APPENDIX 11

FORMS FOR USE IN CHECKING DOSSIERS FOR COMPLETENESS

Part 1 **Evaluation Form 1 -**

for use in checking that the required supporting documentation has been provided

Active substance: micro-organisms

Applicant:

Date:

Document	Description of the document - circumstances in which required	Document provided Y/N[#]	Official use only Data Gap Y/N[#]
A	Statement of the context in which the dossier is submitted - always required	__	__
B	Task Force Information, where relevant, to include -		
	* Member ship of the task force and a contact point for the task force	__	__
	* Contact point for each member of the task force	__	__
	* List of test and study reports generated by the task force - and details of task force members rights of access to the test and study reports generated by the task force - required where relevant	__	__
C	Existing or proposed labels, and where relevant leaflets for each preparation for which a dossier is submitted - required where requested	__	__
	Existing or proposed labels relevant to the uses on the basis of which existing MRLs or import tolerances are supported or new MRLs or import tolerances are proposed - required where requested	__	__
D-1	Details of intended uses (supported by the applicant and for which data are provided or are to be provided) and the conditions of use, on food and feed crops, and on non food and feed crops, in the territory of the country to which application is made, presented using the appropriate form - *always required*	__	__
D-2	A list of the registered uses in the country to which application is made, an indication of whether actually used and of the extent of use, presented using the appropriate form - required for existing active substances	__	__

[#] Y = yes; N = no

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 1** **Evaluation Form 1 Supporting Documentation**

Active substance: **Applicant:** **Date:**

Document	Description of the document - circumstances in which required	Document provided Y/N	Official use only Data Gap Y/N
F	A copy of each statement of intentent to submit in due course , a dossier or dossiers - required for existing active substances in countries in which such a requirement exists.	__	—
G	Whether permitted in food, animal feeding stuffs, medicines or cosmetics in accordance with the legislation of the country to which application is made - required for each formulant unless a dossier is provided for the formulant	__	—
H	Safety data sheet - required for each formulant	__	—
I	Other available toxicological and environmental data on the formulant - required if requested	__	—
J	Confidential data and information, to include -		
	* A listing of the data and information for which confidentiality is requested, cross referenced to the relevant test and study reports, dossier summaries and supporting documentation - *always required*	__	—
	* A justification for the claim to confidentiality for each item for which confidentiality is requested - *always required*	__	—
	* Highlighting of information contained in relevant study reports, dossier summaries and supporting documentation - required where the information concerned is provided in those documents	__	—
	* File containing confidential data and information - optional requirement	__	—

Part 2 Evaluation Form 2 -

for use in checking that the required MPCA and MPCP dossier summaries and an overall assessment, have been provided

Active substance: micro-organisms

Applicant:

Date:

Document	Description of the document - circumstances in which required	Document provided Y/N[#]	Official use only Data Gap Y/N[#]
L (active substance)	*Tier I* reports as to the quality of individual active substance test and study reports - *always required*	—	—
L (Reference List)	Listing of test and study reports, test guidelines and published papers relevant to the active substance dossier:-		
	- papers and reports submitted listed by test and study type	—	—
	- papers and reports submitted listed by alphabetically by author	—	—
	- list of papers and reports not submitted, arranged alphabetically by author	—	—
	- *always required*		
M (active substance)	*Tier II* active substance dossier summary and overall assessment - always required	—	—
L (formulation)	*Tier I* reports as to the quality of individual test and study reports for each formulated product for which a dossier was submitted - always required		
	* First preparation	—	—
	* Second preparation	—	—
	* Third preparation	—	—
	* Fourth preparation	—	—
L (Reference List)	Listing of test and study reports, test guidelines and published papers relevant to each formulated product dossier - *always required*		
	* First preparation		
	- papers and reports submitted listed by Annex point	—	—
	- papers and reports submitted listed by alphabetically by author	—	—
	- list of papers and reports not submitted, arranged alphabetically by author	—	—
	* Second preparation		
	- papers and reports submitted listed by Annex point	—	—
	- papers and reports submitted listed by alphabetically by author	—	—
	- list of papers and reports not submitted, arranged alphabetically by author	—	—

[#] Y = yes; N = no

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 2** **Evaluation Form 2 Dossier Summaries and Overall Assessment**

Active substance: **Applicant:** **Date:**

Document	Description of the document - circumstances in which required	Document provided Y/N	Official use only Data Gap Y/N
	* Third preparation		
	- papers and reports submitted listed by Annex point	__	__
	- papers and reports submitted listed by alphabetically by author	__	__
	- list of papers and reports not submitted, arranged alphabetically by author	__	__
	* Fourth preparation		
	- papers and reports submitted listed by Annex point	__	__
	- papers and reports submitted listed by alphabetically by author	__	__
	- list of papers and reports not submitted, arranged alphabetically by author	__	__
M (formulation)	*Tier II* dossier summary and overall assessment for each formulated product for which a dossier was submitted - *always required*		
	* First preparation	__	__
	* Second preparation	__	__
	* Third preparation	__	__
	* Fourth preparation	__	__
N	An overall summary and assessment of the application - *always required*	__	__

Part 3 **Evaluation Form 3 -**

for use in checking that all test and study reports relating to the MPCA which are required, have been provided; **

Active substance: micro-organisms

Applicant:

Date:

MPCA means Microbial Pest Control Agent

OECD Annex IIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
1	**Identity of the Microbial Pest Control Agent**				☐
1.1	Applicant (name, address, contact, telephone and telefax numbers)				☐
1.2	Producer (name, address, contact, telephone and telefax numbers)				☐
1.3	Scientific information				☐
1.3.1	Scientific name of micro-organism to species level or a level sufficient to show taxonomic relation to known micro-organisms, especially pathogens;				☐
1.3.2	- accession no. of sample in a recognised culture collection				☐
1.3.3	- test procedures and criteria, using best available technology, to characterise the strain or serotype;				☐
1.3.4	- for mutant or genetically-modified strains, indicate all known differences between the modified micro-organism and the parent wild strain(s)				☐
1.3.5	- include any trade names, common names, developmental code names				☐
1.3.6	- indigenous or non-indigenous at the species level to the intended area of application.				☐
1.4	Composition of Technical Grade of MPCA/Active Substance				☐
1.4.1	Concentration of micro-organism (and metabolite, if appropriate) in terms of g/kg or g/L (for US and Canada, also in % w/w) and cfu's/mL or appropriate potency units; include acceptable range for each term. Potency should be expressed in recognised units of potency or an appropriate expression of biological activity per unit weight/volume				☐
1.4.2	Composition of microbial material used for manufacture of end use products in terms of g/kg or g/L (for US and Canada also in % w/w) for each active ingredient including:				☐
1.4.2.1	- the MPCA. This information is not required if Technical Grade of MPCA is a hypothetical stage				☐

OECD Annex IIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
	in a continuous production process of an end-use product.				
1.4.2.2	- additives (preservatives, stabilisers, diluents). This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product.				☐
1.4.2.3	- microbial impurities, classified/identified to a taxonomic level required by quality criteria to support the hygienic state of the production process. This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product.				☐
1.4.2.4	- non-microbial impurities (e.g. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues). This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product.				☐
1.4.2.5	Composition in terms of g/kg or g/L, (for US and Canada also in % w/w), for each ingredient: The identity and maximum content of all microbial impurities must be reported, if possible and appropriate, as outlined in point 1.3, and expressed in appropriate units (in terms of cfu's/mL or appropriate expression of biological activity/viability).				☐
1.4.3	Methods of production and quality criteria for the production and storage of the active micro-organism, including:				☐
1.4.3.1	- criteria for consistency and integrity of the master and working seed stock, typically, measures of biological activity and phenotypic or genotypic properties:				☐
1.4.3.2	- acceptable range for content of MPCA, in appropriate terms;				☐
1.4.3.3	- presence of human/mammalian pathogens;				☐
1.4.3.4	- presence or maximum accepted level of known mammalian toxins, if their presence is suspected at any stage in process, or if MPCA is closely related to a toxigenic human pathogen;				☐
1.4.3.5	- maximum accepted level for microbial impurities, using suitable indicators of an unhygienic process.				☐
1.4.4	Quality control data (measures of quality criteria) from 3 - 5 production batches, including storage stability data. If the Technical Grade of MPCA is a stage in a continuous production process of an end-				☐

OECD Annex IIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
	use product, this information should be provided for the entire production process.				
1.4.5	The formation, presence and/or impact of unintentional ingredients				☐
1.4.5.1	A theoretical discussion regarding the formation and/or presence of unintentional ingredients, including impurities of toxicological concern, likely to occur in the Technical Grade of the MPCA.				☐
1.4.5.2	A theoretical discussion regarding the impact of these ingredients on product quality.				☐
1.4.5.3	A theoretical discussion regarding appropriate quality criteria.				☐
1.4.6	Physical and chemical properties, if MPCA is produced as a manufacturing product that is stored prior to formulation of end-use products: physical state; density; viscosity or surface tension; explosivity, corrosive character, oxidising properties; technical characteristics as appropriate				☐
1.4.7	International regulatory status of micro-organism				☐
1.4.8	Sample of MPCA and analytical standard of metabolite				☐
1.4.8.1	Sample of MPCA: if requested				☐
1.4.8.2	Analytical standard of metabolite: if requested				☐
1.4.8.3	Reference substances for the relevant impurities: if requested				☐
1.5	Patent status				☐
2	**Biological Properties of the Microbial Pest Control Agent**				☐
2.1	Origin of the isolate; method of isolation; preservation and maintenance of strain during development; historical information on testing and use of the strain; history of use of closely related strains or species; Description of any unusual morphological, physiological, pesticidal or resistance characteristics of the MPCA which differ from classical description of the species				☐
2.2	Natural occurrence of the micro-organism including geographic distribution, hosts, habitat, ecological niche, level of natural occurrence				☐
2.3	Information on target organism(s)				☐
2.3.1	Description of the target organism(s)				☐
2.3.2	Information on mode of action, kind of antagonism to target host, infective/toxic dose, transmissibility				☐

OECD Annex IIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
2.4	Available information on host specificity; possible effects on species closely related to the target pest. Any experience of toxic effect of the active substance or its metabolic products on human or animals, of whether the organism is capable of colonising or invading humans or animals and whether it is pathogenic shall be stated. Any experience of wether the active substance or its products may irritate skin, eyes or respiratory organs of humans or animals and wether it is allergenic in contact with skin or when inhaled.				☐
2.5	Life cycle of the micro-organism including various forms that may occur, differences in pathogenic/ toxigenic character of various forms, virulence and survival time of resting stages, interactions with other species (vector, parasitism, competition)				☐
2.6	Potential of the micro-organism to produce metabolites that are of concern for human health and/or the environment.				☐
2.7	Information regarding closely related species				☐
2.7.1	Among closely related species, provide information on pathogenicity to plants, animals or humans				☐
2.7.2	Among closely related species, provide information on formation of toxic metabolites: structure, stability, conditions under which they are formed, mode of action				☐
2.8	Physiological properties, especially effect of environmental parameters on growth, infectivity, dispersal and colonisation ability: temperature, pH, redox potential, humidity, light, nutritional requirements				☐
2.9	Description of any plasmids or other extra chromosomal genetic elements involved in pesticidal activity, pathogenicity, toxicity, *etc*.				☐
2.10	Genetic stability (mutation rate of traits related to the mode of action), factors affecting genetic stability; micro-organism's capacity to transfer genetic information to another population				☐
2.11	Detailed discussion of relationship of micro-organism to any known human dermatophyte (see point 5.2)				☐
2.12	Information on resistance/sensitivity to antibiotics/anti-microbial agents used in human or veterinary medicine				☐
3	**Further information on the Microbial Pest Control Agent (Function, Mode of Action,**				☐

OECD Annex IIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
	Handling)				
3.1	Function, e.g. fungicide				☐
3.2	placeholder				☐
3.3	Field of use, e.g. forestry				☐
3.4	Information on target crop and target organism(s)				
3.4.1	Details of existing and intended uses (crops, groups of crops, plants or plant products treated or protected)				☐
3.4.2	Details of harmful organisms against which protection is afforded				☐
3.4.3	Effects achieved e.g. sprout suppression				☐
3.5	Information on mode of action and metabolites				
3.5.1	Statement of the mode of action of the Microbial Pest Control Agent in terms of biochemical and physiological mechanism(s) and biochemical pathway(s) involved. (see IIM 2.3.2)				☐
3.5.2	Details of active metabolites (especially toxins) and degradation products, cross referenced to the toxicological and residues data provided, to include:				☐
3.5.2.1	- IUPAC and CA names				☐
3.5.2.2	- ISO common name proposed or accepted				☐
3.5.2.3	- CAS, CIPAC, EINECS and ELINCS numbers				☐
3.5.2.4	- molecular and structural formula				☐
3.5.2.5	- molecular mass				☐
3.5.3	Information relative to the formation of active metabolites (especially toxins) and degradation products, to include:				☐
3.5.3.1	- the processes, mechanisms and reactions involved				☐
3.5.3.2	- kinetic and other data concerning the rate of conversion and if known the rate limiting step				☐
3.5.3.3	- environmental and other factors effecting the rate and extent of conversion				☐
3.6	Information on the possible occurrence of the development of resistance or cross-resistance				☐
3.7	A material safety data sheet for the Microbial Active Substance				☐
3.8	Detailed instructions for safe disposal				☐
3.9	Procedures for the decontamination of water in case of an accident				☐
3.10	Other/special studies				☐
3.11	Crops or products to be protected or treated (see IIM 3.4.1)				☐
3.12	Measures to render micro-organism harmless, in case of an accident				☐

OECD Annex IIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
4	**Analytical methods**				☐
4.1	Method to preserve and maintain the master seed stock; criteria for an acceptable level of consistency and integrity of seed stock				☐
4.2	Production process for Technical Grade of MPCA, describing techniques used to ensure a uniform product and procedures when hazardous contamination is detected in a batch. List starting and intermediate materials, with source and purity of each.				☐
4.3	Quality control and post-registration monitoring methods				☐
4.3.1	Methods to detect, isolate, and enumerate the micro-organism				☐
4.3.2	Methods to differentiate a mutant or genetically-modified micro-organism from the parent strain.				☐
4.3.3	Methods to detect spontaneous change in major characteristics of micro-organism.				☐
4.3.4	Methods to define content of micro-organism in appropriate terms (same as IIM 1.4.1), incl. standardisation, sensitivity, reproducibility, statistical validity, and representative data to validate the bioassay.				☐
4.3.5	Methods to show control to a specified and acceptable level, of microbial impurities and of any other impurities of toxicological concern, including toxic metabolites, which are known or suspected to be present at any stage of the manufacturing process.				☐
4.3.6	Methods to show presence of any human and mammalian pathogens.				☐
4.4	Storage stability test, data and determination of shelf life, if MPCA is stored				☐
4.5	Post-registration monitoring methods to determine and quantify residues of viable or non-viable micro-organism and metabolites (especially toxins)				☐
4.5.1	Food (where relevant)				☐
4.5.2	Feed (where relevant)				☐
4.5.3	Animal tissue (where relevant)				☐
4.5.4	Soil (where relevant)				☐
4.5.5	Water (where relevant)				☐
4.5.6	Air (where relevant)				☐
4.5.7	Analytical methods for amount or activity of proteinaceous products (where relevant)				☐
5	**Toxicological and Exposure Data and Information on the Microbial Pest Control**				☐

OECD Annex IIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
	Agent				
5.1	Summary: potential of microbial pest control agent to be hazardous to humans with consideration of its pathogenic potential, its ability to infect and pattern of clearance, and its toxicological effects				☐
5.2	Occupational health surveillance report on workers during production and testing of MPCA, including information on: see IIM 5.2.1 to 5.2.4. Published reports of adverse effects, especially reports of clinical cases and followup studies. Proposed first aid measures and medical treatment.				☐
5.2.1	The sensitisation and allergenic response of workers				☐
5.2.2	Details on any occurrence of hypersensitivity and chronic sensitisation				☐
5.2.3	Any significant clinical findings related to exposure, with special attention to those whose susceptibility may be affected.				☐
5.2.4	Published reports of adverse effects, especially reports of clinical cases and followup studies; list databases and key words used in a literature search.				☐
5.2.5	Proposed first aid measures and medical treatment				☐
5.3	Basic studies				☐
5.3.1	Sensitisation properties				☐
5.3.2	Acute oral infectivity, toxicity and pathogenicity				☐
5.3.3	Acute intratracheal/inhalation infectivity, toxicity and pathogenicity				☐
5.3.4	Acute intravenous/intraperitoneal infectivity				☐
5.3.5	Genotoxic potential, especially for fungi and actinomycetes: a discussion of the potential for genotoxin production based on the relationship of the micro-organism to a genus/species known to produce genotoxins. If a related fungus/ actinomycete produces a genotoxin, either an appropriate and sensitive analytical test (e.g. HPLC) must be done to detect its presence in the MPCA (for Canada), or genotoxicity testing is required (for EC).				☐
5.3.6	Cell culture study, for viruses and viroids or specific bacteria and protozoa with intracellular replication				☐
5.3.7	Short-term toxicity (including inhalatory short-term toxicity), pathogenicity, infectivity				☐
5.3.7.1	Short-term toxicity, pathogenicity, infectivity (28-day minimum)				☐
5.3.7.2	Inhalatory short-term toxicity				☐

OECD Annex IIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
5.4	Toxicity studies on metabolites (especially toxins)				☐
5.5	Other/special studies				☐
5.5.1	Specific toxicity, pathogenicity and infectiveness studies				☐
5.5.2	*In vivo* studies in somatic cells				☐
5.5.3	Genotoxicity - *In vivo* studies in germ cells				☐
5.6	Summary of mammalian toxicity and overall evaluation				☐
6	**Metabolism and Residues Studies on the Microbial Pest Control Agent**				☐
6.1	Rationale for waiver of residue data based on information showing that MPCA is not hazardous to mammals, i.e. lack of potential for a known mammalian toxin and negative result from the acute oral toxicity test.				☐
6.2	Rationale for waiver based on a substantiated estimation that MPCA is unlikely to occur on treated food/feed stuffs in concentrations considerably higher than under natural conditions.				☐
6.3	Persistance and likelihood of multiplication in or on crops, feedingstuffs or foodstuffs				☐
6.4	Further information required				☐
6.4.1	Non-viable residues				☐
6.4.2	Viable residues				☐
6.5	Summary of residue behaviour and overall evaluation				☐
7	**Fate and Behaviour Studies on the Microbial Pest Control Agent in the Environment**				☐
7.1	Sufficient information on the origin, properties, survival and residual metabolites of the micro-organism to assess its fate and behaviour in the environment. Information provided in parts 2 - 6 may suffice. Viability/population dynamics, persistence, multiplication and mobility				☐
7.1.1	Persistance and mobility in soil				☐
7.1.2	Water				☐
7.1.3	Air				☐
7.2	Other/special studies				☐
8	**Ecotoxicological Studies on the Microbial Pest Control Agent (Effects on non-target organisms)**				☐
8.1	Effects on birds				☐
8.2	Effects on fish				☐
8.3	Effects on aquatic invertebrates				☐
8.4	Effects on algal growth and growth rate				☐

OECD Annex IIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 4)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
8.5	Effects on aquatic plants				☐
8.6	Effects on terrestrial plants				☐
8.7	Effects on bees				☐
8.8	Effects on terrestrial arthropods other than bees				☐
8.9	Effects on other terrestrial invertebrates				☐
8.9.1	Effects on earthworms				☐
8.9.2	Effects on other terrestrial invertebrates				☐
8.10	Effects on soil micro-organisms				☐
8.11	Other/special studies				☐
9	**Summary and evaluation of environmental impact: summarise all data relevant to environmental impact and assess environmental risk by:**				☐
9.1	- addressing distribution and fate of MPCA				☐
9.2	- identifying non-target species at risk and the extent of their exposure				☐
9.3	- identifying precautions necessary to minimise environmental contamination and to protect non-target species.				☐

Part 4 **Evaluation Form 4 -**

for use in checking that all test and study reports relating to the MPCP which are required, have been provided;

Active substance: micro-organisms

Applicant:

Date:

MPCP means Microbial Pest Control Product

OECD Annex IIIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
1	**Identity of the Microbial Pest Control Product**				☐
1.1	Applicant (name, address, contact, telephone and telefax numbers)				☐
1.2	Manufacturer(s) of the preparation and producer of the microbial pest control agent				☐
1.2.1	Manufacturer(s) of the preparation (name, address, contact, telephone and telefax numbers)				☐
1.2.2	Producer of the microbial pest control agent (name, address, contact, telephone and telefax numbers)				☐
1.3	Trade name or proposed trade name and manufacturers code number(s), for the preparation and similar preparations (differences to be specified)				☐
1.4	placeholder				☐
1.5	Physical state of MPCP (Crop Life formulation type)				☐
1.6	Function (herbicide, insecticide, *etc*.)				☐
1.6.1	Biological function category and field of use category, using terms defined by each country, e.g. “control of weeds” for “forestry”				☐
1.7	Other/special studies				☐
1.7.1	Concentration of MPCA in MPCP, measured in terms of g/kg or g/L of the MPCP (for US and Canada, also provide figures in % w/w) and in cfu’s or other appropriate potency units; provide content of MPCA in Technical Grade of MPCA, in the same terms.				☐
1.7.1.1	Also indicate: scientific name and strain/serotype of MPCA, its accession number in a recognised culture collection				☐
1.7.1.2	Also indicate: development phase (e.g. spore) of MPCA in MPCP				☐
1.7.2	Composition in terms of g/kg or g/L and % w/w of each ingredient in MPCP, including:				☐
1.7.2.1	- technical Grade of MPCA				☐
1.7.2.2	- each additive: include chemical name and structure; CAS and EEC numbers of components of additive if they exist or an appropriate specification; trade name; function in the MPCP				☐

OECD Annex IIIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
1.7.2.3	- microbial impurities: taxonomic identification as required by quality criteria to support the hygienic state of the production process; express content of microbial impurities in appropriate units, e.g. cfu's/ml.				☐
1.7.2.4	- non-microbial impurities (e.g. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues)				☐
1.7.3	Quality criteria for the production and storage of the MPCP, including:				☐
1.7.3.1	- acceptable range for content of MPCA, in appropriate terms;				☐
1.7.3.2	- presence of human or non-target animal pathogens;				☐
1.7.3.3	- presence or maximum accepted level of known mammalian toxins, if their presence is suspected at any stage in process, or if MPCA is closely related to a toxigenic human pathogen				☐
1.7.3.4	- maximum accepted level for microbial impurities, using suitable indicators of contamination				☐
1.7.4	Quality control data (measures of quality criteria) from 3 - 5 production batches, including product stored for duration of shelf life if it is metabolically active. If the Technical Grade of MPCA is a stage in a continuous production process of an end use product, this information should be provided for the entire production process.				☐
1.7.5	The formation, presence and/or impact of unintentional ingredients				☐
1.7.5.1	A theoretical discussion regarding the formation and/or presence of unintentional ingredients, including impurities of toxicological concern, likely to occur in the MPCP				☐
1.7.5.2	A theoretical discussion regarding the impact of these ingredients on product quality				☐
1.7.5.3	A theoretical discussion regarding appropriate quality criteria.				☐
1.7.5.4	For metabolically-active MPCP, consider degradation or metabolic production during storage in the theoretical discussion.				☐
2	**Physical, Chemical and Technical Properties of the Microbial Pest Control Product**				☐
2.1	Appearance (colour, odour, physical state)				☐
2.2	Storage stability and shelf-life for MPCP which must contain metabolically active MPCA, include QC data for hazardous contaminants originating from degradation or metabolic production during storage.				☐

OECD Annex IIIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
2.3	Explosivity, oxidising properties, flash point, flammability, spontaneous ignition, acidity, alkalinity, pH, viscosity, surface tension				☐
2.3.1	Explosivity, oxidising properties: as appropriate				☐
2.3.2	Flash point, flammability, spontaneous ignition: as appropriate				☐
2.3.3	Acidity, alkalinity, pH: as appropriate				☐
2.3.4	Viscosity, surface tension: as appropriate				☐
2.4	Technical characteristics as appropriate:				☐
2.4.1	Wettability				☐
2.4.2	Persistent foaming				☐
2.4.3	Suspensibility, suspension stability				☐
2.4.4	dry sieve test and wet sieve test				☐
2.4.5	particle size distribution (dustable and wettable powders, granules), content of dust/fines (granules), attrition and friability (granules)				☐
2.4.6	emulsifiability, re-emulsifiability, emulsion stability				☐
2.4.7	flowability, pourability (rinsability), dustability				☐
2.5	Density				☐
2.6	Adherence and distribution to seeds, for seed treatment products				☐
2.7	Summary and evaluation of data on properties of the MPCP				☐
3	**Data on application**				☐
3.1	Pest to be controlled, crop to be protected, available information on mode of action (site of uptake, toxic/competitive effect, is micro-organism transmitted or translocated to another part of plant?)				☐
3.2	Available information on the development of resistence in target pest and appropriate mitigation strategy.				☐
3.3	Application rate in terms of mass/vol of MPCP per unit area/volume (e.g. kg/ha). Content of micro-organism in material used (diluted spray, bait, treated seed).				☐
3.4	Application rate in terms of units of micro-organism per unit area/volume				☐
3.5	Method of application (incl. type of equipment and volume of diluent)				☐
3.6	Number, timing and conditions of applications, related to: host/pest phenology, duration of protection, application of other pesticides, pre-harvest interval				☐
3.6.1	Number, timing and conditions of applications, related to: host/pest phenology, duration of				☐

OECD Annex IIIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
	protection, application of other pesticides.				
3.6.2	Pre-harvest interval.				☐
3.7	Precautions to avoid phytotoxic/ phytopathogenic effects on protected crop or on succeeding crops, if appropriate				☐
3.8	Proposed instructions for use as printed, or to be printed, on labels				☐
4	**Further information on the MPCP**				☐
4.1	Packaging: description				☐
4.2	Specifications of packaging and measures of its suitability				☐
4.3	Label instructions regarding cleaning equipment and protective clothing				☐
4.4	Procedures to clean equipment and protective clothing; measures of their effectiveness				☐
4.5	Necessary waiting periods for re-entry; recommended protective measures to reduce occupational exposure				☐
4.6	Label instructions regarding: safe handling and storage				☐
4.7	Recommendations regarding: handling, storage, transport, fire: specify risks, specify procedures to minimise hazards and the generation of waste.				☐
4.8	Label instructions regarding: cleanup of spills				☐
4.9	Detailed procedures in case of accident to: contain a spill, decontaminate an area or vehicle, dispose of adsorbents and packaging, protect workers and bystanders, first aid.				☐
4.10	Procedures for destruction/disposal of MPCP and its packaging				☐
4.10.1	Controlled incineration				☐
4.10.2	Methods other than controlled incineration				☐
5	**Methods of Analysis, Manufacturing, Quality Control and Post-Registration Monitoring of the Microbial Pest Control Product**				☐
5.1	Quality control and post-registration monitoring methods				☐
5.1.1	Methods to differentiate a mutant or genetically-modified micro-organism from the parent strain.				☐
5.1.2	Methods to detect spontaneous change in major characteristics of micro-organism.				☐
5.1.3	Methods to define content of micro-organism in appropriate terms (same as IIM 1.4.1), incl. standardisation, sensitivity, reproducibility, statistical validity, and representative data to validate the bioassay.				☐
5.1.4	Methods to identify contaminant micro-organisms in MPCP				☐

OECD Annex IIIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
5.1.5	Methods to show control to a specified and acceptable level, of microbial impurities and of any other impurities of toxicological concern, including toxic metabolites, which are known or suspected to be present at any stage of the manufacturing process.				☐
5.1.6	Methods to show presence of any human and mammalian pathogens.				☐
5.2	Storage stability test and determination of shelf life (methods of analysis)				☐
5.3	Production process for MPCP, describing techniques used to ensure a uniform product and procedures when hazardous contamination is detected in a batch. List starting and intermediate materials, with source and purity of each.				☐
5.4	Method for determination of residues: required if information provided for MPCA in Annex II Part 4 is insufficient, for MPCP.				☐
6	**Efficacy Data and Information (including Value Data) for the Microbial Pest Control Product**				☐
6.1	Preliminary range finding tests				☐
6.2	Performance assessment: field studies				☐
6.2.1	Efficacy tests				☐
6.2.2	Minimum effective dose tests				☐
6.3	Toxic or pathogenic effects on the crop or host which is to be protected.				☐
6.4	Compatibility with products in authorised tank mixes and with other products that are applied under expected conditions of use. Recommended interval between application of MPCP and any other products, to avoid loss of efficacy.				☐
6.4.1	Physical compatibility				☐
6.4.2	Chemical compatibility				☐
6.4.3	Biological compatibility				☐
6.5	Contribution to risk reduction and integrated pest management strategies, for the targeted crop or resource.				☐
6.6	Effects on yield and quality				☐
6.6.1	Impact on the quality of plants and plant products				☐
6.6.2	Effects on the processing procedure				☐
6.6.3	Effects on the the yield of treated plants and plant products				☐
6.7	Adverse effects				☐
6.7.1	Impact on succeeding crops				☐
6.7.2	Impact on other plants including adjacent crops				☐
6.7.3	Adverse effects on parts of plants used for propagating purposes (e.g. seeds, cuttings, runners)				☐

OECD Annex IIIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
6.7.4	Adverse effects on beneficial and other organisms apart from target organisms				☐
6.8	Summary and assessment of data according to points 6.1 to 6.7.4				☐
7	**Toxicological Studies and Exposure Data and Information for the Microbial Pest Control Product**				☐
7.1	Acute toxicity studies				☐
7.1.1	Acute oral toxicity				☐
7.1.2	Acute percutaneous (dermal) toxicity				☐
7.1.3	Acute inhalation toxicity to rats				☐
7.1.4	Skin irritation				☐
7.1.5	Eye irritation				☐
7.1.6	Skin sensitisation				☐
7.2	Operator, bystander and worker exposure: monitoring data				☐
7.3	Operator and bystander exposure: reporting of hypersensitivity incidents before and after registration				☐
7.4	Safety data sheet for each additive				☐
7.5	Supplementary information on all data points in part 7: Effects on Human Health, if it is recommended that MPCP be tank-mixed with an adjuvant or another pest control product.				☐
7.6	Summary and evaluation of health effects				☐
8	**Residues in/on Food and Feed products for the Microbial Pest Control Product (Rationale to waive residue studies on MPCP)**				☐
9	**Fate and Behaviour in the environment for the Microbial Pest Control Product (Rationale to waive testing, based on adequacy of information provided for MPCA, to permit an assessment of the fate and behaviour of MPCP in the environment)**				☐
10	**Rationale to waive additional testing, based on adequacy of information provided for MPCA, to permit an assessment of the impact of the MPCP on non-target organisms.**				☐
10.1	Effects on birds				☐
10.2	Effects on aquatic organisms				☐
10.3	Effects on bees				☐
10.4	Effects on terrestrial arthropods other than bees				☐
10.5	Effects on earthworms				☐
10.6	Effects on soil micro-organisms				☐
10.7	Additional studies				☐
11	**Summary and evaluation of environmental impact: summarise all data relevant to**				☐

OECD Annex IIIM point	Information, test or study (according to OECD Dossier Guidance Document, Appendix 6, Part 5)	Information, test or study provided	Justification provided	Undertaking provided	*Data gap*
	environmental impact and assess environmental risk by:				
11.1	addressing distribution and fate of MPCP				☐
11.2	identifying non-target species at risk and the extent of their exposure				☐
11.3	identifying precautions necessary to minimise environmental contamination and to protect non-target species				☐

Active Substance: **Applicant:** **Date:**

Test or Study Title: **Data Point:**

Part 3 **Evaluation Form 5 -**

for use in checking that the *Tier I* quality checks for individual tests and studies are of acceptable quality [31]

Micro-organisms

Applicant:

Date:

Test or Study Point	Description of the requirement	Provided Y/N[#]
1.1	The data point addressed	__
1.2	A descriptive title of the type of test or study	__
2	Reference point (location) of the report in the dossier (*e.g.* volume, section and point)	__
3.1	The names of the authors	__
3.2	The title of the report	__
3.3	The owner of test or study the report	__
3.4	An indication as to whether it is a published or unpublished report	__
3.5	The report number	__
3.6	The date of the report	__
4.1	The name and address of the testing facility involved	__
4.2	The laboratory report/project number	__
5.1	The dates of commencement and completion of experimental work	__
5.1	A statement of the objectives of the test or study	__
6.1	The identity of the test substance or material (ISO common name, batch number and degree of purity)	__
6.2	An explicit reference to the relevant specification of composition of the test substance or material	__

[31] Relevant for tests and studies for which the test methods used were not those currently specified (*e.g.* certain older studies)

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 5** **Evaluation Form 5 - *Tier I* Quality Checks**

Active Substance: **Applicant:** **Date:**

Test or Study Title: **Data Point:**

Test or Study Point	Description of the requirement	Provided Y/N[#]
6.3	Where available, data relevant to the storage stability of the test substance or material	__
6.4	Where relevant and available, data as to the stability of the test substance or material in the dosing vehicle	__
6.5	Where relevant and available, data as to the homogeneity of the test substance or material in the dosing or testing vehicle	__
6.6	Where data relating to the stability or homogeneity of the test substance is not available (*e.g.* certain older studies), a justification of the scientific validity of the study	__
6.7	Where relevant, information as to the physical form of the test substance or material	__
6.8	Full details of the composition of any dosing vehicles or solvents used	__
7.1	The identity of the test method used	__
7.2	Where not a method specified, a reasoned justification for the choice of method used in terms of its scientific validity and comparability with the method currently specified	__
7.3	On request, a copy of the method - full details of methods used which are unlikely to be accessible to the regulatory authority of the country to which the dossier is submitted, should be attached to the study or test report	__
7.4	Where test guidelines provide choice as to the method to be used, a reasoned justification for the choice made	__
7.5	Where deviations from the test guidelines specified, or from other methods used, are employed, a description of and reasoned justification for the deviations	__
8.1	Where relevant, an indication as to whether, or not, the test or study has been conducted by a laboratory certified as to its competence to conduct the test or study in compliance with the principles of GLP	__
8.2	Where relevant, the certifying authority	__
8.3	Where applicable, an indication as to whether, or not, the principles of GLP have been complied with	__
8.4	Where relevant, a justification for non compliance with the principles of GLP	__
9.1	Where relevant, a clear statement that the requirements relating to compliance with the principles of Good Experimental Practice (GEP) have been complied with	_
9.2	Where the requirements relating to compliance with the principles of GEP apply, whether conducted by an official or an officially recognised testing facility or organisation	_
9.3	Where relevant, a justification for non compliance with the principles of GEP	_

Appendix 11 **Forms for use in checking dossiers for completeness** **Part 5** **Evaluation Form 5 - *Tier I* Quality Checks**

Active Substance: **Applicant:** **Date:**

Test or Study Title: **Data Point:**

Test or Study Point	Description of the requirement	Provided Y/N[#]
10	A description of the test system	-
11	The identity of any statistical and other techniques applied to the data to aid interpretation, together with adequate documentation thereof and a justification for the use of the technique selected where non standard techniques are used	-
12.1	Where reference to published papers is made in *Tier I* checks as to the quality of individual test and study reports, the bibliographic references concerned	-
12.2	On request, copies of the papers concerned	-
12	Where reference to unpublished data is made in *Tier I* checks as to the quality of individual test and study reports (*e.g.* historical control data on strains of test animals) a summary of such data	-

Assessment of the Acceptability of the Quality of the Report

Report of acceptable quality ☐ Yes ☐ No

Comments:

Signature: ☐ ☐