# Application Form for Confined Field Trial

This application form must be completed for each individual Living Modified (LM) 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 **Part F** for each submission, **Part G** for each trial site and **Part H** 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.

## Part A: Application Type (tick applicable option)

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| New  Renewal  Amended |  |
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## Part B: Applicant

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| Full Name: |  |  |  |

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| Organization: |  |  |

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| Address: |  |  |  |

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| Phone: |  | Email |  |

## Part C: Applicant Verification

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| This application is submitted in accordance with requirements specified in the Ministerial order No. 001/MoE/25 of 13/01/2025 on the application for a permit for a Living Modified (LM) plant related activities |  |

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Signature of Applicant Date

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief, and I accept full responsibility for compliance with all terms and conditions of authorization.

## Part D: Endorsement by Institutional Biosafety Committee (IBC)

This application is submitted in accordance with requirements specified in the Ministerial order No. 001/MoE/25 of 13/01/2025 on the application for a permit for a Living Modified (LM) plant related activities

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Convener, IBC Date

By my signature, above, I attest that the information contained herein is accurate and complete to the best of my knowledge and belief, and I accept full responsibility for ensuring compliance with all terms and conditions of authorization.

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| **Part E: The Unmodified Plant Species** |

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| **E.1 Latin (Species) name:** |
| **E.2 Common name:** |
| **E.3 Relevant details of the biology of the plant species** *(may include taxonomy, morphology, centres of origin, geographic distribution, reproductive biology, genetics, hybridization and introgression, general interactions with other organisms in the environment, etc.)***:**  *(Attach relevant document describing the biology of the plant species, if available.)* |
| **E.3.1 Is the plant species a known pest in Rwanda, or elsewhere?** |
| **E.3.2 Are there significant free-living populations of the plant species in Rwanda?** |
| **E.3.3 Are there sexually compatible wild relatives of the plant species in Rwanda?** |
| **E.3.4 Known centre(s) of origin of the plant species (add reference):** |
| **E.3.5 Known centre(s) of genetic diversity of the plant species (Add reference):** |
| **E.3.6 Main mechanism of pollen dispersal:** |
| **E.3.7 Mechanisms of natural seed dispersal:** |
| **E.3.8 Seed dormancy (including tubers):** |
| **E.3.9 Is the plant species considered to be weedy or naturally invasive?** |
| **E.4 Is the plant species known to be a source of substances toxic to humans or animals?** |
| **E.5 Is the plant species known to be a source of human allergens?** |
| **E.6 Have any plant variety (s) been released? If yes, indicate the name (s) and year of release** |

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| **Part F: Information on the Living Modified (LM) Plant** |

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

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| **F.1 Name or designation of event(s):**  [Identification code or event name for each LM plant event included in this application] |
| **F.2 Information on import of plant material**  **Did you import the plant materials for use in the confined field trial?  Yes  No**  **If yes, attach the following documents:**   * **Import permit for Living Modified Organisms, issued by the competent authority** * **Phytosanitary certificate of the exporting country** |
| **F.3 Description of modification (introduced trait and genes)** |
| **F.4 Category of genetic modification:**    AP-agronomic properties  BR-bacterial resistant  FR-fungal resistant  HT=herbicide tolerant  IR-insect resistant  MG-marker genes only  NR-nematode resistant  PQ-plant quality  VR-virus resistant    Other (describe): |
| **F.5 Modification method:**  AT-Agrobacterium mediated transformation  PF-protoplast fusion  BT-biolistic/particle gun transformation  OO-other [specify] |
| **F.6 Selection method used in plant regeneration**  AP-antibiotic resistant  HT-herbicide tolerant  SU-substrate utilization  OO-other [specify] |
| **F.7 Introduced DNA**  PL-intact plasmid  T-DNA portion of Ti plasmid  RF-DNA fragment  **F.7-1 Plasmid name:**  **F.7-2 Plasmid and/or construct map attached:  Yes  No**  **F.7-3 Indicate the gene donor organism(s) (Latin name, common name)**  **F.7-4 Is the introduced DNA known to result in any infectious agent?  Yes  No**  **F.7-5 Does the introduced DNA contain any sequence derived from known human or animal pathogen(s)?**  **Yes  No**  **F.7-6 Briefly describe the transformation vector or transforming DNA and production of the modified plant.**  **F.7-7 If you answered Yes to F.7-4 or F.7-5, provide further details below:** |
| **F.8 Data sheet for recording construct composition:**  Provide information for each genetic element (or feature) of the potentially introduced DNA, including coding  and antisense sequences, promoters, enhancers, termination and polyadenylation signal sequences.  **Feature type:** CD-coding; AS-antisense; EH-enhancer; PR-promoter; TR-termination/polyadenylation;  SS-signal sequence; OO-other   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Starting Pos (bp)a** | **Ending Pos (bp)** | **Size (kb)** | **Feature type (see code above)** | **Name** | **Donor organism** | **Donor organism source of toxin(s) or allergen(s)? (Yes/No)** | **Protein expressed? (Yes/No)** | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | | a Numbering is relative to the start of the T-DNA within plasmid p5001 | | | | | | | | |
| **F.9 Stable integration of the inserted DNA**  **F.9-1 Indicate the intended site of integration of the introduced DNA:**  Nuclear genome  Chloroplast genome  Mitochondrial genome  Extrachromosomal plasmid  Transposable element  Viral vector  Other [specify]  **F.9-2 Indicate how stable integration of the inserted DNA was demonstrated:**  Mendelian segregation of introduced trait, within a generation  Multi-generational stability of introduced trait  Other [specify] |
| **F.10 Expression products of introduced gene(s)**  For each protein product of the introduced DNA, provide the following:   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Name** | **Mode of expressiona** | **Specific tissues (if applicable)** | **Known allergen (Yes/No)** | **Known toxin (Yes/No)** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | a Modes of expression: CS-constitutive; TS-tissue specific; IN-inducible; DS-development stage specific | | | | | |  | | | | | |
| **F.11 Intended or anticipated changes to plant characteristics**  **F.11-1 Is the genetic modification intended to alter plant weediness?  Yes  No**  If Yes, describe:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **F.11-2 Is the genetic modification intended to alter seed dormancy, survivability, or germination rate?**  **Yes  No**  If Yes, describe:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **F.11-3 Is the genetic modification intended to alter pollen dispersal?  Yes  No**  If Yes, describe:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **F.11-4 Is the genetic modification intended to alter seed dispersal?  Yes  No**  If Yes, describe:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **F.11-5 Is the genetic modification intended to alter vegetative dispersal?  Yes  No**  If Yes, describe:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **F.12 References** |

**NOTE – A separate Part G shall be provided for each trial site location**

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| **Part G: Information on the trial site** |

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| **G.1 Trial Manager** [Name, Designation, Institution, Address, Email address, Phone number] |
| **G.2 Trial site** [Full location details]  - Village  - Cell:  - Sector:  - District:  - UPI (if available): |
| **G.3 Trial site map** (Attach a complete map *(including GPS coordinates)* of the location of the trial site)  **Has a detailed map of the trial site been enclosed?  Yes  No** |
| **G.4 Indicate the start date of the trial**  **In case of multi-location trial, indicate the start date of each location** |
| **G.5 Habitat**  **G.5-1 Is the trial site part of a managed ecosystem (agricultural land)?  Yes  No**  If Yes, how close is the nearest natural ecosystem?  **G.5-2 Is there an area of special ecological interest (e.g. protected area, sanctuary) near the trial site?**  **Yes  No**  If Yes, briefly describe:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **G.6 Indigenous species**  **G.6-1 Describe any sexually compatible wild or cultivated plant species that are in the vicinity of the trial site:**  **G.6-2 Are there any endangered or threatened species on or near the trial site?  Yes  No**  If Yes, list them (common name/scientific name)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **G.6-3 What mechanisms are in place to prevent local fauna from removing plant material from the trial site?** |
| **G.7 Post-harvest land use**  **G.7-1 Name and address of the person having control over the trial site during the post-harvest period, if different from the Trial Manager:**  **G.7-2 What is the anticipated post-trial land use?**  **G.7-3 Describe how the trial site boundaries will be marked to facilitate subsequent inspection:** |

**NOTE – A separate Part H shall be provided for each Trial Protocol included in the application.**

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| **Part H: Information on the Trial Protocol** |

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| **H.1 Trial protocol (study) title** |
| **H.2 Key activities and associated dates for the confined field trial**   |  |  |  | | --- | --- | --- | | **S/No.** | **Activity** | **Timeline (Dates)** | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |  |  |  | |
| **H.3 Study description**  **Fully describe the purpose of the field trial, the experimental design and the nature and type of data to be collected. Please indicate any proposed herbicide/pesticide use.** |
| **H.4 Reproductive isolation**  **H.4-1 Check one or more as appropriate**  Spatial isolation distance  Detasseling/removal of floral parts  Guard rows  Temporal isolation  Bagging/tents  Trial termination before flowering  **H.4-2 Fully describe the reproductive isolation measures being implemented for this trial and give details.** |
| **H.5 Packaging and transport**  **H.5-1 Describe how Living Modified seed and/or plant material will be packaged for transport**  **H.5-2 Describe how shipping containers and/or packaging material will be sanitized and/or disposed of after use**  **H.5-3 Describe how containers or packages containing Living Modified seed or plant material will be labelled**  **H.5-4 Describe how chain of custody will be ensured and the type of records that will be retained** |
| **H.6 Planting**  **H.6-1 How will material be planted?  By hand  Mechanically**  **H.6-2 Will any unmodified plant of the same or a related species be planted at the trial site location?**  **Yes No**  **H.6-3 If you answered Yes to H.6-2, briefly explain why?**  **H.6-4 If any equipment or utensils are to be used during planting, explain how they will be cleaned on the trial site**  **H.6-5 Describe how surplus planting material will be devitalized (destroyed) at the trial site**  **H.6-6 Describe how quantities of seed planted and any excess will be recorded** |
| **H.7 Pesticide applications**  Complete this section only if an **unregistered** product will be used at the trial sites   |  |  |  |  | | --- | --- | --- | --- | | **Name of Pesticide** | **Active ingredient** | **Number of applications per season** | **Total area to be sprayed (square meters)** | |  |  |  |  | |  |  |  |  | |
| **H.8 Harvesting**  **H.8-1 Will plants be allowed to set seed?  Yes  No**  **H.8-2 How will harvest be done?  By hand  Mechanically**  **H.8-3 Will any harvested plant material be retained from the trial?  Yes  No**  **H.8-4 If you answered Yes to H.8-3, briefly explain the purpose of retaining plant material.**  **H.8-5 If any equipment or utensils are to be used during harvesting, explain how they will be cleaned on the trial site.**  **H.8-6 Name and address of the person responsible for the disposition and/or storage of harvested materials, if it is NOT the trial manager.**  **H.8-7 Describe the storage method and storage location of harvested materials, if applicable.** |
| **H.9 Monitoring the trial site**  **H.9-1 Describe the extent and frequency of trial site monitoring during the current growing season and during the post-harvest period.**  **H.9-2 Describe what monitoring results will be recorded.**  **H.9-3 If any controlled monitoring protocol is proposed (e.g. planting of unmodified plants of a related species to determine the possibility and frequency of gene flow) describe this/these.** |
| **H.10 Contingency plans**  **Describe your contingency plans in the event of an accidental release of seed or plant material or a breach of reproductive isolation.** |

**NOTE – A separate Part I shall be provided for each application.**

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| **Part I: Biosafety Information** |

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| **I.1 Indicate the names and contacts of members of the Institutional Biosafety Committee (IBC)** |
| **I.2 Attach the proceedings/ minutes of IBC meeting(s) and records of any corrective action(s) (where applicable).** |
| **I.3 Describe any other confinement or containment measures that will be used to prevent unintentional release of the Living Modified plant into the environment in addition to those described in sections G and H.**  (*Attach copies of relevant standard operating procedures, if any*.) |
| **I.4 Describe relevant risk assessment information on potential adverse effects to human health, other organisms, or the environment of the Living Modified plant compared to the unmodified plant species in the context of the confinement or containment measures of the trial.** |
| **I.5 Previous confined field trial(s)**  **I.5-1 Has the LM plant event been previously tested in Rwanda?  Yes  No**  **I.5-2 Has the event been previously tested in other regions or countries outside Rwanda?  Yes  No**  If yes, list those regions or countries |
| **I.6 Previous approval for intentional introduction into the environment**  **I.6-1 Has the event received approval for intentional introduction into the environment in countries outside Rwanda?  Yes  No**  If yes, list country(ies) and year(s) of approval: |
| **I.7 Provide any other relevant information** |