National Biosafety Management Agency
NBMA

GOVERNMENT OF THE FEDERAL REPUBLIC OF NIGERIA

Application Form for Permit

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

Ref. No.----------
(official use only)

Title of the application:	General/Commercial release of
	genetically modified for
Applicant organisation name:	

Is your application for a field trial?

☐Yes ☐No (If Yes, this is not the correct application form).

Is this application accompanied by an application for a declaration that certain information be treated as Confidential Business Information (CBI)?

☐Yes ☐No

If any information provided is covered by a previous CBI application or declaration, please provide:

1) Relevant CBI application number(s):----------

2) Organisation name(s):----------

If any information provided is covered by a previous CBI declaration and cannow be made available to the public, please contact the National Biosafety Management Agency (NBMA) to have the declaration revoked.

Section 2. INFORMATION FOR APPLICANTS

Prospective applicants are advised to contact the National Biosafety Management Agency (NBMA) before submitting a written applicationto be guided on the selection of appropriate application form for the service they require and to discuss information requirements. Furthermore, comments for the improvement this form is welcome. The NBMA can be contacted on phone at +234 8180805451 or by email:biosafetyng@gmail.com

1. *Purpose of this application form*

This application form is designed for permit for the release of GM plants into the environment that does **not qualify** as a 'Contained or Confined use' under section 43 of the *National Biosafety Management Agency (NBMA) Act 2015*. Generally, this is because the main aim of the release is not experimental and/or minimal or no limits and controls are proposed. Although the NBMA Act 2015 section 43 refers to this type of releaseas **commercialrelease,** it is also called **general release.**

Applicants are advised not to use this form for any other purpose other than the one specified in this document. Appropriate application formscan be found on the NBMA website (www.nbma.gov.ng) or at the NBMA Office.

2. *Information to be provided*

- This permit application must contain correct and sufficientinformation to address each specified request unless otherwise instructed. Applications that do not contain specified information would be difficult to consider.
- Any information needed to be protected from public disclosure, must be detailed in an *Application form for declaration of confidential business information (CBI), and this must be* submitted together with this permit application form.
- Additional information with respect to requirements for *Application for declaration of information to be dealt with as CBI*is provided on the form.
- Information provided in the application form would be used to prepare a Risk Assessment and Risk Management Plan (RARMP) in relation to the proposed activities. The NBMA decision on the application would be based upon the RARMP.
- Information in this application may be released to the public
- Application fee for a commercial/generalrelease permit

Information on the fees for various biosafety services would be provided to applicants at the NBMA. It is also contained in various biosafety technical information publications freely available at the NBMA office.

3. *Completing the form*

- The application is available at the NBMA office and could be downloaded at the NBMA website (www.nbma.gov.ng). It is recommended that applicants should read through all the specified information requests thoroughly before filling out the form. A separate guide on how to complete the form is freely available at the NBMA office on request.
- Applicants are advised to ensure thateach relevant requested informationbe providedin sufficient detail as failure to provide required information could delay the decision making process or application may not be considered at all.
- Answers to all question must be factual and to the best of the applicant's knowledge. False and misleading information deliberately provided is a punishable offence (section 36 of the NBMA Act 2015).
- Each information provided is expected to be accompanied with adequate supporting material. Scientific information should be comprehensive and supported by data and references. In some cases, electronic or hard copies of journal publications and unpublished information may be requested.
- It is not expected that information would not be repeated, reference to an earlier information could be used where relevant.
- NBMA officers are always available to guide applicants.

On completion, five (5) copies of the forms with the accompanying documents including any CBI and a backup copy in a disk (DVD, CD or flash pen) should be submitted to:

National Biosafety Management Agency,
National Parks Service Hqrs,
Umaru Musa Yar'Adua Express Way,
Airport Road, Abuja ***- Nigeria****.*

Please keep a copy of the application for your records.

4. *Application processing process*

On receipt of application,

a. it isfiled and assigned a unique reference code and acknowledged within 21 days with advice on the applicable fees (for processing and permit);

b. application is reviewed for completeness after payment of processing fee is confirmed;

c. applicant is contacted if dossier is incomplete and informed of stopping of the clock until response is received;

d. notice of the display of application dossier is published in both local and national Newspapers;

e. application and relevant information are displayed at strategic places to enable the general public and relevant government ministries and agencies study and make comments on the application and provide relevant information within 21 days to the Agency;

f. the Agency may, in addition to the comments received, hold public hearings or consultations to obtain further comments and inputs that will assist in the review or processing of the application,

g. National Biosafety Committee (NBC) and/or National Biosafety Technical Sub-Committee (NBTS) is/are constituted if necessary and application dossiers referred to the committees for risk assessment and recommendation. (*NOTE: Not all applications require referral to NBC and NBTS).*

h. after the expiration of the period of the display of application dossier, the NBC embarks on risk assessment of the application within seven working days, taking into account the recommendation of the NBTS, and submits recommendation to Director General/CEO of NBMA;

i. decision on application is taken,decision(Permission/rejection) is communicated to applicant via a Decision Document.

Section 2. GENERAL INFORMATION

PART A: Personal Information

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 B: Information Relating to the Genetically Modified Organism

1. **Description of Genetically Modified Organism (GMO)**

Provide a brief description of the genetically modified plant on the following:

a. Characteristics of the donor, the recipient or where appropriate, the parental organism Scientific name;
b. Additional taxonomic information;
c. Other names (usual name, strain name, cultivar name, transformation event, unique identification code (where applicable) etc);
d. Phenotypic and genetic markers;
e. Degree of relatedness between donor and recipient or between parental organisms;

f. Description of the geographic distribution and of the natural habitat of the organisms including information on natural predators, preys parasites and competitors, symbionts and hosts;
g. Potential for genetic transfer and exchange with other organisms;
h. Verification of the genetic stability of the organism and factors affecting it taking into account the relevance of the laboratory experiments undertaken to the authentic ecological conditions under which the organism lives and used;
i. Pathological, ecological and physiological traits which shall include:
    (i) classification of hazard according to existing national rules concerning the protection of human health and the environment;
    (ii) generation time in natural ecosystems, sexual and asexual reproductive cycle;
    (iii) information on survival, including seasonality and ability to form survival structures (for example, seeds, spores or sclerotic);
    (iv) pathogenicity, infectivity, toxigenecity, virulence, allergenicity, ability to be a carrier (vector) of pathogen, possible vectors, host range including non-target organisms, possible activation of latent viruses (proviruses) and ability to colonise other organisms;
    (v) antibiotic resistance and potential use of these antibiotics in humans and domestic
    animals for prophylaxis and therapy; and
    (vi) involvement in environmental processes, primary production nutrient turnover, decomposition of organic matter, respiration.

2. **Characteristics of the vector should be provided:**
    a. Nature and source of the vector;
    b. sequence of trasposons, vectors and other non-coding genetic segments used to construct the genetically modified organisms or their products and to make the introduced vector and insert function in the genetically modified organisms or their products;
    c. Frequency of mobilization of inserted vector and or genetic transfer capabilities and methods of determination;
    d. Information on the degree to which the vector is limited to the DNA required to perform the intended function;
    e. Factors (chemical biological, climatic, etc) influencing the functional level of the promoter or enhancer and how the functional level is changed.

3. Genetic Modification of Organism(s)

Information relating to the genetic modification on:

(a) Methods used for the modification;

(b) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;
(c) Description of the insert and vector construct; and
(d) Purity of the insert from any unknown sequence and information on the degree to which the inserted sequence is limited to the DNA required to perform the intended function;

4. Nature of the final genetically modified organisms:

(a) Description of genetic trait or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;
(b) Structure and amount of any vector or donor nucleic acid remaining in the final construction of the genetically modified organisms or product ;
(c) Stability of the genetic traits of organisms in them is of both expression and structure;
(d) Rate and level of expression of the new genetic material" Method and sensitivity of measurements;
(e) Activity of the expressed protein;
(f) Expression levels for the recipient's genes situated as far as 100 kbp up and downstream from all DNA inserts;
(g) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques; and
(h) Health consideration that has:
    (i) toxic or allergenic affects of the non-viable genetically modified organism or products and their metabolic products;
    (ii) products hazards;
    (iii) comparison of the genetically modified organisms or products to the donor, recipient or (where appropriate) parental organisms regarding pathogenicity;
    (iv) capacity for colonization; and
    (v) its organisms as pathogenic to humans who are immune competent.
    (vi) Cases caused and mechanism of pathogenicity including invasiveness and virulence;
        - Communicability;
        - Infective dose;
        - Host range, possibility of alteration;
        - Possibility of survival outside of human;
        - Presence of vectors or means of dissemination;
        - Biological stability;
    (vii) Antibiotic resistance patterns;
    (viii) Allergenicity;
    (ix) Availability of appropriate therapies;

(x) Allergenicity availability of appropriate therapies.

PART C: Information relating to the condition for release and the receiving environment

1. Information on the Release

a. Description of the proposed deliberate release, including the purposes and foreseen products;
b. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases;
c. Preparation of the site previous to the release;
d. Size of the site;
e. Methods to be used for the release;
f. Quantities of genetically modified organisms;
g. Disturbance on the site (type and method of cultivation, mining; litigation or other activities);
h. Worker protection measures to be taken during the release;
i. Post release treatment of the site;
j. Techniques foresee for cremation or inactivation of the genetically modified organisms or products, at the end of the experiments;
k. Information on and results of previous release of the genetically modified organism or products, especially at different scales and in different ecosystems including contained experiments.

2. Information on the environment

(*The information shall be for both the site and the wider environment and in the case of genetically modified organisms destined to be used as food, feed or for processing, the environment includes the transposition routes and the market places as well as all the catchment areas of the market places*):

a. Geographical location and grid reference of the site(s) in case of notification, the site(s) of release will be the foreseen areas of use of the product);
b. Physical or biological proximity to humans and other significant biota;
c. Proximity to significant biotopes or protected areas;
d. Size of local human population;
e. Economic activities of local populations which are based on the natural resources of the area;
f. Distance to closes areas protected for drinking water and environmental purposes;
g. Climatic characteristics of the region(s) likely to be affected;
h. Geographical, geological and pedological characteristics;
i. Flora and fauna, including crops, livestock and migratory species;
j. Description of target and non-target ecosystems likely to be affected;
k. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release;

l. Any known planned developments or changes in land use in the region which could influence the environmental impact of the release.

PART D: Information relating to the interactions between the genetically modified organisms or products and the environment

1. Characteristics and Factors affecting survival Multiplication, Gene Expression and Dissemination

a. Biological features which affect survival, multiplication and dispersal.
b. Known or predicted environmental conditions, which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, pollutants such as pesticides, heavy metals, etc).
c. Sensitivity to specific agents

2. Interactions with the Environment

a. Predicted habitat of the genetically modified organisms;
b. Studies of the behaviour and characteristics of the genetically modified organisms or products and their ecological impact carried out in simulated natural environments. Such as microcosms, growth rooms, greenhouses, animal houses and other containment facilities etc.
c. Genetic transfer capability, that is:
   (i) post-release transfer of genetic material from genetically modified organisms or products organisms;
   (ii) post-release transfer of genetic material from indigenous organisms of the genetically modified organisms or product.
d. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the genetically modified organisms or products.
e. Measures employed to ensure and to verify genetic stability, Description of genetic traits which may prevent or minimize dispersal of genetic material.
f. Methods to verify stability.
g. Routes of biological dispersal, known or potential modes of interaction with the disseminating agent including inhalation, ingestion, surface contact, burrowing etc.
   (i) Description of ecosystem to which the genetically modified organism or products could be disseminated;
   (ii) or excessive population increase in the environment;
   (iii) Competitive advantage of the genetically modified organism or products in relation to the unmodified recipient or parental organism;
   (iv) Identification and description of non-target organisms;
   (v) Anticipation mechanisms and result of interaction between the released genetically modified organism or product and the target organism;
   (vi) Identification and description of non-target organism which may be affected directly;
   (vii) Likelihood of post-release shifts in biological or host range;

(viii) Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, host symbionts, predators,parasites and pathogens;
(ix) Known or predicted involvement on bio-geochemical processes;
(x) Other potentially significant interactions with the environment.

PART E: Information on monitoring, control, wastes treatment and emergency response plans

1. Monitoring Techniques

a. Methods for tracing the genetically modified organisms or products and of monitoring their effects;
b. Specificity (to identify the genetically modified organism or product and to distinguish them from the donor, recipient or where appropriate, the parental organism), sensitivity and reliability of the monitoring techniques.
c. Techniques for detecting transfer of the donated genetic material to other organisms.
d. Methods to detect aberrant gene expression.

2. Control of the Release

a. Methods and procedures to avoid or minimize the spread of the genetically modified organisms or products their beyond the site of release or the designated area for use.
b. Methods and procedures to protect the site from intrusion by unauthorized individuals.
c. Methods and procedures to prevent other organisms from entering the site.

3. Wastes Treatment

a. Type of waste generated.
b. Expected amount of waste.
c. Possible risk.
d. Description of treatment envisaged.

4. Emergency Response Plan

a. Methods and procedures for controlling the genetically modified organisms or products thereof in case of unexpected spread.
b. Methods of decontamination of the areas affected (e.g. eradication of the genetically modified organisms or products thereof).
c. Methods for disposal or incineration of plants, animals, soil etc that were exposed during or after the spread.
d. Methods for the isolation of the area affected by the spread.
e. Plans for protecting human health, animals, plants and the environment in case of the occurrence of an undesirable effect.

PART F: Risk assessment parameters

Information provided in this section would assist the NBMA in the preparation of the risk assessment, and would contribute to the estimation of the potential adverseimpact of the GMO on people and the environment.

I. Characteristics of the Organism

1. Characteristics of donor and recipient organisms or parental organisms.
2. Scientific name and taxonomy.
3. Strain, cultivar or other name.
4. Species, it is related to and degree of relatedness.
5. The degree of relatedness between the donor and recipient organisms or between the parental organisms.
6. All sites from where the donor and recipient organisms or between the parental organisms were collected, if known.
7. Information on the type of reproduction (sexual or asexual) and the length of reproductive cycle or generation time, as appropriate, as well as the formation of resting and survival stages.
8. History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified.
9. Phenotypic and genetic markers of interest.
10. Description of identification and detection techniques for the organisms and the sensitivities of these techniques.
11. Geographic distribution and natural habitat of the organism including information and natural predators, prey, parasites, competitors, symbionts and hosts.
12. Climatic characteristics of original habitat.
13. Ability of the organisms to survive and colonise the environment to which release is intended or otherwise.
14. Genetic stability of the organisms and factors affecting the stability.
15. The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability.
16. The potential of the organisms to transfer or exchange genes with other organisms either vertically or horizontally.
17. Pathogenicity to humans or animals, if any.
18. If pathogenic, their virulence, infectivity, toxicity and modes of transmission.
19. Known allergenicity or toxicity of biochemical and metabolic products.
20. Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.

II. Characteristics of the vector(s)

21. Nature and source of the vectors

22. Genetic map of the vectors, position of the genes inserted for the transfer, other coding and non-codling sequences affecting the expressing of introduced genes and marker genes.
23. Ability of the vector to mobilize and transfer genes by integration and methods of determining the presence of the vectors.
24. History of prior genetic manipulation where the donor or recipient organisms are already genetically modified.
25. Potential for pathogenecity and virulence.
26. Natural habitat and geographic distribution of natural and potential hosts.
27. Potential impacts on human and animal health and the environment.
28. Measures for counteracting adverse impacts.
29. Potential to survive and multiply in the environment or to form genetic recombinants.
30. Genetic stability of vectors such as hyper mutability.

III. Characteristics of Genetically Modified Organisms

31. The description of the modifications made using gene technology.
32. The function of the genetic modifications and the new insert including any marker Gene(s).
33. Purpose of the modification and intended use in relation to need and benefit.
34. Method of modification, and in case of transgenic organism, the methods for constructing inserts and to introduce them into the recipient organism.
35. Whether introduced genes integrated or extra-chromosomal.
36. Number of inserts, position in the genome, and its or their structures (for example, the copy number whether in random or other types of repeats).
37. Products of the transferred genes, level of expression and methods for measuring expression.
38. Stability of the introduced genes in terms of expressions, structures and sites of integration.
39. Biochemical and metabolic differences of genetically modified organism compared with the unmodified organisms.
40. Probability of vertical or horizontal gene transfer to other species.
41. Probability of inserts or transferred genes to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria.
42. Allergencity, toxicities, pathogenicities and unintended effects.
43. Autecology of the genetically modified organism to diseases and pest compared with the unmodified organism.
44. Detailed information on past uses including results to diseases and pest leading to previous releases.

IV. Characteristics of Resuscitated Organisms and Genes and Fossils DNA sequences, Resuscitated Organisms

45. Scientific name and taxonomy.
46. Identity of nearest species and their characteristics which are of relevance to the intended use.
47. Site which is found.
48. Method used for resuscitation.
49. Purpose of introducing the organism and benefits, if any,
50. Impacts on human and animal health and the environment.
51. Measures for counteracting adverse impacts.
52. Length of time the organism has been in use.
53. Genetic stability.
54. Likelihood of gene transfer to other organisms.
55. Fossil and living organisms nearest relative species.
56. Biological and biochemical difference from related living species.
57. Information and previous uses since resuscitation.

V. DNA sequences from Fossils or from Resuscitated Organisms

58. Scientific name and taxonomy of the species whether resuscitated or a fossil.
59. Site of origin of the fossil.
60. Site of the gene in the resuscitated genome, if known.
61. Base sequence of the extracted gene.
62. Functions of gene, if known.
63. Purpose of use and benefits, if any.
64. Environment in which it lived before fossilization
65. Fossil species related to the species from which the gene was taken.
66. Living species related to the species from which the gene was taken.

VI. Safety Consideration for Human and Animal Health

67. Capacity of colonization.
68. If the genetically modified organism is pathogenic to humans to animals, the following information is required, that is:
    (a) diseases caused and mechanism of pathogenicity, including invasiveness and virulence and property of virulence;
    (b) Communicability;
    (c) Infective doses;
    (d) host range and possibilities of alteration;
    (e) ability to survive outside of the human or animal host;
    (f) the existence of vectors and other means of transmission;
    (g) Biological stability;
    (h) Allergencity;
    (i) Availability of appropriate therapies.

VII. Environmental considerations

69. Factors affecting the survival reproduction and spread of the genetically modified organism in the environment.
70. Available techniques for detection, identification and monitoring of genes from the genetically modified organisms.
71. Available techniques for detecting transmission of genes from the genetically modified organism to other organisms.
72. Known and predicted habitats of the genetically modified organism.
73. Description of the ecosystems which could be affected by accidental release of the genetically modified organism.
74. Possible interactions between the genetically modified organism and other organisms in the ecosystem which might be affected by accidental release.
75. known or predicted effects on plants and animals such as pathogenicity infectivity, toxicity, virulence, being a vector of pathogens, allergenicity and colonization
76. Possible involvement in bio-geochemical processes.
77. Availability of methods for decontamination of the area in cases of accidental releases.
78. Effects on agricultural practices with possible undesirable impacts on the environment.

VIII. Socio-economic consideration

79. Anticipated changes in the existing social and economic patterns resulting from theintroductionof the genetically modified organism or products .
80. Possible treats to biological diversity, traditional crops or other products and in particular, farmers' varieties and sustainable agriculture.
81. impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agroclimatic zones.
82. anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and in general, means of livelihood of the communities likely to be affected by the introduction of the genetically modified organisms or products.
83. Possible countries and communities to be affected in terms of disruptions to their social and economic welfare.
84. Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use of release of the genetically modified organism or the product.

PART G: Information on post release monitoring and emergency response plans

1. Farmer complaint system

2. Resistance management plan for deployment of GMO
3. Emergency plans in the event of an accidental release of GMO
4. Emergency plan in the event of an unexpected spread of genetically GM plant material after an accidental release
5. Stewardship programme for deployment of GMO

Section 3. FINAL NOTE AND DECLARATION

PART A: Application submission instruction

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 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 be 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.**

PART B: 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 for Applying Institution/Company:----------

Date:----------