National Biosafety Management Agency
NBMA

GOVERNMENT OF THE FEDERAL REPUBLIC OF NIGERIA

Application Form for General Release/Commercialization of Genetically Modified Organisms (GMOs) in Nigeria

Ref. No.---

This form should be forwarded to the **Director General/Chief Executive Officer, National Biosafety Management Agency, National Parks Service, After City Gate, Airport Road-Abuja,** on completion.

1. **Administrative information**

Purpose of Application: [Application for General Release/Commercialization of Genetically Modified (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/Company, which may also include the name of the key personnel.]

Institutional Address: **Telephone (s):** **E-Mail:**
Contact Details of Key Person: **Name of Key Person:** **Designation of Key Person:** **Address:** **Telephone (s):** **E- mail:**

PART I

1. BRIEF DESCRIPTION OF THE GENETICALLY MODIFIED PLANT

   Include specific and common names of the plant, the country of origin of the plant and a description of the genetically modified trait.

2. GENERAL RELEASE

   2.1 Detail specific instructions for the storage and handling of the plant, or viable plant parts

   2.2 When will the general release be implemented?

   2.3 Where will general release take place?

   2.4 detail the type of environment and the geographical areas for which the plant is suited.

   2.5 Who will undertake the general release?

   2.6 Estimate the amount of production of the genetically modified plant within Nigeria per annum, or the amount of viable plant product to be imported into Nigeria per annum per annum.

3. DESCRIPTION OF ANY PRODUCT DERIVED FROM THE PLANT

3.1 identify the part of the plant to be used for the product, the type of product, and the use of the product, the market sector in which the product will be marketed and the trade name of the product.

3.2 Specify the exact conditions of use of the product.

3.3 provide information on the proposed labeling of the product for marketing

3.4 state whether the benefits of the products are available in any other non-genetically modified form. If so, state why the genetically modified form should be approved for general release when other, non-modified products are available.

3.5 Detail specific instructions for the storage and handling of viable plant products that will avoid misuse or escape of the genetically modified plant into an environment for which it was not intended.

3.6 detail the likelihood of the genetically modified plant or its products being exported from Nigeria, particularly if such export could result in the introduction of the plant into its centre of origin.

4. BRIEF SUMMARY OF FIELD TRIALS UNDERTAKEN

4.1 Submit a list of previously authorized activities with the GMO in
(a) Nigeria
(b) other countries

4.2 Include information on the country, year, location and the authority form which permission was obtained to run the field trials.

4.3 Provide full date on the field performance of the genetically modified plant, including the efficacy of the introduced trait

5. POLLEN SPREAD

5.1 identify all methods of pollination applicable to the plant

5.2 Identify pollinating agents and the distances to which pollen is known to spread.

5.3 identify any plants in the are of general release that may become cross-pollinated with the genetically modified pollen.

5.4 Describe methods to be used to prevent the spread of genetically modified pollen to wild type plants

6. SEED DISPERSAL

6.1 If seed is to be sold, state whether the seed is hybrid

6.2 Describe methods to be used to limit the dispersal of genetically modified seed into the environment

6.3 If seed dispersal will occur describe what volumes of seed are likely to be dispersed, how this seed will interact in the environment and what long term effects the seed is likely to have on the environment.

7 VEGETATIVE SPREAD OF THE GENETICALLY MODIFIED PLANTS

7.1 Describe methods of vegetative reproduction that are available to the plant

7.2 Describe methods to be used to limit vegetative spread of the genetically modified plant into the environment

8. FOREIGN GENES AND GENE PRODUCTS

8.1 Identify all foreign genes in the genetically modified plant

8.2 Describe the gene products that are derived from the foreign genes

8.3 Describe the biological activity associated with the foreign gene products

8.4 provide information on the rate and level of expression of the foreign genes and the sensitivity of the measurement of the rate and level. State whether expression is constitutive or inducible. Are foreign gene s expressed throughout the plant or only in certain organs or tissues?

8.5 Provide protocols for the detection of the foreign genes in the environment including sensitivity, reliability and specificity of the techniques

9. RESISTANCE

9.1 Detail whether the genetically engineered plant is able to initiate resistance, in any biotic components of the environment, to any biologically active foreign gene product.

9.2 Detail what methods are available to minimize the risk of resistance developing in the environment

9.3 Detail how resistance will be managed during general release of the genetically modified plant

10. **HUMAN AND ANIMAL HEALTH**

10.1 State whether the genetically modified plant or its products will entre human or animal food chains.

10.2 Detail the results of experiments undertaken to determine the toxicity of the foreign gene products (including market genes) to humans and animals

10.3 if the foreign gene products are toxic or allergenic in any way, detail how the general release will be managed to prevent contact with animals or humans that will lead to discomfort or toxicity.(Attach food safety and allergenicty text report)

10.4 What are the implication of the proposed activity with regard to the health and safety of the workers, cleaning personnel and any other person, that will be directly or indirectly involved in the activity?

10.5 Further to the question raised above, indicate the proposed health and safety measures that would be applied to safeguard employees during the proposed activity

11. ENVIRONMENTAL IMPACT AND PROTECTION

11.1 Detail any long-term effect the general release of the genetically modified plant is likely to have on the biotic and abiotic components of the environment

11.2 provide data and information on ecosystems that could be affected by use of the plant or its products

11.3 Specify what effect the general release of the genetically modified plant will have on biodiversity

11.4 Specify the measures to be taken in the event of the plant or product being misused or escaping into an environment for which it is not intended

11.5 If the foreign genes give rise to crops resistant to agrochemicals, provide information on the registration of the agrochemicals to be used on the crop.

12. SOCIO-ECONOMIC IMPACTS
Specify what, if any, positive or negative socio-economic impacts that genetically modified plant will have on communities in the proposed region of release.

13. MONITORING AND ACCIDENTS
13.1 indicate the methods and plans for monitoring of the GMO

13.2 Indicate any emergency procedures that will be applied in the event of an accident

14. PATHOGENIC AND ECOLOGICAL IMPACTS
14.1 Submit an evaluation of the foreseeable impacts, in particular any pathogenic and ecologically disruptive impacts

15. WASTE DISPOSAL
Where only a portion of the genetically modified plant will be used for the product, how will the unused plant parts be disposed of?

16. RISK MANAGEMENT
16.1 Please indicate any risk management measures that would be required during the trial

17. COMPLETE THE AFFIDAVIT. The affidavit is an inseparable part of the application form.

Directions for the applicant:

(This page must be excluded from the documents submitted to the Director General/CEO's office)

- Please complete all relevant sections f the questionnaire CLEARLY.

- Please provide 5 copies of the application with confidential information.
- Please provide an additional hard copy of the application containing no confidential information. The latter application will be made available for public scrutiny

- Please provide and electronic and hard copy of a risk assessment conducted in accordance with Annex III of the Cartagena Protocol on Biosafety and in the format prescribed below,

- Please submit all relevant documentation to the Director General/Chief Executive Officer at the address indicated in the application form

- The appropriate fee stipulated must paid into the Agency's Bank account after the application has been acknowledged. Please note that the Director General/Chief Executive Officer's office does not accept cash.

18. 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:

Name and Signature of Representative of for Applying Institution/Company:----------

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Date:

COMMON FORMAT FOR RISK ASSESSMENT

(In accordance with Annex III of the Cartagena Protocol on Biosafety)

	Risk Assessment Details	
1.	Country of taking Decision	Nigeria
2.	Title:	<text entry>
3.	Contact details	Standard Contact address details: name, function (job title/designation), organization, address, phone, fax, e-main, website
4.	Name and identification of the living modified organism	<Text entry>
5.	Unique identification of the living modified organism:	<Text entry>
6.	Transformation event:	<Text entry>
7.	Introduced or Modified traits:	Choose the trait from the following list: A. Abiotic Environmental tolerance ✓ Altered photoperiod sensitivity ✓ Cold or heat tolerance ✓ Drought or water tolerance ✓ Other abiotic environmental tolerance B. Altered Growth, Development and product quality ✓ Altered ripening or flowering ✓ Coloration ✓ Fertility ✓ Growth rate or yield ✓ Male sterility ✓ Nutritional composition (inc.allergenicity ✓ Other growth, development and product quality ✓ Selected marker genes and reporter gens ✓ Uptake or degradation of environment pollutants **Chemical Tolerance** ✓ Herbicide tolerance ✓ Other chemical tolerance **Medical Products** ✓ Animal vaccines ✓ Development of transplant organs ✓ Other medical products ✓ Production of pharmaceuticals **Pest Resistance** ✓ Bacterial resistance ✓ Fungus resistance ✓ Insect resistance ✓ Nematode resistance

		✓ Other pest resistance ✓ Virus resistance and ✓ <text entry for other, not on the list>
8.	Techniques used for modification:	<controlled vocabulary for common techniques – please select techniques used for the transformation: plasmid carried by *agrobacterium tumefacients*, biolistic methods, breeding, electric shock (poration), asmotic shock> and <text entry – for other, not on the list>
9.	Description of gene modification:	<Text entry>
		Characteristics of modification
10.	Vector characteristics (Annex III.9(c)):	<Text entry – Characteristics of the vector, should include its identity, if any, and its sources or origin, and its host range
11.	Insert or inserts (Annex III.9(d)):	<Text entry - Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced>
		Recipient organisms or parental organisms (Annex III.9(a)):
12.	Taxonomic name/status or recipient organisms or parental organisms:	<controlled vocabulary: agreed international standards> and <text entry> - for other, not on the list
13.	Common name of recipient organism or parental organisms	<controlled vocabulary with thesaurus> and <text entry – for other not on the list>
14.	Point of collection or acquisition of recipient or parental organisms:	<Text entry>
15.	Characteristics of recipient organism or parental organisms:	<text entry>
16.	Centre(s) of origin of recipient organism or parental organisms	<text entry – Describe the exact location and give geographical coordinates>
17.	Centres of genetic diversity, if known of recipient organism or parental organism may persist or proliferate	<text entry – describe the exact location and geographical coordinates>
18.	Habitats where the recipient organism or parental organisms may persist of proliferate:	<text entry – description of the habitat where the organism may persist or proliferate>
	Donor organism or organism (Annex III.9(B)):	

19.	Taxonomic name/status of donor organism(s)	<Controlled vocabulary: agreed international standards> and <text entry for other, not on the list>
20.	Common name of donor organism(s):	<controlled vocabulary with thesaurus> and <text entry for other, not on the list>
21.	Point of collection or acquisition of donor organism(s):	<text entry – the exact location and geographical coordinates>
22.	Characteristics of donor organism(s) related to biosafety:	<text entry – relevant biological characteristics of donor organisms>
	Intended use and receiving environment	
23.	Intended use of the LMO (Annex III 9(g)):	<text entry – Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms>
24.	Receiving environment (annex III.9(h)):	<Text entry – 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>
	Risk Assessment Summary	
25.	Detection/identification method of the LMO (annex III.9(f)):	<text entry – suggested detection and identification methods and their specificity, sensitivity and reliability>
26.	Evaluation of the consequences (Annex III.8(b)	<text entry – an evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism>
27.	Evaluation of the consequences (Annex III.8(c)):	Text entry – An evaluation of the consequences should these adverse effects be realized>
28.	Overall risk (annex III.8(d))	<Text entry – an estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized>
29.	Recommendation (Annex III.8(e)):	<Text entry – a recommendation as to whether or not the risks are acceptable or manageable, including, where necessary identification of strategies to manage these risks>

30.	Actions to address uncertainty regarding the level of risk (annex III.8(f)):	<text entry – details about any further information that has been requested where there is uncertainty regarding the level of risk as well as any information on risk management strategies and/or monitoring of the LMO in the receiving environment>
31.	Availability of detailed risk assessment information:	<Text entry – Please indicate whether more details on the irks assessment are available and how they can be accessed>
32.	Any other relevant information:	<text entry – any other information that is relevant to the risk assessment. E.g. information of non-CBI nature that was included in the original application but is not included in this form>
33.	Attach document:	Not applicable to applicant <specific types of entry: option to choose a file form the local source and 'upload' a copy of the BCH server>
34.	Notes:	<Text only>