HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. BESLUIT

Op 22 september 2016 is van

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

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

Magic Tandem

op basis van de werkzame stoffen 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 hoofdstuk 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, 28 oktober 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:	20161430 NLWERG
Type aanvraag:	aanvraag tot wederzijdse erkenning van een gewasbeschermingsmiddel
Middelnaam:	Magic Tandem
Verzenddatum aanvraag:	22 september 2016
*Formele registratiedatum: **	7 oktober 2016
Datum in behandeling name:	27 september 2016
Datum compliance check:	n.v.t.

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

2.2 Stofinformatie

Werkzame stof	Gehalte
ethofumesaat	190 g/L
fenmedifam	200 g/L

- 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 expiratiedatum van de werkzame stof is 31 juli 2017, maar deze expiratiedatum wordt middels Uitvoeringsverordening (EG) 2016/1426 d.d. 25 augustus 2016 overruled met een expiratiedatum van 1 november 2016.

- 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:	15186 N
Expiratiedatum:	1 november 2017
Afgeleide parallel of origineel:	n.v.t.
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

2.4 Verpakkingsinformatie

Aard van het preparaat:
Suspensie concentraat

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel Magic Tandem

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

Pictogram	GHS07 GHS09
Signaalwoord	WAARSCHUWING
Gevarenaanduidingen	H319 Veroorzaakt ernstige oogirritatie. H411 Giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P337 + P313 Bij aanhoudende oogirritatie: een arts raadplegen. P501 Inhoud/verpakking afvoeren naar .... SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH208 Bevat 5-chloor-2-methyl-2H-isothiazool-3-on en 2-methyl-2H-isothiazool-3-on (3:1). Kan een allergische reactie veroorzaken. EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

REGISTRATION REPORT
Part A

Risk Management

Product code: 102000000774

Product name Magic Tandem

Active Substance: Ethofumesate + Phenmedipham SC 390 (190+200) G

Country: The Netherlands

Central Zone

Zonal Rapporteur Member State: CZ

NATIONAL ASSESSMENT

Applicant: Bayer CropScience

Date: October 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.

Table of Contents

PART A – Risk Management

This document describes the acceptable use conditions required for the registration of Magic Tandem, specification number 102000000774, which contains the active substances ethofumesate and phenmedipham, in the Netherlands.

In the scope of 'mutual recognition', reference is made for substance and formulation studies as well as for non-country specific assessments to the evaluation and conclusions by the Czech Republic for the identical product TANDEM STEFES FL (authorisation nr: 3904-3).

This document describes the specific conditions of use and labelling required for the Netherlands for the registration of Magic Tandem.

Appendix 1 of this document provides 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 of this document contains the reference list.

Details of the application

1.1 Application background

This application was submitted by Bayer CropScience SA-NV., in September 2016.

The application is for approval of Magic Tandem, a suspension concentrate formulation containing ethofumesate, 190 g/l, and phenmedipham, 200g/l, for the use as post-emergence herbicide in sugar beet and fodder beet.

This formulation is already registered in many European countries; therefore it is not necessary to consider this application on a zonal basis.

1.2 Annex I inclusion

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 yet in force on an EU-Level this new information is not considered within this dossier by the Ctgb.

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 not considered within this dossier by the Ctgb.

1.3 Regulatory approach

To obtain approval, the product Magic Tandem 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 TANDEM STEFES FL (authorisation nr: 3904-3).

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. The authority confirms that these studies and reports are protected for 10 years from the data of authorisation of the product and thus cannot be used for the benefit of another applicant.

1.5 Letters of Access

No letter of access is required as Bayer CropScience is the owner of all studies.

Moreover, 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.

2 Details of the authorisation

2.1 Product identity

Product Name Product code	MAGIC TANDEM ETO + PMP SC 390 *Specification nr: 102000000774-02*
Authorization Number (for re-registration)	Not applicable, first submission
Function	Herbicide
Applicant	Bayer CropScience SA-NV
Composition	200 g/L phenmedipham, 190 g/L ethofumesate,
Formulation type	SC
Packaging	5 L; 10 L HDPE/PA jerry can

2.2 Classification and labelling according to Regulation (EC) 1272/2008

The identity of all substances in the mixture that contribute to the classification of the mixture:			
-			
Pictogram:	GHS07 GHS09	Signal word:	Warning
H-statements:	H319	Causes serious eye irritation.	
	H411	Toxic to aquatic life with long lasting effects.	
P-statements:	P280	Wear protective gloves/protective clothing/eye protection/face protection.	
	P337+P313	If eye irritation persists: Get medical advice/attention.	
	P501	Dispose of contents/container to	
Supplemental Hazard information:	EUH208	Contains mixture of 5-chloro-2-methyl-1,2-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one. May cause an allergic reaction	
	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:	Classification with H411 is based on the active substance acute and chronic studies, their non-rapid degradation and the summation method. The Ctgb deviates from the harmonised classification (Annex VI of 1272/2008) due to new scientific insight with regard to the chronic toxicity of the substance. At the time of Annex VI insertion, this information was not yet available.
P-statements:	P-statements were proposed by the applicant and are 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	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	Beet (sugar beet, fodder beet)	F	Annual broadleaved weeds	Spraying/ Broadcast, overall	BBCH 10-18 March-June	a) 3 (5) b) as in a	a) 1.5 L/ha b) 4 L/ha	a) 285 g/ha (1)+ 300 g/ha (2) b) 760 g/ha (1)+ 800 g/ha (2)	80-100	90	Dose rate: 1-1.5 L/ha (max. 4 L/ha/ season), applied with 1 L/ha methylated adjuvant vegetable oil 1st application (cotyledon stage): 1 L/ha BBCH 10-11 for sugar beet; BBCH 12 -18) 2nd and following application:1-1.5 L/ha Max 1000 g ethofumesaat / ha / 3 year

Note: (1) ethofumesate, (2) 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 TANDEM STEFES FL (authorisation nr: 3904-3).

Magic Tandem is a product in the form of a suspension concentrate (SC) formulation. Content of the active substances: Ethofumesate (190 g/l), Phenmedipham (200 g/l). The formulation is a beige liquid with an unpleasant odor, the product is not flammable or explosive, and it has no oxidizing properties under normal conditions. The pH of a 1% suspension is 6.3. The viscosity is between 184-384 mPa.s at 20˚C (at respectively shear rates of $20s^{-1}$ and $100s^{-1}$) and a surface tension at 20˚C of 35.1 mN/m (at 0.1%) and 28.7 mN/m (at 1%). According the storage stability data of the shelf-life study the product is stable for two years under normal circumstances in HDPE. Its technical characteristics are acceptable for a SC-formulation.

Magic Tandem should be used with an adjuvant (methylated vegetable oil) in the tank mix, forming an SE-formulation (Aqueous Suspo-Emulsion), before application. However, in the core dossier of the Czech Republic no tank mix is proposed and evaluated and therefore no data (e.g. dispersion stability) is provided for the physical and chemical compatibility of the tank mix. Nevertheless the assessment done by the UK (RR April 2008) of Magic Tandem provides evidence that the dispersion characteristics are acceptable and no problems are expected for the use of a tank mix.

Implications for labelling: no implications for labelling.

Compliance with FAO specifications: Magic Tandem complies with FAO specifications.

Nature and characteristics of the packaging: Please refer to the evaluation and conclusions by the Czech Republic for the identical product TANDEM STEFES FL (authorisation nr: 3904-3).

Nature and characteristics of the protective clothing and equipment: Please refer to the evaluation and conclusions by the Czech Republic for the identical product TANDEM STEFES FL (authorisation nr: 3904-3).

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.

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

Please refer to the evaluation and conclusions by the Czech Republic for the identical product TANDEM STEFES FL (authorisation nr: 3904-3).

All analytical methods for residues in food and feed matrices, soil, water, air and tissues have been evaluated and considered acceptable in the EU review of the active substances of ethofumesate and phenmedipham.

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 TANDEM STEFES FL (authorisation nr: 3904-3).

An HPLC-UV method was used. The method is validated.

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 TANDEM STEFES FL (authorisation nr: 3904-3).

The analytical methods for residues in surface water that are considered also a Dutch specific point, have been evaluated and considered acceptable in the EU review of the active substances. Please refer to the respective monographs.

The analytical method for the determination of ethofumesate residues in surface water is compliant with Dutch national requirements (LOQ $\leq$ 0.1 µg/L for ethofumesate)

The analytical method for the determination of phenmedipham and its metabolite MHPC residues in surface water is compliant with Dutch national requirements (LOQ $\leq$ 0.1 µg/L for phenmedipham and MHPC).

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 TANDEM STEFES FL (authorisation nr: 3904-3).

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

The operator exposure assessment made by the Czech Republic for the original authorisation used a spray volume of 150 L. The current intended use applied for is a spray volume of 80-100 L. Therefore, a reassessment of the operator exposure was carried out using the EFSA AOEM and the dermal absorption values as derived by CZ (10% for the concentrate and spray dilution for ethofumesate and 1% for the concentrate and spray dilution for phenmedipham).

The exposure for the unprotected operator was 2.72% of the AOEL for ethofumesate and 5.6% for phenmedipham. It is therefore concluded that the exposure for the unprotected operator is acceptable. This conclusion is also valid for the combined exposure to ethofumesate and phenmedipham (8%of the AOEL).

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

In the assessment made by the Czech Republic it is indicated that the bystander exposure is a maximum of 0.24% of the AOEL. However, it is unclear to which active substance this refers and which exposure model was used to derive this value. Moreover, possible combination toxicity was not addressed and no resident exposure assessment was included. Therefore, the bystander and resident exposure was re-evaluated here using the EFSA AOEM.

The exposure for the unprotected resident was a maximum of 0.72% for ethofumesate and 2.57% for phenmedipham. Based on the calculated %-AOEL for ethofumesate and phenmedipham, the resident exposure of children and adults living next to a field treated with Magic Tandem is considered to be safe. This conclusion is also valid for the combined exposure to the two active substances.

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

In the assessment made by the Czech Republic it is indicated that the bystander exposure is a maximum of 1.15% of the AOEL. However, it is unclear to which active substance this refers and which exposure model was used to derive this value. Moreover, possible combination toxicity was not addressed. Therefore, worker exposure is addressed here using EFSA AOEM. A default DT50 value of 30 days was used for both active substances resulting in a multiple application factor of 2.7.

Based on the risk assessment, it can be concluded that no adverse health effects are expected for the unprotected worker after dermal exposure during re-entry activities in beets after application of Magic Tandem (0.43% of the AOEL for ethofumesate and 0.87% for phenmedipham). This conclusion is also valid for the combined exposure to the two active substances (1.3% of the AOEL).

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 (CZ). 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 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)

Data for this assessment were reviewed in the EU reviews of ethofumesate (SANCO/6503/VI/99-final) and phenmedipham (SANCO/4060/2001-final). Concerning the DT_{50} values of ethofumesate in soil and aquatic systems, the applicant provided additional kinetic evaluations, which are based on experimental data presented in the EU review. For the calculation of PEC groundwater of phenmedipham-metabolite MHPC, Ctgb uses the conservative and recalculated geomean DT_{50} value that is in line with the risk assessment of previously authorized products Betanal Expert (11533N) or Betanal maxxPro (14708 N). In combination with the appropriate endpoints from the EU reviews, the new DT_{50} values for ethofumesate in soil and aquatic systems and the new geomean DT_{50} value for phenmedipham in soil were used to calculate PECs the active substances ethofumesate and phenmedipham and its metabolite MHPC in soil, surface water, ground water and air for the intended use patterns.

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

Ethofumesate

In the Core Assessment the PECsoil of the active substance ethofumesate have been assessed with the FOCUS model and the focus groundwater interception values and the DT_{50} values established in the EU review. Based on a use rate of 3 x 285 gram ethofumesate/ha (interval 5 days, interception 20% and DT_{50} 120 days), the maximum initial predicted environmental concentration in soil (PECs) will be 0.886 mg/kg.

Assuming an annual application rate of 1 kg ethofumesate each year, a plateau concentration in the soil will be reached after 3 years. This is predicted to be 1.5 mg/kg, based on the conservative, realistic worst-case 90th percentile DT_{50} of 119 days. According to the summary report, however, annual application is not permitted. Significant accumulation is not anticipated if applied once every three years, with only 0.1% of the dose administered present in the soil after three years (DT_{90} 119 days).

Phenmedipham

The PECs of the active substance phenmedipham and its metabolite MHPC in soil have been assessed with the FOCUS model and the focus groundwater interception values and the DT_{50} values established in the EU review.

Based on a use rate of 3 x 300 gram phenmedipham/ha (interval 5 days, interception 20% and DT_{50} 39.9 days) in the Core Assessment, the maximum initial predicted environmental concentration in soil (PECs) will be 0.882 mg/kg. Although not mentioned in the Core Assessment, as the logPow of the substance phenmedipham is > 3 (3.59), a PEC_{21days} is needed for the assessment of secondary poisoning of birds and mammals through the consumption of earthworms. The corresponding $PEC_{21\ days}$ is 0.739 mg a.s./kg.

For the metabolite MHPC, an application rate of 900 gram phenmedipham/ha, corrected to a maximum formation fraction of 54% and molar mass ratio of 0.557, results in a maximum initial PECs of 0.289 mg/kg.

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

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

The PEC of the active substance ethofumesate, and the active substance phenmedipham and its metabolite MHPC in groundwater have been assessed with standard FOCUS scenario Kremsmünster to obtain outputs from the FOCUS PEARL (version 4.4.4) models and the endpoints established in the EU review or agreed in the assessment based on new data provided.

The predicted environmental concentration (PEC_{GW}) at 1m depth for ethofumesate following 26 years with the scenario "KREM-SUGARBEET" according to the recommended application rate (i.e., 1 x 190 and 2 x 285 g a.s./ha for ethofumesate and 1 x 200 and 2 x 300 g as/ha for phenmedipham every third year on May 20, 25, and 30) with 20% foliar interception at the applications, was 0.005 µg/L for ethofumesate and <0.001 for phenmedipham and its metabolite MHPC. This is below the standard threshold of 0.1 µg/L and below the standard of 0.01 µg/L for vulnerable groundwater protection areas (NL-specific situation).

Based on the assessment, the use of ethofumesate and phenmedipham is not expected to lead to leaching into groundwater at levels that would be unacceptable when applied according to the recommended use pattern.

Monitoring data groundwater

Ethofumesate

Recent data are presented in RIVM Rapport 607310001/2007. Monitoring results indicate that the substance ethofumesate was detected on several occasions. The 90th percentile concentration does not exceed the limit of 0.1 mg/L. Hence, the monitoring data confirm the predicted concentrations. The active substance meets the standards for the proposed applications.

Phenmedipham

There are no data available regarding the presence of the active substance phenmedipham or its metabolites in groundwater.

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

The PEC of the active substance ethofumesate and of the active substance phenmedipham and its metabolite MHPC in surface water (PEC_{SW} and PEC_{SED}) have been assessed in accordance with the national guidelines for submission to the Netherlands (CTGB, 2014)[1], using the TOXSWA-NL model (v1.2, GUI 1.0). In accordance with the supported uses for the Netherlands, the simulations were based on applications of the plant protection product Magic Tandem to the proposed use in beet crops at the maximum recommended use rate of 1x 0.190 + 2x 0.285 as/ha per year for ethofumesate and 1x 0.200 + 2x 0.300 as/ha per year for phenmedipham. For application of Magic Tandem to beet crops the default drift value of 1% for downward spraying applies (standard 50% drift-reducing nozzles). As application of Magic Tandem to beet crops is intended from the cotyledon stage onwards (BBCH 10 – 18, March - June), the simulations were conducted with the standard spring scenario for the Netherlands.

The resulting maximum predicted concentrations of ethofumesate, phenmedipham and MHPC are shown in Table 3.1.5.3-1.

Table 3.1.5.3-1 PEC_{SW} for ethofumesate in the edge-of-field ditch following spring application

	Max PEC_{SW} (µg/L)	Max PEC_{SED} (µg/kg sediment DW)
ethofumesate	3.404	72.7 (after 23.5 days)
phenmedipham	1.425	16.4 (after 10.5 days)
MHPC	1.091	28.29 (after 17 days)

The results for PEC surface water for the active substance and its metabolites were used for the eco-toxicological risk assessment.

Monitoring data surface water

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

The active substance ethofumesate was observed in surface water (most recent data from 2014). In the Pesticide Atlas, surface water concentrations are compared to the authorisation threshold value of 32 µg/L (04-09-2009, consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case 0.01*NOEC *Daphnia*) and to the indicative Maximum Permissible Concentration (MPC) of 6.4 µg/L as presented in the Pesticide Atlas.

The active substance phenmedipham was observed in the surface water (most recent data from 2014). In the Pesticide Atlas, surface water concentrations are compared to the authorisation threshold value of 61 µg/L (31-01-2012, consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case 0.1*NOEC *Daphnia*) and to the indicative Maximum Permissible Concentration (MPC) of 0.5 µg/L as presented in the Pesticide Atlas.

Currently, the MPC values for ethofumesate and phenmedipham are not harmonised, which means that not all available ecotoxicological data for these substance are included in the threshold value. In the near future and in the framework of the Water Framework Directive, new quality criteria will be developed which will include both MPC data as well as authorisation data. The currently available MPC values are

[1] CTGB (2014) Evaluation Manual for the Authorisation of Plant Protection Products and Biocides according to Regulation (EC) No 1107/2009. Chapter 6 Fate and behaviour in the environment: behaviour in surface water and sediment, version 2.0; January 2014. www.Ctgb.agro.nl

reported here for information purposes. Pending this policy development, however, no consequences can be drawn for the proposed applications.

There are no data available regarding the presence of the metabolite MHPC in the Pesticide Atlas.

As there are no exceedings of thresholds, the monitoring data have no consequences for the proposed uses of the product.

Drinking water criterion
Assessment of the drinking water criterion is in principle not a Dutch specific aspect, however the interpretation is done in a Dutch specific way. Article 8g of the Plant Protection Products and Biocides Decree (BGB) describes the Assessment of the drinking water criterion.

It follows from the decision of the Court of Appeal on Trade and Industry of 19 August 2005 (Awb 04/37 (General Administrative Law Act)) that when considering an application, the Ctgb should, on the basis of the scientific and technical knowledge and taking into account the data submitted with the application, also judge the application according to the drinking water criterion 'surface water intended for drinking water production'.
The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635[2].
Substances are categorized as new substances on the Dutch market (less than 3 years authorisation) or existing substances on the Dutch market (authorised for more than 3 years).

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

An actualized list of substance of concern is published by VEWIN every year. The more recent list has been published in 2015 and contains monitoring data for the period 2009-2013.

Ethofumesate
Active substance ethofumesate has been on the Dutch market for > 3 years (authorised since 28/09/1987). This period is sufficiently large to consider the market share to be established. The existing 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 is needed based on the highest tier data. There are monitoring data concerning the presence of ethofumesate at drinking water abstraction points. The relevant monitoring data (data set VEWIN, 2010-2014) 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.

Phenmedipham

[2] Adriaanse et al. (2008). Development of an assessment methodology to evaluate agricultural use of plant protection products for drinking water production from surface waters - A proposal for the registration procedure in the Netherlands. Alterra-Report 1635

Phenmedipham has not been identified as a substance of concern by VEWIN. The active substance phenmedipham has been on the Dutch market for > 3 years (authorised since 04/04/1996). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected about the product and its active substances, it can be concluded that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. Under this approach no exceeding of the drinking water criterion is expected. The standards for surface water destined for the production of drinking water are met.

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

The fate and behaviour of ethofumesate and phenpmedipham in air was evaluated during the Annex I inclusion. No additional studies have been performed.

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

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

Birds and **Terrestrial vertebrates (other than birds)**

Please refer to the evaluation and conclusions by the Czech Republic for the identical product TANDEM STEFES FL (authorisation nr: 3904-3), for general information.

According to the risk assessment, an unacceptable risk to birds or mammals from dietary exposure after use of the product as described in this dossier is unlikely. Combination toxicology was not taken into account in the Czech dossier, but considering the high TERs of both actives, the risk was considered to be acceptable.
No risk to birds and mammals resulted from exposure via drinking water or secondary poisoning.
The risk from metabolites to vertebrates is considered to be low.

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 TANDEM STEFES FL (authorisation nr: 3904-3), for general information.

Effects on aquatic organisms for ETO+PMP SC 390 were not evaluated as part of the EU review of ethofumesate and phenmedipham. However further data on ETO+PMP SC 390 is not relevant as active substance data on toxicity to aquatic organisms is used and additional formulation data are not considered essential. Therefore, all relevant data were assessed in the EU review. Risk assessments for ETO+PMP SC 390 with the proposed use pattern are provided here and are considered adequate.

All calculated TER values pass the relevant trigger values.

A combined toxicity assessment is also presented.

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

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 TANDEM STEFES FL (authorisation nr: 3904-3).

Other non-target arthropods
Please refer to the evaluation and conclusions by the Czech Republic for the identical product TANDEM STEFES FL (authorisation nr: 3904-3), for general information.

Effects on non-target arthropods for ETO+PMP SC 390 were not evaluated as part of the EU review of ethofumesate of phenmedipham. However, data on the toxicity to arthropods other than bees of ETO+PMP SC 390 have been evaluated as well as data assessed in the EU review of the active substances. Risk assessments for ETO+PMP SC 390 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 TANDEM STEFES FL (authorisation nr: 3904-3).

The off-crop risk assessment was conducted based on Ctgb[3], 2014, under consideration of country specific requirements.

An acceptable off-field risk can be concluded for non-target terrestrial arthropods after use of ETO+PMP SC 390 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 TANDEM STEFES FL (authorisation nr: 3904-3).

Effects on other soil non-target macro-organisms
Please refer to the evaluation and conclusions by the Czech Republic for the identical product TANDEM STEFES FL (authorisation nr: 3904-3).

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 TANDEM STEFES FL (authorisation nr: 3904-3).

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 TANDEM STEFES FL (authorisation nr: 3904-3).

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 ETO+PMP SC 390 were not evaluated as part of the EU review of ethofumesate and phenmedipham. However, data on the toxicity to non-target plants of ETO+PMP SC

[3] Evaluation Manual for the Authorisation of Plant protection products and Biocides according to Regulation (EC) No 1107/2009; NL part – Plant protection products; Chapter 7 Ecotoxicology: terrestrial; non target arthropods and plants; Version 2.0; January 2014; Ctgb, Wageningen, Netherlands

390 have been evaluated as well as data assessed in the EU review of the active substances. Risk assessments for ETO+PMP SC 390 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 results of the deterministic approach involving the most sensitive endpoint in the vegetative vigour study, it can be concluded that the risk can be considered acceptable without any mitigation measure for applications.

Other non-target species (Flora and Fauna)

Tests on other non-target species are not required.

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

Please refer to the core assessment of the Czech Republic.
The product is authorised in the Czech Republic for the use in beets. 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 beets is similar in both countries and there are no country-specific situations for the use of Magic Tandem as a herbicide in the claimed uses.
For the evaluation of the aspect 'Efficacy' we refer to the evaluation of the member state of the original authorisation by the United Kingdom. The evaluation from the Czech Republic is based on the authorisation from the United Kingdom since there were no trials assessed in the Czech Republic.

The authorisation from the United Kingdom mentions 3 applications with a maximum total amount of 4.0 L/ha. This is different compared the label from the Czech Republic (4.25 L/ha). Since the authorisation of the Czech Republic is based on the data of the authorisation from the United Kingdom the total maximum will be equal to the amount on the label from the United Kingdom.
The maximum total application rate is based on 1 L/ha for the first application and 1.5 L/ha for the second and third application. According to the authorisation of the United Kingdom each application is combined with 1 L/ha adjuvant vegetable oil.
In accordance with the United Kingdom authorisation the claimed spray volume is 80-100 litre water per hectare. According to the Dutch spray volume list the common spray volume in the Netherlands for application of herbicides in arable crops is 150 – 400 L/ha. Therefore, a sentence to this effect is stated on the label/WG:

In de teelt van bieten dient Magic Tandem verspoten te worden met een volume van 80 -100 L water /ha.

According to the label of the United Kingdom beet crops may be sown at any time after the use of Magic Tandem. Any other crop may be sown 3 months after using Magic Tandem. Ploughing (mould board) to a minimum depth of 15 cm should precede preparation of a new seed bed. Therefore the following sentence is placed on the label:

<u>Volggewassen</u> In een normale vruchtopvolging zijn er geen beperkingen ten aanzien van volggewassen. Wel dient altijd een kerende grondbewerking te worden uitgevoerd alvorens volggewassen kunnen worden verbouwd.

According to the label in the Czech Republic an additional sentence on the label should be placed on the label/WG in case of a failure of the crop and a new crop has to be sown or planted. Based on practical

experience and expert judgement the requested sentence seems logical and valid. The following sentence is placed on the label:

Vervanggewassen Bij mislukken van een teelt waarin Magic Tandem werd toegepast kunnen de volgende gewassen na kerend ploegen worden gezaaid of geplant: suiker- en voederbieten, maïs, peulvruchten, vlas, luzerne en spinazie. In deze vervanggewassen dan geen middelen op basis van ethofumesaat toepassen.

3.2 Conclusions

The assessment conducted for Magic Tandem is 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

No further information is required.

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.

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	Veiligheidstermijn in dagen
Bieten	Eenjarige breedbladige onkruiden	1-1,5 L/ha**	3	4,0 L/ha	5	90

* 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;
**1ste bespuiting met 1 L/ha, vanaf BBCH 10-11 (eerste blad zichtbaar) voor suikerbiet en vanaf BBCH 12 (tweede blad zichtbaar) voor voederbiet; 2^{e} en 3^{e} bespuiting met maximaal 1,5 L/ha, tot BBCH 18 (8 blad stadium).
In combinatie met 1 L /ha veresterde plantaardige olie.

Overige toepassingsvoorwaarden
In de teelt van bieten dient Magic Tandem verspoten te worden met een volume van 80-100 L water /ha.

Ethofumesaat mag slechts om de 3 jaar worden toegepast op hetzelfde perceel. De totale dosering in één seizoen mag niet hoger zijn dan 1,0 kg ethofumesaat per hectare.

<u>Volggewassen</u>
In een normale vruchtopvolging zijn er geen beperkingen ten aanzien van volggewassen. Wel dient altijd een kerende grondbewerking te worden uitgevoerd alvorens volggewassen kunnen worden verbouwd.

<u>Vervanggewassen</u>
Bij mislukken van een teelt waarin Magic Tandem werd toegepast kunnen de volgende gewassen na een 15-20 cm kerende grondbewerking worden gezaaid of geplant: bieten, maïs, peulvruchten, vlas, luzerne en spinazie. In deze vervanggewassen mogen geen middelen op basis van ethofumesaat worden toegepast.

Appendix 2 – Letter of Access

No letter of access is required as Bayer CropScience is the owner of all studies.

Moreover 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.

Appendix 3 – Refence list

-