



HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. **BESLUIT**

Op 6 mei 2013 is van

BASF Nederland B.V.
Groningensingel 1
6835 EA ARNHEM

een aanvraag tot vrijwillig zonale herregistratie van de toelating met Nederland als betrokken lidstaat ontvangen als bedoeld in artikel 33 Verordening (EG) 1107/2009 (verder te noemen: de Verordening) voor het gewasbeschermingsmiddel

Focus Plus

op basis van de werkzame stof cycloxydim. Nederland is in deze een betrokken lidstaat, als bedoeld in artikel 36, tweede lid; de beoordelend lidstaat is Oostenrijk

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)

Bij de herregistratie wordt het etiket aangepast. Daarom wordt het volgnummer van het etiket verhoogd van W.7 naar W.8.

Het betreft naast uitbreidingen van het etiket met nieuwe toepassingen ook inperkingen ten opzichte van het oude etiket met volgnummer W.7:

- Een PHI van 56 dagen voor bieten (was vrij)
- Beperking van de toepassing in bonen en erwten tot vóór de bloei
- Beperking van de toepassing in druiven tot vóór de vruchtzetting
- Klein aantal toepassingen vervalt en is niet beoordeeld
- Een nieuwe waarschuwingszin voor resistentie management wordt op het etiket geplaatst

Aan deze beperkingen liggen risico's ten grondslag, maar aanvrager geeft aan dat in de praktijk al vrijwel conform deze beperkingen wordt gehandeld met het middel. Daarom zijn de risico's zeer beperkt en is er ruimte voor respijttermijnen. Aanvrager verzoekt de maximale respijttermijnen toe te kennen, om de voorraden in de keten via afleveren en vooral opgebruik af te kunnen bouwen. Echter, omdat enig risico niet uit te sluiten valt wordt een aflevertermijn van 6 maanden en een opgebruiktermijn van aansluitend 8 maanden verleend, zodat verpakkingen met het oude etiket nog het gehele volgende gebruikseizoen opgebruikt mogen worden.

De nieuwe etikettering met W-codering W.8 dient bij de eerstvolgende aanmaak op de verpakking te worden aangebracht. De respijttermijnen vastgesteld volgens het Besluit beleidsregel respijttermijnen voor gewasbeschermingsmiddelen staan vermeld onder Toelatingsinformatie in Bijlage I bij dit besluit.

2. WETTELIJKE GRONDSLAG

Besluit	Artikel 80, vijfde lid juncto artikel 128 Wgb (oud)
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Rgb d.d. 13 juni 2011 en Evaluation Manual 1.1

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.

10866 N

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, 7 oktober 2016

HET COLLEGE VOOR DE TOELATING VAN
GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

Ir. J.F. de Leeuw
Voorzitter

10866 N

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

<i>Aanvraagnummer:</i>	20130607 NLTHG
<i>Type aanvraag:</i>	Vrijwillig zonale aanvraag tot herregistratie van gewasbeschermingsmiddeltoelating met Nederland als betrokken lidstaat
<i>Middelnaam:</i>	Focus Plus
<i>Formele registratiedatum: *</i>	15 mei 2013
<i>Datum in behandeling name:</i>	
<i>Datum compliance check:</i>	11 november 2011

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

2.2 Stofinformatie

Werkzame stof	Gehalte
cycloxydim	100G/L

De stof is per 1 juni 2011 geplaatst op Annex I van Richtlijn 91/414/EEG (Dir 2011/4/EC d.d. 20 januari 2011) en vervolgens bij Uitvoeringsverordening (EU) [540/2011](#) d.d. 25 mei 2011 goedgekeurd) De goedkeuring van deze werkzame stof expireert op 31 mei 2021.

2.3 Toelatingsinformatie

<i>Toelatingsnummer:</i>	10866 N
<i>Expiratiedatum:</i>	1 oktober 2026
<i>Afgeleide parallel of origineel:</i>	n.v.t.
<i>Biocide, gewasbeschermingsmiddel of toevoegingsstof:</i>	Gewasbeschermingsmiddel
<i>Gebruikers:</i>	Professioneel

W-coderingen en aflever- en opgebruiktermijnen:

▪ <i>W-codering professioneel gebruik:</i>	8
▪ <i>Vorige w-codering professioneel gebruik:</i>	7
▪ <i>Aflevertermijn professioneel gebruik:</i>	1 april 2017
▪ <i>Opgebruiktermijn professioneel gebruik:</i>	1 december 2017

2.4 Verpakkingsinformatie

<i>Aard van het preparaat:</i>	Emulgeerbaar concentraat
--------------------------------	--------------------------

BIJLAGE II Etikettering van het middel Focus Plus

Professioneel gebruik

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:
cycloxydim, Koolwaterstoffen, C10, aromaten, <1% naftaleen

Pictogram	GHS07 GHS08
Signaalwoord	GEVAAR
Gevarenaanduidingen	H304 Kan dodelijk zijn als de stof bij inslikken in de luchtwegen terechtkomt. H315 Veroorzaakt huidirritatie. H319 Veroorzaakt ernstige oogirritatie. H336 Kan slaperigheid of duizeligheid veroorzaken. H361d Wordt ervan verdacht het ongeboren kind te schaden.
Voorzorgsmaatregelen	P261 Inademing van stof/rook/gas/nevel/damp/spuitnevel vermijden. P280 Beschermende handschoenen/beschermende kleding/oogbescherming/gelaatsbescherming dragen. P301 + P310 NA INSLIKKEN: Onmiddellijk een ANTIGIFCENTRUM/arts/... raadplegen. P305 + P351 + P338 BIJ CONTACT MET DE OGEN: voorzichtig afspoelen met water gedurende een aantal minuten; contactlenzen verwijderen, indien mogelijk. Blijven spoelen. P308 + P311 Na (mogelijke) blootstelling: een ANTIGIFCENTRUM/arts/... raadplegen. P331 GEEN braken opwekken. P403 + P233 Op een goed geventileerde plaats bewaren. In goed gesloten verpakking bewaren. P501 Inhoud/verpakking afvoeren naar SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Aanvullende etiketelementen	EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

**REGISTRATION REPORT
Part A**

Risk Management

Product code: Focus Plus (BAS 517 24 H)

Active Substance: Cycloxydim 100 g/L

Central Zone

Zonal Rapporteur Member State: Austria

NATIONAL ADDENDUM - The Netherlands

Applicant: BASF

Date: September 2016

Table of Contents

PART A	Risk Management	3
1	Details of the application	3
2	Details of the authorisation	5
3.3	Substances of concern for national monitoring	34
3.4	Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation	34
Appendix 1	Copy of the product label	35
Appendix 2	Letter of Access.....	42

PART A Risk Management

This document describes the acceptable use conditions required for the national registration of Focus Plus containing 100 g/L cycloxydim in the Netherlands. This evaluation is required subsequent to the inclusion of cycloxydim on Annex I, effective from 1st June 2011.

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 level in accordance with the conclusions from the EU review of the active substances. It also includes assessment of data and information relating to Focus Plus where that data has not been considered in the EU review. Otherwise assessments for the safe use of Focus Plus have been made using endpoints agreed in the EU review of cycloxydim.

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

Appendix 1 of this document provides a copy of the final product authorisation.

Appendix 2 of this document is a copy of the approved product label.

1 Details of the application

1.1 Application background

This application was submitted by BASF, represented by the following affiliate:

BASF Nederland B.V.
Groningensingel 1
6835 EA Arnhem
Netherlands

The application was for approval of Focus Plus, an EC (emulsifiable concentrate) formulation containing 100 g/l cycloxydim for use as a herbicide in several crops (for details please see below point 2.3, product uses).

1.2 Annex I inclusion

Cycloxydim was included on Annex I of Directive 91/414/EEC on 01 June 2011 under Inclusion Directive 2011/4/EU.

The Annex I Inclusion Directive of cycloxydim provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles of Regulation (EU) No 546/2011 (formerly Annex VI of Directive 91/414/EEC), the conclusions of the review report on cycloxydim and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 November 2010 shall be taken into account.

In this overall assessment:

Member States must pay particular attention to:

- the risk to non-target plants and ensure that conditions of use prescribe the application of adequate risk mitigation measures

These concerns were all addressed in the submission.

1.3 Regulatory approach

To obtain approval, Focus Plus must meet the conditions of the Annex I inclusions for the active substances and must be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, considering Annex I agreed end-points and additional data where appropriate.

This application was submitted in order to allow the re-registration of Focus Plus in the Netherlands in accordance with the above.

1.4 Data protection claims

Data protection is claimed for studies submitted with this application. For details on data protection claims, please refer to Appendix 1 of each section in the Registration Report.

1.5 Letters of Access

Where third party data have been used information is given in the reference list and the Letter of Access is included in Part K, respectively.

2 Details of the authorisation

2.1 Product identity

Product Name	BAS 517 24 H Focus plus
Authorization Number (for re-registration)	10866 N
Function	Herbicide
Applicant	BASF SE
Composition	100 g/L cycloxydim
Formulation type	Emulsifiable concentrate [Code: EC]

Packaging:

Focus Plus is to be marketed in high-density polyethylene containers with an inner barrier, e.g., polyamide (PA/PE). They are sealed by foil seals or by polyamide laminated PE-foam gaskets, protected by screw caps of polyethylene.

0.15 litre bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 63 mm diameter x 92 mm
	opening:	42 mm inner diameter
	closure:	polyethylene screw cap
	seal:	HF-seal
0.25 litre bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 63 mm diameter x 126 mm
	opening:	42 mm inner diameter
	closure:	polyethylene screw cap
	seal:	HF-seal
0.5 litre bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 69 mm diameter x 185.5 mm
	opening:	42 mm inner diameter
	closure:	polyethylene screw cap
	seal:	HF-seal
1 litre bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
	opening:	42 mm inner diameter
	closure:	Polypropylene/Polyethylene screw cap

	seal:	Induction sealed
1 litre eco-bottle:	material:	PA/PE (Coex)
	shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
	opening:	54 mm mm inner diameter
	closure:	Polypropylene/Polyethylene screw cap
	seal:	gasket
3 litre container:	material:	PA/PE (Coex)
	shape/size:	rectangular / approx. 190 mm x 140 mm x 241 mm
	opening:	54 mm inner diameter
	closure:	polypropylene screw cap
	seal:	Induction sealed
5 litre container	material:	PA/PE (Coex)
	shape/size:	rectangular / approx. 190 mm x 140 mm x 313 mm
	opening:	54 mm inner diameter
	closure:	polypropylene screw cap
	seal:	HF-seal
5 litre eco-container	material:	PA/PE (Coex)
	shape/size:	rectangular / approx. 185 mm x 136 mm x 313 mm
	opening:	54mm inner diameter
	closure:	polypropylene screw cap
	seal:	gasket
10 litre container	material:	PA/PE (Coex)
	shape/size:	rectangular / approx. 230 mm x 165 mm x 375 mm
	opening:	54 mm inner diameter
	closure:	polypropylene screw cap
	seal:	Induction sealed
10 litre eco-container	material:	PA/PE (Coex)
	shape/size:	rectangular / approx. 230 mm x 187 mm x 358 mm
	opening:	54mm inner diameter
	closure:	polypropylene screw cap
	seal:	gasket

2.2 Classification and labelling

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

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 *:

cycloxydim, Hydrocarbons, C10, aromatics, <1% naphthalene

Pictogram:	GHS07 GHS08	Signal word:	danger
H-statements:	H304 H315 H319 H336 H361d	May be fatal if swallowed and enters airways. Causes skin irritation. Causes serious eye irritation. May cause drowsiness or dizziness. Suspected of damaging the unborn child.	
P-statements:	P280 P261 P301 + P310 P308 + P311 P305 + P351 + P338 P331 P403 + P233 P501	Wear protective gloves/protective clothing/eye protection/face protection. Avoid breathing dust/fume/gas/mist/vapours/spray. IF SWALLOWED: Immediately call a POISON CENTER/doctor/... IF exposed or concerned: Call a POISON CENTER/doctor/... IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Do NOT induce vomiting. Store in a well-ventilated place. Keep container tightly closed. Dispose of contents/container to	
Supplemental Hazard information:	EUH401 SP1	To avoid risks to human health and the environment, comply with the instructions for use. Do not contaminate water with the product or its container.	

Child-resistant fastening obligatory?	n.a.
Tactile warning of danger obligatory?	n.a.

Explanation:

Pictogram:	-
H-statements:	The labelling of the mixture is based on the formulation's

	acute/chronic aquatox studies and its degradation.
P-statements:	Proposal by applicant was followed.
Other:	According to Reg. (EC) 547/2011 all plant protection products shall be labelled with the supplement phrase SP1.

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

2.2.2 Other phrases

To avoid risks to man and the environment, comply with the instructions for use. Safety data sheet available for professional user on request.

Based on the evaluation and where indicated on the GAP, the following restrictions and warning sentences have to be included on the Legal Instructions for Use:

In de teelt van vezelvlas, aardbei, sla, spinazie, sluitkool, spruitkool, bloemkool, bladkoolachtigen, alfalfa/luzerne en klaver, het middel toepassen in 100-400 liter water per ha. In de teelt van druif het middel toepassen in 200-400 liter water per ha. In de overige gewassen het middel toepassen in 200-400 liter water per ha. (GAP wijkt af van standaard).

Gebruik is uitsluitend toegestaan door middel van daartoe geëigende apparatuur, te weten een machinaal voortgetrokken veldspuit, omdat gezondheidseffecten niet zijn uit te sluiten bij toepassing met een handspuit.

De volgende veiligheidstermijnen dienen opgenomen te worden in het wettelijk Gebruiksvoorschrift (WG):

- sla: veiligheidstermijn van 21 dagen
- bloemkool, sluitkool, spinazie: veiligheidstermijn van 28 dagen
- bladkoolachtigen en aardbei: veiligheidstermijn van 42 dagen
- bieten en spruitkool: veiligheidstermijn van 56 dagen

In de teelt van druiven het middel vóór vruchtzetting (BBCH 60) toepassen.

In de teelt van peulvruchten, boon met peul, boon zonder peul, erwt met peul en erwt zonder peul het middel vóór de bloei (BBCH 39) toepassen. (part evaluation and part GAP limitations)

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

Gezien het grote aantal variëteiten en de wisselende teeltomstandigheden van sierteeltgewassen is het onmogelijk de gewasverdraagzaamheid voor alle situaties te onderzoeken. Als er nog geen ervaring is opgedaan met dit middel wordt aangeraden om eerst een proefbespuiting uit te voeren om de verdraagzaamheid van het gewas te testen.

Na toepassing geldt een wachttijd van 4 weken voor de zaai van grassen (Poaceae).

Resistentiemanagement

Dit middel bevat de werkzame stof cycloxydim. Cycloxydim behoort tot de cyclohexanedionen. De HRAC code is A. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in voorlichtingsboodschappen, op te volgen.

2.3 Product uses

Table 2.3 A; Uses applied for; Focus Plus – Cycloxydim 100 g/l

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,as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
2	Netherlands	Alfalfa (for seed production only, not for feeding)	F	annual, perennial grasses	spraying	BBCH 11-51 April-October	1	4-5	400-500	100- 400	-	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha
6	Netherlands	Beans (dry without pod)	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	200- 400	56	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
11	Netherlands	Beans (green without pod, green with pod)	F	annual, perennial grasses	spraying	BBCH 12-3 April-June	1	4-5	400-500	200- 400	28	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Max. 5 L product/ha per 12 months

15	Netherlands	Beets	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	200-400	F	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
25	Netherlands	Cabbages (head cabbages and leafy brassica)	F	annual, perennial grasses	spraying	BBCH 12 - 45 April-June	1	4-5	400-500	100-400	F	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
29	Netherlands	Carrot	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	200-400	35	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
32	Netherlands	Cauliflower	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	100-400	F	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
37	Netherlands	Clover (for seed production only, not for feeding)	F	annual, perennial grasses	spraying	BBCH 12-19 April-June	1	4-5	400-500	100-400	F	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha
42	Netherlands	Corn/Maize (cycloxydim-tolerant varieties)	F	annual, perennial grasses	spraying	BBCH 12-19 April-June	1	4	400	100-400	F	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha

45	Netherlands	Fescue grasses, Festuca (for seed production)	F	annual, perennial grasses	spraying	BBCH 14-34 April-October	1	4-5	400-500	200-400	n.a.	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use apply in autumn
55	Netherlands	Flax/Linseed	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	100-400	F	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha
57	Netherlands	Grapes	F	annual, perennial grasses	spraying	application before the fruit is present (<BBCH 60) April-July	1	4-5	400-500	200-400	42	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
59	Netherlands	Green fertiliser crops except grass family green fertilisers	F	annual, perennial grasses	spraying	BBCH 14-34 April-October	1	4-5	400-500	200-400	-	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha apply July to September
63	Netherlands	Leek	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	200-400	42	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
67	Netherlands	Lettuce	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	100-400	F	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha Max. 5 L product/ha per 12 months

78	Netherlands	Oilseed rape, spring and winter	F	annual, perennial grasses	spraying	BBCH 12-32 April-June	1	4-5	400-500	200-400	F	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha apply in autumn
86	Netherlands	Spring onions	F	annual, perennial grasses	spraying	BBCH 15-45 April-June	1	4-5	400-500	200-400	28	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
92	Netherlands	Ornamentals	F	annual, perennial grasses	spraying	throughout the season BBCH 00-97 Feb-Sept	1	4-5	400-500	200-400	n.a.	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Flower bulbs and flower corm crops including amaryllis and dahlia, Flower seed crops, Perennial plants, Tree nursery crops, Woody plantings
97	Netherlands	Peas (dry without pod), excluding lentils	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	200-400	56	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
104	Netherlands	Peas (green without pod, green with pod)	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	200-400	35	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
109	Netherlands	Pome Fruits	F	annual, perennial grasses	spraying	throughout the season, below the crop BBCH 00-97 Feb-Sept	1	4-5	400-500	300-400	28	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha After BBCH 70 max 2 l/ha
116	Netherlands	Potatoes	F	annual, perennial grasses	spraying	BBCH 10-39 April-June	1	4-5	400-500	200-400	56	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha

127	Netherlands	Spinach	F	annual, perennial grasses	spraying	BBCH 12-19 April-June	1	4-5	400-500	100-400	F	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Max. 5 L product/ha per 12 months Minor use Based on acreage < 5000 ha
129	Netherlands	Stone Fruits (Peach, Nectarine, Apricot)	F	annual, perennial grasses	spraying	throughout the season, below the crop Feb-Sept	1	4-5	400-500	200-500	28	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha After BBCH 70 max 2 l/ha
133	Netherlands	Strawberry	F	annual, perennial grasses	spraying	BBCH 11-16 April-June	1	4-5	400-500	100-400	F	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha

The use in cycloxydim tolerant varieties of 'maize was withdrawn in the intake phase of the application.

The use in pome fruit and stone fruit is withdrawn by the applicant during the evaluation. For those aspects for which the risk assessment for pome and stone fruits turned out acceptable, these uses were not removed from the evaluation.

Table 2.3 B; Authorized Uses; Focus Plus – Cycloxydim 100 g/l

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,as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
2	Netherlands	Alfalfa (for seed production only, not for feeding)	F	annual, perennial grasses	spraying	BBCH 11-51 April-October	1	4-5	400-500	100-400	-	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha
6	Netherlands	Beans (dry without pod)	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	200-400	56	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
11	Netherlands	Beans (green without pod, green with pod)	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	200-400	28	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Max. 5 L product/ha per 12 months
15	Netherlands	Beets	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	200-400	56	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha

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,as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
25	Netherlands	Kale	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	100-400	42	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
25	Netherlands	Chinese cabbage	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	100-400	42	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
25	Netherlands	head cabbages excluding Brussels sprouts	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	100-400	28	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
25	Netherlands	Brussels sprouts	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	100-400	56	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
29	Netherlands	Carrot	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	200-400	35	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
32	Netherlands	Cauliflower	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	100-400	28	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha

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,as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
37	Netherlands	Clover (for seed production only, not for feeding)	F	annual, perennial grasses	spraying	BBCH 12-19 April-June	1	4-5	400-500	100-400	-	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha
45	Netherlands	Fescue grasses, Festuca (for seed production)	F	annual, perennial grasses	spraying	BBCH 14-34 April-October	1	4-5	400-500	200-400	-	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use
55	Netherlands	Flax/Linseed	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	100-400	-	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha
57	Netherlands	Grapes	F	annual, perennial grasses	spraying	application before the fruit is present (<BBCH 60) April-July	1	4-5	400-500	200-400	42	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha

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,as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
59	Netherlands	Green fertiliser crops except grass family green fertilisers	F	annual, perennial grasses	spraying	BBCH 14-34 April-October	1	4-5	400-500	200-400	-	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
63	Netherlands	Leek	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	200-400	42	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
67	Netherlands	Lettuce	F	annual, perennial grasses	spraying	BBCH 12-45 April-June	1	4-5	400-500	100-400	21	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha Max. 5 L product/ha per 12 months
78	Netherlands	Oilseed rape, spring and winter	F	annual, perennial grasses	spraying	BBCH 12-32 March-May Aug-Nov	1	4-5	400-500	200-400	-	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
86	Netherlands	Spring onions	F	annual, perennial grasses	spraying	BBCH 15-45 April-June	1	4-5	400-500	200-400	28	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha

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,as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
92	Netherlands	Ornamentals	F	annual, perennial grasses	spraying	throughout the season BBCH 00-97 Feb-Sept	1	4-5	400-500	200-400	-	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Flower bulbs and flower corm crops including amaryllis and dahlia, Flower seed crops, Perennial plants, Tree nursery crops,
92	Netherlands	Woody plantings	F	annual, perennial grasses	spraying	throughout the season BBCH 00-97 Feb-Sept	1	4-5	400-500	200-400	-	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
97	Netherlands	Peas (dry without pod), excluding lentils	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	200-400	56	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
104	Netherlands	Peas (green without pod, green with pod)	F	annual, perennial grasses	spraying	BBCH 12-39 April-June	1	4-5	400-500	200-400	35	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha
116	Netherlands	Potatoes	F	annual, perennial grasses	spraying	BBCH 10-39 April-June	1	4-5	400-500	200-400	56	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha

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,as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
127	Netherlands	Spinach	F	annual, perennial grasses	spraying	BBCH 12-19 April-June	1	4-5	400-500	100-400	28	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Max. 5 L product/ha per 12 months Minor use Based on acreage < 5000 ha
133	Netherlands	Strawberry	F	annual, perennial grasses	spraying	BBCH 11-16 April-June	1	4-5	400-500	100-400	42	annual grasses: 1-2 L product/ha perennial grasses: 4-5 L product/ha Minor use Based on acreage < 5000 ha

Risk management

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

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

The product is an emulsifiable concentrate. All studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. Focus Plus is a clear liquid with a moderate aromatic odour which can be diluted with water resulting in a low-foaming emulsion. Focus Plus is non-explosive and not oxidizing. The flash point was found to be 74°C and the self-ignition temperature is approx. 350°C. Its technical characteristics are acceptable for an emulsifiable concentrate formulation.

An accelerated storage test for two weeks at 54°C and shelf-life study in HDPE/PA for 24 months at ambient temperature indicated a storage stability of two years of Focus Plus.

Focus Plus

Implications for labelling: The product will be classified with the risk phrase H304 (May be fatal if swallowed and enters airways.)

Compliance with FAO specifications: The investigations of the physical and chemical properties have shown that the product Focus Plus complies with FAO specifications.

Compatibility of mixtures: No mixing is proposed on the Dutch label

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

Focus Plus is to be marketed in high-density polyethylene containers with an inner barrier, e.g., polyamide (PA/PE). They are sealed by foil seals or by polyamide laminated PE-foam gaskets, protected by screw caps of polyethylene.

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

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

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

Focus Plus was the representative formulation in the EU review of cycloxydim. Analytical methods for determination of the active substance cycloxydim, the impurities and relevance of

CIPAC methods in Focus Plus were evaluated as part of the EU review of cycloxydim and are considered adequate.

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

Analytical methods developed for cycloxydim in plant and animal matrices were provided in the EU review for cycloxydim and were considered adequate.

Analytical methods for residues of cycloxydim in food of plant or animal origin

Crop/Matrix	EU agreed method (EFSA Conclusion, July 2010; EFSA Journal 2010; 8(7):1669)	Proposed Method
Food of plant origin (risk assessment)	Not specified	Method No. 263 Method No. 263/1 Method No. 263/2 Method No. 263/3 Method No. 407 Method No. 407/1 Method No. 493
Food of plant origin (MRL enforcement)	Method No. 407/1, LC-MS/MS Method No 407/0 (onions) LC-MS/MS	Method No. 407/1, LC-MS/MS
Food of animal origin (risk assessment)	Not specified	Method No 982 Method No 513 Method No. L0105/01
Food of animal origin (MRL enforcement)	Method No. L0105/01, LC-MS/MS	Method No. L0105/01, LC-MS/MS

These methods fulfil the EU requirements regarding specificity, repeatability, and limit of quantitation and are considered adequate.

All analytical methods for determination of cycloxydim residues in the environmental matrices soil, water, and air are active substance data. The analytical methods for determination of cycloxydim residues were already EU reviewed and considered adequate. One additional soil, water method (not yet EU reviewed) is provided. This method fulfils the EU requirements regarding specificity, repeatability, and limit of quantitation and are considered adequate. The analytical method for the determination of residues in surface water has an LOQ < 0.1 µg/L and meets the Dutch national requirement.

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

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

Focus Plus was the representative formulation in the EU review of cycloxydim. The acute toxicity studies for Focus Plus were evaluated during the review and were considered adequate.

Table 3.1.3.1-1: Acute toxicological data

Parameter [Reference]	Species	Result mg/kg bw or mg/L or effect	Classification according to Reg (EC) No 1272/2008
Acute oral LD ₅₀ *	Rat	> 2200 mg/kg bw	–
Acute dermal LD ₅₀ *	Rat	> 2000 mg/kg bw	–
Acute inhalation LC ₅₀ *	Rat	> 5.3 mg/L;	–
Skin irritation*	Rabbit	Skin irritant	Skin irrit. 2; H315
Eye irritation	Rabbit	Reversible eye irritation not resulting in classification according to DSD criteria Considered as eye irritant according to CLP criteria	Eye irrit. 2; H319
Skin sensitisation	Guinea pig	Not a skin sensitizer	–

* Studies were performed with BAS 517 22 H (minor change in composition compared to BAS 517 24 H)

Focus Plus containing 100 g/L Cycloxydim has a low toxicity in respect to acute oral, dermal and inhalation toxicity and is not a skin sensitizer in the guinea pig. In rabbit studies signs of skin and eye irritation were found. Due to the presence of solvent naphtha, the product is additionally considered to be an aspiration hazard and to result in narcotic effects.

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

Focus Plus was the representative formulation in the EU review of Cycloxydim. Based on a new EFSA guidance on dermal penetration (EFSA Journal 2012;10(4):2665) and additionally based on the intention to use Focus Plus in combination with the adjuvant Dash, it was necessary to recalculate the dermal penetration of Cycloxydim in Focus Plus.

The following endpoints were used in the risk assessment:

Endpoint	Endpoint used in risk assessment
	Cycloxydim
Dermal penetration ¹	
Concentrate:	5%
Spray dilutions:	16% for a spray dilution of 400 L water/ha (various crops, except stone fruits) and 24% for a spray dilution 500 L water/ha (only stone fruits).
EU-AOEL	0.1 mg/kg bw/day

For the uses applied for also manual downward spraying should be taken into account. However, the applicant proposed the following restriction sentence which excludes manual application:

In Dutch: *Gebruik is uitsluitend toegestaan door middel van daartoe geëigende apparatuur, te weten een machinaal voortgetrokken veldspuit, omdat gezondheidseffecten niet zijn uit te sluiten bij toepassing met een handspuit.*

According to the model calculations, it can be concluded that the risk for the operator using Focus Plus is acceptable for mechanical application. For the application in various crops, except stone fruits the estimated operator exposure is 99% of the EU-AOEL and for stone fruits the exposure is 41% of the NL-AOEL.

Given the skin irritating potential of Focus Plus impermeable gloves should be worn when handling the concentrate. Gloves should also be used for the maintenance of the sprayer during application.

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

The bystander exposure estimated using EUROPOEM II is below the EU-AOEL for cycloxydim. Therefore, it is concluded that there is no undue risk to any bystander during and following application of Focus Plus (the estimated exposure is 4% of the EU-AOEL).

In addition, with the use of the German and UK model also no adverse health effects are expected for nearby non-work related bystanders and residents due to exposure to cycloxydim during application of Focus Plus (the highest estimated exposure is 6% of the systemic AEL).

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

Exposure and risk evaluations for re-entry workers were performed for the application of Focus Plus in vegetable crops. The dermal exposure assessment was performed according to EUROPOEM guidance using default dislodgeable foliar residue (DFR) estimates for Cycloxydim. Based on default assumptions for dislodgeable foliar residues it is concluded that the risk is acceptable for the worker wearing adequate work clothing (but no PPE), when re-entering crops treated with BAS 517 24 H. The predicted systemic exposure for Cycloxydim is 12% of the AOEL for crop inspection activities and 80% for harvesting vegetables.

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

The metabolism and residue studies of cycloxydim have been evaluated by Austria as the Rapporteur Member State (RMS) in context of the Annex I inclusion procedure. Cycloxydim is included in Annex I since June 2011 (Commission Decision 2011/4/EU). The representative uses evaluated in the peer review were outdoor foliar applications against perennial grasses in oilseed rape, sugar beet, potato, bean, and tolerant maize. The Draft Assessment Report (DAR) of cycloxydim has been peer reviewed and an EFSA conclusion is available (EFSA, 2010). In addition to these, uses on pome fruits, stone fruits, grapes, strawberries, carrots, spring onions, cauliflower, head cabbages, Brussels sprouts, curly kale/Chinese cabbage, lettuce, spinach, green peas, leek and linseed are applied for national registration and are included in this dossier.

For the implementation of the uniform principles as referred to in Article 29 (6) of Regulation (EC) No. 1107/2009, the conclusions of the Review Report on the cycloxydim, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23/11/10 shall be taken into account.

The MRLs for cycloxydim are published in Regulation (EC) No 396/2005 by Reg. (EU) No 149/2008. On 5 July 2013 the Codex Alimentarius Commission (CAC) adopted Codex maximum residue limits (CXLs) for cycloxydim. Many of these CXLs have been taken over in the EU legislation by Regulation (EU) 491/2014.

In accordance with Article 6 of Regulation (EC) No 396/2005, Germany received an application from company BASF SE to modify the existing MRLs for cycloxydim in a wide range of crops. Many of the MRL proposals had in the meanwhile been evaluated by the Joint FAO/WHO Meeting on Pesticide Residues and implemented in the EU legislation. Only those crops for which an increase in the existing MRL for cycloxydim is still required according to the original application were considered by EFSA. According to EFSA, the data are sufficient to derive MRL proposals on beetroots, celeriacs, horseradishes, Jerusalem artichokes, parsnips, salsifies, swedes, aubergines, Brussels sprouts, head cabbages, Chinese cabbages, kales, escaroles, purslanes, beet leaves, rapeseeds, herbal infusions from roots and horseradish spices. These new MRLs were adopted in the Standing Committee on Plants, Animals, Food and Feed (SCPAFF) in December 2015 (SANTE/12095/2015) and are published in Commission Regulation (EU) 2016/486 of 29 March 2016.

Assessment concerning residue behaviour is covered by detailed evaluations presented in the Core assessment, Part B, section 4 prepared by ZRMS Austria. Where appropriate this document refers to the Core assessment prepared by ZRMS Austria. The national addendum reviews additional information that has not previously been considered by ZRMS Austria. In this document the GAPs applied for in the Netherlands will be compared with the critical GAPs used to set the EU MRL. A justification is presented to show that the GAPs applied for at National level are covered by the critical EU GAPs for MRL setting.

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

MRLs for cycloxydim are established in Regulation (EC) No 396/2005 published in Commission Regulation (EU) 2016/486 of 29 March 2016. Provided that Focus Plus is applied according to the proposed outdoor GAPs on potatoes, beets, dry beans and peas (excluding lentils), rape seed, grapes, green beans (with and without pods), green peas (with and without pods), cauliflower, leafy brassica, head cabbage, Brussels sprouts, carrots, spring onions, leek, linseed, strawberry, lettuce and spinach, the currently established MRL for cycloxydim will not be exceeded. However, in accordance with the residue trials provided by the applicant a PHI must be stated in the Legal Conditions for Use (WG) for the following crops:

- Lettuce: PHI 21 days
- Cauliflower, head cabbage, spinach: PHI 28 days
- Leafy brassica and strawberry: PHI 42 days
- Beets and Brussels sprouts: PHI 56 days

For grapes it needs to be stated in the Legal Conditions for Use (WG) that application must take place before the fruit is present. For green beans without pods it needs to be stated in the Legal Conditions for Use (WG) that application must take place before flowering.

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

In the most recent Reasoned opinion on the modification of the existing MRLs for cycloxydim (EFSA Journal 2015; 13 (9): 4219) all uses supported in this national addendum were included in the TMDI calculation. For the calculation of the chronic exposure, EFSA used median residue values (STMR) derived from the residue trials on the crops under consideration. Where lower MRL or no MRL values were derived from the submitted trials, the existing MRL was used as input value. For the remaining commodities of plant and animal origin, the existing MRLs as established by Regulation (EU) No 491/2014 were taken as input values. For several crops, the STMR values corresponding to the CXL available from the JMPR evaluation (FAO, 2013) were considered.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo model. The highest chronic intake was estimated to be 68 % of the ADI (FR, toddler).

The acute exposure assessment was carried out by means of the EFSA chronic and acute risk assessment model revision 2, the estimated highest residues values resulting from supervised residue were used for calculation.

Based on the different calculations made to estimate the risk for consumer through diet and other means it can be concluded that the use of the product Focus Plus does not lead to an unacceptable risk for consumers when applied according to the recommended use pattern.

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

The environmental fate and behaviour of the active substance cycloxydim and its main metabolites were assessed in the context of Annex I inclusion and the results of the peer review are summed up in the EFSA conclusion on cycloxydim (EFSA Journal 2010; 8(7):1669; SANCO/12492/2010 final).

All environmental fate studies performed with the active substances or metabolites are adequate to support the proposed use of the formulated product Focus Plus. Thus, no extra studies with the product were conducted.

Appropriate endpoints for PEC calculations were derived from the study data in accordance with the conclusions from the EU review and national requirements. A summary of the PEC values is given hereafter.

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

Calculations for the active substance cycloxydim and its soil metabolites were based on the recommendations of the FOCUS workgroup on degradation kinetics, assuming a soil bulk density of 1.5 g cm⁻³ and a soil layer depth of 5 cm for the calculations. A crop-independent worst-case scenario for application of Focus Plus as pre-emergence scenario without interception was considered for calculating PEC_{soil}. Since the worst-case field DT₅₀ value of BH 517-T2SO and BH 517-T2SO2 in soil exceeded 90 days, their potential of accumulation in soil was assessed.

Table Fout! Gebruik het tabblad Start om Überschrift 4 toe te passen op de tekst die u hier wilt weergeven.-1: $PEC_{soil,max}$ and $PEC_{soil,accu}$ values of cycloxydim and its metabolites after application of 500 g cycloxydim ha^{-1} (no interception)

Compound	$PEC_{soil,max}$	$PEC_{soil, plateau}$	$PEC_{soil,accu}$ (= $PEC_{soil,plateau} + PEC_{soil,max}$)
	0 - 5 cm depth	0 - 20 cm depth	0 - 5 cm depth
	[$mg\ kg^{-1}$]	[$mg\ kg^{-1}$]	[$mg\ kg^{-1}$]
Cycloxydim	0.667	-	-
BH 517 - TSO	0.699	-	-
BH 517 – TSO2	0.070	-	-
BH 517 – T2SO	0.246	0.045	0.291
BH 517 – T2SO2	0.063	0.002	0.065

The results are considered acceptable for subsequent ecotoxicological assessments.

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

Calculations for cycloxydim and its metabolites were based on the guidance of the FOCUS groundwater workgroup (2000, 2009, 2011). The simulations were performed assuming worst-case application scenarios with the model FOCUS-PEARL 4.4.4 for the FOCUS groundwater scenario relevant at national level (Kremsmünster) available for all relevant field crops in a post-emergence scenario.

In addition, grass as surrogate crop for alfalfa, oil poppy, clover and fescue grass seed production, was simulated throughout the year. Moreover, application to grass underneath grapes was simulated with FOCUS_{gw} crop “vines”. For the NL specific scenario, winter cereals was simulated for the spring and autumn scenario as well.

The leaching potential of substances to the shallow groundwater is calculated using the GeoPEARL model. Results are examined against the standard of 0.01 $\mu g/L$. This is the standard of 0.1 $\mu g/L$ with an additional safety factor of 10 for vulnerable groundwater protection areas (NL-specific situation). The results show that the predicted leachate concentrations, for active substance and metabolites are smaller than 0.01 $\mu g/L$. Leaching of unacceptable amounts of the active substance and its metabolites after application of the formulated product Focus Plus for the requested uses is not expected.

3.1.5.2.2 Monitoring data groundwater

There are no data available regarding the presence of the substance cycloxydim in groundwater.

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

The calculations for PEC of cycloxydim and its metabolites in surface water (PEC_{sw}) and sediment (PEC_{sed}) were calculated with TOXSWA v1.0 for autumn and spring application

according to the Dutch recommendations on the surface water assessment. Since spray drift is the only entry path in the Dutch surface water assessment, formation of metabolites in soil is not considered in the PEC_{sw} and PEC_{sed} calculations. Calculations were carried out for a single crop-independent (pre-emergence) application of Focus Plus, taking into account the maximum application rate in the GAP.

Table Fout! Gebruik het tabblad Start om Überschrift 4 toe te passen op de tekst die u hier wilt weergeven.-1: Maximum PEC_{sw} , TWA_{sw} and PEC_{sed} of cycloxydim following single application of 500 g ha⁻¹;

Scenario	PEC_{sw} [$\mu\text{g L}^{-1}$]	TWA_{sw} [$\mu\text{g L}^{-1}$]	TWA_{sw} [$\mu\text{g L}^{-1}$]	TWA_{sw} [$\mu\text{g L}^{-1}$]	PEC_{sed} [mg L^{-1}]	$PEC_{sed}^{\#}$ [$\mu\text{g kg}^{-1}$]
	0 days	4 days	21 days	28 days	0 days	0 days
Dutch Spring Scenario	2.380	2.243	1.91	1.781	0.002	28.625
Dutch Autumn Scenario	2.380	1.718	0.331	0.248	0.002	25.125

[#] Bulk density of 80 kg m⁻³

Table Fout! Gebruik het tabblad Start om Überschrift 4 toe te passen op de tekst die u hier wilt weergeven.-2: Maximum PEC_{sw} , TWA_{sw} and PEC_{sed} of the aquatic metabolites of cycloxydim following a single application of 500 g ha⁻¹ (calculated with TOXSWA for the Dutch spring and autumn scenarios)

Scenario	PEC_{sw} [$\mu\text{g L}^{-1}$]	TWA_{sw} [$\mu\text{g L}^{-1}$]	TWA_{sw} [$\mu\text{g L}^{-1}$]	TWA_{sw} [$\mu\text{g L}^{-1}$]	PEC_{sed} [mg L^{-1}]	$PEC_{sed}^{\#}$ [$\mu\text{g kg}^{-1}$]
	0 days	4 days	21 days	28 days	0 days	0 days
BH 517-TSO						
Spring Scenario	1.661	1.606	1.528	1.485	0.002	26.750
Autumn Scenario	1.661	1.223	0.2354	0.1767	0.002	20.375
BH 517-T2SO						
Spring Scenario	0.395	0.379	0.357	0.346	0.001	9.200
Autumn Scenario	0.395	0.290	0.056	0.042	0.001	6.625
BH 517-T1S						
Spring Scenario	0.574	0.561	0.542	0.528	0.010	118.875
Autumn Scenario	0.574	0.425	0.082	0.061	0.004	52.250
BH 517-T1SO						
Spring Scenario	1.497	1.461	1.412	1.377	0.025	310.000
Autumn Scenario	1.497	1.108	0.213	0.160	0.011	136.250
BH 517-T2S						
Spring Scenario	2.044	1.995	1.928	1.880	0.034	422.500
Autumn Scenario	2.044	1.513	0.291	0.218	0.015	186.250
BH 517-TGSO						
Spring Scenario	0.480	0.468	0.452	0.441	0.008	99.250
Autumn Scenario	0.480	0.355	0.068	0.051	0.003	43.625

[#] Bulk density of 80 kg m⁻³

The predicted concentrations in surface water and sediment are appropriate to be used for the subsequent risk assessment for aquatic organisms.

3.1.5.3.2 Monitoring data surface water

In 2014, version 3 of the Pesticide Atlas was launched, which includes a statistical correlation analysis between concentrations, threshold exceedance and land use, which may indicate probable relationships. In this version also the correlation analysis of land use with the environmental quality standards (EQS) of the Water Framework Directive (WFD) is included.

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards (MKN in Dutch, data source <http://www.rivm.nl/rvs/Normen>). These environmental quality standards consist either of the harmonised WFD thresholds derived according to the Fraunhofer methodology¹ (AA-EQS and MAC-EQS) or of an MPC value (which is usually derived on the basis of outdated guidance). When EQS values according to the Water Framework Directive are available, the MPC value is not used further in the analysis of monitoring data for the purpose of the registration.

The active substance cycloxydim was observed in the surface water (most recent data from 2014). As there is no exceedance of thresholds, the monitoring data have no consequences for the proposed uses of the product.

3.1.5.3.3 Drinking water criterion

Cycloxydim has been on the Dutch market for > 3 years (authorised since 1991). This period is sufficiently large to consider the market share to be established.

For cycloxydim exceeding the drinking water criterion, at the intake point of surface water for drinking water, is not expected. It is concluded that the proposed use of Focus Plus will not give an unacceptable risk for drinking water from surface water.

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

Based on vapour pressure (1.0×10^{-5} Pa), Henry's Law Constant (6.1×10^{-8} kPa m³/mol) and information on photochemical oxidative degradation in air (DT₅₀: 2.1 h) no significant residues of cycloxydim are expected in the atmosphere. Even if metabolite BH 517-TSO would enter the atmosphere, it would be degraded quickly (DT₅₀: 0.65 h) and would not be subject to long-range transport.

¹ P.L.A. van Vlaardingen and E.M.J. Verbruggen, Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Revision 2007'. RIVM report 601782001.

Implications for labelling resulting from environmental fate assessment:

Directive 99/45/EC (as amended):

None

Directive 2003/82/EC (Annex IV and V):

None

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

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

Effects on birds

Dietary risk assessment

Under the conservative assumptions of a tier 1 assessment all TER_A values and all TER_{LT} values for cycloxydim exceed the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects indicating a low and acceptable risk to birds.

Food chain behaviour (secondary poisoning) and bioaccumulation

Based on the tier 1 assessment all TER values for the risk assessments for earthworm-eating birds exceed the trigger of 5 set by Commission regulation (EU) 546/2011 for acceptability of effects for secondary poisoning. No assessment could be performed for fish-eating birds as no bioconcentration study is available. Based on the available data on bioaccumulation in hens, goats and rats, the risk to fish-eating birds is expected to be low. The overall bioaccumulation potential of cycloxydim was considered as low in the respective EU reviews and therefore further evaluation on biomagnification is not necessary. It can therefore be concluded that the application of Focus Plus does not raise concerns regarding food chain behaviour (secondary poisoning) or biomagnification.

Drinking water risk assessment

The drinking water risk assessment for the leaf scenario resulted in TER values above the trigger set by Commission regulation (EU) 546/2011 and a quantitative drinking water risk assessment for the puddle scenario is not triggered, indicating an acceptable risk for the intended use of Focus Plus.

Overall conclusion

It can be concluded that the application of Focus Plus according to good agricultural practice will not adversely affect birds under natural conditions.

Effects on Terrestrial Vertebrates Other Than Birds

Dietary risk assessment

Under the conservative assumptions of a tier 1 acute dietary risk assessment, all TER_A for cycloxydim exceed the trigger value as set by Commission Regulation (EU) 546/2011 for acceptability of effects. Under the conservative assumptions of the tier 1 long-term dietary risk assessment the TER_{LT} values fail the trigger set by Commission Regulation (EU) 546/2011 for acceptability of effects for the following scenarios in arable crops (leafy vegetables, bulbs and

onion like crops, legume forage, maize, grassland) and tree/bush like crops (orchards, ornamentals/nurseries, vineyards) and need to be refined.

To allow the competent authority of The Netherlands Ctgb to come to a final conclusion on the risk assessment for small mammals, a national addendum is provided that includes an update of the risk assessment for the “vole”. A higher tier risk assessment for the small herbivorous mammal scenario “vole” in grassland, leafy vegetables, legume forage, maize, orchards, ornamentals/nursery, vineyards and bulbs & onion like crops is presented.

Compound-specific foliar residue data were used as refinement step, resulting in TER_{LT} values for small herbivorous mammals “vole” in all relevant crops exceeding the trigger of 5.

As all relevant exposure scenarios pass the trigger value of 5, the reproductive risk to mammals from Focus Plus) according to the proposed use pattern is low and acceptable.

Food chain behaviour (secondary poisoning) and bioaccumulation

Based on the tier 1 assessment the TER value for the risk assessment for earthworm-eating mammals exceed the trigger of 5 set by Commission regulation (EU) 546/2011 for acceptability of effects for secondary poisoning. No assessment could be performed for fish-eating mammals as no bioconcentration study is available. Based on the available data on bioaccumulation in hens, goats and rats, the risk to fish-eating mammals is expected to be low. The overall bioaccumulation potential of cycloxydim was considered as low in the respective EU reviews and therefore further evaluation on biomagnification is not necessary. It can therefore be concluded that the application of Focus Plus does not raise concerns regarding food chain behaviour (secondary poisoning) or biomagnification.

Drinking water risk assessment

Following EFSA/2009/1438, the puddle scenario is the one relevant for mammals. Since the ratio of the effective application rate to the relevant toxicity endpoints is below the value of 50, conducting a quantitative risk assessment for the proposed use pattern of Focus Plus is not necessary. In conclusion the proposed use pattern of Focus Plus does not pose a risk to mammals via uptake of contaminated drinking water.

Overall conclusion

It can be concluded that the application of Focus Plus according to good agricultural practice will not adversely affect mammals under natural conditions.

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

All acute and chronic TER values for the active substance cycloxydim exceed the Commission regulation (EU) 546/2011 trigger values based on standard worst-case assumptions, indicating low risk to aquatic organisms following application of Focus Plus according to the proposed use pattern with no need for any additional mitigation measures.

The TER values for the major metabolites of cycloxydim are significantly above the respective triggers values based on worst-case standard assumptions; they are thus considered not to be of ecotoxicological relevance.

The results obtained with the formulated product Focus Plus show, based on the content of the active substance within the formulation, a higher toxicity to aquatic organisms compared to the studies performed with the active substance (please refer to the core dossier). Additional TER calculations for

drift entry of the formulated product were performed for all tested organism and exceeded the required acute and chronic trigger values of 100 and 10, respectively, demonstrating low risk to aquatic organisms following the proposed uses of Focus Plus with no need for any additional mitigation measures.

Overall conclusion

The standard risk assessments provided for the formulated product Focus Plus, the active substance cycloxydim and its major metabolites demonstrate that application of Focus Plus in various crops according to good agricultural practice is of low risk to aquatic ecosystem with no need for additional mitigation measures.

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

Bees

All calculated HQs for acute oral and acute contact exposure of honeybees to cycloxydim, Focus Plus are considerably below the Commission Regulation (EU) 546/2011 trigger value of 50 indicating low risk to honeybees from exposure to the active substance and the the formulated product.

It is concluded that the proposed use of Focus Plus according to good agricultural practice presents a low risk to honeybees and will not adversely affect honeybees or honeybee colonies.

Other non-target arthropods

No national specific in-field exposure needs to be considered (please refer to the core assessment). The off-field exposure is calculated based on the spray drift rates as given in the CTGB Evaluation Manual for the Authorization of Plant Protection Products and Biocides.

The calculated hazard quotients of the first tier risk assessment indicate an in-field risk but no off-field risk for *Typhlodromus pyri* and *Aphidius rhopalosiphi*. In a second TIER assessment the in-field risk was addressed. Worst-case laboratory studies were carried out with *Typhlodromus pyri*, *Aphidius rhopalosiphi*, *Chrysoperla carnea*, *Aleochara bilineata* and *Paradosa spec.* For all species, low in-field and off-field risk following application of Focus Plus is indicated.

Considering drift rates according to the CTGB Evaluation Manual it can be concluded that no unacceptable effects for non-target arthropods are expected from the use of Focus Plus at the proposed use rate.

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

Earthworms

Cycloxydim and the metabolite BH 517-T2SO₂ were tested in acute toxicity studies on earthworms. The metabolites BH 517-TSO and BH 517-TSO₂ were considered to be covered by the acute study with the active substance due to their formation during the course of the study. The metabolite BH 517-T2SO₂ was tested in an acute study. The metabolite BH 517-T2SO was considered to be covered by the acute study with the metabolite BH 517-T2SO₂ due to their close structural similarity. In the risk assessment, all TER values exceeded the Commission Regulation (EU) 546/2011 trigger value of 10 for acute exposure. Acute studies on earthworms were performed with Focus Plus, alone (tested as minor change

formulation BAS 517 22 H) In the risk assessment the TER values exceeded the Commission Regulation (EU) 546/2011 trigger of 10 for acute exposure. A chronic study on earthworms was performed with Focus Plus (tested as the similar formulation BAS 517 25 H). The calculated TER value exceeded the Commission Regulation (EU) 546/2011 trigger of 5 indicating low risk to earthworms.

It is concluded that the proposed use of Focus Plus, will not pose an unacceptable risk to populations of earthworms or other soil macro-organisms, when applied according to the recommended use pattern.

Effects on other soil non-target macro-organisms

Tests on other soil non-target macro-organisms are not required.

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

Tests on organic matter breakdown are not required.

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

Cycloxydim had no significant effect on soil micro-organisms at 7.0 mg a.s./kg dry soil, tested as active substance alone and at 3.33 mg a.s./kg dry soil, tested as formulation BAS 517 22 H. This is approximately 5-times higher than the maximum PEC of 0.667 mg a.s./kg dry soil. Furthermore, the NOEC of 1.6 mg/kg dry soil for BH 517-T2SO₂ is approximately 23-times higher than the maximum PEC of 0.071 mg/kg dry soil (PEC_{accu}).

The proposed use of Focus Plus will not pose an unacceptable risk to non-target soil micro-organisms, if applied according to the recommended use pattern.

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

Non-Target Plants

The TER values for all tested plants species of the seedling emergence test were above 5, the TER trigger proposed by the EU Guidance Document on Terrestrial Ecotoxicology, indicating an acceptable risk for non-target plants due to pre-emergence application of Focus Plus. Regarding Focus Plus, the probabilistic assessment of the post-emergence greenhouse data results in a median HC₅-value of 88.3 mL/ha. Taking into account the worst case PER value of 235 mL Focus Plus/ha, the TER value is 0.38. To refine the risk assessment, post-emergence field studies were conducted. The factors from greenhouse to field is between 1.5 and 3.3, i.e. the plants were at least the factor 1.5 less sensitive under field conditions than under greenhouse conditions. To be close to the available data, i.e. the existing greenhouse SSD and the determined field results, it is proposed to apply the lowest factor from greenhouse to the field of 1.5 directly to the HC₅ value obtained for the post-emergence greenhouse data (see Cycloxydim Additional Report, 2009). This would result in an HC₅ value of 132 mL Focus Plus/ha (1.5 x 88.3 mL/ha) for data obtained under field conditions. Compared to the worst-case PER value of 235 mL Focus Plus this results in a TER value of 0.6. However, if 50% drift reducing nozzles are considered, the required trigger value of 1 is exceeded and thus, low risk to non-target plants is demonstrated.

Populations of terrestrial non-target higher plants are not at risk according to the proposed uses if 50% drift reduction are used for the application of Focus Plus

Therefore the following restriction sentence should be added on the label;

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

Other non-target species (Flora and Fauna)

Tests on other non-target species are not required.

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

Focus Plus contains a single active ingredient; cycloxydim. Preliminary range finding studies are considered to be not required as the product has been approved for more than 20 years.

Data on minimum effective dose were presented. The intended dose rates of Focus Plus performed slightly better than reduced rates. Therefore the intended dose of Focus Plus is justified.

Referring to efficacy, Focus Plus was applied at the proposed label rates of 1.0 to 5.0 l/ha dependent on the target. Perennial, annual and volunteer cereal weed species were well controlled with the intended dose rate(s) of Focus Plus. The average efficacy ranged between 90-100%. The majority of weeds were controlled from 1-2 leaves unfolded up until the end of tillering or the start of stem elongation. The authorization of Focus Plus against annual grasses is fully supported. Efficacy was only tested in three perennial grass species, namely *Elytrigia repens*, *Cynodon dactylon* and *Sorghum halepense*. In the Netherlands *Elytrigia repens* is the most common perennial grass weed. An application with Focus Plus resulted in a good control of *Elytrigia repens*. In combination with good control of the two other less common perennial grass weeds, it can be expected that Focus Plus is effective against a wide range of perennial grass weeds. Therefore the whole group of perennial grass weeds can be mentioned on the label.

No effects on yield and quality should be expected with Focus Plus on dicotyledonous or tolerant monocotyledonous crops because it is a specific graminicide active against grass weeds only and selective on all broadleaf crops.

Focus Plus can be used without any risk of phytotoxicity in the intended uses of the GAP. The use on nursery crops and ornamental plants, as well as for crops, where no data is presented (clover, green cover, green fertilizer crops, fescue grasses or strawberry), label phrases may be considered at national level.

On the label the following warning sentence has been placed on the label:

Gezien het grote aantal variëteiten en de wisselende teeltomstandigheden van sierteeltgewassen is het onmogelijk de gewasverdraagzaamheid voor alle situaties te onderzoeken. Als er nog geen ervaring is opgedaan met dit middel wordt aangeraden om eerst een proefbespuiting uit te voeren om de verdraagzaamheid van het gewas te testen.

In The Netherlands application in strawberry, clover and fescue grass is applied for as a minor use. Effectiveness and adverse effects will not be evaluated in these crops. For the use in green fertiliser crops: based on the selectivity trails in many dicotyledonous crops, it is unlikely that Focus Plus will have any detrimental effect on green fertiliser crops (except grass family).

Concerning propagation purposes, applications of Focus Plus in alfalfa and clover are only supported before growth stage BBCH 51. Application at later timings will need to be supported in the National Assessments. In The Netherlands application in alfalfa and clover is applied for as a minor use. Effectiveness and adverse effects will not be evaluated in these crops.

For succeeding crops as well as for adjacent crops, a label phrase may be considered at national level. On the label the following warning sentence has been placed on the label:

Na toepassing geldt een wachttijd van 4 weken voor de zaai van grassen (*Poaceae*).

Considering the resistance risk to the active substance Cycloxydim, it can be concluded that the overall risk for the development of resistance to Focus Plus is medium to high. Therefore, a label warning may be considered at national level. The following sentence has been placed on the label:

Resistentiemanagement

Dit middel bevat de werkzame stof cycloxydim. Cycloxydim behoort tot de cyclohexanedionen. De HRAC code is A. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in voorlichtingsboodschappen, op te volgen.

The product has been evaluated to the Uniform Principles.

2.5 Conclusions

An authorization can be granted

3.3 Substances of concern for national monitoring

No further information is required.

3.4 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 product label**Wettelijk Gebruiksvoorschrift**

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

Toepassingsgebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per 12 maanden	Maximaal aantal liter middel per ha per 12 maanden	Veiligheids termijn in dagen
Aardappelen	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	56
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Bieten	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	56
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Peulvruchten m.u.v. linzen	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	56
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Koolzaad	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per 12 maanden	Maximaal aantal liter middel per ha per 12 maanden	Veiligheids-termijn in dagen
Groenbemestergewassen m.u.v. grasachtige groenbemesters	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Druif (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	42
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Boon met peul (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	28
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Boon zonder peul (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	28
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Erwt met peul (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	35
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Erwt zonder peul (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	35
		Meerjarige grasachtige onkruiden	4-5 l/ha			

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per 12 maanden	Maximaal aantal liter middel per ha per 12 maanden	Veiligheids-termijn in dagen
Sluitkool	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	28
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Spruitkool	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	56
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Bloemkool (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	28
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Bladkoolachtigen (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	42
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Wortelen (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	35
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Bosui (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	28
		Meerjarige grasachtige onkruiden	4-5 l/ha			

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per 12 maanden	Maximaal aantal liter middel per ha per 12 maanden	Veiligheids-termijn in dagen
Prei (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	42
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Bloembol- en bloemknolgewassen (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Bloemisterijgewassen (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Boomkwekerijgewassen (onbedekte teelt)	tussen het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Vaste plantenteelt (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Houtige beplanting	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			

Het gebruik in de teelt van vezelvlas, lijnzaad, aardbei, sla (*Lactuca* spp.), spinazie en zaadproductie van alfalfa /luzerne, klaver en zwenkgras is beoordeeld conform artikel 51 EG 1107/2009. Er is voor deze toepassingen geen werkzaamheids- en fytotoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren, voordat het middel gebruikt wordt. Gebruik van dit middel in deze toepassingsgebieden, komt voor risico en verantwoordelijkheid van de gebruiker.

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per 12 maanden	Maximaal aantal liter middel per ha per 12 maanden	Veiligheidsinterval in dagen
Vezelvlas, lijnzaad	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Aardbei (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	42
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Sla (<i>Lactuca</i> spp.) (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	21
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Spinazie (onbedekte teelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	28
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Alfalfa/luzerne (zaadteelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			

Toepassings-gebied	Type toepassing	Te bestrijden organisme	Dosering (middel) per toepassing	Maximaal aantal toepassingen per 12 maanden	Maximaal aantal liter middel per ha per 12 maanden	Veiligheidsperiode in dagen
Klaver (zaadteelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			
Zwenkgras (graszaadteelt)	tussen of over het gewas	Eenjarige grasachtige onkruiden	1-2 l/ha	1	5 l/ha	-
		Meerjarige grasachtige onkruiden	4-5 l/ha			

Toepassingsvoorwaarden

In de teelt van vezelvlas, aardbei, sla, spinazie, sluitkool, spruitkool, bloemkool, bladkoolachtigen, alfalfa/luzerne en klaver, het middel toepassen in 100-400 liter water per ha. In de teelt van druif het middel toepassen in 200-400 liter water per ha. In de overige gewassen het middel toepassen in 200-400 liter water per ha.

Gebruik is uitsluitend toegestaan door middel van daartoe geëigende apparatuur, te weten een machinaal voortgetrokken veldspuit, omdat gezondheidseffecten niet zijn uit te sluiten bij toepassing met een handsput.

In de teelt van druiven het middel vóór vruchtzetting (BBCH 60) toepassen.

In de teelt van peulvruchten, boon met peul, boon zonder peul, erwt met peul en erwt zonder peul het middel vóór de bloei (BBCH 39) toepassen.

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

Na toepassing geldt een wachttijd van 4 weken voor de zaai van grassen (*Poaceae*).

Gezien het grote aantal variëteiten en de wisselende teeltomstandigheden van sierteeltgewassen is het onmogelijk de gewasverdraagzaamheid voor alle situaties te onderzoeken. Als er nog geen ervaring is opgedaan met dit middel wordt aangeraden om eerst een proefbespuiting uit te voeren om de verdraagzaamheid van het gewas te testen.

Resistentiemanagement

Dit middel bevat de werkzame stof cycloxydim. Cycloxydim behoort tot de cyclohexanedionen. De HRAC code is A. Bij dit product bestaat er kans op resistentieontwikkeling. In het kader van resistentiemanagement dient u de adviezen die gegeven worden in voorlichtingsboodschappen, op te volgen.

Appendix 2 Letter of Access

No data protected studies of third parties were included in this dossier. Therefore, no letter of access was necessary.

Appendix 3 Reference List

Annex point	Year	Title Source (where different from company) Company, Report No. GLP or GEP status (where relevant) Published or Unpublished	Data protection claimed Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.5/1	2007 b	Study on the residue behavior of Cycloxydim in grape after soil application of Focus Plus under field conditions in France (North and South), Germany, Greece, Italy, and Spain, 2006 Agrologia SL, Palomares, Spain 2007/1020717 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.5/2	2009 b	Amendment No. 1: Study on the residue behavior of Cycloxydim in grape after soil application of Focus Plus under field conditions in France (North and South), Germany, Greece, Italy and Spain, 2006 Agrologia SL, Palomares, Spain 2009/1102133 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.5/3	2006 a	Study on the residue behaviour of Cycloxydim and its metabolite in grapes after soil treatment with Focus Plus under field conditions in France (N & S), Germany, Italy and Greece, 2005 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2006/1030352 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.6/1	2009 a	Residue study (decline) with Focus Plus applied to strawberries (field) in the UK, Germany and the Netherlands in 2008 Huntingdon Life Sciences Ltd., Huntingdon Cambridgeshire PE28 4HS, United Kingdom 2009/1069375 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.6/5	1997 a	Study on the residue behaviour of Cycloxydim in strawberries after treatment with Laser (BAS 517 01 H) under field conditions in Great Britain, 1995 BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 1997/10554 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.6/6	1992 a	Residues of Cycloxydim in strawberries BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 1992/12145 Yes, study was conducted prior to the implementation of GLP certificates 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.7/1	2010 a	Residue study (decline) with Focus Plus and BAS 160 00 S (DASH) applied to potatoes in Germany, the Netherlands, Denmark and the UK in 2009 Huntingdon Life Sciences Ltd., Huntingdon Cambridgeshire PE28 4HS, United Kingdom 2009/1111381 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.8/1	2009 a	Study on the residue behaviour of BAS 517 H in carrot after treatment with Focus Plus under field conditions in Northern and Southern Europe during 2007 Agriseach UK Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom 2009/1075173 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.8/4	1991 a	Pflanzenschutzmittel-Rueckstaende - Winterkarotten Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany Fed.Rep. 1990/10609 No Unpublished	No	Y	N	BASF
KIIIA 8.3.8/5	1991 b	Pflanzenschutzmittel-Rueckstaende - Winterkarotten Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany Fed.Rep. 1990/10589 No Unpublished	No	Y	N	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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.8/6	1991 c	Pflanzenschutzmittel-Rueckstaende - Winterkarotten Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany Fed.Rep. 1990/10608 No Unpublished	No	Y	N	BASF
KIIIA 8.3.8/7	1991 d	Pflanzenschutzmittel-Rueckstaende - Winterkarotten Dr. Specht & Partner Chemische Laboratorien GmbH, Hamburg, Germany Fed.Rep. 1990/10657 No Unpublished	No	Y	N	BASF
KIIIA 8.3.11/1	2006 b	Study on the residue behaviour of Cycloxydim and its metabolite in bulb onions (field) after treatment with Focus Plus under field conditions in France (N & S), England, Sweden, The Netherlands, Italy, Spain and Greece, 2005 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2006/1029595 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.11/5	1997 b	Study on the residue behaviour of BAS 517 H (Cycloxydim) in salad-onions after treatment with Laser (BAS 517 01 H) under field conditions in Great Britain, 1995 BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 1997/10561 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.14/1	2007 h	Study on the residue behavior of Cycloxydim in cauliflower after the application of Focus Plus under field conditions in France (North), Germany, Sweden and United Kingdom, 2006 Agrologia SL, Palomares, Spain 2007/1020720 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.14/3	2002 a	Study on the residue behaviour of Cycloxydim in white cabbage and cauliflower after application of Focus Plus under field conditions in Belgium, France (N), United Kingdom and Sweden, 2001 BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2002/1004111 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.14/4	2002 b	Report amendment No. 1 to final report: Study on the residue behaviour of Cycloxydim in white cabbage and cauliflower after application of Focus Plus under field conditions in Belgium, France (N), United Kingdom and Sweden, 2001 BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2002/1012095 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.15/1	2007 i	Study on the residue behavior of Cycloxydim in head cabbage after the application of Focus Plus under field conditions in Belgium, France (North), Germany and United Kingdom, 2006 Agrologia SL, Palomares, Spain 2007/1020721 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.15/3	2002 a	Study on the residue behaviour of Cycloxydim in white cabbage and cauliflower after application of Focus Plus under field conditions in Belgium, France (N), United Kingdom and Sweden, 2001 BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2002/1004111 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.15/4	2002 b	Report amendment No. 1 to final report: Study on the residue behaviour of Cycloxydim in white cabbage and cauliflower after application of Focus Plus under field conditions in Belgium, France (N), United Kingdom and Sweden, 2001 BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2002/1012095 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.16/1	2007 j	Study on the residue behavior of Cycloxydim in brussels sprouts after the application of Focus Plus under field conditions in France (North and South), Germany, Netherlands, Spain and United Kingdom, 2006 Agrologia SL, Palomares, Spain 2007/1020722 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.16/2	2007 a	Study on the residue behaviour of Cycloxydim and its metabolite in brussels sprouts (field) after treatment with Focus Plus under field conditions in France (N), England, Sweden, Belgium, Italy and Greece, 2005 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2006/1034211 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.17/1	2009 c	Study on the residue behaviour of BAS 517 H in curly kale and Chinese cabbage after treatment with Focus Plus under field conditions in Northern and Southern Europe during 2007 Agrisearch UK Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom 2009/1075174 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.17/2	2007 k	Study on the residue behavior of Cycloxydim in curly kale after the application of Focus Plus under field conditions in France (North and South), Netherlands and Spain 2006 Agrologia SL, Palomares, Spain 2007/1020723 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.18/2	2009 f	Amendment No. 1: Study on the residue behavior of Cycloxydim in head lettuce after the application of Focus Plus under field conditions in France (South), Greece, Italy and Spain, 2006 Agrologia SL, Palomares, Spain 2009/1102131 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.18/5	2005 a	Processing and field residue study on the residue behaviour of Cycloxydim in lettuce after application of Focus Plus under field conditions in North France, Denmark and Sweden, 2003 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2004/1015935 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.18/6	2002 c	Study on the residue behaviour of Cycloxydim in head lettuce after application of Focus Plus under field conditions in Denmark and France (N), 2001 BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 2002/1008792 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.19/1	2013 a	Study on the residue behavior of Cycloxydim (BAS 517 H) on spinach after the application of Focus Plus with and without the adjuvant Dash under field conditions in Germany, United Kingdom, Italy and Spain, 2012 Agrologia SL, Utrera, Spain 2012/1343254 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.19/2	2013 b	Report Amendment no. 1 to final report: Study on the residue behavior of Cycloxydim (BAS 517 H) on spinach after the application of Focus Plus with and without the adjuvant Dash under field conditions in DE, UK, IT and ES, 2012 Agrologia SL, Utrera, Spain 2013/1037968 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.19/3	2007 b	Study on the residue behavior of Cycloxydim (BAS 517 H) in spinach after the application of Focus Plus under field conditions in France, Germany, Greece, Italy and Spain, 2005 Agrologia SL, Palomares, Spain 2006/1029326 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.21/1	2009 g	Amendment No. 1: Study on the residue behavior of Cycloxydim in green peas after the application of Focus Plus under field conditions in France (North and South), Greece, Germany, Italy, Netherlands, Spain and United Kingdom, 2006 Agrologia SL, Palomares, Spain 2009/1102116 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.21/2	2007 m	Study on the residue behavior of Cycloxydim in green peas after the application of Focus Plus under field conditions in France (North and South), Greece, Germany, Italy, Netherlands, Spain and United Kingdom, 2006 Agrologia SL, Palomares, Spain 2007/1020725 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.21/3	2007 b	Study on the residue behaviour of Cycloxydim and its metabolite in green peas (field) after treatment with Focus Plus under field conditions in France (N & S), England, Sweden, The Netherlands, Italy, Spain and Greece, 2005 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2006/1034132 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.21/4	1989 a	Pflanzenschutzmittel-Rueckstaende - Erbsen BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 1988/10698 No, studies were conducted prior to the implementation of GLP but are scientifically valid Unpublished	No	Y	N	BASF
KIIIA 8.3.22/1	2009 d	Study on the residue behaviour of BAS 517 H in leek after treatment with Focus Plus under field conditions in Northern Europe during 2007 Agrisearch UK Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom 2009/1075171 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.22/4	1992 b	Residues of Cycloxydim in leeks - BAS 517 01 H BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 1992/12153 No, not subject to GLP regulations Unpublished	No	Y	N	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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.22/5	1992 c	Residues of Cycloxydim in leeks BASF AG Agrarzentrum Limburgerhof, Limburgerhof, Germany Fed.Rep. 1992/12146 Yes, study was conducted prior to the implementation of GLP certificates Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.23/1	2009 i	Amendment No. 2: Study on the residue behavior of Cycloxydim in dry beans (<i>Vicia faba</i>) after the application of Focus Plus under field conditions in France (North and South), Germany, Greece, Italy, Netherlands and Spain, 2006 Agrologia SL, Palomares, Spain 2009/1102124 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.3.23/2	2006 c	Study on the residue behaviour of Cycloxydim and its metabolite in dry beans (<i>Vicia faba</i>) after treatment with Focus Plus under field conditions in France (N & S), England, Sweden, Denmark, Italy, Spain and Greece, 2005 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2006/1024330 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.3.26/1	2010 b	Residue study (decline) with Focus Plus and BAS 160 00 S (DASH) applied to oilseed rape in Germany, the Netherlands, Northern France and the UK in 2009 Huntingdon Life Sciences Ltd., Huntingdon Cambridgeshire PE28 4HS, United Kingdom 2009/1111383 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.4.1/1	2011 a	A meat and egg magnitude of the residue study with BAS 517 H (Cycloxydim) and its metabolite BH 517-5-OH-TSO in laying hens; reanalysis of specimen using the common moiety method BASF SE, Limburgerhof, Germany Fed.Rep. 2010/1177209 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.5.3/1	2009 a	Determination of residues of BAS 517 H in strawberries and its processed products after one application of Focus Plus in Germany BioChem agrar Labor fuer biologische und chemische Analytik GmbH, Gerichshain, Germany Fed.Rep. 2009/1065669 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.5.3/2	2005 a	Determination of the residues of Cycloxydim and its metabolites in carrots and processed products following treatment with Focus Plus under field conditions in Germany and Italy 2001 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2005/1026923 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.5.3/3	2003 a	Determination of the residues of Cycloxydim and its metabolite in onions and processed products following treatment with Focus Plus under field conditions in Italy and Greece 2001 Institut Fresenius Chemische und Biologische Laboratorien AG, Taunusstein, Germany Fed.Rep. 2003/1001289 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.5.3/5	2005 a	Processing and field residue study on the residue behaviour of Cycloxydim in lettuce after application of Focus Plus under field conditions in North France, Denmark and Sweden, 2003 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2004/1015935 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 Y/N	studies relied on Y/N	data protection granted Y/N	Owner
KIIIA 8.5.3/6	1995 b	Determination of the residues of Cycloxydim in sunflowers following treatment with BAS 517 01 H under field conditions in Italy 1993 Institut Fresenius Chemische und Biologische Laboratorien GmbH, Taunusstein, Germany Fed. Rep. 1995/10368 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.5.3/7	1995 a	Addendum No. 1 to the report: Determination of the residues of Cycloxydim in sunflowers following treatment with BAS 517 01 H under field conditions in Italy 1993 Institut Fresenius Chemische und Biologische Laboratorien GmbH, Taunusstein, Germany Fed. Rep. 1995/10419 Yes Unpublished	Yes	Y	Y	BASF
KIIIA 8.5.3/8	2006 a	Determination of the residues of Cycloxydim and its metabolite in white cabbage and processed products following treatment with Focus Plus under field conditions in Germany and Southern France 2001 SGS Institut Fresenius GmbH, Taunusstein, Germany Fed. Rep. 2006/1008084 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	Used for evaluation Yes/No	Data protection granted Y/N	Owner
KIIIA 10.2.2.1/1	2007 a	Acute toxicity study of Focus Plus to freshwater fish, Cyprinus carpio 2006/1019779 Yes Unpublished	Yes	Yes	Yes	BASF
KIIIA 10.2.2.2/1	2007 a	Acute immobilisation test with Focus Plus in Daphnia magna IIBAT - International Institute of Biotechnology and Toxicology, Padappai, India 2006/1019780 Yes Unpublished	Yes	Yes	Yes	BASF
KIIIA 10.2.2.2/2	2013 a	Focus Plus + BAS 160 00 S (Dash) - Daphnia magna acute immobilization test Institute of Industrial Organic Chemistry, Pszczyna, Poland 2012/1219557 Yes Unpublished	Yes	Yes	Yes	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	Used for evaluation Yes/No	Data protection granted Y/N	Owner
KIIIA 10.2.2.3/1	2013 b	Focus Plus + BAS 160 00 S (Dash) - Pseudokirchneriella subcapitata SAG 61.81 growth inhibition test Institute of Industrial Organic Chemistry, Pszczyna, Poland 2012/1219560 Yes Unpublished	Yes	Yes	Yes	BASF
KIIIA 10.4.2.1/1	2012 a	Effects of Focus Plus + BAS 160 00 S (Dash E.C.) (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1202294 Yes Unpublished	Yes	Yes	Yes	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	Used for evaluation Yes/No	Data protection granted Y/N	Owner
KIIIA 10.4.2.1/2	2013 a	1st Final report Amendment (2nd original) - Effects of Focus Plus + BAS 160 00 S (Dash E.C.) (acute contact and oral) on honey bees (<i>Apis mellifera</i> L.) in the laboratory Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2013/1018287 Yes Unpublished	Yes	Yes	Yes	BASF
KIIIA 10.6.2/1	2012 a	Acute toxicity (14 days) of Focus Plus + BAS 160 00 S (Dash E.C.) to the earthworm <i>Eisenia fetida</i> in artificial soil with 5% peat Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1202292 Yes Unpublished	Yes	Yes	Yes	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	Used for evaluation Yes/No	Data protection granted Y/N	Owner
KIIIA 10.6.3/1	2012 a	Effects of BAS 517 25 H on reproduction and growth of earthworms <i>Eisenia fetida</i> in artificial soil with 5% peat Institut fuer Biologische Analytik und Consulting IBACON GmbH, Rossdorf, Germany Fed.Rep. 2012/1216473 Yes Unpublished	Yes	Yes	Yes	BASF
KIIIA 10.8.1.2/1	2013 a	Focus Plus + BAS 160 00 S (Dash): A test to determine the effects on non-target plants Rheinland Pfalz AgroScience GmbH, Neustadt/Weinstrasse, Germany Fed.Rep. 2013/1000282 Yes Unpublished	Yes	Yes	Yes	BASF
KIIIA 10.8.1.2/2	2013 b	Final report Amendment No. 01 - Focus Plus + BAS 160 00 S (Dash): A test to determine the effects on non-target plants Rheinland Pfalz AgroScience GmbH, Neustadt/Weinstrasse, Germany Fed.Rep. 2013/1074475 Yes Unpublished	Yes	Yes	Yes	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	Used for evaluation Yes/No	Data protection granted Y/N	Owner
KIIIA 10.10.2/1	2014 a	Study on the residue behavior of Cycloxydim (BAS 517 H) on pea (young plants) after the application of Focus Plus under field conditions in Germany, Netherlands, France (North and South), United Kingdom, Greece, Italy and Spain, 2013 Agrologia SLU, Utrera, Spain 2014/1281155 yes Unpublished	Yes	Yes	Yes	BASF
KIIIA 10.10.2/2	2014 a	Calculation of DT50 dissipation times for BAS 517 H - Cycloxydim in pea plants from field trials conducted in the Northern and Southern Zones of Europe BASF SE, Limburgerhof, Germany Fed.Rep. 2014/1305820 no Unpublished	No	Yes	No	BASF