminated water was also assessed, according to the new guidance EFSA document (2009).

It can be concluded that the risk of use of the product according to the proposed use pattern is acceptable.

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

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation nr: 4155-4), for general information.

Effects on aquatic organisms for DMP+ETO+PMP EC 274 were not evaluated as part of the EU review of desmedipham, ethofumesate and phenmedipham. Risk assessments for DMP+ETO+PMP EC 274 with the proposed use pattern are provided here and are considered adequate. Risk from the formulated product was addressed in the present assessment.

All calculated TER values pass the relevant trigger values. However, for the combined chronic toxicity risk to *Daphnia* and green algae, a refinement was necessary. According to the refined calculations, the chronic risk to *Daphnia* and green algae from exposure to the product was concluded to be acceptable if 75% drift reducing nozzles are applied.

Overall, a safe use of the product for aquatic organisms was concluded when the appropriate mitigation measure is applied:
Om in het water levende organismen te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

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

Bees

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

Other non-target arthropods
Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4), for general information.

Effects on non-target arthropods for DMP+ETO+PMP EC 274 were not evaluated as part of the EU review of desmedipham, ethofumesate of phenmedipham. However, data on the toxicity to arthropods other than bees of DMP+ETO+PMP EC 274 have been evaluated as well as data assessed in the EU review of the active substances. Risk assessments for DMP+ETO+PMP EC 274 with the proposed use pattern were provided and are considered adequate.

An in-field risk assessment was not conducted in the Dutch addendum because there are no national specifications for the Netherlands. Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).
The higher tier off-crop risk assessment was conducted according to the guidance document of the ESCORT 2 workshop (2001)[2] and the Dutch Manual for the Authorisation of Pesticides (Chapter 7 Ecotoxicology: terrestrial; non targets, version 2.0; January 2014 by Ctgb).

An acceptable off-field risk can be concluded for non-target terrestrial arthropods after use of DMP+ETO+PMP EC 274 according to the proposed use pattern.

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

Earthworms
Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

Effects on other soil non-target macro-organisms
Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

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

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

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

Please refer to the evaluation and conclusions by the Czech Republic for the identical product BETANAL EXPERT (authorisation number: 4155-4).

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

Non-Target Plants
Effects on non-target plants for DMP+ETO+PMP EC 274 were not evaluated as part of the EU review of desmedipham, ethofumesate and phenmedipham. However, data on the toxicity to non-target plants of DMP+ETO+PMP EC 274 have been evaluated as well as data assessed in the EU review of the active

[2] Candolfi, M.P., *et al.* (2001): Guidance document on regulatory testing and risk assessment procedures for plant protection products with non-target arthropods; ESCORT 2 workshop (European Standard Characteristics Of Non-Target Arthropod Regulatory Testing), Wageningen, NL, March 21-23, 2000, SETAC Europe; SETAC publication August 2001 M-083833-01-1.

substances. Risk assessments for DMP+ETO+PMP EC 274 with the proposed use pattern were provided and are considered adequate.

The risk assessment is based on the Dutch Manual for the Authorisation of Pesticides (Chapter 7 Ecotoxicology: terrestrial; non targets, version 2.0; January 2014 by Ctgb).

According to the deterministic risk assessment and a higher-tier assessment based on drift deposition rates for bare soil and short crops (<20 cm) resulting from research performed in the Netherlands by Van de Zande et al (2013), WUR-PRI, it can be concluded that the risk for non-target plants for applications of DMP+ETO+PMP EC 274 is acceptable if at least 50% drift reducing nozzles are used for applications without and with air-assistance:
Om niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 50% driftreducerende spuitdoppen in combinatie met een kantdop.

Other non-target species (Flora and Fauna)
Test on other non-target species are not required.

3.1.6.8 Overall conclusion

No unacceptable risk to non-target organisms is to be expected from the application of the product when following appropriate risk mitigation measures for aquatic organisms and non-target plants.

The following restrictions are needed:

Om in het water levende organismen te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

Om niet tot de doelsoorten behorende planten te beschermen is toepassing uitsluitend toegestaan indien gebruik wordt gemaakt van minimaal 50% driftreducerende spuitdoppen in combinatie met een kantdop.

As there is a sentence concerning aquatic organisms and non-target plants, the following restriction sentences have to be placed on the label:

Om in het water levende organismen te beschermen is toepassing in de teelt van suiker en voederbiet uitsluitend toegestaan wanneer in perceelsstroken die grenzen aan oppervlaktewater in de eerste 14 m vanaf de insteek van de sloot gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing uitsluitend toegestaan wanneer in perceelsstroken die niet grenzen aan oppervlaktewater in de eerste 14 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van minimaal 50% driftreducerende spuitdoppen in combinatie met een kantdop.

3.1.7 Efficacy (Part B, Section 7, Point 8)

The product is authorised in the Czech Republic for the use in fodder and sugar beet. Climatological and environmental circumstances relevant for the aspect efficacy in the claimed uses in The Netherlands are comparable to those in the Czech Republic. The cultivation method in sugar and fodder beet is similar in both countries and there are no country-specific situations for the use of the product as a herbicide in the claimed uses.

The claim by the applicant is for an application with a normal label claim (no LDS). There is no trial data in the Czech dossier. Based on the label claim in the Czech Republic (LDS only), the lack of data in the Czech dossier supporting a non-LDS application method of the product in the Czech dossier, and

authorisations of similar products in the Netherlands it has to be concluded that the product should be applied in an LDS programme in the Netherlands.

The Czech evaluation concludes that a phytotoxicity warning has to be added to the label. The following sentence needs to be included on the Dutch label:

Het valt niet uit te sluiten dat na een behandeling met Betanal Elite fytotoxiciteit optreedt. Dit leidt in het algemeen niet tot opbrengstderving.

In addition the Czech label states that the product can only be used after BBCH 12 in fodder beet, the same restriction has to be included on the Dutch label:

In de teelt van voederbiet toepassen vanaf het 2^{e} bladstadium (BBCH 12).

The following label warnings for succeeding and replacement crops should be included on the label:

Indien wintergraan wordt geteeld, dient voor het zaaien eerst geploegd te worden om schade ten gevolge van eventuele residuen in de grond te voorkomen. Bij mislukken van een teelt waarin Betanal Elite werd toegepast, kunnen na een kerende grondbewerking suiker- en voederbieten, maïs, bruine bonen, tuinbonen, erwten, raaigrassen, knolselderij, wortelen, zaai- en plantuien en spinazie als vervanggewassen worden verbouwd.

The following resistance management paragraph should be added to the label:

<u>Resistentiemanagement</u> Dit middel bevat de werkzame stoffen desmedifam ethofumesaat en fenmedifam. Desmedifam en fenmedifam behoren tot de fenylcarbamaten. De Hrac code is C1. Ethofumesaat behoort tot de Benzofuranen. De HRAC code is N. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in de voorlichtingsboodschappen, op te volgen.

3.2 Conclusions

The assessment conducted for Betanal Elite was in accordance with the Uniform Principles and demonstrates an acceptable risk to human health and the environment. An authorisation can therefore be granted.

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

None.

Appendix 1 – Copy of the proposed product label

Wettelijk Gebruiksvoorschrift
Het middel is uitsluitend toegelaten als onkruidbestrijdingsmiddel voor het professionele gebruik door middel van een na opkomst toepassing in de volgende toepassingsgebieden, (volgens Definitielijst toepassingsgebieden versie 2.1, Ctgb juni 2015) onder de hierna vermelde toepassingsvoorwaarden.

Toepassingsvoorwaarden:

Toepassings-gebied	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus	Maximaal aantal liter middel per ha per teeltcyclus	Minimum interval tussen toepassingen in dagen
Suikerbiet	Eenjarige onkruiden	1-1,5 L/ha[1,2]	4	4,5	6
Voederbiet	Eenjarige onkruiden	1-1,5 L/ha[1]	4	4,5	6

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is bij lagere dosering niet beoordeeld.
[1] In LDS systeem.
[2] Eerste toepassing met maximaal 1 L/ha.

Overige toepassingsvoorwaarden
In de teelt suiker- en voederbiet dient Betanal Elite verspoten te worden met een volume van 200 liter water per ha.

In de teelt van voederbiet het middel toepassen vanaf het 2e bladstadium (BBCH 12).

Om in het water levende organismen te beschermen is toepassing in de teelt van suiker- en voederbiet uitsluitend toegestaan wanneer in perceelsstroken die grenzen aan oppervlaktewater in de eerste 14 m vanaf de insteek van de sloot gebruik wordt gemaakt van minimaal 75% driftreducerende spuitdoppen.

Om niet tot de doelsoorten behorende terrestrische planten te beschermen is toepassing in de teelt van suiker- en voederbiet uitsluitend toegestaan wanneer in perceelsstroken die niet grenzen aan oppervlaktewater in de eerste 14 m van het gewas, gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij, gebruik wordt gemaakt van minimaal 50% driftreducerende spuitdoppen in combinatie met een kantdop.

Het valt niet uit te sluiten dat na een behandeling met Betanal Elite fytotoxiciteit optreedt. Dit leidt in het algemeen niet tot opbrengstderving.

Volggewassen
Indien wintergraan wordt geteeld, dient voor het zaaien eerst geploegd te worden om schade ten gevolge van eventuele residuen in de grond te voorkomen.

Vervanggewassen
Bij mislukken van een teelt waarin Betanal Elite werd toegepast, kunnen na een kerende grondbewerking suiker- en voederbieten, maïs, bruine bonen, tuinbonen, erwten, raaigrassen, knolselderij, wortelen, zaai- en plantuien en spinazie als vervanggewassen worden verbouwd.

Resistentiemanagement
Dit middel bevat de werkzame stoffen desmedifam, ethofumesaat en fenmedifam. Desmedifam en fenmedifam behoren tot de fenylcarbamaten. De Hrac code is C1. Ethofumesaat behoort tot de Benzofuranen. De HRAC code is N. 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

Bayer CropScience is the owner of most of the studies. For these studies no Letter of Access is required.

However, a general Letter of Access has been submitted to Ctgb in which it is stated that all studies and reports belonging to Bayer CropScience AG and/or any other Bayer affiliate can be used by any interested affiliate within the Bayer Group, including but not limited to, Bayer CropScience SA-NV.

In addition, a Letter of Access from UPL is submitted for a report referred to in Section 6.

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

Annex point / reference number	Year	Title Source *(where different from company)* Company name, Report No., Date, GLP/GEP status *(where relevant)*, published or not	Data protect. claimed	Data protection granted Y/N	Study used Y/N	Owner
Human toxicology						
KIIIA 7.6.1 /01	2000	In vivo dermal penetration study in the rat Desmedipham Code: AE B049913 01 EC25 A8 Report No.: C009291, Report includes Trial Nos.: TOX00025 UR0632 Date: 2000-08-10 GLP/GEP: yes, unpublished	Y	N	Y	Bayer CropScience
KIIIA 7.6.2 /01	2000	In vitro absorption through human and rat epidermis Desmedipham Code: AE B049913 01 EC25 A8 Report No.: C009292, Report includes Trial Nos.: JV1613 TOX00027 Date: 2000-08-22 GLP/GEP: yes, unpublished	Y	N	Y	Bayer CropScience
Environmental fate						
KIIIA 9.6.1 /01	2015	Desmedipham (DMP) and metabolite: PECgw FOCUS PEARL NLD - Use in sugar beets in the Netherlands Bayer CropScience, Report No.: EnSa-15-0796, Date: 2015-09-29 GLP/GEP: no, unpublished	N	N	Y	Bayer CropScience

Annex point / reference number	**Year**	**Title Source *(where different from company)* Company name, Report No., Date, GLP/GEP status *(where relevant)*, published or not**	**Data protect. claimed**	**Data protection granted Y/N**	**Study used Y/N**	**Owner**
KIIIA 9.6.1 /02	2015	Ethofumesate (ETO): PECgw FOCUS PEARL NLD - Use in sugar beets in the Netherlands Bayer CropScience, Report No.: EnSa-15-0795, Date: 2015-09-29 GLP/GEP: no, unpublished	N	N	Y	Bayer CropScience
KIIIA 9.6.1 /03	2015	Phenmedipham (PMP) and metabolite: PECgw FOCUS PEARL NLD - Use in sugar beets in the Netherlands Bayer CropScience, Report No.: M-534550-02-1, Date: 2015-09-29 ...Amended: 2015-09-28 GLP/GEP: no, unpublished	N	N	Y	Bayer CropScience
KIIIA 9.6.2 /01	2015	Desmedipham (DMP) and metabolite: PECgw FOCUS PEARL NLD - Use in sugar beets in the Netherlands Bayer CropScience, Report No.: EnSa-15-0796, Date: 2015-09-29 GLP/GEP: no, unpublished	N	N	Y	Bayer CropScience
KIIIA 9.6.2 /02	2015	Phenmedipham (PMP) and metabolite: PECgw FOCUS PEARL NLD - Use in sugar beets in the Netherlands Bayer CropScience, Report No.: M-534550-02-1, Date: 2015-09-29 ...Amended: 2015-09-28 GLP/GEP: no, unpublished	N	N	Y	Bayer CropScience

Annex point / reference number	Year	Title Source *(where different from company)* Company name, Report No., Date, GLP/GEP status *(where relevant)*, published or not	Data protect. claimed	Data protection granted Y/N	Study used Y/N	Owner
KIIIA 9.7 /01	2008	Kinetic evaluation of the degradation of ethofumesate in an aerobic water/sediment system Bayer CropScience, Report No.: MEF-08/247, Date: 2008-05-13 GLP/GEP: no, unpublished	N	N	Y	Bayer CropScience
Ecotoxicology						
KIIIA 10.2.5.3 /01	2013	Zebra fish (Danio rerio), life cycle test, flow through conditions - Ethofumesate Report No.: BAY-035/4-60/A, Date: 2013-08-20 ...Amended: 2013-12-12 GLP/GEP: yes, unpublished	Y	Y	Y	Bayer CropScience
KIIIA 10.3.3 /01	2009	Half-life of desmedipham and phenmedipham residues on sugar beet leaves Bayer CropScience, Report No.: M-352365-01-1, Date: 2009-07-20 GLP/GEP: n.a., unpublished	Y	N	Y	Bayer CropScience
KIIIA 10.3.3 /03	2005	Generic field monitoring of birds and mammals on maize and beet fields in Austria Bayer CropScience, Report No.: WFC/FS 017, Date: 2005-01-20 GLP/GEP: yes, unpublished	Y	N	Y	Bayer CropScience

Annex point / reference number	**Year**	**Title Source *(where different from company)* Company name, Report No., Date, GLP/GEP status *(where relevant)*, published or not**	**Data protect. claimed**	**Data protection granted Y/N**	**Study used Y/N**	**Owner**
KIIIA 10.8.2 /01	2011	Toxicity of ethofumesate technical to the aquatic macrophyte, Myriophyllum spicatum (amended final report) Report No.: EBADL019-1, Date: 2011-07-25 ...Amended: 2013-05-22 GLP/GEP: yes, unpublished	Y	Y	Y	Bayer CropScience