

 **NATIONAL BIOSAFETY AUTHORITY**

**PART I**

**APPLICATION form for contained use activity (LABORATORY, GREENHOUSe and growth chambers)**

**GENERAL REQUIREMENTS FOR THE APPLICATIONS**

This application form must be completed for each individual genetically modified organism for the intended contained use activity. The application may include more than one experiment (genetic modification of that particular species) or protocols and 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 contained use should be submitted separately.

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| 1.0 Name and Contact Address of Applicant |
| 1. 1 Date of Submission: |  |
| 1.2 Name of applicant | 1. 3 Name of Institutional Biosafety Committee (IBC) |
|  |   |
| 1.4 Institution of applicant | 1.5 Registration Status in Kenya |
|  |  |
| 1.6 Affiliating institution *(if institution of applicant is not registered in Kenya)* |
|  |
| 1.4.1 Address of applicant’s institution | 1.6.1 Address of affiliating institution |
|  |  |
| 1.4.2 Telephone | 1.4.3 Facsimile /email | 1.6.2 Telephone | 1.6.3 Facsimile/email |
|  |  |  |  |

**2.0 Nature and purpose of contained use**

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| 2.1 Brief Description of Proposed contained use activity |
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| 2.2 Purpose of contained use - character of the activity that will be carried out by applicant (e.g. research, laboratory control, manufacture) |
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| 2.3 If the contained use work is successful, indicate whether a general release of the GMO is planned |
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| 2.4 Total period of contained use and date of its expected starting-up |
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**3.0 Risk assessment**

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| 3.1 Summary of the risk assessment for the genes and species of GMO involved. |
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| 3.2 Description of potential risks associated with the transformed organism, transformation genes or gene elements. |
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| 3.3 Description of potential risks associated with the activities to be undertaken |
|  |

**4. 0 Location where contained use activities are to be undertaken**

**4.1 Contained Use Facility: Laboratory and growth chambers**

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| --- | --- | --- |
| 4.1.1 Facility Location | 4.1.2 Approval No. or reference | 4.1.3 Number of other contained use activities currently approved within the same facility |
|  |  |  |
| * + 1. Biosafety level assigned to facility during approval *(Level1, or level 2, or level 3 or level 4)*
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|  |
| * + 1. Layout of premises and of the location of main facilities *(Attach additional annex if more space is required)*
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|  |
| * + 1. Code of practice of a workplace *(Indicate type)*
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|  |
| * + 1. Emergency Response Plan in the event of an accident
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|  |
| 4.1.8 Characteristics of the workplace *(Tick as appropriate)* |
| 4.1.8.1 Microbiological laboratory | 4.1.8.2 Pilot plant |
|  |   |
| 4.1.8.3 Production facilities | 4.1.8.4 Glasshouse/growth room |
|  |  |
| 4.1.8.5 Animal breeding facility | 4.1.8.6 Other *(Specify)* |
|  |  |
| 4.1.9 Species and amount of used organism and the used genetic modifications including nominally mentioned validated methods for detection of occurrence of genetically modified organisms. |
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| * + 1. Waste management plan
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### 4.2 Contained Use Facility: Greenhouse Facility

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| --- | --- | --- |
| 4.2.1 Facility Location | 4.2.2 Approval No. or reference. | 4.2.3 Number of other activities currently approved within the same facility. |
|  |  |  |
| 4.2.4 Protocol **:** Fully describe the following |
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| 4.2.4.1 Purpose of the greenhouse trial |
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| 4.2.4.2 Experimental design |
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| 4.2.4.3 Nature and type of data to be collected |
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| 4.2.5 Arrangements for transporting the GMO to the greenhouse |
|  |
| 4.2.6 Proposed herbicide/pesticide use, if any  |
| 4.2.6.1 Name of the pesticide /herbicide | 4.2.6.2 Active ingredient  | 4.2.6.3 Total area to be sprayed *(m2 /hectarage)* |
|  |  |  |
| 4.2.7 Provide work schedule *(post approval)* of key activities including but not limited to: |
| 4.2.7.1 Dates of movement of material | 4.2.7.2 Planting *(anticipated)* | 4.2.7.3 Harvest/Sampling *(anticipated)* |
|  |  |  |
| 4.2.8 Describe your plan for recording the quantities of seed planted/GMO used and accounting for any excess |
|  |
| 4.2.9 Describe the disposition plan, including how and where any excess, or non-planted seed/GMO will be disposed of or stored. |
|  |
| 4.2.10 State whether plants will be allowed to set seed or to reproduce |
|  Yes 🞏 No 🞏 |
| 4.2.11 Indicate whether any harvested plant material will be retained from the trial  | 4.2.11.1 If yes, Type *(e.g. seed, leaves, etc.)* |
|  Yes 🞏 No 🞏 |  |
| 4.2.11.2 Quantity to be retained  | 4.2.11.3 Purpose of retaining material |
|  |  |
| 4.2.12 For harvested plant material, describe the following if applicable:  |
| 4.2.12.1 The storage method. | 4.2.12.2 Storage location |
|  |  |
| 4.2.12.3 Person in the institution responsible for the storage of the material  |
|  |
| 4.2.12.3.1 Name  | 4.2.12.3.2 Telephone |
|  |  |
| 4.2.12.4 Proposed storage records |
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**5.0. Nature and identity of Genetically modified organism**

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| 5.1 Name of GMO  |
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| 5.2 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) |
| 5.3 Modified Trait(s) Describe each specific new trait associated with this GMO. |
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| 5.4 For each gene construct, describe all genes, regulatory elements, gene products, non-translated DNA sequences and, where applicable, affected metabolic pathways. |
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| 5.5 Provide Information on the donor organism including its origin |
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| 5.6 Provide Information on recipient and parental organism including origin  |
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| 5.7 Provide Information on the vector including its origin |
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| 5.8 Provide the name of plasmid *(construct)* and genetic map *(map of each genetic construct is required)*. |
|  |
| 5.9 Describe Mode of action of traits *(gene product, metabolic pathways)*. |
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| 5.9.1 Is the vector naturally pathogenic? | 5.9.2 Is the vector disarmed? | 5.9.3 If yes, how was the vector disarmed? |
|  🞏 Yes 🞏 No   | 🞏 Yes 🞏 No |  |
| 5.10 Description of elements of the constructs(s): This area should be filled for all constructs and GMO gene elements |
| 5.10.1 Genetic Element | 5.10.2 Size (bp) | 5.10.3 Source | 5.10.4 Function |
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| 5.11 Method of introduction of the insert |
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| 5.12 Method for detection of genetically modified organism |
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| 5.13 Amount of genetically modified organism to be used *(volume of the culture, number of plants or animals)* |
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| 5.14 Information on whether the genetically modified organism has already been approved in some other country and for what purpose. |
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**6.0 Nature and purpose of the contained use activities**

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| 6.1 In case of import or export of the genetically modified organism intended for contained use |
| 6.1.1 The country of origin or destination, as appropriate | 6.1.2 Importer or exporter, as appropriate |
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| 6.1.3 Maximum amount of genetically modified organism to be imported or exported | 6.1.4 Means of transportation |
|  |  |
| 6.1.5 Means of packaging and labeling |
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| 6.2 Measures to protect human health and the environment and biological diversity |
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| 6.3 Frequency and the manner of carrying out control of the occurrence of genetically modified organism inside and outside of the contained space |
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| 6.4 Description of waste management plan |
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### 7.0 Containment measures

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| 7.1 List all protocols proposed to be used at this facility for this application *(Separate sheets may be annexed***.***)* |
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| 7.2 Attach inspection report if facility is not yet assigned a biosafety level |
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| 7.3 State proposed documentation procedures on the use of genetically modified organisms |
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| 7.4 Plan of training of employees prior to the commencement of the use of genetically modified organisms, and the plan of their refresher training |
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**8.0 Declaration of correctness of information**

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 \_\_\_\_\_\_\_\_\_\_\_\_

**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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_