**Application form for introduction of Bio-stimulants**

**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 (*Country, *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):<br>a) Research<br>b) Commercial<br>c) Personal use<br>d) Other (Specify)_____ | |
| 8. Intended use (Tick where appropriate): | |

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| | a) Veterinary<br>b) Public health<br>c) Industrial<br>d) Agriculture<br>e) Forestry<br>f) Environment<br>g) Other (specify) | |
| 9. | Quantity of trial sample to be imported | |

| **PART B: Details of the Organic Source** | |
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| 1. Common Name of the organic source | |
| 2. The scientific name(s) of the organic source where the product was derived (Genus, species, subspecies, strain/variety) *All must be provided* | |
| 3. Biology of the organic source (*attach annexes and acceptable and peer reviewed publications*) | |
| 4. Contaminants, pathogens, pests or weeds likely to be associated with the organic source (*Provide detailed descriptions*). | |
| 5. Description of benefit | |
| 6. Origin of organic source and world distribution | |
| 7. Natural occurrence (Ecosystem where it is found naturally) | |
| 8. Relationship of the organic source to known plant and animal pathogens | |

| **Part C: Identity and Information of Product** | | |
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| 1. Trade/commercial name | | |
| 2. Origin of Product (*country and state/district)* | | |
| 3. Product function such as root development, stress tolerance, moisture retention e.t.c. | | |
| 4. **Formulation Details** | | |
| 4.1 Type of formulation: (e.g. EC, WP, other (specify) | | |
| 4.2 Declare full composition of the product (Active agent (s) and inert ingredients) (Detailed information on formulation may be provided separately in a sealed envelope) | | |
| Active agents(s): (Common name/s) | Minimum Active agent purity | Active agent Range |

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| 4.3 | Details of Formulator (*Country *Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) **All must be provided* | |
| 4.4 | Details of trademark owner (*Country, *Physical location, *Postal address, *Telephone, *Cell phone, *Email, website) | |
| 4.5 | Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration) | Yes ☐<br>No ☐<br>If no give reasons |
| 4.6 | Is the product registered in other countries | Yes ☐<br>No ☐<br>State the countries |
| 4.7 | Certificate of analysis from the Country of origin. | Available ☐<br>Not available ☐<br>(Give reasons) |
| 4.8 | Specify other Physical and chemical characteristics of the product such as grade, matrix etc. | |
| 5. | **Production details** | |
| 5.1. | Describe production method | |
| 5.2. | Provide the quality control procedures applied in the production and check for contaminants (Attach quality control procedures and reports) | |
| 5.3. | Shelf life (attach reports) | |
| 5.4. | Copy of market label for the country of origin *(Attach as annex)* | |
| 6. | **Usage information** | |
| 6.1. | Mode of application | |
| 6.2. | Area of application (Greenhouse/ open field) | |
| 6.3. | Stage of the crop | |
| 6.4. | Dosage rates and frequency, interval of application | |
| 7. | Mode of action | |

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| *(Attach supporting evidence)* | |
| 8. Description of benefits *(Attach supporting scientific publications)* | |
| 9. Environmental requirements *(Attach supporting scientific publications)* | |
| 10. Information on compatibility (tank mixing) (attach reports) | |
| 11. Information on efficacy of the product | |
| 12. Packaging | |
| 12.1. Type of Packaging material / container | |
| 12.2. Pack size(s) | |
| 12.3. Disposal of empty container(s) | |
| 13. Describe containment measures (where applicable) | |
| 14. Handling, storage and transport | |
| 15. Describe destruction procedures | |
| 16. The proposed point of entry into the country where applicable | |
| 17. Describe decontamination procedures | |

| **PART D. SAFETY INFORMATION** | | | |
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| 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: | None ☐ Mild ☐ Moderate ☐ Severe ☐ | | |

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| (tick) | |
| WHO classification: | |
| d. 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) | |
| b. Any other additional information (impurities and metabolites of toxicological concern) | |

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| **Any additional information that will be useful to support the evaluation process will be accepted.** | |
| **PART F: DECLARATION** | |
| For and on behalf of.....<br>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. | |
| .....<br>Name in full (Printed)<br>.....<br>Official Title | .....<br>Signed : Date: |
| Official Stamp<br>of Applicant / Company | **FOR OFFICIAL USE**<br>Remarks<br>.....<br>Signed : Date: |

**Guideline for application form for introduction of Bio-stimulants**

| **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<br>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<br>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<br>All that have (*) must be provided. |
| 7. Purpose of introduction/multiplication (Tick where appropriate):<br>a) Research<br>b) Commercial<br>c) Personal use<br>d) Other (Specify)_____ | Indicate the reason for introduction of the product by selecting from the options given |
| 8. Intended use (Tick where appropriate):<br>a) Veterinary<br>b) Public health<br>c) Industrial<br>d) Agriculture<br>e) Forestry<br>f) Environment<br>g) Other (specify) | Indicate the area of intended use by selecting from the options given |

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| 9. | Quantity of trial sample to be imported | Indicate the desired quantity of the product to be imported |

| **PART B: Details of the Organic Source** | |
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| 1. Common Name of the organic source | 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 and acceptable and 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. Contaminants, pathogens, pests or weeds likely to be associated with the organic source (*Provide detailed descriptions*). | Provide details of possible 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. Origin of organic source and world distribution | Provide details of the origin of the organic source and its distribution in the world |
| 7. Natural occurrence (Ecosystem where it is found naturally) | Provide details of place in the ecosystem (host plant, host animal, soil etc) of the organic source |
| 8. Relationship of the organic source to known plant and animal pathogens | Provide details of possible existence of one or more species of the same genus of the organic source which are known to be |

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| | pathogens and/or are known be hosts of pathogens of humans, animals, crops or any other non-target. |

| **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 Product (*country and state/district)* | | Indicate the country, state/district of origin of the product |
| 3. Product function such as root development, stress tolerance, moisture retention etc | | Provide details of functions of the product |
| 4. **Formulation Details** | | |
| 4.1 Type of formulation: (e.g. EC, WP, other (specify) | | Indicate the formulation |
| 4.2 Declare full composition of the product (Active agent (s) and inert ingredients) (Detailed information on formulation may be provided separately in a sealed envelope) | | |
| Active agents(s): (Common name/s) | Minimum Active agent purity | Active agent Range |
| 4.3 Details of Formulator (*Country, *Physical location, * 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<br>All that have (*) must be provided. |
| 4.4 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<br>All that have (*) must be provided. |
| 4.5 Is the product registered in country of manufacture? (Provide copy of certificate of registration, approval for use or exemption from registration) | | Indicate whether the product is registered in the country of origin and provide a copy of the certificate of registration, approval for use or exemption from registration.<br>If not, provide reasons and supporting evidence |

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| 4.6 Is the product registered in other countries | Indicate whether or not the product is registered in other countries<br>If yes, state the countries and provide copies of registration certificate, approval for use or exemption from registration. |
| 4.7 Certificate of analysis from the Country of origin. | Provide certificate of analysis from the Country of origin |
| 4.8 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 |
| 5. **Production details** | |
| 5.1 Describe production method | Provide details of the production process of the product |
| 5.2 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.<br>Attach quality control procedures and reports |
| 5.3 Shelf life (attach reports) | Provide real time or accelerated storage stability studies |
| 5.4 Copy of market label for the country of origin (*Attach as annex*) | Attach copy |
| 6. **Usage information** | |
| 6.1. Mode of application | State the method of application of the product eg. soil drench, foliar etc |
| 6.2. Area of application (Greenhouse/ open field) | Indicate the area of application eg. greenhouse or open field |
| 6.3 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 |
| 24.4. Dosage rates and frequency, interval of application | Provide dosage rate, interval and frequency of application of the product for each of the targeted crops |
| 7. Mode of action<br>*(Attach supporting evidence)* | Provide details on how the product works to achieve the stated benefits |

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| | Attach supporting evidence |
| 8. Description of benefits<br>*(Attach supporting scientific publications)* | Provide details of benefits of the product in the area application<br>Attach supporting scientific publications |
| 9. Effect on availability of soil nutrients and water | Provide details of the effect of the product on availability of soil nutrients and water |
| 10. Environmental requirements<br>*(Attach supporting scientific publications)* | Provide details of the suitable environmental conditions for optimum benefits of the product in the area of application |
| 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 | Provide reports of efficacy trials for the product done elsewhere |
| 13. **Packaging** | |
| 30.1 Type of Packaging material / container | State the nature of packaging material/ container of the product |
| 30.2 Pack size(s) | State the pack sizes of the product |
| 30.3 Disposal of empty container(s) | Provide information on disposal procedures of the empty containers |
| 14. Describe containment measures (where applicable) | Provide methods and precautions concerning containment of the product where applicable |
| 15. Handling, storage and transport | Provide methods and precautions on handling, storage and transport of the product |
| 16. Describe destruction procedures | Provide procedures for destruction of the product. |
| 17. Describe decontamination procedures | Provide procedures for decontamination of the product. |
| 31. The proposed point of entry into the country where applicable | 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. | |

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| **2. Toxicology** (Formulated product) | | | | |
| c. 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 |
| d. 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 |
| e. Skin Sensitization in guinea pig: (tick) | None ☐ Mild ☐ Moderate ☐ Severe ☐ | | | Provide copies of the studies |
| f. WHO classification: | | | | State the WHO classification of the product |
| g. Summary of other mammalian toxicological studies: e.g. livestock, wildlife, poultry, pets | | | | Provide copies of the studies |
| h. **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 |

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| viii. Other effects (Specify) | | Provide evidence or copy of studies |
| i. Any other additional information (impurities and metabolites of toxicological concern) | | Provide evidence or copy of studies |