List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
SPAIN	**February 2018**	**Hydrolysed proteins**

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Hydrolysed proteins. Beet molasses - urea hydrolysate
Function (*e.g.* fungicide)	Attractant

Rapporteur Member State	Spain
Co-rapporteur Member State	Greece

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	Not applcable
Chemical name (CA)	Not applcable
CIPAC No	Not applcable
CAS No	Not applcable
EC No (EINECS or ELINCS)	Not applcable
FAO Specification (including year of publication)	Not applcable
Minimum purity of the active substance as manufactured	360g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Not applcable
Molecular formula	Not applcable
Molar mass	Not applcable
Structural formula	Not applcable

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
SPAIN	**February 2018**	**Hydrolysed proteins**

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	Not applicable
Boiling point (state purity)	Not applicable
Temperature of decomposition (state purity)	Not applicable
Appearance (state purity)	Dark brown liquid with characteristic odour
Vapour pressure (state temperature, state purity)	Not applicable
Henry's law constant (state temperature)	Not applicable
Solubility in water (state temperature, state purity and pH)	Insoluble in water max 0.7% w/w
Solubility in organic solvents (state temperature, state purity)	Not applicable
Surface tension (state concentration and temperature, state purity)	70.6mN/m at 20 °C deionized water used
Partition coefficient (state temperature, pH and purity)	Not applicable
Dissociation constant (state purity)	Not applicable
UV/VIS absorption (max.) incl. ε (state purity, pH)	Not applicable
Flammability (state purity)	Not fllammable
Explosive properties (state purity)	Not explosive
Oxidising properties (state purity)	Not an oxidising agent

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Olive crop	Southern zone	ENT50	F	*Olive fruit fly-Bactrocera oleae*	SL	170g/kg of Urea Min 500g/kg of Hyd. Protein	Low volume Spot bait sprays	Fruit	6 applications per crop season. (1)	depends on the insecticide used.(1)	Min 0.320kg Urea /hL Max 0.360g Urea/hL Min 1.0kg Hyd. prot. /hL Max 1.155kg Hyd.prot. /hL	30L/ha	Min 0.096kg Urea/ha Max 0.108kg Urea/ha Min 0.300kg Hyd. prot. /ha Max 0.347kg Hyd. prot/ha	Depends on the insecticide used. (1)	(1) Number of application, interval between applications and PHI depends on the insecticide used.
Olive crop	Southern zone	ENT50	F	*Olive fruit fly-Bactrocera oleae*	SL	170g/kg of Urea	Very Low volume Spot bait spray	Fruit	6 applications per crop season. (1)	depends on the insecticide used.(1)	Min 0.96kg Urea /hL Max 1.08kg	10L/ha	Min 0.096kg Urea/ha Max 0.108kg Urea/ha	Depends on the insecticide used.	(1) Number of application, interval between applications and PHI depends on the insecticide used.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
						Min 500g/kg of Hyd. Protein	s				Urea/hL Min 3.0kg Hyd. prot. /hL Max 3.465kg Hyd.prot. /hL		Min 0.3kg Hyd. prot. /ha Max 0.347kg Hyd. prot/ha	(1)	

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (*name of active substance or the respective variant*)
Regulation (EC) N° 1107/2009 Article 8.1(g))

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

Low volume spot bait spray supported by appropriate data

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

No adverse effects have been observed

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

No undesirable or unintended side effects have been observed

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism						

Not applicable

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	Nitrogen determination
Impurities in technical a.s. (analytical technique)	Not applicable
Plant protection product (analytical technique)	Nitrogen determination & Physicochemical characteristics-properties determination

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin		Not applicable
Food of animal origin		Not applicable
Soil		Not applicable
Sediment		Not applicable
Water	surface	Not applicable
	drinking/ground	Not applicable
Air		Not applicable
Body fluids and tissues		Not applicable

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not applicable
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Not applicable
Soil (analytical technique and LOQ)	Not applicable
Water (analytical technique and LOQ)	Not applicable
Air (analytical technique and LOQ)	Not applicable
Body fluids and tissues (analytical technique and LOQ)	Not applicable

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 1 Identity, Physical/ Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	Hydrolysed proteins. Beet molasses - urea hydrolysate
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	Not classified
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	Not classified

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[2] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 2 Mammalian Toxicology

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	
Toxicokinetics	Urea is produced in large quantities by the human body as a product of normal metabolism and is excreted unchanged in the urine
Distribution	
Potential for bioaccumulation	No evidence for accumulation
Rate and extent of excretion	
Metabolism in animals	Urea is widely distributed within the natural world, as a by-product in protein synthesis in ureotelic animals, including mammals whence it is excreted in urine.
In vitro metabolism	
Toxicologically relevant compounds (animals and plants)	
Toxicologically relevant compounds (environment)	

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD_{50} oral	> 2000 mg/kg bw	
Rat LD_{50} dermal	> 2000 mg/kg bw	
Rat LC_{50} inhalation	> 5.5 mg/L air /4h (*state way, e.g. nose only*)	
Skin irritation	Non-irritant	
Eye irritation	Non-irritant	
Skin sensitisation	Non sensitising	
Phototoxicity	Not relevant	

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Various organs/No treatment-related toxic syndromes	
Relevant oral NOAEL	For urea: 2250 mg/kg bw/d in the rat 6750 mg/kg bw/d in the mouse	
Relevant dermal NOAEL	No dose-dependent toxicity was observed	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 2 Mammalian Toxicology

Relevant inhalation NOAEL	No potential for inhalation exposure	

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

In vitro studies		
In vivo studies		
Photomutagenicity		
Potential for genotoxicity	*Based on its physiological role and presence in the body at high concentrations, urea is not considered to be genotoxic.*	

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Various organs/No treatment-related toxic syndromes	
Relevant long-term NOAEL	For urea: 2250 mg/kg bw/d in the rat	
Carcinogenicity (target organ, tumour type)	There is no evidence from animal studies that urea is carcinogenic.	
Relevant NOAEL for carcinogenicity		

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	For urea: It is considered extremely unlikely that occupational, primary or secondary exposure to urea will result in any effects on fertility as the levels of exposure will be insignificant compared to those present in the body as a result of protein catabolism.	(*mention proposed classif*)
Relevant parental NOAEL		
Relevant reproductive NOAEL		
Relevant offspring NOAEL		

Developmental toxicity

Developmental target / critical effect	For urea: Developmental toxicity testing in rats dosed orally up to 1000 mg/kg bw did not result in adverse effects. There are no studies in animals showing clear evidence of reproductive effects. The results of the available studies do not trigger classification	

	according to Directive 67/548/EEC.	
Relevant maternal NOAEL		
Relevant developmental NOAEL		

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	Not available	
Repeated neurotoxicity	Not available	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Not available	

Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	*Not available*
Endocrine disrupting properties	*Not available*
Studies performed on metabolites or impurities	*Not available*

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

Not available

Summary[3] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)

	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)			
Acute Reference Dose (ARfD)			
Acceptable Operator Exposure Level (AOEL)			
Acute Acceptable Operator Exposure Level (AAOEL)			

* Including correction for limited oral absorption/bioavailability (xx %).

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation (*indicate name, type e.g.* EC *and concentration of active substance*)	*Dermal absorption values of 7.2-9.5% is reported for urea.*

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators	*Operator exposure to Urea applied as a low volume bait spray (10-30L water volume)* Use: FIELD APPLICATIONS - Tractor Mounted Upward Spraying Application rate: 0.159 kg Urea/ha

[3] If available include also reference values for metabolites

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 2 Mammalian Toxicology

Workers

Exposure estimates (model): % of AOEL

AOEM

Without PPE: 2.35

PPE (gloves and coverall): 0.17

Use: FIELD APPLICATIONS – Manual Handheld Upward Spraying Application rate: 0.159 kg Urea/ha

AOEM:

Without PPE: 67.62

PPE (gloves and coverall): 3.41

Use: FIELD APPLICATIONS – Manual Knapsack Upward Spraying Application rate: 0.159 kg Urea/ha

AOEM:

Without PPE: 67.22

PPE (gloves and coverall): 3.41

Europoem II worker exposure estimate without PPE:

Application type	High level/olive tree
Dermal exposure (mg a.s /day)	77.274
Systemic Exposure (mg/kg bw/day	1.10
AOEL	22.5
% of AOEL	5.0

*bodyweight taken as 70kg (EUROPOEM default)

Europoem II worker exposure estimate with PPE:

Application type	High level/olive tree
Dermal exposure (mg a.s /day)	15.455
Systemic Exposure (mg/kg bw/day	0.22
AOEL	22.5
% of AOEL	1

*bodyweight taken as 70kg (EUROPOEM default)

Bystanders and residents

Europoem II

Estimated bystander exposure to Urea and % of the AOEL

Crop	Olive Trees
Dermal absorption)	100%
Dermal exposure (mg a.s day)	4.77
Inhalation exposure (mg a.s day)	1.1925
Total systemic exposure (mg a.s day)	5.963
% of AOEL (1575 mg a.s day)	0

UK Model

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 2 Mammalian Toxicology

Estimated bystander exposure to Urea and % of the AOEL

Crop	Olive Trees
Dermal absorption)	100%
Dermal exposure (mg a.s day)	58.83
Inhalation exposure (mg a.s day)	0.0318
Total systemic exposure (mg a.s day)	0.98
% of AOEL (1575 mg a.s day)	4.4

Resident Exposure values:

Orchard application to Olive trees

Application	High level tree fruit
Parameter/Active	Urea
AR (kg a.s./ha)	0.954
Dabs (%)	100%
AOEL (mg/kg bw/d)	22.5
AR µg/cm2	9.54
DF %	11.01%
TTR % (d, HtM)	5%
TTR % (OtM)	20%
TC cm2/hour	5200
SE%	50%
SA cm2/event	20
Frequency events/hour	20
Hours	2
BW (kg)	15
IgR cm2/day	25
SE(d) ug/kg bw/d	36.41
SE(h) ug/kg bw/d	1.40
SE(o) ug/kg bw/d	0.35
Tot mg/kg bw/day	0.04
% AOEL	0.2

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 2 Mammalian Toxicology

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :	Beet molasses urea hydrolysate

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 2 Mammalian Toxicology

Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][4] :	*GHS Pictogram:* *GHS07* *Signal word:* *WARNING* *Hazard statements (because of the use with insecticides on bait application):* *H317 May cause an allergic skin reaction (Cat. 1)* *EUH401 To avoid risks to human health and the environment, comply with the instructions for use.* *Precautionary statements:* *P102+405 Keep out of the reach of Children. Store locked up* *P270 Do not eat, drink or smoke when using this product* *P280 Wear protective gloves/protective clothing/eye protection/face protection* *P301+312 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell* *P302 + 352 IF ON SKIN: Wash with plenty of soap and water* *P333 + P313 If skin irritation or rash occurs: Get medical advice/attention* *P305+351+ 338 IF IN EYES: Rinse cautiously with water for several minutes Remove contact lenses, if present and easy to do. Continue rinsing* *P363 Wash contaminated clothing before reuse* *P370+260 In case of fire: Do not breathe dust/fume/gas/mist/vapours/spray* *Other phrases* *Other precautionary phrases because of the use with insecticide:* *- Take all the necessary measures for the insecticide.* *- Do not spray against the wind.* *- After use wash with water and soap.* *- Do not spill in watercourse or water irrigating systems.*

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 2 Mammalian Toxicology

Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	In accordance with Regulation (EC) No 1272/2008.

[5] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 3 Residues

Residues in or on treated products food and feed

No data available or needed in residues section for Hyrodlysed proteins – Beet molasses urea hydrolysate.

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) **OECD Guideline 501**	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Fruit crops			
	Root crops			
	Leafy crops			
	Cereals/grass crops			
	Pulses/Oilseeds			
	Miscellaneous			
	(up to 250 characters)			

Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	Root/tuber crops			
	Leafy crops			
	Cereal (small grain)			
	Other			
Rotational crop and primary crop metabolism similar?	(up to 250 characters)			

Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**					
	20 min, 90°C, pH 4					
	60 min, 100°C, pH 5					
	20 min, 120°C, pH 6					
Residue pattern in processed commodities similar to residue pattern in raw commodities?	(up to 250 characters)					

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	
Plant residue definition for risk assessment (RD-RA)	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 3 Residues

Conversion factor (monitoring to risk assessment)	

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and **SANCO/11187/2013 rev. 3** (fish)	**Animal**	**Dose** (mg/kg bw/d)	**Duration** (days)	**N rate/comment**
Animals covered	Laying hen			
	Goat/Cow			
	Pig			
	Fish	mg/kg DM		
	(up to 250 characters)			

Time needed to reach a plateau concentration in milk and eggs (days)	
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	
Animal residue definition for risk assessment (RD-RA)	
Conversion factor (monitoring to risk assessment)	
Metabolism in rat and ruminant similar (Yes/No)	
Fat soluble residues (Yes/No) **(FAO, 2009)**	

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	(up to 500 characters)
Field rotational crop study **OECD Guideline 504**	(up to 500 characters)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 3 Residues

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

OECD Guideline 506

Plant products (Category)	**Commodity**	**T** (°C)	**Stability** (Month/Year)			
High water content						
High oil content						
High protein content						
High starch content						
High acid content						

(up to 250 characters)

Animal	**Animal commodity**	**T** (°C)	**Stability** (Month/Year)			
	Muscle					
	Liver					
	Kidney					
	Milk					
	Egg					

(up to 250 characters)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 3 Residues

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop	**Region/ Indoor** (a)	**Residue levels** (mg/kg) **observed in the supervised residue trials relevant to the supported GAPs** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
Representative uses (row to be deleted if not relevant)						
MRL application (row to be deleted if not relevant)						
Summary of the data on formulation equivalence OECD Guideline 509						
Crop	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)						
Product(s)	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
(b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$).

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 3 Residues

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	**Comment**	(mg/kg)	**Comment**
Representative uses (row to be deleted if not relevant)				
MRL application (row to be deleted if not relevant)				

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 3 Residues

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle		Ram/Ewe		Breeding		Broiler		Carp	
	Dairy cattle		Lamb		Finishing		Layer		Trout	
							Turkey		Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	Yes/No		Yes/No		Yes/No		Yes/No		Yes/No	
Feeding study submitted										
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb: N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals
Muscle										
Fat										
Meat[(b)]										
Liver										
Kidney										
Milk[(a)]										
Eggs										
Method of calculation[(c)]										

[(a)]: Estimated HR calculated at 1N level (**estimated mean level for milk**).

[(b)]: HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry

[(c)]: The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 3 Residues

STMR calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Median expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle		Ram/Ewe		Breeding		Broiler		Carp	
	Dairy cattle		Lamb		Finishing		Layer		Trout	
							Turkey			
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level	Beef: N Dairy: N	Level	Lamb : N Ewe: N	Level	N rate Breed/Finish	Level	B or T: N Layer: N	Level	N rate Carp/Trout
	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N	Mean level in feeding level	Estimated **STMR**[(b)] at 1N
Muscle										
Fat										
Meat[(a)]										
Liver										
Kidney										
Milk										
Eggs										
Method of calculation[(c)]										

[(a)]: STMR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
[(b)]: When the mean level is set at the LOQ, the STMR is set at the LOQ.
[(c)]: The OECD guidance document on residues in livestock (series on pesticide 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 3 Residues

Conversion Factors (CF) for monitoring to risk assessment

Animal products

Table to be deleted if not relevant (RD-Mo = RD-RA)

Conversion factors derived from the livestock feeding studies at the different feeding levels								
Study	**Ruminant/Pig**				**Poultry**			
Feeding levels	Level 1	Level 2	Level 3	Level 4	Level 1	Level 2	Level 3	Level 4
Muscle								
Fat								
Liver								
Kidney								
Milk								
Egg								
Comments (up to 250 characters)								

Plant products

Table to be deleted if not relevant (RD-Mo = RD-RA)

Mean Conversion Factors (CF) calculated at the different PHIs in the supervised residues trials[a] **OECD Guidance, series on Pesticides No 66**								
PHI[b] (days)								**Comments**
Representative uses (row to be deleted if not relevant)								
MRL application (row to be deleted if not relevant)								
Comments (up to 250 characters):								

[a]: CF calculated at the supported PHI are underlined.
[b]: 0-/0+ for samples collected just before/after the last application

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 3 Residues

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	**Number of studies**[a]	**Processing Factor** (PF)		**Conversion Factor** (CF_P) **for RA**[b]
		Individual values	Median PF	
Representative uses (row to be deleted if not relevant)				
MRL application (row to be deleted if not relevant)				

[a]: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
[b]: When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Including all uses (representative uses and uses related to an MRL application).

ADI	mg/kg bw per day		
TMDI according to EFSA PRIMo	Highest TMDI:	XX % ADI	(MS, diet)
NTMDI, according to (to be specified)	Highest NTMDI:	XX % ADI	(MS, diet)
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI:	XX % ADI	(MS, diet)
NEDI (% ADI), according to (to be specified)	Highest NEDI:	XX % ADI	(MS, diet)
Factors included in the calculations			
ARfD	mg/kg bw		
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI:	XX % ARfD	(Commodity)
NESTI (% ARfD), according to (to be specified)	Highest NESTI:	XX % ARfD	(commodity)
Factors included in IESTI and NESTI			

Consumer risk assessment limited to the representative uses **To be deleted if not relevant**

TMDI (% ADI), according to EFSA PRIMo	Highest TMDI:	XX % ADI	(MS, diet)
NTMDI (% ADI), according to (to be specified)	Highest NTMDI:	XX % ADI	(MS, diet)
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI:	XX % ADI	(MS, diet)
NEDI (% ADI), according to (to be specified)	Highest NEDI:	XX % ADI	(MS, diet)
Factors included in the calculations			
IESTI (% ARfD, according to EFSA PRIMo)	Highest IESTI:	XX % ARfD	(Commodity)
NESTI (% ARfD, according to (to be specified)	Highest NESTI:	XX % ARfD	(commodity)
Factors included in IESTI and NESTI			

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
Spain	**February 2018**	**Hydrolysed proteins**

Section 3 Residues

Additional contribution to the consumer intakes through drinking water resulting from groundwater metabolite(s) expected to be present above 0.75 µg/L **To be deleted if not relevant**

Metabolite(s)	
ADI (mg/kg bw per day)	
Intake of groundwater metabolites (% ADI)	Adult (60 kg bw, 2 L): XX % ADI
WHO Guideline (WHO, 2009)	Child (10 kg bw, 1 L): XX % ADI
	Infant (5 kg bw, 0.75 L): XX % ADI

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code[a]	Commodity/Group	MRL/Import tolerance[b] (mg/kg) and Comments	
Plant commodities			
Representative uses (row to be deleted if not relevant)			
MRL application (row to be deleted if not relevant)			
Animal commodities			

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Environmental fate and behaviour

*No data available in the environmental fate section the active substance is considered to be readily biodegradable and will be rapidly degraded in the environment***.**

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	
Non-extractable residues after 100 days	
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	
Non-extractable residues after 100 days	
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	
Mineralisation at study end	
Non-extractable residues at study end	

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark aerobic conditions						
Soil type	*X*[6]	pH[a)]	t. ºC / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Geometric mean (if not pH dependent)							
pH dependence, *Yes or No*							

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Met 1	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was *xxx*							
Soil type	*X*[7]	pH[a)]	t. ºC / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Geometric mean (if not pH dependent)								
Arithmetic mean								
pH dependence, *Yes or No*								

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

[6] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Parent	Aerobic conditions								
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	*X*[7]	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	Method of calculation
Geometric mean (if not pH dependent)									
pH dependence, *Yes or No*									

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix

Met 1		Aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was *xxx*								
Soil type	Location	*X*[8]	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90} (d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	f. f. k_f / k_{dp}	Method of calculation
Geometric mean (if not pH dependent)										
Arithmetic mean										
pH dependence, Yes or No										

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7 values are DegT50matrix

[7] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)		
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)		
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean		

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark anaerobic conditions						
Soil type	*X*[8]	pH[a)]	t. ºC / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Geometric mean (if not pH dependent)							

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Normalised using a Q10 of 2.58

[8] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Met 1	Dark anaerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was *xxx*.							
Soil type	*X*[10]	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20°C[b)]	St. (χ^2)	Method of calculation
Geometric mean (if not pH dependent)								
Arithmetic mean								

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Normalised using a Q10 of 2.58

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3

Parent	Soil photolysis					
Soil type	*X*[9]	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d) calculated at ??°N	St. (χ^2)	Method of calculation

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]

[9] X This column is reserved for any other property that is considered to have a particular impact on the degradation rate. Column and this footnote may be removed if not used.

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Parent							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Geometric mean (if not pH dependent)*							
Arithmetic mean (if not pH dependent)							
pH dependence, *Yes or No*							

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]

* Only relevant after implementation of the published EFSA guidance.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Metabolite 1							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Geometric mean (if not pH dependent)*							
Arithmetic mean (if not pH dependent)							
pH dependence, *Yes or No*							

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]

* Only relevant after implementation of the published EFSA guidance.

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies	

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1

Hydrolytic degradation of the active substance and metabolites > 10 %	

Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %	
Quantum yield of direct phototransformation in water at Σ > 290 nm	

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)	*yes*

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a]	t. °C[b]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to *x* °C[c]		At study temp	Normalised to x °C[c]		

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C
[c] Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

Metabolite *X*	Max in total system *x* % after *n* days									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a]	t. °C[b]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to x °C[c]		At study temp	Normalised to x °C[c]		

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C
[c] Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation *x* % after *n* d. (end of the study).	Non-extractable residues. max *x* % after *n* d (suspended sediment test)	Non-extractable residues. max *x* % after *n* d (end of the study) (suspended sediment test)

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent	Distribution (*e.g. max in water x after n d. Max. sed x % after n d*)									
Water / sediment system	pH water phase	pH sed [a)]	t. ºC	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Geometric mean at 20ºC[b)]										

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Normalised using a Q10 of 2.58

Metabolite	Distribution. Max in total system x % after n days, kinetic formation fraction (k_f/k_{dp}):									
Water / sediment system	pH water phase	pH sed [a)]	t. ºC	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Geometric mean at 20ºC[b)]										

[a)] Measured in [medium to be stated, usually calcium chloride solution or water]
[b)] Normalised using a Q10 of 2.58

Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after n d (end of the study)

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	
Photochemical oxidative degradation in air	
Volatilisation	
Metabolites	

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5

Soil (indicate location and type of study)	
Surface water (indicate location and type of study)	
Ground water (indicate location and type of study)	
Air (indicate location and type of study)	

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent Method of calculation	
Application data	

List of end points

Rapporteur Member State	Month and year	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial					
Short term	24h				
	2d				
	4d				
Long term	7d				
	28d				
	50d				
	100d				
Plateau concentration		*x* mg/kg after *n* yr			

Metabolite I	
Method of calculation	
Application data	

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial					
Short term	24h				
	2d				
	4d				
Long term	7d				
	28d				
	50d				
	100d				
Plateau concentration					

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	
Application rate	

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

* Only relevant after implementation of the published EFSA guidance.

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

Model /Crop	Scenario	Parent (µg/L)	*Metabolite* (µg/L)		
			Met I	*Met II*	*Met III*
	Chateaudun				
	Hamburg				
	Jokioinen				
	Kremsmunster				
	Okehampton				
	Piacenza				
	Porto				
	Sevilla				
	Thiva				

Model /Crop	Scenario	Metabolite (µg/L)			
		Met IV	*Met V*	*Met VI*	*Met VII*
	Chateaudun				
	Hamburg				
	Jokioinen				
	Kremsmunster				
	Okehampton				
	Piacenza				
	Porto				
	Sevilla				
	Thiva				

PEC$_{(gw)}$ From lysimeter / field studies

Parent	1st year	2nd year	3rd year
Annual average (µg/L)			

Metabolite X	1st year	2nd year	3rd year
Annual average (µg/L)			

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent Parameters used in FOCUSsw step 1 and 2	
Parameters used in FOCUSsw step 3 (if performed)	
Application rate	

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h				
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h				
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				
Southern EU	0 h				
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		0 h				
		24 h				
		2 d				
		4 d				
		7 d				
		14 d				
		21d				
		28 d				
		42 d				
		0 h				
		24 h				
		2 d				
		4 d				
		7 d				
		14 d				
		21 d				
		28 d				
		42 d				
		0 h				
		24 h				
		2 d				
		4 d				
		7 d				
		14 d				
		21 d				
		28 d				
		42 d				

Metabolite Parameters used in FOCUSsw step 1 and 2	
Parameters used in FOCUSsw step 3 (if performed)	

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Application rate	
Main routes of entry	

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h				
	24h				
	2d				
	4d				
	7d				
	14d				
	21d				
	28d				
	42d				

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h				
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				
	21 d				
	28 d				
	42 d				
Southern EU	0 h				
	24 h				
	2 d				
	4 d				
	7 d				
	14 d				

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	21 d				
	28 d				
	42 d				

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		0				
		24				
		2d				
		4d				
		7d				
		14d				
		21d				
		28d				
		42d				
		0 h				
		24 h				
		2 d				
		4 d				
		7 d				
		14 d				
		21 d				
		28 d				
		42 d				
		0 h				
		24 h				
		2 d				
		4 d				
		7 d				
		14 d				
		21 d				

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
		28 d				
		42 d				

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 4 Environmental fate and behaviour

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

Method of calculation	

PEC

Maximum concentration	

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 5 Ecotoxicology

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Indicate species	a.s.	Acute	LD_{50}	
	Preparation	Acute	LD_{50}	
	Metabolite 1	Acute	LD_{50}	
	a.s.	Long-term	LD_{50}/10	
	a.s.	Long-term	NOEC/NOAEC/NOAEL [*amend as appropriate*]	
Mammals				
Indicate species	a.s.	Acute	LD_{50}	
	Preparation	Acute	LD_{50}	
	Metabolite 1	Acute	LD_{50}	
	a.s.	Long-term [*for screening step*]	NOAEL	
	a.s.	Long-term [*for first tier risk assessment*]	NOAEL [*amend as appropriate*]	
Endocrine disrupting properties (Annex Part A, points 8.1.5) *[list evidence/indication on the potential for endocrine disrupting properties]*				
Additional higher tier studies (Annex Part A, points 10.1.1.2): *[To be provided if the tier 1 risk assessment fails]*				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): *[To provide available data]*				

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 5 Ecotoxicology

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

[Representative use] at [application rate] g a.s./ha [x number of applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All		Acute			10
All		Long-term			5
Tier 1 (Birds)					
Higher tier (birds): [*in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)]*					
Screening Step (Mammals)					
All		Acute			10
All		Long-term			5
Tier 1 (Mammals)					
Higher tier (Mammals): [*in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)]*					

Risk from bioaccumulation and food chain behaviour[*indicate when not relevant* i.e *if Log kow≤3]*

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term			5
Earthworm-eating mammals	Long-term			5
Fish-eating birds	Long-term			5
Fish-eating mammals	Long-term			5

Higher tier : [*in higher tier refinement provide brief details of any refinements used]*

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute			5
Puddle scenario, Screening step 1)Application rate (g a.s./ha)/relevant endpoint <50 (koc<500 L/kg), TER calculation not needed 2)Application rate (g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute			10
Puddle scenario	Mammals	acute			10
Puddle scenario	Birds	Long-term			5

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Puddle scenario	Mammals	Long-term			5

Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
l				
Fish				
Golden orfe	urea	Acute 96 hr (static, or semi-static or flow-through)	Mortality, LC_{50}	>10000 mg/l
O. mossambicus	urea	Acute 96 hr (static, or semi-static or flow-through)	Mortality, LC_{50}	28000 mg L−1
B. barnawas	urea	Acute 96 hr (static, or semi-static or flow-through)	Mortality, LC50	> 9100 mg/l)
Aquatic invertebrates				
Daphnia	urea	24 h (static, or semi-static or flow-through)	Mortality, EC_{50}	>10000 mg/l
Freshwater snail eggs	urea	24/ h (static, or semi-static or flow-through)	Mortality, LC50	14241 mg/l
Freshwater juveniles	urea	24/ h (static, or semi-static or flow-through)	Mortality, LC50	18255 mg/l

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Freshwater adults	urea	24/ h (static, or semi-static or flow-through)	Mortality, LC50	22998 mg/l
Freshwater adults	urea	48/ h (calculated)	Mortality, LC50	13477 mg/l
Aedes aegypti (mosquito larvae)	urea	4/ h (static, or semi-static or flow-through	Mortality, LC50	60000 mg/l
Sediment-dwelling organisms				
Algae				
Blue-green algae	urea	192 h (static, or semi-static or flow-through)	toxicity threshold	47 mg/l
Scenedesmus quadricauda	urea	7 day	toxicity threshold	>10000 mg/l
Higher plant				
Further testing on aquatic organisms *[To report a short summary of mesocosms and SSD assessments and to include the associated AF for the representative use and explain the reason (briefly)]*				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) *[list evidence/indication on the potential for endocrine disrupting properties]*				

[1] ($_{nom}$) nominal concentration; ($_{mm}$) mean measured concentration; prep.: preparation; a.s.: active substance

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
Spain	**February 2018**	**Hydrolysed proteins – ENTOMELA 50SL**

Section 5 Ecotoxicology

Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$				
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	X*			
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)				
Annex VI Trigger for the bioconcentration factor				
Clearance time (days) (CT_{50})				
(CT_{90})				
Level and nature of residues (%) in organisms after the 14 day depuration phase				
Higher tier study				

* based on total ^{14}C or on specific compounds

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**

Section 5 Ecotoxicology

Toxicity/exposure ratios for the most sensitive aquatic organisms (Regulation (EU) N° 284/2013, Annex Part A, point 10.2)

$FOCUS_{sw}$ step 1-3 - TERs for [active substance] – [representative use] at [application rate] g a.s./ha [x number of applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**fish chronic**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Higher plant**	**Sed. dweller prolonged**	**Microcosm / Mesocosm**
		Indicate species	*Indicate species*	*Indicate species*	*Indicate species*	*Indicate species*	*Indicate species*	*Indicate species*	
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC_{50}	NOEC	NOEC
		x.xx µg/L	x.xx µg/L	x.xx µg/L	x.xx µg/L	x.xx µg/L	x.xx µg/L	x.xx µg/L	x.xx µg/L
FOCUS Step 1									
FOCUS Step 2									
North Europe									
South Europe									
FOCUS Step 3*									
D3 / ditch									
D4 / pond									
D4 / stream									
D5 / pond									
D5 / stream									
R1 / pond									
R1 / stream									
R2 / stream									
R3 / stream									
R4 / stream									
Trigger**		100	10	100	10	10	10	10	

*[Only scenarios where the trigger is not met at FOCUSsw step 1-2 should be included in step 3.]

**[If the Trigger value has been adjusted during the risk assessment, it should always be clear on what basis the risk assessment has been performed, i.e. what the AF value is and for which organism and endpoint it refers.]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**

Section 5 Ecotoxicology

$FOCUS_{sw}$ step 4 - TERs [active substance] – [representative use] at [application rate] g a.s./ha [x number of applications]

[Fate experts should also be asked to review this table to check if it is in line with their assessments]

Organisms *Indicate species***:**

Toxicity endpoint: x.xx µg/L

Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (x.xx µg/L)**	**TER**	**Trigger**
FOCUS Step 4*					
D3 / ditch					
D4 / pond					
D4 / stream					
D5 / pond					
D5 / stream					
R1 / pond					
R1 / stream					
R2 / stream					
R3 / stream					
R4 / stream					

*[Only scenarios where the trigger is not met at FOCUSsw step 3 should be included in step 4].

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**

Section 5 Ecotoxicology

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Indicate species	a.s.,	Acute	Oral toxicity (LD_{50})	µg/bee
	preparation			
	a.s.,	Acute	Contact toxicity (LD_{50})	µg/bee
	preparation			
	a.s.,	Chronic	10 d-LC50	µg/bee/day
	preparation			
	a.s.,	Bee brood development	NOEClarvae	µg/larva/developmental period
	preparation			
	a.s.,	Sub-lethal effects (behavioural and reproductive)	NOEC hypopharyngeal glands	
	preparation			

Potential for accumulative toxicity: *yes/no*
Semi-field test (Cage and tunnel test)
Field tests

Risk assessment for – [representative use] at [application rate] g a.s./ha [x number of applications]

Species	Test substance	Risk quotient	HQ/ETR	Trigger
Indicate species	a.s., preparation	HQcontact		
	a.s., preparation	ETRacute adult oral		
	a.s., preparation	ETRchronic adult oral		

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**

Section 5 Ecotoxicology

	a.s., preparation	ETRlarvae		
	a.s., preparation	ETRhpg		

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
Typhlodromus pyri	a.s., preparation	Mortality, LR_{50} Reproduction, ER_{50}	g/ha g/ha
Aphidius rhopalosiphi	a.s., preparation	Mortality, LR_{50} Reproduction, ER_{50}	g/ha g/ha
Additional species			

First tier risk assessment for – [representative use] at [application rate] g a.s./ha [x number of applications]

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
	Typhlodromus pyri				2
	Aphidius rhopalosiphi				2

[1]indicate distance assumed to calculate the drift rate

Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	ER_{50}
					Mortality, reproduction		

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation
[3] indicate if positive percentages relate to adverse effects or not

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**

Section 5 Ecotoxicology

Risk assessment for – [representative use] at [application rate] g a.s./ha [x number of applications] based on extended lab test or aged residue tests

Species	ER_{50} (g/ha)	In-field rate	Off-field rate[1]

[1]indicate distance assumed to calculate the drift rate and if 3D or 2D.

Semi-field tests
Field studies
Additional specific test

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Earthworms					
	a.s.		Chronic	Growth, reproduction, behaviour	EC_{10}, EC_{20}, NOEC mg a.s./kg d.w.soil (mg a.s/ha)
	preparation				
	metabolite 1				
Other soil macroorganisms					
Folsomia candida	a.s.			Mortality, reproduction, behaviour [*amend as appropriate*]	EC_{10}, EC_{20}, NOEC [*amend as appropriate*]
	preparation				
	metabolite 1				
Hypoaspis aculeifer	a.s.			Mortality, growth, reproduction, behaviour [*amend as appropriate*]	EC_{10}, EC_{20}, NOEC [*amend as appropriate*]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**

Section 5 Ecotoxicology

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
	preparation				
	metabolite 1				

[1]To indicate whether the test substance was oversprayed/to indicate the organic content of the test soil (e.g. 5 % or 10 %).

Higher tier testing (e.g. modelling or field studies)

Nitrogen transformation	a.s. preparation		% effect at day xx at mg a.s./kg d.w.soil (mg a.s/ha) *[In line with the OECD test guideline the endpoint should be based on nitrogen transformation rate and not nitrogen levels*]
	metabolite 1		

Toxicity/exposure ratios for soil organisms

[Representative use] at [application rate] g a.s./ha [x number of applications]

Test organism	Test substance	Time scale	Soil PEC[1]	TER	Trigger
Earthworms					
	a.s.	Chronic			5
	preparation	Chronic			5
	metabolite 1				
Other soil macroorganisms					
	a.s.				
	preparation				
	metabolite 1				
	a.s.				
	preparation				
	metabolite 1				

[1]indicate which PEC soil was used (e.g. plateau PEC)

Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not required for herbicides or plant growth regulators as ER_{50} tests should be provided

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**

Section 5 Ecotoxicology

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Extended laboratory studies : Semi-field and field test:						

[1] explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	
Pseudomonas sp	

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s. Available monitoring data concerning effect of the PPP.

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	
water	
sediment	
groundwater	

[1] metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**

Section 5 Ecotoxicology

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	Hydrolysed proteins – Beet molasses urea hydrolyaste
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][10]:	No classification is proposed substance is of low toxicity.
Peer review proposal[11] for harmonised classification according to Regulation (EC) No 1272/2008:	No classification is proposed substance is of low toxicity.

[10] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[11] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**

Appendix

Used compounds code(s)

Code/Trivial name*	**IUPAC name/SMILES notation**	**Structural formula**

* The compound code / trivial name in bold is the name used in the list of endpoints.