

Application for introduction of bio-pesticides and beneficial organisms

Information for applicants

1. The applicant is responsible for the information submitted.
2. The application shall be submitted in 4 hard copies, separately bound.
3. All parts shall be filled by summarising the required information in the spaces provided and referenced to clearly labelled annexes.
4. A cover letter addressed to the Secretariat (Managing Director KEPHIS) shall accompany this application form.
5. In case of more than one product, the applicant shall fill a separate form for each product.
6. All confidential business information shall be submitted in a separate and sealed file and clearly marked as `CBI`.
7. An applicant who is not a resident in Kenya shall appoint an authorised local agent permanently residing in Kenya. An original letter of appointment must accompany this application.
8. Additional information relating to the application shall be provided if required.
The use of genetically modified organisms (GMOs) shall be cleared by the National Biosafety Authority before an application is made

PART A: GENERAL INFORMATION	
1. Name of applicant	
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) <i>*All must be provided</i>	
3. Name of Local agent (if different from applicant)	
4. Address of the local agent where applicable (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) <i>*All must be provided</i>	
5. Name of Manufacturer	
6. Address of the Manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) <i>*All must be provided</i>	
7. Purpose of introduction/multiplication (Tick where appropriate): a) Research b) Commercial	

c) Personal use d) Other (Specify)_____	
8. Intended use (Tick where appropriate): a) Veterinary b) Public health c) Industrial d) Agriculture e) Forestry f) Environment g) Other (specify)	
9. Quantity proposed for importation	

PART B:DETAILS OF THE ORGANISM	
1. The scientific name(s) of the organism (Genus, species, strain/variety) <i>All must be provided</i>	
2. Common Name	
3. The type of organism/ micro-organism (Tick appropriately) a) Bacteria, b) Virus c) Fungus d) Nematode e) Insect f) Mite g) Other (specify))	
4. Category of organism (Tick appropriately) a) Macrobial b) Microbial c) Other (specify)	
5. Methods of identification, enumeration and bioassay (attach detailed methodology and report)	
6. Biology of the organism (<i>attach annexes including peer reviewed publications</i>)	
7. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism (<i>Detailed descriptions</i>)	
8. Any relationship to known plant, animal and human parasites/pathogens	
9. Mode of dispersal/ spread, invasiveness, and/or colonization ability of	

the organism	
10. Mode of action of the organism	
11. Natural occurrence (Ecosystem where it is found naturally)	
12. Origin of organism and world distribution	
13. Uses of the organism	
14. Host range of the organism	
15. Specificity to targets	
16. Description of benefit of the organism (<i>Provide evidence</i>)	
17. Effect of the organism to non-target organisms	
18. Genetic stability of the organism in the environment	
19. Environmental requirements of the organism	
20. Impact of the organism in its area of distribution	
21. List of countries where the organism/product is approved for use (<i>attach evidence</i>)	

PART C: IDENTITY AND INFORMATION OF PRODUCT		
1. Trade/commercial name		
2. Origin of the Product (<i>country and state/district</i>)		
3. Product function (e.g. control of disease, control of insect, pollinator e.t.c.)		
4. Target pest and host		
5. Formulation Details		
5.1. Type of formulation: (e.g. EC, WP, other (specify))		
5.2. Declare full composition of the product (Active agent (s) and inert material) (Detailed information on formulation may be provided separately in a sealed envelope)		
Active agent (s): (Common name/s)	Minimum Active agent purity	Active agent Range
5.3. Details of Formulator (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) <i>*All must be provided</i>		
5.4. Details of Trademark Owner (Names, Postal address, Physical address)		
5.5. Is the product registered in the country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration)		Yes <input type="checkbox"/> No <input type="checkbox"/> If no give reasons

5.6. Is the product registered in other countries	Yes <input type="checkbox"/> No <input type="checkbox"/> State the countries
5.7. Certificate of analysis from the country of origin.	Available <input type="checkbox"/> Not available <input type="checkbox"/> Give reasons
5.8. Physical and chemical characteristics of the product	
6. Production	
6.1 Describe production method	
6.2 Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports)	
6.3 Shelf life (attach reports)	
6.4 Copy of market label from the country of origin (<i>Attach as annex</i>)	
7. Information for product use	
7.1. Mode of application	
7.2. Area of application a) Green house b) Open field c) Other (Specify)	
7.3. Dosage rates and frequency of application	
8. Mode of action (<i>Attach supporting scientific publications</i>)	
9. Description of benefits (<i>Attach supporting scientific publications</i>)	
10. Environmental requirements (<i>Attach supporting scientific publications</i>)	
11. Information on compatibility (tank mixing) (attach reports)	
12. Information on efficacy of the product	
13. Packaging	
13.1. Type of packaging material / container	
13.2. Pack size (s)	
13.3. Disposal of empty container(s)	
14. Describe decontamination procedures	

PART D. SAFETY INFORMATION			
1. Toxicology (Formulated product) For microbial products only			
1.1. Rat:	Acute Oral (LD 50 mg/kg)	Acute Dermal (LD50 mg/kg)	Inhalation LC 50 (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
1.2. Rabbit	Skin irritation	Eye irritation	
	None <input type="checkbox"/>	Mild <input type="checkbox"/>	Moderate <input type="checkbox"/>
			Severe <input type="checkbox"/>
1.3. Skin Sensitization in guinea pig:(tick)	None <input type="checkbox"/>	Mild <input type="checkbox"/>	Moderate <input type="checkbox"/>
			Severe <input type="checkbox"/>
1.4. WHO classification:			
1.5. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets			
1.6. Summary of Ecotoxicological Effects For microbial products only			
1.6.1. Toxicity to bees			
1.6.2. Toxicity to fish and other aquatic organisms			
1.6.3. Toxicity to birds			
1.6.4. Toxicity to earthworms and soil micro-organisms			
1.6.5. Toxicity to other non-target organisms			
1.6.6. Persistence in environment			
1.6.7. Metabolites and their identity			
1.6.8. Other effects (Specify)			

Any additional information that will be useful to support the evaluation process will be accepted.

PART F: 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)	
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Guideline Application for introduction of bio-pesticides

PART A: GENERAL INFORMATION	
1. Name of applicant	Full name of the legal entity making the application
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) <i>*All must be provided</i>	Give information on Physical location, Postal address, Telephone, Cell phone, Email, website
3. Name of Local agent (if different from applicant)	Indicate full company name
4. Address of the local agent where applicable (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) <i>*All must be provided</i>	Give information on Physical location, Postal address, Telephone, Cell phone, Email, website
5. Name of Manufacturer	Indicate the name of Manufacturer
6. Address of the Manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) <i>*All must be provided</i>	Give information on Physical location, Postal address, Telephone, Cell phone, Email, website
7. Purpose of introduction/multiplication (Tick where appropriate): e) Research f) Commercial g) Personal use h) Other (Specify)_____	Indicate the reason for introduction
8. Intended use (Tick where appropriate): a) Veterinary b) Public health c) Industrial d) Agriculture e) Forestry f) Environment g) Other (specify)	Indicate intended use of the product(articles)
9. Quantity proposed for importation	Specify the quantity of product to be imported

PART B:DETAILS OF THE ORGANISM	
1. The scientific name(s) of the organism (Genus, species, strain/variety) <i>All must be provided</i>	Give full scientific name of the organism including any relevant information
2. Common Name	Indicate where possible, the common name
3. The type of organism/ micro-organism (Tick appropriately) a) Bacteria, b) Virus c) Fungus d) Nematode e) Insect f) Mite g) Other (specify))	Tick the appropriate type of organism
4. Category of organism (Tick appropriately) a) Macrobial b) Microbial c) Other (specify)	Give the available information
5. Methods of identification, enumeration and bioassay (attach detailed methodology and report)	Give identification report and methods used
6. Biology of the organism (<i>attach annexes including peer reviewed publications</i>)	Give information on life cycle, reproduction, parasitism, competition, virulence etc.
7. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism (<i>Detailed descriptions</i>)	Give detailed descriptions; attach analysis and quality control reports
8. Any relationship to known plant, animal and human parasites/pathogens	Give information on the behaviour of the organism under typical environmental condition
9. Mode of dispersal/ spread, invasiveness, and/or colonization ability of the organism	Provide information on possible dispersal routes, host organisms such as vectors and behaviour under typical environmental conditions

10. Mode of action of the organism	Describe how the product works. Principal mode of action should be indicated. Give information on site of action and mode of entry in the target. State whether there are any metabolites involved.
11. Natural occurrence (Ecosystem where it is found naturally)	Give the geographical region and the place in the ecosystem from where the organism naturally occurs.
12. Origin of organism and world distribution	Give information on the geographical distribution and the place in the ecosystem where the organism was isolated
13. Uses of the organism	Give reports on uses and effectiveness of the organism.
14. Host range of the organism	Describe in details the host range of the organism
15. Specificity to targets	Provide any information on effect on non-targets
16. Description of benefit of the organism (Provide evidence)	Provide information on positive effects of the product
17. Effect of the organism to non-target organisms	Provide available information on the effects of the organism on non-target organism within the area in which it would be spread and the occurrence of non-target organisms that are closely related to the target species
18. Genetic stability of the organism in the environment	Provide any information on possible mutation traits and uptake of exogenous genetic materials and the environmental conditions of the proposed use.
19. Environmental requirements of the organism	Give the conditions required for the optimum establishment of the organism (e.g. pH, Temperature, humidity, UV)
20. Impact of the organism in its area of distribution	Give information on the positive and negative effects of the organism in its

	area of distribution.
21. List of countries where the organism/product is approved for use (<i>attach evidence</i>)	Provide copies of certificates of approval for countries where the organism is in use and letters of exemption where applicable

PART C: IDENTITY AND INFORMATION OF PRODUCT		
1. Trade/commercial name		Specify
2. Origin of the Product (<i>country and state/district</i>)		Give details
3. Product function (e.g. control of disease, control of insect, pollinator etc.)		Give details on the function of the product
4. Target pest and host		Specify the target pest and host of the product
5. Formulation Details		
5.1. Type of formulation: (e.g. EC, WP, other (specify))		Specify
5.2. Declare full composition of the product (Active agent (s) and inert material) (Detailed information on formulation may be provided separately in a sealed envelope)		
Active agent (s): (Common name/s)	Minimum Active agent purity (Give details)	Active agent Range (Give details)
5.3. Details of Formulator (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) *All must be provided		Give information on Physical location, Postal address, Telephone, Cell phone, Email, website
5.4. Details of Trademark Owner (Names, Postal address, Physical address)		Indicate the reason for introduction Give information on Physical location, Postal address, Telephone, Cell phone, Email, website
5.5. Is the product registered in the country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration)		Yes <input type="checkbox"/> No <input type="checkbox"/> If no give reasons (Tick appropriately)
5.6. Is the product registered in other countries?		Yes <input type="checkbox"/> No <input type="checkbox"/> State the countries (Tick appropriately)

5.7. Certificate of analysis from the country of origin.	Available <input type="checkbox"/> Not available <input type="checkbox"/> Give reasons (Tick appropriately)
5.8. Physical and chemical characteristics of the product	Give the physical and chemical properties of the product.
6. Production	
6.1 Describe production method	Describe the method
6.2 Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports)	
6.3 Shelf life (attach reports)	
6.4 Copy of market label from the country of origin (<i>Attach as annex</i>)	
7. Information for product use	
7.1. Mode of application	Specify the application method
7.2. Area of application a) Green house b) Open field c) Other (Specify)	Specify the area where the product will be used
7.3. Dosage rates, frequency and interval of application	Specify the recommended application rates and the frequency of application.
8. Mode of action (<i>Attach supporting scientific publications</i>)	Describe how the product works. Principal mode of action should be indicated. Give information on site of action and mode of entry in the target. State whether there are any metabolites involved.
9. Description of benefits (<i>Attach supporting scientific publications</i>)	Give information on positive impacts of the product
10. Environmental requirements (<i>Attach supporting scientific publications</i>)	Provide information on the optimal conditions for the organism
11. Information on compatibility (tank mixing) (attach reports)	Provide information on use of the product with other inputs eg. tank mixing, side effects
12. Information on efficacy of the product	Give details

13. Packaging	
13.1. Type of packaging material / container	Give the type of the container used in packaging the product
13.2. Pack size (s)	Give details on the intended pack sizes
13.3. Disposal of empty container(s)	Give details on the disposal procedures of the packaging material
14. Describe decontamination procedures	Give details

PART D. SAFETY INFORMATION					
Studies should be conducted in a Good Laboratory Practice (GLP) certified laboratory.					
1. Toxicology (Formulated product)					
a. Rat	Acute Oral (LD 50 mg/kg)	Acute Dermal (LD50 mg/kg)	Inhalation LC 50 (mg/l/hour)		Provide copies of the studies
	Experimental	Experimental	Experimental		Provide copies of the studies
	Calculated	Calculated	Calculated		Provide copies of the studies
b. Rabbit: (tick)	Skin irritation				Provide copies of the studies
	None <input type="checkbox"/>	Mild <input type="checkbox"/>	Moderate <input type="checkbox"/>	Severe <input type="checkbox"/>	Provide copies of the studies
	Eye irritation				
c. Skin Sensitization in guinea pig: (tick)	None <input type="checkbox"/>	Mild <input type="checkbox"/>	Moderate <input type="checkbox"/>	Severe <input type="checkbox"/>	Provide copies of the studies
d. WHO classification:					State the WHO classification of the product
e. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets					Provide copies of the studies

2. Summary of Eco-toxicological effects	Attach evidence or copy of studies	
i. Toxicity to bees		Provide evidence or copy of studies
ii. Toxicity to fish and other aquatic organisms		Provide evidence or copy of studies
iii. Toxicity to birds		Provide evidence or copy of studies
iv. Toxicity to earthworms and soil micro-organisms		Provide evidence or copy of studies
v. Toxicity to other non-target organisms		Provide evidence or copy of studies
vi. Persistence in environment		Provide evidence or copy of studies
vii. Metabolites and their identity		Provide evidence or copy of studies
viii. Other effects (Specify)		Provide evidence or copy of studies