

# **NATIONAL BIOSAFETY MANAGEMENT AGENCY ACT, 2015**

## **EXPLANATORY MEMORANDUM**

This Act establishes the National Biosafety Management Agency charged with the responsibility for providing regulatory framework, institutional and administrative mechanism for safety measures in the application of modern bio-technology in Nigeria with the view to preventing any adverse effect on human health, animals, plants and environment.

# **NATIONAL BIOSAFETY MANAGEMENT AGENCY ACT, 2015**

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# NATIONAL BIOSAFETY MANAGEMENT AGENCY ACT, 2015

## A Bill

### For

**An Act to establish the National Biosafety Management Agency charged with the responsibility for providing regulatory framework, institutional and administrative mechanism for safety measures in the application of modern biotechnology in Nigeria with the view to preventing any adverse effect on human health, animals, plants and environment; and for related matters 2015**

{ } Commencement.

**ENACTED** by the National Assembly of the Federal Republic of Nigeria:

#### PART I- ESTABLISHMENT OF NATIONAL BIOSAFETY MANAGEMENT AGENCY

1. (1) There is established the National Biosafety Management Agency (in this Act referred to as the Agency) which:
  - (a) shall ensure the effective management of all component of the Nation's Biosafety;
  - (b) shall be a body corporate with perpetual succession and a common seal; and
  - (c) may sue and be sued in its corporate name.
- (2) The Agency shall be the national authority on Biosafety in Nigeria.
2. The objectives of the Agency shall be to:
  - (a) establish and strengthen the institutional arrangement on Biosafety matters in Nigeria;
  - (b) safeguard human health, biodiversity and the environment from any potential, adverse effect of genetically modified organism including food safety;
  - (c) ensure safety in the use of modern biotechnology and provide holistic approach to the regulation of genetically modified organisms;
  - (d) provide measures for the case by case assessment of genetically modified organisms and management of risk in order to ensure safety in the use of genetically modified organisms to human health and the environment;
  - (e) provide measures for effective public participation, public awareness and access to information in the use and application of modern

biotechnology and genetically modified organisms; and

- (f) ensure that the use of the genetically modified organisms does not have adverse impact on socio-economic and cultural interest either at the community or national level.

## PART II FUNCTIONS AND POWERS OF THE AGENCY

### 3. The Agency shall:

Functions and Powers of  
the Agency.

- (a) propose, for the approval of the Board, the overall policy guidance on issues of Biosafety in Nigeria;
- (b) implement the provisions of the Conventions and the Protocols on matters relating to genetically modified organisms;
- (c) render reports to the secretariat of the Convention on the implementation of the Convention and Protocol on matters relating to the use of genetically modified organisms;
- (d) develop measures and requirements and criteria for risk assessment peer review and decision making;
- (e) develop measures and requirements for risk assessment;
- (f) develop risk management plan and strategy for protecting human health, biological diversity and the environment from potential risks associated with genetically modified organisms;
- (g) accept and verify applications in respect of genetically modified organisms and keep records of all approvals and unapproved applications as contained in Part VIII, subsection 24 (1);
- (h) take samples and carry out laboratory analysis of crops, products or materials for purposes of determining if they contain genetically modified organisms and ensure compliance with this Act;
- (i) carry out actions necessary to ensure compliance with the legal obligations set out in this Act, including, but not limited to, the inspection of facilities, conduct research activities with genetically modified organisms covered by this Act, the collection and analysis of samples of materials covered by the Act, the monitoring of human health and the environment to determine the effects of genetically modified organisms regulated by the Act;

- (j) liaise with the secretariat of the convention and the Biosafety clearing house with respect to the administrative functions required under the Protocol;
- (k) carry out and maintain inventory of laboratories with physical and human capacities to conduct research in modern biotechnology;
- (l) monitor the activities of institutional committees and Biosafety officers;
- (m) build, equip and maintain offices and premises for the performance of its action under the Act;
- (n) pay remuneration, allowances, expenses and any other benefit to members of the Board and employees of the Agency or any other persons, in accordance with the National Salaries, Income and Wages Commission;
- (o) carry out capacity building activities;
- (p) perform other duties as may be necessary for the full discharge of its functions under this Act; and
- (q) partner with other relevant local and international agencies for the speedy realization of the Agency's mandate.

**PART III- STRUCTURE AND STAFF OF THE AGENCY**

- 4. The Agency shall have such Departments as it may deem appropriate. Structure of the Agency.
- 5. There shall be for the Agency a Director - General who shall: Appointment of Director General and staff of the Agency.
  - (a) be appointed by the President, Commander-in-Chief of the Armed Forces on the recommendation of the Minister;
  - (b) not be qualified for appointment as a Director-General unless he possesses outstanding qualifications and has at least 15 years cognate experience in the Management of Biodiversity, Biosafety or related field;
  - (c) be a holder of at least a Masters Degree in biological sciences or other related field;
  - (d) be the Chief Executive of the Agency and be responsible for:
    - i. the day to day administration of the Agency;
    - ii. the execution of the policies of the Agency; and

iii. Performing other functions as the Board or Minister may from time to time assign to him.

(e) hold office in the first instance for a term of 4 years and may be reappointed for another term of 4 years and no more.

6. Notwithstanding the provisions of section 5 of this Act, the Director-General may be removed from office by the President, Commander-in-Chief of the Armed forces:

Cessation or removal from office.

(a) for inability to discharge the functions of his office (whether arising from infirmity of mind or body or any other cause) or for misconduct;

(b) if the President is satisfied that it is not in the interest of the Agency or the public for him to continue in the office;

(c) if the Director-General resigns his appointment by a notice in writing under his hand addressed to the President.

7. The Agency shall appoint a Secretary and Legal Adviser, who shall be:

Appointment of Secretary and Legal Adviser of the Agency.

(a) a legal practitioner of not less than 10 years post-call experience;

(b) subject to the control and supervision of the Board and Director-General; and

(c) keeping the books and records, conducting the correspondence of the Board and performing such other duties as the Board or the Director-General may from time to time direct and without prejudice to the generality of the foregoing, the Secretary shall be responsible for:

(i) making arrangements for meetings of the Board;

(ii) preparing the agenda and minutes of meetings of the Board; and

(iii) such other functions as may be assigned to him by the Board and the Director-General.

8. The terms and conditions of service and remuneration of employees of the Agency shall be determined in line with the appropriate authorities.

Terms and condition of service.

9. The removal and discipline of staff shall be in accordance with existing Public Service Rules and Regulations.

Removal and discipline of staff.

#### PART IV - ESTABLISHMENT OF THE GOVERNING BOARD

10. (1) There is established for the Agency, a Board which shall consist of:

Establishment of the Governing Board and its composition.

(a) a Chairman who shall be appointed by the President, Commander-in-Chief of the Armed Forces;

(b) the Director-General of the Agency;

(c) a representative not below the rank of a Director, from each Federal Ministry responsible for:

(a) Environment;

(ii) Agriculture;

(iii) Science and Technology;

(iv) Trade and Investment;

(v) Health;

(vi) Nigeria Customs Service;

(vii) National Agency for Food and Drug Administration and Control (NAFDAC); and

(viii) National Biotechnology Development Agency (NABDA).

(d) one representative each of conservation Non-Governmental Organizations (NGOs) and organized private sector;

(e) one representative of the Biotechnology Society of Nigeria.

(2) All appointments in this section shall be made by the President, Commander-in- Chief of the Armed Forces.

(3) Membership of the Board is on part-time, except the office of the Director-General.

11. A member of the Board appointed, other than the Director-General, shall hold office for a term of 4 years, and subject to the provisions of this Act. Tenure.

12. (1) The office of a member of the Board shall become vacant if: Vacancy.

(a) he resigns as a member of the Board by notice in writing under his hand addressed to the President; and

(b) if it appears to the Board that a member of the Board other than an ex-officio member or Director-General should be removed from office on the grounds of misconduct or inability to perform the functions of his office, the Board shall make a recommendation to the President.

(2) Notwithstanding the provisions of subsection (1) of this section, the President may remove any member of the Board if he is satisfied that it is in the public interest to do so.



## PART V - FUNCTIONS AND POWERS OF THE BOARD

### 13. The Board shall:

Functions and Powers of the Board.

- (a) advise on the overall policy formulation of the Agency in particular with regard to financial, operational and administrative matters;
  - (b) establish committees as may be expedient and charged with specific functions;
  - (c) encourage and promote activities related to the functions of the Agency;
  - (d) carry out such other activities as may be directed by the President.
- (2) The Board shall have power to appoint for the Agency either directly or on secondment from any public or civil service of the Federal such number of employees as may, in the opinion of the Board, be required to assist the Agency in the discharge of any of its functions under this Act.

## PART VI- FINANCIAL PROVISIONS

### 14. The Agency shall establish and maintain a fund from which it shall defray all expenditures incurred.

Fund of the Agency.

#### (2) There shall be paid and credited to the fund:

- (a) annual budget allocation from the Federal Government;
- (b) such other sums as may be given to the Agency by the Federal government;
- (c) all moneys accruing to the Agency, including grants-in-aid, endowments and donations;
- (d) all charges, dues, fees or other amounts collected by the Agency; and
- (e) all interests on moneys invested by the Agency.

### 15. The Agency shall, when necessary, apply the funds at its disposal for the purpose of the Agency.

Expenditure of the Agency.

### 16. The Agency may borrow according to the provisions of the Debt management Act.

Power to borrow Act No 18 2003.

17. (1) The Agency may, subject to the provisions of this Act and conditions of any trust created in respect of any property, invest all or any of its funds in accordance with section 15 (1) of this Act. Power to invest.
- (2) The Agency may invest any of its surplus funds in such securities as may be permitted by law.
18. (1) The Agency may, accept gifts of land, money or other property or things from within and outside Nigeria, on such terms and conditions, if any as may be specified by person or organization offering the gift. Power to accept gift.
- (2) The Agency shall not accept any gift if the terms and conditions attached by person or organization offering the gift are inconsistent with its functions under the Act.
19. The Agency shall submit to the President, in accordance with the prescription in the annual budget cycle each year, its programme of work and estimates of its income and expenditure for the following year. Annual Estimates.
20. (1) The Director-General shall keep proper accounts of the Agency and proper records in relation and to those accounts. Account and Audit.
- (2) The accounts of the Agency shall be audited after the end of the year to which the audit relates, by auditors appointed by the Agency from among the list and in accordance with the guidelines supplied by the Auditor-General of the Federation.
21. The Agency shall prepare and submit to the President not later than 6 months after the end of the year a report, in such form as the President directs on the activities of the Agency during the immediate preceding year and shall include in the report a copy of the audited accounts of the Agency or that year and the auditor's report thereon. Annual Report.

## PART VII- REQUEST AND AUTHORISATION

22. As from the commencement of this Act, no person, institution or body shall import, export, transit, carry out the contained use, confined field trial, multi-locational trial without the approval or permit of the Agency. Import and Export Permit.
23. (1) Any person, institution or body who wishes to import, export, transit or otherwise carry out a contained field trial, multi-locational trial or commercial release of a genetically modified organism shall apply to the Director General of the Agency not less than 270 days to the date of import, export, transit or the commencement of such activity. Application of Import and Export Permit.
- (2) Any application under subsection (1) of this section shall include:
- (a) the information and data requirement that may be specified by the Agency in the regulations, guidelines, and policy documents;

- (b) a risk assessment report indicating the potential risk, if any that the genetically modified organisms may pose to human health including food safety, biological diversity or the environment including the consequence of unintentional releases;
- (c) the nature and identity of the genetically modified organisms involved in the activity being proposed to be carried out;
- (d) information relating to any release of the genetically modified organisms in Nigeria or elsewhere;
- (e) the nature and purpose of the activities including such activities as storage, transportation, production, culture and processing;
- (f) destruction, disposal or usage of the genetically modified organisms in any way whatsoever;
- (g) a management plan for remediation measures to be undertaken in the event of:
  - (i) any unintentional introduction into the environment of the genetically modified organisms from contained laboratory;
  - (ii) the escape or persistence in the environment of a genetically modified organisms from a confined field trial; and
  - (iii) any unintended consequence to the environment from the placing of genetically modified organisms in the market.
- (h) the place where, and the purpose for which the genetically modified organisms or the product is planned to be developed, used, kept, released or marketed including detailed instructions for use and a proposed labelling and packaging scheme in accordance with the First Schedule to this Act; and
- (i) a declaration to the effect that the information provided to correct including where appropriate, the undertaking from the origination of such information affirming its accuracy and completeness.

First Schedule

- (3) In all cases, the Agency shall set out requirements for each activity with genetically modified organisms to determine the level of potential risk posed by such category of activity in accordance with the second schedule to this Act.

Second Schedule.

- 24. (1) No person, institution or body shall import, export, transit or commercialize any genetically modified organism or a product intended for

Import or transit of products to be approved.

direct use as food or feed or for processing unless with the approval of the Agency.

- (2) Application under this section may only be granted upon completion of safety risk assessment to determine if there is not substantial risk that the genetically modified organism could be eaten by humans or animals.
- (3) Any person, institution or body that submits an application under this section for the commercial release of a genetically modified organism must ensure that the application addresses the socio-economic considerations set out in the Third Schedule to this Act.
- (4) The Agency shall consider such analysis in the risk or benefit assessment to determine whether it is to be approved or denied.
- (5) Review of the food safety assessment and the determination that the food is safe for human consumption shall be certified by the National Agency for Food, Drug Administration and Control.

Third Schedule.

- 25.
- (1) The Agency shall upon the receipt of the application and the accompanying information under section 23 of this Act, display copies of such application and relevant information at such places and for such period as the Agency may, from time to time determine to enable the general public and relevant government ministries and agencies study and make comments on the application and relevant information within 21 days.
  - (2) The Agency may, prior to the display, make announcement in at least 2 national and one local newspapers, the national Biosafety clearing house or such other news media as the Agency may from time to time determine, giving summary of the application and brief information on the place, duration and time for the display.

Public display of application.

- 26.
- (1) The Agency may, in addition to the comment received pursuant to section 23 of this Act, hold public hearings or consultations to obtain further comments and inputs that will assist in the review or processing of the application.
  - (2) Notwithstanding any other provisions in this Act the Agency shall not disclose any confidential business information submitted by any person, institution or body to the Agency under this Act.
  - (3) To determine if any information identified by an applicant qualifies as confidential business information that cannot be disclosed to the public the Agency shall ascertain that:
    - (a) the information has not previously been released to the public anywhere in the world;

Public Hearings.

- (b) the applicant has shown that it has taken steps to prevent the release of such information;
- (c) release of the information would be detrimental to the applicant; and
- (d) the information is not required to be released under section 23 of this Act.

27. The following information shall not be considered confidential business information and can be disclosed to the public: Disclosable information.

- (a) the name and address of the applicant;
- (b) a general description of the genetically modified organism;
- (c) a summary of the risks assessment for the genetically modified organisms;
- (d) any scientific data that specifically addresses potential environmental or food risk from genetically modified organisms and any method; and
- (e) plans for emergency response.

28. With respect to any decision taken under section 23 of this Act, the Agency: Procedure for granting approval.

- (a) shall take into consideration, the relevant comments, inputs or concerns of the public received under the provisions of this Act;
- (b) shall notify the applicant in writing and the Biosafety clearing house of the decision and information, facts and analysis supporting the decision;
- (c) shall notify the public of any genetically modified organism for which approval or permit has been granted for import, contained use, confined field trials, multi-locational trials or commercial release and provide the information, facts and analysis supporting the decision;
- (d) may specify the steps to be taken in the implementation of the risk management plan where there are potential risk to human health, animal, plant and the environment.
- (e) may in respect of any approval for import, transit, contained use, confined field trial, multi-locational trials or commercial release of any genetically modified organisms, direct the applicant to carry out monitoring and evaluation of risk for a specified period equivalent to the life cycle of the relevant species or for such period as the Director General may, from time to time, determine;

- (f) impose any additional measure for risk management as provided in this Act;
- (g) do such other things as take such other steps as he may consider necessary and expedient for carrying into effect this decision.

29. The Agency may:

Revocation and review of application.

- (a) revoke or suspend the approval or permit or otherwise review any decision taken under section 23 of this Act if it is of the opinion that there is new information to the effect that the genetically modified organisms or its products is capable of having adverse effect on human health, animal, plant or the environment; and
- (b) review the refusal of an application if there is new and relevant information.

30. (1) Any applicant who is aggrieved by any decision of the Agency under sections 24 and 25 of this Act may appeal to the Board to reconsider that decision, stating his grounds of appeal, including any additional information.

Appeal by the applicant.

(2) Any applicant who is not satisfied with the decision of the Minister may apply to the Federal High Court for a review of the decision.

#### PART VII - RISK ASSESSMENT AND MANAGEMENT

31. (1) Every applicant seeking approval for any genetically modified organism under this Act shall, prior to the submission of the application, carry out a mandatory risk assessment of the potential risk the genetically modified organisms poses to human health, animal, plant or the environment in Nigeria.

MandatoryRiskAssesment.

(2) The risk assessment mentioned in subsection (1) of this section shall be carried out in Nigeria and in accordance with policies and guidelines set forth by the Agency and under the Third Schedule to this Act.

(3) Without prejudice to subsections (1) and (2) of this section, the Agency may constitute a National Biosafety Committee (NBC) to carry out risk assessment of any genetically modified organism under this Act.

(4) Where the National Biosafety Committee (NBC) carries out the risk assessment, the Agency may direct that such applicant bears the cost of carrying out the risk assessment notwithstanding that the applicant has previously carried out his own risk assessment.

32. No person, shall be involved in a risk assessment review by the Agency in

Conflict of interest.

respect of a subject matter in which:

- (a) he has direct or indirect interest of any kind; or
- (b) there is likely to be conflict of interest as a result of his participation in the risk assessment process.

33. Every person, institution or body that carries out any activity relating to genetically modified organisms shall develop and maintain a risk management plan and strategy in accordance with the provisions of the Forth Schedule to this Act.

Risk management plan and strategy.

34. The Agency may impose additional measures for management of risks associated with any genetically modified organisms and without prejudice to the generality of the foregoing, may:

Additional measure for risk management.

- (a) direct that any genetically modified organisms undergo a period of observation commensurate with the life cycle or generation time, at the cost of the applicant before or after such genetically modified organism is certified for usage;
- (b) prohibit the import transit, contained use, release or placing on the market of any genetically modified organism if it contains characteristics or specific traits which pose significant risk to human health, animal, plant and the environment;
- (c) require any person, institution or body responsible for any activity relating to genetically modified organisms to take such measures as may be necessary, from time to time, to prevent or limit any human health animal, plant or the environment;
- (d) direct any applicant under section 24 of this Act to submit periodic report of the monitoring and evaluation of risk carried out after the approval or permit granted under this Act; and
- (e) undertake any measure, as may be reasonably necessary to avert risk or danger to human health, animal, plant and the environment where the person responsible for such action fails to act and the person so responsible shall bear the cost of any measure taken;

#### PART IX - OFFENCES, PENALTIES AND ENFORCEMENT

35. (1) Any person, institution or body who:

Offences and Penalties.

- (a) imports, export transit or otherwise carries out the activity

of contained use or commercial release of any genetically modified organisms without a prior approval or permit of the Agency; or

(b) contravenes the conditions of the grant of an approval or permit under this Act, commits an offence and shall be liable on conviction:

(i) in the case of an individual, to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both such fine and imprisonment; or

(ii) in the case of a body corporate to a fine of not less than N5,000,000 and, in addition, the directors or officers of the body corporate shall each be liable to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both such fine and imprisonment.

(2) For the purpose of section 24 (1) of this Act, any applicant who:

(a) becomes aware, after the grant of approval or permit to him, of any new information which indicates that the genetically modified organism poses possible risk to human health, animal, plant or the environment and fails to give such information to the Agency; and

(b) gives any false information purporting to be new information that suggest that the genetically modified organisms in respect of which approval or permit was refused has not adverse effect on human health, animal, plant or the environment,

commits an offence under this Act and shall on conviction be liable to:

(i) in the case of an individual, to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both such fine and imprisonment; or

(ii) in the case of a body corporate to a fine of not less than N5,000,000.00 and in addition, the directors or officers of the body corporate shall each be liable to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 5 years or both fine and imprisonment.

36. Any person, institution or body who submits or supplies false information in respect of any activity relating to genetically modified organism under this Act commits an offence and shall be liable on conviction:

False Information.

(a) in the case of an individual, to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 3 years or both such fine and imprisonment; or



(b) in the case of a body corporate, to a fine of not less than N5,000,000.00.

37. Any person who obstructs an authorized officer in the course of his duties under this Act, commits an offence and is liable on conviction to a fine of not less than N2,500,000.00 or imprisonment for a term of not less than 3 years or both such fine and imprisonment. Obstruction of officer.
38. (1) Any person who contravenes any provision of this Act for which no specific penalty is specified, commits an offence and is liable on conviction to a fine of not less than N2,500,000.00 or imprisonment for a term not exceeding 3 years or both such fine and imprisonment. Penalty where it is not specified under the Act.
- (2) Notwithstanding the punishments provided under section 36, 37 and 38 of this section, the Agency shall, in addition, revoke the permit granted to the individual or institution or body.
39. The Agency shall have powers to: Powers of enforcement..
- (a) in company of a Law Enforcement Officer, enter the premises, facility, laboratory, field, farm or other place, institutions or bodies covered by this Act to take action necessary to determine compliance with the Act;
  - (b) conduct, monitor and assess the impact of genetically modified organisms covered by the Act on human health, animal, plant or the environment;
  - (c) take other actions that include, but not limited to review and copy documents collecting samples, data interview individuals and seizing genetically modified organisms; and
  - (d) in addition to paragraphs (a), (b) and (c) of this section, seal or close down any facility, Confined Field Trials (CFT) sites, farms and laboratories.
40. (1) The Federal High Court shall have jurisdiction to try offences under this Act. Jurisdiction.
- (2) The Court may, in addition to the penalties provided under this Act, order the forfeiture of any specimen, genetically modified organisms, or any genetic material, asset, other materials or anything in connection with commission of an offence under this Act.
- (3) Without prejudice to subsection (2) of this section, the Court may order that:
- (a) premises, laboratory, facility, field, farm or any place be sealed up for such period as be specified in such order; or

(b) remediation measures be undertaken by the offender.

## PART X- MISCELLANEOUS PROVISIONS

41. (1) The Board may, on the recommendation of the management of the Agency, make regulations generally for carrying into effect the provisions of this Act, and in particular, handling, transporting, packaging; fault-based liability and redress for damages from the activities of modern biotechnology and genetically modified organisms. Regulations.

(2) Liability and Redress for a damage that occurs as a result of an activity under this ACT is subject to applicable laws.

(3) Without prejudice to the generality of the provisions of subsection (1) of this section, the Agency may provide safety standards, guidelines and rules on:

- (a) public participation processes and procedures;
- (b) risk assessment and risk management;
- (c) laboratories and relevant equipments relating to genetically modified organisms;
- (d) identification or labeling of genetically modified organisms; and
- (e) fees and charges payable by applicants for any activities of the Agency under this Act.

42. The Agency may: Power to own property.

- (a) purchase, hold, take on lease or dispose of any interest in land, building or property;
- (b) build, equip and maintain offices and premises for the performance of its action under the Act;

43. In this Act: Interpretation.

“Agency” means National Biosafety Management Agency establishment under section 1 (1) of this Act;

“Appropriate authority” includes the National Salaries Incomes and Wages Commission”;

“Biosafety Clearing House” means a pool of information mechanism established under Article 20 of the Protocol for exchange of scientific, technical, environment and legal information on and experience with genetically modified organisms, as part of the clearing house mechanism under Article 18 of the Convention;

“Biosafety” means the application of measures, policies, knowledge, techniques, equipment and procedures for minimizing potential risks that modern biotechnology may pose to the environment and human health;

“Board” means the National Biosafety Management Agency Governing Board

established under Section 11 (1) of this Act;

“Committee” means the National Biosafety Committee referred to under Section 32 (3) of this Act;

“Contained use” means any operation using modern biotechnology undertaken within a facility, installation or other physical structure, such as a building, laboratory or greenhouse;

“confidential business information” consist of trade secrets and other proprietary information of commercial value;

“confined field trial” means a small scale experimental release into the environment of a genetically modified organism under physical and biological confinement conditions that limit the genetically modified organism's persistence in the environment after the experiment is completed;

“commercial release” means the release of genetically modified organism into the market as a product that can be purchased and use by any individual, such as a genetically engineered seed or animal;

“Conservation” means the protection of maintenance of nature while allowing for its ecologically sustainable use;

“convention” means the Convention on Biological Diversity;

“Court” means the Federal High Court;

“food and feed product” means a genetically modified organism or its product that is used for food, feed or processing and is primarily intended for consumption by humans or animals or for the consumption of both humans and animals;

“genetic material” means any part of a plant or animal or microbial containing functional units of the heredity;

“genetically modified organisms” means any organism living or non living that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

“modern biotechnology” means the application:

- (a) in-vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (rDNA) and direct injection of nucleic acid into cells or organelles; or
- (b) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and

selection;

“member” means a member of the committee and includes the Chairman;

“Minister” means Minister in charge of Environment;

“Director-General” means Chief Executive Officer of the Agency;

“Protocol” means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;

“products” means processed materials that are of genetically modified origin containing detectable novel combination of replicable genetic material obtained through the use of modern biotechnology;

“Institutional Biosafety Officer” means officer who is knowledgeable in Biosafety and has a degree in any of the biological science that is, Medical Science, Zoology, Genetic, Microbiology, Biochemistry, Veterinary Medicine, Animal Science, Soil Science, Agronomy or Plant Science (Botanist) and Ecology and appointed by the Institute dealing with Modern biotechnology for the purpose of ensuring compliance with the provisions of this Act.

44. This Act may be cited as the National Biosafety Management Agency Act, 2015.

Citation.

## ADDITIONAL INFORMATION REQUIRED IN THE CASE OF NOTIFICATION FOR PLACING ON THE MARKET

1. The following information shall be provided in the notification for placing on the market of products:
  - (a) name of the product and names of genetically modified organisms from which they were made;
  - (b) name of the manufacturer or distributor and his address, including the address in the country;
  - (c) specificity of the product, exact conditions of use including; when appropriate, the type of environment or of the geographical areas of the country for which the product is suited; and
  - (d) proposed packaging which must be appropriate so as to avoid unintended release of the genetically modified products.
  
2. The following additional information shall be provided when required or relevant:
  - (a) measures to take in case of unintended release of misuse;
  - (b) specific instructions or recommendations for storage and handling;
  - (c) estimated production in or imports to the country;
  - (d) propose packaging when must be appropriate so as to avoid unintended release of the genetically modified organisms;
  - (e) proposed labeling which must include at least in summarized form, the information referred to in paragraphs 1, 2, and 3 of this Schedule.
  
3. The following information concerning labelling of product shall be provided on a label or in accompanying documents:
  - (a) the words “This product contains genetically modified organisms” wherever there is evidence of the presence of genetically modified organisms;
  - (b) the words “This product may contain genetically modified organisms” where the presence of genetically modified organisms in a product cannot be excluded but there is no evidence of any presence of genetically modified organisms;
  - (c) the words “this product may cause reactions, allergies or other side-effects” where it is known that a particular reaction, allergy or other side effect may be caused by the product;
  - (d) where applicable, further or as a qualification to subparagraph (c) of this paragraph, the words “this product contains genetic material (nucleic acids); and
  - (e) genetically modified organisms or “this product is based on raw materials from genetically modified organisms.

## REQUIREMENT OF INFORMATION TO BE CONTAINED IN THE APPLICATION FOR APPROVAL OR PERMIT

## PART A - GENERAL INFORMATION

- (1) Name, address, telephone, fax, website or e-mail of applicant;
- (2) Information on personnel and training which shall include qualifications and training of persons who shall be responsible for planning and carrying out the implementation of the project, including those responsible for supervision, monitoring and evaluation of the safety measures.

## PART B - INFORMATION RELATING TO GENETICALLY MODIFIED ORGANISMS OR THE PRODUCTS

1. Characteristics of the donor, the recipient or where appropriate, the parental organism Scientific name;
2. Additional taxonomic information;
3. Other names (usual name, strain name, cultivar name, transformation event, unique identification code (where applicable) etc);
4. Phenotypic and genetic markers;
5. Degree of relatedness between donor and recipient or between parental organisms;
6. 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;
7. Potential for genetic transfer and exchange with other organisms;
8. 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;
9. Pathological, ecological and physiological traits which shall include:
  - (a) classification of hazard according to existing national rules concerning the protection of human health and the environment;
  - (b) generation time in natural ecosystems, sexual and asexual reproductive cycle;
  - (c) information on survival, including seasonality and ability to form survival structures (for example, seeds, spores or sclerotic);
  - (d) pathogenicity, infectivity, toxigenicity, 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;
  - (e) antibiotic resistance and potential use of these antibiotics in humans and domestic animals for prophylaxis and therapy; and
  - (f) involvement in environmental processes, primary production nutrient turnover, decomposition of organic matter, respiration, etc.

**Characteristics of the vector:**

- (a) Nature and source of the vector;
- (b) sequence of transposons, 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.

### **Characteristics of Genetically Modified Organisms or Product**

Information relating to the genetic modification that is:

- (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;

### **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;
  - a. Communicability;
  - b. Infective dose;
  - c. Host range, possibility of alteration;
  - d. Possibility of survival outside of human;
  - e. Presence of vectors or means of dissemination;
  - f. 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**

**Information on the Release**

- 1) Description of the proposed deliberate release, including the purposes and foreseen products;
- 2) Foreseen dates of the release and time planning of the experiment including frequency and duration of releases;
- 3) Preparation of the site previous to the release;
- 4) Size of the site;
- 5) Methods to be used for the release;
- 6) Quantities of genetically modified organisms;
- 7) Disturbance on the site (type and method of cultivation, mining; litigation or other activities);
- 8) Worker protection measures to be taken during the release;
- 9) Post release treatment of the site;
- 10) Techniques foresee for elimination or inactivation of the genetically modified organisms or products , at the end of the experiments;
- 11) 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.

**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):

1. 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);
2. Physical or biological proximity to humans and other significant biota;
3. Proximity to significant biotopes or protected areas;
4. Size of local human population;
5. Economic activities of local populations which are based on the natural resources of the area;
6. Distance to closes areas protected for drinking water and environmental purposes;
7. Climatic characteristics of the region(s) likely to be affected;
8. Geographical, geological and pedological characteristics;
9. Flora and fauna, including crops, livestock and migratory species;



10. Description of target and non-target ecosystems likely to be affected;
11. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release;
12. 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

##### **Characteristics and Factors affecting survival Multiplication, Gene Expression and Dissemination**

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

##### **Interactions with the environment**

4. Predicted habitat of the genetically modified organisms;
5. 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.
6. Genetic transfer capability, that is:
  - (a) post-release transfer of genetic material from genetically modified organisms or products organisms;
  - (b) post-release transfer of genetic material from indigenous organisms of the genetically modified organisms or product .
7. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the genetically modified organisms or products .
8. Measures employed to ensure and to verify genetic stability, Description of genetic traits which may prevent or minimize dispersal of genetic material.
9. Methods to verify stability.
10. Routes of biological dispersal, known or potential modes of interaction with the disseminating agent including inhalation, ingestion, surface contact, burrowing etc.
  - (a) Description of ecosystem to which the genetically modified organism or products could be disseminated;
  - (b) or excessive population increase in the environment;
  - (c) Competitive advantage of the genetically modified organism or products in relation to the unmodified recipient or parental organism;
  - (d) Identification and description of non-target organisms;
  - (e) Anticipation mechanisms and result of interaction between the released genetically modified organism or product and the target organism;
  - (f) Identification and description of non-target organism which may be affected directly;
  - (g) Likelihood of post-release shifts in biological or host range;
  - (h) Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, host symbionts, predators,

- parasites and pathogens;
- (i) Known or predicted involvement on bio-geochemical processes;
- (j) (j) Other potentially significant interactions with the environment.

## **PART E - INFORMATION ON MONITORING, CONTROL, WASTES TREATMENT AND EMERGENCY RESPONSE PLANS**

### **Monitoring Techniques**

11. Methods for tracing the genetically modified organisms or products and of monitoring their effects;
12. 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.
13. Techniques for detecting transfer of the donated genetic material to other organisms.
14. Methods to detect aberrant gene expression.

### **Control of the Release**

15. Methods and procedures to avoid or minimize the spread of the genetically modified organisms or products theirbeyond the site of release or the designated area for use.
16. Methods and procedures to protect the site from intrusion by unauthorized individuals.
17. Methods and procedures to prevent other organisms from entering the site.

### **Wastes Treatment**

18. Type of waste generated.
19. Expected amount of waste.
20. Possible risk.
21. Description of treatment envisaged.

### **Emergency Response Plan**

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

## RISK ASSESSMENT PARAMETERS

The user or applicant in respect of genetically modified organisms shall carry out an assessment prior to use or release of genetically modified organisms or products as regards the risks to human, animal health, biological diversity, the environment and the socio-economic welfare of societies and its assessments shall take the following parameters into consideration including any other parameter seemed to be relevant in the circumstances).

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.

### **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-coding 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 pathogenicity 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.

### **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 transgeneric 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. Allergenicity, 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.

### **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.

### **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.

### **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) Allergenicity;
  - (i) Availability of appropriate therapies.

### **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.

### **Socio-economic consideration**

79. Anticipated changes in the existing social and economic patterns resulting from the introduction of the genetically modified organism or products .

80. Possible threats 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. 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 .

## RISK MANAGEMENT PLANS

1. The user shall employ the following risk management plans and procedures from the development, through all stages of testing of the genetically modified organism or the product, to its intended use or commercialization. Imported products of genetically modified organisms used for human or animal health (for example, antibiotics, drugs and hormones):

- (a) observation to ensure that changes in food habits, nutrition and other factors that could conceivably modify the expected impacts are insignificant; and
- (b) such observation in subparagraph (a) of this paragraph can be limited in scope when it is shown that adequate trials on the specific products have been made on humans or animals, as appropriate, in areas other than the country of import.

2. Imported microbial genetically modified organisms for human health:

Besides the limited observation specified in paragraph 1 of this schedule, experiments shall be carried out to evaluate viability and risk of reacquiring virulence or lending virulence to other microorganisms when in the body and in the environment, since some spilling is inevitable.

3. Imported genetically modified organism for contained use:

- (a) The products of genetically modified organisms and packaging will be treated as in paragraph 1 of this schedule;
- (b) Experiments will be made in complete laboratory containment to determine:
  - (i) longevity of the genetically modified organism in cases of unintended releases should be specified;
  - (ii) methods for counteracting adverse impacts resulting from unintended releases should be specified; and
- (c) methods for counteracting adverse impacts from the releases of genetically modified organisms resulting from unintended releases should be specified.

4. Where products of genetically modified organism are made:

- (a) locally, trials on experimental animals shall be made when the product of the genetically modified organism is intended to be used on humans; and
- (b) in all other cases, trials shall be made on species for which the product of the genetically modified organism has been designed.

5. Where genetically modified organism are made locally for use as vaccines for humans or animals there shall be:

- (a) initial molecular, tissue culture, serological laboratory in complete containment;
- (b) trials with experimental animals under strict containment;
- (c) Experiments in complete containment to evaluate the extent of transfer of the

gene of vector introduced or other genes through the agency of the vector to the

genetically modified organism or to other species which will be found in association with the genetically modified organisms to ensure that virulence is not acquired by the genetically modified organism in question or by other micro-organisms;

- (d) Trials on animals completely contained from their species and from related species and species known to be susceptible to the gene recipient micro-organism from which the genetically modified organisms has been made; and
- (e) Statistically valid trials in conditions in which the vaccinated individuals live in their communities.

6. Where plants or microbial genetically modified organisms are imported for release:

- (a) the reports from releases in areas other than the country of import shall be thoroughly evaluated by the National Biosafety Committee and particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;
- (b) in the case of inadequacy of the regulations mentioned in sub-paragraph (a) of this paragraph, the National Biosafety Committee shall decide what step to take and which step of the observations should be applicable;
- (c) and if it is found that the previous release mechanism have been rigorous enough, observations shall be made in experimental conditions completely contained from the outside environment, but others kept at the same soil community, moisture, air, temperature and plant and animal community conditions as the intended area of release;
- (d) the observation shall include the health of the genetically modified organism, the health of the organism within the area of limited release. And the biological diversity and the ecology of the area; and
- (e) Nationally approved limited field release shall be carried out with appropriate emergency procedures in place to deal with possible cases of escape.

7. Where genetically modified animal are imported for release:

- (a) the reports from releases in areas other than the country of import shall be thoroughly evaluated by the national Biosafety Committee and particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate in ensuring safety;
- (b) if the regulations mentioned in sub-paragraph (a) of this paragraph have not been adequate, the National Biosafety Committee may decide which step of the observations should commence;
- (c) if it is decided that the regulations sued in the previous release have been rigorous enough, then the observation will be made in complete containment in the expected ambient climatic, nutritional and other environmental conditions to monitor physiological functions, adaptations and gene transfers; and
- (d) when the results have met the stated requirements, then a trial release may be authorized with adequate emergency plants put in place to deal with cases of escape.

8. Where plant or microbial genetically modified organisms are for eventual release:



- (a) laboratory bio-molecular experiments on transformation or resuscitation and other phenomena shall be carried out in complete containment;
- (b) Tissue culture experiments to develop the genetically modified organisms. When required shall be carried out in complete containment;
- (c) Observations aimed at understanding the nature of the genetically modified organism shall be carried out in complete containment;
- (d) Experiments with the soil, soil micro-organisms, plant and animal species, under the environmental conditions of the areas of intended release shall be carried out in complete containment;
- (e) Complete observation of the genetically modified organisms with the environment (soil including micro-organisms and terrestrial communities) shall be made in enclosed fields but not fully contained. At the end of the experiment, the products of the genetically modified organism may be used on an experimental basis, otherwise they shall be destroyed;
- (f) the product from the genetically modified organisms shall be subjected to the procedure in paragraph 4 of this schedule;
- (g) the monitoring of the spread and behaviors of any released genetically modified plant or micro-organism shall continue for at least 150 years in the case of trees, and for at least 30 years in the case of animals and micro-organisms. The duration for perennial, which live shorter than trees, may be between 30 - 50 years. The user who was responsible for releasing the genetically modified organism or its successor shall provide annual reports to the Minister through the National Biodiversity Management Agency.

9. Where animal genetically modified organism are produced locally for eventual release:

- (a) laboratory bio-molecular experiments on transformation (or resuscitation if it is possible) and other phenomena will be carried out in complete contained;
- (b) methods of incubating the transformed generative cell or the resuscitated animal shall be carried out under complete containment;
- (c) the rearing of and observations on the genetically modified organisms shall be carried out under complete containment;
- (d) the genetically modified organisms shall be observed under complete containment in an experimental environment which simulates the intended area of release in climatic microbial, animal and plant communities. The observations shall include the condition of the transgenic animal and those of its microorganisms especially in the context of gene transfer and those of the microbia” plant and animal communities in the experimental including gene transfer;
- (e) a limited release shall be carried out in an area with appropriate enclosure and emergency measures shall be put in place to prevent escape. Observations shall include the condition of the genetically modified organisms, its micro-organisms focusing on gene transfer and the ecology of the microbial, plant and animal communities in the area including gene transfer;
- (f) if the animal is intended to yield a product, the regulation of the product shall follow the procedure in paragraph 4 of this Schedule;
- (g) the monitoring of the spread and behavior of any released animals genetically modified organism shall continue for at least 30 years.

10. General requirements with respect to risk management shall be as follows that is:

- (a) all trials experiments or observations specified in this Schedule shall be put in their logical sequence and shall be subjected to the hierarchical procedures of approval by the institutional Biosafety Committees or the respective National Biosafety Technical Sub-Committee and the National Biosafety Committee;
- (b) experiments starting from transformation of living organisms or resuscitation of fossil organisms carried out under completely contained laboratory conditions and continuing in the development of genetically modified organisms or products shall be subjected to the approval by the respective Institutional Biosafety Committee or the International Biosafety Committee as the case may be;
- (c) all experiments outside the strict laboratory isolations and initial experiments involving imported genetically modified organisms or products shall be subject to approval of the national Biosafety Committee;
- (d) all final approvals for the use of genetically modified organisms shall be made by the Agency upon the recommendation of the National Biosafety Committee;
- (e) any disposal of the genetically modified organisms or the products upon the completion of every trial or experiment, shall be made through complete incineration or other approved disposal by the National Biosafety Committee.

I, CERTIFY, IN ACCORDANCE WITH SECTION 2 (1) OF THE ACTS AUTHENTICATION ACT CAP. A2, LAWS OF THE FEDERATION OF NIGERIA 2004, THAT THIS IS A TRUE COPY OF THIS BILL PASSED BY BOTH HOUSES OF THE NATIONAL ASSEMBLY.




SALISU ABUBAKAR MAIKASUWA, OON, mni  
CLERK TO THE NATIONAL ASSEMBLY


14<sup>th</sup> DAY OF APRIL, 2015

**Schedule to National Biosafety Management Agency Bill, 2015**

SHORT TITLE OF THE BILL	LONG TITLE OF THE BILL	SUMMARY OF THE CONTENTS OF THE BILL	DATE PASSED BY THE SENATE	DATE PASSED BY THE HOUSE OF REPRESENTATIVES
National Biosafety Management Agency Bill, 2015	An Act to establish the National Biosafety Management Agency charged with the responsibility for providing regulatory framework, institutional and administrative mechanism for safety measures in the application of modern biotechnology in Nigeria with a view to preventing any adverse effect on human health, animals, plants and environment; and for related matters.	This Bill establishes the National Biosafety Management Agency charged with the responsibility for providing regulatory framework, institutional and administrative mechanism for safety measures in the application of modern biotechnology in Nigeria with the view to preventing any adverse effect on human health, animals, plants and environment.	12 <sup>th</sup> March, 2015	12 <sup>th</sup> March, 2015

I certify that this Bill has been carefully compared by me with the decision reached by the National Assembly and found by me to be true and correct decision of the Houses and is in accordance with the provisions of the Acts Authentication Act Cap. A2, Laws of the Federation of Nigeria, 2004.

  
**SALISU MAIKASUWA, OON mni**  
 Clerk to the National Assembly  
 12<sup>th</sup> Day of April, 2015

  
**DR. GOODLUCK EBELE JONATHAN, GCFR**  
 President of the Federal Republic of Nigeria  
 12<sup>th</sup> Day of April, 2015

I ASSENT