

FEDERAL REPUBLIC OF NIGERIA



Biosafety Application Form : FGN A1

Application Form for a Confined Field Trial of Genetically Modified Crop

This form should be forwarded to **Director General/Chief Executive Officer/, National Biosafety Management Agency, National Parks Premises , Airport Road ,Abuja, Nigeria** on completion.

This application form consists of seven parts:

1. Administrative information
2. Plant information
3. Trial Description
4. Genetic Confinement
5. Material Confinements
6. Records, Personnel, and Planning
7. Declaration

1. Administrative information

Purpose of Application:

[Application for a confined field trial for (name of Crop species and introduced trait).]

Previous Applications or Approvals:

[Information on the status of this crop and trait, including pending, approved, or denied applications for field trials and commercial releases here or in other jurisdictions. Indicate also if this is a new application or a renewal.]

Applicant:

[Name of applying institution, which may also include the name of the Principal Investigator or other key personnel.]

Institutional Address:**Telephone (s):****Fax:****E-Mail:****Contact Details of Principal Investigator:****Name of Lead Scientist:****Address:****Telephone (s):****Fax:****E- mail:****Proposed Location and Size of Trial:**

[Name, address, e-mail, phone, and facsimile of the Trial Manager as well as GPS information or description of the exact location and size of the trial site (attach sketch map).]

Proposed Duration of Trial:**Expected starting date:****Expected termination date:**

2. Plant Information
- 2.1 Unmodified Plant Information

This section describes the characteristics of the unmodified plant as it relates to confinement. Important information pertains to the plant's reproductive mechanisms and its ability to escape, establish, and persist in the environment into which it is being introduced.

Plant Species Name (Common and Scientific):

Center of Origin:

[What is the center of origin of the unmodified plant?]

Reproductive Mechanism of the Plant:

[Describe the reproductive biology of the plant. This information may be obtained from Organization for Economic Co-operation and Development (OECD), biology consensus documents or similar sources, and should include relevant information on: inter – and intra-specific breeding; pollen production, dispersal and viability; seed production and dispersal; seed dormancy, capacity for vegetative reproduction.]

Tendency and Weediness:

[Is the unmodified plant regarded by agricultural experts as a weed in regions where it is cultivated? If so, are control methods available that may be used to effectively limit the dispersal and establishment of the unmodified plants? NOTE: The information on the confined field trial location and how the genetically modified plant will be managed are described elsewhere in this application.]

Toxicity and Allergenicity:

[Is the plant species known to be a source of substances that are toxic or allergenic to humans or animals? If yes, identify the substances and levels that induce toxicity or allergenicity and the affected species.]

2.2 Modified Plant Information

This section is intended to provide information on known or intended effects of the genetic modification or introduced trait that may effect confinement measures employed in the confined trial.

Describe the Intended Phenotypic Changes to the Plant

Intended Reproductive Effects:

[Does the genetic modification intentionally alter the reproductive biology of the plant? How do these changes affect strategies for confinement?]

What is the source of the genetic material? Is the source of the genetic material likely to affect the safe conduct of a confined field trial? If yes, how?

[Describe any known or intended introduction of infectious agents, plant, animal or human pathogens or allergens or toxins.]

Changes in Toxicity or Plant Composition:

[Describe any changes or toxicity, allergenicity, or significant changes in composition intended by the genetic modification.]

Describe the Features of the Genetic Construct:

[Include coding sequences, promoters, enhancers, termination and polydenylation signal sequences. Attach a genetic map and describe the method of modification in an annex.]

3. Trial Description

This section describes the purpose of the field trial, the experimental design and data to be collected, including anticipated pesticides use. Include a description of the habitat at the site, and any organisms of conservation concern that may be in the general area.

Trial Description:

4. Genetic Confinement

This section describes the measures to be taken to ensure confinement of the genetically modified plants and genes. It is based on knowledge of the unmodified crop and the intended genetic modification.

Provide a map showing the location of the trial site, surrounding fields and relevant geographic features such as streams or waterways.

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Are there wild plant species in the vicinity of the trial site that could be fertilized by pollen from the trial plants, resulting to viable seeds?

Describe mechanisms in place to prevent pollen-mediated gene flow from the plants in the trial site:
[Genetic confinement or reproductive isolation measures are based on the biology of the unmodified plant and the introduced genetic modification, and include isolation distance and /or other measures as justified by the reproductive biology of the unmodified plants, and any intended effects of the introduced traits on their reproductive biology.]

Describe measures in place to control trial plant volunteers after termination of the trial:
[Describe the crops to be allowed following the confined trial, duration of monitoring or volunteers, frequency of monitoring, methods of destruction and disposal of any identified volunteers, and any other measures needed to ensure that the trial plants do not persist on the trial site.]

5. Material Confinement

This section describes the mechanisms by which trial personnel will maintain control of the genetically modified plant material, so that it is not mixed with non-modified plant material, does not escape into the environment, and is not eaten by humans or livestock.

Packaging:
[Describe how the genetically modified plant material will be packaged and labeled for transport to the trial site and measures for cleaning and/or disposing of the packaging material. Note that the chain of custody documentation is required for all genetically modified material being transported.]

Harvesting, Transport and Storage:
[Describe how the plant material will be harvested, including plans for any material to be retained, and how that material will be stored and/or transported.]

Disposal and Clean-up:
[Describe how surplus planting material will be disposed of at the trial site, how any equipment used during plating or other farm operations will be cleaned, and how harvested materials and crop residues will be disposed.]

Site Security:

[Describe measures in place to ensure security of the trial site to prevent incursion by humans or animals. Measures may include fencing, security patrols, lockable gates, etc...]

6. Records, Personnel, and Planning

Records and Documentation:

[Describe measures in place to ensure adequate documentation of all confinement measures and data requirements as described herein.]

Personnel:

[Describe measures in place to ensure that trial personnel will have appropriate education, experience and training to adequately perform assigned duties for confinement and technical requirements of the trial.]

Contingency Plans:

[Describe planned response to the loss of control or accidental release of genetically modified plant material, including notification of authorities and the Authorized Party, recovery and disposal of plant material, and any other measures to be taken to mitigate any potential adverse effects.]

7. Declaration

I hereby certify that the information in the application and all attachments is complete and accurate to the best of my knowledge and belief:

Signature of Principal Investigator for Applying Institution:

Date:

Signature of Lead Scientist of Collaborating Institution:

Date: