Form PPCR1

Application for introduction of bio-fertilizers (R.12 (1))

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.
9. 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 (full name of the legal entity making the application)	
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
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) **All must be provided*	
5. Name of Manufacturer	
6. Address of the Manufacturer (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) *All must be provided	
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 of trial sample to be imported	

PART B:DETAILS OF THE ORGANISM	
1. The scientific name (s) of the organism (Genus, species, strain/variety) *All must be provided.*	
2. Common Name	
3. The type of organism/micro-organism (Tick where appropriate) a) Bacteria b) Protozoa c) Virus d) Fungus e) Nematode f) Other (Specify)_____	
4. Are the organisms live or deactivated? If deactivated describe the process used (*Attach evidence)*	
5. Biology of the organism (*attach annexes including peer reviewed publications*)	
6. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism (*Detailed descriptions; attach analysis and quality control reports*)	
7. Mode of dispersal/ spread of the organism	
8. Mode of action of the organism	
9. Origin of organism and world distribution	
10. Natural occurrence (Ecosystem where it is found naturally)	
11. Target plant species and environment	
12. Information on efficacy of the organism	

13. Description of any negative effects caused by the organism	
14. Stability of the organism in the environment	
15. Environmental requirements of the organism	
16. Effect of the organism on availability of soil nutrients and water	
17. Impact of the organism in its area of distribution	
18. List of countries where the organism is approved for use *(attach evidence*)	

PART C: IDENTITY AND INFORMATION OF FORMULATED PRODUCTS	
1. Trade/commercial name	
2. Purpose of introduction (Tick where appropriate) a) Research b) Commercial c) Personal use d) Other (specify)	
3. Details of Formulator (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
4. Details of trademark owner (Names, Postal address, Physical address)	
5. Origin of the Product (*country and state/district)*	
6. Product function (e.g. nitrogen fixing, phosphate solubilizing etc.)	
7. Intended use: (Tick appropriately) a) Agriculture b) Forestry c) Veterinary b) Public health c) Industrial f) Other (Specify)	
8. **Formulation Details**	
8.1 Physical state of formulation: (solid, liquid, etc.)	
8.2 Type of formulation (EC, WP, SC etc.)	
8.2 Declare full composition of formulation(s) (active organisms) (Information may be attached in a sealed envelope)	
Active organism(s): (Common name/s)	Minimum count of active organism

8.3 Identification of contaminants	Maximum count of contaminants (CFU)
9. Is the product registered in the country of origin?	Yes ☐ No ☐ If no give reasons
10. Is the product registered in other countries?	Yes ☐ No ☐ State the countries
11. Certificate of analysis from the country of origin	Available ☐ Not available ☐
12. Specify physical characteristics of the product	

13. **Production**	
13.1. Describe the production method	
13.2. Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports)	
14. Shelf life (attach reports)	
15. Market label for the country of manufacture (Attach as an annex)	
16. **Information on product use**	
16.1. Mode of application	
16.2. Area of application a) Green house b) Open field c) Other (Specify)	
16.3. Dosage rates and frequency of application	
17. Mode of action *(Attach supporting scientific publications)*	
18. Description of benefits *(Attach supporting scientific publications)*	
19. Effect on availability of soil nutrients and water	
20. Environmental requirements *(Attach supporting scientific publications)*	
21. Information on tank mixing (combined use/compatibility) (attach reports)	
22. Information on efficacy of the product	
23. **Packaging**	
23.1. Type of Packaging material / container	
23.2. Pack size (s)	
23.3. Describe the disposal of packaging material	

24. Describe decontamination procedures	
25. The proposed final disposition of the product (e.g. incineration, burying, treatment etc)	

PART D. SAFETY INFORMATION			
1. **Toxicology** (Formulated product)			
a. Rat	Acute Oral (LD 50 mg/kg)	Acute Dermal (LD50 mg/kg)	Inhalation LC 50 (mg/l/hour)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
b. Rabbit (tick appropriately)	Skin irritation	Eye irritation	
	None ☐	Mild ☐	Moderate ☐ Severe ☐
c. Skin Sensitization in guinea pig (tick appropriately)	None ☐	Mild ☐	Moderate ☐ Severe ☐
d. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets			
2. Material Safety data (Attach MSDS)			
3. **Summary of Eco toxicological effects**	Attach evidence or copy of studies		

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	
1.6.5 Toxicity to soil micro-organisms	
1.6.6 Toxicity to other non-target organisms	
1.6.7 Toxicity to other non-target plants	
1.6.8 Fate in the environment (persistent, biodegradable)	
Metabolites and their identity	
1.6.9 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) …… Official Title	…… Signed : Date:
Official Stamp of Applicant / Company	**FOR OFFICIAL USE** Remarks …… Signed : Date:

Guidelines for application for introduction of bio-fertilizers

PART A: GENERAL INFORMATION	
1. Name of applicant	Indicate name of the person/ company making the application.
2. Address of the applicant/company (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	Indicate address of the person/company making the application including; *Physical location, *Postal address, *Telephone, *Cell phone, *Email, website All that have (*) must be provided.
3. Name of Local agent	Indicate the full name of the local agent. Where the applicant is not a resident in Kenya
4. Address of the local agent where applicable (*Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	Indicate address of the local agent including; *Physical location, *Postal address, *Telephone, *Cell phone, *Email, website All that have (*) must be provided.
5. Name of Manufacturer	Indicate name of the manufacturer
6. Address of the Manufacturer (*Country, *Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) *All must be provided	Indicate address of the manufacturer including; *Country, *Physical location, *Postal address, *Telephone, *Cell phone, *Email, website All that have (*) must be provided.
7. Purpose of introduction/multiplication (Tick where appropriate): a) Research b) Commercial c) Personal use d) Other (Specify)_____	Indicate the reason for introduction of the product by selecting from the options given
8. Intended use (Tick where appropriate): a) Veterinary b) Public health c) Industrial d) Agriculture e) Forestry f) Environment	Indicate the area of intended use by selecting from the options given

	g) Other (specify)	
9.	Quantity of trial sample to be imported	Indicate the desired quantity of the product to be imported

PART B:DETAILS OF THE ORGANISM		
1.	The scientific name (s) of the organism (Genus, species, strain/variety) *All must be provided.*	Give full scientific name of the organism including any changes in naming in the recent past.
2.	Common Name	Indicate where possible, the common name
3.	The type of organism/micro-organism (Tick where appropriate) a) Bacteria b) Protozoa c) Virus d) Fungus e) Nematode f) Other (Specify)_____	Tick the appropriate type of organism
4.	Are the organisms live or deactivated? If deactivated describe the process used (*Attach evidence)*	Give information on deactivated organisms Attach evidence of deactivation process or production (deactivation certificate/flow chart or any other available document
5.	Biology of the organism (*attach annexes including peer reviewed publications*)	Give information on life cycle, reproduction, parasitism, competition, virulence etc.
6.	Hyper-parasites, contaminants, pests or likely pests to be associated with the organism (*Detailed descriptions; attach analysis and quality control reports*)	Give detailed descriptions; attach analysis and quality control reports
7.	Mode of dispersal/ spread of the organism	Give information on the behaviour of the organism under typical environmental condition
8.	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.
9.	Origin of organism and world distribution	Give the geographical region and the place in the ecosystem from where the organism was isolated. Give the method of isolation and indicate whether the organism is Generally Regarded as Safe (GRAS).
10.	Natural occurrence (Ecosystem where it is found naturally)	Give information on the specific ecosystem where the organism is found.
11.	Target plant species and environment	Give any available information on the plant species and the environment in which the plant species is grown
12.	Information on efficacy of the organism	Give reports on uses and performance of the organism.
13.	Description of any negative effects caused by the organism	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.
14.	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.
15.	Environmental requirements of the organism	Give the conditions required for the optimum establishment of the organism (e.g. pH, Temperature, humidity, UV)
16.	Effect of the organism on availability of soil nutrients and water	Give information on the interaction of the organism with the soil Macro and micro nutrients with water.

17.	Impact of the organism in its area of distribution	Give information on the negative and positive effects of the organism in its area of distribution.
18.	List of countries where the organism is approved for use *(attach evidence*)	Provide evidence of approval or evidence for exemption for approval for registration

PART C: IDENTITY AND INFORMATION OF FORMULATED PRODUCTS	
1. Trade/commercial name	Specify
2. Purpose of introduction (Tick where appropriate) a) Research b) Commercial c) Personal use d) Other (specify)	Indicate the reason for introduction
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
4. Details of trademark owner (Names, Postal address, Physical address)	Give information on Physical location, Postal address, Telephone, Cell phone, Email, website
5. Origin of the Product (*country and state/district)*	Specify the origin of the product
6. Product function (e.g. nitrogen fixing, phosphate solubilizing etc.)	Specify product function
7. Intended use: (Tick appropriately) d) Agriculture e) Forestry f) Veterinary b) Public health c) Industrial f) Other (Specify)	Tick appropriately
8. **Formulation Details**	
8.1 Physical state of formulation: (solid, liquid, etc.)	Must be provided
8.2 Type of formulation (EC, WP, SC etc.)	
8.2 Declare full composition of formulation(s) (active organisms) (Information may be attached in a sealed envelope)	

Active organism(s): (Common name/s)	Minimum count of active organism (Give details)
8.3 Identification of contaminants	Maximum count of contaminants (CFU) (Give details)
8.4.1 Is the product registered in the country of origin?	Yes ☐ No ☐ If no give reasons (Tick appropriately)
8.4.2 Is the product registered in other countries?	Yes ☐ No ☐ State the countries (Tick appropritely)
8.5 Certificate of analysis from the country of origin	Available ☐ Not available ☐ (Tick appropriately)
8.6 Specify physical and chemical characteristics of the product	Give the physical and chemical properties of the product.
9. **Production**	
9.1 Describe the production method	Describe the method
9.2 Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports)	
9.3 Shelf life (attach reports)	
9.4 Market label for the country of manufacture (Attach as an annex)	
10. **Information on product use**	
10.1. Mode of application	Specify the application method
10.2. Area of application a) Green house b) Open field c) Other (Specify)	Specify the area where the product will be used
10.3. Dosage rates and frequency of application	Specify the recommended application rates and the frequency of application.
11. Mode of action *(Attach supporting scientific publications)*	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.		
12. Description of benefits *(Attach supporting scientific publications)*	Give information on positive impacts of the product		
13. Effect on availability of soil nutrients and water	Give information on the interaction of the product with the soil Macro and Micro nutrients with water.		
14. Environmental requirements *(Attach supporting scientific publications)*	*Provide information on the optimal conditions for the organism*		
15. Information on tank mixing (combined use/compatibility) (attach reports)	Give details		
16. Information on efficacy of the product	.		
17. **Packaging**			
17.1 Type of Packaging material / container	Give the type of the container used in packaging the product		
17.2 Pack size (s)	Give details on the intended pack sizes		
17.3 Describe the disposal of packaging material	Give details on the disposal procedures of the packaging material		
18. Describe decontamination procedures	Give details		
20. The proposed final disposition of the product (e.g. incineration, burying, treatment etc)	Give details		
PART D. SAFETY INFORMATION			
4. TOXICOLOGY (Formulated product) (Provide)			
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 (tick appropriately)	Skin irritation		
	None ☐ Mild ☐ Moderate ☐ Severe ☐		
	Eye irritation		
	None ☐ Mild ☐ Moderate ☐ Severe ☐		

1.3 Skin Sensitization in guinea pig (tick appropriately)	None ☐	Mild ☐	Moderate ☐	Severe ☐
1.5 Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets				
Material Safety data (Attach MSDS)				
1.6 Summary of Eco toxicological effects				
1.6.1 Toxicity to bees	Provide information			
1.6.2 Toxicity to fish and other aquatic organisms	Provide information			
1.6.3 Toxicity to birds	Provide information			
1.6.4 Toxicity to earthworms	Provide information			
1.6.5 Toxicity to soil micro-organisms	Provide information			
1.6.6 Toxicity to other non-target organisms	Provide information			
1.6.7 Toxicity to other non-target plants	Provide information			
1.6.8 Fate in the environment (persistent, biodegradable)	Provide information			
1.6.9 Metabolites and their identity	Provide information			
1.6.9 Other effects: Specify	Provide information			