

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** **Microbial Pest Control Agent (Name)** **page of**

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

General remark:

Testing of micro-organisms will often be made using specifically tailored studies. Therefore, e. g. toxicity/effects endpoints may differ from case to case. These endpoint list can therefore be seen as indicative only, to be amended in order to fit individual cases.

Chapter 1: Identity, Biological properties, Details of uses, Further information, and Proposed Classification and Labelling

Active micro-organism:	
Function (<i>e.g.</i> control of fungi):	
Country to which application is made:	
Identity of the Microbial Pest Control Agent / Active Substance (OECD data point IIM 1)	
Name of the organism:	
Taxonomy:	
Species, subspecies, strain:	
Identification / detection:	
Culture collection:	
Minimum and maximum concentration of the MPCA used for manufacturing of the formulated product (cfu; g/kg):	
Identity and content of relevant impurities, additives, contaminating organisms in the technical grade of MPCA:	
Is the MPCA genetically modified; if so provide type of modification	

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

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** **Microbial Pest Control Agent (Name)** **page of**

Biological properties of the micro-organism (OECD data point IIM 2)

Origin and natural occurrence,	
Background level:	
Target organism(s):	
Mode of action:	
Host specificity:	
Life cycle:	
Infectivity, dispersal and colonisation ability:	
Relationships to known plant, animal or human pathogens:	
Genetic stability:	
Information on the production of relevant metabolites (especially toxins):	
Resistance/ sensitivity to antibiotics / anti-microbial agents used in human or veterinary medicine:	

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 Microbial Pest Control Agent (Name) page of

Summary of uses supported by available data

Crop and /or situation	Member state or Country	Product name	F G or	Pest or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
					Type (d-f)	Conc. of MPCA (i)	Method Kind (f-h)	Growth stage & season (j)	Number min max (k)	Interval between applications (min)	kg MPCA/hL min max	water L/ha min max	kg MPCA/ha cfu MPCA/ha min max		
(a)			I (b)	(c)									(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) (h)
 - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I) (I)
 - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds (j)
 - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (j)
 - (e) GCPF Codes - Crop Life Technical Monograph No 2, 1989 (k)
 - (f) All abbreviations used must be explained (l)
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (m)
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant - type of equipment used must be indicated
 cfu = colony forming units and g/kg or g/L
 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
 Indicate the minimum and maximum number of application possible under practical conditions of use
 PHI - minimum pre-harvest interval
 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** **Microbial Pest Control Agent (Name)** **page of**

Classification and proposed labelling (Symbol, Indication of danger, Risk phrases, Safety phrases)

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

Chapter 2: Methods of analysis

Analytical methods for the micro-organism (OECD data point IIM 4.2, 4.3 and IIM 5.4)

manufactured micro-organism (principle of method):	
Impurities and contaminating micro-organisms in manufactured material (principle of method):	
Microbial Pest Control Product (principle of method):	

Analytical methods for residues (viable and non-viable) in exposed compartments and organisms
(OECD data point IIM 4.5)

of the active micro-organism (principle of method):	
of relevant metabolites (principle of method):	

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 Microbial Pest Control Agent (Name) page of

Chapter 3: Impact on Human and Animal Health

Medical data: (including medical surveillance on manufacturing plant personnel) (OECD data point IIM 5.1 & 5.2 & 5.8.1)	
Sensitisation: (OECD data point IIM 5.3.1 & IIM 7.1.6)	
Acute oral infectivity, toxicity and pathogenicity: (OECD data point IIM 5.3.2 & IIM 7.1.1)	
Acute intratracheal/inhalation infectivity, toxicity and pathogenicity: (OECD data point IIM 5.3.3 & IIM 7.1.3)	
Acute intravenous/intraperitoneal infectivity: Intraperitoneal/Subcutaneous single dose: (OECD data point IIM 5.3.4 & IIM 7.1.2)	
Genotoxicity: (OECD data point IIM 5.3.5)	
Cell culture study: (OECD data point IIM 5.3.6)	
Information on short-term toxicity and pathogenicity: (OECD data point IIM 5.3.7)	
Dermal toxicity: (OECD data point IIM 7.1.2)	
Specific-toxicity, pathogenicity and infectivity: (OECD data point IIM 5.5)	
Genotoxicity – in vivo studies in germ cells: (OECD data point IIM 5.5.3)	
Exposure (operator, workers, bystander, consumer): (OECD data point IIM 6.1, IIM 7.2, 7.3 and 8.0)	

Chapter 4: Residues (normally not required)

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 Microbial Pest Control Agent (Name) page of

Chapter 5: Fate and Behaviour in the Environment (OECD IIM 7 & IIM 9)

Persistence and multiplication in soil, water and air:	
Mobility:	

Chapter 6: Effects on non-target organisms (OECD IIM 8 & IIM 10)

Effects on birds (OECD IIM 8.1 & IIM 10.1)

Application rate (kg MPCA/ha)	Crop	Category (e.g. insectivorous bird)	Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)

Effects on aquatic organisms (OECD IIM 8.2, 8.3, & IIM 10.2)

Group	Test substance	Time-scale	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory tests			
Fish species (specify):			
Invertebrate species: (specify)			

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 Microbial Pest Control Agent (Name) page of

Effects on algae: (growth, growth rate, capacity to recover) (OECD IIM 8.4 & IIM 10.2)	
Effects on aquatic plants (OECD IIM 8.5 & IIM 10.2)	

Effects on bees (OECD IIM 8.7 & IIM 10.3)

Application rate (kg MPCA/ha)	Crop	Route	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory Tests			

Effects on terrestrial arthropods other than bees (OECD IIM 8.8 & IIM 10.4)

Species	Stage	Test Substance	Dose (kg MPCA/ha)	Toxicity, infectivity and pathogenicity (endpoint, value or other description of effects)
Laboratory Tests				

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 Microbial Pest Control Agent (Name) page of

Effects on other terrestrial invertebrates (OECD IIM 8.9, 8.9.1, 8.9.2 & IIM 10.5)

Toxicity, infectivity and pathogenicity: (endpoint, value or other description of effects)	
Further information:	

Effects on non-target soil micro-organisms (OECD IIM 8.10 & IIM 10.6)

--

Additional studies (OECD IIM 8.11 & IIM 10.7)

--