HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. VOORGENOMEN BESLUIT

Op 27 januari 2015 is van

BASF Nederland B.V.
Postbus 1019
6801 MC ARNHEM

een aanvraag tot toelating ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

Pontos

op basis van de werkzame stoffen flufenacet en picolinafen. Nederland is in deze een betrokken lidstaat, als bedoeld in artikel 36, tweede lid; de beoordelend lidstaat is het Verenigd Koninkrijk.

HET COLLEGE IS VOORNEMENS OM TE BESLUITEN 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 28 en artikel 36, derde lid, 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

Toelating op oude eindpunten

De datum van goedkeuring van de werkzame stof picolinafen is bij Uitvoeringsverordening (EU) 2016/1423 vastgesteld op 1 november 2016 en de geldigheidsduur is daarbij verlengd tot 30 juni 2031. De onderhavige aanvraag betreft een aanvraag op grond artikel 33 Verordening (EG) 1107/2009 en van oude eindpunten. Een toelating op basis van oude eindpunten kan volgens het Guidance Document on the renewal of authorisations according to article 43 of Regulations (EC) 1107/2009 (SANCO/2010/13170 rev.14) door de Concerned Member State (CMS) worden afgegeven tot 3 maanden na de datum van toepassing gesteld in de uitvoeringsverordening van de renewal van de werkzame stof. Na deze termijn dient een toelating door de CMS te worden afgegeven op grond van nieuwe eindpunten.

Volgens bovengenoemde regels (SANCO/2010/13170 rev.14) heeft het Ctgb niet tijdig een besluit genomen op deze aanvraag voor de toelating van Pontos op basis van oude eindpunten voor picolinafen. Echter, de opgelopen vertraging is veroorzaakt door de zonale rapporteur (zRMS) Verenigd Koninkrijk en het Ctgb en dus buiten de schuld van de aanvrager. Daarom staat het Ctgb op grond van behoorlijk bestuur alsnog een besluit op deze aanvraag toe, op voorwaarde dat aanvrager een aanvraag tot renewal artikel 43 Verordening (EU) 1107/2009 heeft ingediend om de toelating in lijn te brengen met de nieuwe eindpunten voor picolinafen.

Aanvrager heeft conform artikel 43 de renewal aanvraag ingediend bij de zRMS. De zRMS heeft ingestemd met uitstel voor het genereren van Categorie 4 data en ook voor het combineren van de renewal voor beide actieve stoffen in 1 dossier en beoordeling, omdat de expiratiedatum van flufenacet binnen 1 jaar lag van de renewal van picolinafen. Daarbij heeft de zRMS ook expliciet gesteld dat dit uitstel gekoppeld blijft aan de expiratiedatum/renewal datum van flufenacet, ook als deze verder wordt uitgesteld. De expiratiedatum van flufenacet is bij Uitvoeringsverordening (EU) 2018/1262 d.d. 20 september 2018 uitgesteld tot 31 oktober 2019. De zRMS handelt hiermee in lijn met het Guidance Document on the renewal of authorisations according to article 43 of Regulations (EC) 1107/2009 (SANCO/2010/13170 rev.14).

Aanvrager heeft tevens bij het Ctgb een aanvraag tot artikel 43 renewal voor het aangevraagde gebruik van Pontos ingediend. Als CMS dient het Ctgb dient echter te wachten op de oplevering van het Core dossier door zRMS en volgt de zRMS ook in haar conclusies met betrekking tot het uitstel voor het indienen van het dossier en van de beoordeling.
De vertraging in het afhandelen van de artikel 33 -aanvraag voor Pontos is niet te wijten aan de aanvrager. Aan de voorwaarde dat een aanvraag tot renewal is ingediend is voldaan. Op grond van

behoorlijk bestuur staat het Ctgb daarom een besluit op de aanvraag toe na de datum van toepassing voor de renewal van de werkzame stof plus 3 maanden.

Expiratiedatum van de toelating
De uiterste renewal datum voor middelen op basis van picolinafen is gesteld op 1 november 2017 conform de datum van toepassing van de renewal voor de werkzame stof gesteld in Uitvoeringsverordening (EU) 2016/1423 + 12 maanden conform artikel 32 en artikel 43 vijfde lid van Verordening (EU) 1107/2009. Daarmee zou een toelating van Pontos formeel op 1 november 2017 expireren. Deze datum is echter al gepasseerd door de vertraging in de afhandeling van de artikel 33 aanvraag bij de zRMS en het Ctgb.
Artikel 43, zesde lid van Verordening (EU) 1107/2009 geeft recht op een procedurele uitbreiding van de toelatingstermijn voor een bestaande toelating als de vertraging in het afhandelen van de aanvraag niet aan de aanvrager te wijten is.
De zRMS heeft voor de artikel 43 renewal aanvraag ingestemd met uitstel voor het indienen van het dossier en het dRR tot 3 maanden na de datum van toepassing van de renewal van flufenacet. Daarmee staat vast dat de vertraging in het afhandelen van de artikel 43 aanvraag tot renewal van de toelating niet te wijten is aan de aanvrager.

Op grond van bovenstaande wordt de toelating van Pontos verleend tot de huidige expiratiedatum van de goedkeuring van de werkzame stof flufenacet plus 12 maanden, conform artikelen 32 en 43 lid 5 van de Verordening (EU) 1107/2009 tot 31 oktober 2020.

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.

Zienswijzenprocedure

Ingevolge artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 geldt dat dit ontwerpbesluit gedurende twee weken ter inzage wordt gelegd op het Ctgb; hiervan wordt mededeling gedaan in de Staatscourant. Het ontwerpbesluit wordt gedurende deze periode tevens op de website van het Ctgb geplaatst. Belanghebbenden kunnen gedurende de ter inzagenlegging schriftelijk bij het Ctgb aangeven dat zij een zienswijze zullen indienen; de zienswijze dient schriftelijk binnen twee weken na de inzageperiode te worden ingediend.

Ede, PM

Het College voor de toelating van
gewasbeschermingsmiddelen en biociden,
voor deze:
de voorzitter,

Ir. J.F. de Leeuw

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

Aanvraagnummer:	20140151 NLTG
Type aanvraag:	aanvraag tot nationale toelating gewasbeschermingsmiddel (NL=CMS)
Middelnaam:	Pontos
Verzenddatum aanvraag:	22 januari 2014
*Formele registratiedatum: **	3 februari 2015
Datum in behandeling name:	19 mei 2017
Datum compliance check:	n.v.t.

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

Aangezien Pontos een voor Nederland nieuwe werkzame stof bevat (picolinafen, zie hieronder), is de zienswijzeprocedure zoals bedoeld in artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 van toepassing.

2.2 Stofinformatie

Werkzame stof	Gehalte
flufenacet	240 g/L
picolinafen	100 g/L

- De stof flufenacet is per 1 januari 2004 geplaatst op Annex I van Richtlijn 91/414/EEG (2003/84/EC d.d. 25 september 2003) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van deze werkzame stof expireert op 31 oktober 2019 (Uitvoeringsverordening (EU) 2018/1262 d.d. 20 september 2018).

- De stof picolinafen is geplaatst op Annex I van Richtlijn 91/414/EEG (2002/64/EC d.d. 15 juli 2002) en vervolgens bij Uitvoeringsverordening (EU) 540/2011 d.d. 25 mei 2011 goedgekeurd. De goedkeuring van de werkzame stof picolinafen is per 1 november 2016 verlengd volgens Verordening EG 1107/2009 (Uitvoeringsverordening (EU) 2016/1423 d.d. 25 augustus 2016). De goedkeuring van de werkzame stof expireert op 30 juni 2031. Dit besluit is nog gebaseerd op de oude eindpunten (plaatsing in 2002) voor picolinafen die ook gebruikt zijn door de beoordelende lidstaat het Verenigd Koninkrijk.

2.3 Toelatingsinformatie

Toelatingsnummer:	15482 N
Expiratiedatum:	31 oktober 2020
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 Pontos

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

Pictogram	GHS08 GHS09
Signaalwoord	Waarschuwing
Gevarenaanduidingen	H373 Kan schade aan organen <of alle betrokken organen vermelden indien bekend> veroorzaken bij langdurige of herhaalde blootstelling. H410 Zeer giftig voor in het water levende organismen, met langdurige gevolgen.
Voorzorgsmaatregelen	SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt. P101 Bij het inwinnen van medisch advies, de verpakking of het etiket ter beschikking houden. P102 Buiten het bereik van kinderen houden. P260 Stof/rook/gas/nevel/damp/spuitnevel niet inademen. P280A Beschermende handschoenen dragen. P311 Een ANTIGIFCENTRUM/arts/... raadplegen. P391 Gelekte/gemorste stof opruimen. P501 Inhoud/verpakking afvoeren naar ....
Aanvullende etiketelementen	EUH208 Bevat <naam van de sensibiliserende stof>. Kan een allergische reactie veroorzaken. EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

REGISTRATION REPORT
Part A

Risk Management

Product name:	**Pontos**
Product code:	**BAS 758 00 H**
Active Substance:	**Picolinafen 100 g/L** **Flufenacet 240 g/L**

Central Zone
Zonal Rapporteur Member State: United Kingdom

NATIONAL ADDENDUM - The Netherlands

Applicant:	**BASF**
Date:	**November 2018**
Evaluator:	**Ctgb, NL**

PART A Risk Management

This document describes the acceptable use conditions required for the national registration of Pontos containing 100 g/L picolinafen and 240 g/L flufenacet. This evaluation is required to authorise Pontos as a new product in the Netherlands.

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

This document describes the specific conditions of use and labelling required for the national registration of Pontos.

Appendix 1 of this document provides a copy of the proposed product label.

Appendix 2 of this document provides a list of data in support of the evaluation.

1 Details of the application

1.1 Application background

This application was submitted by BASF, represented by the affiliate BASF Nederland B.V.

The application is for authorisation of Pontos a suspension concentrate containing 100 g/L picolinafen and 240 g/L flufenacet for use as a herbicide in winter cereals. This is a new product in The Netherlands.

1.2 Annex I inclusion

Picolinafen was included in Annex I of Council Directive 91/414/EEC by Commission Directive 2002/64/EC and was consequently approved under Regulation 1107/2009 in accordance with Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011.

The following specific provisions are included in the approval (entry 38, Regulation 540/2011):

- Member States must pay particular attention to the protection of aquatic organisms. Conditions of authorisation should include risk mitigation measures, where appropriate.

These issues are addressed in the submission.

Flufenacet was included in Annex I of Council Directive 91/414/EEC by Commission Directive 2003/84/EC and was consequently approved under Regulation 1107/2009 in accordance with Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011.

The following specific provisions are included in the approval (entry 65, Regulation 540/2011):

Member States shall pay particular attention to the:

- protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions.

- protection of algae and aquatic plants.

- protection of operators.

These issues are addressed in the submission.

1.3 Regulatory approach

Pontos is a new product and was not therefore assessed during the EU substance approval procedure for picolinafen and flufenacet. New product data has been provided where necessary and risk assessments presented in accordance with Uniform Principles.

The Part B document only reviews data and additional information that have not previously been considered within the EU procedure for substance approval.

The application was submitted in January 2015. An EFSA conclusion for picolinafen was published on the 22/10/2015 as part of the AIR2 renewal programme. The authorisation by the zonal RMS was completed on the 28/10/2016. As the application was received before the publication of EFSA (2015) and the approval completed before application of the Regulation renewing picolinafen, the endpoints from the EFSA conclusion could not be used within the risk assessment. The newly available picolinafen endpoints presented within EFSA (2015) will be considered when this product undergoes renewal.

1.4 Data protection claims

The dossier for Pontos includes new studies to support authorisation of the product. These studies are eligible for 10 years data protection from the date of the first authorisation of BAS 758 00 H in The Netherlands according to Article 59 of Regulation 1107/2009.

1.5 Letters of Access

BASF was the only notifier who supported picolinafen for substance approval-and all the study references that were relied upon for that decision are owned by BASF. Furthermore, all of the product data for Pontos which are submitted with this dossier are also owned by BASF. No letters of access are required. Data on the flufenacet are owned by Bayer CropScience AG and a letter of access is included with this application (BASF DocID 2014/1117137). See Appendix 3.

2 Details of the authorisation

2.1 Product identity

Product Name	Pontos (BAS 758 00 H)
Authorisation Number (for re-registration)	Not applicable (new product)
Function	Herbicide
Applicant	BASF
Composition	100 g/L picolinafen and 240 g/L flufenacet
Formulation type	Suspension Concentrate [Code: SC]
Packaging	1, 5 and 10 L HDPE container

2.2 Classification and labelling

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

The identity of all substances in the mixture that contribute to the classification of the mixture *:		
flufenacet		
Pictogram:	GHS08 GHS09	Signal word: Warning
H-statements:	H373	May cause damage to organs through prolonged or repeated exposure.
	H410	Very toxic to aquatic life with long lasting effects.
P-statements:	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.
	P260	Do not breathe dust/fume/gas/mist/vapours/spray.
	P280a	Wear protective gloves.
	P311	Call a POISON CENTER/doctor/...
	P391	Collect spillage.
	P501	Dispose of contents/container to ....
Supplemental Hazard information:	EUH208	Contains flufenacet and 1,2-benzisothiazol-3(2H)-one. May produce 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:	-
P-statements:	P-statements proposed by the applicant were granted. P280a was assigned based on the operator risk assessment.
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	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1a	NL	Winter cereals – winter wheat	F	APESV (Apera spica-venti) and annual dicots, poa annua (POAAN)	Broadcast foliar application	BBCH 00 - 09 (autumn / spring)	a) 1 (-) b) 1 (-) -	a) 0.5 (-) b) 0.5 (-)	a) 0.050* 0.120** b) 0.05* 0.120**	100 / 400	-	In total (pre and post emergence) max 0,5 L/ha per season
	NL	Winter cereals – winter wheat	F	APESV (Apera spica-venti) and annual dicots poa annua (POAAN)	Broadcast foliar application	BBCH 10 – 29 (autumn / spring)	a) 1 (-) b) 1 (-)	a) 0.5 (-) b) 0.5 (-)	a) 0.050* 0.120** b) 0.05* 0.120**	100 / 400	-	In total (pre and post emergence) max 0,5 L/ha per season
1b	NL	Winter cereals- winter barley	F	APESV (Apera spica-venti) and annual dicots poa annua (POAAN)	Broadcast foliar application	BBCH 00 - 09 (autumn / spring)	a) 1 (-) b) 1 (-) -	a) 0.5 (-) b) 0.5 (-)	a) 0.050* 0.120** b) 0.05* 0.120**	100 / 400	-	In total (pre and post emergence) max 0,5 L/ha per season
	NL	Winter cereals- winter barley	F	APESV (Apera spica-venti) and annual dicots poa annua (POAAN)	Broadcast foliar application	BBCH 10 – 29 (autumn / spring)	a) 1 (-) b) 1 (-)	a) 0.5 (-) b) 0.5 (-)	a) 0.050* 0.120** b) 0.05* 0.120**	100 / 400	-	In total (pre and post emergence) max 0,5 L/ha per season
1c	NL	Winter cereals – winter rye	F	APESV (Apera spica-venti) and annual dicots poa annua (POAAN)	Broadcast foliar application	BBCH 00 - 09 (autumn / spring)	a) 1 (-) b) 1 (-) -	a) 0.5 (-) b) 0.5 (-)	a) 0.050* 0.120** b) 0.05* 0.120**	100 / 400	-	In total (pre and post emergence) max 0,5 L/ha per season
	NL	Winter cereals – winter rye	F	APESV (Apera spica-venti) and annual dicots poa annua	Broadcast foliar applicatio	BBCH 10 – 29 (autumn / spring)	a) 1 (-)	a) 0.5 (-)	a) 0.050* 0.120**	100 / 400	-	In total (pre and post emergence) max 0,5 L/ha per season

				(POAAN)	n		b) 1 (-)	b) 0.5 (-)	b) 0.05* 0.120**			
1d	NL	Winter cereals - triticale	F	APESV (Apera spica-venti) and annual dicots poa annua (POAAN)	Broadcast foliar applicatio n	BBCH 00 - 09 (autumn / spring)	a) 1 (-) b) 1 (-) -	a) 0.5 (-) b) 0.5 (-)	a) 0.050* 0.120** b) 0.05* 0.120**	100 / 400	-	In total (pre and post emergence) max 0,5 L/ha per season
	NL	Winter cereals - triticale	F	APESV (Apera spica-venti) and annual dicots poa annua (POAAN)	Broadcast foliar applicatio n	BBCH 10 – 29 (autumn / spring)	a) 1 (-) b) 1 (-)	a) 0.5 (-) b) 0.5 (-)	a) 0.050* 0.120** b) 0.05* 0.120**	100 / 400	-	In total (pre and post emergence) max 0,5 L/ha per season
1e	NL	Winter cereals - spelt	F	APESV (Apera spica-venti) and annual dicots poa annua (POAAN)	Broadcast foliar applicatio n	BBCH 00 - 09 (autumn / spring)	a) 1 (-) b) 1 (-) -	a) 0.5 (-) b) 0.5 (-)	a) 0.050* 0.120** b) 0.05* 0.120**	100 / 400	-	In total (pre and post emergence) max 0,5 L/ha per season
	NL	Winter cereals - spelt	F	APESV (Apera spica-venti) and annual dicots poa annua (POAAN)	Broadcast foliar applicatio n	BBCH 10 – 29 (autumn / spring)	a) 1 (-) b) 1 (-)	a) 0.5 (-) b) 0.5 (-)	a) 0.050* 0.120** b) 0.05* 0.120**	100 / 400	-	In total (pre and post emergence) max 0,5 L/ha per season

3 Risk management

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

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

Overall Summary: The product Pontos is a suspension concentrate containing 100 g/L picolinafen and 240 g/L flufenacet. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of an off-white viscous liquid, with a burnt odour. It is not explosive and has no oxidising properties. It has no flash point below 55°C and an auto-ignition temperature of 493°C. In aqueous solution (1%), it has a pH value around 8.6. The kinematic viscosity at 40˚C at a shear rate of 100 s^{-1} is 47 mm^2/s. The surface tension of the neat formulation at 25˚C is 18.9 mN/m at 1% 37.1 mN/m and at 0.125% 43.0 mN/m and therefore the product is considered to be surface active. The relative density is 1.144. The stability data for 8 weeks at 40˚C, 7 days at 0˚C and 2 years at 23˚C in HDPE indicate a shelf life of 2 years at ambient temperature in HDPE. Its technical characteristics are acceptable for an SC formulation.

Implications for labelling: None

Compliance with FAO specifications: The product Pontos complies with FAO specifications.

Compatibility of mixtures: 24 mixtures of Pontos with other plant protection products were tested. All mixtures were determined to be physically and chemically compatible and can be used in spray applications. In all mixtures, no lumping or flocculation occurred and no chemical reactions were observed and the mixtures appeared to be homogeneous. Pontos is therefore physically and chemically compatible with the tested products; Illoxan CE, Actirob B, Hauban, Cent 7, Defy, Allie Star SX, CTU 500, Lexus XPE, Brennus Plus, Mandarin Pro, Karate Zeon, Decis Protech, Atlantis (with Biopower antidoam), Auxiliary (with Toil), Broadway Sunrise (with Toil), Alpha Tolugan 700, Roundup, Lexus, Quantum SX, Hurricane SC, Atlantis (with Genapol LRO antifoam), Corello (with Dash), Fastac, Sumi Alpha, Axial (with Fastac). In 2 mixtures a antifoam is used to suppress foaming.

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

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

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

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

Analytical methods for determination of the active substances in Pontos were not evaluated as part of the EU review of flufenacet or picolinafen. Analytical method AFL0846/01 has been provided and has been successfully validated in accordance with the requirements of SANCO/3030/99 rev.4, 11/07/00.

There are no CIPAC methods available for the determination of flufenacet and picolinafen in SC formulations.

The active substances flufenacet and picolinafen do not contain any relevant impurities and they will not be formed during manufacturing or up on storage and therefore no analytical method is required.

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

All analytical methods are active substance data and were provided in the EU review of picolinafen and flufenacet and were considered adequate.

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

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

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

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

Acute toxicity studies for Pontos were not evaluated as part of the EU review of picolinafen or flufenacet. Therefore, all relevant data were provided and are considered adequate.

Pontos has a low toxicity in respect to acute oral, dermal and inhalation exposure and is not irritating to the skin or eye. Pontos is not a skin sensitiser to the mouse.

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

Operator exposure to Pontos was not evaluated as part of the EU review of picolinafen or flufenacet. Therefore all relevant data and risk assessments have been provided and are considered to be adequate.

Based on the calculations made in the core assessment it can be concluded that the use of Pontos is considered acceptable provided that appropriate PPE are used (gloves during mixing and loading). This conclusion is also valid for the simultaneous exposure to flufenacet and picolinafen.

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

Bystander exposure to Pontos was not evaluated as part of the EU review of picolinafen or flufenacet.. Predicted levels of bystander and resident exposure using the UK method and the approach set out by Martin *et al*. respectively, demonstrate that the risk to bystanders and residents is acceptable. It is concluded that there is no undue risk to any bystander after accidental short-term exposure to Pontos. This conclusion is also valid for the simultaneous exposure to flufenacet and picolinafen.

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

Worker exposure to Pontos was not evaluated as part of the EU review of picolinafen or flufenacet. Therefore, all relevant data and risk assessments have been provided and are considered adequate. Worker exposure has been estimated in the core dossier using the recommendations made by the re-entry group of EUROPOEM II (Post-Application Exposure of Workers to Pesticides in Agriculture, Report of the Re-Entry Working Group, December 2002). It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no PPE), when re-entering crops treated with Pontos. This conclusion is also valid for the simultaneous exposure to flufenacet and picolonafen.

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

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

Subsequent to the EU review of picolinafen an evaluation of all uses has been made to establish EU MRLs (EFSA Journal 2013;11(5):3222). The evaluation reviewed all the data relevant to establishing MRLs for all supported uses and considered the dietary risk assessments appropriate for all EU member states utilising the EFSA PRIMo model. The MRLs for picolinafen are published in Annex III of Regulation (EC) No 396/2005.

Subsequent to the EU review of flufenacet an evaluation of all uses has been made to establish EU MRLs (EFSA Journal 2012;10(4):2689). The evaluation reviewed all the data relevant to establishing MRLs for all supported uses and considered the dietary risk assessments appropriate for all EU member states utilising the EFSA PRIMo model. The MRLs for flufenacet are published in Annex III of Regulation (EC) No 396/2005.

All crops and application parameters applied for, for the National registration of BAS 758 00 H including climatic condition (zonal) parameters are within the use parameters assessed for EU MRLs for picolinafen and flufenacet.

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

Picolinafen

In EFSAs "Reasoned opinion on the review of the existing maximum residue levels (MRLs) for picolinafen according to Article 12 of Regulation (EC) No 396/2005" (EFSA Journal 2013;11(5):3222), a refined chronic risk assessment using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) was performed. The (tentative) median residue values selected for chronic intake calculations are based on the residue levels in the raw agricultural commodities reported in EFSAs review report. New results on picolinafen obtained from field trials performed in 2012 do not alter the tentative median residue value reported by EFSA.

With the current EFSA model the chronic risk assessment ranges from 0.6 to 4.0% of ADI. The diet with the highest TMDI is "Netherland child" with 4.0% of ADI. For this diet, the highest contributor is "milk and milk products: cattle" with 2.1% of ADI. The diet with the second highest TMDI is "Danish child" with wheat as the highest contributor with 2.0% of ADI.

NESTI calculations were performed for the crops/commodities relevant to this application. The proposed HR values for wheat, barley and rye grain of 0.05 mg/kg have been used. The dietary risk assessment has been performed using the current residue definition for monitoring and risk assessment (parent picolinafen). Using the current EFSA model, the ARfD is not exceeded for wheat, barley and rye by adults/general population or by children. The highest NESTI is from wheat at 1.4 % ARfD for children and 0.8% ARfD for adults/general population.

Flufenacet

In EFSA's "Reasoned opinion on the review of the existing maximum residue levels (MRLs) for flufenacet according to Article 12 of Regulation (EC) No 396/2005" (EFSA Journal 2012;10(4):2689), a refined chronic risk assessment using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) was performed. The median residue values selected for chronic intake calculations are based on the residue levels in the raw agricultural commodities reported in EFSAs review report. New results on flufenacet obtained from field trials performed in 2012 do not alter the tentative median residue value reported by EFSA.

With the current EFSA model the chronic risk assessment ranges from 4.4 to 24.7% of ADI. The diet with the highest TMDI is "WHO Cluster diet B" with 24.7% of ADI. For this diet, the highest contributor is "wheat" with 8.5% of ADI. The diet with the second highest TMDI is "Netherlands child" with potatoes as the highest contributor with 5.9% of ADI.

NESTI calculations were performed for the crops/commodities relevant to this application. The HR values for wheat, barley and rye grain of 0.09 mg/kg obtained from new field trials performed in southern Europe in 2012 have been used. The dietary risk assessment has been performed using the current residue definition for monitoring and risk assessment (sum of all compounds containing the N-fluorophenyl-N-isopropyl moiety expressed as flufenacet equivalent). Using the current EFSA model, the ARfD is not exceeded for wheat, barley and rye by adults/general population or by children. The highest NESTI is from wheat at 7.6% ARfD for children and 4.1% ARfD for adults/general population.

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

No new studies are presented; all data were reviewed in the EU review procedure for picolinafen and flufenacet. Appropriate endpoints from the EU review were used to calculate PECs for BAS 758 00 H, and metabolites in soil, surface water, ground water and air for the intended use patterns. For flufenacet a refined assessment was carried out using end points provided by Bayer CropScience (BCS dossier FFA+TBA SC 533. Dossier Number D-011425-01), which are covered by the letter of access provided for the flufenacet data (see BASF DocID 2014/1314084). See Appendix 3.

Monitoring data in The Netherlands were examined. There are no data available regarding the presence of the substances picolinafen and flufenacet in groundwater. There are data available in the Pesticide Atlas regarding the presence of the substance picolinafen and flufenacet in surface water.

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

The PEC of BAS 758 00 H, picolinafen, CL 153815, flufenacet, FOE sulfonic acid and FOE oxalate in soil has been assessed with the FOCUS model and the FOCUS groundwater interception values and the DT_{50} values established in the EU review.

Based on the recommended use rate, PECs were calculated. The results for PEC soil for the active substances 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 assessment of the potential for contamination of groundwater by plant protection products in The Netherlands follows a tiered approach (van der Linden *et al* (2004)).

Following application of flufenacet to winter cereals, 90th percentile PEC_{gw} in the upper levels of groundwater in The Netherlands calculated using the GEOPEARL 3.3.3 groundwater model for flufenacet are predicted to be below 0.01 µg/L.

The 90th percentile concentration for FOE sulfonic acid is 4.309 µg/l The 90th percentile concentration for FOE oxalate is 0.085 µg/l.

In the field studies, treated at rates of 240, 480 or 600 g flufenacet /ha, with samples analysed down to 50 cm for FOE oxalate and FOE sulfonic acid and only few values were found which were slightly above the limit of determination (0.01 mg/kg) and they were detected only in the top layer 0 – 10 cm. The lysimeter studies showed that FOE oxalate did not exceed 0.1µg/L. For repeat applications to corn at 480 g flufenacet /ha, FOE sulfonic acid amounted to maximum concentration of 3.7 µg/L and annual mean concentrations were 0.49- 0.59 µg/L (year 1) and 0.15- 0.24 µg/L (year 2).

An assessment of the toxicological relevance of groundwater metabolites according to SANCO/221/2000 – rev. 10 Guidance Document on the assessment of the relevance of metabolites in groundwater (http://ec.europa.eu/food/plant/plant_protection_products/approval_active_substances/docs/wrkdoc21_en.pdf), for the ground water metabolites FOE sulfonic acid and FOE oxalate has been performed in Part B.5. The conclusion of these assessments was that these metabolites were not relevant.

Monitoring data groundwater

There are no data available regarding the presence of the substances picolinafen and flufenacet 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 picolinafen and flufenacet in surface water (PEC_{sw} and PEC_{sed}) has been assessed with the TOXSWA-NL model and Dutch specific drift figures and the DT_{50} water/sediment values established in the EU review. For metabolites, maximum PECsw values were calculated from the respective maximum parent value correcting for molecular ratio and the maximum amount formed.

Surface water modelling of picolinafen, flufenacet and their metabolites has been undertaken using the TOXSWA GUI model (Version 1.0) and the National Guidelines of The Netherlands. The modelling was based on the use of a pre-emergence spray application to winter cereals with one application of 1L BAS 758 00 H/ha. Additionally, PECsw calculations are included assuming a lower dose rate.

In the SANCO/1418/2001-final review report for picolinafen the metabolite CL 153815 was identified as being potentially relevant with regard to the risk assessment for surface water. CL 153815 represented up to 92.4% in the water sediment study.

In the SANCO/7469/VI/98-Final for flufenacet, two metabolites FOE methylsulfide and thiadone which are only formed in aquatic systems at maximum levels of 11.4% and 84.3%, respectively, are considered.

Calculation of PECsw and PECsed were conducted according to recommendations in the Netherlands.

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
There are data available in the Pesticide Atlas regarding the presence of the substance picolinafen and flufenacet in surface water.

Picolinafen
As there is no exceeding of thresholds, the monitoring data have no consequences for the proposed uses of the product. For details, please refer to IIIA 9.8.7 of the NL Addendum.

Flufenacet
As there is no exceeding of the authorisation threshold, the monitoring data have no consequences for the proposed uses of the product. For details, please refer to IIIA 9.8.7 of the NL Addendum.

Drinking water criterion
Article 8g of the Plant Protection Products and Biocides Decree (BGB) describes the Assessment of the drinking water criterion.

Flufenacet
Active substance flufenacet has been on the Dutch market for > 3 years (authorised since 03-02-2012; prior to this date, it already has been authorised from 2002-2004). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this

product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water as laid down in the RGB/BGB are met.

Picolinafen

As is a new active substance, there are no data available regarding its presence in surface water at drinking water abstraction points.
The decision tree as outlined in Alterra report 1635 (2010) should be followed. The tool DROPLET (described in Alterra report 2020, 2010) to calculate concentrations on drinking water abstraction points is available at Ctgb and is used since it represents the current scientific insight.
Results show that for all drinking water abstraction points the predicted concentrations are below 0.1 µg/L. For details, please refer to IIIA 9.8.7 of the NL Addendum.

Therefore, the application of Pontos is not expected to exceed the drinking water criterion. The standards for surface water destined for the production of drinking water as laid down in the BGB are met.

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

The results from a study on volatilisation from soil and leaf surfaces have shown that picolinafen exhibits no significant volatilisation (i.e. < 10% from both matrices) over the 24-hour period of the laboratory experiment. These findings are in good agreement with its vapour pressure of 1.66 x 10^{-7} Pa at 20°C and its Henry's law constant of 1.6 x 10^{-3} Pa m^3 mol^{-1}. Volatility from soil and plants is therefore not expected to be a major entry route into air after application of picolinafen.

Flufenacet has a vapour pressure of is 9 x 10^{-5} Pa and a calculated Henry's Law Constant is 9 x 10^{-6} Pa m^3 mol^{-1} and can be classified as slightly volatile from plant surface, indicating that losses due to volatilisation would be expected. In a field study three individual spray applications with radioactive formulated flufenacet were conducted on 1 target area of $1m^2$. Up to 29% of the applied amounts ware not deposited on the soil. However, the losses might be mainly due to spray drift. Calculations using the method of Atkinson for indirect photo-oxidation in the atmosphere through reaction with hydroxyl radicals resulted in an atmospheric half-life of 4.7 hours, indicating that the small proportion of applied flufenacet that will volatilise would be unlikely to be subject to long-range atmospheric transport.

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
The risk assessment for birds was conducted in line with EFSA's Bird and Mammal Guidance Document (EFSA Journal 2009; 7(12):1438). No acute or long-term avian toxicity endpoint for BAS 758 00 H is available. A worst-case dietary screening risk assessment demonstrated an acceptable acute risk from exposure to picolinafen, flufenacet and BAS 758 00 H and acceptable long-term risk from exposure to picolinafen. A low reproductive risk (including combitox) to birds from exposure to flufenacet was concluded on the basis of a refinement of the PT value.

The secondary poisoning assessments was conducted using surface water PEC values generated according to the national requirements in the Netherlands and resulted in TERs for fish-eating birds above the trigger value, therefore demonstrating an acceptable risk to birds from the proposed use of BAS 758 00 H.

Terrestrial vertebrates (other than birds)

Mammals
The risk assessment for mammals was conducted in line with EFSA's Bird and Mammal Guidance Document (EFSA Journal 2009; 7(12):1438). Acute toxicity data is available for the formulation BAS 758 00 H. A worst-case dietary screening risk assessment demonstrated an acceptable acute risk from exposure to picolinafen, flufenacet and BAS 758 00 H and acceptable long-term risk from exposure to flufenacet. However, in order to achieve an acceptable long term risk for large herbivorous mammals for picolinafen the GAP has been adapted limiting use after BBCH 10 to 0.5 L product/ ha (50 g picolinafen/ ha).

The secondary poisoning assessment was conducted using surface water PEC values generated according to the national requirements in The Netherlands and resulted in TERs for fish-eating mammals above the trigger value, therefore demonstrating an acceptable risk to mammals from the proposed use of BAS 758 00 H.

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

Effects on aquatic organisms for BAS 758 00 H were not evaluated as part of the EU review of picolinfaen and flufenacet. The results from the tests using the formulation indicate that the toxicity of the formulation reflects the toxicity of the constituents. Algae and aquatic plants were the most sensitive test species to the active substances and the formulation.

The risk assessment for aquatic organisms was conducted in line with the Aquatic Guidance Document (SANCO/3268/2001).

Based on the maximum instantaneous PECsw value for a single application to cereals from the application site using the national requirements of the Netherlands an acceptable risk to fish *Daphnia,* aquatic insects and sediment dwelling organisms was demonstrated. The combitox risk was also acceptable.

A refined risk assessment for algae from exposure to picolinafen was conducted and the risk to algae is considered acceptable if the product is applied at 1 x 50 g a.s./ha with 90% drift reduction measures.

The risk to aquatic plants is considered acceptable if the product is applied at 1 x 50 g a.s./ha with 90% drift reduction measures.

Om in het water levende organismen te beschermen, is toepassing in de teelt van wintergraan met uitzondering van kanariegras, op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik wordt gemaakt van een techniek uit tenminste de klasse DRT90.

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

Bees

Effects on bees for BAS 758 00 H were not evaluated as part of the EU review of picolinafen or flufenacet. Formulation toxicity studies have been conducted for BAS 758 00 H.

The risk assessment for bees was conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002). An acceptable risk acute risk to adult bees from the proposed use of BAS 758 00 H was demonstrated based on a first tier risk assessment.

Other non-target arthropods

Effects on non-target arthropods for BAS 758 00 H were not evaluated as part of the EU review of picolinafen or flufenacet. Formulation studies have been conducted for BAS 758 00 H.

The non-target arthropod risk assessment was conducted in line with ESCORT 2 (Candolfi *et al.*, 2001), but following Dutch national requirements for drift rates to calculate exposure to off-field areas.

Laboratory studies on *A. rhopalosiphi* and *T. pyri* are available for the formulation BAS 758 00 H. Based on the results of these studies an acceptable in-field risk to *A. rhopalosiphi* and off-field risk to both indicator species could be concluded. An acceptable in-field risk to *T. pyri* could not be demonstrated. Consequently an extended laboratory studies were performed on *T. pyri*. *T. pyri* exhibited acceptable recovery following a 21 DAT aged residue study.

Two additional species, *Orius laevigatus* and *Aleochara bilineata* were exposed via natural substrates in extended laboratory studies conducted with BAS 758 00 H. Based on the findings from *O. laevigatus* and A. *bilineata*, no unacceptable effects (i.e. < 50% effects, according to ESCORT 2) on mortality or reproduction were observed at the maximum rate of 1.0 L BAS 758 00 H/ha.

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

Effects on earthworms and other soil macro-organisms for BAS 758 00 H were not evaluated as part of the EU review of picolinafen and flufenacet.

The risk assessment for soil macro-organisms was conducted in line with the Terrestrial Guidance Document (SANCO/10329/2002). All the acute TER values are above the trigger value of 10, demonstrating an acceptable acute risk to earthworms from exposure to both active substances and their relevant metabolites. The long-term TER for flufenacet is also above the trigger value of 5, demonstrating an acceptable chronic risk to earthworms from exposure to flufenacet. However, the long-term TER for picolinafen is below this trigger, indicating a potential concern.

The chronic study conducted with the formulated product BAS 758 00 H showed an acceptable risk to earthworms for both active substances and BAS 758 00 H. Moreover, with its high Koc of 22745, picolinafen is expected to bind strongly to organic matters present in the soil, and hence

will not be available to the earthworms. Therefore an acceptable long-term risk to earthworms from the propose use of BAS 758 00 H can be concluded.

No tests are required for other non-target soil macro-organisms considering the persistence trigger in accordance with the EU Guidance Document (SANCO/10329/2002 rev2-final), since the field DT_{90} is between 100 and 365 days for picolinafen (mean DT_{90F} = 107 d) and flufenacet (max. DT_{90F} = 198 d), the TER_{LT} for earthworms is > 5, the risk to non-target arthropods is acceptable (see IIIA 10.5), effects on soil micro-organisms are < 25% (see IIIA 10.7.1) and only a single application is recommended per year, indicating that there will be no long-term exposure or accumulation of residues.

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

No tests or assessments are required considering the persistence trigger in accordance with the EU Guidance Document (SANCO/10329/2002 rev2-final), since the field DT_{90} is <365 days for both picolinafen (mean DT_{90F} = 107 d) and flufenacet (max. DT_{90F} = 198 d), the TER_{LT} for earthworms is > 5, effects on soil micro-organisms are < 25% (see IIIA 10.7.1) and only a single application is recommended per year. This indicates that there will be no long-term exposure or accumulation of residues.

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

Effects on soil micro-organisms for BAS 758 00 H were not evaluated as part of the EU review of picolinafen or flufenacet. It is considered possible to extrapolate effects data from the individual active substances to the product.

The NOEC of 0.67 mg a.s./kg for picolinafen is approximately 5 times higher than the maximum PEC_S of 0.133 mg a.s./kg, the NOEC of 0.30 mg/kg for CL 153815 is approximately 6 times higher than the maximum PEC_S of 0.055 mg/kg and the NOEC of 4.0 mg a.s./kg for flufenacet is approximately 13 times higher than the maximum PEC_S of 0.320 mg a.s./kg. This supports the conclusion that under field conditions, the use of BAS 758 00 H at the proposed rate poses no unacceptable effects on soil micro-organisms.

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

The risk assessment has been conducted in line with the Terrestrial Guidance Document (SANCO/10329/ 2002, rev. 2 final), following Dutch national requirements. The TER values based on the ER_{50} values for the most sensitive species tested in the vegetative vigour and seedling emergence studies with BAS 758 00 H are above the proposed trigger of 5, for 75% drift reducing nozzle (without air assistance) or low drift nozzle with end nozzle (with air assistance), demonstrating an acceptable risk to non-target plants the proposed use of BAS 758 00 H.

Since 1st of January 2018 a minimum of 75% drift nozzles are used by default on the entire field, restriction sentences to protect non-target terrestrial plants are not needed.

Other non-target species (Flora and Fauna)

Tests on other non-target species are not required.

Toxicity of BAS 758 00 H to activated sludge in a respiration inhibition test was tested. At a rate of 100 mg/L BAS 758 00 H had no toxic effects on respiration activity of activated sludge.

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

This dossier concerns an application for the plant protection product BAS 758 00 H ((240 g/l of flufenacet + 100 g/l of picolinafen). The United Kingdom is the zRMS, the Netherlands act as CMS. In the Netherlands the product is claimed against ALOMY, LOLSS, APESV, and annual dicotyledonous weeds in winter cereals, at a dosage of 0.5-1.0 L/ha pre-emergence, and 0.5L/ha post-emergence.
Due to the evaluation of other aspects, the claim at 1 L/ha can not be granted, therefore only a dose rate of 0,5 L/ha is claimed, both for the pre-emergence and the post-emergence use.

Mixture and ratio justification
The Ctgb agrees with zRMS conclusion that agrees the co-formulation combines the complimentary nature of the two actives, and also in agreement with the justification for ratio "The pre-emergence and post-emergence trials demonstrate that the two actives target broad-leaf and grass weeds differently and justify further the complimentary of the actives in the product. The data support the ratio of the actives and the proposed two rates of product, with 1.0L /ha providing greater level of efficacy for ALOMY and GALAP (pre-emergence), 0.5 L/ha provided sufficient levels of control for broad-leaved weeds.
Justification of the ratios was determined through trials conducted in the maritime climatic zone".

Minimum effective dose tests
The applicant has addressed MED in the Maritime and North-east climatic zone, looking at the two key weed species representing broad-leaved and grass weed species (GALAP and ALOMY) in accordance with EPPO 1/225, looking at three rates; 0.5N, 0.75N and N and weed populations established in plots. Below is the results from MED tests for both weed species. Ctgb agrees with the zRMS that this is sufficient to justify minimum effective doses in winter cereals.

	EPPO zone	% efficacy	Weed GS at Appl.	DAFT	% efficacy		
					BAS 758 00 H at 0.5 l/ha	BAS 758 00 H at 0.75 l/ha	BAS 758 00 H at 1.0 l/ha
GALAP	Maritime	Mean (N=13)	Pre-emergence	175	82.5	83.6	92.1
		Range (min-max)		122 - 256	57.5 - 100	31.25 - 100	68.75 - 100
		Mean (N=12)	Post: 10-12	166.8	86.6	91	94.7
		Range (min-max)		122 - 248	30 - 100	46 - 100	63.3 - 100
ALOMY	Maritime	Mean (N=21)	Pre- emergence	180	79.5	84.9	89.2
		Range (min-max)		124 - 290	46.7 - 95.7	55 - 97.7	65 - 98.7
		Mean (N=34)	Post: 10-13	161	68.9	78.0	84.8
		Range (min-max)		102 - 219	30 - 100	37.5 - 99	53.3 - 100

There are however some changes comparted to the label claim in the zonal dossier. In the zonal dossier a pre-emergence rate of 0.5-1 L/ha was claimed, and a claim of 0.5 L/ha for post-emergence use. Rates above 0.5 L/ha can't be claimed due to aspects other than efficacy.

Based on the dose justification provided above, the dose rate of 0.5 L/ha is still acceptable for GALAP, even if higher rates would have been preferable. For ALOMY however a rate of 0.5 L/ha results in efficacy levels that are considered to be too low for a herbicide, and higher rates are clearly better.

Conclusion: If the rate had not been restricted by other aspects a rate of 0,5-1 L/ha would have been chosen as the minimum effective dose. The proposed rate of only 0,5 L/ha for the Netherlands can still be considered an effective dose, however it may not be acceptable for all weeds. This will be evaluated in the efficacy section.

Efficacy

A series of efficacy trials tested the proposed label range rate of BAS 758 00 H (0.5 and 1.0 l/ha) applied either pre-emergence or early post-emergence of the crop, against a range of weed species commonly occurring in winter cereals. Dependent on site, application was made pre-emergence or early post-emergence to the target weeds.

The trials always included standard products, usually 'Herold SC' (a suspo-emulsion containing 400 g/l flufenacet, 200 g/l diflufenican) applied at 0.6 L/ha to give identical loadings of flufenacet as full rate BAS 758 00 H.

A summary table of efficacy in the Maritime zone is provided below using the following scale for control: 95-100%= excellent; 85-94.9= very good; 70-85= moderately good, with the conclusion stated below. On the NL GAP, *Lolium* sp. was claimed, yet only *Lolium multiflorum* was assessed, thus the claim was adjusted to represent the tested weed. As stated above, the product can only be authorized at a rate of 0,5 L/ha, while the original claim was 0,5-1 L/ha for the pre-emergence use.

Emergence	Weed species, Water volume, Weed growth stage	Untreated pl/m^2 (numbers of trials)	0.5 l/ha	1.0 l/ha	no of trial	standard	**Conclusion BAS 758 00 H**
pre	BRSNN	2.7 (6)	**89.1**	93.2	5	91.8	Maritime - 0.5 and 1.0l/ha -comparable to standard, control = Very good
post	BRSNN	4.9 (14)	**88.4**	91.5	12	88.8	Maritime - 0.5l/ha and 1.0l/ha comparable to standard. Control – Very good
post	BRSNN	6.5 (7)	**83.5**	89.8	7	85.7	Maritime 0.5l/ha. Comparable to standard. - control - Moderately good; 1.0l/ha, also comparable to control but slightly higher level of control = Very good
pre	CAPBP (200-300l/ha)	7.2 (9)	**96.2**	96.5	9	98.4	Maritime
post	CAPBP (200-300l/ha)	7.3 (4)	**99.7**	99.7	4	98.8	Maritime -0.5l/ha and 1.0l/ha comparable to standard. Control = Excellent.
pre	FUMOF (200-300l/ha)	4.7 (1)	**90.2**	93.3	2	97.8	Maritime-,0.5l/ha and 1.0l/ha, lower than the standard. Control=Very good .2 trials yet since many other broadleaved weeds are well controlled we can extrapolate to authorize all broadleaved weeds for NL
post	FUMOF (300l/ha) 10-11 BBCH	5.7 (1)	**99.7**	100	1	100	Maritime-1 trial. 0.5l/ha, slightly lower than the standard, claim not accepted too few trials.

Pre	GALAP (180-400l/ha) 00-10 BBCH	6.4 (14)	**83**	90.8	20	91.8	Maritime.- 0.5l/ha, control = Moderately good 1.0l/ha comparable to standard: control = Very good
post	GALAP (200-400l/ha) 10-13 BBCH	9.2 (9)	**95.1**	92.3	8	93.7	Maritime - 0.5 and 1.0l/ha comparable to standard. Control 1.0l/ha= Very good, 0.5l/ha = Excellent, 3% greater control than 1.0l/ha which is considered insignificant.
pre	MATCH (200-300l/ha) 00-10 BBCH	8.5 (13)	**91**	92.8	14	91.7	Maritime -0.5l/ha and 1.0l/ha comparable to standard. Control = Very good
post	MATCH (200-250l/ha)	5.4 (6)	**97**	99	7	97.5	Maritime - 0.5l/ha and 1.0l/ha comparable to the standard.
pre	MATIN (150-300l/ha)	4.7 (7)	**94.5**	97.1	7	95.9	Maritime 0.5l/ha and 1.0l/ha comparable to standard
post	MATIN (150-300l/ha)	4.5 (6)	**91.2**	96	8	91.9	.0.5 l/ha gave level of control –Very good just below control level of 1.0l/ha (Excellent)
pre	MATMA (200l/ha) 00-11 BBCH	11.2 (4)	**49.5**	97.5	4	95	Maritime – four trials and variable data. 0.5l/ha lower than standard, control = less than Moderate, whereas 1.0l/ha gave control = Excellent
pre	MATMT (200-400l/ha)	20 (2)	**100**	100	2	100	Maritime – (two trials), 0.5 and 1.0l/ha control = Excellent, comparable to standard.
post	MATMT (200-400l/ha)	15.6 (3)	**100**	100	3	100	Maritime – (three trials), 0.5 and 1.0l/ha control = Excellent, comparable to standard
post	MATSS (200l/ha) BBCH 12-14	5 (1)	**96**	98	1	99.3	Maritime – (one trial), 0.5 and 1.0l/ha control = Excellent, comparable to standard
pre	PAPRH (150-200l/ha)	5.8 (7)	**92.4**	97.7	12	99.3	Maritime – 0.5l/ha lower than standard, control = Very good, 1.0l/ha, comparable to the standard, control = Excellent.
post	PAPRH (190-250l/ha)	7.6 (9)	**91.3**	98.3	12	99.2	Maritime – 0.5l/ha lower than standard, control = Very good, 1.0l/ha, comparable to the standard, control = Excellent
pre	SENVU (200l/ha)	5 (1)	**98.8**	99	2	98.9	Maritime -two trials. 0.5l/ha and 1.0l/ha comparable to standard. Control = Excellent for the two rates. 2 trials yet since many other broadleaved weeds are well controlled we can extrapolate to authorize all broadleaved weeds for NL
post	SENVU (200l/ha)	3 (1)	**100**	100	1	97.5	Maritime -one trial. 0.5l/ha and 1.0l/ha comparable to standard. Control = Excellent for the two rates.
pre	SINAR (200l/ha)	7.8 (3)	**99**	99	2	98.5	Maritime -two trials. 0.5l/ha and 1.0l/ha comparable to standard. Control = Excellent for the two rates. 2 trials yet since many other broadleaved weeds are well controlled we can extrapolate to authorize all broadleaved weeds for NL
post	SINAR (190-200l/ha)		**100**	100	1	100	Maritime - one trial. 0.5l/ha and 1.0l/ha comparable to standard. Control = Excellent for the two rates .
pre	STEME (200-300l/ha)	6.9 (10)	**93.4**	97.8	11	98.2	Maritime; 0.5l/ha lower than standard. Control = Very good. 1.0l/ha comparable to standard, control = Excellent.
post	STEME (190-300l/ha)	7 (17)	**95.3**	99.6	19	99.4	Maritime; 0.5l/ha lower than standard. However 0.5 and 1.0l/ha, control = Excellent

pre	VEHRE	6.6 (9)	**85.8**	95.4	11	97.8	Maritime; 0.5l/ha lower than standard; control = Moderately good. 1.0l/ha comparable to standard, control = Excellent
	(100-300l/ha)						
post	VEHRE (180-285l/ha)	7.4 (3)	**95.9**	99.6	10	100	Maritime; 0.5l/ha lower than standard; however 0.5 and 1.0l/ha control = Excellent.
pre	VERPE (200-300l/ha)	7.5 (7)	**92**	98.8	8	99.9	Maritime; 0.5l/ha lower than standard; control = Very good. 1.0l/ha comparable to standard, control = Excellent.
post	VERPE	7.2 (3)	**85.3**	94.8	6	97.1	Maritime; 0.5l/ha lower than standard; control = Very good. 1.0l/ha comparable to standard, control = Very good.
pre	VIOAR (150-300l/ha) 00-01 BBCH	7.1 (10)	**87.1**	95.1	14	96.5	Maritime; 0.5l/ha lower than standard; control = Very good. 1.0l/ha comparable to standard, control = Excellent
post	VIOAR (180-400l/ha) 10-14 BBCH	11.5 (13)	**97.1**	99.5	21	98.1	Maritime; 0.5l/ha and 1.0l/ha comparable to standard, control = Excellent
pre	APESV (200-300l/ha)	8.8 (12)	**98.9**	99.8	9	95.8	Maritime; 0.5l/ha and 1.0l/ha better than standard, control = Excellent
post	APESV (200-400l/ha) 10-12 BBCH	8.4 (3)	**95.1**	99.9	6	98.4	Maritime; 0.5l/ha and 1.0l/ha comparable to standard, control = Excellent
pre	LOLMU (150-250l/ha)	5.5 (2)	**87**	95.5	5	96	Maritime; 0.5l/ha lower than standard; control = Very good. 1.0l/ha comparable to standard, control = Excellent
post	LOLMU (150-250l/ha) 10-21 BBCH	6.5 (2)	**79.5**	91.6	6	88.4	Maritime; 0.5l/ha lower than standard; control = Moderately good. 1.0l/ha better than the standard, control = Very good
pre	POAAN (100-250l/ha) 00-03 BBCH	14.7 (10)	**98.4**	99	12	98.3	Maritime; 0.5l/ha and 1.0l/ha comparable to standard, control for the two rates = Excellent
post	POAAN (150-250l/ha)	14 (13)	**96**	98	13	98.6	Maritime; 0.5l/ha and 1.0l/ha comparable to standard, control for the two rates = Excellent
pre	ALOMY (150-300l/ha) 00-09 BBCH	20.7 (11)	**79.7**	92.6	32	92.8	Maritime; 0.5l/ha lower than standard; control = Moderately good. 1.0l/ha comparable to standard, control = Very good.
post	ALOMY (100-300l/ha) 09-13 BBCH	19.3 (17)	**73.3**	89.1	38	89.7	Maritime; 0.5l/ha lower than standard; control = Moderately good. 1.0l/ha comparable to standard, control = Very good. In NL- no moderate control accepted on label, therefore post emergence application at 0.5L/ha cannot be authorized.

Conclusion:
At the rate of 0,5 L/ha sufficient broad-leaved weeds were controlled for a claim against all broad-leaved weeds.

Of the grass weeds control of POAAN and APESV was acceptable at 0,5 L/ha both pre- and post-emergence.
For LOLMU only a limited amount of trials are available that show results that are not fully conclusive. For ALOMY control at 0,5 L/ha is insufficient (below 80/85%), in addition too few trials are available for the pre-emergence claim for ALOMY.

Impact on the crop yield

The product has demonstrated no overall effect on yield for wheat, barley, triticale and rye. However small numbers of trials did record a significant yield reduction at 2N. The applicant therefore proposes a label statement of "Do not overlap spray swaths".

In addition for wheat, triticale and rye the applicant states that important crop thinning was recorded in a small number of trials possibly associated with heavy rain following application. Therefore the applicant proposes to add the following label statement "Do not apply when heavy rain is forecast and do not use on waterlogged soil or soils prone to waterlogging. Crop thinning or reductions in crop vigour can occur if there is very wet weather after application".

In rye one trial showed significant yield reduction for the double rate of BAS 758 00 H, phytotoxicity was observed, however the sowing depth was very shallow (1.37 cm), which is not recommended for any products containing flufenacet. The applicants will add the label statement In the Netherlands, the usual seed depth is between 2-4cm and thus does not require a label statement.

In triticale three trials; showed a significant yield reduction for the double rate application, bleaching and biomass reduction were observed for one trial and bleaching and crop thinning symptoms were observed in another of these trials. The applicant proposes a label amendment.

In triticale 2 trials had recorded phytotoxicity and resulting reductions in single and double rate of BAS 758 00 H. It is proposed to add the statement "BAS 758 00 H is suitable for use on all soil types except sands and very light soils" to the product label in order to minimise any potential effects.

Bij de bespuiting dient overlap van spuitbanen zorgvuldig te worden vermeden. Na een periode met langdurige, overvloedige neerslag in de winter of bij overdosering kan gewasschade (uitdunning) optreden na een toepassing. Vanwege het risico voor gewasschade wordt de toepassing gevoelige gronden (löss; zeer lichte, humusarme zavel) ontraden.

3.1.7.1 Impact on the quality of plants and plants products

Thousand Grain Weight (TGW)
The results support a claim of no effect of BAS 758 00H at the highest recommended rate of 1.0 L/ha (240 g a.s./L flufenacet, 100g a.s./L picolinafen) on TGW, HLW for winter wheat, barley, rye and triticale. A total of 16 trials were submitted, conducted in the maritime climate zone. Across the four crops BAS 758 00H, at 1.0 L/ha produced comparable TGW to the untreated plots and the standard products at label rates.

Effects on the processing procedure
The data presented supports the applicants claim that the product at the proposed rate does not affect the processing procedure.

Adverse effects
Table 3.1.7-1: Summary of trials with phytotoxicity - post emergence

POST EMERGENCE	Efficacy trials (169 trials)		Selectivity trials (41 trials)	
Number of trials with …	BAS 758 00 H	Standard	BAS 758 00 H	Standard

		N	N	N	2N	N	2N
Maximum of phytotoxicity recorded during the trials	0%	88	102	26	23	26	27
	0% to 5%	43	45	7	8	11	8
	> 5% to 10%	19	15	3	0	3	2
	> 10% to 20%	16	3	2	2	0	2
	> 20%	3	4	3	8	1	2
Level of symptoms at the last assessments	0%	160	159	35	33	37	37
	0% to 5%	4	6	4	2	4	3
	> 5% to 10%	3	1	0	0	0	0
	> 10% to 20%	0	0	1	3	0	0
	> 20%	2	3	1	3	0	1

The data of the efficacy trials show that the product can cause phytotoxic symptoms, mostly comparable to standards and transient. However in the efficacy trials it can be seen that under certain environmental conditions the product can produce some unacceptable levels of phytotoxicity, and therefore the Ctgb has provided adequate amendments to the Dutch label to prevent the potential for phytotoxicity under certain environmental conditions.

Adverse effects on parts of plant used for propagating purposes
Germination
The results show that at 1.0 L/ha BAS 758 00H, applied pre and post-emergence produced comparable levels of germination to the untreated check and the standards. Therefore the applicant's claim of no effect on plant parts for propagation is accepted.

Succeeding crops
The data presented by the zRMS for persistence in soil and plant uptake from soil confirm that there is no reasonable risk of adverse effects on the tested succeeding crops after use of BAS 758 H, when these crops are sown/planted in the usual course of crop rotations, i.e. upon the regular harvest date of the crop treated.

The Ctgb agree with the following amendments proposed by the zRMS;
Following crops after normal harvest: There are no restrictions on following crops after the normal harvest of crops treated with BAS 758 00 H alone.

Re-drilling due to crop failure
In the event of crop failure, winter wheat can be re-sown in the same autumn provided soil is cultivated to a minimum depth of 15 cm.
Any of the following crops may be sown provided there has been a minimum of 60 days after the application of BAS 758 00 H and the soil is cultivated to a minimum depth of 15cm; legumes, maize, sugar beet and sunflower.
Oilseed rape can be re-sown after 90 days following a pre-emergence application of BAS 758 00 H, or 60 days following a post –emergence application of BAS 758 00 H and the soil is cultivated to a minimum depth of 15 cm.
Spring barley can be re-drilled 120 days following application of BAS 758 00 H and the soil is cultivated to a minimum depth of 15 cm.

The Ctgb agrees with the zRMS that a buffer zone of 1 m between a crop treated with BAS 758 00 H and a neighbouring field in which a crop is not yet or already emerged has been justified to be sufficient for not causing harmful injury to the neighbouring crop.

For the Dutch label the following statements will be required:
Bij herinzaai na het mislukken van de teelt kan na een kerende grondbewerking van minimaal 15 cm:
- wintertarwe in dezelfde herfst gezaaid worden,
- peulgroenten, mais, suikerbiet en zonnebloem 60 dagen na toepassing van het middel gezaaid worden,
- koolzaad 90 dagen na een voor-opkomst toepassing of na 60 dagen van een na-opkomst toepassing van het middel gezaaid worden,
- zomergerst 120 dagen na toepassing van het middel gezaaid worden.

Resistance
The applicant did not provide adequate information in the RR. The zRMS has used information submitted from the BAD and a separate study for resistance analysis. Ctgb agrees with the zRMS considers resistance management has been addressed with appropriate resistance statement. BAS 758 00 H contains picolinafen which is an inhibitor of carotenoid biosynthesis at the PDS step (a group that includes picolinafen and diflufenican). To prevent the development of resistant weeds herbicides with different modes of action must be used when applying in sequence.

A Dutch resistance statement will be added to the label:
Dit middel bevat de werkzame stoffen flufenacet en picolinafen. Flufenacet behoort tot de oxyacetamiden. De HRAC code is K3. Picolinafen behoort tot de pyridinecarboxamiden. De HRAC code is F1. 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.

Water volume
The applicant provides support for the water volume of 100-400 L/ha from trials submitted under 6.1.3.; efficacy and selectivity trials. All trials undertaken at the lower water volume where undertaken in the Maritime climatic zone.
Four efficacy trials and 2 selectivity trials have generated data on the safety of BAS 758 when applied in post emergence with a reduced water volume of 100 litres per hectare. No phytotoxicity symptoms were reported. No differences on the yield and quality have been recorded for these trials.

For the Dutch label the following statements will be required:
Het middel toepassen in 100-400 liter water per ha.

Tank Washing
The Ctgb agrees with the zRMS: Although a small amount of 0.25 ppm Picolinafen and 0.77 ppm Flufenacet is still left in the spray tank, after simulation the cleaning process and the refilling with a solvent- containing solution. It is not necessary to use detergents for effective cleaning. Water is sufficient for cleaning spray application equipment to avoid plant damage in crops.

3.2 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 in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.1 Ctgb juni 2015) onder de vermelde toepassingsvoorwaarden.

Toepassingsvoorwaarden:

Toepassingsgebied	Type toepassing	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per teeltcyclus
Wintergraan m.u.v. kanariegras	voor opkomst of na opkomst	Straatgras[1], windhalm[2] en eenjarige breedbladige onkruiden	0,5 L/ha	1

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is vastgesteld voor de genoemde dosering per toepassing en niet voor verlaagde doseringen.
[1] Straatgras (*Poa Annua*)
[2] Windhalm (*Apera spica-venti)*

Overige toepassingsvoorwaarden
Het middel toepassen in 100-400 liter water per ha.

Om in het water levende organismen te beschermen, is toepassing in de teelt van wintergraan met uitzondering van kanariegras, op percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruik wordt gemaakt van een techniek uit tenminste de klasse DRT90.

Bij herinzaai na het mislukken van de teelt kan na een kerende grondbewerking van minimaal 15 cm:
- wintertarwe in dezelfde herfst gezaaid worden,
- peulgroenten, mais, suikerbiet en zonnebloem 60 dagen na toepassing van het middel gezaaid worden,

- koolzaad 90 dagen na een voor-opkomst toepassing of na 60 dagen van een na-opkomst toepassing van het middel gezaaid worden,
- zomergerst 120 dagen na toepassing van het middel gezaaid worden.

Bij de bespuiting dient overlap van spuitbanen zorgvuldig te worden vermeden. Na een periode met langdurige, overvloedige neerslag in de winter of bij overdosering kan gewasschade (uitdunning) optreden na een toepassing. Vanwege het risico voor gewasschade wordt de toepassing gevoelige gronden (löss; zeer lichte, humusarme zavel) ontraden.

Dit middel bevat de werkzame stoffen flufenacet en picolinafen. Flufenacet behoort tot de oxyacetamiden. (De HRAC code is K3). Picolinafen behoort tot de pyridinecarboxamiden. (De HRAC code is F1). 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 List of data submitted

Physical and chemical properties

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Yes/No	Data protection granted Y/N	Studies relied on Y/N	Owner
KIIIA 2.1/1 KIIIA 2.4.1/1 KIIIA 2.4.2/1 KIIIA 2.5.2/1 KIIIA 2.5.3/1 KIIIA 2.6.1/1 KIIIA 2.7.1/1 KIIIA 2.7.4/1 KIIIA 2.8.2/1 KIIIA 2.8.3.1/1 KIIIA 2.8.3.2/1 KIIIA 2.8.5.2/1 KIIIA 2.8.6.1/1 KIIIA 2.8.8.2/1 KIIIA 4.1.3/1	2012 a	Physical and chemical properties of BAS 758 00 H: Accelerated storage stabiliy up to 8 weeks at 40°C in original container Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom 2012/1071936 yes Unpublished	Yes	Y	Y	BASF
KIIIA 2.2.1/1 KIIIA 2.2.2/1 KIIIA 2.3.1/1 KIIIA 2.3.3/1	2012 a	Evaluation of physical and chemical properties according to Directive 94/37/EC (Regulation (EC) No 440/2008) BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. 2012/1024848 yes Unpublished	Yes	Y	Y	BASF
KIIIA 2.7.5/1 KIIIA 2.7.6/1	2014 a	Physical and chemical properties of BAS 758 00 H: Storage stability up to 104 weeks at 23°C in original container Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom 2014/1095613 yes Unpublished	Yes	Y	Y	BASF

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Yes/No	Data protection granted Y/N	Studies relied on Y/N	Owner
KIIIA 2.9.1/1 KIIIA 2.9.2/1	2012 a	Physical and Chemical Compatibility in Aqueous Tank Mixtures of BAS 758 00 H BASF SE Agricultural Center Limburgerhof, Limburgerhof, Germany Fed.Rep. 2012/1342301 no Unpublished	Yes	Y	Y	BASF
KIIIA 4.1.2/1	2012 a	BAS 758 00 H Chemical compatibility test with HDPE BASF SE, Ludwigshafen/Rhein, Germany Fed.Rep. 2012/1024842 no Unpublished	Yes	Y	Y	BASF
KIIIA 4.2.1/1	2013 a	BAS 758 00 H: Effectiveness of procedures for cleaning application equipment and protective clothing BASF SE Agricultural Center Limburgerhof, Limburgerhof, Germany Fed.Rep. 2013/1286243 no Unpublished	Yes	Y	Y	BASF

Analytical methods

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Yes/No	Data protection granted Y/N	Studies relied on Y/N	Owner

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Yes/No	Data protection granted Y/N	Studies relied on Y/N	Owner
KIIIA 5.2.2/1	2012 a	GC method for the determination of Picolinafen and Flufenacet in BAS 758 00 H Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom 2012/1057730 no Unpublished	Yes	Y	Y	BASF
KIIIA 5.2.2/2	2013 a	GC method for the determination of Picolinafen and Flufenacet in BAS 758 00 H and BAS 758 01 H Battelle UK Ltd., Havant Hampshire PO9 1SA, United Kingdom 2013/1043052 no Unpublished	Yes	Y	Y	BASF

Mammalian toxicology

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Yes/No	Owner	Data protection granted Y/N	Studies relied on Y/N
KIIIA 7.1.1/1	2012 a	BAS 758 00 H - Acute oral toxicity in the rat - Fixed dose method 2012/1184397 yes Unpublished	Yes Used by CRD tox	BASF	y	Y
KIIIA 7.1.2/1	2012 b	BAS 758 00 H - Acute dermal toxicity (Limit test) in the rat 2012/1184399 yes Unpublished	Yes Used by CRD tox	BASF	y	Y

Annex point	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Yes/No**	**Owner**	**Data protection granted Y/N**	**Studies relied on Y/N**
KIIIA 7.1.3/1	2012 a	BAS 758 00 H - Acute inhalation toxicity (nose only) study in the rat 2012/1184400 yes Unpublished	Yes Used by CRD tox	BASF	y	Y
KIIIA 7.1.4/1	2012 a	BAS 758 00 H - Determination of skin irritation potential using the EPISKIN reconstructed human epidermis model 2012/1184401 yes Unpublished	Yes Used by CRD tox	BASF	y	Y
KIIIA 7.1.5/1	2012 b	BAS 758 00 H - The bovine corneal opacity and permeability assay 2012/1184402 yes Unpublished	Yes Used by CRD tox	BASF	y	Y
KIIIA 7.1.5/2	2012 c	BAS 758 00 H - Acute eye irritation in the rabbit 2012/1308581 yes Unpublished	Yes Used by CRD tox	BASF	y	Y
KIIIA 7.1.6/1	2012 d	BAS 758 00 H - Local lymph node assay in the mouse 2012/1184403 yes Unpublished	Yes Used by CRD tox	BASF	y	Y

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Yes/No	Owner	Data protection granted Y/N	Studies relied on Y/N
KIIIA 7.3.3/1	2000 a	Determination of dermal and inhalation exposure to operators during mixing, loading and application using Corbel with field sprayers in cereals BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2000/1013419 yes Unpublished	Yes	BASF	y	y
KIIIA 7.6.2/1	2014 b	In vitro study to investigate the dermal penetration of radiolabeled Flufenacet, formulated as BAS 758 00 H, through human skin Harlan Laboratories Ltd., Itingen, Switzerland 2012/1184396 yes Unpublished	Yes Used by CRD tox	BASF	y	y

Residues
No new studies were submitted.

Fate and behaviour
No new studies were submitted.

Ecotoxicology

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Yes/No	Data protection granted Y/N	Studies relied on Y/N	Owner

Annex point	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Yes/No**	**Data protection granted Y/N**	**Studies relied on Y/N**	**Owner**
KIIIA 10.4.2.1/1	2012 a	Effects of BAS 758 00 H (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1184410 yes Unpublished	Yes	Y	Y	BASF
KIIIA 10.4.2.2/1	2012 a	Effects of BAS 758 00 H (acute contact and oral) on honey bees (Apis mellifera L.) in the laboratory Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1184410 yes Unpublished	Yes	Y	Y	BASF
KIIIA 10.5.1/1	2012 a	Effects of BAS 758 00 H on the parasitoid Aphidius rhopalosiphi in the laboratory - Dose response test Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1184412 yes Unpublished	Yes	Y	Y	BASF

Annex point	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Yes/No**	**Data protection granted Y/N**	**Studies relied on Y/N**	**Owner**
KIIIA 10.5.1/2	2012 a	Effects of BAS 758 00 H on the predatory mite Typhlodromus pyri in the laboratory - Dose response test Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1184413 yes Unpublished	Yes	Y	Y	BASF
KIIIA 10.5.2/1	2013 b	Effects of BAS 758 00 H on the predatory mite Typhlodromus pyri, extended laboratory study - Dose response test Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2013/1132507 yes Unpublished	Yes	Y	Y	BASF

Annex point	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Yes/No**	**Data protection granted Y/N**	**Studies relied on Y/N**	**Owner**
KIIIA 10.5.2/2	2013 a	Effects of BAS 758 00 H on the predatory mite Orius laevigatus, extended laboratory study - Dose response test Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2013/1132508 yes Unpublished	Yes	Y	Y	BASF
KIIIA 10.5.2/3	2013 a	Effects of BAS 758 00 H on the reproduction of rove beetles Aleochara bilineata – Extended laboratory study - Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2013/1003081 yes Unpublished	Yes	Y	Y	BASF
KIIIA 10.5.2/3	2015	Aged-residue extended laboratory tests to determine the effects of BAS 758 00 H on the predatory mite, *Typhlodromus pyri* (Acari: Phytoseiidae)	Yes	Y	Y	BASF

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KIIIA 10.6.3/1	2012 a	Effects of BAS 758 00 H on reproduction and growth of earthworms Eisenia fetida in artificial soil with 5% peat Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1184414 yes Unpublished	Yes	Y	Y	BASF
KIIIA 10.8.1.2/1	2014 a	Effects of BAS 758 00 H on terrestrial (non-target) plants: Vegetative vigour test Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1184416 yes Unpublished	Yes	Y	Y	BASF
KIIIA 10.8.1.3/1	2014 b	Effects of BAS 758 00 H on terrestrial (non-target) plants: Seedling emergence and seedling growth test Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1184415 yes Unpublished	Yes	Y	Y	BASF

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Yes/No	Data protection granted Y/N	Studies relied on Y/N	Owner
KIIIA 10.8.2.1/1	2014 c	Toxicity of BAS 758 00 H to the aquatic plant Lemna gibba in a static growth inhibition test Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1184409 yes Unpublished	Yes	Y	Y	BASF
KIIIA 10.10.1/1	2012 a	Toxicity of BAS 758 00 H to activated sludge in a respiration inhibition test (limit study) Institut fur Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1184417 yes Unpublished	Yes	Y	Y	BASF

Efficacy

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Annex point	**Author**	**Year**	**Title** **Source (where different from company)** **Company, Report No.** **GLP or GEP status (where relevant)** **Published or Unpublished**	**Data protection claimed Yes/No**	**Data protection granted Yes/No**	**Relied on?**	**Owner**
KIIIA 6/1	Bousquet L.	2014 a	Biological Assessement Dossier - BAS 758 00 H and BAS 758 01 H - Core Dossier - Central Zone BASF plc, Cheadle Cheshire SK8 6QG, United Kingdom 2014/1099092 no Unpublished	Yes	Yes	Yes	BASF