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)

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.* mating disruption)	

Identity (Data point number IIP, point 1)

Active Ingredient Component 1 (to be completed for every Active Ingredient Component)

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	

Physical-chemical properties (Data point number IIP, point 2)

Technical Grade of the Active Ingredient (TGAI)

Melting point (state purity)	
Boiling point (state purity)	
Appearance (state purity)	
Relative density (state purity)	
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_____:
	pH_____:
	pH_____:
Solubility in organic solvents (in g/l or mg/l, state temperature)	
Partition co-efficient (log P_{OW}) (state pH and temperature)	pH_____:
	pH_____:
	pH_____:
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH_____:
	pH_____:
	pH_____:
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	
Photostability (DT_{50}) (aqueous, sunlight, state pH)	

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)**

Regulatory Authority	Month and year	Active Substance (Name)	page of

Active Ingredient Component 1 (to be completed for every Active Ingredient Component)

Melting point (state purity)	
Boiling point (state purity)	
Appearance (state purity)	
Relative density (state purity)	
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_____:
	pH_____:
	pH_____:
Solubility in organic solvents (in g/l or mg/l, state temperature)	
Partition co-efficient (log P_{OW}) (state pH and temperature)	pH_____:
	pH_____:
	pH_____:
Hydrolytic stability (DT_{50}) (state pH and temperature)	pH_____:
	pH_____:
	pH_____:
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	
Photostability (DT_{50}) (aqueous, sunlight, state pH)	

Summary of intended uses

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation	Application	Application rate per treatment	PHI (days)	Remarks: - A6/4 - Appendix 6 Format for the listing of end points to be included in the Reasoned Statement of the Overall Co

(a)			(b)	©	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	(l)	(m)

(a) For crops, the EU and Codex classifications (both) 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)(I)
©) *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
(l) 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
PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

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)**

Regulatory Authority	Month and year	Active Substance (Name)	page of

Classification and proposed labelling

with regard to physical/chemical data	
with regard to toxicological data	
with regard to fate and behaviour data	
with regard to ecotoxicological data	

Chapter 2: Methods of Analysis

Analytical methods for the active substance (Data point number IIP, point 4.2.1 and 4.2.3)

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

Chapter 3: Impact on Human and Animal Health

Acute toxicity (Data point number IIP, point 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)	

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)**

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Acceptable exposure scenarios (including method of calculation)

Operator	
Workers	
Bystanders	
Consumer	

Chapter 4: Residues (not normally required)

Chapter 5: Fate and Behaviour in the Environment

Soil adsorption/desorption (Data point number IIP, point 7.4.1)

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

Mobility in soil (Data point number IIP, point 7.4.3)

Column leaching	

Route and rate of degradation in water (Data point number IIP, point 7.6)

Photolytic degradation of active substance and relevant metabolites	

Volatility (Data point number IIP, point 7.4.9)

Laboratory study	

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)**

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Monitoring data, if available (Data point number IIP, point 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 (Data point number IIP, point 8.1, Data point number IIIP, points 10.1 and 10.3)

Acute toxicity to mammals	
Dietary toxicity to birds	

Toxicity/exposure ratios for terrestrial vertebrates (Data point number IIIP, points 10.1 and 10.3)

Application rate (kg as/ha)	Crop	Category (*e.g.* insectivorous bird)	Time-scale	TER	Data point number VI Trigger

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)**

Regulatory Authority **Month and year** **Active Substance (Name)** **page of**

Toxicity data for aquatic species (most sensitive species of each group) (Data point number IIP, point 8.2.1, 8.3, 8.4 and 8.6, Data point number IIIP, point 10.2)

Group	Test substance	Time-scale	Endpoint	Toxicity (mg/l)
Laboratory tests				
Microcosm or mesocosm tests				

Toxicity/exposure ratios for the most sensitive aquatic organisms (Data point number IIIP, point 10.2)

Application rate (kg as/ha)	Crop	Organism	Time-scale	Distance (m)	TER	Data point number VI Trigger

Effects on honeybees (Data point number IIP, point 8.7, Data point number IIIP, point 10.4)

Acute oral toxicity	
Acute contact toxicity	

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)**

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Hazard quotients for honey bees (Data point number IIIP, point 10.4)

Application rate (kg as/ha)	Crop	Route	Hazard quotient	Data point number VI Trigger
Laboratory tests				

Field or semi-field tests

Effects on other arthropod species (Data point number IIP, point 8.8, Data point number IIIP, point 10.5)

Species	Stage	Test Substance	Dose (kg as/ha)	Endpoint	Effect	Data point number VI Trigger
Laboratory tests						

Field or semi-field tests

Effects on earthworms (Data point number IIP, point 8.9, Data point number IIIP, point 10.6)

Acute toxicity	
Reproductive toxicity	

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)**

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Toxicity/exposure ratios for earthworms (Data point number IIIP, point 10.6)

Application rate (kg as/ha)	Crop	Time-scale	TER	Data point number VI Trigger

Effects on soil micro-organisms (Data point number IIP, point 8.10, Data point number IIIP, point 10.7)

Nitrogen mineralization	
Carbon mineralization	

Effects on terrestrial vascular plants (Data point number IIP, point 8.12, Data point number IIIP, point 10.8)
