## THIRD SCHEDULE

## Part III

## APPLICATION FORM FOR CONFINED FIELD TRIAL (PLANTS)

This application form must be completed for each individual genetically modified plant. The application may include more than one submission of a genetic modification of that particular species, Trial site Location and/or Trial Protocol.

Complete section 2 for each submission, section 3 for each trial site and section 4 for each trial protocol included in the application. All sections must be completed. Additional pages can be attached if the space provided is not sufficient.

**Applications for new and renewal of previously authorized confined research field trials should be submitted separately.**

**Section 1.0 General Information**

|  |  |
| --- | --- |
| 1.1 Application Type | 1.2 Plant Species Name1.2.1 Latin Name(s) |
| * New
* Renewal
* Date of submission of the application
 |  |
| 1.2.2 Common Name(s) |
|  |
|  | *(Indicate if perennials, annuals, trees etc.)* |
| **1.3 Feed Section** Indicate whether any plant material generated in the confined field trials will be used as research material for livestock feed.  |
|  | Yes No 🞏 🞏 |
| **1.4 Applicant**1.4.1 Name | **1.5** **Name of Institutional Biosafety Committee**.*(Attach signed minutes of Institutional Biosafety Committee discussions)* |
|  |  |
|  |   |
| 1.5.1 Institution of applicant |
|  |
| 1.5.2 Registration Status in Kenya |
|  |
| 1.5.2.1 Affiliating institution *(if institution of applicant is not registered in Kenya)* |
|  |
| 1.4.2 Address | 1.5.3 Address |
|  |  |
| 1.4.3 Telephone | 1.4.4 Facsimile/email | 1.5.3 Telephone | 1.5.4 Facsimile/email |
|  |  |  |  |

**1.6 Summary of trial**

|  |
| --- |
| 1.6.1 Brief Description of Proposed Trial  |
|  |
| 1.6.2 Objective |
|  |
| 1.6.3 What is the aim of the proposed trial of the genetically modiﬁed organism? |
|  |
| 1.6.4. What are the beneﬁts of this approach compared with other possible methods, especially those not involving planned trial? |
|  |
| 1.6.5 If the trial is successful, do you intend to propose a general release of the GMO? |
|  |
| 1.6.6 Summary of the risk assessment |
|  |

1.7 Description of unmodified plant species

|  |
| --- |
|  |
| 1.7.1 Describe mechanisms and frequency of intra-and inter-specific out-crossing. |
|  |
| 1.7.2 Describe the mechanism of infertility |
|  |

**1.8 Phenotypic Characteristics**

Provide information on plant mechanisms responsible for:

|  |
| --- |
| 1.8.1 Tendency to weediness |
|  |
| 1.8.2 Allelopathy |
|  |
| 1.8.3 Dormancy |
|  |
| 1.8.4 Pollen dispersal |
|  |
| 1.8.5 Seed dispersal |
|  |
| 1.8.6 Vegetative dispersal |
|  |
| 1.8.7 Other dispersal |
|  |
| 1.8.8 Other Characteristics |

**1.9 Toxins**

|  |
| --- |
| 1.9.1 List any known toxins from this species, including natural defence compounds. |
|  |
| 1.9.2 Indicate the levels at which these compounds induce toxicity. |
|  |
| 1.9.3 Indicate the species affected by these toxins. |
|  |

**1.10 Allergens**

|  |
| --- |
| 1.10.1 List any known allergens for this species, including natural defence compounds. |
|  |

|  |
| --- |
| **1.11** Describe any pathological, ecological and physiological traits that relate to the genetically modified organism but not to the unmodified plant. |
|  |

### Section 2: Submission

**Fill out section 2 for each individual submission (genetic modification of that particular species) included in the application.**

|  |
| --- |
| **2.1 Name or Designation of genetically modified organism**  |
|  |
| **2.2** Modified trait**(s) Identification**  |
| 🞏 Herbicide Tolerance | 🞏 Modified Oil Composition | 🞏 Pharmaceutical |
| 🞏 Male sterility/restoration | 🞏 Virus Resistance | 🞏 Genetic Research |
| 🞏 Insect Resistance | 🞏 Stress Tolerance | 🞏 Generation of mutants |
| 🞏 Nutritional change | 🞏 Fungal Resistance | 🞏 Other *(Specify)* |
| 2.3 Modified Trait(s) Describe each specific novel trait associated with this genetically modified organism. |
|  |
| **2.4 Status of authorization**2.4.1 Is genetically modified organism Imported or generated locally. |
|  |
| 2.4.2 If imported, provide the import permit number issued under any other authorization. |
|  |
| **2.5 History**Has this Genetically Modified Organism been previously tested in Kenya? |
|  🞏 Yes 🞏 No |
| If yes, please provide information on trial (s), year(s) of authorization and location(s) tested.  |
|  |

**2.6 Trait Introduction and Selection Method**

|  |
| --- |
| 2.6.1 Describe Introduction Method(s). |
|  |
| 2.6.2 Describe Trait Selection Method. |
| 2.6.3 Describe Mode of action of traits *(gene product, metabolic pathways)*. |
|  |
| 2.6.4 Other techniques of modificationProvide details of modification by means other than mutagenesis or recombinant DNA techniques. |
|  |

**2.7 Gene Donor (s)**

|  |
| --- |
| Indicate the gene donor organism(s) *(for plants transformed using rDNA techniques)*. |
|  |

**2.8 Transformation Vectors and/or Plasmids**

Please provide the following information:

|  |
| --- |
| 2.8.1 Name of plasmid (construct) and genetic map *(map of each genetic construct required)*. |
|  |
| 2.8.2 Is the vector naturally pathogenic? | 2.8.3 Is the vector disarmed? | 2.8.4 If yes, how was the vector disarmed? |
|  🞏 Yes 🞏 No   | 🞏 Yes 🞏 No |  |
| 2.8.5 For each gene construct, describe all genes, regulatory elements, gene products, non-translated DNA sequences and, where applicable, affected metabolic pathways. |
|  |

**2.9 Characteristics of the transformed Trait(s)**

|  |
| --- |
| **2.9.1 Spatial and Temporal Trait Expression** |
|  Trait  |  Expression |
| 2.9.1.1 Constitutive 🞏 Yes 🞏 NoIf not constitutive, indicate the specific tissue(s) in which the trait is expressed *(green tissue, seed, pollen, roots, other)* | 2.9.1.2 Is the trait expressed during specific developmental stage?🞏 Yes 🞏 NoIf yes, when? | 2.9.1.3 Is the trait inducible?🞏 Yes 🞏 NoIf yes, how? |
|  |  |  |  |
|  |  |  |  |

**2.10 Toxicity and Allergenicity of the Transformed Trait(s)**

|  |
| --- |
| 2.10.1 To what extent are transformed gene products toxic when ingested by native fauna populations, including mammals, birds, reptiles, and insects?  |
|  |
| 2.10.1.1How has this been determined? |
|  |
| 2.10.2 To what extent are transformed gene products allergens?  |
|  |
| 2.10.2.1 How has this been determined? |
|  |

**2.11 Altered Plant Characteristics**

*Please indicate any changes with respect to the following:*

|  |
| --- |
| 2.11.1 Persistence and invasiveness |
|  |
| 2.11.2 Allelopathy |
|  |
| 2.11.3 Dormancy |
|  |
| 2.11.4 Pollen Dispersal |
|  |
| 2.11.5 Seed Dispersal |
|  |
| 2.11.6 Vegetative Dispersal |
|  |
| 2.11.7 Any other Dispersal Mechanism |
|  |
| 2.11.8 Any other altered characteristic (s) Are any of the likely gains directly linked to losses in other characteristics of the species? |
|  |
| 2.11.9 Please describe if any toxins and allergens are produced by the GMO that were not produced by the unmodified plant. |
|  |
| 2.11.10 What is the frequency of reversion, i.e., loss of genetic modiﬁcation? |
|  |
| 2.11.11 How do you verify that you have the desired GMO? |
|  |
| 2.11.12 What methods are to be used to test for batch-to-batch consistency? |
|  |

**2.12 Trial Site Locations and Trial Protocols**

|  |  |  |
| --- | --- | --- |
| **2.12.1 Town and Province** | **2.12.2 Legal land location** | **2.12.3 Trial Protocol(s)** ***(Attach trial Protocol)*** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

*Please note: Section 3 must be completed for each Trial Site Location listed above and Section 4 must be completed for each Trial Protocol listed above.*

### Section 3: Confined Field Trial Site

Please fill out Section 3 for each Trial Site Location included in the application.

|  |  |  |
| --- | --- | --- |
| **3.1 Town/City** *(Nearest city)* | **3.2 Province** | **3.3 Legal Land Location** *(The National Biosafety Authority will not authorize a confined field trial until the legal land location of the trial site has been given)* |
|  |  |  |
|  |  |  |
| **3.4 Field Manager** responsible for the trial site 3.4.1 Name (*Must be affiliated to a research institution registered in Kenya* ) | 3.4.2 Address |
|  |  |
| 3.4.3 Telephone | 3.4.4 Facsimile |
|  |  |
| **3.5 Trial Size**Trial size in meters2 / Hectarage | **3.6 Location Map** Attach a complete map *(including GPS coordinates)* of the location of the trial site |
|  |    |
| 3.6.1 Has the suitability of the contained use facility to conduct contained use activity been assessed. Explain |
|  |

**3.7 Habitat**

|  |
| --- |
| 3.7.1 Describe the biological diversity of the trial site, including: |
|  |
| 3.7.1.0 Potential impacts resulting from the field test |
|  |
| 3.7.1.1 Soil  |
|  |
| 3.7.1.2 Groundwater level  |
|  |
| 3.7.1.4 Topography  |
|  |
| 3.7.1.5 Flora and fauna  |
|  |
| 3.7.1.6 Climate, especially prevailing winds direction and Temperate |
|  |
| 3.7.1.7 Previous use of the facility  |
|  |
| 3.7.1.8 Distance from nearest human settlements  |
|  |
| 3.7.1.9 Distance from surface water body  |
|  |
| 3.7.2 Is the trial site part aof a managed ecosystem? | 3.7.3 If yes, how close is the nearest natural ecosystem? |
| Yes 🞏 No🞏 |  |
| 3.7.4 How close is the site from an area of special ecological interest, including protected areas and sanctuaries? |
|  |

**3.8 Indigenous Species**

|  |
| --- |
| 3.8.1 Specify the related wild and domesticated species/organisms present at the trial site and how close they are to the modified plant material under test.  |
|  |
| 3.8.2 Are there any endangered species on or near the site? | 3.8.3 If yes, list |
|   Yes 🞏 No🞏 |  |
| *NB: For information on endangered species that may be near the trial site location, contact the Kenya Wildlife Service, P.O. Box 40241 NAIROBI, Email: kws@kws.org, Website: www.kws.org, Langata Road, Telephone +245-20-501081*. |
|  |
| 3.8.4 What mechanisms are in place to prevent the local fauna from removing the modified plants material from the site? |
|  |

**3.9 Post-Trial Land Use**

|  |
| --- |
| 3.9.1 **P**erson(s) having control over the site during the post-harvest/trial land use period, including the isolation area |
| 3.9. 1.1 Name  | 3.9.1.2 Address |
|  |  |
| 3.9.1.3 Telephone | 3.9.1.4 Facsimile |
|  |  |
| 3.9.2 Describe how the site boundaries will be marked to facilitate subsequent inspection. |
|  |

**3.10 Submissions and Trial Protocols**

Please list all submissions and trial protocols used at this site.

|  |  |
| --- | --- |
| **3.10.1 Submission *(genetically modified organism designation – List of possible designations/unique identifier)***  | **3.10.2 Trial Protocol(s)** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

***Please note: Section 2 must be completed for each Submission listed above and Section 4 must be completed for each Trial Protocol listed above.***

**Section 4: Confined Field Trial Protocol**

*Please fill out Section 4 for each Trial Protocol included in the application.*

|  |  |
| --- | --- |
| **4.1 Trial Protocol (Study) Title:** |  |

|  |
| --- |
| **4.2 Protocol** 4.2.1 Fully describe the following  |
|  |
| 4.2.2 Purpose of the field trial |
|  |
| 4.2.3 Experimental design |
|  |
| 4.2.4 Nature and type of data to be collected |
|  |
| 4.2.5 Arrangements for transporting the GMO to the trial site |
|  |
| 4.2.6 Proposed, if any, herbicide/pesticide use |
|  |
| **4.3 Provide work schedule *(post approval)* to include:** |
| 4.3.1 Planting *(anticipated)*  | 4.3.2 Harvest/Sampling *(anticipated)* |
|  |  |

|  |
| --- |
| **4.4 Isolation** State the isolation measures being implemented for this trial and give details. |
|  |
| 4.4.1 If using bags or nets, please provide the mesh size of the material being used and justify the effectiveness. |
|  |

**4.5 Seeding**

|  |  |
| --- | --- |
| 4.5.1 Material will be planted by: | 4.5.2 Will any unmodified plants of the same or a related species be planted at the trial site location? |
| 4.5.1.1 Hand 🞏Or4.5.1.2Mechanically 🞏   |  |  |
| 4.5.3 If yes, state reason |
|  |  |
| 4.5.4 Describe your management plan to avoid the dissemination, e.g. of seed, from the trial site.  |
|   |
| 4.5.5 Describe your plan for recording the quantities of seed planted/GMO used and accounting for any excess |
|  |
| 4.5.6 Describe the disposition plan, including how and where any excess, or non-planted seed/GMO will be disposed of or stored. |
|  |

**4.6 Spraying\***

*Complete this section if the trial site is subject to the use of an unregistered product, or a registered product used for a non-registered purpose.*

|  |
| --- |
| 4.6.1 Registered pesticide for unregistered use |
| 4.6.1.1 Name of the pesticide  | 4.6.1.2 Total area to be sprayed *(m2 /hectarage)* | 4.6.1.3 Active ingredient |
|  |  |  |
| **4.6.2 Unregistered Pesticide Use** |  Yes 🞏 No 🞏 |
| 4.6.2.1 Name of the pesticide  | 4.6.2.2 Total area to be sprayed *(m2 /hectarage)* | 4.6.2.3 Active ingredient |
|  |  |  |
| \* *This information is required to determine compliance with the Pest Control Products Act (Cap 346).* |

**4.7 Harvesting**

|  |  |
| --- | --- |
| 4.7.1 Will plants be allowed to set seed or to reproduce? | 4.7.2 Describe the method of harvest for seed and other plant material *(e.g. by hand, small plot combine, etc.)* |
|   Yes 🞏 No 🞏 |  |
| 4.7.3 Will any harvested plant material be retained from the trial? | 4.7.4 Material retention If yes |
|   Yes 🞏 No 🞏  | 4.7.4.1 Type *(e.g. seed, leaves, etc.)* |
|  |
| 4.7.4.2 Quantity to be retained |
|  |
| 4.7.4.3 Purpose of retaining material |
|  |
| 4.7.5 For harvested plant material, describe the following if applicable: 4.7.5.1 The storage method. |
|  |
| 4.7.5.2 Storage location  |
|  |
| 4.7.6 Person responsible for the storage of the material  |
| 4.7.6.1 Name  | 4.7.6.2 Address |
|  |  |
| 4.7.6.3 Telephone | 4.7.6.4 Facsimile |
|  |  |
| 4.7.6.5 Proposed storage records |
|  |
| 4.7.7 Describe how the site boundaries will be marked to facilitate subsequent inspection. |
|  |
| 4.7.8 Describe your management plan to avoid dissemination of seed/GMO from the trial site during harvesting. |
|  |

**4.8 Disposal**

|  |
| --- |
| 4.8.1 Describe your disposal plan for all propagules and non-propagule plant material; including how and where the material will be disposed of. |
|  |
| 4.8.2 Person responsible for the disposal of the material |
| 4.8.2.1 Name  | 4.8.2.2 Address |
|  |  |
| 4.8.2.3 Telephone | 4.8.2.4 Facsimile |
|  |  |
| 4.8.2.5 Proposed disposal records |
|  |

**4.9 Contingency Plans**

|  |
| --- |
| 4.9.1 Describe your contingency plan in the case of accidental release of seed/GMO plant material (e.g. spills), or the breakdown of isolation. |
|  |
| 4.9.2 Describe your contingency plans if after accidental release there is unexpected spread of the transformed plant material. |
|  |

**4.10 Monitoring the Trial Site**

|  |
| --- |
| 4.10.1 Describe the extent and frequency of trial site monitoring during the course of the field trial. |
|  |
| 4.10.2 Describe the extent and frequency of trial site monitoring during the post-trial period. |
|  |
| 4.10.3 Person responsible for monitoring |
|  |
| 4.10.3.1 Describe what monitoring results will be recorded |
|  |
| 4.10.3.2 Describe how monitoring results will be recorded |
|  |
| 4.10.4 If any controlled monitoring procedures are proposed for this trial (e.g. planting of unmodified plants of a related species to determine possibility and frequency of gene flow), detail these. |
|  |
| 4.10.5 Describe the provisions to remove or eliminate the GMO from the test site or any other place where it may be found upon completing the trial and to restore the test site and any such other place to its status quo. |
|  |

**4.11 Public Notice**

|  |
| --- |
| 4.11.1 How will you provide public notification of your proposed field trial? |
|  |

### Section 5: Hectarage

***Please indicate the number of hectares per submission per province***

*(Limit of 5 ha cumulative per submission per province)*

**Province A:**

**Submission (genetically modified organism designation):**

|  |  |
| --- | --- |
| Trial site location |  |
| Legal land location | Town | Number of hectares |
|  |  |  |
|  |  |  |
|  |  |  |

Total number of hectares:

**Province B:**

**Submission (Genetically modified organism designation):**

|  |  |
| --- | --- |
| Trial site location |  |
| Legal land location | Town | Number of hectares |
|  |  |  |
|  |  |  |
|  |  |  |

Total number of hectares:

**Add other tables for any other Province, if applicable**

### Section 6: Certification

I certify that the above information is true to the best of my knowledge.

**Principal Investigator**

Name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_

**Collaborator(s)**

Name(s) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_

**Institutional Biosafety Committee (IBC) Review**

This application has been reviewed by IBC

Name of IBC\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of chairperson\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_