Application form for soil conditioners and organic fertilizers

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 Service (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) **All must be provided*	
3. Name of Local agent	
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 proposed for importation	

PART B: ORGANIC ACTIVE INGREDIENTS	
Details of the Organic Source	
1. Common Name of the active ingredient	
2. The scientific name(s) of the plant/animal/other where the product was derived (Genus, species, subspecies, strain/variety) *All must be provided*	
3. Biology of the organic source (*attach annexes including peer reviewed publications*)	
4. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism (*Detailed descriptions; attach analysis and quality control reports*)	
5. Description of benefit	
6. Details of invasiveness of the organic source used	
7. Effect of the organic source used on availability of soil nutrients and water	

PART C: IDENTITY AND INFORMATION OF PRODUCT		
1. Trade/commercial name		
2. Origin of the product (*country and state/district)*		
3. Product function (e.g. water retention, aeration, enhanced organic matter etc)		
4. Formulation Details		
4.1. Type of formulation: (e.g. EC, WP, etc.)		
4.2. Declare full composition of formulation(s) (active organisms) (Information may be attached in a sealed envelope)		
Active ingredient(s): (Common name/s)	Minimum a.i.% purity	a.i. Range %
4.3. Identification of contaminants	Maximum count of contaminants (CFU)	

4.4. Details of Formulator (*Physical location, *Country, Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*	
4.5. Details of trademark owner (*Country, *Physical location, *Postal address, *Telephone, *Cell phone, *Email, website)	
5. Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration)	Yes ☐ No ☐ If no give reasons
6. Is the product registered in other countries	Yes ☐ No ☐ If yes state the countries
7. Certificate of analysis from the country of origin	Available ☐ Not available ☐
8. Specify other physical and chemical characteristics of the product such as grade, matrix etc.	
9. Production details	
9.1. Describe the production method	
19.2. Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports)	
10. Shelf life (attach reports)	
11. Copy of market label for the country of origin *(Attach as annex)*	
12. Product usage information	
12.1. Mode of application	
12.2. Area of application a) Green house b) Open field c) Other (Specify)	
12.3. Stage of the crop	
12.4. Dosage rates and frequency, interval of application	
13. Mode of action *(Attach supporting scientific publications)*	
14. Description of benefits *(Attach supporting scientific publications)*	

15. Effect on availability of soil nutrients and water	
16. Environmental requirements *(Attach all supporting scientific publications)*	
17. Information on combined use/compatibility (tank mixing)	
18. Information on efficacy of the product	
19. Packaging	
19.1. Type of Packaging material / container:	
19.2. Pack size(s)	
20. Disposal of empty container(s)	
21. Describe containment measures (where applicable)	
22. Handling, storage and transport	
23. Describe destruction procedures	
24. Describe decontamination procedures	
25. The proposed point of entry into the country	

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)
	Experimental	Experimental	Experimental
	Calculated	Calculated	Calculated
b. Rabbit: (tick)	Skin irritation		
	None ☐ Mild ☐ Moderate ☐ Severe ☐		
	Eye irritation		
	None ☐ Mild ☐ Moderate ☐ Severe ☐		
c. Skin Sensitization in guinea pig: (tick)	None ☐ Mild ☐ Moderate ☐ Severe ☐		
d. WHO classification:			
e. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets			

2. Summary of Eco-toxicological effects	Attach evidence or copy of studies
i. Toxicity to bees	
ii. Toxicity to fish and other aquatic organisms	
iii. Toxicity to birds	
iv. Toxicity to earthworms and soil micro-organisms	
v. Toxicity to other non-target organisms	
vi. Toxicity to other non-target plants	
vii. Persistence in environment	
viii. Other effects (Specify)	
f. Any other additional information (impurities and metabolites of toxicological concern)	

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:

Guideline for application form for soil conditioners and organic 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
1. 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.
6. Purpose of introduction/multiplication (Tick where appropriate): e) Research f) Commercial g) Personal use	Indicate the reason for introduction of the product by selecting from the options given

h) Other (Specify)_____	
7. Intended use (Tick where appropriate): a) Veterinary b) Public health c) Industrial d) Agriculture e) Forestry f) Environment g) Other (specify)	Indicate the area of intended use by selecting from the options given
8. Quantity of trial sample to be imported	Indicate the desired quantity of the product to be imported

PART B: ORGANIC ACTIVE INGREDIENTS	
Details of the Organic Source	
1. Common Name of the active ingredient	Provide the common name of the plant, animal or any other organic source where the product was derived
2. The scientific name(s) of the organic source where the product was derived (Genus, species, subspecies, strain/variety) *All must be provided*	Provide details of the Genus, species, subspecies, strain/variety of the plant, animal or any other organic source where the product was derived
3. Biology of the organic source (*attach annexes including peer reviewed publications*)	Provide details of the taxonomy, lifecycle, reproduction, parasitism, competition and any other organic attribute of the plant, animal or any other organic source where the product was derived
4. Hyper-parasites, contaminants, pests or likely pests to be associated with the organism (*Detailed descriptions; attach analysis and quality control reports*)	Provide details of possible hyper-parasites contaminants, pathogens, pests or weeds likely to be associated with the organic source. Attach certificates of analysis and quality control reports.
5. Description of benefit	Provide details of benefits of the plant, animal or any other organic source where the product was derived that are relevant to this application

6. Details of invasiveness of the organic source used	Provide details of the possible invasiveness of the plant, animal or any other organic source where the product was derived
7. Effect of the organic source used on availability of soil nutrients and water	Provide details of the possible effect of the organic soil on the availability of soil nutrients and water where the product will be used.

PART C: IDENTITY AND INFORMATION OF PRODUCT		
1. Trade/commercial name		State the proposed trade name of the product to be used in Kenya
2. Origin of the product (*country and state/district)*		Indicate the country, state/district of origin of the product
3. Product function (e.g. water retention, aeration, enhanced organic matter etc)		Provide details of functions of the product
4. **Formulation Details**		
4.1. Type of formulation: (e.g. EC, WP, etc.)		Indicate the formulation
4.2. Declare full composition of formulation(s) (active organisms) (Information may be attached in a sealed envelope)		
Active ingredient(s): (Common name/s)	Minimum a.i.% purity	a.i. Range %
4.3. Identification of contaminants	Maximum count of contaminants (CFU)	
4.4. Details of Formulator (*Physical location, *Country, Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided*		Indicate details of the formulator including; *Country, *Physical location, *Postal address, *Telephone, *Cell phone, *Email, website All that have (*) must be provided.
4.5. Details of trademark owner (*Country, *Physical location, *Postal address, *Telephone, *Cell phone, *Email, website)		Indicate details of trademark owner including; *Country, *Physical location, *Postal address, *Telephone, *Cell phone, *Email, website All that have (*) must be provided.
5. Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or		Indicate whether the product is registered in the country of origin and provide a copy of the

exemption from registration)	certificate of registration, approval for use or exemption from registration. If not provide reasons and supporting evidence
6. Is the product registered in other countries	Indicate whether or not the product is registered in other countries If yes, state the countries and provide copies of registration, approval for use or exemption from registration.
7. Certificate of analysis from the country of origin	Provide certificate of analysis from the Country of origin
8. Specify other physical and chemical characteristics of the product such as grade, matrix etc.	Provide copy of physical chemical studies from Good Laboratory Practises (GLP) certified/acrredited facilities laboratories
9. **Production details**	
9.1. Describe the production method	Provide details of the production process of the product
9.2. Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports)	Provide details of the quality control procedures applied during production to ensure the product is free from contaminants. Attach quality control procedures and reports
10. Shelf life (attach reports)	Provide the study on shelf life
11. Copy of market label for the country of origin *(Attach as annex)*	Attach copy
12. **Product usage information**	
12.1.Mode of application	State the method of application of the product eg. soil drench, foliar etc
12.2. Area of application a) Green house b) Open field c) Other (Specify)	Indicate the area of application eg. greenhouse or open field
12.3. Stage of the crop	State stage of the crop when the product should be applied eg.

	flowering, fruiting etc for each of the targeted crops
12.4. Dosage rates and frequency, interval of application	Provide dosage rate, interval and frequency of application of the product for each of the targeted crops
13. Mode of action *(Attach supporting scientific publications)*	Provide details on how the product works to achieve the stated benefits Attach supporting evidence
14. Description of benefits *(Attach supporting scientific publications)*	Provide details of benefits of the product in the area application Attach supporting scientific publications
15. Effect on availability of soil nutrients and water	Provide details of the effect of the product on availability of soil nutrients and water
16. Environmental requirements *(Attach all supporting scientific publications)*	Provide details of the suitable environmental conditions for optimum benefits of the product in the area of application
17. Information on combined use/compatibility (tank mixing) (attach reports)	Provide information on use of the product with other inputs eg. tank mixing, side effects
18. Information on efficacy of the product	Provide reports of efficacy trials for the product done elsewhere
19. **Packaging**	
19.1. Type of Packaging material / container:	State the nature of packaging material/ container of the product
19.2. Pack size(s)	State the pack sizes of the product
20. Disposal of empty container(s)	Provide information on disposal procedures of the empty containers
21. Describe containment measures (where applicable)	Provide methods and precautions concerning containment of the product where applicable
22. Handling, storage and transport	Provide methods and precautions on handling, storage and transport of the product
23. Describe destruction procedures	Provide procedures for destruction of the product.

24. Describe decontamination procedures	Provide procedures for decontamination of the product.
25. The proposed point of entry into the country	State the port of entry where the product will be cleared upon entry

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 ☐ Mild ☐ Moderate ☐ Severe ☐			Provide copies of the studies
	Eye irritation			
	None ☐ Mild ☐ Moderate ☐ Severe ☐			Provide copies of the studies
c. Skin Sensitization in guinea pig: (tick)	None ☐ Mild ☐ Moderate ☐ Severe ☐			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. Toxicity to other non-target plants		Provide evidence or copy of studies
vii. Persistence in environment		Provide evidence or copy of studies
viii. Other effects (Specify)		Provide evidence or copy of studies
f. Any other additional information (impurities and metabolites of toxicological concern)		Provide evidence or copy of studies