

NIGERIA BIOSAFETY BILL 2006

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A BILL

Commencement.

FOR

AN ACT TO PROVIDE FOR THE BIOSAFETY REGULATORY FRAMEWORK AND INSTITUTIONAL ARRANGEMENTS TO REGULATE MODERN BIOTECHNOLOGY AND GENETICALLY MODIFIED ORGANISMS IN NIGERIA AND FOR MATTERS CONNECTED THEREWITH

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WHEREAS modern biotechnology may have the capacity for being used as a means of improving human well-being, its potential adverse effects on human health, biological diversity and the environment in general are causing growing concerns to the general public and scientific community;

WHEREAS the Convention on Biological Diversity to which Nigeria is a signatory and has ratified (**same**), makes it the duty of Contracting Parties to establish and maintain the means to regulate and control the risks derived from the use and release of genetically modified organisms as a result of modern biotechnology;

WHEREAS the Cartagena Protocol on Biosafety to the Convention on Biological Diversity to which Nigeria has signed and ratified (**same**) (in this Act referred to as “the Protocol”) enjoins each Party to take appropriate legal (**action and**) administrative measures to regulate the development, handling, transport, use, transfer and release and other measures to regulate the transboundary movement of Genetically Modified Organisms;

WHEREAS Nigeria acknowledges the need to ensure the safe use of modern biotechnology activities, including the import, contained use, confined field trials, and commercial release of genetically modified organisms;

NOW THEREFORE BE IT ENACTED by the National Assembly of the Federal Republic of Nigeria as follows -

PART I - SCOPE AND OBJECTIVES

1. The objectives of the Act shall be -

Objectives of the Act.

- (a) to ensure safety in the use of modern biotechnology;
- (b) to safeguard human health and the environment from any potential adverse effects of genetically modified organisms; including food safety;
- (c) to establish and strengthen institutional arrangements on biosafety in Nigeria;
- (d) provide holistic approach to the regulation of Genetically Modified Organisms to avoid risks based on the precautionary principle
- (e) provide measures for the case-by-case assessment of genetically modified organisms and management of risks in order to ensure safety in the use of genetically modified organisms to human health and the environment

(f) to provide measures for effective public participation, public awareness, access to information and consensus building in the use and application of modern biotechnology and genetically modified organisms; and

(g) to ensure that the use of or genetically modified organisms does not have adverse impact on socio-economic and cultural interests either at the community or national levels

2. The general principles guiding the operation of this Act shall be

Guiding principles.

(a) the precautionary principle; and

(b) regulatory costs shall be borne by the applicants .

3. (a) This Act shall apply to the import, export, transit, contained use, confined field trials, pre-commercial and commercial release, of any genetically modified organisms whether intended for release into the environment, for use as a pharmaceutical, or for food, feed or processing

Application, etc.

(b) Notwithstanding the provisions of subsection (1) of this section, this Act shall not apply to any genetically modified organism as the Minister may, **[from time to time, on the advice of the NBC, and such exemption shall be]** by an Order published in the *Federal Gazette* and on the advice of the National Biosafety Council, exempt from time to time.

(c) In making such an order for exemption of certain genetically modified organisms **[herein after called GMO]** or their products, the public participation mechanism would be used involving scientific hearings, prior to determination.

(d) The food safety and environmental risks assessment for the particular GMO including an analysis of the different products that might be produced from the GMO and whether those products might pose any environmental or food safety risks must be carried out by the applicant.

PART II - INSTITUTIONAL ARRANGEMENTS

National Focal Point and National Competent Authority

4. (a) The National Biosafety Agency herein after called The Agency of the Federal Ministry of Environment is hereby designated as the National Focal Point and National Competent Authority on biosafety in Nigeria

Designation of a national focal point

(b) there shall be appointed a Registrar for the Agency who will be the Chief Executive and be responsible for the administrative functions of the Agency and reporting to the Honourable Minister of Environment

(c)The National Biosafety Agency shall act through the Minister with responsibility for matters relating to environment and biodiversity conservation in Nigeria and any reference to the Minister in this Act shall also mean the national focal point.

(d)*The Agency* shall be responsible

for exercising the duties as set out, in this Act, liaise with the Secretariat of the Convention on Biological Diversity (CBD), for

the performance of administrative functions required under the Cartagena Protocol on Biosafety and shall be responsible for all correspondence with importers exporters and applicants on movement and use of products of modern biotechnology (GMOs).

5. The Agency shall -

Functions of the Agency.

- (a) provide the overall policy guidance on issues of biosafety in Nigeria;
- (b) implement the provisions of the Convention and the Protocol on matters relating to genetically modified organisms;
- (c) render reports to the secretariat of the Convention on the implementation of the Convention and the Protocol on matters relating to use of genetically modified organisms; develop measures and requirements for risk assessment; environmental impact assessments and assessments of socio-economic impacts;
- (d) develop measures, requirements and criteria for risk evaluation, peer review and decision-making;
- (e) develop measures and requirements for risk assessment; environmental impact assessments and assessments of socio-economic impacts;
- (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) approve applications in respect of genetically modified organisms; and keep records of all approvals made and non approved applications
- (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 forth in this Act, including but not limited to the inspection of facilities conducting activities with GMOs covered by the 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 GMOs regulated by the Act , and the initiation of legal actions against violators of 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) appoint Biosafety Enforcement Officers for the purposes of enforcement of the provisions of this Act,

- (l) carry out and maintain inventory of laboratories with physical and human capacities to conduct research in modern biotechnology;
- (m) monitor the activities of institutional committees and biosafety officers;
- (n) carry out such other duties as may be necessary for the full discharge of its functions under this Act;
- (o) shall carry out public awareness and enlightenment programmes in Biosafety
- (p) carry out capacity building activities.

6. *Staff of the Agency*

6. (a) (1) There shall be for the Agency a Registrar of a rank equivalent to a Director-General in the public service of the Federation, who shall be the chief executive of the Agency and be appointed by the President Commander-in-Chief of the Armed Forces on the recommendation of the Minister.

Registrar of the Agency

- (2) The Registrar shall hold office for a term of five years in the first instance on such terms and conditions as the President Commander-in-Chief of the Armed Forces may on the recommendation of the Minister determine and may be re-appointed for one further term of five years and no more.
- (3) Subject to such general direction as the Council may give, the Secretary shall be responsible for the day-to-day administration of the Agency and the implementation of the decisions of the National Biosafety Council.
- (4) The Registrar shall perform the functions of keeping the record of proceedings decisions of the council and such other functions as the council may, from time to time, direct.

6. (b) (1) The Agency shall have power to appoint either on transfer, new staff or on secondment from any public service in the Federation. Such number of employees as may in the opinion of the Council be required to assist the Agency the discharge of any of its functions under this Decree: and shall have power to pay the persons so employed such remuneration (including allowances as the Council may determine

Other staff of the Agency

(2) The terms and conditions of service (including terms and conditions as to remuneration, allowances, pensions, gratuities and other benefits) of the persons employed by the Agency shall be as determined by the council from time to time.

(3) The Agency may engage such consultants and advisers as it may required for the proper and efficient discharge of the functions of the Agency.

***National
Biosafety
Council***

6. (c) The Agency may subject to the provision of this Act make Staff regulations relating generally to the conditions of service of the Employees of the Agency and without prejudice to the generality of the foregoing, such regulations may provide for –

- (i) the appointment, promotion and disciplinary control (including dismissal) of employees of the Agency
- (ii) appeals by such employees against dismissal or other disciplinary measures.

6. (d) The Agency shall determine its conditions of service including pensions and gratuities as appropriate for its employees.

6. (e) (1) It is hereby declared that service in the Agency is a schedule Service and shall be deemed to be pensionable under the Pension Act and, accordingly, employees of the Agency shall in respect of their service in the Agency be entitled to pensions, gratuities and other retirement benefits as the prescribed there under.

(2) Notwithstanding the provision of subsection (1) of this section Nothing in this Act shall prevent the appointment of a person to any office on terms which preclude the grant of a pension or gratuity in respect of that office.

6. (f) The council may, on the recommendations of the Secretary create Such departments in the Agency as it may deem fit for the efficient discharge of the functions of the Agency.

***Departments of
the Agency***

7. FINANCIAL PROVISIONS

12. –(1) The Agency shall establish and maintain a fund which shall be applied towards the discharge of its functions under this Act.

(2) These shall be paid and credited to the fund established pursuant to subsection (1) of this section.

***Fund of the
Agency***

(a) such sums as may be provided by the Government of the Federation for the Agency

(b) Any fees charged for services rendered by the Agency and

(c) All other sums accruing to the Agency by way of gifts, testamentary depositions, endowments and contributions from philanthropic persons and organisations or otherwise howsoever

13. -(1) The Agency may accept gifts of land, money or other property on such terms and conditions, if any be specified by the person or organisation making the gift.

Power to accept gift

(2) The Agency shall not accept any gift if the conditions attached by the person or organisation making the gift are inconsistent with the functions of the Agency.

14. -(1) The Council may, with the consent or in accordance with any specific authority given by the Minister, borrow by way of loan or overdraft

Borrowing Power, etc

Departments of the Agency

7. Establishment of National Biosafety Council

(a) There is hereby established a committee to be known as the National Biosafety Council which will advise the Competent National Authority on biosafety matters in Nigeria.

Establishment of the National Biosafety Council

(b) The Secretariat of the National Biosafety Council is the National Biosafety Agency

8 (1) The National Biosafety Council shall consist of -

Composition of the National Biosafety Council.

(a) A Chairman who shall be a person knowledgeable in biosafety, modern biotechnology, socio-economics, industry, commerce, law or related fields;

(b) representatives of the following Federal Ministries or Agencies

- (i) Environment;
- (ii) Agriculture and Rural Development;
- (iii) Science and Technology;
- (iv) Industry;
- (v) Foreign Affairs;
- (vi) Justice;
- (vii) Commerce;
- (viii) Education;
- (ix) National Agency for Food and Drug Administration and Control;
- (x) Nigeria Customs Service;

- (c) a representative of the Organised Private Sector;
- (d) a biologist;
- (e) a physical scientist;
- (f) a socio-economist;
- (g) a representative of Non-Governmental Organisations distinguished in biodiversity conservation and environmental matters; and
- (h) the Secretary to the National Biosafety Council.

(2) The Chairman and other members of the National Biosafety Council, other than *ex-officio* (from Government agencies) members, shall be appointed by the President on the recommendation of the Minister.

Appointment of members of the Agency

(3) The Registrar of the Agency shall;

- (a) be the Secretary to the National Biosafety Council
- (b) be knowledgeable in biodiversity, biosafety, biology, agricultural sciences, or related fields;
- (c) be the head of the Secretariat of the National Biosafety Council;
- (d) perform the day-to-day activities of the Secretariat;
- (e) perform any duty or function as the Minister or the National Biosafety Council may, from time to time, direct.

Appointment of staff of the NBA

9 (1) The Chairman and other members of the National Biosafety Council, other than *ex-officio* members, shall each hold office -

Tenure of office.

- (a) for a term of 4 years in the first instance and may be re-appointed for a second term and on such terms and conditions as may be specified in his letter of appointment.

9 (2) Notwithstanding the provisions of section **9 (1)** of this Act, a member of the National Biosafety Council shall cease to hold office as a member of the National Biosafety Council if -

Cessation of membership.

- (a) he resigns his appointment as a member of the National Biosafety Council by notice, under his hand, addressed to the President through the Minister; or
- (b) he becomes of unsound mind; or
- (c) he becomes bankrupt or makes a compromise with his creditors; or
- (d) he is convicted of a felony or of any offence involving dishonesty or corruption; or
- (e) he becomes incapable of carrying on the functions of his office either arising from an infirmity of mind or body; or
- (f) the President is satisfied that it is not in the interest of the National Biosafety Council or in the interest of the public for the person to continue in office and the President removes him from office.

9 (3) Where a vacancy occurs in the membership of the National Biosafety Council, it shall be filled by the appointment of a successor to hold office for the remainder of the term of office of his predecessor, so however that the successor shall represent the same interest as his predecessor.

10 The Chairman and members of the National Biosafety Council shall be paid such allowances and benefits as the Federal Government may, from time to time, direct.

Allowances, etc.
of members.

11. The National Biosafety Council shall -

Functions of the
National Biosafety
Council.

(a) advise the Minister through the Agency on matters relating to genetically modified organisms;

(b) review and analyze risk assessments, environmental impact assessments and socio-economic impacts for GMOs;

(c) review and advise, from time to time, on guidelines for physical and biological containment or control procedures appropriate to the level of assessed risks or potential risks involved (in any research, development and application activities relating to genetically modified organisms).

(d) consult with relevant government agencies and other organisations as appropriate on GMOs;

(e) advise, where appropriate, on the training of personnel with regard to safety procedures relating to genetically modified organisms;

(f) assess any application submitted for import, export, transfer, transit or any other application under this Act and make recommendations to the Agency;

(g) validate information provided to it by any applicant in this Act and carry out such duties as may be expedient and necessary for the full discharge of its functions under this Act.

National Biosafety Technical Sub-Committees

12 (1) There shall be established for the National Biosafety Council, the following technical sub-committees, that is -

Establishment and
composition of
National Biosafety
Technical Sub-
Committees.

(a) the Technical Sub-Committee on Agriculture;

(b) the Technical Sub-Committee on Health;

(c) the Technical Sub-Committee on Industry;

(d) the Technical Sub-Committee on Environment; and

(e) any other technical sub-committee as the Minister may, on the recommendation of the National Biosafety Council, determine, from time to time.

(2) The technical committees established under subsection (1) of this section shall be composed and constituted by the Minister with membership from all relevant ministries, agencies and bodies as may be determined, from time to time, by the Minister upon the recommendation of the National Biosafety Council.

13. The technical sub-committees established pursuant to section 12 of this Act shall -

Functions of the Technical Sub-Committees.

- (a) be responsible for the review of applications for contained use, confined field trial, commercial release or other form of

deliberate release and recommend the conditions under which any experiment on genetically modified organisms shall be conducted;

- (b) provide technical advice to the National Biosafety Council on all matters referred to it by the Agency

- (c) assist in risk assessment and; perform such other duties as may be directed, from time to time, by the National Biosafety Council or the Minister.

Institutional Biosafety Committees

14. -(1) Any Institution or Body in Nigeria which plans to or undertakes any modern biotechnology process or otherwise engages in modern biotechnology or uses genetically modified organisms shall first establish a biosafety committee

Establishment and composition of Institutional Biosafety Committees.

(2) The Institutional Biosafety Committee established pursuant to subsection (1) of this section shall consist of -

- (a) a Chairman who shall be the biosafety officer;

- (b) three other persons from the Institution or Body; and

- (c) two other persons representing public interest, each of who -

- (i) shall not be an employee or in any way affiliated with the Institution or Body;

- (ii) shall be knowledgeable in modern biotechnology or related field;

- (iii) may be an employee or officer of a government's public health or environmental agency, or;

- (iv) may be active in human, plant or animal health concerns, or

- (v) may be a member of a Non-Governmental Organisation or Community Based Organisation active in environmental matters.

(3) Notwithstanding the provisions of subsection (2) of this section, the Institutional Biosafety Committee may invite any Principal Investigator, a member of the National Biosafety Council or any biosafety technical sub-committee or any other person to its meetings where the technical input of such Principal Investigator, member or such other person is required.

(4) For purposes of subsection (1) of this section, "Institution or Body" shall include any University, Research Institute, Polytechnics, Research Centre, Agency, Industrial Research and development units or such other Body as may be designated, from time to time, by the Minister.

15. Any Institution or Body that establishes an Institutional Biosafety Committee shall, not later than three months from the date of such establishment, notify the Minister of the following, that is -

Notification of establishment of the Institutional Biosafety Committee

(a) name of the chief executive officer, director or manager of the institution or body;

(b) the name, address, telephone, fax, website and email of the Institution or Body;

(c) the name, address, telephone, fax, website and email of the members of the Institutional Biosafety Committee;

(d) the terms of reference of the Institutional Biosafety Committee;

(e) the date of the establishment of the Institutional Biosafety Committee and its tenure, if any;

16. Any Institutional Biosafety Committee established pursuant to section 15 of this Act shall have responsibility for -

Functions of the Institutional Biosafety Committees.

(a) advising the Institution or Body on the formulation of Policies and guidelines for safety in modern biotechnology research in the Institution or Body in accordance with the provisions of this Act;

(b) rendering technical assistance to the Institution or Body on matters relating to risk assessment and risk management with respect to genetically modified organisms;

(c) seeking approvals of the National Biosafety Agency on matters for which the Institution or Body requires approval under this Act;

(d) implementing the terms and conditions of approval/ permits of the National Biosafety Agency;

(e) reviewing and recommending applications of the Principal Investigators to the National Biosafety Council;

(f) the establishment and maintenance of records of books, articles, newsletters, safety equipment, availability and level of biological containment for various host vector systems, suitable training of personnel and data on the potential biological hazards associated with certain technologies existing in the institution or body;

(g) certifying the internal safety of facilities, procedures and practices of the Institution or Body;

(h) recommending periodic training and capacity building of personnel of the Institution or Body on matters relating to Biosafety;

(i) the development of a safety and operation manual and assisting the Principal Investigators in the required Staff training;

(j) facilitating the exchange of Scientific, Technical, Environmental and legal information on the Institutional experience with respect to genetically modified organisms;

(k) approving Principal Investigators and project supervisors for particular projects and maintaining the list of such Principal Investigators and project supervisors; and proposals/requests under their domain

- (l) preparing and submitting annual reports on biosafety matters in the relevant Institution or Body to the National Biosafety Council through the Institution or Body concerned; and
- (m) performing such other duties as may be assigned to it from time to time by the Institution or the National Biosafety Council.

17. (1) Every person, Institution or Body to which subsection (1) of section 15 of this Act applies shall appoint a Biosafety Officer who shall be knowledgeable in matters relating to biosafety.

Appointment and Functions of biosafety officers, etc.

(2) Any Biosafety Officer appointed pursuant to subsection (1) of this section shall have responsibility for -

- (a) making a day-to-day check on compliance with biosafety issues in the Institution or Body; ensuring that safety is not compromised by the Institution or Body in any of its activities;
- (b) assisting the Institutional Biosafety Committee in the preparation of its annual report;
- (c) liaising between the Institutional Biosafety Committee and the National Biosafety Council or any Biosafety Technical Sub-Committee; and
- (d) rendering any duty that may be assigned to him by the Institution's, Institutional Biosafety Committee or the National Biosafety Committee.

(3) Every Institution or Body shall notify the National Biosafety Agency of any employment, termination or dismissal of a biosafety officer.

18. For every project, the Institution or Body shall designate a Principal Investigator who shall -

Principal investigator.

- (a) be responsible for conducting research in modern biotechnology as an agent of the Institution;
- (b) ensure that experiments, for which he is responsible are carried out in strict compliance with the provisions of this Act, any regulations made there under and relevant Institutional guidelines;
- (c) ensure that safety procedures and best practices are complied with;
- (d) report promptly, to the Institutional Biosafety Committee on any significant problems with respect to the implementation of relevant laws, regulations, standards and guidelines;
- (e) promptly notify National Biosafety Council(NBC) of any research-related accidents that have resulted or could result in injury to the health of humans, animals or plants or in the escape of organisms under study from the intended confinement;
- (f) ensure compliance with shipping requirements regarding the protection policies on the health of humans, animals and plants as well as permit requirements and containment conditions for possession of certain organisms; and

(g) carry out such duties as may be assigned to him by the Institutional Biosafety Committee, the Institution or Body.

PART III - NOTIFICATION AND AUTHORISATION, ETC.

19. As from the commencement of this Act, no person, institution or body shall import, export, transit, carry out the contained use, confined field trial or commercial release of genetically modified organisms unless with the prior approval or permit of the National Biosafety Agency.

Approval or permit on **genetically** modified organisms, etc.

20. (1) Any person, institution or body who wishes to import, export, transit or otherwise carry out a confined field trial or commercial release of a genetically modified organism shall apply to the Registrar of the National Biosafety Agency not less than 270 days prior to the date of import, export, transit or the commencement of such activity.

Requirement of application for approval or permit, etc.

(2) Any application under subsection (1) of this section shall include -

(a) the information and data requirements that may be specified by the Agency in regulations, guidelines, and policy documents. The Agency will set forth requirements for each activity with a GMO (import, export, transit, confined field trial, and commercial release) that take into account the level of potential risks posed by such category of activity in accordance with the first Schedule

First Schedule.

(b) a risk assessment report indicating the potential risks, if any, that the living modified living organisms or genetically modified organisms may pose to human health including food safety, biological diversity or the environment, including the consequences of unintentional release;

(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, processing, destruction, disposal or usage of the genetically modified organisms in any way whatsoever;

(f) a management plan for remediation measures to be undertaken in the event of:

(i) any intentional introduction into the environment of the genetically modified organisms from contained laboratory;

(ii) the escape or persistence in the environment of a GMO from a confined field trial, and /or

(iii) any unintended consequences to the environment from the placing of GMO in the market.

(g) the place where and the purpose for which the genetically modified organisms or the product thereof is planned to be developed, used, kept, released or marketed including detailed instructions for use and a proposed

Second Schedule

labelling and packaging scheme in accordance with the Second Schedule to this Act; and

(h) a declaration to the effect that the information provided is correct including, where appropriate, an undertaking from the originator of such information affirming its accuracy and completeness.

21 (1) No Person, Institution or Body shall import, transit or commercialise any genetically modified organism or a product thereof intended for direct use as food or feed or for processing unless with the approval of the National Biosafety Agency.

Genetically modified organisms for food, feed etc

(2) For any application under this section seeking the Agency's approval under this provision, if there is a substantial likelihood that the GMO could be eaten by humans and/ or animals, then approval cannot be granted unless a food safety risk assessment has been conducted.

(3) Any Person, Institution or Body that submits an application under this section for the commercial release of a GMO must ensure that the application addresses the socio- economic considerations set forth in third Schedule .

(4) The Agency shall consider such analysis in the risk /benefit assessment that determines 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 .

22. (1) The Agency shall, upon the receipt of the application and the accompanying information under section 20 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 to study and make comments on the application and relevant information.

Public display of application on genetically modified organisms, etc.

(2) The Agency may prior to the display make announcements in at least two 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.

23 (1). The Agency may, in addition to the comments received pursuant to section 21 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 of this Act the Agency shall not disclose any confidential business information submitted by any Person, Institution or Body to the Agency pursuant to 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 must find that:

Public hearings and consultations.

(a) the information has not previously been released to the public anywhere in the world

(b) the applicant has shown that it has taken steps to prevent the release of the 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 .

24 Notwithstanding the provisions of section 22 the following information shall not be considered confidential business information and can be disclosed to the public:

Confidentiality of Information

(a) the name and address of the applicant

(b) a general description of the GMO

(c) a summary of the risk assessment for the GMO

(d) any scientific data that specifically addresses potential environmental or food risks from GMO and any methods and plans for emergency response

25. (1) The Agency may on the recommendation of the National Bio safety Committee, grant an approval or permit in respect of the genetically Modified organisms if;

(a) satisfied that the application meets the criteria set out in this Act

(b) the genetically modified organism would not be harmful;

(c) in the case of Agricultural Crops, livestock, fish and any other genetically modified organisms, that the genetically modified organism in question does not pose new substantial risks different from the non-genetically modified counterparts;

(d) a pesticide or other such component in the GMO which may have insecticidal, fungicidal, rodenticidal or other activity should not pose unreasonable adverse risks to the environment;

(e) satisfied that measures have been taken or would be taken for remediation of any adverse effect on human health, animal, plant or the environment

(2) The Agency may also grant an approval or permit in respect of the genetically modified organism subject to the provision of Section

[Approval, permit and refusal of the Agency]

26. With respect to any decision taken under section 25 of this Act, the Agency -

Decisions of the Agency

(a) shall take into consideration, the relevant comments, inputs or concerns of the public received pursuant to sections 23 and 24 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, transit, contained use, confined field 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 risks to human health, animal, plant and the environment;

(e) may, in respect of any approval for import, transit, contained use, confined field trial, or commercial release of any genetically modified organism, direct the applicant to carry out monitoring and evaluation of risks for a specified period equivalent to the life cycle of the relevant species or for such period as the Minister may, from time to time, determine;

(f) impose any additional measure for risk management under section 32 of this Act; and

(g) do such other things or take such other steps as he may consider necessary and expedient for carrying into effect his decisions.

27. -(1) Notwithstanding anything to the contrary in any enactment or law, the Agency may -

Revocation and review of decisions, etc.

(a) revoke or suspend the approval or permit or otherwise review any decision taken under section 25 of this Act if he is of the opinion that there is new information to the effect that the genetically modified organism or its products thereof is capable of having adverse effect on human health, animal, plant or the environment;

(b) review the refusal of an application if there is new and relevant information

28. -(1) Any applicant who is aggrieved by any decision of the Agency under sections 25, 26 and 28 (1) of this Act may appeal to the Minister to reconsider that decision, stating his grounds of appeal, including any additional information.

Right of appeal

(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.

(3) Notwithstanding anything to the contrary in any enactment or law, no applicant shall apply to the Federal High Court or any court without first complying with subsection (1).

PART IV - RISK ASSESSMENT AND RISK MANAGEMENT, ETC.

29. -(1) Every applicant in respect of 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 organism poses to human health, animal, plant or the environment in Nigeria.

Risk assessment.

(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 Schedule Three of this Act.

Third Schedule.

(3) Without prejudice to subsections (1) and (2) of this section, the National Biosafety Agency may decide to request that the NBC Technical Subcommittees carry out risk assessment of any genetically modified organism under this Act.

(4) Where the National Biosafety Council carries out the risk assessment, the Agency may direct that the applicant bears the cost of carrying out the risk assessment notwithstanding the fact that the applicant has carried out or is about to carry out a risk assessment.

30. No person shall be involved in a risk assessment review by the Agency in respect of a subject matter in which -

Certain Persons not be involved in risk assessment.

(a) he has direct or indirect interest of any kind whatsoever; or

(b) there is likely to be conflict of interest as a result of his participation in the evaluation process.

31. 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 Fourth Schedule to this Act.

Fourth Schedule.

32. The Agency may impose additional and specific measures for management of risks associated with any genetically modified organism and without prejudice to the generality of the foregoing, may -

Additional measures for risk management.

- (a) direct that any genetically modified organism 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 risks 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 harm to human health, animal, plant or the environment;
- (d) direct any applicant under section 20 of this Act to submit periodic reports of the monitoring and evaluation of risks carried out after the approval or permit granted under this Act;
- (e) undertake any measures, 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 measures taken; and
- (f) undertake such other measures as the Agency may, from time to time, determine.

PART V - OFFENCES, ENFORCEMENT POWERS, ETC.

33 (1) Any person, institution or body who:

- (a) imports, exports, transits 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 Minister, or
- (b) contravenes the conditions of the grant of an approval/permit under this Act commits an offence and shall be liable on conviction –
- (c) in the case of an individual, to a fine of not less than ₦2,500,000 or imprisonment for a term not less than 5 years or to both such fine and imprisonment; or
- (d) in the case of a body corporate to a fine of not less than ₦5,000,000 and, in addition, the directors or officers of the body corporate shall each be liable to a fine not less than ₦2,500,000 or imprisonment for a term not less than 5 years or to both such fine and imprisonment.

(2) For purposes of section 27 subsection (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 Registrar; or

(b) gives any false information purporting to be new information that suggests that the genetically modified organism in respect of which approval or permit was refused has no 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 ₦2,500,000 or imprisonment for a term not less than 5 years or to both such fine and imprisonment; or
(ii) in the case of a body corporate to a fine of not less than ₦5,000,000 and, in addition, the directors or officers of the body corporate shall each be liable to a fine not less than ₦2,500,000 or imprisonment for a term not less than 5 years or to both such fine and imprisonment.

False information.

34 (1) Any person, institution or body who submits or supplies false information in respect of any activity relating to genetically modified organisms under this Act commits an offence and shall be liable on conviction ,

(a) in the case of an individual, to a fine of not less than ₦ 2,500,000 or imprisonment for a term not less than 3 years or to both such fine and imprisonment; or

(b) in the case of a body corporate, to a fine of not less than ₦5,000,000.

35. Any person who obstructs any authorised officer in the course of his duties under this Act, commits an offence and shall be liable on conviction to a fine of not less than ₦2,500,000 or imprisonment for a term not less than 3 years or to both such fine and imprisonment.

Obstruction.

36 (1) Any person who contravenes any provisions of this Act for which no specific penalty is specified, commits an offence and shall be liable on conviction to a fine of not less than ₦2,500,000 or imprisonment for a term not exceeding 3 years or to both such fine and imprisonment.

General penalty.

(2) Notwithstanding the punishments provided under sections 33, 34 35 and 36 (1) above the Agency shall in addition revoke the permit granted to the individual or institution or body.

37. Biosafety Enforcement Officer(s) accompanied by a police officer may enter the premises , facility, laboratory, field, farm or other place of persons, institutions or bodies covered by this Act to take actions necessary to determine compliance with the Act and/or to conduct monitoring to assess the impact of GMOs covered by the Act on human

health ,animal , plant , or the environment . The actions that may be taken include, but are not limited to reviewing and copying documents , collecting samples interviewing individuals , and seizing GMOs.

General enforcement powers.

38. The Federal High Court shall have jurisdiction to try offences under this Act.

Criminal proceedings.
Jurisdiction.

39. -(1) 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, material or anything in connection with the commission of an offence under this Act.

Consequential orders.

(2) Without prejudice to subsection (1) of this section, the Court may order that -

(a) any premises, laboratory, facility, field, farm or any place be sealed up for such period as may be specified in such order; or

(b) any remediation measures be undertaken by the offender.

PART VI - MISCELLANEOUS PROVISIONS

40. -(1) The Agency may, upon the recommendation of the National Biosafety Council, make Regulations generally for carrying into effect the provisions of this Act.

Power to make regulations.

(2) 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 equipment relating to genetically modified organisms;

(d) handling, transport, packaging and identification or labelling of genetically modified organisms; and

(e) fees and charges payable by applicants for any activities of the Minister or the National Biosafety Council under this Act.

41. Notwithstanding anything to the contrary in any enactment or law, the Minister may, on the recommendation of the Agency, by Order published in the Federal *Gazette*, modify, amend or delete any of the Schedules to this Act to bring the provisions in line with the decisions of the Conference of Parties to the Protocol, international best practices or advancement in science and technology.

Modification, etc. of the Schedules to this Act.

42. Subject to the Provisions of the Constitution of the Federal Republic of Nigeria, if any enactment or law, on matters relating to modern biotechnology or biosafety, is inconsistent with this Act, this Act shall prevail and the provisions of such enactment or law shall be read as if it has been consequentially amended by this Act.

Inconsistency of other laws with this Act.

43. In this Act, unless the context otherwise requires -

“Biosafety Enforcement Officer” means any person appointed by the Agency for the purpose of ensuring compliance and enforcement of the provisions of this Act;

“Biosafety Clearing House” means a pool of information mechanism established under Article 20 of the Protocol for exchange of scientific, technical, environmental 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 range of measures, policies and procedures for minimizing potential risks that modern biotechnology may pose to the environment and human health;

“Biosafety Council” means the National Biosafety Council established under section 7 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.

“confined field trial” means a small scale experimental release into the environment of a GMO under physical and biological confinement conditions that limit the GMO’s persistence in the environment after the experiment is completed.

“commercial release” means the release of a GMO into the market as a product that can be purchased and used by any individual, such as a genetically engineered seed or animal.

“food and feed product” means a GMO or its product that is used for food, feed or processing and is primarily intended for consumption by humans and/or animals.

“Modern biotechnology” means the application of:

- (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.

“Confidential business information” consists of trade secrets and other proprietary information of commercial value

“Convention” means the Convention on Biological Diversity;

“Court” means the Federal High Court

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

“Institutional Biosafety Committee” means the Institutional Biosafety Committee established by any institution or body pursuant to section 14 of this Act;

...

“Minister” means the Minister with responsibility for matters relating to environment;

The Agency means National Biosafety Agency

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

44. This Act may be cited as the Nigerian Biosafety (Special Provisions, Etc.) Act 2006.

Short title.

FIRST SCHEDULE

Section 20 (a)

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

PART A - GENERAL INFORMATION

1. Name, address, telephone, fax, website or email 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 of the implementation of the project, including those responsible for supervision, monitoring and evaluation of the safety measures.

PART B - INFORMATION RELATING TO THE GENETICALLY MODIFIED ORGANISM(S) OR THE PRODUCTS THEREOF

Characteristics of the donor, the recipient or where appropriate, the parental organism -

3. Scientific name.
4. Additional taxonomic information.
5. Other names (usual name, strain name, cultivar name, transformation event, unique identification code (where applicable) etc.).
6. Phenotypic and genetic markers.
7. Degree of relatedness between donor and recipient or between parental organisms.
- 8.. 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.
9. Potential for genetic transfer and exchange with other organisms.
10. 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.
11. 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 sclerotia);
- (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;
- (f) Involvement in environmental processes, primary production nutrient turnover, decomposition of organic matter, respiration, etc.

Characteristics of the vector

- 12. Nature and source of the vector
- 13. Sequence of transposons, vectors and other non-coding genetic segments used to construct the genetically modified organisms or their products thereof and to make the introduced vector and insert function in the genetically modified organisms or their products thereof.
- 14. Frequency of mobilisation of inserted vector and or genetic transfer capabilities and methods of determination.
- 15. Information on the degree to which the vector is limited to the rDNA required to perform the intended function.
- 16. Factors (chemical, biological, climatic, etc.) influencing the functional level of the promoter/enhancer and how the functional level is changed.

Characteristics of genetically modified organisms or product thereof

- 17. 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/or vector construct.
 - (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.
 - (e) Number of intact and truncated vector inserts. Sequence and methylation pattern of the recipient DNA as far as 100 kbp up and down stream from all DNA inserts.
- 18. Information on the final genetically modified organisms -
 - (a) Description of genetic trait(s) of 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 and/or donor nucleic acid remaining in the final construction of the genetically modified organisms or product thereof.
- (c) Stability of the genetic traits of organism in terms of both expression and structure.
- (d) Rate and level of expression of the new genetic material. Method and sensitivity of measurement.
- (e) Activity of the expressed protein(s).
- (f) Expression levels for the recipient's genes situated as far as 100 kbp up and down stream from all DNA inserts.
- (g) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques.
- (h) History of previous releases or uses of the genetically modified organisms or products thereof.
- (i) Health considerations, that is -
- (j) toxic or allergenic effects of the non-viable genetically modified organisms or products thereof and/or their metabolic products,
- (ii) products hazards,
- (iii) comparison of the genetically modified organisms or products thereof to the donor, recipient or (where appropriate) parental organism regarding pathogenicity,
- (iv) capacity for colonisation,
- (v) if the organism is pathogenic to humans who are immunocompetent -
 - diseases 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
 - antibiotic resistance patterns
 - allergenicity
 - availability of appropriate therapies
 - allergenicity availability of appropriate therapies.

PART C - INFORMATION RELATING TO THE CONDITIONS OR RELEASE AND THE RECEIVING ENVIRONMENT

Information on the release

- 19. Description of the proposed deliberate release, including the purpose(s) and foreseen products.
- 20. Foreseen dates of the release and time planning of the experiment including frequency and duration of releases.
- 21. Preparation of the site previous to the release.
- 22. Size of the site.

23. Method(s) to be used for the release.
24. Quantities of genetically modified organisms.
25. Disturbance on the site (type and method of cultivation, mining, irrigation or other activities).
26. Worker protection measures to be taken during the release.
27. Post-release treatment of the site.
28. Techniques foreseen for elimination or inactivation of the genetically modified organisms or products thereof at the end of the experiment.
29. Information on and results of previous releases of the genetically modified organisms or products thereof, especially at different scales and in different ecosystems including contained experiments.

Information on the environment

(It should be noted that the information should be for both the site and the wider environment. In the case of genetically modified organisms destined to be used as food, feed or for processing, the environment includes the transportation routes and the market places as well as all the catchment areas of the market places)

30. 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).
31. Physical or biological proximity to humans and other significant biota.
32. Proximity to significant biotopes or protected areas.
33. Size of local population.
34. Economic activities of local populations which are based on the natural resources of the area.
35. Distance to closest areas protected for drinking water and/or environmental purpose.
36. Climatic characteristics of the region(s) likely to be affected.
37. Geographical, geological and pedological characteristics.
38. Flora and fauna, including crops, livestock and migratory species.
39. Description of target and non-target ecosystems likely to be affected.
40. A comparison of the natural habitat of the recipient organism with the proposed site(s) of release.
41. 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 THEREOF AND THE ENVIRONMENT

Characteristics and factors affecting survival, multiplication, gene expression and dissemination

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

Interactions with the environment

- 45. Predicted habitat of the genetically modified organisms.
- 46. Studies of the behaviour and characteristics of the genetically modified organisms or products thereof and their ecological impact carried out in simulated natural environments, such as microcosms, growth rooms, greenhouses, animal houses and other containment facilities etc.
- 47. Genetic transfer capability, that is -
 - (a) post-release transfer of genetic material from genetically modified organisms or products thereof into organisms in affected ecosystems;
 - (b) post-release transfer of genetic material from indigenous organisms of the genetically modified organisms or products thereof.
- 48. Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the genetically modified organisms or products thereof.
- 49. Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal or genetic material. Methods to verify stability.
- 50. Routes of biological dispersal, known or potential modes of interaction with the disseminating agent including inhalation, ingestion, surface contact, burrowing, etc.
- 51. Description of ecosystems to which the genetically modified organisms or products thereof could be disseminated.

Potential environmental impact

- 52. Potential for excessive population increase in the environment.
- 53. Competitive advantage of the genetically modified organisms or products thereof in relation to the unmodified recipient or parental organism(s).
- 54. Identification and description of the target organisms.
- 55. Anticipated mechanism and result of interaction between the released genetically modified organism or product thereof and the target organism.
- 56. Identification and description of non-target organisms which may be affected indirectly.

57. Likelihood of pos-release shifts in biological or host-range.
58. Known or predicted effects on non-target organisms in the involvement, impact on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens.
59. Known or predicted involvement in bio-geochemical processes.
60. Other potentially significant interactions with the environment.

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

Monitoring techniques

61. Methods for tracing the genetically modified organisms or products thereof and of monitoring their effects.
62. Specificity (to identify the genetically modified organism(s) or products thereof and to distinguish them from the donor, recipient or, where appropriate, the parental organisms), sensitivity and reliability of the monitoring techniques.
63. Techniques for detecting transfer of the donated genetic material to other organisms.
64. Methods to detect aberrant gene expression.

Control of the release

65. Methods and procedures to avoid and/or minimise the spread of the genetically modified organism(s) or products thereof beyond the site of release or the designated area for use.
66. Methods and procedures to protect the site from intrusion by unauthorised individuals.
67. Methods and procedures to prevent other organisms from entering the site.

Wastes treatment

68. Type of wastes generated.
69. Expected amount of waste.
70. Possible risks
71. Description of treatment envisaged.

Emergency response plan

72. Methods and procedures for controlling the genetically modified organism(s) or products thereof in case of unexpected spread.
73. Methods for decontamination of the areas affected (e.g. eradication of the genetically modified organism(s) or products thereof).
74. Methods for disposal or sanitation of plants, animals, soils, etc. that were exposed during or after the spread.
75. Methods for the isolation of the area affected by the spread.
76. Plans for protecting human health, animal, plants and the environment in case of the occurrence of an undesirable effect.

SECOND SCHEDULE *Section 20 (g)*

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 products, in addition to that of the First Schedule -
 - (a) name of the product and name(s) of genetically modified organisms contained therein;
 - (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 and/or the geographical area(s) of the country for which the product is suited; and
 - (d) type of expected use industry, agriculture and skilled trades, consumer use by the public at large.
2. The following additional information shall be provided when required or relevant -
 - (a) measures to take in case of unintended release or misuse;
 - (b) specific instructions or recommendations for storage and handling;
 - (c) estimated production in and/or imports to the country;
 - (d) proposed packaging which must be appropriate so as to avoid unintended release of the genetically modified organism(s) ;
 - (e) proposed labelling which must include at least in summarised form, the information referred to in paragraph 1, 2, 3, 4 and 5.
3. The following information concerning labelling of product thereof shall be provided on a label and /or in accompanying documents -
 - (a) the words “This product contains genetically modified organisms” whenever 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 organism(s);
 - (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; and
 - (d) where applicable, further or as a qualification to sub-paragraph (c) of this paragraph, the words “This product contains genetic material (nucleic acids) from living modified organism(s) or genetically modified organism(s) or “This product is based on raw materials from genetically modified organism(s).

THIRD SCHEDULE *Section 29*
RISK ASSESSMENT PARAMETERS

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

Characteristics of donor and recipient organisms or parental organisms

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

Characteristics of the vector(s)

20. Nature and source of the vector(s).
21. Genetic map of the vector(s), position of the gene(s) inserted for the transfer, other coding and non-coding sequences affecting the expressing of introduced gene(s) and marker gene(s).
22. Ability of the vector(s) to mobilise and transfer genes by integration and methods for determining the presence of the vector(s).
23. History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified.
24. Potential for pathogenicity and virulence.
25. Natural and host range of vectors.
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 vector(s) 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/or the new insert including any marker gene(s).
33. Purpose of the modification and intended use in relation to need for benefit.
34. Method of modification, and in case of transgenic organisms, the methods for constructing inserts and to introduce them into the recipient organism.
35. Whether introduced gene(s) integrated or extra-chromosomal.
36. Number of insert(s), position(s) in the host genome, and its/their structure(s) (for example, the copy number whether in random or other types of repeats).
37. Product(s) of the transferred gene(s), levels of expression and methods for measuring expression.
38. Stability of the introduced gene(s) in terms of expression(s), structure(s) and site(s) of integration.
39. Biochemical and metabolic differences of genetically modified organism compared with the unmodified organism.
40. Probability of vertical or horizontal gene transfer to other species.
41. Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria.
42. Allergenicities, toxicities, pathogenicities and unintended effects.
43. Autecology of the genetically modified organism to diseases and pests compared with the unmodified organism.
44. Susceptibility of the genetically modified organism to diseases and pests compared with the unmodified organism.

45. Detailed information on past uses including results on all experiments leading to previous releases.

Characteristics of resuscitated organism(s) and gene(s) and fossil DNA sequences.

Resuscitated organism

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

DNA sequences from fossils or from resuscitated organism

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

Safety considerations for human and animal health

68. Capacity for colonisation.
69. If the genetically modified organism is pathogenic to humans or 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 dose;
 - (d) host range and possibilities of alteration;
 - (e) ability to survive outside of the human or animal host;
 - (f) the existence of vectors or other means of transmission;
 - (g) biological stability;
 - (h) allergenicity;
 - (i) availability of appropriate therapies.

Environmental considerations

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

Socio-economic considerations

80. Anticipated changes in the existing social and economic patterns resulting from the introduction of the genetically modified organism or products thereof.
81. Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture.
82. Impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agro-climatic zones.
83. 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 thereof.
84. Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare.
85. Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the genetically modified organism or the product thereof.

FOURTH SCHEDULE *Section 31.*
RISK MANAGEMENT PLANS

(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 thereof, to its intended use or commercialisation)

1. Imported products of genetically modified organisms used for human or animal health (for example, antibiotics, drugs and hormones), that is -
 - (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 sub-paragraph (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 risks of reacquiring virulence or lending virulence to other micro-organisms when in the body and in the environment, since some spilling is inevitable.
3. Imported genetically modified organisms 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 release in the premises and in the surrounding environment, and
 - (ii) methods for counteracting adverse impacts resulting from unintended releases should be specified; and
 - (c) methods for counteracting adverse impacts 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 organisms 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 organisms are made locally for use as vaccines for humans or animal there shall be -
 - (a) initial molecular, tissue culture, serological and other related studies in the 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 genes of vector introduced or of 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 organism 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 -

(c) 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

(d) 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 Council 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 mechanisms have been rigorous enough, observations shall be made in experimental conditions completely contained from the outside environment, but otherwise 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 releases 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 Council 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 Council may decide which step of the observations should commence;

- (c) if it is decided that the regulations used in the previous release have been rigorous enough, then the observations 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 authorised with adequate emergency plans 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 organisms 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 area of intended release, shall be carried out in complete containment;
- (e) complete observations of the interactions 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 organisms 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 behaviour 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 perennials which live shorter than trees may be between 30 to 50 years. The user who was responsible for releasing the genetically modified organisms or its successor shall provide annual reports to the Minister through the National Biosafety Council.

9. Where animal genetically modified organisms 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 containment;

(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 micro-organisms especially in the context of gene transfer and those of the microbial, 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 organism, 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 behaviour of any released animal genetically modified organisms 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 Council.

(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 thereof shall be subject to the approval by the respective Institutional Biosafety Committee or the National Biosafety Council, as the case may be.

(c) all experiments outside of strict laboratory isolation and initial experiments involving imported genetically modified organisms or products thereof shall be subject to approval of the National Biosafety Council.

(d) all final approvals for the use of genetically modified organisms shall be made by the Minister upon the recommendation of the National Biosafety Council;

- (e) any disposal of the genetically modified organisms or the products thereof upon the completion of every trial or experiment, shall be made through complete incineration or other approved disposal by the National Biosafety Council; and
- (f) the release of genetically modified organisms or the products thereof shall be monitored appropriately and emergency plans shall be put in place to prevent escape and accident.

EXPLANATORY MEMORANDUM

The Bill seeks to provide regulatory frameworks, institutional and administrative mechanisms 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 the environment.

DRAFT

FEDERAL REPUBLIC OF NIGERIA

NIGERIA NATIONAL BIOSAFETY BILL

2006