APPENDIX 9

FORMAT FOR THE LISTING OF END POINTS TO BE INCLUDED IN THE *TIER III* OVERALL SUMMARY AND ASSESSMENT

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	
Function (*e.g.* fungicide)	
Country to which application is made	

Identity (OECD data point IIA 1)

Chemical name (IUPAC)	
Chemical name (CA)	
CIPAC No	
CAS No	
EEC No (EINECS or ELINCS)	
FAO Specification (including year of publication)	
Minimum purity of the active substance as manufactured (g/kg)	
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	
Molecular formula	
Molecular mass	
Structural formula	

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Physical-chemical properties (OECD data point IIA 2)

Melting point (state purity)	
Boiling point (state purity)	
Temperature of decomposition	
Appearance (state purity)	
Relative density (state purity)	
Surface tension	
Vapour pressure (in Pa, state temperature)	
Henry's law constant (Pa m^3 mol^{-1})	
Solubility in water (g/l or mg/l, state temperature)	pH 5:
	pH 7:
	pH 9:
Solubility in organic solvents (in g/l or mg/l, state temperature)	
Partition co-efficient (log P_{OW}) (state pH and temperature)	pH 5:
	pH 7:
	pH 9:
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH 5:
	pH 7:
	pH 9:
Dissociation constant	
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	
Photostability (DT_{50}) (aqueous, sunlight, state pH)	
Quantum yield of direct phototransformation in water at λ > 290 nm	
Flammability	
Explosive properties	

Summary of intended uses

Crop and/ or situation	Country and / or Region	Product name	F G or I	Pests or Group of pests Controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type	Conc. of as	Method Kind	growth stage & season	number min max	interval between applications (min)	Kg as/hL min max	water L/ha min max	kg as/ha min max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)					(l)	(m)

(a) For crops, the Codex and EU (or other) classifications should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(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
(j) Growth stage at 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 application possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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Classification and proposed labelling (OECD data point IIA 10)

with respect to physical/chemical data	Classification: Proposed Label: Symbol: Indication of danger: Risk phrases: Safety phrases:
with respect to toxicological data	Classification: Proposed Label: Symbol: Indication of danger: Risk phrases: Safety phrases:
with respect to fate and behaviour data	Classification: Proposed Label: Symbol: Indication of danger: Risk phrases: Safety phrases:
with regard to ecotoxicological data	Classification: Proposed Label: Symbol: Indication of danger: Risk phrases: Safety phrases:

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Chapter 2: Methods of Analysis

Analytical methods for the active substance (OECD data point IIA 4.2)

Technical as (principle of method)	
Impurities in technical as (principle of method)	
Plant protection product (principle of method)	

Analytical methods for residues (OECD data points IIA 4.3 to IIA 4.8)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	
Soil (principle of method and LOQ)	
Water (principle of method and LOQ)	
Air (principle of method and LOQ)	
Body fluids and tissues (principle of method and LOQ)	

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Chapter 3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals (OECD data point IIA 5.1)

Rate and extent of absorption:	
Distribution:	
Potential for accumulation:	
Rate and extent of excretion:	
Metabolism in animals	
Toxicologically significant compounds (animals, plants and environment)	

Acute toxicity (OECD data point IIA 5.2)

Rat LD_{50} oral	
Rat LD_{50} dermal	
Rat LC_{50} inhalation	
Skin irritation	
Eye irritation	
Skin sensitization (test method used and result)	

Short term toxicity (OECD data point IIA 5.3)

Target/critical effect	
Lowest relevant oral NOAEL / NOEL	
Lowest relevant dermal NOAEL / NOEL	
Lowest relevant inhalation NOAEL / NOEL	

Genotoxicity (OECD data point IIA 5.4)

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Long term toxicity and carcinogenicity (OECD data point IIA 5.5)

Target/critical effect	
Lowest relevant NOAEL / NOEL	
Carcinogenicity	

Reproductive toxicity (OECD data point IIA 5.6)

Reproduction target/critical effect	
Lowest relevant reproductive NOAEL / NOEL	
Developmental target/critical effect	
Lowest relevant developmental NOAEL / NOEL	

Neurotoxicity/Delayed neurotoxicity (OECD data point IIA 5.7)

Acute neurotoxicity	
Subchronic neurotoxicity	

Other toxicological studies (OECD data points IIA 5.8 and IIA 5.10)

Medical data (OECD data point IIA 5.9)

Summary (OECD data point IIA 5.11)	Value	Study	Safety factor
ADI			
AOEL			
Drinking water limit			
ARfD (acute reference dose)			

Dermal absorption (OECD data points IIA 5.9.9 & IIIA 7.6)

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Acceptable exposure scenarios (including method of calculation)

Operator	
Workers	
Bystanders	

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Chapter 4: Residues

Metabolism in plants (OECD data points IIA 6.2.1, IIA 6.7, IIIA 8.2 & IIIA 8.7)

Plant groups covered	
Rotational crops	
Plant residue definition for monitoring	
Plant residue definition for risk assessment	
Conversion factor (monitoring to risk assessment)	

Metabolism in livestock (OECD data points IIA 6.2.2 to IIA 6.2.5, IIA 6.7, IIIA 8.4 & IIIA 8.7)

Animals covered	
Animal residue definition for monitoring	
Animal residue definition for risk assessment	
Conversion factor (monitoring to risk assessment)	
Metabolism in rat and ruminant similar (yes/no)	
Fat soluble residue: (yes/no)	

Residues in succeeding crops (OECD data points IIA 6.6 and IIIA 8.6)

Stability of residues (OECD data points IIA 6.1 and IIIA 8.1)

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Residues from livestock feeding studies (OECD data points IIA 6.4 and IIIA 8.4)

Intakes by livestock ≥ 0.1 mg/kg diet/day:	Ruminant: yes / no	Poultry: yes / no	Pig: not assessed
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

Summary of critical residues data (OECD data points IIA 6.3 and IIIA 8.3)

Crop	Country and /or Region	Trials results relevant to the critical GAP (a)	Recommendation/comments	MRL	STMR (b)

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP

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Consumer risk assessment (OECD data points IIA 6.9 and IIIA 8.10)

ADI	
TMDI (State diet *e.g.* North American) (% ADI)	
NEDI (% ADI)	
Factors included in NEDI	
ArfD	
Acute exposure (% ARfD)	

Processing factors (OECD data points IIA 6.5 and IIIA 8.5)

Crop/processed crop	Number of studies	Transfer factor	% Transference *

* Calculated on the basis of distribution in the different portions, parts, or products as determined through balance studies

Proposed MRLs (OECD data points IIA 6.7.2 and IIIA 8.7.2)

Proposed MRLs	

Chapter 5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil (OECD data point IIA 7.1.1)

Mineralization after 100 days	
Non-extractable residues after 100 days	
Relevant metabolites [28] - name and/or code % of applied (range and maximum)	

Route of degradation in soil (anaerobic & photolysis) (OECD data points IIA 7.1.2 & IIA 7.1.3)

Anaerobic degradation	
Soil photolysis	

Rate of degradation in soil (OECD data points IIA 7.2, IIA 7.3, IIIA 9.1 & IIIA 9.2)

Method of calculation	
Laboratory studies (range or median, with n value, with r^2 value)	DT_{50lab} (20 °C, aerobic):
	DT_{90lab} (20 °C, aerobic):
	DT_{50lab} (10 °C, aerobic):
	DT_{50lab} (20 °C, anaerobic):
	degradation in the saturated zone:
Field studies (state location, range or median with n value)	DT_{50f}:
	DT_{90f}:
Soil accumulation and plateau concentration	

[28] An internationally agreed definition of the term *relevant metabolites* has not been elaborated. Pending the development of such a definition, applicants should consult the regulatory authority of the country to which application is to be made, for guidance concerning selection of the metabolites for which information must be reported

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Soil adsorption/desorption (OECD data points IIA 7.4.1 & IIA 7.4.2)

K_f /K_{oc}	
K_d	
pH dependence (yes / no) (if yes type of dependence)	

Mobility in soil (OECD data points IIA 7.4.3 to IIA 7.4.8 and IIIA 9.3)

Column leaching	
Aged residues leaching	
Lysimeter/ field leaching studies	

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PEC (soil) (OECD data point IIIA 9.4)

Method of calculation	
Application rate	

PEC$_{(s)}$	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				

Route and rate of degradation in water (OECD data point IIA 2.9 and IIA 7.5 to IIA 7.9)

Hydrolysis of active substance and relevant metabolites [28] (DT_{50}) (state pH and temperature)	pH 4:
	pH 7:
	pH 9:
Photolytic degradation of active substance and relevant metabolites [28]	
Readily biodegradable (yes/no)	
Degradation in water/sediment - DT_{50} water - DT_{90} water - DT_{50} whole system - DT_{90} whole system	
Mineralization	
Non-extractable residues	
Distribution in water / sediment systems (active substance)	
Distribution in water / sediment systems (metabolites) [28]	

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PEC (surface water) (OECD data point IIIA 9.7)

Method of calculation	
Application rate	
main routes of entry	

PEC$_{(sw)}$	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				
14d				
21d				
28d				
42d				

PEC (sediment)

Method of calculation	
Application rate	

PEC$_{(sed)}$	Single application Actual (Tg/g)	Single application Time weighted average	Multiple application Actual (Tg/g)	Multiple application Time weighted average
Initial				
Short term 7d				
14 d				
Long term 32 d				
60 d				
90 d				
120 d				
152 d				

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PEC (ground water) (OECD data point IIIA 9.6)

Method of calculation and type of study (*e.g.* Modelling, monitoring, lysimeter)	
Application rate	

PEC$_{(gw)}$

Maximum concentration	
Average annual concentration	

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Fate and behaviour in air (OECD data points IIA 7.10 and IIIA 9.9)

Direct photolysis in air	
Quantum yield of direct phototransformation	
Photochemical oxidative degradation in air	Latitude: ..... Season: ..... DT_{50}: .....
	Henry's Law Constant:
Volatilization	from plant surfaces:
	from soil:

PEC (air)

Method of calculation	

$PEC_{(a)}$

Maximum concentration	

Definition of the Residue (OECD data point IIA 7.11)

Relevant to the environment	

Monitoring data, if available (OECD data point IIA 7.12)

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)	

Chapter 6: Effects on Non-target Species

Effects on terrestrial vertebrates (OECD data point IIA 8.1, IIIA 10.1 and IIIA 10.3)

Acute toxicity to mammals	
Acute toxicity to birds	
Dietary toxicity to birds	
Reproductive toxicity to birds	

Toxicity/exposure ratios for terrestrial vertebrates (OECD data point IIIA 10.1 and IIIA 10.3)

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	TER risk assessment trigger *

* in the EU a risk assessment must be carried relevant to practical conditions of use where the TER values reported are less than these values

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Toxicity data for aquatic species (most sensitive species of each group) (OECD data point IIA 8.2 & IIIA 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Fish species (specify)				
Invertebrates species (specify)				
Algal species (specify)				
Aquatic plants (specify)				
Microcosm or mesocosm tests:				

Toxicity/exposure ratios for the most sensitive aquatic organisms (OECD data point IIIA 10.2)

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	TER risk assessment trigger *

* in the EU a risk assessment must be carried relevant to practical conditions of use where the TER values reported are less than these values

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Bioconcentration

Bioconcentration factor (BCF)	
Risk assessment trigger (practical conditions of use) for the biconcentration factor	
Clearance time (CT_{50})	
(CT_{90})	
Level of residues (%) in organisms after the 14-day depuration phase	

Effects on honeybees (OECD data points IIA 8.7 and IIIA 10.4)

Acute oral toxicity	
Acute contact toxicity	

Hazard quotients for honey bees (OECD data point IIIA 10.4.1)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Hazard quotient risk assessment trigger *
Laboratory tests				
Field or semi-field tests				

* in the EU a risk assessment must be carried relevant to practical conditions of use where the hazard quotient values reported are greater than these values

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Effects on other arthropod species (OECD data points IIA 8.8.1, IIA 8.8.2 and IIIA 10.5)

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Risk assessment trigger *
Laboratory tests						
Field or semi-field tests						

* in the EU a risk assessment must be carried relevant to practical conditions of use where the level of the effects reported is greater than these values

Effects on earthworms (OECD data point IIA 8.9 and IIIA 10.6)

Acute toxicity	
Reproductive toxicity	

Toxicity/exposure ratios for earthworms (OECD data point IIIA 10.6.1)

Application rate (kg as/ha)	Crop	Time-scale	TER	TER risk assessment trigger *

* in the EU a risk assessment must be carried relevant to practical conditions of use where the TER values reported are less than these values

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Effects on soil micro-organisms (OECD data point IIA 8.10 and IIIA 10.7)

Nitrogen mineralization	
Carbon mineralization	