

**NATIONAL BIOSAFETY AUTHORITY.**

**FIRST SCHEDULE**

**APPLICATION FORM FOR ENVIRONMENTAL RELEASE AND****/OR PLACING ON THE MARKET OF GENETICALLY MODIFIED ORGANISM(S)**

Part A of this schedule shall be filled by an Applicant making an application for either Environmental Release or placing on the market of genetically modified organism(s), or both.

Part A and B of this schedule shall be filled by an Applicant making an application for placing on the market of genetically modified organism(S)

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| **PART A** |
| **1.0 General Information** |
| **1.1 Name of Applicant** | **1.2 Physical Address** |
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| **1.3** **Telephone** | **1.4 E – Mail address** |
|  |  |
| **1.5 Title of the Application** | **1.6 Type of Application** |
|  |  NewRenewal |
| **2.0 Information on the Genetically Modified Organism** |
| **2.1 Name and identity of the genetically modified organism**(*Differences between the biological characteristics of the genetically modified organism and those of the recipient organism or parental organisms*) | 2.2 Transformation event (s) |
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| **2.3 Intellectual Property Ownership of the Novel Trait, if any** | 2.4 Unique Identifier for the Genetically Modified Organism if any |
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| 2.5 Introduced or Modified Trait (choose the trait from the following list) |
| **2.5.1 A biotic environmental tolerance** | **2.5.2 Altered growth, development and product Quality** |
| [ ] Altered photoperiod sensitivity[ ]  Cold or heat tolerance[ ]  Drought or water tolerance[ ]  Other (specify)  |  [ ]  Altered ripening or flowering  [ ]  Coloration [ ]  Fertility restoration [ ]  Growth rate or yield [ ]  Male sterility [ ]  Nutritional composition (including allergenicity) [ ]  Selectable marker genes and reporter genes [ ]  Uptake or degradation of environmental pollutants [ ]  Other (specify growth, development and product quality):  |
| **2.5.3 Chemical tolerance** | **2.5.4 Medical products** |
| [ ]  Herbicide tolerance [ ]  Other chemical tolerance | [ ]  Animal vaccines [ ]  Development of transplant organs  [ ]  Production of pharmaceuticals  [ ]  Other medical products |
| **2.5.5 Pest resistance** | **2.5.6 Other — specify** |
|   [ ]  Bacterial resistance  [ ]  Fungus resistance  [ ]  Insect resistance [ ]  Nematode resistance  [ ]  Virus resistance  [ ]  Other pest resistance: |  |
| **2.6** **Technique Used For Modification** (please select techniques used for the transformation) |
|  [ ]  Plasmid carried by *Agrobacterium tumefaciens* **[ ]** Electric shock polarization [ ] Biolistic methods [ ]  Osmotic shock [ ]  Other (specify) |
| **2.7 Description of Gene Modification** |
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| **2.8 Summary of contained use and confined field trial data** *(Provide information on key results of trials at both contained level and confined field trials whether conducted in Kenya or outside Kenya)* |
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| **3.0. Characteristics of Genetic Modification** |
| **3.1 Vector Characteristics** |
| **3.1.1 Vector(s) Identity**  | **3.1.2 Source(s) or origin**  | **3.1.3 Host range** |
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| **3.2 Insert or inserts** *(Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced)* |
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| **3.3 Description of phenotypic characteristics** (in particular any new traits and characteristics which may be expressed or no longer expressed) |
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| **3.4 Rate and level of expression of the new genetic material. Method and sensitivity of measurement** |
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| **3.5 Activity of the expressed protein (s)** |
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| **3.6 Description of identification and detection techniques of the inserted sequence and vector** |
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| **4.0 Recipient organism or parental organisms** |
| **4.1. Taxonomic name/status of recipient organism or parental organisms** | 4.2. Common name of recipient organism or parental organisms |
|  |  |
| **4.3 Point of collection or acquisition of parental organisms** | **4.4** **Center(s) of origin of the recipient organism or parental organisms** *(Describe the exact location and give geographical coordinates)* |
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| **4.5** **Center(s) of genetic diversity, if known, of Recipient organism or Parental organisms** (Describe the exact location and give geographical coordinates) |
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| **4.6**  **Habitats where the Recipient organism or Parental organism may persist or proliferate** |
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| **4.7 Description of the habitat where the genetically modified organism may persist or proliferate**  |
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| **5.0** **Donor organism (s)** |
| **5.1** **Taxonomic name/status of the donor organism or parental organisms** | **5.2** **Common name of donor organism** |
|  |  |
| **5.3** **Point of collection or acquisition of donor organism***(Describe the exact location and geographical coordinates)* | **5.4** **Biological characteristics of donor organisms** |
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| **6.0** **Intended use and receiving environment.** |
| **6.1** **Description of the proposed deliberate release, including the purpose (s) and foreseen products** |
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| **6.2** **Foreseen dates of the release** | **6.3** **Quantities of genetically modified organisms to be released** |
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| 6.4 Suggested method(s) for safe handling, transport and storage during release |
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| **6.5. History and results of previous environmental release, as well as uses of the genetically modified organism** *(Country, region, dates of releases especially at different scales and in different ecosystems, any adverse effects on the health of human, animal and plant, and environment)* |
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| 6.6 Intended use of the genetically modified organism (Information relating to the intended use of the genetically modified organism, including new or changed use compared to the recipient organism or parental organisms) |
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| **6.7 Receiving environment** *(Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment)* |
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| **7.0** **Risk assessment summary (cite references)** |
| **7.1** **Detection/Identification method of the genetically modified organisms** (*Suggested detection and identification methods and their specificity, sensitivity and reliability)* |
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| **7.2** **Evaluation of the likelihood of adverse effects** (*An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential to the health of human, plant and animal, and the receiving environment to the genetically modified organism)* |
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| **7.3 Evaluation of the consequences** *(An evaluation of the consequences should these adverse effects be realized)* |
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| **7.4** **Overall risk** *(An estimation of the overall risk posed by the genetically modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized)* |
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| **7.5** **Recommendation** *(A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks)* |
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| **7.6 Information on post release monitoring and emergency response plans**(describe post release monitoring methods, recall procedures) |
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| **8.0** **Additional information** |
| **8.1** **Availability of detailed risk assessment information** (*Please indicate whether more details on the risk assessment are available and how they can be accessed)* |
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| **8.2** **Any other relevant information** |
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| **8.3** **Additional notes** |
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| **PART B** |
| **1.0 General Information** |
| 1.1Name or names, as appropriate, and surname (**trade company**), if the applicant is the natural person authorized to operate a business | 1.2 Title (trade company) and the legal form, if the applicant is legal person |
|  |  |
| **1.3** **Nationality** (in case of natural persons) | **1.4** **Place of business** (*in case of legal persons*) or **place of business and place of residence** **(***in case of natural persons)* |
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| **1.5 Company Registration Number** (if assigned) |  **1.6 Tax identification number** *(if assigned)* |
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| **1.7** **Subject of activity**  | **1.8 Name of person(s), who represents a statutory body of the applicant, including the manner of acting on behalf of the applicant** *(in case of legal persons),* **as appropriate** |
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| **1.9** **Address of residence** | **1.10 Contact Address** |
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| **1.11 Telephone Number**  | **1.12 Fax Number** | **1.13 E-mail** |
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| 2.0 Information on the Genetically Modified Organism |
| 2.1 Name of each constituent genetically modified organism contained in a package | 2.2 Origin of each constituent genetically modified organism contained a package |
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| 2.3 The properties of each constituent genetically modified organism contained in a package |
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| 3.0 Purpose and procedure of the placing of genetically modified organism |
| 3.1 The purpose of placing of the genetically modified organism on the market |
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| 3.2 Date of expected commencement of the placing genetically modified organism on the market and its binding schedule (details and the periods of the individual stages) | 3.3 Expected amount of the genetically modified organism that will be used in the individual stages including information on whether the production comes from Kenya or whether it's imported. |
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| 4.0 summary of the risk assessment of genetically modified organism to be placed on the market |
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| 5.0 information, data or results from placing on the market if any, of the same genetically modified organism previously or currently applied for or carried out by the applicant |
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| 5.1 Additional information |
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**DECLARATION BY APPLICANT**

I,…………………………………………., of P.O. Box…………………; of (Company/Institution)……………,ID No…………….,hereby declare that to the best of my knowledge and belief the particulars given in this application are true and correct.

Declared by…………………….}

This…. day of………… } **DECLARANT**

at………… }

**Before me**

**Commissioner for Oaths/Magistrate/Judge**