Part 3 Evaluation Form 3 -
for use in checking that all test and study reports required in accordance with Annex IIB have been provided

Active Substance: Applicant: Date:

OECD Annex IIM point	EC Annex IIB 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	**1**	**Identity of the Microbial Pest Control Agent**				☐
1.1	1.1	Applicant (name, address, contact, telephone and telefax numbers)				☐
1.2	1.2	Producer (name, address, contact, telephone and telefax numbers)				☐
(1.3)	1.3	Scientific information				☐
1.3.1	1.3	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	1.3	- accession no. of sample in a recognised culture collection				☐
1.3.3	1.3	- test procedures and criteria, using best available technology, to characterise the strain or serotype;				☐
1.3.4	1.3	- for mutant or genetically-modified strains, indicate all known differences between the modified micro-organism and the parent wild strain(s)				☐
1.3.5	1.3	- include any trade names, common names, developmental code names				☐
1.3.6	1.3	- indigenous or non-indigenous at the species level to the intended area of application.				☐
1.4	1.4	Composition of Technical Grade of MPCA/Active Substance				☐
1.4.1	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	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	1.4.2	- the MPCA. This information is not required if Technical Grade of MPCA is a hypothetical stage in a continuous production process of an end-use product.				☐
1.4.2.2	1.4.2	- 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	1.4.2	- 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	1.4.2	- non-microbial impurities (e.g. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues).				☐

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		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	1.4.2	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, expressed in appropriate units, as outlined in point 1.3 (in terms of cfu's/mL or appropriate expression of biological activity/viability). *proposed new wording:* 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	3.4	Methods of production and quality criteria for the production and storage of the active micro-organism, including:				☐
1.4.3.1	3.4	- 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	3.4	- acceptable range for content of MPCA, in appropriate terms;				☐
1.4.3.3	3.4	- presence of human/mammalian pathogens;				☐
1.4.3.4	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	3.4	- maximum accepted level for microbial impurities, using suitable indicators of an unhygienic process.				☐
1.4.4	1.4.3	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-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				☐

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		properties; technical characteristics as appropriate				
1.4.7	#	International regulatory status of micro-organism	_____			☐
1.4.8	4	Sample of MPCA and analytical standard of metabolite	_____			☐
1.4.8.1	4	Sample of MPCA: if requested	_____			☐
1.4.8.2	4	Analytical standard of metabolite: if requested	_____			☐
1.4.8.3	4	Reference substances for the relevant impurities: if requested	_____			☐
1.5	#	Patent status	_____			☐
2	**2**	**Biological Properties of the Microbial Pest Control Agent**	_____			☐
2.1	2.1 2.1.1 2.1.2	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	2.1.2	Natural occurrence of the micro-organism including geographic distribution, hosts, habitat, ecological niche, level of natural occurrence	_____			☐
2.3	2.2	Information on target organism(s)	_____			☐
2.3.1	2.2.1	Description of the target organism(s)	_____			☐
2.3.2	2.2.2	Information on mode of action, kind of antagonism to target host, infective/toxic dose, transmissibility	_____			☐
2.4	2.3	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	2.4	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	2.8	Potential of the micro-organism to produce metabolites that are of concern for human health and/or the environment.	_____			☐
2.7	2.6 2.8	Information regarding closely related species	_____			☐
2.7.1	2.6	Among closely related species, provide information on pathogenicity to plants, animals or humans	_____			☐
2.7.2	2.8	Among closely related species, provide information on formation of toxic metabolites: structure, stability, conditions under which they are formed, mode of action	_____			☐

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2.8	2.5	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	2.7	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	2.9	Information on resistance/sensitivity to antibiotics/anti-microbial agents used in human or veterinary medicine				☐
3	**3**	**Further information on the Microbial Pest Control Agent (Function, Mode of Action, Handling)**				☐
3.1	3.1	Function, e.g. fungicide				☐
(3.2)		*placeholder*				☐
3.3	3.2	Field of use, e.g. forestry				☐
(3.4)	3.3 2.2.1	Information on target crop and target organism(s)				
3.4.1	3.3	Details of existing and intended uses (crops, groups of crops, plants or plant products treated or protected)				☐
3.4.2	2.2.1	Details of harmful organisms against which protection is afforded				☐
3.4.3	#	Effects achieved e.g. sprout suppression				☐
(3.5)	2.2.2 2.8	Information on mode of action and metabolites				
3.5.1	2.2.2	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	2.8	Details of active metabolites (especially toxins) and degradation products, cross referenced to the toxicological and residues data provided, to include:				☐
3.5.2.1	2.8	- IUPAC and CA names				☐
3.5.2.2	2.8	- ISO common name proposed or accepted				☐
3.5.2.3	2.8	- CAS, CIPAC, EINECS and ELINCS numbers				☐
3.5.2.4	2.8	- molecular and structural formula				☐
3.5.2.5	2.8	- molecular mass				☐
3.5.3	2.8	Information relative to the formation of active metabolites (especially toxins) and degradation products, to include:				☐
3.5.3.1	2.8	- the processes, mechanisms and reactions involved				☐
3.5.3.2	2.8	- kinetic and other data concerning the rate of conversion and if known the rate limiting step				☐
3.5.3.3	2.8	- environmental and other factors effecting the rate and extent of conversion				☐

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3.6	3.5	Information on the possible occurrence of the development of resistance or cross-resistance				☐
3.7	3.7	A material safety data sheet for the Microbial Active Substance				☐
3.8	3.8	Detailed instructions for safe disposal				☐
3.9	3.9	Procedures for the decontamination of water in case of an accident				☐
3.10	3	Other/special studies				☐
3.11	3.3	Crops or products to be protected or treated (see IIM 3.4.1)				☐
3.12	3.9	Measures to render micro-organism harmless, in case of an accident				☐
4	**4**	**Analytical methods**				☐
4.1	3.6	Method to preserve and maintain the master seed stock; criteria for an acceptable level of consistency and integrity of seed stock				☐
4.2	3.4	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	4.1 3.4	Quality control and post-registration monitoring methods				☐
4.3.1	4.1 3.4	Methods to detect, isolate, and enumerate the micro-organism				☐
4.3.2	4.1 3.4	Methods to differentiate a mutant or genetically-modified micro-organism from the parent strain.				☐
4.3.3	4.1 3.4	Methods to detect spontaneous change in major characteristics of micro-organism.				☐
4.3.4	4.1 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	4.1 3.4	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	4.1 3.4	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	4.2	Post-registration monitoring methods to determine and quantify residues of viable or non-viable micro-organism and metabolites (especially toxins)				☐
4.5.1	4.2	Food (where relevant)				☐
4.5.2	4.2	Feed (where relevant)				☐
4.5.3	4.2	Animal tissue (where relevant)				☐
4.5.4	4.2	Soil (where relevant)				☐
4.5.5	4.2	Water (where relevant)				☐
4.5.6	4.2	Air (where relevant)				☐
4.5.7	4.2	Analytical methods for amount or activity of proteinaceous products (where relevant)				☐
5	**5**	**Toxicological and Exposure Data and**				☐

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		Information on the Microbial Pest Control Agent				
5.1	5.1.1	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	5.1.2 5.1.3 5.1.4 5.2.6	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	5.1.2 5.1.3 5.1.4	The sensitisation and allergenic response of workers	_____			☐
5.2.2	5.1.2 5.1.3 5.1.4	Details on any occurrence of hypersensitivity and chronic sensitisation	_____			☐
5.2.3	5.1.2 5.1.3 5.1.4	Any significant clinical findings related to exposure, with special attention to those whose susceptibility may be affected.	_____			☐
5.2.4	5.1.4	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	5.2.6	Proposed first aid measures and medical treatment	_____			☐
(5.3)	5.2	Basic studies	_____			☐
(5.3.1)	5.2.1	Sensitisation properties	_____			☐
5.3.2	5.2.2.1	Acute oral infectivity and toxicity *proposed new wording:* Acute oral infectivity, toxicity and pathogenicity	_____			☐
5.3.3	5.2.2.2	Acute intratracheal/inhalation infectivity and toxicity *proposed new wording:* Acute intratracheal/inhalation infectivity, toxicity and pathogenicity	_____			☐
5.3.4	5.2.2.3	Acute intravenous/intraperitoneal infectivity	_____			☐
5.3.5	5.2.3.1	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	5.2.4	Cell culture study, for viruses and viroids or specific bacteria and protozoa with intracellular replication	_____			☐
5.3.7	5.2.5 5.2.5.1	Short-term toxicity (including inhalatory short-term toxicity), pathogenicity, infectivity	_____			☐
5.3.7.1	5.2.5	Short-term toxicity, pathogenicity, infectivity (28-day minimum)	_____			☐
(5.3.7.2)	5.2.5.1	Inhalatory short-term toxicity	_____			☐
5.4	5.2.3	Toxicity studies on metabolites (especially toxins)	_____			☐

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5.5	5.3 5.4 5.5	Other/special studies				☐
(5.5.1)	5.3	Specific toxicity, pathogenicity and infectiveness studies				☐
(5.5.2)	5.4	*In vivo* studies in somatic cells				☐
(5.5.3)	5.5	Genotoxicity - *In vivo* studies in germ cells				☐
5.6	5.6	Summary of mammalian toxicity and overall evaluation				☐
6	**6**	**Metabolism and Residues Studies on the Microbial Pest Control Agent**				☐
6.1	6	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)	6.1	Persistance and likelihood of multiplication in or on crops, feedingstuffs or foodstuffs				☐
(6.4)	6.2	Further information required				☐
(6.4.1)	6.2.1	Non-viable residues				☐
(6.4.2)	6.2.2	Viable residues				☐
6.5	6.3	Summary of residue behaviour and overall evaluation				☐
7	**7**	**Fate and Behaviour Studies on the Microbial Pest Control Agent in the Environment**				☐
7.1	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)	7.1.1 7.2	Persistance and mobility in soil				☐
(7.1.2)	7.1.2	Water				☐
(7.1.3)	7.1.3	Air				☐
7.2	7	Other/special studies				☐
8	**8**	**Ecotoxicological Studies on the Microbial Pest Control Agent (Effects on non-target organisms)**				☐
8.1	8.1	Birds *proposed new wording:* Effects on birds				☐
8.2	8.2.1	Fish *proposed new wording:* Effects on fish				☐
8.3	8.2.2	Aquatic invertebrates *proposed new wording:* Effects on aquatic invertebrates				☐
8.4	8.2.3	Effects on algal growth and growth rate (2 species) *proposed new wording:* Effects on algal growth and growth rate				☐
(8.5)	8.2.4	Effects on aquatic plants				☐

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8.6	#	Effects on aquatic or terrestrial plants. *proposed new wording:* Effects on terrestrial plants				☐
8.7	8.3	Bees *proposed new wording:* Effects on bees				☐
8.8	8.4	Non-target terrestrial arthropods *proposed new wording:* Effects on terrestrial arthropods other than bees				☐
8.9	#	Other terrestrial invertebrates *proposed new wording:* Effects on other terrestrial invertebrates				☐
8.9.1	8.5	Effects on earthworms				☐
(8.9.2)	#	Effects on other terrestrial invertebrates				☐
8.10	8.6	Effects on non-target soil micro-organisms *proposed new wording:* Effects on soil micro-organisms				☐
8.11	8.7	Other/special studies				☐
9	**9**	**Summary and evaluation of environmental impact: summarise all data relevant to environmental impact and assess environmental risk by:**				☐
9.1	9	- addressing distribution and fate of MPCA				☐
9.2	9	- identifying non-target species at risk and the extent of their exposure				☐
9.3	9	- identifying precautions necessary to minimise environmental contamination and to protect non-target species.				☐

Explanations:

OECD Annex point in brackets = proposed new OECD point

= No EC data requirement (the OECD point concerned is not a data requirement according to Council Directive 91/414/EEC)