FORM A1

PEST CONTROL PRODUCTS ACT, CAP 346, 1982, KENYA

APPLICATION FOR THE REGISTRATION OF A MICROBIAL PEST CONTROL PRODUCT

Introduction

1. These guidelines are for any proposed use of naturally occurring bacteria, protozoa, fungi, viruses, rickettsia, for the control of invertebrate pests, weeds, plant parasitic nematodes or microbial pathogens of crops. The use of microbial agents for the control of vertebrate pests is not contemplated. Nematodes are handled as macrobial pest control products.
2. Information in support of a request for registration, both published and unpublished (fully cited) should be supplied in the form of a summary data sheet laid out according to the format given in Form A1
3. A pre-registration consultation between the applicant and the registration authority is strongly recommended.

Information for Applicants

1. The application form must be completed by a person duly authorized by the applicant/company.
2. The application must be submitted in triplicate to:

   Pest Control Products Board (PCPB)
   P.O. Box 13794 - 00800 Nairobi.
   E-mail address: pcpboard@todays.co.ke/md@pcpb.or.ke
   Tel: 254- 020 – 8021846/7/8 Fax: 254- 020- 8021865
   Website: www.pcpb.or.ke

3. Every application must be accompanied by:-
   a. registration fee as prescribed.
   b. 3 copies of the draft label as per PCPB requirements.
4. The applicant shall be required to submit:-
   a. a sample of the pest control product;
   b. a sample of the technical grade of its active agent;
   c. a sample of the laboratory standard of its active agent;
   d. any other sample as may be required by PCPB.
5. All applicants intending to import/export live organisms into or out of the country should seek clearance from the Kenya Standing Technical Committee on Imports and Exports on live organisms (KSTCIE).
6. The use of genetically modified organisms (GMOs) and living modified organisms (LMOs) for use as microbial pest control products should be cleared by the National Biosafety Committee on GMOs before an application is made. Genetically modified crops are handled by the National Biosafety Committee.
7. List MI and MII are supplied as check lists and an index to ensure that the applicant has provided all relevant data and all cited material.
8. The application must be accompanied by a technical dossier as per PCPB data requirements i.e. Lists MI and MII
9. An applicant who is not a resident in Kenya must appoint an agent permanently resident in Kenya.

PURPOSE OF APPLICATION (tick as appropriate)

a. Pest control products containing a new active agent	☐
b. Pest control products where source of active and/or formulation is not identical to that of a registered product	☐
c. Registration transfer	☐
d. Amendments to existing registration	☐
e. Other (Explain)	
Will the product be marketed under own label? Yes ☐ No ☐ If No, specify ……	

1. APPLICANT		
Name of applicant		
Corporate name of company		
Reg No.:		
Name of registration holder.		
Name of local agent in country: (if different from registration holder)		
Status: (Importer / formulator / distributor etc.)		
Physical Address		
Postal Address:		
Telephone (and area code):		
Fax (and area code):		
E-Mail:		

2. PRODUCT			
2.1 Identity and stage(s) of active agent and culture collection code			
2.2 Concentration of active agent in technical material.			
2.3 Designation (Description of product)	Trade name:		
	Trade mark:		
	Trade mark holder:		
	Internal code:		
2.4 Function of product: (eg. Insecticide, herbicide etc.)			
2.5 Intended use: (Veterinary, horticultural, public health, industrial, agriculture, forestry, etc).			
2.6 Target pest(s) and host(s)			
2.7 Method, dosage rates and frequency of application:			
2.8 Type of formulation: (eg. Suspension, WP, etc.)			
2.9 Is the product registered in country of a) origin b) manufacture: c) formulation:	Yes ☐ No ☐ If no, specify …… Yes ☐ No ☐ If no, specify ……		
2.10 Registration in SEARCH country/ies: (country names, product name and registration number)			
2.11 Registration in other country/ies, particularly OECD countries: (country names, product name and registration number)			
2.12 Customs Tariff Code: (Brussels Tariff Nomenclature)			

3. **IDENTIFICATION**

Identification of Microorganism	Life stage (spore, hyphae etc)		
3.1 Identification	Genus	Species	Sub species
Scientific name			
Common name(s)			
3.2 Contents (number per Unit)			

4. COMPOSITION OF MICROBIAL PEST CONTROL AGENT(S) (Technical grade) (Information on active agent may be attached in sealed envelope)			
Active agent(s): (Common name/s)	Manufacturer: (Name and address)	Minimum a.i.% purity	a.i. Range %

5. FORMULATION	
5.1 Formulator: (Name)	Postal Address:
Internal code:	Physical address:

5.2 Composition (Information on composition may be attached in sealed envelope)			
Ingredients and Function:	Units (w/w, w/v etc.)	Units (e.g. cfu or IUP)	Range

6. BIOLOGICAL PROPERTIES OF ACTIVE AGENT	
6.1 History and geographical distribution of active agent	
6.2 Mode of action and host range	
6.3 Life cycle	
6.4 Infectivity, dispersal and colonizing ability	
6.5 Relationships to known plant, animal or human pathogens	
6.6 Genetic stability	
6.7 Information on the production of metabolites, especially antibiotics and toxins	

7. **TOXICOLOGY (active agent)**			
7.1 Rat:	Acute Oral (LD_{50} mg/kg)	Inhalation LC_{50} (mg/4/hour)	Intra-peritoneal injection for infectivity (LD_{50} g/kg)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
Hypersensitivity / allergies in humans			

8. **TOXICOLOGY (formulated product)**			
8.1 Rat:	Acute Oral (LD_{50} mg/kg)	Acute Dermal (LD_{50} g/kg)	Inhalation LC_{50} (mg/4/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
8.2 Rabbit:	Skin irritation	Eye irritation	
None			
Mild			
Moderate			
Severe			
8.3 Skin Sensitization in guinea pig: (tick)		None Mild Moderate Severe	

8.4 WHO classification (tick):	Ia	Ib	II	III	Others

8.5 Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets	
9. ECOTOXICOLOGY	
9.1 Toxicity to bees:	
9.2 Toxicity to fish and other aquatic organisms:	
9.3 Toxicity to birds:	
9.4 Toxicity to earthworms or other soil invertebrates, and soil micro-organisms:	
9.5 Toxicity to other non-target organisms:	

9.6 Persistence in environment:	
9.7 Available toxicological data relating to other ingredients in formulation (non-active additives in formulation).	
9.8 Other effects: Specify	
10. PACKAGING	
10.1 Packaging material / container:	
10.2 Pack size(s):	
10.3 Disposal of empty container(s):	
11. OTHER SPECIFIC REQUIREMENTS	
11.1 Operator exposure	
11.2 Sanitary and phytosanitary measures	

11.3 Has the product been cleared by the phytosanitary authorities? (tick):	Yes (provide evidence)	No (give reasons)
a. in the country of origin	☐	☐
b. the recipient country	☐	☐

12. DECLARATION	
For and on behalf of ……..…….. I hereby certify that the above mentioned information and data provided in support of this application are to the best of my knowledge true, correct and complete.	
…….. Name in full (printed)	……. Signature
……..…… Official Title	…… Date
Official Stamp of Applicant / Company	FOR OFFICIAL USE Remarks …….. ……..…….… ……. …….. ……..…… Signed: Date:

NOTE: The format of this application form is recognized by all SEARCH countries.

FORM A1, LIST MI

ACTIVE AGENT: DOSSIER INDEX FOR A MICROBIAL PEST CONTROL AGENT

The dossier accompanying the application must provide full details (as applicable) of the information requested in this list. i.e., details of the methods used and results of toxicological and ecotoxicological studies, methods of analysis, etc. Numbering used in the dossier must correspond to that used in the application form. If the product contains more than one active agent, compile a separate dossier for each active agent.

1. DESIGNATION / IDENTITY OF ACTIVE AGENT (PURE)

	Annex No. in dossier if study included	**Official use only**
1.1 Common name		
1.2. Full taxonomic name including isolate, strain or subspecies (where appropriate)		
1.3 Full taxonomic classification		
1.4 Methods of identification, enumeration, and bioassay		
1.5 Manufacturer or Development code		
1.6 Source, Name and Address of manufacturer and address and location of manufacturing plants.		
1.7 Methods of production and quality control.		
1.8 Collection and culture reference number where culture is deposited.		
1.9 Patent status of formulation		
a) Is the product under patent?		
b) Who is patent holder?		
c) When was product patented?		
d) What is the Expiry date of patent?		

2. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM

	Annex No. in dossier if study included	**Official use only**
2.1 History of the micro-organism and its uses. Natural occurrence and geographical distribution		
2.2 Description of the target organism(s) and mode of action		
2.3 Host specificity range and effects on species other than the target harmful organism		
2.4 Development stages/life cycle of the micro-organism		
2.5 Infectivity, dispersal and colonisation ability		
2.6 Effect of environmental parameters (UV, temperature, soil pH, humidity, nutrition requirements, etc.) on stability and survival		

2.7 Relationships to known plant, animal or human pathogens		
2 8 Genetic stability and factors affecting it		
2.9 Information on the production of metabolites (especially toxins)		
2.10 Show antibiotics and other anti-microbial properties		

3. FURTHER INFORMATION ON THE MICRO-ORGANISM

	Annex No. in dossier if study included	**Official use only**
3.1 Biological function (control of insects, fungi, mites, ticks, bacteria, viruses, nematodes, weeds, molluscs, etc)		
3.2 Information on the occurrence or potential development of resistance of the target organism(s) and resistance management strategy.		
3.3 Methods to prevent loss of virulence of seed stock of the micro-organism		
3.4 Recommended methods and precautions concerning handling, storage, transport etc.		
3.5 Procedures for destruction or decontamination		
3.6 Measures in case of an accidental spillage		

4. PHYSICAL AND CHEMICAL PROPERTIES
(Active agent –technical grade)

	Annex No. in dossier if study included	**Official use only**
4.1 Physical state (liquid, solid etc)		
4.2 Colour		
4.3 Odour		
4.4 Stability in water, air, effect of temperature, effect of light, identity of breakdown products		
4.5 Reactivity towards container material		

5. TOXICOLOGY

Toxicological data may be waived where there is sufficient evidence that the product is safe. This would be based on results of medical surveillance, published data, as well as actual studies on the product. Where no evidence is provided, or where there is insufficient evidence, toxicological studies have to be conducted as indicated under Tier 1 in the first instance. Tier 2 is applied when, in the absence of evidence of pathogenicity, either toxicity or infectivity is observed in Tier 1. Tier 3 is applied when there are issues of known or suspected subchronic toxicity and human pathogenicity and tests for effects following long-term exposure and particular adverse effects of intracellular parasites of mammalian cells.

TIER 1 STUDIES (Active agent and/or technical grade)	**Annex No. in dossier if study included**	**Official use only**
5.1 Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies)		
5.2 Acute oral LD_{50} mg/kg LC_{50} (rat/rabbit)		
5.3 Inhalation LC_{50} mg/4 hours (rat/rabbit)		
5.4 Mutagenicity / Genotoxicity		
5.5 Intra-peritoneal (fungi and protozoa) / intravenous (others) injection for infectivity		
5.6 Discussion of the effects of repeated human exposure		
5.7 Other studies		

TIER 2 STUDIES (Active agent and/or technical grade)		
5.8 Subchronic toxicity 28 day NOEL mg/kg/day		

TIER 3 STUDIES (Active agent and/or technical grade)		
5.9 Chronic toxicity / carcinogenicity NOEL mg/kg/day (mouse/rat)		
5.10 Neurotoxicity NOEL mg/kg/day		
5.11 Teratogenicity NOEL mg/kg/day		
5.12 Reproduction (rat/rabbit)		

6. ECO-TOXICOLOGY
(Active agent / Technical grade)

Waivers may be granted on presentation of evidence that exposure to the particular non-target organism will not occur, or where effects of exposure are already documented. Selection of test non-target organisms will be on a case by case basis and according to mode of action and ecological relevance. TIER 1 studies should report any observed pathogenicity / infectivity to the test species. TIER 2 studies are required on representative non-target species if acute studies indicate that adverse effects would occur during routine application.

TIER 1		**Annex No. in dossier if study included**	**Official use only**
6.1 Birds (2 species)	LD_{50} mg/kg		
	LD_{50} mg/kg		
6.2 Aquatic organisms (2 species)	LC_{50} mg/ml		
	LC_{50} mg/ml		
6.3 Aquatic invertebrate	EC_{50} mg/ml		
6.4 Algae	EC_{50} mg/ml		
6.5 Bees	LD_{50} µg/bee		
6.6 Representative natural enemies	LD_{50} µg/individual		
6.7 Earthworms or other relevant soil invertebrate (eg termites)	LC_{50} mg/kg		
6.8 Soil micro-organisms	EC_{50} mg/ml		
6.9 Representative non-target plant	LC_{50} mg/ml		

TIER 2			
6.10 Birds (1 species)	Reproduction		
	NOEL		
6.11 Aquatic organisms (2 species)	Reproduction		
	BCF		
	NOEL		
	Reproduction		
	BCF		
	NOEL		

7. BEHAVIOUR IN ENVIRONMENT
(Active agent– technical grade)

	Annex No. in dossier if study included	**Official use only**
Behaviour in soil:		
7.1 Persistence of active agent (days)		
7.2 Mobility of active agent		
7.3 Major metabolites where appropriate		
Behaviour in surface and ground water:		
7.4 Persistence of active agent (days)		
7.5 Major metabolites where appropriate		

8. RESIDUES

	Annex No. in dossier if study included	**Official use only**
8.1 Identity of residues		
8.2 Level and behaviour of residues		
8.3 Major metabolites/agents (viable and non-viable)		
8.4 PHI, withholding periods in case of post-harvest use.		
8.5 Method of residue analysis.		

9. OTHER SPECIFIC REQUIREMENTS

	Annex No. in dossier if study included	**Official use only**
9.1 Residue data from a GLP certified lab or as directed by the Secretary PCPB.		
9.2 Effects on taint, odour, taste or other quality aspects due to residues in or on fresh or processed products (where appropriate).		
9.3 Effects on industrial processing and/or household preparation on the nature and magnitude of residues (where appropriate).		
9.4 Residue data in succeeding or rotational crops where presence of residues might be expected (where appropriate).		
9.5 Assessment of the likely residue levels encountered by persons handling treated produce.		

FORM A1, LIST MII

FORMULATED PRODUCT: DOSSIER INDEX FOR MICROBIAL PEST CONTROL PRODUCTS

The dossier accompanying the form should provide more details of the information requested in this list. Summaries of the methods and results used in toxicological and ecotoxicological studies, methods of analysis etc.
Numbering used in the dossier must correspond with that used in the application Form A1

1. IDENTITY

	Annex No. in dossier if study included	**Official use only**
1.1 Formulation type and code:		
1.2 Source and specifications for components included in the formulation		
1.3 Methods of identification, enumeration, and bioassay		
1.4 Material safety data sheet for formulation and each co-formulant		

2.PHYSICAL AND CHEMICAL PROPERTIES

	Annex No. in dossier if study included	**Official use only**
2.1 Physical state (solid, liquid etc)		
2.2 Colour		
2.3 Odour		
2.4 Effects of light, air, temperature, water on technical characteristics of the formulation		
2.5 Storage stability in proposed packaging		
2.6 Shelf life		
2.7 Density		
2.8 Bulk density		
2.9 Flammability		
2.10 Compatibility with other pesticides		
2.11 pH		
2.12 pH of 1% aqueous dilution		
2.13 Oxidizing properties		
2.14 Water content		
2.15 Wettability		
2.16 Solubility in water		
2.17 Persistent foaming		

2.18 Particle size		
2.19 Wet or Dry sieve test as appropriate		
2.20 Suspensibility / emulsifiability		
2.21 Emulsion stability		
2.22 Viscosity		
2.22 Other properties (e.g. adherence to seeds for seed dressings)		

Note: This information is required as applicable to the formulation type

3. TOXICOLOGY

	Annex No. in dossier if study included	**Official use only**
3.1 Rat Acute oral LD_{50} mg/kg		
3.2 Acute dermal LD_{50} mg/kg		
3.3 Acute Inhalation LC_{50} mg/4 hour		
3.4 Rabbit Skin irritation		
3.5 Rabbit Eye irritation		
3.6 Skin sensitisation in guinea pig		
3.7 WHO classification		
3.8 Other studies (if applicable)		

4. EMERGENCY PROCEDURES IN CASE OF ACCIDENTAL EXPOSURE OR POISONING

	Annex No. in dossier if study included	**Official use only**
4.1 Symptoms of human poisoning		
4.2 Mode of action in man		
4.3 First aid treatment		
4.4 Skin contact		
4.5 Eye contact		
4.6 Inhalation		
4.7 Ingestion		
4.8 Antidote		
4.9 Note to physician		

5. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE

5.1 Fire fighting measures		
5.2 Procedures in case of spillage		

6. INTENDED USES (New label claims with this application)

	Annex No. in dossier if study included	**Official use only**
6.1 Function (control of insects, fungi, mites, ticks, bacteria, viruses, nematodes, weed, molluscs, etc)		
6.2 Target pest(s)		
6.3 Area of use		
6.4 Application rate (appropriate units and cfu)		
6.5 Method of application		
6.6 Recommended number and timing of applications		
6.7 Stage of treatment		
6.8 Directions for use		
6.9 Residue data and pre-harvest interval		
6.10 Phytotoxicity		

6.11 Contraindications		
6.12 Local Biological Efficacy data (guidelines provided separately)		

7. MINIMUM LABEL REQUIREMENTS – (provided separately)**.**

To be developed

8. REGISTRATION IN OTHER COUNTRIES

	Annex No. in dossier if study included	**Official use only**
8.1 Evidence of registration in other countries		

9. OTHER SPECIFIC REQUIREMENTS

	Annex No. in dossier if study included	**Official use only**
9.1 Medical surveillance on manufacturing plant personnel		
9.2 Health records of occupationally exposed personnel, industry, agriculture, forestry, fisheries.		

10. PROPOSED PACKAGING

10.1	Type of packaging in which the product is imported		
10.2	Type of packaging for distribution in Kenya		
10.3	Packaging material		
10.4	Sizes of individual packaging		

11. PROCEDURES FOR DESTRUCTION AND DECONTAMINATION

11.1	Possibility of neutralization		
11.2	Controlled discharge		
11.3	Controlled incineration		
11.4	Water purification		
11.5	Procedures of cleaning application equipment		
11.6	Recommended methods and precautions concerning handling during storage, display or transport.		

GUIDELINE: DOSSIER FOR MICROBIAL PEST CONTROL AGENT

The dossier accompanying this form should provide details of the information requested. Methods used (physical and chemical), details of the methods used in and results of toxicological and ecotoxicological studies, methods of analysis etc. have to be given. Numbering used in the dossier must correspond with that used in the application form.

ACTIVE INGREDIENT/AGENT (TECHNICAL GRADE)

REQUIREMENTS:	**REMARKS:**
1.1 Common name (ISO)	Indicate where applicable
1.2. Full taxonomic name including isolate, strain or subspp. (where appropriate)	Full scientific name including any relevant information
1.3 Full taxonomic classification	Indicate full systemic classification including any relevant information
1.4 Methods of identification, enumeration, and bioassay	Give morphology, histology, molecular biolgy, methodof counting microbes per unt volume/weight, etc.
1.5 Manufacturer or Development code	Specify Source/manufacturer
1.6 Source, Name and Address of manufacturer and address and location of manufacturing plants.	Indicate company and country of origin. Name, address, location of manufacturing plant.
1.7 Methods of production and quality control.	Developer will outline how the microbial agent is isolated, purified, bulked, quality control, and maintenance and assay methods,
1.8 Collection and culture reference number where culture is deposited.	Agent is to be deposited in a recognised culture collection, the name of the collection and the culture reference number is to be given.
1.9 Patent status of formulation	
a) Is the agent under patent?	
b) Who is patent holder?	
c) When was the product patented?	
d) What is the expiry date of the patent?	

2. BIOLOGICAL PROPERTIES OF THE MICRO-ORGANISM

REQUIREMENTS:	**REMARKS:**
2.1 History of the micro-organism and its uses, natural occurrence and geographical distribution	The geographical region and the place in the ecosystem (e.g. host plant, host animal, or soil from which the micro-organism was isolated) must be stated. The method of isolation of the micro-organism should be reported. The natural occurrence of the micro-organism in the relevant environment shall be given if possible at strain level. Indicate whether the micro-organism has been GRAS (Generally Regarded As Safe) listed

2.2 Description of the target organism(s) and mode of action	The principal mode of action should be indicated and if the micro-organism produces a toxin with a residual effect on the target organism, then the mode of action of this toxin should be described. If relevant, information on the site of infection and mode of entry into the target organism and its susceptible stages should be given. The results of any experimental studies must be reported. It must also be stated whether or not the micro-organism or its metabolites are translocated in plants and, where relevant, how this translocation takes place. In case of pathogenic effect on the target organism, infective dose (the dose needed to cause infection with the intended effect on a target species) and transmissibility (possibility of spread of the micro-organism in the target population, but also from one target species to another (target) species) after application under the proposed condition of use shall be indicated.
2.3 Host specificity range and effects on species other than the target harmful organism	Any available information on the effects of the micro-organism on non-target organisms within the area to which the micro-organism may spread shall be given. The occurrence of non-target organisms being either closely related to the target species or being especially exposed shall be indicated.
2.4 Development stages/life cycle of the micro-organism	Information on the life cycle of the micro-organism described, including symbiosis, parasitism, competitors, etc., on the target host organisms, as well as vectors for viruses, must be presented. The generation time and the type of reproduction of the micro-organism must be stated. Information on the occurrence of resting stages and their survival time, their virulence and infection potential must be provided.
2.5 Infectivity, dispersal and colonisation ability	Information is to be provided on the behaviour of the micro-organism under typical environmental conditions of use and compared to the environmental conditions, if any, under which the micro-organism may infect, colonise or damage mammalian tissues Information on possible dispersal routes of the micro-organism (via air as dust particles or aerosols, with host organisms as vectors, etc.), under typical environmental conditions relevant to the use, must be provided

2.6 Effect of environmental parameters (UV, temperature, soil pH, humidity, nutrition requirements etc.) on stability and survival	The persistence of the micro-organism and its toxins under the typical environmental conditions of use must be indicated. Any particular sensitivity to certain components of the environment (e.g. UV light, soil, water) must be stated. The environmental requirements for survival, reproduction, and effectiveness of the micro-organism must be stated.
2.7 Relationships to known plant, animal or human pathogens	The possible existence of one or more species of the genus of the active agent and/or, where relevant, contaminating micro-organisms known to be pathogenic to humans, animals, crops or other non-target species and the type of disease caused by them shall be indicated. It shall be stated whether it is possible, and by which means, to clearly distinguish the active micro-organism from the pathogenic species
2.8 Genetic stability and factors affecting it.	Where appropriate, information on genetic stability (e.g. mutation rate of traits related to the mode of action or uptake of exogenous genetic material) under the environmental conditions of proposed use must be provided. Information must also be provided on the micro-organism's capacity to transfer genetic material to other organisms as well as its capacity to being pathogenic for plants, animals or man..
2.9 Information on the production of metabolites (especially toxins).	If other strains belonging to the same microbial species as the strain subject to the application are known to produce metabolites (especially toxins) with unacceptable effects on human health and/or the environment during or after application, the nature and structure of this substance, its presence inside or outside the cell and its stability, its mode of action (including external and internal factors of the micro-organism necessary to action) as well as its effect on humans, animals or other non-target species shall be provided. The conditions under which the micro-organism produces the metabolite(s) (especially toxin(s)) must be described. Any available information on the mechanism by which the micro-organisms regulate the production of the(se) metabolite(s) should be provided. Any available information on the influence of the produced metabolites on the micro-organism's mode of action should be provided.

2.10 Antibiotics and other anti-microbial agents.	Some micro-organisms produce antibiotic substances which may interfere with the use of antibiotics in human and veterinary medicine. This must be avoided at any stage of the development of a microbial plant protection product. Information on the micro-organism's resistance or sensitivity to antibiotics or other anti-microbial agents must be provided, in particular the stability of the genes coding for antibiotic resistance, unless it can be justified that the micro-organism has no harmful effects on human or animal health, or that it can not transfer its resistance to antibiotics or other anti-microbial agents.

3. FURTHER INFORMATION ON THE MICRO-ORGANISM

REQUIREMENTS:	**REMARKS:**
3.1 Biological function (control of insects, fungi, mites, bacteria, plant pathogens, nematodes, weed, molluscs, etc)	The biological function must be specified
3.2 Information on the occurrence or possible occurrence of the development of resistance of the target organism(s) and resistance management strategy.	Available information on the possible occurrence of the development of resistance or cross-resistance of the target organism(s) must be provided. Where possible, appropriate management strategies should be described
3.3 Methods to prevent loss of virulence of seed stock of the micro-organism	Methods to prevent loss of virulence of starting cultures are to be provided. In addition, any method, if available, that could prevent the micro-organism from losing its effects on the target species must be described.
3.4 Recommended methods and precautions concerning handling, storage, transport, etc.	Provide information that would be required for safe handling
3.5 Procedures for destruction or decontamination	In many cases the preferred or sole means of safe disposal of micro-organisms, contaminated materials, or contaminated packaging, is through controlled incineration. Methods to dispose safely of the micro-organism or, where necessary, to kill it prior to disposal, and methods to dispose of contaminated packaging and contaminated materials, must be fully described. Data must be provided for such methods to establish their effectiveness and safety.
3.6 Measures in case of an accidental spillage	Information on procedures for rendering the micro-organism harmless in the environment (e.g. water or soil) in case of an accidental spillage must be provided.

4. PHYSICAL AND CHEMICAL PROPERITES

REQUIREMENTS:	**REMARKS:**
4.1 Physical state (liquid, solid etc)	State whether powder, liquid or solid
4.2 Colour	Specify
4.3 Odour	If applicable
4.4 Stability in water, effect of light, identity of breakdown products	Provide information with evidence
4.5 Reactivity towards container material	Provide information with evidence

5. TOXICOLOGY
(Active Ingredient – technical grade)

Include a copy of an executive summary discussing **ALL ISSUES** named under section 3 of the form or provide copies of the individual summaries from each study relating to issues mentioned under section 3 of the form. Information on the methods of testing used must be provided.

TIER 1 STUDIES	
REQUIREMENTS:	**REMARKS:**
5.1 Medical surveillance data for manufacturing plant and agricultural workers (such as occurrence of hypersensitivity / allergies)	Available reports of occupational health surveillance programmes, must be submitted. These reports shall, where available, include data from persons exposed in manufacturing plants or after application of the micro-organism (e.g. in efficacy trials). Special attention should be devoted to those whose susceptibility may be affected, e.g. pre-existing disease, medication, compromised immunity, pregnancy or breast feeding. Available information on the sensitisation and allergenic response of workers, including workers in manufacturing plants, agricultural and research workers and others exposed to the micro-organism must be provided, and include, where relevant, details of any incidences of hypersensitivity and chronic sensitisation. Available reports from the open literature on the micro-organism or closely related members of the taxonomic group (relating to clinical cases), where they are from reference journals or official reports, must be submitted.
5.2 Acute oral LD_{50} mg/kg LC_{50} (rat/rabbit)	This should be provided for the technical grade for all kinds of agents listed in the application form. Potential risks due to infectivity and pathogenicity should be given.
5.3 Inhalation LC_{50} mg/4 hours (rat/rabbit)	
5.4 Mutagenicity / Genotoxicity	If the micro-organism produces exotoxins, then these toxins and any other relevant metabolites in the culture medium must also be tested for genotoxicity. Such tests on toxins and metabolites should be performed using the purified chemical if possible. If toxic metabolites are not formed, studies on the

	micro-organism itself should be considered depending on expert judgement on their relevance. Genotoxicity of cellular micro-organisms should be studied after breaking of the cells where ever possible. In the case of a virus the risk of insertional mutagenesis in mammal cells or the risk of carcinogenicity has to be addressed.
5.5 Intra-peritoneal (fungi and protozoa) / intravenous (others) injection for infectivity	The intraperitoneal/subcutaneous test is considered a highly sensitive assay to elicit response in particular infectivity studies. The intraperitoneal injection is always required for all micro-organisms. However, expert judgement may be exercised to evaluate whether subcutaneous injection is preferred instead of intraperitoneal injection if the maximum temperature for growth and multiplication is lower than 37 ºC.
5.6 Discussion of the effects of repeated human exposure	Provide any available information on the subject
5.7 Other studies	Provide any available information on other studies

TIER 2 STUDIES **(Active agent and/or technical grade)**	
REQUIREMENTS:	**REMARKS:**
5.8 Subchronic toxicity 28 day NOEL mg/kg/day	Examine for toxicological and pathological changes in appropriate organs.

TIER 3 STUDIES **(Active agent and/or technical grade)**	
REQUIREMENTS:	**REMARKS:**
5.9 Chronic toxicity / carcinogenicity NOEL mg/kg/day (mouse/rat)	The assessment of risk from lifetime exposure to micro-organisms/toxins of concern may require examination for longterm toxicological and pathological changes in appropriate organs.
5.10 Neurotoxicity NOEL mg/kg/day	The assessment of risk from lifetime exposure to micro-organisms/toxins of concern may require examination for toxicological and pathological changes in nervous system.
5.11 Teratogenicity NOEL mg/kg/day	The assessment of risk from lifetime exposure to micro-organisms/toxins of concern may require examination of toxicological and pathological changes in appropriate organs.
5.12 Reproduction (rat/rabbit)	The assessment of risk from lifetime exposure to micro-organisms/toxins of concern may require examination of toxicological and pathological changes in the reproductive system.

Other studies:

Provide further information relevant to the toxicity profile of the product e.g. toxicity of major metabolites, reaction or breakdown products of the pest control products formed in/or on treated plant/crop etc, which are likely to be consumed in cases where different from those identified in animal studies. Toxic effects on livestock, poultry, pets should be stated.

6. ECO-TOXICOLOGY

Provide either an executive summary or individual summaries of studies on the behaviour in the environment providing information requested in the form.

TIER 1	
REQUIREMENTS:	**REMARKS:**
6.1 Birds (2 species)	Provide details of toxicity, infectivity and pathogenicity to at least one land and one water bird, LD_{50} in mg product and cfu or equivalent / kg bird weight.
6.2 Aquatic organisms Fish (2 species) Daphnia (2 species)	Provide details of toxicity, infectivity and pathogenicity to at least two species studied, LC_{50} (in mg of product and cfu or equivalent / litre of water)
6.3 Aquatic invertebrate	Specify and provide details on other organisms according to the information requested on the form.
6.4 Algae	
6.5 Bees	
6.6 Representative natural enemies	
6.7 Earthworms or other relevant soil invertebrate (eg termites)	
6.8 Soil micro-organism	
6.9 Representative non-target plant	If the agent is closely related to a crop pathogen or a pathogen of a vertebrate species, laboratory evidence of genetic stability using appropriate tests is required.

TIER 2	
REQUIREMENTS:	**REMARKS:**
Birds (1 species)	Provide NOEL from one species studied and information on the effect on reproduction.
Aquatic organisms (2 species)	Provide NOEL details on at least two species studied and the effect on reproduction. Indicate the bioconcentration factor (BCF) on the active ingredient in tissues.

7. BEHAVIOUR IN ENVIRONMENT
(Active ingredient/agent – technical grade)

REQUIREMENTS:	**REMARKS:**
Behaviour in soil:	
7.1 Persistence of active agent (days)	Indicate the degradation path of the active agent in the soil and the degradation products formed. Indicate also persistence and retention of biological activity.
7.2 Mobility of active agent	Indicate vertical and horizontal movement of agent in soil.. Specify the degree of mobility of the active agent in the soil hence leaching potential and possibility for ground water contamination.
7.3 Major metabolites where	Specify the major metabolites/ viable or non-viable

appropriate	residues in the soil and their behaviour
Behaviour in surface and ground water:	
7.4 Persistence of active agent (days)	Describe ways and speed of degradation in surface and ground water.
7.5 Major metabolites where appropriate	Specify the major break down products formed and their adsorption/desorption on sediments.

8. RESIDUES

REQUIREMENTS:	**REMARKS:**
8.1 Identity of residues	Specify
8.2 Level and behaviour of residues	Describe the process of metabolization of the active agent in the plant and the degradation products formed. Indicate the action and the persistence of the metabolites/agent/viable and non-viable residues in the plants and animals.
8.3 Major metabolites/agents (viable and non-viable)	Provide either an executive summary or individual summaries of studies conducted concerning the issues listed. Specify the metabolites/viable and non-viable residues. State their toxicological effects and retention of microbial activity.
8.4 PHI, withholding periods in case of post-harvest use.	For each crop, state the Pre-Harvest Interval (PHI), and withholding period. State MRLs where applicable.
8.5 Method of residue analysis.	Provide a copy in the dossier for countries requiring it.

Residue data has to be provided for bioproducts if they are found to have toxicological, infectivity and pathogenicity concerns to mammals.

9. OTHER SPECIFIC REQUIREMENTS

REQUIREMENTS:	**REMARKS:**
9.1 Residue data from a GLP certified laboratory or as directed by the Secretary, PCPB	Provide an executive summary or copies of summaries from each study relating to the issues highlighted in the form.
9.2 Effects on taint, odour, taste or other quality aspects due to residues in or on fresh or processed products.	Provide an executive summary or copies of summaries from each study relating to the issues highlighted in the form.
9.3 Effects of industrial processing and/or household preparation on the nature and magnitude of residues.	Provide an executive summary or copies of summaries from each study relating to the issues highlighted in the form.
9.4 Residue data in succeeding rotational crops where presence of residues might be expected (where appropriate)	
9.5 Assessment of the likely residue levels encountered by persons handling treated produce.	

***** For pest control products found to have allergenic effects, detailed studies (on their residues) have to be provided.

GUIDELINE: DOSSIER FOR A FORMULATED MICROBIAL PEST CONTROL PRODUCT

The dossier accompanying this form should provide details of the information requested. Methods used (physical and chemical), details of the methods used in and results of toxicological and ecotoxicological studies, methods of analysis etc. have to be given. Numbering used in the dossier must correspond with that used in the application form

1. IDENTITY

	Remarks
1.1 Formulation type and code	Provide information on the formulation type e.g. Liquid concentrate, powder, etc.
1.2 Source and specifications for components included in the formulation	Geographical origin, company, reference laboratory
1.3 Methods of identification, quantification, and bioassay	Indicate procedures for identification and quantification of AI and impurities in the formulation.
1.4 Material safety data sheet for formulation and each co-formulant	Provide information on safe handling, storage, transportation etc.

2.PHYSICAL AND CHEMICAL PROPERTIES

Clearly state method used to determine properties under the appropriate section of the dossier. CIPAC methods are recommended.

	Remarks
2.1 Physical state (solid, liquid etc)	
2.2 Colour	
2.3 Odour	
2.4 Effects of light, air, temperature, water on technical characteristics of the formulation	Provide information with evidence
2.5 Storage stability in proposed packaging	Specify conditions for storage with evidence
2.6 Shelf life	Indicate production date and expiration date Provide supportive data
2.7 Density	Indicate the density of the liquids.
2.8 Bulk density	Indicate the density of solids after compression.
2.9 Flammability	Specify if product is flammable
2.10 Compatibility with other pesticides	Indicate types of pest control products which the product is or is not compatible with. Give evidence.
2.11 pH	State the effect of pH on stability and effectiveness.
2.12 pH of 1% aqueous dilution	Relevant to products to be diluted in water.
2.13 Oxidizing properties	Indicate materials that can be damaged by oxidizing properties of the formulation.
2.14 Water content	Indicate the maximum water content when it has an influence on the quality.
2.15 Wettability	The wettability has to be indicated for solid formulations used in dilution (wettable

	powders, powder soluble in water and granules soluble in water).
2.16 Solubility in water	Specify
2.17 Persistent foaming	State the extent foaming occurs for formulations diluted in water.
2.18 Particle size	Specify if applicable
2.19 Wet or Dry sieve test as appropriate	Specify if applicable
2.20 Suspensibility / emulsifiability	Specify if applicable
2.21 Emulsion stability	Specify if applicable
2.22 Viscosity	Specify if applicable
2.22 Other properties (e.g. adherence to seeds for seed dressings)	Provide details

Other studies

Provide detailed studies on any other relevant toxicological or ecotoxicological studies conducted on the formulated product.

3. TOXICOLOGY

	Remarks
3.1 Rat Acute oral LD_{50} mg/kg	Provide details
3.2 Acute dermal LD_{50} mg/kg	
3.3 Acute Inhalation LC_{50} mg/4 hour	
3.4 Rabbit Skin irritation	
3.5 Rabbit Eye irritation	
3.6 Skin sensitisation in guinea pig	
3.7 WHO classification	
3.8 Other studies (if applicable)	

The dossier must contain a detailed Material Safety Data Sheet. Furthermore either an executive summary discussing all aspects mentioned under section 3 must be included, or the summaries from each individual toxicity study and field in the same order.

The FAO/WHO class must be given as per the table hereunder.

WHO-Classification Scheme

Class	LD50 for the rat (mg/kg body weight)			
	Solids	Liquids	Solids	Liquids
	Oral		Dermal	
Ia Extremely Hazardous	5 or less	20 or less	10 or less	40 or less
Ib Highly hazardous	5-50	20-200	10-100	40-400
II Moderately hazardous	50-500	200-2000	100-1000	400-4000
III Slightly hazardous	Over 500	Over 2000	Over 1000	Over 4000
Others				

4. EMERGENCY MEASURES IN CASES OF ACCIDENTAL EXPOSURE OR POISONING

	Remarks
4.1 Symptoms of human poisoning	Provide details
4.2 Mode of action in man	
4.3 First aid treatment	
4.4 Skin contact	
4.5 Eye contact	
4.6 Inhalation	
4.7 Ingestion	
4.8 Antidote	
4.9 Note to physician	

5. EMERGENCY PROCEDURES IN CASE OF FIRE/SPILLAGE

	Remarks
5.1 Fire fighting measures	Specify
5.2 Procedures in case of spillage	

6. INTENDED USES

	Remarks
6.1 Function (control of insects, fungi, mites, ticks, bacteria, viruses, nematodes, weed, molluscs, etc)	State whether it will be used as a fungicide, insecticide, etc.
6.2 Target pest(s)	Give name of target pest(s) and stage at which the pest control product should be applied
6.3 Area of use	Specify (crops, livestock, public health, or

	environment)
6.4 Application rate (appropriate units and cfu)	Specify rate
6.5 Method of application	Specify
6.6 Recommended number and timing of applications	Specify timing and frequency
6.7 Stage of treatment	Specify growth stage of host
6.8 Directions for use	Specify on label and / or leaflet
6.9 Residue data and pre-harvest interval	Specify on label and / or leaflet
6.10 Phytotoxicity	Specify on label and / or leaflet
6.11 Contraindications	Specify on label and / or leaflet
6.12 Efficacy data (guidelines provided separately)	Provide from country of origin and other countries of similar climatic conditions in addition to the local data

7. MINIMUM LABEL REQUIREMENTS

Specify the warnings, use restrictions and safety precautions which must be present on the label in all countries.The proposed label must be included in the dossier, should contain the specified warnings, use restrictions and safety precautions as well as meet PCPB label requirements.
PCPB label requirements will be provided separately.

8. REGISTRATION IN OTHER COUNTRIES

8.1 Evidence of registration in other countries	Provide evidence

9. OTHER SPECIFIC REQUIREMENTS

	Remarks
9.1 Medical surveillance on manufacturing plant personnel	Provide details
9.2 Health records of occupationally exposed personnel, industry, agriculture, forestry, fisheries.	Provide details

10. PROPOSED PACKAGING

10.1 Type of packaging in which the product is imported	Provide details
10.2 Type of packaging for distribution in Kenya	Provide details
10.3 Packaging material	Provide details
10.4 Sizes of individual packaging	Provide details

11. PROCEDURES FOR DESTRUCTION AND DECONTAMINATION

11.1 Possibility of neutralization	Provide details
11.2 Controlled discharge	Provide details
11.3 Controlled incineration	Provide details
11.4 Water purification	Provide details
11.5 Procedures of cleaning application equipment	Provide details
11.6 Recommended methods and precautions concerning handling during storage, display or transport.	Provide details

LIST OF ABREVIATIONS

a.a.	Active Agent
BCF	Bio Concentration Factor
CFU	Colony Forming Units
CIPAC	Collaborative International Pesticides Analytical Council
EC	Emulsifiable Concentrate
EC_{50}	Median Effective Concentrate
FAO	Food and Agriculture Organization of the United Nations
g/kg	Grams per Kilogram
g/l	Grams per litre
ISO	International Standards Organisation
LC_{50}	Median Lethal concentrate
LD_{50}	Median Lethal Dose
mg/l	Milligrams per litre
MSDS	Material Safety Data Sheet
NOEL	Non Observable Effective Level
OECD	Organisation for Economic Co-operation and Development
^{o}C	Degrees centigrade
PCPB	Pest Control Products Board
PHI	Pre Harvest Interval
SEARCH	Southern and Eastern African Regulatory Committee on Harmonization of Pesticide Registration .
μg	Microgram
WHO	World Health Organization
WP	Wettable Powder
GLP	Good Laboratory Practice