List of end points

Rapporteur Member State	Month and year	Active Substance (Name)

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
Function (*e.g.* fungicide)	Insect attractant and bait

Rapporteur Member State	
Co-rapporteur Member State	

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

Chemical name (IUPAC)	
Chemical name (CA)	*Not applicable*
CIPAC No	*Not applicable*
CAS No	*Not applicable*
EC No (EINECS or ELINCS)	*Not applicable*
FAO Specification (including year of publication)	
Minimum purity of the active substance as manufactured	*300* g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	none
Molecular formula	*Not applicable*
Molar mass	*the average molecular weight is 2.200 dalton*
Structural formula	*Not applicable*

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)

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)	Melting point : < 4°C
Boiling point (state purity)	Boiling point : > 100 °C
Temperature of decomposition (state purity)	°C ( )
Appearance (state purity)	*Brown liquid, average viscosity, undefined smell*
Vapour pressure (state temperature, state purity)	-
Henry's law constant (state temperature)	-
Solubility in water (state temperature, state purity and pH)	*Total*
Solubility in organic solvents (state temperature, state purity)	in g/L at °C ( )
Surface tension (state concentration and temperature, state purity)	53.5 mN/m at °C (solution 1 g/L)
Partition coefficient (state temperature, pH and purity)	-
Dissociation constant (state purity)	pKa = ( )
UV/VIS absorption (max.) incl. ε (state purity, pH)	enlarged absorption bands in the range 3260-2940 cm-1, bands at cm -1 1630 (s,l), 1580 (s,l), 1455 (w), 1395 (s) l=large, s=sharp, w=weak
Flammability (state purity)	Flammability point > 100°C. The formulated product is not flammable (water based)
Explosive properties (state purity)	The product has no explosive properties
Oxidising properties (state purity)	-

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Rapporteur Member State	Month and year	Active Substance (Name)

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)		
Olea europaea L. (olive) Malus pumila Mill., Pyrus communis L. (Pome fruits) Prunus spp, Persica vulgaris Mill., (stone fruits) Juglans regia L. (walnut) Citrus spp (citrus) Fig, Actinidia and Blueberries	Italy, Spain, Greece, Portugal, France	*NUTREL*	F	Adult insects (Dyptera) laying eggs on fruits	SL (n)	*3780G /L*	Normal volume spraying, / high pressure	7 (o)	2 - 4	10 - 30	-	100-200	0.907	(p)	(2.4 L product/ ha)
				Mass trapping			Product in Traps	Development of fruits	N.A.	N.A.	90 Traps/Ha	N.A.	8,5	N.A.	(22.5 L product/ ha).

(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)

(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.

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Rapporteur Member State	Month and year	Active Substance (Name)

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

(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

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)

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)

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)

Attracting power against Mediterrarnean Fruit Fly Cherry Fly, Olive Fly Bactrocera oleae and other flies like the Walnut Fly

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

None

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

None

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

	Met1	*Met2*	*Met3*	*Met4*	*Met5*	*Met6*
Activity against target organism	*no*	*no*	*no*	*/no*	*no*	*no*

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)

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)	The determination of organic nitrogen is made subtracting the ammonium nitrogen content to total nitrogen content. (nitrogen determination according to Kjeldahl method)
Impurities in technical a.s. (analytical technique)	none
Plant protection product (analytical technique)	The determination of organic nitrogen is made subtracting the ammonium nitrogen content to total nitrogen content. (nitrogen determination according to Kjeldahl method) DETERMINATION OF SACCHARIDES Principle: for the determination of the saccharides the method MP-1114 rev. 0

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		No MRLS
Food of animal origin		No MRLS
Soil		No MRLS
Sediment		No MRLS
Water	surface	No MRLS
	drinking/ground	No MRLS
Air		No MRLS
Body fluids and tissues		No MRLS

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	Not required
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	Nor required
Soil (analytical technique and LOQ)	Not required
Water (analytical technique and LOQ)	Nor required

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)

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

Air (analytical technique and LOQ)	not required
Body fluids and tissues (analytical technique and LOQ)	Not required

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

Substance	Hydrolysed proteins
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. Not hazardous mixture.
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	

[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)

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	No data- not required
Toxicokinetics	No data- not required
Distribution	No data- not required
Potential for bioaccumulation	No data- not required
Rate and extent of excretion	No data- not required
Metabolism in animals	No data- not required
In vitro metabolism	No data- not required
Toxicologically relevant compounds (animals and plants)	No data- not required
Toxicologically relevant compounds (environment)	No data- not required

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

Rat LD_{50} oral	Not oral noxious	-
Rat LD_{50} dermal	Not dermal noxious	-
Rat LC_{50} inhalation	Not required	-
Skin irritation	Non-irritant	-
Eye irritation	Non-irritant	-
Skin sensitisation	Not sensitising	-
Phototoxicity	*Not required*	-

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

Target organ / critical effect	No data - not required	-
Relevant oral NOAEL	No data - not required	-
Relevant dermal NOAEL	No data - not required	-
Relevant inhalation NOAEL	No data - not required	-

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

In vitro studies	*not required*	
In vivo studies	*not required*	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)

Section 2 Mammalian Toxicology

Photomutagenicity	*not required*	-
Potential for genotoxicity	*Substance* is unlikely 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)	*not required*	-
Relevant long-term NOAEL	*not required*	-
Carcinogenicity (target organ, tumour type)	*not required*	-
Relevant NOAEL for carcinogenicity	*not required*	-

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

Reproduction toxicity

Reproduction target / critical effect	*not required*	-
Relevant parental NOAEL	*not required*	-
Relevant reproductive NOAEL	*not required*	-
Relevant offspring NOAEL	*not required*	-

Developmental toxicity

Developmental target / critical effect	*not required*	-
Relevant maternal NOAEL	*not required*	-
Relevant developmental NOAEL	*not required*	*

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

Acute neurotoxicity	*study not required*	-
Repeated neurotoxicity	*study not required*	-
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	*studies not required*	-

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

Supplementary studies on the active substance	*study not required*
Endocrine disrupting properties	*study not required*
Studies performed on metabolites or impurities	*study not required.*

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Rapporteur Member State	Month and year	Active Substance (Name)

Section 2 Mammalian Toxicology

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

Limited; new active substance, no detrimental effects on health in manufacturing personnel

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)	0.03	rat, 2-year	100
Acute Reference Dose (ARfD)	0.1	rabbit, developmental	100
Acceptable Operator Exposure Level (AOEL)	0.14	dog, 90-day	142*
Acute Acceptable Operator Exposure Level (AAOEL)	0.1	rabbit, developmental	100*

* 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*)	*study not required.* n

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

Operators	*study not required since* o risk is anticipated
Workers	*study not required since* o risk is anticipated
Bystanders and residents	*study not required since* o risk is anticipated

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

Substance :	name
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] :	*Hydrolysed proteins*
Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	Not classified. Not hazardous substance

[3] If available include also reference values for metabolites

[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.

[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.

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Rapporteur Member State	Month and year	Active Substance (Name)

Section 2 Mammalian Toxicology

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Rapporteur Member State	Month and year	Active Substance (Name)

Section 3 Residues

Residues in or on treated products food and feed

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			
	Nor required			

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?	Nor required			

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?	(Nor required				

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	
Plant residue definition for risk assessment (RD-RA)	Not required
Conversion factor (monitoring to risk assessment)	Not required

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Rapporteur Member State	Month and year	Active Substance (Name)

Section 3 Residues

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		
	Not required			

Time needed to reach a plateau concentration in milk and eggs (days)	Not required
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Not required
Animal residue definition for risk assessment (RD-RA)	Not required
Conversion factor (monitoring to risk assessment)	Not required
Metabolism in rat and ruminant similar (Yes/No)	Not required
Fat soluble residues (Yes/No) **(FAO, 2009)**	Not required

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**	Not required
Field rotational crop study **OECD Guideline 504**	Not required

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)

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)

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 ($STMR_{Mo}$).

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Rapporteur Member State	Month and year	Active Substance (Name)

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)				

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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.

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Rapporteur Member State	Month and year	Active Substance (Name)

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.

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Rapporteur Member State	Month and year	Active Substance (Name)

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)

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)

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)**

Section 4 Environmental fate and behaviour

Environmental fate and behaviour

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

Mineralisation after 100 days	*x-y* % after *x* d, [^{14}C-*X*]-label (n[6]= *x*) *x-y* % after *x* d, [^{14}C-*Y*]-label (n= *x*)
Non-extractable residues after 100 days	*x-y* % after *x* d, [^{14}C-*X*]-label (n= *x*) *x-y* % after *x* d, [^{14}C-*Y*]-label (n= *x*)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	*Met I - x-y* % at *x* d (n= *x*) [^{14}C-*X*] & [^{14}C-*Y*] labels … *Met VII - x-y* % (n= x) at x d [^{14}C-*Y*] label Sterile conditions: *x* % after *x* d (n= *x*)

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

Mineralisation after 100 days	*x-y* % after *x* d, [^{14}C-*X*]-label (n= *x*) *x-y* % after *x* d, [^{14}C-*Y*]-label (n= *x*)
Non-extractable residues after 100 days	*x-y* % after *x* d, [^{14}C-*X*]-label (n= *x*) *x-y* % after *x* d, [^{14}C-*Y*]-label (n= *x*)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	*Met I - x-y* % at *x* d (n= *x*) [^{14}C-*X*] & [^{14}C-*Y*] labels … *Met VII - x-y* % (n= x) at x d [^{14}C-*Y*] label Sterile conditions: *x* % after *x* d (n= *x*)

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)	*Met I - x-y* % at *x* d (n= *x*) [^{14}C-*X*] & [^{14}C-*Y*] labels … *Met VII - x-y* % (n= x) at x d [^{14}C-*Y*] label Sterile conditions: *x* % after *x* d (n= *x*)
Mineralisation at study end	*x-y* % after *x* d, [^{14}C-*X*]-label (n= *x*) *x-y* % after *x* d, [^{14}C-*Y*]-label (n= *x*)
Non-extractable residues at study end	*x-y* % after *x* d, [^{14}C-*X*]-label (n= *x*) *x-y* % after *x* d, [^{14}C-*Y*]-label (n= *x*)

[6] n corresponds to the number of soils.

List of end points

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

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*[7]	pH[a)]	t. °C / % 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. °C / % 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

[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)**

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*[8]	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

[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)**

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)	(d)	
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	*Met I* *?? (d)*	Met II ?? (d)
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	Met I from *??define precursor*	Met 2 from *??define precursor*

* 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	Plateau concentration of *x* mg/kg reached after *x* years (based on calculation) *or* Application of *x* g/ha per annum in field studies. Accumulation factor: *n.*

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*[9]	pH[a)]	t. °C / % 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

[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)**

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*[10]	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]

[10] 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)**

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)**

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	Elution (mm): *x* mm Time period (d): *x* d
	Leachate: *x* % total residues/radioactivity in leachate *x* % active substance, *x* % *Met I*,… *x* % *Met VII* >*x* % total residues/radioactivity retained in top *x* cm Koc (mL/g) =*(When it has not been possible to determine it by batch sorption experiments)*.

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	Elution (mm): *x* mm Time period (d): *x* d
	Leachate: *x* % total residues/radioactivity in leachate *x* % active substance, *x* % *Met I*,… *x* % *Met VII* >*x* % total residues/radioactivity retained in top *x* cm Koc (mL/g) =*(When it has not been possible to determine it by batch sorption experiments)*.

List of end points

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

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	Location: Study type (e.g. lysimeter, field): *lysimeter* Soil properties: texture, pH = , OC= , MWHC = Dates of application : Crop : /Interception estimated: Number of applications: **x** years, **x** applications per year Duration. Application rate: **x** g/ha/year Average annual rainfall (mm): **x** mm Average annual leachate volume (mm): **x** mm % radioactivity in leachate (maximum/year): **x** % AR Individual annual maximum concentrations (e.g. 1st, 2nd, 3rd yr): **x** µg/L active substance, **x** µg/L *Met I*, *…x*µg/L *Met VII*. Unidentified radioactivity, no of components, *x* µg/L parent equivalents. Individual annual average concentrations (e.g. 1st, 2nd, 3rd yr): *x* µg/L active substance, *x* µg/L *Met I, x*µg/L *… Met VII*. Unidentified radioactivity, no of components, *x* µg/L parent equivalents. Amount of radioactivity in the soils at the end of the study = % AR; *XX* % AR as parent, *XX* % AR as *Met X*

List of end points

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

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 %	pH 5: *y* h at 20 °C *(1st order, χ^2=x)* *Met I: x* % AR (*x* d) … *Met VII*: *x* % AR (*x* d)
	pH 7: *y* h at 20 °C *(1st order, χ^2=x)* *Met I: x* % AR (*x* d) … *Met VII*: *x* % AR (*x* d)
	pH 9: *y* h at 20 °C *(1st order, χ^2=x)* *Met I: x* % AR (*x* d) … *Met VII*: *x* % AR (*x* d)

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 %	DT_{50} : *x* h Natural light, *xx*°N; DT_{50} *x* days *Met II: x* % AR (*x* d) Estimated DT_{50} at *xx* °N *x* days
Quantum yield of direct phototransformation in water at Σ > 290 nm	*z* · 10 $^{-y}$ mol · Einstein $^{-1}$

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

Readily biodegradable (yes/no)	*No data submitted, substance considered not readily biodegradable* *or if there is a study indicate yes or no.*

List of end points

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

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)**

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. °C	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 20°C[b]										

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

Metabolite *X*	Distribution (*e.g. max in water x after n d. Max. sed x % after n d*). Max in total system x % after n days, kinetic formation fraction (k_f/k_{dp}): *where possible indicate a value for each experiment, clarifying whether fraction was derived for whole system or sediment and or water compartments. The identity of the precursor should also be included (e.g. from parent). Arithmetic mean of kinetic formation fractions to be stated. When calculating arithmetic means, the compartments: whole system, water, sediment should not be mixed.*									
Water / sediment system	pH water phase	pH sed [a]	t. °C	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 20°C[b]										

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

List of end points

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

Section 4 Environmental fate and behaviour

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)

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

Direct photolysis in air	*Not studied - no data requested* *or* *[@]Latitude: ..... Season: ..... DT_{50} .....*
Photochemical oxidative degradation in air	DT_{50} of *x* hours derived by the Atkinson model (version *x.x*). OH (*12 or 24 h*) concentration assumed = *xxx*
Volatilisation	from plant surfaces (BBA guideline): *<x* % after *x* hours
	from soil surfaces (BBA guideline): *negligible after x hours*
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	Soil: Surface water: Sediment: Ground water: Air:

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)	

[@] If direct photolysis data is provided, information on the latitude etc. should be included.

List of end points

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

Section 4 Environmental fate and behaviour

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

Parent Method of calculation	DT_{50} (d): *x* days Kinetics: *SFO* Field or Lab: *representative worst case from field studies.*
Application data	Crop: *wheat* Depth of soil layer: *5cm or 20cm* Soil bulk density: *1.5g/cm³* % plant interception: *Pre-emergence therefore no crop interception* Number of applications: *x* Interval (d): *x* Application rate(s): *x* g a.s./ha

$PEC_{(s)}$ (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	Molecular weight relative to the parent: DT_{50} (d): *x* days Kinetics: *SFO* Field or Lab: *representative worst case from field studies.*
Application data	Application rate assumed: *x g/ha (assumed Met I is formed at a maximum of x % of the applied dose) or formation fraction (if sequential modelling is employed)*

List of end points

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

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			

List of end points

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

Section 4 Environmental fate and behaviour

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)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: *(with version control no.(s))* Crop: Crop uptake factor: Water solubility (mg/L): *X* at pH 7 and 20°C Vapour pressure: *X* Pa at 20°C Geometric mean parent $DT_{50\ lab/field}$ *x d (normalisation to 10kPa or pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).* K_{OC}: *parent, geometric* mean x mL/g, arithmetic mean* $^{1}/_{n}$ *= y.* Metabolites: *all above information required for each metabolite plus the kinetic formation fraction from the precursor(k_f/k_{dp}). The identity of the precursor should also be included (e.g. from parent).* For field and lysimeter studies Location: *UK, N. Yorkshire* Study type (e.g. lysimeter, field): *lysimeter* Soil properties: pH = , OC= , MWHC = Dates of application : Crop : /Interception estimated: Number of applications: *x* years, *x* applications year Duration. Average annual rainfall (mm): *x* mm Average annual leachate volume (mm): *x* mm
Application rate	Gross application rate: *x* g/ha. Crop growth stage: Canopy interception %: Application rate net of interception: *x* g/ha. No. of applications: Time of application (absolute or relative application dates): *e.g. 1 April or 10 days post emergence*

* 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)**

Section 4 Environmental fate and behaviour

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)**

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	Version control no. of FOCUS calculator: Molecular weight (g/mol): K_{OC}/K_{OM} (mL/g): DT_{50} soil (d): *x days (Lab or field. In accordance with FOCUS SFO)* DT_{50} water/sediment system (d): *x d(geomean from sediment water studies if not pH dependent)* DT_{50} water (d): DT_{50} sediment (d): Crop interception (%):*e.g. X % (no, minimal, average or full canopy)*
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: Water solubility (mg/L): Vapour pressure: *X* Pa at 20°C Kom/Koc (mL/g): 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively) Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor:
Application rate	Crop and growth stage: wheat BBCH X-X Number of applications: *x* Interval (d): *x* Application rate(s): *x* g a.s./ha Application window: *early or late spray drift selected (for vines and top fruit)*

List of end points

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

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)**

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				

List of end points

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

Section 4 Environmental fate and behaviour

Metabolite *X* Parameters used in FOCUSsw step 1 and 2	Molecular weight: Soil or water metabolite: Koc/Kom (mL/g): DT_{50} soil (d): *x days (If necessary, Lab or field. In accordance with FOCUS SFO)* DT_{50} water/sediment system (d): *x d (representative worst case from sediment water studies)* DT_{50} water (d): DT_{50} sediment (d): Crop interception (%):*e.g. X % (no, minimal, average or full canopy)* Maximum occurrence observed (% molar basis with respect to the parent) Total Water and Sediment: Soil: *(if necessary)*
Parameters used in FOCUSsw step 3 (if performed)	Water solubility (mg/L): Vapour pressure: *X* Pa at 20°C Kom/Koc (mL/g): 1/n: (Freundlich exponent general or for soil, susp. solids or sediment respectively) Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: Metabolite kinetically generated in simulation (yes/no): Formation fraction in soil (k_f/k_{dp}): *(If formation / degradation of metabolite is kinetically simulated by PRZM and MACRO) the identity of the precursor should also be included (e.g. from parent).* Formation fraction in sediment water (k_f/k_{dp}): *(If formation / degradation of metabolite is kinetically simulated by TOXSWA) the identity of the precursor should also be included (e.g. from parent).*
Application rate	Crop and growth stage: *wheat BBCH X-X* Number of applications: *x* Interval (d): *x* Application rate(s): *x* g a.s./ha Application window: *early or late spray drift selected (for vines and top fruit)*
Main routes of entry	

List of end points

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

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
	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				
	21 d				
	28 d				
	42 d				

List of end points

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

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				
		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				
		28 d				
		42 d				

List of end points

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

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	*e.g.* *from dust drift* *exposure via sewers* *run-off from hard surfaces*

List of end points

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

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)**

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
Puddle scenario	Mammals	Long-term			5

List of end points

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

Section 5 Ecotoxicology

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]
Laboratory tests				
Fish				
Indicate species	a.s.	Acute 96 hr (static, or semi-static or flow-through)	Mortality, LC_{50}	mg or µg a.s./$L_{(nom)\ or\ (mm)}$
	Preparation	Acute 96 hr (static, or semi-static or flow-through)	Mortality, LC_{50}	mg or µg prep./L (mg or µg a.s./$L_{(nom)\ or\ (mm)}$)
	a.s.	Chronic (static, or semi-static or flow-through)	Growth, or development, or behaviour, or reproduction NOEC	mg or µg a.s./$L_{(nom)\ or\ (mm)}$
	Metabolite 1	96 hr (static, or semi-static or flow-through)	Mortality, LC_{50}	
Aquatic invertebrates				
Indicate species	a.s.	48 h (static, or semi-static or flow-through)	Mortality, EC_{50}	mg or µg a.s./$L_{(nom)\ or\ (mm)}$
	Preparation	48 h (static, or semi-static or flow-through)	Mortality, EC_{50}	mg prep./L (mg or µg a.s./$L_{(nom)\ or\ (mm)}$)
	a.s.	21 d (static, or semi-static or flow-through)	Reproduction or development, NOEC	mg or µg a.s./$L_{(nom)\ or\ (mm)}$

List of end points

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

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
	Metabolite 1	48 h (static, or semi-static or flow-through)	Mortality, EC_{50}	
Sediment-dwelling organisms				
Indicate species	a.s.	28 d (static, or semi-static or flow-through)	NOEC	mg or µg a.s./kg dry $sediment_{(nom) or (mm)}$ (mg or µg a.s./$L_{(nom) or (mm)}$)
	Metabolite 2	28 d (static, or semi-static or flow-through)	NOEC	
Algae				
Indicate species	a.s.	72 h (static, or semi-static or flow-through)	Growth rate: E_rC_{50} (NOEC) [Biomass: E_bC_{50} (NOEC) Yield: E_yC_{50} (NOEC)]	mg or µg a.s./$L_{(nom) or (mm)}$
	Preparation			mg prep./L (mg or µg a.s./$L_{(nom) or (mm)}$)
	Metabolite 1	72 h (static, or semi-static or flow-through)	Growth rate: E_rC_{50} (NOEC) [Biomass: E_bC_{50} (NOEC) Yield: E_yC_{50} (NOEC)]	

List of end points

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

Section 5 Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Higher plant				
Indicate species	a.s.	(static, or semi-static or flow-through)	Fronds number, EC_{50} (NOEC) Frond area/fresh weight/dry weight, E_rC_{50} (NOEC)	mg or µg a.s./$L_{(nom)\ or\ (mm)}$
	Preparation			mg prep./L (mg or µg a.s./$L_{(nom)\ or\ (mm)}$)
	Metabolite 1	14 d (static, or semi-static or flow-through)	Fronds number, EC_{50} (NOEC) Frond area/fresh weight/dry weight, E_rC_{50} (NOEC)	
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)**

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	Parent (state name), Metabolite 1 (state name)
water	Parent (state name), Metabolite 1 (state name)
sediment	Parent (state name), Metabolite 1 (state name)
groundwater	Parent (state name), Metabolite 1 (state name)

[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	name
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][11]:	
Peer review proposal[12] for harmonised classification according to Regulation (EC) No 1272/2008:	

[11] 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.

[12] 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.