

APPENDIX 6

FORMAT FOR THE LISTING OF END POINTS TO BE INCLUDED IN THE REASONED STATEMENT OF THE OVERALL CONCLUSIONS DRAWN BY THE REGULATORY AUTHORITY (LEVEL 2)⁸

Chapter 2.1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	
Function (<i>e.g.</i> fungicide)	
Country to which application is made	

Identity

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	

⁸ Other end points will be relevant in particular cases - decisions as to the additional end points to be included can only be made on a case by case basis.

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Physical-chemical properties

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	

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Summary of intended uses

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

- (a) For crops, the Codex (or other, e.g. EU) 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			
		with regard to physical/chemical data	
			Classification: Proposed Label: Symbol: Indication of danger: Risk phrases: Safety phrases:
		with regard to toxicological data	
			Classification: Proposed Label: Symbol: Indication of danger: Risk phrases: Safety phrases:
		with regard 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 2.2: Methods of Analysis

Analytical methods for the active substance

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

Analytical methods for residues

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 2.3: Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism in mammals

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

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

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

Genotoxicity

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Long term toxicity and carcinogenicity			
Target/critical effect			
Lowest relevant NOAEL / NOEL			
Carcinogenicity			
Reproductive toxicity			
Reproduction target / critical effect			
Lowest relevant reproductive NOAEL / NOEL			
Developmental target / critical effect			
Lowest relevant developmental NOAEL / NOEL			
Neurotoxicity / Delayed neurotoxicity			
Acute neurotoxicity			
Subchronic neurotoxicity			
Other toxicological studies			
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Medical data			
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Summary			
	Value	Study	Safety factor
ADI			
AOEL			
Drinking water limit			
ARfD (acute reference dose)			
Dermal absorption			
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Acceptable exposure scenarios (including method of calculation)

Operator	
Workers	
Bystanders	

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Chapter 2.4: Residues

Metabolism in plants

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

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

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Stability of residues

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Residues from livestock feeding studies

Intakes by livestock \geq 0.1 mg/kg diet/day:	Ruminant: yes/no	Poultry: yes/no	Pig: yes/no
Muscle			
Liver			
Kidney			
Fat			
Milk			
Eggs			

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Consumer risk assessment

ADI	
TMDI (State diet <i>e.g.</i> North America, Europe) (% ADI)	
NEDI (% ADI)	
Factors included in NEDI	
ArfD	
Acute exposure (% ARfD)	

Processing factors

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

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Chapter 2.5: Fate and Behaviour in the Environment

Route of degradation (aerobic) in soil

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

Route of degradation in soil - Supplemental studies

Anaerobic degradation	
Soil photolysis	

Rate of degradation in soil

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	

Soil adsorption/desorption

K _f /K _{oc}	
K _d	
pH dependence (yes / no) (if yes type of dependence)	

Mobility in soil

Column leaching	
Aged residues leaching	
Lysimeter/ field leaching studies	

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PEC (soil)

Method of calculation

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Application rate

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PEC_(s)

	Single application	Single application	Multiple application	Multiple application
	Actual	Time weighted average	Actual	Time weighted average
Initial				
Short term 24h				
2d				
4d				
Long term 7d				
28d				
50d				
100d				

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT₅₀) (state pH and temperature)

pH 4:

pH 7:

pH 9:

Photolytic degradation of active substance and relevant metabolites

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Readily biodegradable (yes/no)

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Degradation in - DT₅₀ water
water/sediment - DT₉₀ water

- DT₅₀ whole system
- DT₉₀ whole system

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Mineralization

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Non-extractable residues

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Distribution in water / sediment systems (active Substance)

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Distribution in water / sediment systems (metabolites)

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PEC (surface water)

Method of calculation

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Application rate

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Main routes of entry

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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

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Application rate

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PEC_(sed)

	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				
Short term 24d 14d				
Long term 32d 60d 90d 120d 152d				

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PEC (ground water)			
Method of calculation and type of study (<i>e.g.</i> modelling, monitoring, lysimeter)			
Application rate			
PEC_(gw)			
Maximum concentration			
Average annual concentration			
Fate and behaviour in air			
Direct photolysis in air			
Quantum yield of direct phototransformation			
Photochemical oxidative degradation in air		Latitude: Season: DT ₅₀	
Volatilization		Henry's Law Constant:	
		from plant surfaces:	
		from soil:	
PEC (air)			
Method of calculation			
PEC_(a)			
Maximum concentration			
Definition of the Residue			
Relevant to the environment			
Monitoring data, if available			
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)			

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Chapter 2.6: Effects on Non-target Species

Effects on terrestrial vertebrates

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

Toxicity/exposure ratios for terrestrial vertebrates

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

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

Toxicity data for aquatic species (most sensitive species of each group)

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

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Toxicity/exposure ratios for the most sensitive aquatic organisms

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

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

Bioconcentration

Bioconcentration factor (BCF)

Risk assessment trigger (practical conditions of use) for the bioconcentration factor

Clearance time (CT₅₀)
(CT₉₀)

Level of residues (%) in organisms after the 14 day depuration phase

Effects on honeybees

Acute oral toxicity

Acute contact toxicity

Hazard quotients for honey bees

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 relevant to practical conditions of use must be carried out where the hazard quotient values reported are greater than these trigger values

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Effects on other arthropod species

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

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

Effects on earthworms

Acute toxicity	
Reproductive toxicity	

Toxicity/exposure ratios for earthworms

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

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

Effects on soil micro-organisms

Nitrogen mineralization	
Carbon mineralization	