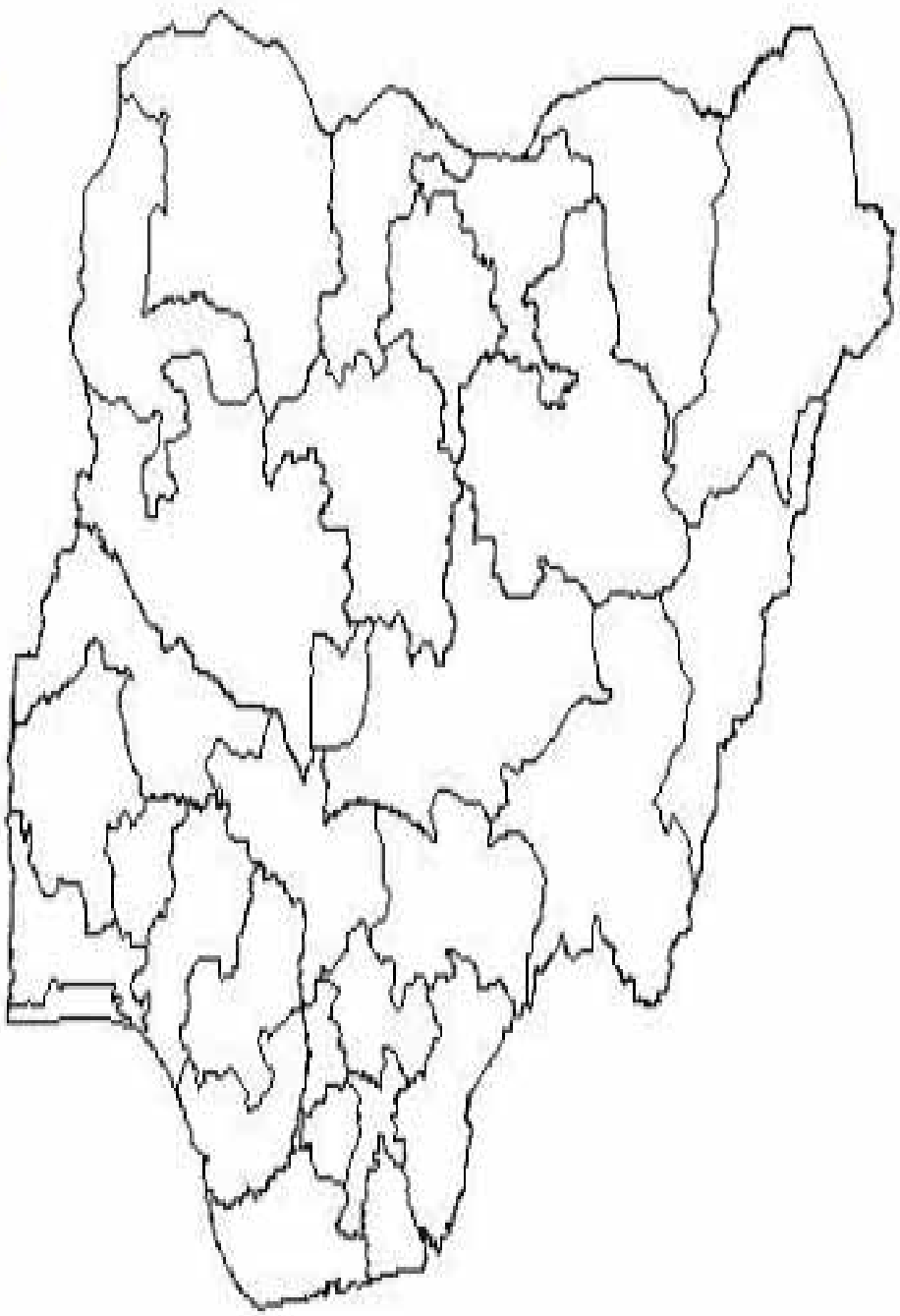

NIGERIA NATIONAL BIOSAFETY FRAMEWORRKS

FEDERAL MINISTRY OF ENVIRONMENT

JULY 2005

DOCUMENT ONE:

NIGERIA NATIONAL BIOSAFETY POLICY

DOCUMENT TWO

DRAFT: NIGERIA NATIONAL BIOSAFETY FRAMEWORK

DOCUMENT THREE:

DRAFT SYSTEM TO HANDLE NOTIFICATION **AND REQUESTS FOR AUTHORIZATIONS IN NIGERIA**

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DOCUMENT 1: NIGERIA NATIONAL BIOSAFETY POLICY

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Acronyms

Biosafety Officer(s) – BO

Competent National Authority (CNA)

Convention on Biological Diversity (CBD)

Genetic Use Restriction Technologies, (GURTs)

Genetically Modified Organisms – GMOs

Institutional Biosafety Committee – IBC

National Biosafety Committee (NBC)

National Biosafety Technical Sub-Committee – NBTS

National focal point (NFP)

Principle Investigator (PI)

Research and Development (R&D)

The Cartagena Protocol on Biosafety – CPB

Trade Barriers To Trade (TBT)

United Nations Conference on Environment and Development (UNCED)

World Trade Organization (WTO)

ACKNOWLEDGMENT

The preparation of this Policy document involved a number of Federal Ministries and Agencies, Non-Governmental Organizations (NGO), Public and private sector institutions and individuals from all walks of life. We would like to specially acknowledge the support, and financial contribution from UNEP/GEF for the execution of the Nigeria National Biosafety Framework Project from which the Policy emanated.

In particular, the Africa Regional Manager of the Project, Mr Charles Gbedemah deserves special mention for his patience and constant advice.

Mention must be made of the following Federal Ministries and Agencies that constituted the National Coordinating Committee of the National Biosafety Framework responsible for the development of the Policy: Federal Ministries of Agriculture and Rural Development; Environment; Science and Technology (National Biotechnology Development Agency, Sheda Science and Technology Complex (SHESTCO)); Health (National Food and Drug Administration and Control); Industries; Commerce; Justice; Education; Foreign Affairs; Custom Service; Other member organizations; as well as other individuals that deserve acknowledgement.

Prof. J.Ekpere (Chairman of NBC/NCC) was always on hand to ensure that ; Dr. S. Uzochukwu; Dr.(Mrs) Lamin Lombim, Mr Chris Ugwu; Prof. A.H. Ekpo; Prof. M G. Ogbe; Dr. Aghimien, Dr. O. Omoerefe Asemota, Mrs. M. Usoro IITA., and and many others. They all made worth while contributions for the final document.

FORWARD

Nigeria signed the Cartagena Protocol on Biosafety as a means of ensuring that it joins the international community, under the auspices of the United Nations to make sure that the transboundary movement of Genetically Modified Organisms is controlled. During the negotiations, it became obvious that there was a distinct need to revamp our Biosafety Guidelines to meet the broader scope encompassed in the text of the Articles. The Biosafety Guidelines just could not meet the legal, socio-economic and administrative structures called for in the prevailing circumstances.

The UNEP/GEF-inspired NBF has five pillars- a government-approved Biosafety Policy, Regulatory Regime, System of Handling Requests, System for monitoring, enforcement and inspection and Mechanism for public participation. A multi-pillar system ensures that in a democratic setting, there is transparency in decision making, conscious efforts are taken to educate the generality of the Nigerian populace and in particular stakeholder participation is assured.

The development of these documents are taking place at a particularly auspicious time when Nigeria has committed its self to excellence, transparency, liberalisation, encouraging the private sector to drive the economy in other for Nigeria to be competitive in the global economy.

These policy documents are in consonance with our environmental policy, will form the guiding light of our quest to meet our obligations under the Protocol and other thrusts deriving from the need for sustainable development.

1. PREAMBLE AND INTRODUCTION

There is limited public awareness and widespread misinformation on the techniques, basic applications, opportunities, utility and safe use of biotechnology. The knowledge and science of the technology as well as its full implications is still very much limited to a few advanced scientists in the biological sciences in academic or research and development (R&D) life science institutions. The little awareness and the focus of the scientific discourse has been confined to genetically modified food/feed. This is, but only one component of the application of biotechnology. The application of modern biotechnology in an integrated multi-disciplinary approach can be a valuable "tool" for addressing the several challenges of Nigeria in food production, genetic improvement of living systems (crops and animals) as well as health and environment. Consequently, Nigeria has adopted a National Biotechnology Policy designed to take advantage of the potential benefit impact in agriculture, industry, health care delivery and the environment.

The potential benefits, notwithstanding, there are indications that the products of biotechnology could have adverse effects on human, plant and animal health, biological diversity and the environment. Also there are several important socio-economic, cultural and ethical issues to be considered in the adoption and use of the products of biotechnology.

Nigeria is a signatory to the Convention on Biological Diversity (CBD) and its first spawned protocol (the Cartagena Protocol on Biosafety - CPB) which advocates regulation to ensure the safe application and use of biotechnology. The Nigerian legal system is currently inadequate for the regulation of biotechnology.

The "International" CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY (The Cartegena Protocol on Biosafety) was negotiated between 1998 and 2000. It was adopted in Nairobi, Kenya in 2000, ratified by the requisite number of member states and came into force on September 11, 2003. It is now an internationally binding legal instrument. Nigeria, having signed and ratified the protocol is now under obligation to implement it.

This policy instrument is proposed to give authority to the National Executive Organization to establish the necessary legal instrument, and procedure to guide the implementation of the protocol, based on sound scientific, economic, social, cultural and ethical considerations.

Consequently:

- Recognizing the central role of the Federal Government of Nigeria in the protection of national biodiversity in order to promote its sustainable use, ensure access and equitable sharing of benefits.
- Recognizing the potential human, health and environmental risks that may occur from the unregulated exploitation, development, use, transboundary movement or trade in modern biotechnology products for agriculture, health, waste management, food, feed and other purposes.
- Recognizing the need for the development of National capacity essential for biosafety and modern biotechnology practice through research and development.
- Recognizing that it is the responsibility of the Government of Nigeria to ensure the safety of her citizens and environment from the risks arising from the use of the products of modern biotechnology.
- Whereas it is important to enhance the capacity of Nigerians (scientists, policy makers, government operatives, regulators, civil society and other stakeholders) to cope with the nature and scale of the known and potential risks associated with the products of modern biotechnology.
- Reaffirming Nigeria's commitment to the Principles of the Declaration on Environment and Development, especially in Rio de Janeiro (1992).
    - Liability and redress as well as compensation for damage, including that occasioned by transboundary movements, incidents and processes (Principle 13) and
    - The Precautionary Principle, which stipulates that "lack of reasonable scientific certainty about environmental and human risks shall not be used to justify avoiding or postponing cost-effective measures to prevent these risks (principle 15)
- Reaffirming Nigeria's Commitment to the Principles of the World Trade Organization (WTO) Agreements, especially those related to Technical Barriers to Trade (TBT)

- Reaffirming Nigeria's commitment to the principles, goals and objectives of the Convention on Biological Diversity (CBD), especially:
    - Article 3 (Principle of Sovereign Rights and Responsibilities)
    - Article 8g (Control of Risks Associated with Genetically Modified Organisms – GMOs)
    - Article 14 (Assessment and Minimization of Environmental Impact)
    - Article 15 (Access to Genetic Resources)
    - Article 16 (Access and Transfer of Technology)
    - Article 19 (Handling of Technology and Distribution of Benefits)

Hereby enunciates the following national policy enabling the safe use of modern biotechnology.

2. FUNDAMENTAL PRINCIPLES OF POLICY

This policy is informed by the essential and fundamental principles that:

- Nigeria has inalienable sovereign rights over all natural resources (including genetic resources) in its territorial area of jurisdiction, and the authority to regulate access to such resources and activities which might have adverse effect on such resources.
- As a party to the Convention on Biological Diversity (CBD) and Cartagena Protocol Biosafety (CPB), Nigeria is under obligation to regulate the application of modern biotechnology and use of its products, which may cause harm to its biodiversity or human health.
- Nigeria shall endeavour to maintain an appropriate balance between the use of modern biotechnology as a tool for development and its regulation in a sustainable manner to enhance meaningful growth of its economy and to the welfare of its people.
- The import, use, export, sale (trade), transboundary movement, etc. of modern biotechnology products and practices must fully conform to existing national law.
- The regulation to ensure the safe use of modern biotechnology and its products shall be by a Competent National Authority advised by professional/technical, whose decision-making process is transparent,

scientifically sound and fully cognisant of environmental, public health, socio-economic and cultural considerations.

- Applies the precautionary principle and approach.
- Modern biotechnology applications and inventions derived from or inspired by traditional knowledge, innovations and practices of local communities or individuals in Nigeria shall be subject to appropriate national legislation related to community or individual intellectual property rights, and shall include contractual agreement on benefit sharing (financial or otherwise) arising from such application and invention with the concerned community and/or individuals. The State shall provide the desired assistance and advise to ensure equitable negotiation and conclusion of such a contractual agreement.
- Nigeria shall endeavour to cooperate with other states in the sub-region and Africa to ensure the safe use of modern biotechnology, its applications and products within its borders.
- Nigeria shall not allow/permit the importation and transboundary movement and/or use of modern biotechnology products and procedures which do not meet minimum safety standards as identified by the Competent National Authority and specified in this policy document and other established legislation. Nigeria shall undertake local field trials (as shall be determined) of such products and products, financed by the applicant, where existing information is considered inapplicable or inadequate to local conditions.
- Where, on appropriate risk assessment, a biotechnology product, application or procedure turns up a negative recommendation, this shall not be over-ruled for reason of political or economic expediency. However, a positive recommendation may be over-ruled if it is not politically and economically expedient.

As a general principle, pending the outcome of global and regional assessment of the potential severe socio-economic, ethical, environmental risks posed by "Genetic Use Restriction Technologies, (GURTs)", Nigeria shall impose a ten year renewable moratorium on the import, export, transboundary movement, sale or use of genetic materials such as seeds, other planting materials, altered by these technologies including the so called "Terminator Technology" and related processes and procedures. Such a moratorium shall take effect on the adoption of this policy by Cabinet. A public, transparent review of this moratorium shall be conducted by the Competent National Authority (CNA) every two years

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3. POLICY STATEMENT

In compliance with Nigeria's adoption of a "National Biotechnology Policy" and ratification of the "Cartagena Protocol on Biosafety to the Convention on Biological Diversity" this policy sets out the essential pre-requisites for regulating the practice and products of modern biotechnology while accessing its potential benefits.

3.1MISSION

The mission of this policy instrument is to promote the basic tenets of biosafety as enunciated in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity and facilitate the development, enactment and implementation of a regulatory regime (legislation) that ensures the safe application and use of the products of Modern Biotechnology.

3.2 VISION

The vision embedded in this policy is to ensure that the practice, processes and procedures of Modern Biotechnology are undertaken within the limits of a regulatory system that guarantees its safe use, protects Nigeria's biodiversity and provides minimum risk .to human health and the environment.

4. OBJECTIVE

The overall objective of this policy is to provide a regulatory regime and guidance for the sustainable development of the science of modern biotechnology, its application and safe use of its products without prejudice and risk to public health, environmental health, national sovereignty, human dignity and fundamental human rights.

The Specific objectives will include:

- Regulation of modern biotechnology practice and procedures to ensure the safe use of its products.
- Guide the development of appropriate legislation and implementation mechanism established through a transparent participatory process.

- Develop the necessary human and infrastructural capacity to effectively manage the regulatory system
- Ensure effective control of transboundary movement of Genetically Modified Organisms (GMOs) and products thereof resulting from modern biotechnology, through information exchange and a science-based, transparent system of advanced information agreement.
- Provide for the establishment of a comprehensive, coordinated central monitoring and oversight system for all modern biotechnology research and development activities in Nigeria.
- Provide an institutional framework for national decision making and linkage with the international community on biosafety issues.
- Institute an aggressive public enlightenment campaign on biosafety as an essential counterbalance for modern biotechnology.

5. POLICY FRAMEWORK

5.1 SCOPE

This policy covers all GMOs and their products including all living organisms, germplasms, and all elements of genetic materials used in genetic manipulation.

It covers in detail:

- Laboratory and field applications of modern biotechnology, currently known to science as well as those that may be developed in future.
- Current and future applications in agriculture, human and veterinary medicine, food/feed and beverage production, industry, environmental management, bioremediation, industrial and domestic waste management etc.
- Regulatory regime including:
    - Notification
    - Information transfer and review
    - Risk assessment, including socio-economic impact and ethical consideration
    - Monitoring and enforcement measures relevant to input, export, transboundary movement of the products of biotechnology,

laboratory and field testing/use of biotechnology including handling, containment disposal, control, monitoring and release

- Research and development in modern biotechnology including applications in academic, agricultural, industrial and other categories of research.
- Occupational safety in the workplace where modern biotechnology procedures are used or products handled
- Labeling of Genetically Modified Organisms (GMOs) in food/feed produced locally, sold domestically or imported.
- Any other measures that may be required to safe use of modern biotechnology while protecting human health, the environment and national biodiversity.
- Promotion of public awareness on biosafety involving policy makers, legislators, administrators, the organized private sector, industry and the rural community.
- Development and establishment of a comprehensive and up-to-date scientific database and infrastructure for information exchange to enable risk assessment and evaluation of products and provide a mechanism for effecting advance informed agreement.

6. IMPLEMENTATION STRATEGY AND INSTITUTIONAL FRAMEWORK

This policy seeks to facilitate the establishment and development of national capacity to assess and manage potential risks associated with modern biotechnology practice and products. The Government of the Federal Republic of Nigeria, shall, therefore, as provided for in this policy establish well-coordinated, funded and sustainable mechanisms and institutional structures for the effective implementation of the Biosafety Policy. The structure shall comprise, but not limited to:

- National Focal Point (NFP) which shall be the National Biosafety Agency
- Competent National Authority (National Biosafety Committee)
- National Biosafety Technical Sub-Committee(s) - NBTS
- Institutional Biosafety Committee(s) - IBC
- Biosafety Officer(s) - BO

- Principle Investigator (PI)

7.1 NATIONAL FOCAL POINT

The Government of the Federal Republic of Nigeria shall establish ONE National Focal Point for Biosafety. The National Focal Point is the National Biosafety Agency. It shall be responsible for liaison with the Secretariat of the Convention on Biological Diversity (CBD), for the administrative functions required under the Cartagena Protocol on Biosafety. The National Focal Point shall be responsible for all correspondence with importers, exporters and applicants on movement of products of modern biotechnology (GMOs).

7.2 COMPETENT NATIONAL AUTHORITY

A National Biosafety Committee (NBC) shall be instituted and shall serve as the Competent National Authority for Biosafety in Nigeria. National Biosafety Committee shall be responsible for the safe management of biotechnology activities, including research, development, introduction and the use of the products of modern biotechnology (GMOs).

Sub-committees shall be established by the NBC for sectoral interests such as agriculture, health, industry and environment.

i. Membership:

Table 1: Membership of NBC should comprise the following:

Relevant Ministries/Agencies	*Number*
Federal Ministry of Environment	(1)
Federal Ministry of Agriculture	(1)
Federal Ministry of Science & Tech.	(1)
Federal Ministry of Industry	(1)
Federal Ministry of Environment	(1)
Federal Ministry of Health /NAFDAC	(1)
Federal Ministry of Justice	(1)

Federal Ministry of Commerce	(1)
Federal Ministry of Foreign Affairs	(1)
Nigerian Custom Service	(1)
NACCIMA/ Organized private sector	(1)
Biologist	(1)
Physical Scientist	(1)
Social Scientist	(1)
A Representative of NGOs distinguished in environmental matters and biodiversity conservation	(1)
Registrar of National Biosafety Agency	(1)

i. **Secretariat and Chairman**

The National Biosafety Agency will provide the Secretariat of the National Biosafety Committee and the chairman shall be appointed by the President on the advise of the Honourable Minister of Environment. The Registrar of National Biosafety Agency shall be the Secretary of National Biosafety Committee.

ii. **Appointment**

Relevant Ministries shall appoint their Representatives.

iii. Tenure

Non-civil servant members of the NBC shall be appointed by the Minister of Environment in consultation with other Ministries. They shall serve for four years in the first instance and are eligible for reappointment for a second term of three years only.

Functions of the NBC

NBC Shall:

a) Be responsible for risk assessment and risk management
b) Establish and review, as necessary, legal regulations and guidelines for both physical and biological containment and/or control procedures appropriate to the level of assessed risk involved in relevant research, development and application activities.

c) Consult with relevant government agencies and other organizations as appropriate.

d) Advise, where appropriate, on the training of personnel with regard to safety procedures.

e) Maintain an inventory of laboratories with physical and human capacities to conduct research in rDNA, undertake risk assessment and create a database of experiences in the releases of GMOs in the country.

f) Be responsible for advising Government on the release of and trade in GMOs

g) Assess applications and send to Technical Committee.

h) Monitor and validate information provided to it by the applicant.

i) Submit an annual report of its activities to the National Focal Point (NFP).

7.3 Functions of the National Biosafety Agency

- Central coordinating body for the safe use, handling and all other aspects of safety in application of biotechnology materials and practice
- Regulation of activities of biotechnology including
  - Handling of Applications and Notification
  - Information transfer and review
  - Risk assessment and Risk Management
  - Monitoring and enforcement measures relevant to input, export, transboundary movement of the products of biotechnology, laboratory and field testing/use of biotechnology including handling, containment disposal, control, monitoring and release
- Monitoring and oversight system for all modern biotechnology research and development activities in Nigeria
- Inspection of facilities, field trial plots, experiments and pre-commercial releases
- Provide an institutional framework for national decision making and linkage with the international community on biosafety issues
- Develop the necessary human and infrastructural capacity to effectively manage the regulatory system
- Promotion of Public Awareness, Education and create a platform for democratic decision making

- Monitoring Research and development in modern biotechnology internationally
- Implementing the Cartagena Protocol on Biosafety
- All administrative functions necessary for Nigeria to fully address its mandate under the CBD and CPB
- Accreditation of IBCs and IBOs
- Ensuring that safety standards are adhered to by all laboratories engaged in biotechnology research and development.

7.4 NATIONAL BIOSAFETY TECHNICAL SUB-COMMITTEE:

National Biosafety Technical Sub-committee(s) shall be established:

i. One each for the various disciplines (e.g. agriculture, health, industry environment) to support the work of the NBC.
ii. Review proposals for research and recommend the conditions under which experiments should be conducted.
iii. Provide technical advice to the NBC and contribute to its functions in relation to contained use, field trials, release and placement on the market etc.

7.5 INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

All institutions in Nigeria, both private and public (e.g. research institutes, universities and polytechnics, international research centers, industrial research and development units which plan to undertake biotechnology research and/or development), shall each establish an Institutional Biosafety Committee (IBC), which will be responsible to, and co-operate with the NBC.

i Membership of Institutional Biosafety Committee

Membership of an institutional biosafety committee shall include:

a) Five members from the respective institution, including the Biosafety Officer.

b) Two other members not affiliated with the institution .but knowledgeable in biotechnology or related fields, and representing the interests of the community, such as:
    I. Members of government's public health or environmental agencies;
    II. Persons active in human, plant or animal health concerns and,
    III. Persons or NGOs active in environmental concerns.
c) The IBC may invite any Principal Investigator (PI) or representative of NBC or any other person to its meetings.

ii. **Functions of the Institutional Biosafety Committee**

The IBC shall perform the following functions:

a. Consult with and seek approvals from the NBC;
b. Implement the recommendation of the NBC;
c. Review and recommend to the NBC applications from Pls;
d. Create and maintain a central reference file and library of catalogues, books, articles, newsletters and other communications as a source of advice and reference, including such items as the availability of safety equipment, the availability and level of biological containment for various host-vector systems, suitable training of personnel and data on the potential biohazards associated with certain technologies;
e. Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with GMOs and other products of modern biotechnology;
f. Develop a safety and operation manual and assist PIs in required staff training;
g. Certify the safety of facilities, procedures and practices as well as the level of training and experts of the personnel;
h. Review and monitor all biotechnology research conducted and sponsored by the institution to ensure compliance with established law;
i. Maintain a list of PIs, project supervisors, approved by the IBC as competent to perform supervisory duties for particular projects;
j. Maintain records and files of each research project;

k. Investigate and report promptly to the NBC all accidents and unexplained absence due to illness;

l. Submit an annual report to the NBC.

8 BIOSAFETY OFFICER (BO)

The institution's authorities shall appoint a Biosafety Officer. It is expected that the biosafety officer will be familiar with biosafety requirements for rDNA work. In addition he should be sufficiently independent to exercise some authority as related to responsibilities of this office.

Functions of the Biosafety Officer:

The Biosafety Officer shall:

- Undertake checks and provide advise on biosafety issues on a day-to-day basis;
- Ensure that biosafety is not compromised by any other considerations;
- Appointment as a member of the IBC;
- Provision of report, which should be part of the IBC's annual report to the NBC.

9 PRINCIPAL INVESTIGATOR (PI)

The PI who is responsible for conducting biotechnology research is the agent of an institution. The PI is accountable to the IBC and leads the efforts in a safe manner and in compliance with the appropriate research guidelines and all applicable laws..

Functions of the Principal Investigator:

The PI shall perform the following functions:

- Ensure that experiments, for which the PI is responsible, are undertaken in strict compliance with institutional and national laws;
- Ensure that safety procedures and practices are complied with;
- Report promptly to the IBC on any significant problems with respect to the implementation of relevant laws, regulations and guidelines;
- Notify the IBC promptly of any research-related accidents that have resulted or could result in human illness, in unanticipated plant or animal disease, or in the escape of organisms under study from an intended confinement;

- Obtain approval of the IBC before embarking on, or modifying biotechnology research projects requiring prior approval of the IBC;
- Ensure compliance with applicable shipping requirements regarding human, plant and animal health protection policies, permit requirements and containment conditions for possession of certain organisms.

10. REGULATORY AND ADMINISTRATIVE PROCEDURES

This policy seeks to facilitate the establishment and development of national capacity to assess and manage potential benefits and risks associated with modern biotechnology practice and products. This requires the establishment of appropriate regulatory mechanisms and administrative procedures for the effective implementation of the policy.

11.LEGAL AND REGULATORY SYSTEM

The Government of the Federal Republic of Nigeria shall establish the requisite legal and regulatory regime with emphasis on biosafety, but without prejudice to the potential benefits of modern biotechnology. Such legislation shall conform to the country's obligation to international law without undermining local and national development objectives and opportunities.

12.ADMINISTRATIVE IMPLEMENTATION PROCEDURES

In order to effectively implement the legal regime and the regulation of safety in biotechnology practice, the Government of the Federal Republic of Nigeria shall establish and institute administrative procedures, which include:

- Notification
- Information transfer and review
- Acknowledgement of notification
- Risk assessment
- Approval or refusal

- Risk management including monitoring and enforcement measures pertaining to laboratory use, research and development activities or field release procedures – handling, containment, monitoring, agreed disposal or destruction procedures, contingency plans for spillage or accidental release. In order to trace GMOs at port of entry of imports, existing sectoral legislation on import control may require review and amendment.
- Liability and redress.

Some of the procedures are briefly described in appendix 1.

13.FINANCIAL IMPLICATION

Modern biotechnology is an exceptionally expensive and specialized technology to develop. The implementation of its regulatory regime is even more expensive. Both biotechnology and biosafety require huge investments in infrastructure, equipment and specialist training. The regulation and monitoring of biotechnology is costly. To be successful, Government shall endeavour to allocate adequate funds to support the activities of the National Biosafety Agency and National Competent Authority, the implementation of the biosafety policy and enforcement of the ensuing legislation (law).

14.PUBLIC AWARENESS

The Government through the relevant institutions shall promote and facilitate public awareness on issues of Biosafety, the risks and benefits of biotechnology and its products. It shall ensure, through the Competent National Authority that GMOs imported and sold in Nigeria are appropriately labeled and the consumer provided with adequate information and choice.

15.BIO - ETHICS

Government shall ensure that appropriate mechanisms are established to ensure that the practice of modern biotechnology and the development of

products is undertaken in accordance with acceptable societal norms and code of ethics.

16.POLICY LINKAGES

This National Policy on Biosafety focuses on a specialized technology. However, biotechnology as the technology which biosafety portends to regulate is gaining increasing global relevance and importance in agriculture, public health, mining, trade, waste management etc., hence policies in these areas need to be reviewed to determine what, if any, amendments need to be made in compliance with global trends.

Important related national Policies Include:

- National Policy on Biotechnology
- National Policy on Environment
- National Policy on Agriculture
- National Policy on Health
- National Policy on Science and Technology
- National Policy on Trade etc.

17. APPENDIX 1

17.1.BRIEF DESCRIPTION OF ADMINISTRATIVE AND MANAGEMENT PROCEDURES IN THE IMPLEMENTATION OF THE BIOSAFETY POLICY.

1 NOTIFICATION

a) Applications for the movement of products of modern biotechnology into Nigeria shall be based on the Advance Informed Agreement. For the purpose of compliance with the provisions of the policy, notification shall cover import, export, research and development activities. For import, notification should be prior to the first intentional trans-boundary movement for all that fall within the scope of the policy and should address the relevant information contained in the relevant Annex of the law.

b) Notification should be sent to Nigeria's Focal Point National Biosafety Agency using the appropriate form. The Party of export shall ensure that legal requirements for the accuracy of information provided by the exporter are met.

2. ACKNOWLEDGEMENT OF NOTIFICATION

a) Acknowledgement of notification shall be made in accordance with the details as may be set out from time to time by the National Biosafety Committee which is the Competent National Authority, through the National Focal Point.

b) Failure by the Focal Point to acknowledge receipt of notification shall not imply its consent to an intentional release or transboundary movement of modern biotechnology products.

3. DECISION-MAKING PROCEDURE

a) The decision-making procedures shall take into consideration risk assessment, which involves scientific, socio-economic, cultural and ethical considerations. The decision to permit research and development in rDNA, import and release of products of modern biotechnology for whatever purpose shall be on a case-by-case basis.

b) Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of products of modern biotechnology on the conservation and sustainable use of biological diversity and risk to human health and the environment shall not prevent the relevant authorities from taking appropriate decision, with regard to the release or importation of such products.

c) As part of the requirement for taking decisions, the applicant is obliged to provide accurate information on the modern biotechnology product(s) in question.

d) The decision making procedure shall cover field trials, releases for domestic use as food or feed, or for processing, and placing in the market of modern biotechnology product(s) including those that are subject to transboundary movement.

e) A decision taken pursuant to this policy by the relevant authorities shall not render it liable for any adverse impact directly or indirectly

resulting from the use of the products of modern biotechnology and does not exclude the applicant from the requirements of other applicable regulatory instruments.

f) Approval to import, export or carry out releases shall be given by the National Biosafety Committee, the Competent National Authority.

4. REVIEW OF DECISIONS

a) A decision may be reviewed by the appropriate authority dealing with products of modern biotechnology on the basis of new information on adverse effects on conservation and sustainable use of biological diversity, also taking into consideration the risks to human health and the environment.

b) The National Focal Point shall take steps to inform applicants and the Biosafety Clearing House of the Convention on Biological Diversity as appropriate.

c) An applicant, notifier, exporter may request for review of a decision taken by the appropriate agency under the following conditions:

- A change in a piece of relevant information or
- Other circumstance as has become available.

5. TRANSIT

a) Any person who wishes to use a port in Nigeria for transit purposes in connection with the transboundary movement of products of modern biotechnology shall notify the National Focal Point accordingly in writing.

b) A written consent, stating the conditions under which transit is granted, shall be obtained before the transit can take place.

c) Failure to acknowledge receipt of the request for transit shall not be regarded as consent.

6. UNINTENTIONAL TRANS-BOUNDARY RELEASE AND EMERGENCY

a) All cases of unintentional transboundary release of products of modern biotechnology must be reported immediately to the National Focal Point (NFP).

b) Information accompanying such declaration should include, at a minimum:

   i. Quantities and details provided for in relevant Annex of the Biosafety Law.

   ii. Details of circumstances, estimated date of the release, and the use in the country of origin.

   iii. Possible harmful effects on conservation and sustainable use of biodiversity, taking into consideration risks to human health as well as risk management measures.

   iv. Any other relevant information and points of contact for further information.

7. RISK ASSESSMENT

a) The risk assessment shall take the following into consideration: The guiding principle of risk assessment is the Precautionary Approach. Where the transboundary movement, use or handling of products of modern biotechnology may cause, or has a proven or theoretical potential to cause harm to biodiversity, ecosystems, human or animal health, the lack of full scientific certainty or consensus regarding the level of risk should not be interpreted as the lack of risk, or as acceptable risk.

b) The risk assessment should take into account, inter alia, all relevant scientific theory, evidence and experience, including previous risk assessments (see details in relevant Annex of the law).
   This enables the risk assessment to evolve in the light of new evidence and knowledge. For example, a product of modern biotechnology previously considered acceptable at an earlier date may no longer be acceptable, at a future date and vice versa.

c) It should be acceptable as a principle underlying the risk assessment that every transgenic line is different because of random insertion, even if they are made with the same vector system, the same gene constructs and the same variety, and that it has to be well characterised to be stable for at least five generations under a reasonable range of environmental conditions that it may

encounter. If the risk assessment at first shows that the level of risk of the intended use is not acceptable, additional risk-management measures are to be taken and assessed until the risks have been minimised to an acceptable level. If the risk cannot be minimized in this way, it might be concluded that the intended operation should not proceed, or a risk/benefit analysis might be carried out to determine whether a higher level of risk is acceptable and whether the intended operation should proceed.

d) Risk assessment shall be carried out by person(s) approved by the NBC.

e) The cost of risk assessment and other administrative charges shall be borne by the applicant.

8. RISK MANAGEMENT

a) Risk management is employed during the development and evaluation of an organism in a systematic fashion, for example from the laboratory, through stages of field-testing, to commercialization. The number and forms of these stages are not fixed, but depend on the outcome of risk assessment at the different stages.

b) The type of risk management procedure to be adopted will depend on the Genetically Modified Organism, the particular application or product. For contained use, the degree of containment achieved depends primarily on the type of physical barriers and the application of appropriate work procedures. In the case of controlled release, different types of barriers, such as biological, chemical, physical or temporal barriers can be used to minimize or limit the dissemination and impacts of organisms with novel traits and/or to provide genetic isolation as required. Different risk-management practices may be applied, depending on the scale of the proposed release and its duration.

9. MEASURES FOR CONTROLLED RELEASES

Appropriate risk management measures for releases will vary considerably from case to case. They will be determined by the risk assessment, the organisms involved and the method of release. In addition to general precautions to control release, risk management measures often focus on the control of the dissemination of the released organisms and control of the gene flow from the released organisms (See relevant Annex of the biosafety

law). The type of risk management measures to be employed should be commensurate with the risk identified.

10.HANDLING PACKAGING AN IDENTIFICATION

a) All products of modern biotechnology should be handled, packaged and transported under conditions of safety taking into consideration local and international requirements.

b) All GMOs and derivatives as well as products made from GMOs irrespective of their use should be properly identified and labelled.

11. LIABILITY AND REDRESS

a) Any person who carries out any activity in relation to GMOs or products thereof shall be strictly liable for any harm, injury or loss caused directly or indirectly by such GMOs or products thereof or any activity in relation to them. The harm, injury or loss includes personal injury, damage to property, financial loss and damage to the environment or to biological diversity.

b) Liability shall attach to the applicant, the person responsible for the activity, which results in the damage, injury or loss, as well as to the provider, supplier or developer of the GMOs or products thereof.

c) Where liability under this section is incurred by a corporate body, any director, manager, secretary or similar officer of the corporate body shall be similarly liable unless he/she can show that he/she did everything in his/her power to prevent the import, deliberate release, placing on the market or contained use which caused the damage in question.

d) If there is more than one person responsible for the damage, injury or loss the liability shall be joint and several.

e) Where proceedings are brought against more than one person it shall not be a requirement for the person bringing the proceedings to identify the person who caused the damage in question, provided that he/she can prove that one or more of the persons so proceeded against could have caused the damage.

f) In case of harm to the environment or to biological diversity, redress shall include the costs of reinstatement, rehabilitation or clean-up measures actually incurred or to be incurred and, where applicable,

the costs of preventive measures and any loss or damage caused by the taking of the preventive measures; provided that the person responsible may be required to carry out the reinstatement or rehabilitation at its own cost and to the satisfaction of the Competent National Authority.

g) Liability shall also extend to harm or damage caused directly or indirectly by the GMOs or products thereof to the economy, social or cultural practices, livelihoods, indigenous knowledge systems, or indigenous technologies. Such harm includes the following: disruption or damage to production systems, agricultural systems, reduction in yields, and damage to the economy of an area or community.

h) An applicant shall indemnify:

   i. Any other person who deliberately release or markets GMOs or products thereof; and

   ii. Any person who manufactures, processes or markets food, food ingredients or animal feed containing or derived from GMOs against any civil liability where the GMOs or products thereof in question was first imported, deliberately released, used in contained conditions, or placed on the market by the applicant.

   iii. Any person who fails to label seeds, food, a food ingredient or animal feed containing or derived from GMOs, against any civil liability.

i) The right to bring any action to redress the harm caused by the GMOs or products thereof shall lapse only after a reasonable period from the date on which the affected person or community could reasonably be expected to have learned of the harm, taking due account of:

   i. The time the harm may take to manifest itself; and

   ii. The time that it may reasonably take to correlate the harm with the GMO(s) or products thereof, having regard to the situation or circumstance of the person or community affected.

j) Any person or group of persons may be entitled to bring a claim and seek relief in respect of the breach or threatened breach of any provision of this policy, including any provision relating to damage to the environment and biological diversity:

   i. In that person's or group of persons' interest;

   ii. In the interest of or on behalf of, a person who is, for practical reasons, unable to institute such proceedings;

iii. In the interest of or on behalf of, a group or class of persons whose interests are affected;

iv. In the public interest; and

v. In the interest of protecting the environment or biological diversity.

k) No costs shall be awarded against any of the above persons who fail in any action as aforesaid if the action was instituted reasonably out of concern for the public interest or in the interest of protecting the environment or biological diversity.

l) It shall not be a defence to any claim for compensation or damage that the activity had been consented to by the Competent National Authority.

12. PROTECTED DISCLOSURES

a) Notwithstanding the provisions of any other law, no person is civilly or criminally liable or may be dismissed, disciplined, prejudiced or harassed on account of having disclosed any information, if the person in good faith reasonably believed at the time of the disclosure that he/she was disclosing evidence of any risks posed by GMOs or products thereof to human or animal health, the environment or biological diversity in accordance with relevant section of the biosafety law

b) The person disclosing the information concerned to one or more news media and on clear and convincing grounds believes at the time of the disclosure that:

- It was necessary to avert an imminent and serious threat to human or animal health, the environment or biological diversity, to ensure that such a threat was properly and timely investigated, or to protect himself/herself against serious or irreparable harm from reprisals; or
- Giving due weight to the importance of open, accountable and participatory administration, that the public interest in disclosure of the information clearly outweighed any need for non-disclosure; or:
- The person disclosing information, which, before the time of the disclosure of the information, had become available to the public, whether in the country or elsewhere.

c) Section 12(a) applies whether or not the person disclosing the information concerned has used or exhausted any other applicable external or internal procedure to report or otherwise remedy the matter concerned.

d) No person may induce any other person to exercise of refrain from exercising his/her right as aforesaid by giving or promising any advantage.

e) No person may threaten to take any action against any other person for exercising or intending to exercise his/her right as aforesaid.

7. GLOSSARY OF TERMS

Acknowledgement: means response indicating receipt of application to import .

Advance Inform Agreement (AIA): Entails notification by an applicant, to acknowledgement of receipt of notification to final approval for import of GMO/products.

Bio-Ethics: Means conformity of practice of modern biotechnology with societal norms and code of ethics.

Biosafety: Is a range of measures, policies and procedures for minimizing potential risks that modern biotechnology may pose to the environment and human health.

Biosafety Officer: Means a person who is familiar with biosafety, appointed by an institution that is engaged in modern biotechnology activities to ensure that biosafety is not compromised and provides reports to NBC,

Cartagena Protocol on Biosafety: Is an international Protocol which Came into existence in 2000 and ratified on the 11th of September 2003 as an internationally binding legal instrument to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health and specifically focusing on transboundary movements.

Competent National Authority (CNA): Means the National Biosafety Committee (NBC) that shall advise the NFP on matters relating to GMOs, including research, development, introduction and use of the products of modern biotechnology (GMOs).

Convention on Biological Diversity (CBD): Is an international Convention which came into existence in 1992 .It provides a comprehensive and holistic approach to the

Conservation of biological diversity, the sustainable use of natural resources and fair and equitable sharing of benefits deriving from the use of genetic resources.

Export: Means intentional transboundary movement from one country to another country of GMO.

Genetically modified Organism (GMO): Means any organism that possesses a novel combination of genetic materials obtained through the use of modern biotechnology.

Import: Means intentional transboundary movement into one country from another country of GMO.

Institution Biosafety Committee (IBC): Means committee establishment by any institution which plans to undertake modern biotechnology research and/or development to guide the institute on biosafety in line with existing rules and regulations.

Labelling: means any inscription, logo or mark to indicate the presence of GMO in products on whole GMO.

Liability: It entails that any person who carries out any activity in relation toGMO of products thereof shall be strictly liable to any harm, injury or loss caused directly or indirectly by such GMO or products thereof or any activity in relations to them.

Modern Biotechnology: Means the application of:

a) In-vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into the calls or organelles: or

b) Fusion of cells beyond the taxonomic family that overcomes natural physiological reproductive or combination barriers and that are not techniques used in traditional breeding and selection.

National Biosafety Committee (NBC): means the National Competent Authority.

National Biosafety Technical Sub-Committee (NBTS): Means sub technical committees of the National Biosafety Committee for sectoral interests such as Agriculture, health, industry and Environment, to support work of NBC, in proposals for research and provide technical advise to NBC in relation to contained use, field trials, release and placement into the market.

National Focal Point (NFP): Means the National Biosafety Agency responsible for liaison with the Secretariat of the Convention on Biological Diversity (CBD) for the

administrative functions required under the Cartagena Protocol on Biosafety, it is also responsible for all correspondence with importers, exporters and applications on movement on introduction of products of modern biotechnology into the environment and field or confined testing.

Notification: Means prior information to intentionally introduce GMO/Products into the market, field or carry out research on modern biotechnology made to a country by an applicant.

Notifier : Means applicant seeking permit to develop GMO, release into the environment, import/export or use GMO products or place on the market.

Principal Investigation (PI): means an agent of an institution who is responsible for conducting modern biotechnology research. He is accountable to IBC and leads research efforts in a safe manner and in compliance with appropriate research guidelines and all applicable laws.

Protective Disclosure: It means not withstanding the provisions of any other law no person is civilly or criminally liable or may be dismissed, discipline prejudiced or harassed on account of having disclosed any information, if the person in good faith reasonably believed at the time of disclosure that he/she was disclosing evidence of any risks posed by GMO or products thereof to human or animal health, the environment or biodiversity in accordance with relevant section of the biosafety law.

Risk Assessment: Means the scientific identification and evaluation of potential adverse effects that GMO may have on conservation and sustainable use of biodiversity and to human health in the receiving environments.

Risk Management: Means management, control of any risks that may be identified by risk assessment, it entails monitoring.

Transboundary Movement: Means the movement of a GMO from one country to another country.

Unintentional Release: Means accidental release of GMO into the environment.

DOCUMENT TWO

DRAFT NATIONAL BIOSAFETY FRAMEWORK

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LIST OF TABLES

ACRONYMS

CAN – Competent National Authority

CBD - Convention on Biological Diversity

COP – Conference of Parties

CPB – Cartagena Protocol on Biosafety

GEF – Global Environment Facility

GMOs - Genetically Modified Organisms

GURTs - Genetic Use Restriction Technologies

MOP – Meeting of Parties

NBA – National Biosafety Agency

NBC - National Biosafety Committee

NBF - National Biosafety Framework

NBTS - National Biosafety Technical Sub-Committee

NCC - Coordinating Committee

NFP - National Focal Point

RA - Risk Assessment

UNCED - United Nations Conference on Environment and Development

UNEP - United Nations Environment Programme

DRAFT NATIONAL BIOSAFETY FRAMEWORK

NIGERIA NATIONAL BIOSAFETY FRAMEWORK

1.Purpose: an overview of what has been done in Nigeria during the National Biosafety Framework development and what is in place.

Preamble

Nigeria's quest for regulating biotechnology started in the early 1990s and by 1994 a draft Biosafety Guideline was widely circulated for use in the country. This edition of the guideline however did not bear the stamp of official authority and thus was not used. Current efforts at developing a National Biosafety Framework is meant to address the subject of regulating biotechnology in a more robust and encompassing approach. Whereas the first edition was a stand-alone document, the present effort under the aegis of the UNEP/GEF global programme addresses present five documents as the pillars upon which transparent decision-making will be made:

- a government policy,
- a legal framework,
- a method of assuring public participation in decision making,
- a well defined system for handling requests and
- follow-up activities including inspections, monitoring and enforcement. These were lacking in the 1994 document and the revised edition of 2001done in anticipation of the challenges posed during the negotiations leading to the Cartagena Protocol on Biosafety (CPB).

The National Biosafety Framework (NBF) has been developed by the National Coordinating Committee (NCC), a body charged with bringing together the NBF. The body comprises of federal government ministries and parastatals, in collaboration with independent groups and individuals knowledgeable in the subject of biotechnology,

biosafety and socio-economic considerations in national development. When ready in its final form it would have been subjected to comments from the organised private sector, consumer groups, academia and several other concerned stakeholders.

In this new document, biosafety is seen as a tool to assure that the use of biotechnology leads to sustainable development, is compatible with environmental, agricultural and other policies, protects the environment and biodiversity as well as human health. The drafting of the framework has taken place at a time of emphasis on transparency, excellence in service delivery and promotion of quality assurance in Nigerian culture. Reforms are also being carried out in practically all sectors of the economy in the country and the role of the private sector in the economy is gaining wide recognition. Public health concerns have become a national issue as effort is being made to stamp out substandard drugs and the incidence of fake of faking in the health industry. Thus the need for Nigeria to be competitive in the international market place is recognised. Democratic norms and principles are being engendered in national issues and the need to ensure wide participation has become more evident. Probably the most significant consideration is that there exists a National Biotechnology policy which had not been properly articulated by 1994. National obligation to comply with the CPB also did not exist in 1994 coupled with the heightened awareness brought about by concerns expressed by a variety of groups which have taken centre stage during the negotiations leading to the Protocol.

2. Missing legislation that still has to be drafted/adopted, gaps in administrative or enforcement systems etc

Strategic government ministries and specialised agencies which may have relevance in handling certain aspects need to harmonise their activities with the development of the

NBF and participate more actively in defining roles to be played in a seamless administrative mechanism for addressing notifications, risk assessment, management and monitoring. The need to obtain the cooperation and recognise the roles to be played by different organs of government under one umbrella so as to provide a truly national platform for decision making in biosafty becomes more compelling since some other agencies have been used to working alone to meet national and international obligations in related fields.

3. Introduction

Nigeria UNEP/GEF National Biosafety Framework:

Start year **2002**

End year **2005**

4. National Executing Agency: **Nigeria Federal Ministry of Environment**

5. NPC Name: **Matthew Pendry Omare Dore**

→Postal Address :Federal Ministry of Environment
PMB 468, Garki, Abuja, Nigeria

→National Coordinating Committee consist of 19 members as detailed in table below

SNo	Name	Institution
1	Professor J.A. Ekpere,	Chairman, Biologist
2	Mr. M.A. Oyebo	Federal Ministry of Environment
3	Professor Omaliko, CPE	National Biotechnology Development Agency
4	Mr.Mogaji	Ministry of Agriculture
5	Mr. P.C Gumwesh	Ministry of Commerce
6	Mr. Musa Shaba	Ministry of Industry
7	Mr. Babatunde Ismail	Ministry of Education
8	John Ugolo, Esq	Ministry of Justice
9	Mr. T.B. Nkem	Ministry of Foreign Affairs
10	Mr. O. Ogbonna	National Food and Drug Administration and Control [Health]
11	Dr. Tobore Wanogho	Customs
12	Dr. Mrs. Lamin Lombi	National Veterinary Research Institute

13	Dr. Mrs Sylvia Uzochukwu	Univ.of Agriculture Abeokuta
14	Professor. H Ekpo	Socio-economist
15	Mr. Chris Ugwu	Civil Society
16	NACCIMA	Private sector
17	Dr. Christian Fatokun	International Institute of Tropical Agriculture, **Co-opted Member**
18	Professor G.H Ogbadu	Sheda Science and Technology Complex, **Co-opted Member**
19	Matthew Pendry Omare Dore	NPC

DESCRIPTION OF DRAFT National Biosafety Framework

Objectives

The overall objective of the framework is to provide a regulatory regime and guidance for the sustainable development of the science of modern biotechnology, its application and safe use of its products without prejudice and risk to public health, environmental health, national sovereignty, human dignity and fundamental human rights. The specific objectives include:

- Regulation of modern biotechnology practice and procedures to ensure the safe use of its products
- Guide the development of appropriate legislation and implementation mechanism established through a transparent participatory process
- Develop the necessary human and infrastructural capacity to effectively manage the regulatory system

- Ensure effective control of transboundary movement of Genetically Modified Organisms (GMOs) and products thereof resulting from modern biotechnology, through information exchange and a science-based, transparent system of Advanced Informed Agreement
- Provide for the establishment of a comprehensive, coordinated central monitoring and regulatory system for all modern biotechnology research and development activities in Nigeria
- Institute a balanced public enlightenment campaign on biosafety as an essential counterbalance for modern biotechnology

Principles

This policy is informed by the essential and fundamental principles that:

- Nigeria has inalienable sovereign rights over all natural resources (including genetic resources) in its territorial area of jurisdiction, and the authority to regulate access to such resources and activities which might have adverse effect on such resources.
- As a party to the Convention on Biological Diversity (CBD) and the United Nations Conference on Environment and Development (UNCED), Nigeria is under obligation to regulate the application of modern biotechnology and use of its products, which may cause harm to its biodiversity or human health.
- Nigeria shall endeavour to maintain an appropriate balance between the use of modern biotechnology as a tool for development and its regulation in a

sustainable manner to enhance meaningful growth of its economy and to the welfare of its people.

- The import, use, export, sale (trade), transboundary movement, etc. of modern biotechnology products and practices must fully conform to existing national law.
- The regulation to ensure the safe use of modern biotechnology and its products shall be by a Competent National Authority advised by professional/technical committees independent of government and industry, whose decision-making process is transparent, scientifically sound and fully cognizant of environmental, public health, socio-economic and cultural considerations.
- Applies the precautionary principle and approach.
- Modern biotechnology applications and inventions derived from or inspired by traditional knowledge, innovations and practices of local communities or individuals in Nigeria shall be subject to appropriate national legislation related to community or individual intellectual property rights, and shall include contractual agreement on benefit sharing (financial or otherwise) arising from such application and invention with the concerned community and/or individuals. The State shall provide the desired assistance and advise to ensure equitable negotiation and conclusion of such a contractual agreement.
- Nigeria shall endeavour to cooperate with other states in the sub-region and Africa to ensure the safe use of modern biotechnology, its applications and products within its borders.
- Nigeria shall not allow/permit the importation and transboundary movement and/or use of modern biotechnology products and procedures which do not meet minimum safety standards as identified by the Competent National Authority and

specified in this policy document and other established legislation. Nigeria shall undertake local field trials (as shall be determined) of such products and products, financed by the applicant, where existing information is considered inapplicable or inadequate to local conditions.

- Where, on appropriate risk assessment, a biotechnology product, application or procedure turns up a negative recommendation, this shall not be over-ruled for reason of political or economic expediency. However, a positive recommendation may be over-ruled if it is not politically and economically expedient.

As a general principle, pending the outcome of global and regional assessment of the potential severe socio-economic, ethical, environmental risks posed by "Genetic Use Restriction Technologies, (GURTs)", Nigeria shall impose a ten year renewable moratorium on the import, export, transboundary movement, sale or use of genetic materials such as seeds, other planting materials, altered by these technologies including the so called "Terminator Technology" and related processes and procedures. Such a moratorium shall take effect on the adoption of this policy by Cabinet. A public, transparent review of this moratorium shall be conducted by the Competent National Authority every two years.

How does it relate to other national development policies and priorities

8. POLICY LINKAGES

This National Policy on Biosafety focuses on a specialized technology. However, biotechnology as the technology which biosafety portends to regulate is gaining increasing global relevance and importance in agriculture, public health, mining, trade,

waste management etc., hence policies in these areas need to be reviewed to determine what, if any, amendments need to be made in compliance with global trends.

Important related national Policies Include:

- National Policy on Environment
- National Biodiversity Strategy and Action Plan
- National Policy on Biotechnology
- National Policy on Agriculture
- National seed Policy
- National Policy on Health
- National Policy on Science and Technology
- National Policy on Trade etc.

The national biotechnology policy has as its focus the harnessing of biotechnology as a developmental tool to contribute in several sectors to the well-being of the Nigerian economy. In doing this it is responsive to the National Biodiversity strategy and Action Plan and several other policy documents.

The national agriculture policy specifically declares that it is a priority of the policy to mobilize biotechnology in the development of agriculture. It elaborates this to the point of indicating how seeds would be a tool in the advancement and development of agriculture.

What are the priorities and targets for Nigeria in relation to biosafety

Priority includes all GMOs and their products including all living organisms, germplasms, and all elements of genetic materials used in genetic manipulation and Conservation of biological diversity.

It covers:

- Laboratory and field applications of modern biotechnology, currently known to science as well as those that may be developed in future.

- Current and future applications in agriculture, human and veterinary medicine, food/feed and beverage production, industry, environmental management, bioremediation, industrial and domestic waste management etc.
- Regulatory regime including:
    - Notification
    - Information transfer and review
    - Risk assessment, including socio-economic impact and ethical consideration
    - Monitoring and enforcement measures relevant to input, export, transboundary movement of the products of biotechnology, laboratory and field testing/use of biotechnology including handling, containment disposal, control, monitoring and release
- Research and development in modern biotechnology including applications in academic, agricultural, industrial and other categories of research.
- Occupational safety in the workplace where modern biotechnology procedures are used or products handled
- Labeling of Genetically Modified Organisms (GMOs) in food/feed produced locally, sold domestically or imported.
- Any other measures that may be required to safe use of modern biotechnology while protecting human health, the environment and national biodiversity.
- Promotion of public awareness on biosafety involving policy makers, legislators, administrators, the organized private sector, industry and the rural community.
- Development and establishment of a comprehensive and up-to-date scientific database and infrastructure for information exchange to enable risk assessment and evaluation of products and provide a mechanism for effecting advance informed agreement.

Additional information required

Status of ratification
Convention on Biological Diversity: signed 1992 and ratified 1994

Cartagena Protocol on Biosafety: signed 2000 and ratified November 2002

2. Regulatory regime

There is no specific Law/Act addressing Biotechnology and Biosafety as subject matters

- Title of laws, acts, decrees
- Draft Nigeria Biosafety Bill
- Status (draft, adopted, year of adoption)

-Draft: under circulation prior to national debate and refinement

- What does it regulate (releases, marketing, contained use of LMOs, transit, etc)
    a) This Act *shall apply to the import, export, transit, contained use, release, research and development or placing on the market of any living modified organisms or genetically modified organisms whether intended for release into the environment, for use as a pharmaceutical, for food, feed or processing or a product of a living modified organism or genetically modified organism*.

    b) Notwithstanding the provisions of subsection (a) of this section, this Act *shall not apply to any living modified organism or genetically modified organism as the Minister may, by an Order published in the Federal Gazette and on the advice of the National Biosafety Committee, exempt from time to time.*

The objectives of the Act
(a) to ensure safety in the use of biotechnology;
(b) to safeguard human health and the environment from any potential adverse effect of living modified organisms or genetically modified organisms;
(c) to establish and strengthen institutional arrangements on biosafety in Nigeria;
(d) establish adequate measures for sustaining biotechnology processes in Nigeria;
(e) promote and use regular risks assessment and monitoring mechanisms to ensure the safety in the use of living modified organisms and genetically modified organisms to human health and the environment;
(f) to foster public participation, public awareness and consensus building in the use and application of biotechnology and living modified organisms or genetically modified organisms; and
(g) to ensure that the use of living modified organisms or genetically modified organisms does not jeopardize socio-economic and cultural interests

- **Brief summary of procedures and content (couple of paragraphs)**

Procedure
The regulatory and administrative mechanisms for the effective implementation of the NBF.

Takes appropriate legal administrative and other measures to regulate the import, transit, contained use, release or placing on the market of Living Modified Organisms or Genetically Modified Organisms
-Precautionary principle
- User (notifier) pays principle.

- **Responsible institutions for implementing these laws, acts, decrees. Provide gaps information on gaps in legislation on biosafety**

The relevant and related laws which pertain to aspects of biosafety specify government ministries and parastatals with powers of enforcement and making regulations to ensure proper adherence to the laws. Important among these are the Ministries of Agriculture, Health, Science and Technology and their specialized agencies and parastatals. These include: Plant quarantine Services, National Agency for Food and Drug Administration and Control.

National Focal Point

- The National Biosafety Agency designated as the National Focal Point on biosafety in Nigeria.
- The national focal point 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.

National Biosafety Committee/National Competent Authority

There is established a committee to be known as the National Biosafety Committee which shall be designated as "the national competent authority" on biosafety matters in Nigeria.

Biosafety Technical Subcommittee

National Biosafety Technical Sub-committee(s) shall be established:

iv. One each for the various disciplines (e.g. agriculture, health, industry environment) to support the work of the NBC.

v. Review proposals for research and recommend the conditions under which experiments should be conducted.

vi. Provide technical advice to the NBC and contribute to its functions in relation to contained use, field trials, release and placement on the market etc.

- Full inventory of relevant national legislation
    a) Federal Environmental Protection Agency Act Cap 191 LFN 1990
    b) National Agency for Food and Drugs Administration and Control (Amendment) Decree No. 15 1993
    c) Animal Diseases (Control) Act Cap 18 LFN 1990
    d) Harmful waste (Special criminal Provision) Act Cap 165 LFN 1990
    e) Agricultural (Control of Importation) Act Cap 12 LFN 1990
    f) Plants, etc (Control of Importation) Act Cap 12 LFN 1990
    g) National Agricultural Seeds Decree No. 72 1992
    h) National Crop Varieties and Livestock Breeds (Registration etc) Act Cap 249
    i) Pesticide and Registration regulation No.1.10 of 1996
    j) Federal Approval Gazette Vol. 79, 31st December 1992- inland Fishing decree No.108 1992
    k) Live fish (Control of Importation) Act Cap 209 LFN 1990
    l) Bees (Import Control and Management) Act Cap 209, 1962
    m) Food products registration regulation Decree No. 1.7 of 1996
    n) Pest Control of Produce (Special Powers) Act Cap 349 LFN 1990
    o) Export (Prohibition) Act Cap 121 LFN 1990
    p) Food Products (Advertisement) Regulation decree No. 1.13 of 1996
    q) Food and drugs act Cap 150 1990

- **Attach guidelines published during the project**

In view of the development of a draft Act, there is need to harmonize the Act and existing Guideline so as to remove duplications and address more salient issues in the Guideline.

A new Guideline is therefore necessary.

3. System to handle notification or requests for authorizations

Brief description of Nigeria's system to handle notifications or requests for authorization for activities, such as release of LMOs into the environment.

Administrative functions

In Nigeria, the National Focal Point (NFP) for Biosafety is the proposed National Biosafety Agency. The NFP shall:

- liaise with the Secretariat of the Convention on Biological Diversity for the administrative functions required under the Cartagena Protocol on Biosafety
- will be responsible for all matters relating to Biosafety including risk assessment and risk management, correspondence with importers, exporters and applicants on movement of GMOs
- shall receive all applications for approval for trial releases and eventually commercial releases of GMOs.

The powers and functions of the National Focal Point shall be vested in the Honourable Minister for Environment or whomsoever he shall delegate such to. The Minister shall:

- provide overall policy guidance on Biosafety in Nigeria
- implement the provisions of the Convention and the Protocol on matters relating to living modified organisms
- develop risk management plan and strategy for protecting human health, biological diversity and the environment from accidents in biotechnology, living modified organisms and genetically modified organisms.
- approve applications in respect of living modified organisms and genetically modified organisms.
- render reports to the Secretariat of the Convention on the implementation of the Convention and the Protocol on matters relating to the use of living modified organisms and genetically modified organisms

- liaise with the Secretariat of the Convention and the Biosafety Clearing House with respect to the administrative functions required under the Protocol and
- carry such other duties as may be necessary for the full discharge of the functions under the Act

Functions Of The NBC

The functions of the NBC shall include

- Risk assessment and management.
- Establishment and review, as necessary, of guidelines for both physical and biological containment and/or procedures appropriate to the level of assessed risk involved in relevant research, development and application activities.
- Consultation with relevant governmental agencies and other organizations as appropriate.
- Advise, where appropriate on the training of personnel with regard to safety procedures
- Maintain an inventory of laboratories with physical and human capacities to conduct research on rDNA, undertake risk assessment and create a database of experiences in the releases of LMOs/GMOs in the country.
- Advise the Government on the release of LMOs and GMOs.
- Receive requests for permits and decide on their issuance or otherwise
- Ensure law enforcement under the guidelines/Act as appropriate.
- Responsible for inter-country liaison
- Monitoring and validation of information sent to it by the applicant
- Submission of annual reports of its activities to the National Focal Point

The NBC shall have its secretariat at the Federal Ministry of Environment.

- Risk assessment

A unified approach is adopted under the Nigerian framework for the receipt of and processing of applications .This is meant to provide a one-stop mechanism where the clearing house is the NBC. NBC ensures the movement of the notification through the various sub-committees, participation of relevant bodies in the decision –making process, monitoring its movement to ensure timeliness of identified events which are supposed to take place especially to ensure consistency with specified time limits for handling

requests, and Compliance with existing legislation and policies. Thus applications deemed to be for agricultural purposes will be dealt with at the technical level by the Agriculture Technical Sub-Committee. The same applies to the Health, Environment/Industry Technical Sub-Committees. These sub-committees are free to use the expertise of anybody including the research institutes/parastatals in their ministries. Sub-committees would be encouraged to keep to strict time frames. The budgetary implication of the work of sub-committees will be considered as part of the costs of risk assessment administration. Frugality will be the key aspect of such budgets. Specialized agencies in the ministries, e.g Plant Quarantine Services should be properly engaged in the elucidation of the implications and the roles inter-governmental cooperation would play in assuring a seamless and conflict-free handling of notifications as well as administration of entries and their local movement. Care should be taken to reduce costly agency duplication of effort.

- Decision-making

All applications are to be routed through the Honourable Minister of Environment. NBC to receive applications from Honourable Minister of Environment. NBC to meet and direct relevant Technical sub-committee to elucidate issues including policy implications of applications and the need for cross-sectoral cooperation among institutions. National Biosafety Technical Sub-Committee (NBTSC) to carry out Risk Assessment (RA) and ensure participation of all relevant stakeholders. Findings of NBTSC are submitted to NBC within stipulated time in order to meet timeframe for RA. License to carry out event is given by NBC

- Public participation

-Membership of the NBC includes independent stakeholders represented by A Biologist, a Physical scientist, a Socio-economist and a representative Non Governmental Organization, representative of the private sector .

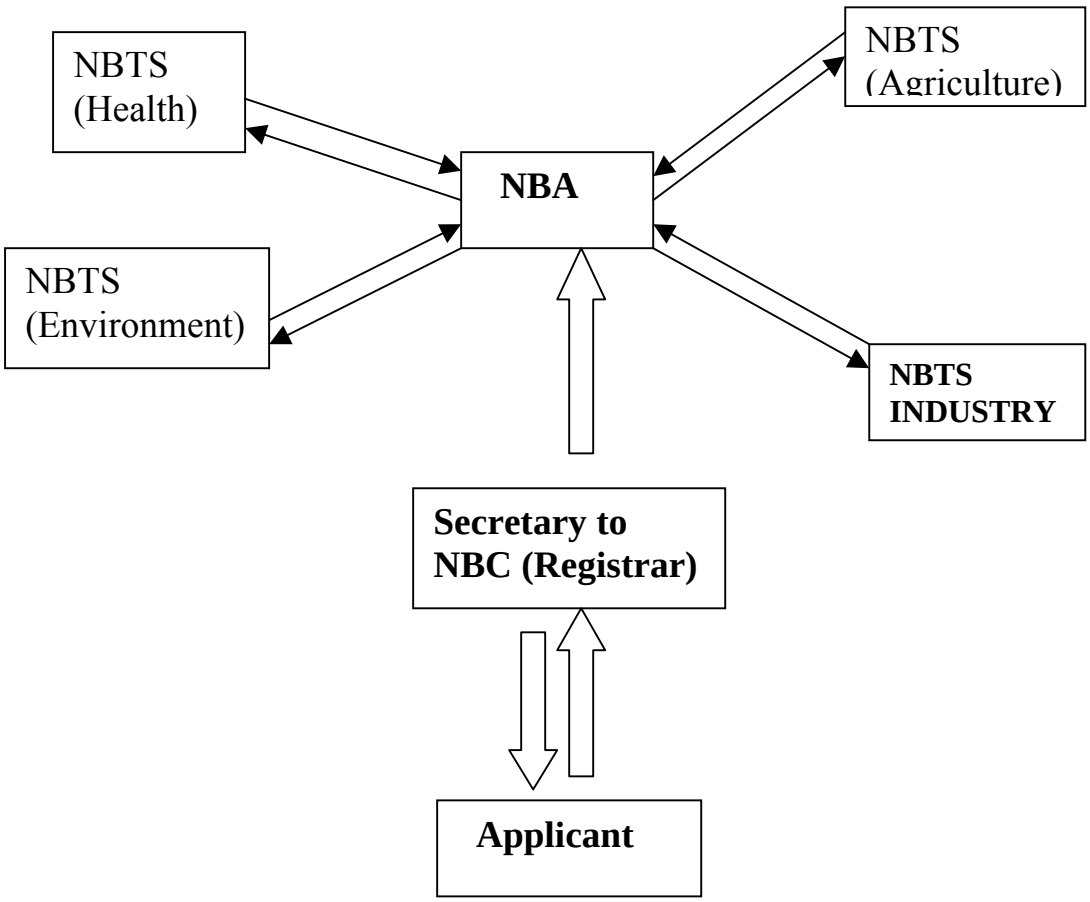
-Publication of requests in three wide circulating newspapers

-Public hearing would be used as appropriate for applications

-Public hearing cost would be part of risk assessment

- Competent National Authority responsible for handling requests for permits (imports, exports, domestic use, including placing on the market, intentional introduction into the environment, field trials, contained use, transit, pharmaceuticals)

- The system(s)/procedure(s) for handling notifications and requests and permits, flow chart is useful way to explain and illustrate



NBTS (National Biosafety Technical Subcommittee): A subcommittee of experts in different fields such as Agriculture, Health, Industry and Environment.

NBC: National Biosafety Committee

- Future plans where relevant [attach any relevant forms where relevant
    - Capacity building for implementation of laws developed to ensure safety, e.g customs, police, plant quarantine, members of varietal release committees, Institutional Biosafety Officers, Biotechnology research institutes, National Agricultural Research Institutes
    - Generally getting the various organs to accept/adopt a central platform to ensure functioning of Biosafety.
    - Ensuring the creation of centres of excellence within existing organizations in participation and scientific verification required in risk assessment.
    - Strengthening of laboratories and ensuring that operators are willing to comply with regulatory regimes.
    - Development of detailed of guidelines dealing with specific aspects of biosafety procedures
    - Regular updating of laws/regulations/guidelines to respond to international obligations, decisions of relevant United Nations bodies (e.g decisions of CPB COP/MOP)
    - Curriculum development for all levels within the educational system to introduce biosafety
    - Development of publicity materials for mass media to reach diverse audience.

4. Monitoring and enforcement

The principle for monitoring would be:

a) Cradle to grave--- from national project conception to market and export for national initiatives

b) From entry at designated port to laboratory (contained use), field testing, pre-commercial release, commercial release, placing on the market and post-release monitoring.

Monitoring through the medium of field visits will be the main source of information that will drive the management of risks and other aspects of biosafety. To be meaningful, formal reports will be filed for monitoring purposes.

Detailed formats will be developed to spell out the following: (a) what will be monitored (b) the purpose of monitoring (c) how monitoring should be carried out and (d) frequency for particular items and events.

It may be needed to categorise the various levels of monitoring which are appropriate to the events which may be handled. Thus, the following groups may be discerned: monitoring experiments, monitoring for purposes of following products placed on the market, regulatory fulfilment, examination of specific events and anticipate unforeseen outcomes.

The following need further articulation and development:

- Format for monitoring and enforcement for environmental effects
- evaluating actual impacts on the environment and human health
- scales of monitoring
- formats for grains, monitoring items in general commerce, monitoring manuals
- reporting formats for monitors

5. Nigeria's system for enforcement

Enforcement procedures would be further developed and articulated to ensure practical translation of the draft policy and regulatory framework.

- Linkage between monitoring and enforcement

  Enforcement would be joint responsibility of several organs with cognate responsibility working in cooperation with notifiers/applicants and identified organs of the NBC/CNA.

  Outcome of monitoring would be used for enforcement and ensuring compliance with terms of permits and conditions of operations.

- How can the system be proactive and be ahead of prospective violators?

  Since developments in the field are internet based, liaison with other bodies would be maintained, a reporting format would be encouraged for developers and promoters of biotechnology within the country to ensure that their plans are well known before hand so as to avoid delays in processing notifications. A need for expansion of appropriate organs for administration of biosafety nationally may be warranted.

  - Institutions responsible for these actions

  The Federal Ministry of Environment, Customs, Plant Quarantine, National Biotechnology Development Agency working under the auspices of the NBC/NCA would be the arrow-head of enforcement/monitoring function.

- Future plans for monitoring and enforcement systems where relevant

Training of responsible officials for monitoring and enforcement will be arranged.

Mechanisms for promoting and facilitating public awareness, education and participation

- Informing and involving the public in the development and implementation of the NBF
    - Copious use of radio and television, especially those with mass participation.

Nigeria's system for public awareness, education and participation

- Examples of best practices and lessons learned, if available.

The Federal Ministry of Environment currently subjects developmental projects of a particular magnitude to Environmental Impact Assessment (EIA) where public hearings are held. These public hearings take the form of proponents pitching arguments based on grounds derived from published materials by the developer. A decision is reached after all parties have had objections addressed. The system assures that environmental concerns are addressed prior to commencement of development which might have adverse impacts on the environment.

- Address of the national component of BCH or any other biosafety related website

Federal Ministry of Environment,

PMB, 468, Abuja,

Nigeria

- Future plans for systems of public awareness, education and participation, in biosafety, where relevant.

The remaining time for the development and adoption of the NBF would be devoted to massive publicity on the NBF. Public awareness materials and radio, television interviews would be used. Since there exists public participation/phone-in radio and television programmes, these would be used. Translation of the NBF would be made into three major Nigerian languages- Hausa, Igbo and Yoruba.

DOCUMENT THREE:

DRAFT SYSTEM TO HANDLE NOTIFICATION **AND REQUESTS FOR AUTHORIZATION IN NIGERIA**

TABLE OF CONTENTS

4.1 Product movement through the regulatory framework
4.2 Research & Development
4.3 Variety registration
4.4 Labelling
4.5 Transit
4.6 Environmental safety
5.0 MONITORING AND ENFORCEMENT
5.1 What to monitor
5.2 Levels of monitoring
5.3 Tracking
5.4 Surveillance
5.5 Capacity building

ANNEX I

INFORMATION REQUIRED FOR THE APPLICATION

I. GENERAL INFORMATION

20

A. Name and Address of applicant
B. Information on personnel and training

II. Information relating to the GMO(s) or products thereof

A. Characteristics of (a) the donor, (b) the recipient or (c) (Where appropriate) parental organism(s)

B. Characteristics of the vector
C. Characteristics of the GMO(s) or products thereof
III. Information relating to the conditions of release and the receiving environment

Information on the release

B. Information on the environment (both of the site and the wider environment)
IV. Information relating to the interactions between the GMO(s) or products thereof and the environment
A. Characteristics and factors affecting survival, multiplication, gene expression and dissemination
B. Interactions with the environment
C. Potential environmental impact
(v). Characteristics of resuscitated organisms and gene(s) and fossil DNA sequences:

A. Resuscitated organism
B. DNA sequences from fossils or from resuscitated organism

2. SOCIO-ECONOMIC CONSIDERATIONS:
3 Risk Management Measures

A. General precautions

(i) PLANTS
(ii) ANIMALS
(iii) MICRO-ORGANISMS
B. Monitoring techniques
C. Waste treatment

PREAMBLE

Nigeria's quest for regulating biotechnology started in the early 1990s and by 1994 a Biosafety Guideline was widely circulated for use in the country. This edition of the guideline however did not bear the stamp of official authority and thus was not used. Current efforts at developing a National Biosafety Framework is meant to address the subject of regulating biotechnology in a more robust and encompassing manner consistent with the obligations inherent in Nigeria's signing of the Cartagena Protocol on Biosafety (CPB). Whereas the first edition was a stand alone document, the present documents comprise: a government policy, a legal framework, a method of assuring

public participation in decision making, a proper and well defined system for handling requests and follow-up activities. These were lacking in the 1994 document and the revised edition of 2001 done in anticipation of the challenges posed during the negotiations leading to the Cartagena Protocol on Biosafety (CPB).

The National Biosafety Framework has been put together by the National Coordinating Committee (NCC), consisting of federal government ministries and parastatals, in collaboration with independent individuals and groups knowledgeable in the subject of biotechnology, biosafety and socio-economic considerations in national development. This final document is the outcome of subjecting the initial drafts to wide consultations, reviews and comments from a broad range of stakeholders including the organised private sector, consumer groups, academia and several other concerned groups.

In this new document, Biosafety is seen as a tool to assure that the use of the technology leads to sustainable development, is compatible with environmental, agricultural and other policy thrusts, protects the environment and biodiversity as well as human health. Biosafety therefore should be a tool to ensure contribution to national development. Its structure is therefore meant to address all sectors in which the use of modern biotechnology is recognised. The composition of its controlling structure draws from several disciplines. The drafting of the framework has taken place at a time of emphasis on excellence, due process, transparency and anti-corruption as cardinal principles and imperatives of governance, service delivery and promotion of quality assurance in Nigerian culture. Reforms are also being carried out in practically all sectors of the economy in the country and the role of the private sector in the economy is gaining wide recognition. Public health concerns have become a national issue as effort is being made to stamp out substandard and fake drugs. Thus the need for Nigeria to be competitive in the international market place is recognised. Democratic norms and principles are being engendered in national affairs and the need to ensure wide participation has become more evident. Probably the most significant consideration is that there now exists a National Biotechnology Policy which had not been developed by 1994 and 2001 when the earlier editions of the Biosafety Guidelines were published. National obligation to comply with the Cartagena Protocol on Biosafety also did not exist in 1994 coupled with the heightened awareness brought about by concerns expressed by a variety of groups which have taken centre stage during the negotiations.

BACKGROUND

Nigeria together with about 168 other countries, adopted Agenda 21 and the Convention on Biological Diversity (CBD) at the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil. Both Agenda 21 and the CBD while recognizing that biotechnology is essential for the attainment of conservation and sustainable use of biological diversity, cautioned that its application be pursued judiciously.

In particular, the Convention on Biological Diversity, CBD, in article 8 (g) encourages Parties to the convention to '*establish or maintain means to regulate, manage and control the risks associated with the use and release of living modified organisms (LMO) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account risks to human health*'.

Nigeria is a signatory to the Cartagena Protocol on Biosafety which specifically focuses on transboundary movements of any Living Modified Organisms/Genetically Modified Organisms (LMOs/GMOs) resulting from biotechnology that may have adverse effects on the conservation and use of biodiversity and the adoption of appropriate procedures for Advanced Informed Agreement.

Pursuant to Agenda 21 and the Convention on Biological Diversity, Biosafety Guidelines for Nigeria were put in place, first in 1994 and revised in 2001 after the negotiations of the Cartagena Protocol on Biosafety (The Protocol). The guidelines were aimed at providing the regulatory framework to assist stakeholders in the establishment and maintenance of national and institutional capacity for safety in biotechnology.

In line with global trends and refinement to Biosafety administration especially with the coming into force of the Protocol on the 11th September 2003, it has become necessary to review the existing machinery in Nigeria and align it with the requirements of the Biosafety Clearing House so as to be able to address the diverse issues. This document is a product of that review process aimed at producing a more efficient process.

2.0 ADMINISTRATIVE ARRANGEMENTS

The outstanding features of the administrative arrangements is the provision of a central window to receive and process notifications, a unified approach for dealing with external bodies such as reporting to the Secretariat of the Convention on Biological Diversity while giving ample room for sectoral groups to ensure that specific policy and legal requirements are adhered to. It is desegregated enough to assure the reduction of

conflicts, identifies leading roles for different agencies of government, is flexible enough to ensure mobilization of expertise and assures independent and private sector participation.

A single Agency, the Nigerian Biosafety Agency (NBA) is proposed to be responsible for general direction and handling of all biosafety matters in Nigeria. The NBA shall execute the offices and functions of both the National Focal Point and the National Competent Authority. This arrangement is the recommendation of the exhaustive consultations between the National Coordinating Committee and stakeholders on the administrative process.

2. 1.NATIONAL FOCAL POINT

In Nigeria, the National Focal Point (NFP) for Biosafety is the National Biosafety Agency, a parastatal under the Federal Ministry of Environment. The NFP shall:

- liaise with the Secretariat of the Convention on Biological Diversity and the Biosafety Clearing House as required under the Cartagena Protocol on Biosafety
- implement the provisions of the Convention and the Protocol on matters relating to Genetically Modified Organisms (GMOs)
- be responsible for all matters relating to Biosafety including risk assessment and risk management, correspondence with importers, exporters and applicants on movement of GMOs
- develop risk management plans and strategies for protecting human health, biological diversity and the environment from accidents involving modern biotechnology products and processes.
- render reports to the Secretariat of the Convention on the implementation of the Convention and the Protocol on matters relating to the use of GMOs
- carry out such other duties as may be necessary for the full discharge of the functions under the Act

2.2 COMPETENT NATIONAL AUTHORITY (CAN) (NATIONAL BIOSAFETY COMMITTEE)

In accordance with the National Biosafety Bill, a National Biosafety Committee (NBC), set up as an organ of the National Biosafty Agency shall serve as the Competent National Authority for Biosafety in Nigeria and shall be responsible for the management

of safety in biotechnology activities including research, development, introduction placing on the market and the use of GMOs generally.

2.3 COMPOSITION OF THE NBC

The NBC shall comprise the representative of each of the following, with knowledge of the implications of GMOs with respect to each department or organization:

- Federal Ministry of Environment
- Federal Ministry of Agriculture and Rural Development
- Federal Ministry of Science and Technology [NABDA]
- Federal Ministry of Industry
- Federal Ministry of Health (NAFDAC)
- Federal Ministry of Justice
- Federal Ministry of Commerce
- Federal Ministry of Foreign Affairs
- Federal Ministry of Finance (Nigerian Customs Service)
- Federal Ministry of Education
- NACCIMA/ Organized Private Sector
- A Biologist
- Physical Scientist
- Social Scientist
- A representative of NGOs distinguished in environmental matters and biodiversity conservation.
- The Registrar of the National Biosafety Agency

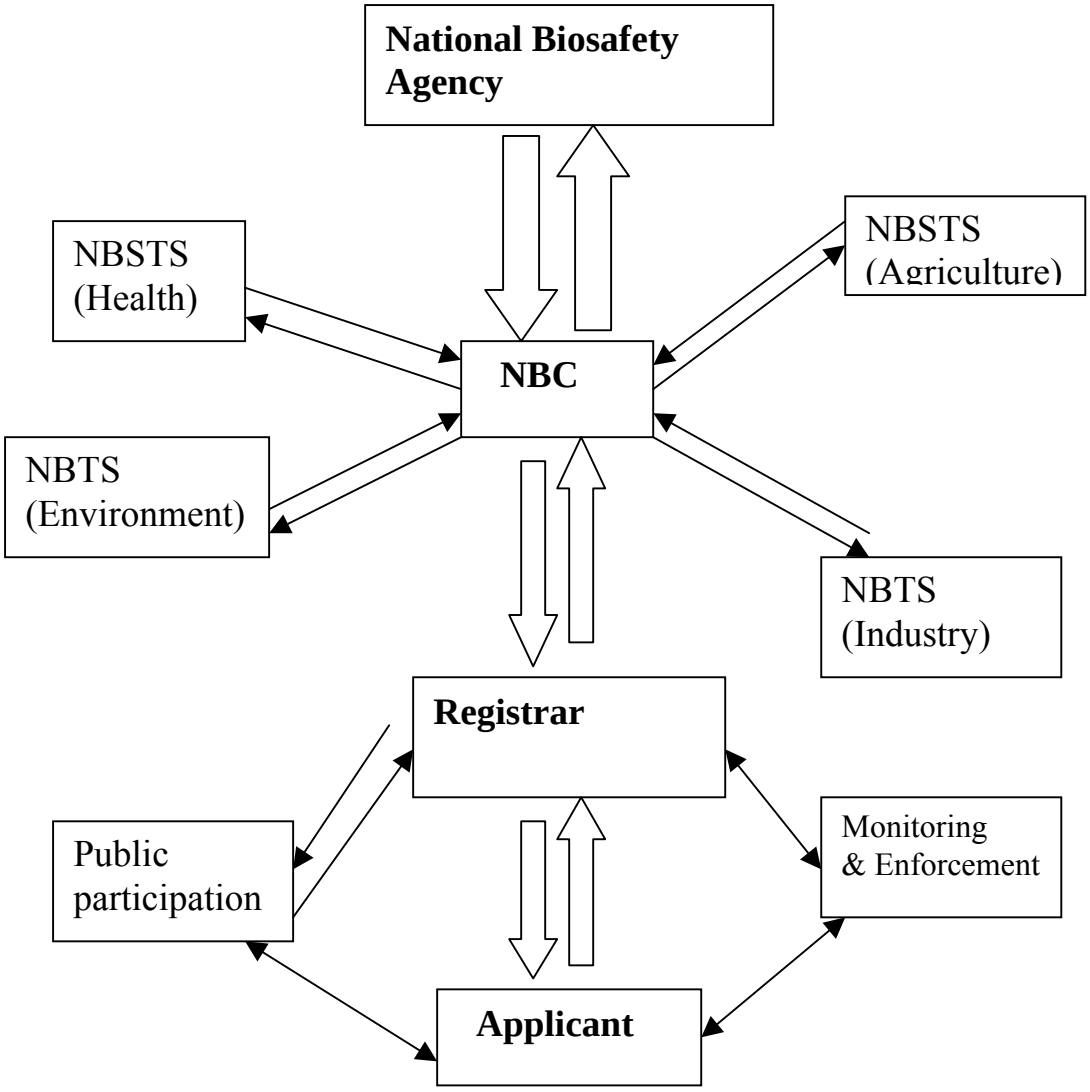
2.3.1 FUNCTIONS OF THE NBC

The functions of the NBC shall include

- Provide overall policy guidance on Biosafety in Nigeria
- Risk assessment and management.
- Establishment and review, as necessary, of guidelines for both physical and biological containment and/or procedures appropriate to the level of assessed risk involved in relevant research, development and application activities.
- Receive and process all applications for field trial and all forms of releases of GMOs.

- Make approval in respect of Genetically Modified Organisms.
- Consultation with relevant governmental agencies and other organizations as appropriate.
- Advise, where appropriate on the training of personnel with regard to safety procedures
- Maintain an inventory of laboratories with physical and human capacities to conduct research on rDNA, undertake risk assessment and create a database of experiences in the releases of GMOs in the country.
- Advise the Government on the release of GMOs.
- Ensure law enforcement under the Regulations, Guidelines/Act as appropriate.
- Monitoring and validation of information sent to it by the applicant
- Production of annual reports of its activities.

Figure 1: PROCESS FOR HANDLING APPLICATION AND REQUESTS FOR PERMITS Schematic representation



NBTS (National Biosafety Technical Subcommittee): A subcommittee of experts in different fields/subsectors such as Agriculture, Health, Industry and Environment.

2.3.2 REGISTRAR

There shall be a Registrar who shall serve as Secretary to the NBC. The Registrar shall :

- Administer the Act

- Oversee secretariat and documentation at National Focal Point
- Convenes NBC meetings
- Serve as the Secretary to the NBC
- Be proactive on contraventions of Act
- Appoint inspectors and enforcement officers
- Ensure adherence to conditions of permits
- Ensure that all monitoring is conducted promptly
- Liaise with international groups
- Manage the Nigerian Biosafety Clearing House (BCH)
- Obtain outside input and information as required
- Ensure transparency and public participation in processing of requests
- Responsible for annual report on the activities of the secretariat and that these are available to the public both in electronic form and hard copies

2.3.3 GENERAL PROVISIONS

- NBA shall have an inspectorate cadre and work jointly with other agencies to ensure compliance with decisions and directives of NBC
- As much as possible, the NBC shall carry out the evaluation of an application submitted to it within 270 days, beginning from the date of receipt of such an application or in any case such reasonable time duration as would permit the national focal point to carry out adequate verification including where necessary, laboratory analysis and field trials.

  The above provision notwithstanding, an additional period of time may be added if in the judgment of the NBC, such becomes imperative for thorough evaluation
- Time intervals used for communication or delays on the part of notifiers/applicants etc shall not be included in the counting of periods spent on evaluations
- There could be continuous interaction between the applicant and the Registrar such as in the request for more information/clarification etc by the Registrar from the applicant during the evaluation process.

- The applicant shall bear the cost of evaluation by paying what necessary costs/fees as may be prescribed by NBA (the competent authority) as contained in relevant guidelines.
- The Registrar may cause to be published, a notification of intent to introduce, or use or test a Genetically Modified Organism in a designated location.
- The Registrar may, acting in the public interest, request to be conducted, such tests or other verification as may be necessary to facilitate a decision.
- Without prejudice to the composition of the NBC and other provisions of this document, the NFP or NBC may from time to time request for technical input from persons who are knowledgeable in particular aspects of its assignments to facilitate its decision making.

2.4 Existing legislation and the need for collaboration

Several pieces of legislation, originating from many departments of government cover broad areas of agricultural practice, fisheries, health, seeds environmental protection and conservation of biodiversity. This gives ample room for cooperation since they may be applied in a broad sense of their meaning to cover the regulation of biotechnology or products derived there from. Four government ministries are responsible for implementing related legislations on products currently produced from processes other than biotechnology. These are Federal Ministries of Environment, Agriculture, Science & Technology and Health.

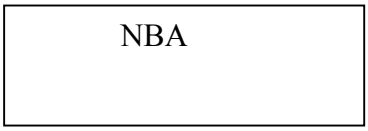
The Federal Ministry of Science ad Technology regulates variety release.

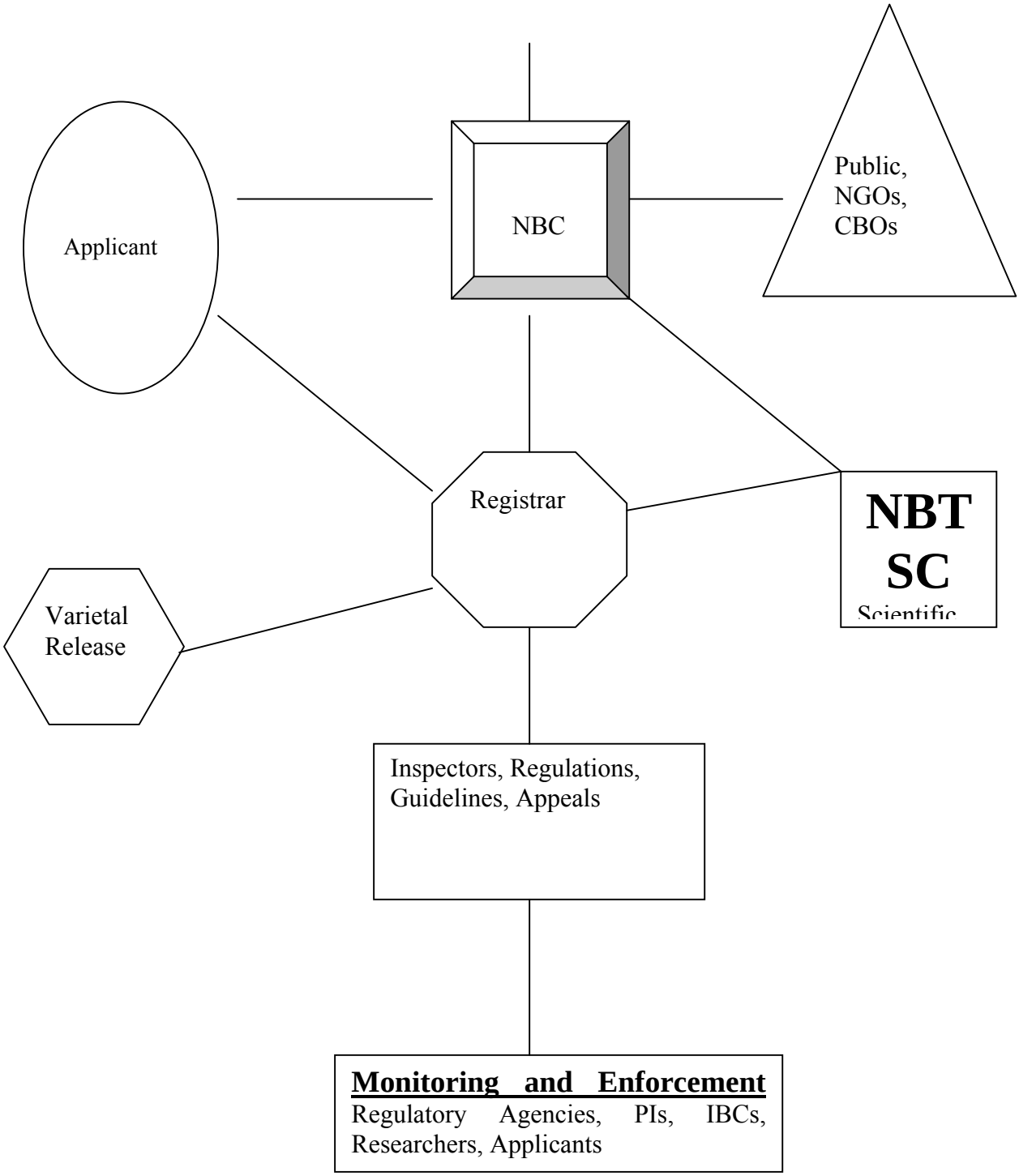
Federal Ministry of Health (NAFDFAC): Areas covered include assessing the human health safety of foods in general, whether traditional (or otherwise).

Agriculture: ensures compliance with national Seeds Policy and National Seeds Act as well as use of pesticides.

Environment enforces EIA, ensures conformity with obligations of CBD, chemicals, environmental health, pesticides, use of microbes in remediation and mop up of spills in the oil industry.

FIGURE 2: REGULATORY SYSTEM- FLOW CHART





4.1 Product movement through the regulatory framework

At least three international control regimes influence the development of the biosafety administrative machinery for biotechnology. The implication is that different arms of government may be involved and give ample room for conflicts which may cause delays and confusion as to responsibilities. A broad range of regulatory issues may thus

be involved in one notification. The three are : Cartagena Protocol on Biosafety, Codex Alimentarius (CA) and the International Plant Protection Convention (IPPC).

Whereas CPB is administered by the Secretariat of the CBD internationally and in Nigeria by the FME, Codex Alimentarius and IPPC are administered by FAO internationally and the FMARD nationally. Both CA and IPPC are developing guidelines for use in dealing with such issues as national standards, labelling codes or recommendations as well as the trade related aspects related to GMOs. The WTO recognizes IPPC and has developed the Agreement on Application of Sanitary and Phytosanitary Measures (WTO-SPS Agreement).Agencies responsible for national compliance with these international obligations will have to play critical roles in the Biosafety administration in Nigeria especially in enforcement and monitoring.

> The biosafety framework is developed as an additional instrument to existing ones and is not intended to replace existing laws, rules, protocols or procedures but rather as a domestic regulatory framework to contribute to assuring safety in the use of modern biotechnology activities and products derived from it. Where an application attracts multi-sectoral interests, cooperation must be invoked to obtain the required inter-agency collaboration. This seems to be a necessary prerequisite for success. Such agencies would therefore function and make their contribution through the NBTS.

A unified approach is thus adopted under the Nigerian framework for the receipt of and processing of applications. This is meant to provide a one-stop mechanism where the clearing house is the NBC. NBC ensures the movement of the notification through the various sub-committees, participation of relevant bodies in the decision –making process, monitoring its movement to ensure timeliness of identified events which are supposed to take place especially to ensure consistency with specified time limits for handling requests, and compliance with existing legislation and policies. Thus applications deemed to be for agricultural purposes would be dealt with at the technical level by the Agriculture Technical Sub-Committee. The same applies to the Health, Environment/Industry Technical Sub-Committees. These sub-committees are free to use the expertise of anybody including the research institutes/parastatals in their ministries or outside. Sub-committees would be encouraged to keep to strict time frames. The budgetary implication of the work of sub-committees will be considered as part of the costs of risk assessment administration. Frugality will be the key aspect of such budgets.

Specialized agencies in the ministries, e.g Plant Quarantine Services should be properly engaged in the elucidation of the implications and the roles inter-governmental cooperation would play in assuring a seamless and conflict-free handling of notifications

as well as administration of entries, their local movement. Care should be taken to reduce costly agency duplication of effort.

4.2 Research & Development

All work involving genetic manipulation should be in accordance with relevant laws. Consequently, a BiohazaRd or Institutional Biosafety Committee shall be instituted for all competent and accredited institutions. The establishment of Bio-hazard or Institutional Biosafety Committees (IBC) is meant to ensure compliance with relevant legislation. Thus the path of innovation called for in genetic manipulation would be a lot easier if the responsible government departments work in close collaboration for safety and development of the GMO from conception of a programme through field trials to commercialisation and placing on the market.

Confined trials which are meant to observe GMOs under green house, animal house conditions and any designated containment facility or in the field are also subject to regulatory oversight. These trials can only be implemented after approval from the NBC in collaboration with the IBCs. Variations in permits may be called for depending on what is being evaluated: agronomic, environmental, safety characteristics of the plant for feed, food. Requests for Permits will be treated on a on a case-by-case basis. Conditions for confinement shall be specified in Guidelines to be developed for the different sectors and materials. This is with a view to minimizing unintended effects as well as any environmental impacts. To this end, strict guidelines for transportation, planting, packaging, cultivation, and harvesting will be provided and subject to inspection by designated authorized personnel. The guidelines to be developed would include provisions to prevent movement of pollen to other plants, monitoring by inspectorate staff of the trial site, post-harvest land use restrictions, as well as current season and post harvest trial sites. Standards for confined field trials taking into consideration Nigerian environmental indices will be worked out

Experience gained based on evaluations in field trials over a period of time may lead to commercial release after meticulous environmental, food safety and human safety needs have been met.

4.3 Variety registration

All approved applications, if for agricultural purposes will have to be subjected to variety registration in Nigeria. The need for testing of new varieties to ensure that the merits are proven before they enter into commerce is thus outside the purview of the biosafety framework. Consequent upon the above, meeting the standard requirements for registration, plants produced through biotechnology would need authorization for environmental and other requirements, e.g food safety and livestock feed as appropriate.

4.4 Labelling

With a large illiterate population, the question of identification is a certain challenge. The challenge is not necessarily whether approved items are safe or not, it is also meant to prevent fraudulent transactions, and ensure that consumer choice is respected. This will also ensure that monitoring is done deliberately and open reporting is anticipated.

Items to be labelled will need to conform to existing norms in the various sectors e.g, seeds, food and drugs industry in Nigeria.

4.5 Transit

The Ministry of Transport, the Nigerian Customs Service and other regulatory agencies may be involved significantly for specific transit events to ensure that no legislations/rules/guidelines are breached. These specialised bodies may thus be part of the requisite NTSC.

4.6 Environmental safety

The environmental data requested for safety assessment currently is in the form specified for notifications. This form may be reviewed after further discussions with the scientific community, environmental and agriculture industry stakeholders. Periodic reviews of the form will also be done as new information become available. This is to ensure that every notification is assessed on a case-by-case basis and reflect strictly Nigerian agro-climatological indices.

5.0 MONITORING AND ENFORCEMENT

Monitoring and Enforcement under Biosafety administration will instil faith in the regulatory mechanism. The main ingredient in enforcement include adequate authority to

conduct examinations and checks, sampling for food products, laboratory testing, recalling products that are either unsafe or do not meet the characteristics claimed in dossier, reducing environmental problems and taking appropriate legal actions against violators of conditions of permits. Inspections may be conducted with or without a warrant as specified by law.

Monitoring is expected to enable post-approval checks for environmental or health effects. In this regard, labelling would be an added advantage to assist in tracing product movement. The relevant Agencies responsible for carrying out different aspects f monitoring may, be part of the Technical Sub-Committees.

There is no experience in biosafety monitoring in Nigeria. This is because no approval have been given for items which need monitoring under the context of the protocol. Monitoring methodologies and the objectives thus have no precedence. To breach this void, capacity building for all concerned would be a *sine qua non.* Proper monitoring may thus be an assurance-building mechanism in the short-to-medium term. This would give all stakeholders opportunity to develop familiarity with the concepts, conclusions and procedures inbuilt in monitoring.

For the purposes of biosafety, monitoring shall be used as a tool to ensure that concerns expressed by all stakeholders are addressed, ensure compliance with the terms of approval, confirm claims and trace the fate of LMOs/GMOs. Tracking will provide opportunity for familiarity with the movement, performance under Nigerian environment, and thus the unanticipated consequences of the use of the items. Monitoring will be for the following, field-trials, confined tests, pre-commercial and commercial approvals as well as placing on the market. Post-harvest plots of field trials will also be monitored. It will be regarded as a fundamental pillar in the implementation of the regulatory framework on biosafety.

Table 1: Schematic Inter-Agency Monitoring & Cooperation.

Regulatory framework for biotechnology in Nigeria/Regulatory responsibility and convergence

Department /Agency	Category	Products regulated	Relevant legislation/policy instruments	Regulations
FMARD/Plant Quarantine, Veterinary Services	Agricultural items. Field trials, environmental releases, quarantine issues	Plants, seeds, animals/livestock, vaccines, biologicals, pest control, fertilizers, feeds and fisheries and other aquatic organisms Releases into the environment in collaboration with Environment (Field trials)	National seed policy, fisheries Act, legislation on insects importation	National Agricultural Seeds Decree No. 72 1992, 1996 - Agricultural (Control of Importation) Act Cap 12 LFN of 1990. Export (Prohibition) Act Cap 121 LFN 1990 Import (Prohibition) Act Cap 172 LFN 1990 Export of Nigerian Produce Act Cap119 LFN 1990 Inland Fishing Decree No. 108 1992 Live Fish (Control of Importation) Act Cap 209 LFN Sea Fisheries Decree No. 71 of 1992 Bees (Import Control & Management) Act Cap 33 LFN 1990 Animal Diseases (Control) Act, Cap 18, LFN 1990
Health /NAFDAC	Human health and food safety, vaccines	Foods, cosmetics, drugs, medical devices,	Nutritional content, novel foods containing LMO/GMO, presence absence of toxins, Allergens Special dietary needs Fake,	-National Agency for Food and Drug Administration and Control (Amendment), Decree No. 15 of 1993 -Pesticide and Registration Regulation No. 1.10 of 1996 -Food Product Registration Regulation Decree No. 1.13 of

			counterfeit, imitation and consumer protection	1996
Environment/Industry	Environmental releases and impacts	Biotechnology products: micro-organisms used in mineral leaching or enhanced oil recovery bioremediation, waste disposal, pest control	FEPA Decree, safety at work	
FMS & T				National Crop Varieties and Livestock Breeds (Registration, Etc.) Act, Cap 249, LFN 1990
Transport	GMOs in transit		Transport of hazardous materials	All relevant regulations
Nigeria Customs Service	Port handling			Article 18 of CPB
Ministry of Trade				Merchandise Marks Act Cap 223 LFN 1990

Monitoring shall serve the following objectives:

- Used to evaluate the effectiveness of risk management measures
- To verify underlying premises upon which risk assessment judgement were made
- Will be the joint duty of notifier and regulatory authorities

- The scale of monitoring will be reached based on mutual acceptance of both the notifier and regulatory authorities
- Monitoring by designated authorities will be at the cost of the notifier
- Audit claims in dossiers.

Monitoring through the medium of field visits will be the main source of information that will drive the management of risks and other aspects of biosafety. To be meaningful, formal reports will be filed for monitoring purposes.

Detailed formats will be developed to spell out the following:

(a) what will be monitored

(b) (b) the purpose of monitoring

(c) how monitoring should be carried out and

(d)frequency for particular items and events.

It may be needed to categorise the various levels of monitoring which are appropriate to the events which may be handled. Thus, the following groups may be discerned: monitoring experiments, monitoring for purpose of following products placed on the market, regulatory compliance, examination of specific events and anticipate unforeseen outcomes.

In the evolution of regulatory regimes which is expected to arise from the commencement of implementation of the framework under development, monitoring may radically influence the future editions of the regulatory or management procedures

5.1 What to monitor

The challenge for monitoring would be influenced by the biosafety considerations on a case-by-case basis, what the goal/concern is for the particular item and what the level of monitoring should be. A major issue is the technical capacity and competence

necessary to confirm assertions contained in dossiers/notifications. In particular transgenic materials referred to in notifications need precise, competent and reliable identification.

5.2 Levels of monitoring

All levels of monitoring will be carried out. Specifically. Monitoring will be carried out for experimentation, tracking and surveillance.

Experimentation

Protocols will have to be developed for experiments to avoid unnecessary expenses, engender efficiency. Monitoring field experiments will need to maintain equilibrium in concerns expressed and scientific realities.

5.3 Tracking

In dealing with the issue of movement and spread of genes and organisms through the Nigerian environment, a system would be evolved that ensures that they can be traced. Research data upon which to base monitoring designs are needed for items such as pollen movement, biodiversity of a variety of taxa which may be impacted and thus of significance in different traits to be considered in Nigerian environment is required.

Ports are therefore designated for entry by sea and air into Nigeria.

5.4 Surveillance

Surveillance would cover the following:

(a) approved items

(b) unapproved imports

(c) releases under false pretext and

(d) approved post-release events..

Surveillance may thus involve government agencies who function at the ports and other entry points. For approved events, surveillance requirements would be designed to suit case-by-case basis. Surveillance would be required for such long-term events as developing resistance, failure to provide claimed properties or other environmental effects.

5.5 Capacity building

Due to the complexity and strategic nature of the monitoring function in successful biosafety administration, capacity building for the details of what is entailed in proper and well-thought monitoring programme is necessary. The basis for monitoring, design of monitoring and other details would be needed. Given the variety of items coming from the biotechnology industry, basic and specialised training, illustration of best practices in industrialised and developed countries would be required.

ANNEX I

INFORMATION REQUIRED FOR THE APPLICATION

I. GENERAL INFORMATION

A. Name and Address of applicant

B. Information on personnel and training

(a) Name of person(s) responsible for planning and carrying out the release, including those responsible for supervision, monitoring and safety, and qualification(s) of the responsible scientist(s).

II. Information relating to the GMO(s) or products thereof

A. Characteristics of (a) the donor, (b) the recipient or (c) (Where appropriate) parental organism(s)

(a) Scientific name;

(b) Taxonomy;

(c) Other names (usual name, strain name, cultivar name etc);

(d) Phenotypic and genetic markers;

(e) Degree of relatedness between donor and recipient or between parental organisms;

(f) Description of identification and detection techniques;

(g) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

(h) 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;

(i) Potential for genetic transfer and exchange with other organisms;

(j) Verification of the genetic stability of the organism and factors affecting it, taking into account the relevance of the laboratory experiments undertaken for the authentic ecological conditions under which the organisms live or are used;

(k) Pathological, ecological and physiological strains:

(i) Classification of hazards according to existing national rules concerning the protection of human health and/or environment;

(ii) Generation time in natural ecosystems, sexual and asexual reproductive cycles;

(iii) Information on survival, including seasonality and the ability to form survival structures e.g., seeds, spores or sclerotia;

(iv) Pathogenicity: infectivity, toxicity, virulence, allergenicity, carrier (vector) of pathogen, possible vectors, host range including non-target organisms, possible activation of latent viruses (proviruses) and ability to colonise other organisms;

(v) Antibiotic resistance, and potential use of these antibiotics in humans and domestic animals for prophylaxis and therapy;

(vi) Involvement in environmental processes: Primary production, nutrient turnover, decomposition of organic matter, respiration, etc.

(l) Nature of indigenous vectors:

(i) Sequence

(ii) Frequency

(iii) Specification

(iv) Presence of genes which confer resistance

(m) History of previous genetic modifications.

B. Characteristics of the vector

(a) Nature and source of the vector;

(b) Genetic map of the vector(s), position of the gene(s) intended for transfer, other coding and non-coding sequences affecting the expression of the introduced gene(s), and marker(s);

(c) Frequency of mobilisation 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/enhancer, and how the functional level is changed.

C. Characteristics of the GMO(s) or products thereof

(a) Methods used for the modification

(b) Purpose of the modification and intended use in relation to need or benefit;

(c) Methods used to construct and introduce the insert(s) into the recipient or to delete a sequence;

(d) Description of the insert and/or vector construction;

(e) 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;

(f) Number of intact and truncated vector inserts. Sequence, functional identify and location of the altered/inserted/deleted nucleic acid

segment(s) in question with particular reference to any known harmful sequence;

(g) Sequence and methylation pattern of the recipient DNA as far as 100kbp up and down stream from all DNA inserts.

(h) Description of genetic trait(s) or phenotypic characteristics and in particular any new traits and characteristics which may be expressed or no longer expressed;

(i) Structure and amount of any vector and/or donor nucleic acid remaining in the final construction of the GMO(s) or product thereof;

(j) Stability of the organism in terms of genetic traits;

(k) Rate and level of expression of the new genetic material. Method and sensitivity of measurement;

(l) Activity of the expressed protein(s);

(m) Expression levels for the recipient's genes situated as far as 100kbp up and down stream from all DNA inserts;

(n) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;

(o) History of previous releases or uses of the GMO(s) or products thereof;

(p) Health consideration:

  (i) Toxic or allergenic effects of the non-viable GMO(s) or products thereof and/or their metabolic products;

  (ii) Product hazards;

  (iii) Comparison of the GMO(s) or products thereof to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;

  (iv) Capacity for colonisation;

  (v) If the organism is pathogenic on humans who are immuno-competent:

    - 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;
- Antibiotics-resistance patterns;
- Allergenicity;
- Availability of appropriate therapies.

III. Information relating to the conditions of release and the receiving environment

A. Information on the release

(a) Description of the proposed deliberate release, including the purpose(s) and foreseen products;

(b) Foreseen dates of the release and time of planning the experiment including frequency and duration of releases;

(c) Preparation of the site previous to the release;

(d) Size of the site;

(e) Method(s) to be used for the release;

(f) Quantities of GMO(s) or products thereof to be released;

(g) Disturbance on the site (type and method of cultivation, mining, irrigation or other activities);

(h) Worker protection measures taken during the release;

(i) Post-release treatment of the site;

(j) Techniques foreseen for elimination or inactivation of the GMO(s) or products thereof at the end of the experiment;

(k) Information on, and result of, previous releases of the GMO(s) or products thereof, especially at different scales and in different ecosystems.

B. Information on the environment (both of the site and the wider environment)

(a) Geographical location and grid reference of the site(s) (in case of notifications the site(s) of release will be the foreseen areas of use of the product);

(b) Physical or biological proximity to humans and other significant biota;

(c) Proximity to significant biotypes or protected areas;

(d) Size of local population;

(e) Economic activities of local population which are based on the natural resources of the area;

(f) Distance to closest areas protected for drinking water and/environmental purpose;

(g) Climatic characteristics of the region(s) likely to be affected;

(h) Geographical, geological and pedological characteristics;

(i) Flora and fauna, including crops, livestock and migratory species;

(j) Description of target and non-target ecosystems likely to be affected;

(k) A comparison of the natural habitat of the recipient organism with the proposed site(s) of release;

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

IV. Information relating to the interactions between the GMO(s) or products thereof and the environment

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

(a) Biological features which affect survival, multiplication and dispersal;

(b) Known or predicted environmental conditions which may affect survival, multiplication and dissemination (wind, water, soil, temperature, pH, pollutants such as pesticides, heavy metals and others etc.);

(c) Sensitivity to specific agents.

B. Interactions with the environment

(a) Predicted habitat of the GMO(s) or products thereof;

(b) Studies of the behaviour and characteristics of the GMO(s) or products thereof and their ecological impact carried out in simulated natural environment, such as microsms, growth rooms, greenhouses;

(c) Genetic transfer capability:

(i) Post-release transfer of genetic material from GMO(s) or products thereof into organism in affected ecosystems;

(ii) Post-release transfer of genetic material from indigenous organism to the GMO(s) or products thereof;

(d) Likelihood of post-release selection leading to the expression of unexpected and/or undesirable traits in the GMO(s) or products thereof;

(e) Measures employed to ensure and to verify genetic stability. Description of genetic traits which may prevent or minimise dispersal of genetic material. Methods to verify stability;

(f) Routes of biological dispersal, known or potential modes of interaction with the disseminating agent, including inhalation, ingestion, surface contact, burrowing, etc.;

(g) Description of ecosystem to which the GMO(s) or products thereof would be disseminated.

C. Potential environmental impact

(a) Potential for excessive population increases in the environment;

(b) Competitive advantage of the GMO(s) or products thereof in relation to the unmodified parental organism(s);

(c) Identification and description of the target organisms;

(d) Anticipated mechanism and result of interaction between the released GMO(s) or products thereof and the target organism;

(e) Identification and description of non-target organisms which may be affected unwittingly;

(f) Likelihood of post-release shifts in biological, or in host range;

(g) Known or predicted effects on non-target organisms in the environment, impact on population levels of competitors, preys, hosts, symbionts, predators, parasites and pathogens;

(h) Known or predicted involvement in biogeochemical processes;

(i) Other potentially significant interaction with the environment.

(v). Characteristics of resuscitated organisms and gene(s) and fossil DNA sequences:

A. Resuscitated organism

(a) Scientific name and taxonomy;

(b) Identity of nearest species and their characteristics which are of relevance to the intended use;

(c) Site at which it was found;

(d) Method used for resuscitation;

(e) Purpose of introducing the organism and benefits, if any;

(f) Impacts on human and animal health and the environment;

(g) Measures for counteracting adverse impacts;

(h) Length of time the organism has been in use;

(i) Genetic stability;

(j) Likelihood of gene transfer to other organisms;

(k) Fossil and living nearest related species;

(l) Biological and biochemical differences from related living species;

(m) Information on previous uses since resuscitation.

B. DNA sequences from fossils or from resuscitated organism

(a) Scientific name and taxonomy of the species whether resuscitated or a fossil;

(b) Site of origin of the fossil;

(c) Site of the gene in the resuscitated genome, if known;

(d) Base sequence of the extracted gene;

(e) Method used in extracting the gene;

(f) Function of gene, if known;

(g) Purpose of use and benefits, if any;

(h) Environment in which it lived before fossilisation;

(I) Fossil species related to the species from which the gene was taken;

(j) Living species related to the species from which the gene was taken;

2. SOCIO-ECONOMIC CONSIDERATIONS:

(a) Anticipated changes in the existing social and economic patterns resulting from the introduction of the GMO or product thereof;

(b) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture;

(c) 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;

(d) 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 GMO or product thereof;

(e) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;

(f) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the GMO or product thereof.

3 Risk Management Measures

A. General precautions

(a) Appropriate information and training is provided for those involved in handling the organisms;

(b) Monitoring procedures are applied in such a way that appropriate measures can be taken in case of unexpected effects during or after the release;

(c) The dissemination of the released organisms and/or gene flow from the released organisms is controlled;

(d) Controlling access to the release site.

(j) PLANTS

(a) Applying reproductive isolation, by:

- Spatial separation;
- Temporal separation: use of plants that will flower either earlier or later than plants of nearby reproductively compatible species;
- Biological prevention of flowering (e.g. by omitting vernalisation);
- Removal of the male or female reproductive structures';
- Bagging of flowers;
- Making use of sterility;

(b) Controlling the persistence or dispersal of reproductive structures such as propagules or seeds.

(c) Destroying volunteer plants after harvest;

(ii) **ANIMALS**

(a) Confining by appropriate means such as fences, filters, islands, and ponds;

(b) Applying reproductive isolation by using sterile animals

(c) Isolation from feral animals of the same species

(d) Controlling the persistence or dispersal of reproductive structures such as larvae or eggs.

(iii) **MICRO-ORGANISMS**

(a) Using organisms with impaired ability to grow or persist in the environment;

(b) Minimising gene transfer by:

- using organisms that do not contain known self-transmissible mobilisation or transposable genetic elements;
- ensuring that introduced traits is stably located on the chromosome.

B. Monitoring techniques

a. Methods for tracing the GMO(s) or products thereof, and for monitoring their effects;

b. Specify (to identify the GMO(s) or products thereof, and distinguish them from the donor, recipient or, where appropriate, the parental organisms) sensitivity and reliability of the monitoring techniques;

c. Techniques for detecting transfer of the donated genetic material to other organisms;

d. Methods to detect aberrant gene expression.

C. Waste treatment

(a) Types of waste generated;

(b) Expected amount of waste;

(c) Possible risks;

(d) Description of treatment envisaged.

D. Emergency response plan

(a) Methods and procedures for controlling the GMO(s) or products thereof in case of unexpected spread;

(b) Methods for decontamination of the areas affected, e.g. eradication of the GMO(s) or products thereof;

(c) Methods for disposal or sanitation of plants, animals, soil, etc. that were exposed during or after the spread;

(d) Methods for the isolation of the area affected by the spread;

(e) Plans for protecting human health and the environment in case of the occurrence of an undesirable effect.

Annex II

CONTAINMENT FACILITIES & BIOSAFETY PRACTICES

Containment is the term used to describe the safety methods for managing infectious agents or hazardous compounds in the laboratory environment where they are being handled or maintained in order to prevent their distribution outside the prescribed space. The purpose of containment is to reduce exposure of laboratory workers, other persons and the outside environment to potentially hazardous agents.

A. BIOSAFETY LEVELS

Different levels of physical containment, designated BL1, BL2, BL3 and BL4 can be achieved with combinations of laboratory practices, containment equipment and special laboratory design. The onus of proof of the Biosafety level designation and the level of hazards posed by any biological entity for a given biosafety level and the consequences thereof rest with the applicant/ researcher/facility owner.

BIOSAFETY LEVEL 1 (BL1)

This level is suitable for work, which involves agents of no known or minimal potential hazard to laboratory personnel and the environment. No special accommodation or equipment is required but the laboratory personnel have specific training in laboratory procedures and are supervised by a scientist in a related field. Special containment equipment is generally not required for manipulation of agents assigned to Biosafety level 1.

(i) LABORATORY FACILITIES

(a) The Laboratory should be designed so that it can be easily cleaned.

(b) Bench-tops should be impervious to water, and resistant to acids, alkalis, organic solvents, and moderate heat.

(c) Each laboratory should contain a sink for hand washing preferably near the exit.

(d) Safety systems covering fire, electrical, shower and eyewash should be provided.

(e) Laboratory furniture should be sturdy.

(f) If the laboratory has windows that open, they should be fitted with fly screens.

(g) Doors should have appropriate fire ratings, be self-closing and have vision panels.

(h) Facilities for storing outer garments and personnel items and for eating, drinking and smoking should be provided outside the working areas.

(i) First aid rooms suitably equipped and readily accessible should be provided.

(j) An autoclave for decontamination of infectious laboratory wastes should be provided in the same building as the laboratory.

B. BIOSAFETY LEVEL 2 (BL2)

This level is suitable for work involving a broad-spectrum of moderate-risk agents. Safety guidelines similar to that for the BL1 have to be observed. In addition the following special practices should be adhered to:

(i) LABORATORY FACILITIES

These are same as for BL1

(ii) SPECIAL PRACTICES

(a) Laboratory personnel should have specific training in handling pathogenic agents and must be under competent supervision.

(b) Access to the laboratory should be limited or restricted by the laboratory director who should ensure that only persons that have been advised of the potential hazard and meet the specific entry requirements (e.g. immunisation) could enter the laboratory or animal rooms.

(c) Contaminated materials meant for disposal are to be decontaminated. Before decontamination they are to be placed in leak-proof durable containers which are closed and labeled.

(d) All wastes from the laboratories and animal rooms should be properly decontaminated before disposal.

(e) When organisms containing DNA molecules are handled in the laboratory a hazard warning sign such as the biohazard symbol must be boldly displayed on the access door to the laboratory.

(f) Special care should be taken to avoid skin contact with organisms containing rDNA molecules; gloves should be worn when handling experimental animals and when skin contact with the agent is unavoidable.

(g) Spills and accidents, which result in overt exposures to organisms containing rDNA molecules must be immediately, reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate, while written records are also maintained.

(h) A biosafety manual should be prepared and adopted for use by laboratory personnel. Personnel are advised of special hazards and are required to be conversant with practices and procedures and adhere to them at all times.

(iii)CONTAINMENT EQUIPMENT

Biological safety cabinets or other personal protective or physical containment devices are used whenever:

(a) Procedures with a high potential for creating aerosols are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers or materials whose internal pressure may be different from ambient pressures, inoculating animals intra-nasally, and harvesting infected tissues from animals or eggs.

(b) High concentrations or large volumes of organisms containing rDNA molecules are used. Such materials may be centrifuged in open laboratory if sealed heads or centrifuge safety caps are used and if they are opened only in a biological safety cabinet.

C. BIOSAFETY LEVEL 3 (BL3)

These practices are applicable to clinical, diagnostic, research or production facilities in which work is done with indigenous or exotic agents, which may have adverse effects on the environment and biodiversity, human health, cause serious or potentially lethal disease due to exposure, by ingestion, inhalation, or other contact. In addition to the conditions required for BL2, it is necessary that the under-listed special guidelines be strictly adhered to.

(i) LABORATORY FACILITIES

(a) The laboratory is separated from areas, which are open to unrestricted human traffic flow. Passage through two sets of doors is the basic requirement for entry into the laboratory from access corridors or other contagious areas. Physical separation of the high risk containment laboratory from access corridors or other laboratories or activities may also be provided by a double-doored clothes change room (showers may be included), air lock, or other access facility which requires passage through two sets of doors before entering the laboratory.

(b) The laboratory is designed so that it can be easily cleaned, and sealing must block penetrations in the interior surfaces of walls, floors and ceilings or be capable of being sealed to facilitate decontaminating the area.

(c) Windows in the laboratory must be closed and sealed.

(d) The access door to the laboratory or containment module should be self-closing.

(ii) SPECIAL PRACTICES

(a) All activities involving organisms containing rDNA molecules should be conducted in Biological Safety Cabinets or other physical containment devices within the containment module. No work in open vessels should be conducted on the open bench.

(b) The work surfaces of Biological Safety Cabinets and other containment equipment must be decontaminated when work with organisms containing rDNA molecules is finished.

(c) Laboratory clothing (e.g. wrap-around gowns) that protects street clothing must be worn in the laboratory; front button laboratory coats are unsuitable. Laboratory clothing must be decontaminated before being laundered.

(d) Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the needle sheath or guard or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture–resistant container and decontaminated preferably by autoclaving before being discarded.

(e) Laboratory animals kept in the BL3 areas shall be housed in partial – containment caging systems, such as open cages placed in ventilated enclosures, solid wall and bottom cages covered by filter bonnets or solid wall and bottom cages placed on holding racks equipped with ultraviolet radiation lamps and reflectors.

(iii)CONTAINMENT EQUIPMENT

As in BL2

D. BIOSAFETY LEVEL 4 (BL4)

These practices, safety equipment and facilities are applicable to work with highly pathogenic or exotic agents, which pose a high individual risk resulting in life-threatening disease.

In addition to the conditions required for BL3, it is necessary that following practices be strictly complied with:

(i) LABORATORY FACILITIES

(a) The maximum containment facility consists of either a separate building or a clearly demarcated and isolated zone within a building. Outer and inner change rooms separated by a shower are provided for personnel entering and leaving the facility. A double doored autoclave, fumigation chamber or ventilated airlock should be provided for passage of those materials, supplies or equipment which are not brought into or out of the facility through change room.

(b) The autoclave door, which opens to the area external to the facility, should be sealed to the outer wall and automatically controlled so that the outside can only be opened after the autoclave sterilization cycle has been completed.

(c) Walls, floors and ceilings of the facility should be constructed to form a sealed internal shell, which facilitates fumigation and is animal and insect proof. The internal surfaces of this shell should be resistant to liquids and chemicals and thus facilitates cleaning and decontamination of the area. All penetrations in these structures and surfaces are sealed. Any drains in the floors should contain traps filled with a chemical disinfectant of proven efficacy against the target agent. They should be connected directly to the liquid wastes decontamination system. Sewer and other ventilation lines should contain in-line HEPA filters.

(d) A pass-through "drunk" tank, fumigation chamber, or an equivalent decontamination method should be provided so that materials and equipment that cannot be decontaminated in the autoclave can be safely removed from the facility.

(e) Liquid effluents from the sinks, biological safety cabinets, floors and autoclave chambers should be decontaminated by heat treatment before release from the maximum containment facility. Liquid wastes from shower rooms and toilets should be decontaminated with chemical disinfectants or by heat in a liquid waste decontamination system. The procedure used for heat decontamination of liquid wastes should be evaluated mechanically and biologically by using a recording thermometer and an indicator microorganism with a defined heat susceptibility pattern. If liquid wastes from the shower room are decontaminated with chemical disinfectants the chemical used should be of proven efficacy against the target or indicator microorganisms.

(f) A specially designed suit area may be provided in the facility. Personnel who enter this facility or area wear a one-piece positive pressure suit that is ventilated by a self-support system. The life support system includes alarms and emergency backup breathing air tanks. Entry to this area should be through an airlock fitted with airtight doors. A chemical shower should be provided to decontaminate the surface of the suit before the worker leaves the area. The exhaust air from the suit area should be filtered by two sets of HEPA filters installed in series. A duplicate filtration unit, exhaust fan and a power source with an automated switching system should be provided. The design should be such that air pressure within the

suit area is lower than that of any adjacent area. Emergency lighting and communication systems are provided. All penetrations into the internal shell of the suit are sealed. A double-doored autoclave should be provided for decontaminating waste materials to be removed from the suit area.

(ii) SPECIAL PRACTICES

(a) Access to the facility is highly restricted and the Laboratory Director or the Biohazard Control Officer manages accessibility. A logbook signed by all personnel indicates the date and time of each entry and exit.

(b) Street clothing should be removed in the outer clothing change room and kept there. Complete laboratory clothing including undergarments, pants and shirts or jumpsuits, shoes and gloves should be provided and used by all personnel entering the facility. Head covers are provided for personnel who do not wash their hair during the exit shower. When leaving the laboratory and before proceeding into the shower area, personnel should remove their laboratory clothing and store it in a locker or hamper in the inner change room.

(c) Biological materials to be removed from the class III Biological Safety Cabinets or from the Maximum containment laboratory in a viable or intact state should be transferred to a non-breakable, sealed primary container and then closed in a non-breakable, sealed secondary container which is removed from the facility through a disinfectant "dunk" tank, fumigation chamber, or an airlock designed for this purpose.

(d) No materials, except for biological materials that are to remain in a viable or intact state are removed from maximum containment laboratory unless they have been autoclaved or decontaminated before they leave the facility. Equipment or material which might be damaged by high temperatures or steam is decontaminated by gaseous or vapour methods in an airlock or chamber designed for this purpose.

(e) A system should be set up to report laboratory accidents and exposures and employee absenteeism and for medical surveillance for potential laboratory – associated illness. Written records should be prepared and maintained. An essential adjunct to such a reporting – surveillance system is the availability of a

facility for a quarantine, isolation and medical care of personnel with potential or known laboratory – associated illnesses.

(iii) CONTAINMENT EQUIPMENT

All procedures within the facility with agents assigned to BL4 can be conducted in Class III Biological Safety Cabinets or in Class I or II Cabinets used in conjunction with one-piece positive pressure personnel suits ventilated by a life–support system.

GLOSSARY

Accident: Any incident involving a significant and unintended release of genetically modified organism in the course of their contained use, which could present an immediate or delayed hazard to human health or the environment.

Biosafety: The policies and procedures adopted to ensure the environmentally safe applications of modern biotechnology in medicine, agriculture, and the environment, and to avoid endangering public health or environmental safety.

Biotechnology: Any technique that uses living organisms or substances from these organisms to make or modify a product, to improve plants or animals, or to develop microorganisms for specific uses.

Cell: The smallest component of life. A membrane-bound protoplasmic body capable of carrying on all essential life processes. A single-cell unit is a complex collection of molecules with many different activities.

Confinement/Containment: Measures to limit the interaction of the regulated organisms with the environment or with human, procedures include but are not limited to isolation from related species, destruction of residues, and sterilisation using, physical, chemical and/or biological barriers to limit their contact with the general population and the environment.

Deliberate release: Any intentional introduction into the environment of a GMO or a combination of GMOs without provision for containment, such a physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to limit their contact with the general population and the environment.

Environment: Components of the earth, including air, land, water, all layers of the atmosphere, all organic and inorganic matter and living organisms, and all interacting natural systems that include components referred to above. Includes the natural and managed ecosystems, including agricultural ecosystems.

Environmental Release: The controlled, intentional resting of genetically engineered living organisms, outside of a confinement structure.

Environment Risk Assessment: The evaluation of the risk to human health and the environment (which includes plants and animals) connected with the release of GMOs or products containing GMOS.

Gene: The fundamental physical and functional unit of heredity, the portion of a DNA molecule that is made up of an ordered sequence of nucleotide base pairs that produce a specific product or have an assigned function.

Genetic Engineering: Technologies (including rDNA technologies) used to isolate genes from an organism, manipulate them in the laboratory, and insert them into another organism.

Genetically Modified Organism (GMO): An organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Notification: The presentation of documents containing the requisite information to the component authorities of a national state. The person making the presentation shall be refereed to as the notifier.

Organism: Any biological entity capable of replication or of transferring genetic material.

Phenotype: The physical appearance of an organism as distinguished from its genetic constitution (genotype).

Product: A preparation consisting of, or containing, a GMO or a combination of GMOs, which is placed on the market.

Shipping: Movement of materials, which includes transportation, exchange, introduction, acquisition and transfer.

Tissue Culture: The propagation of tissue removed from organisms in a laboratory environment that has strict sterility, temperature, and nutrient requirements.

Transformation: Introduction and assimilation of DNA by one organism from another.

Use: The deliberate application of a product, which has been placed on the market. The persons carrying out this use shall be referred to as users.

DOCUMENT FOUR

Policy On Public Awareness, Education And Participation In Biosafety

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ACRONYMS

CBOs - Community Based Organizations

CCA - Community change agents

FEPA - Federal Environmental Protection Agency

GMO - Genetically modified organisms

ICCP - Intergovernmental Committee for the Cartagena Protocol on Biosafety

NABDA - National Biosafety Agency, National Biotechnology Development Agency

SHESTCO - Sheda Science and Technology Complex

NAFDAC – National Agency for Food, Drugs and Administration Control

NBA - National Biosafety Agency

NBCH - National Biosafety Clearing House

NBF- National Biosafety Framework

NDLEA – Nigerian Drug Law Enforcement Agency

NGOs - Non Governmental Organizations

NMA - Nigeria Medical Association

NUJ - Nigeria Union of Journalists

OPS - Organized Private Sector

PA - Public Awareness

PA - Public Awareness

UNCED - United Nations Conference on Environment and Development

1. Introduction

The Federal Ministry of Environment has the mandate to provide policy and legal framework for all environmental matters in Nigeria towards ensuring sustainable development in the country. Specifically the ministry through its organs provides high quality, timely comprehensive advise on environmental policy and legislation and its relationship to national, social and economic issues. The Ministry is responsible for informing the general public about environmental and sustainable development issues by promoting understanding and awareness of environment and conservation issues.

In addition to the Federal Ministry of Environment, most states of the Nigerian federation have established environmental protection agencies, with appropriate regulations designed to suit their peculiar environmental circumstance. To achieve its mandate, the ministry works in effective partnership with other government agencies, industries, environmental organizations, community and international bodies to achieve environmental performance in accordance with the provisions of the National Policy on Environment.

The declared goal of the National Policy on Environment is to achieve sustainable development in Nigeria and in particular to:

- Secure for all Nigerians a quality of environment adequate for their health and well-being
- Conserve and use the environment and natural resources for the benefit of present and future generations
- Restore, maintain and enhance the ecosystems and ecological processes essential for the functioning of the biosphere to preserve biological diversity and the principle of optimum sustainable yield in the use of living natural resources and ecosystems
- Raise public awareness and promote understanding of essential linkages between environment and development and to encourage individual and community participation in environmental improvement efforts; and
- Co-operate in good faith with other countries, international organizations or agencies to achieve effective prevention or abatement of transboundary environmental pollution.

The implementation of the National Policy on Environment depends on specific actions aimed at raising the knowledge base and perceptions of the global public on environmental degradation issues. There is also the need to develop various public participation and awareness packages that adopt a sufficiently broad and flexible mandate. This should be genuinely open and responsive to what the public considers to be the key to environmental issues drawing on cultural, social and economic benefits or risks.

2. Current Efforts At Public Participation In Environmental Management in Nigeria

Public participation in environmental matters in Nigeria gained attention as a response to policy of government which had identified threats to environmental protection by creating the Federal Environmental Protection Agency (FEPA) which formulated in 1989 a national policy on environment. This body initiated the Environmental Impact Assessment Decree of 1992 specifically to address impacts of development on the environment and how to create intervention mechanisms. The Decree (Act) has opportunity for the public, NGOs and other stakeholders to participate in decision making in environmental matters through a mechanism of public hearings, including the publication and wide circulation of developmental proposals by all sectors of the economy.

Further impetus for prevailing environmental awareness and participation policy in Nigeria is an outcome of the influence of the events linked to the United Nations Conference on Environment and Development (UNCED) process. In accordance with the spirit of UNCED, Nigeria's National Agenda 21 identifies the need to properly situate public awareness and participation in decision-making in environmental matters.

The National Agenda 21 in agreement with chapter 36 of the Global Agenda 21 identifies the creation of an environmentally informed and literate citizenry towards sustainable development as its mission statement in Environmental Education. The document also has the following as its objectives:

1. Promotion of the acquisition of appropriate knowledge and skills in Environmental Protection and Natural Resources Management.
2. Promotion of a high level of Public Awareness in Environmental Issues with a view to affecting positive attitudinal changes

Furthermore, in response to chapter 36 of the Global Agenda 21, Nigeria developed **National Master Plan for Public Awareness in Environment and Natural Resources Conservation**. The document identified threats to Nigeria's environment and natural resources to include

Erosion, Environmental Pollution, Desertification, Deforestation, Declining Biological Diversity, Rapid and Unplanned urbanization Ecological Degradation among others and thus needing specific intervention mechanisms. The threat posed to Biodiversity by modern biotechnology was not included, an indication of the low awareness level and inclusion of cross-sectoral issues in public policy analysis. Declining biological diversity was viewed through the traditional prisms of plants, large-scale deforestation, fisheries depletion, invasive species etc.

The Public Awareness Master Plan further asserted that the broadest public participation cannot be achieved if relevant stakeholders are not sufficiently sensitized with respect to the issues at stake, as well as with respect to the needed intervention at various levels of society. The major objectives therefore stated in the Strategy include:

a) To facilitate the inventorizing of critical environmental issues,
b) To highlight and promote an informed understanding of the causes of major environmental issues in Nigeria, as well as suggest appropriate remedial interventions to forestall or mitigate them,
c) To provide critical analysis of available traditional and modern communication media in the country, that could be utilized in promoting Public Awareness (PA)
d) To reinforce governmental and non-governmental efforts by developing a systematic and consistent action plan for the application of communication management in Nigeria within clearly defined time frames,
e) To identify and network relevant target groups for Public Awareness Strategy implementation,
f) To promote an effective mechanism, for coordinating and evaluating environmental awareness activities in the country, and
g) To identify funding sources and propose disbursement mechanisms for PA implementation

The Policy documents mentioned above were expected to elucidate a clear road map that articulates Public Participation as an essential ingredient in Environmental Management across various strata of stakeholders in the nation's environment.

The stakeholders identified include public decision makers and implementers, the organized private sector, the independent sector Non Governmental Organizations (NGOs), Community Based Organizations (CBOs) and consumer protection groups; educational institutions, opinion leaders, professional associations, rural inhabitants (farmers, pastoralists, fisher-folk, gatherers, hunters etc) as well as other groups which include youth and children and urban informal sector workers.
The MP recommended a multi-media or synergistic media-mix approach to public environmental awareness by coordinating and implementing agencies.

Box 1 Agenda 21 Education Awareness and Training components

Agenda 21 Chapter 36 - Education, Awareness and Training

Both formal education and non-formal education are indispensable to changing people's attitude so that they have the capacity to access and address their sustainable development concerns. It is also critical for achieving environmental and ethical awareness, values, and attitudes, skills and behaviour consistent with sustainable development and for effective public participation in decision-making.

Public participation in natural resource management has been given impetus in international systems of negotiation thus making it a requirement and treaty obligation. There are many challenges to popular participation in the administration of biosafety in a society that is largely illiterate. Access to information is a big challenge for a rational and science-based decision making thus a public education and participation policy should draw from already existing broad policy guidelines as well as obligations inherent in our signing and ratifying treaties.
The scope and depth of the requirement for public awareness and participation derive from two sources of obligations:

Convention on Biological Diversity (CBD)
Specific Articles in the convention dwell on important elements of regulating safety in biotechnology as well as demanding the development of internationally binding instruments to handle the subject.

- Article 8 *In situ* conservation establish or maintain means to regulate, manage or control the risks associated with the use and release of genetically modified organisms (GMOs) resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health.,

- Article 13 – Public Education and Awareness.

  (i) Promote and encourage understanding of the importance and measures required for the conservation of biological diversity, as well as its propagation through media, and the inclusion of these in educational programmes, and
  Co-operate as appropriate with other state and international organizations in developing educational and public awareness programme, with respect to conservation and sustainable use of biological diversity.

- Article 19 - Handling of Biotechnology and Distribution of its Benefits

  (i) The Parties shall consider the need for and modalities of setting appropriate procedures, including, in particular advance informed agreement, in the field of the safe transfer, handling and use of any genetically modified organisms. GMO resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

  (ii) Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by the Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

3. Biosafety Framework in Nigeria

The fast pace of development in Biotechnology and the potentials it holds in its application in agriculture, healthcare delivery, trade, economic, politics and environmental protection are strongly recognized internationally. The concern that its development may have adverse effects on Biodiversity and human health led the international communities to negotiate an internationally binding protocol to cover the transboundary movement of Genetically Modified Organisms(GMOs) across national boundaries. Nigeria took the bold step in keeping with the international expectations and signed the Convention on Biological Diversity in June 1992 at Rio de Janeiro during the earth summit. She went further in 2000 to sign the Cartagena Protocol on Biosafety (CPB) and ratified it in November 2002. The Cartagena Protocol which came into force in September 2002 focuses specifically on the transboundary movement of GMOs

resulting from modern Biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity taking also into consideration human health.

The implications of signing and ratifying the Cartagena Protocol is that all strata of society, in particular those at the vanguard of the use of Biotechnology both traditional and modern should get ready and familiarize themselves with the intricacies of transboundary movements as they might have bearing on their activities and possibly technical co-operation agreements of different stakeholders.

These international commitments impose far- reaching obligations on the nation. In realization of this, and the concomitant possibility of receiving applications for the deliberate release of GMOs, Nigeria has taken appropriate steps to address her obligations arising from signing the Cartagena Protocol.

Nigeria's National Biosafety Framework consists of the following:

a) A government policy on biosafety
b) A regulatory regime
c) A system to handle requests for authorizations
d) Systems for follow-up
e) System for public awareness and participation.

4.0 Public Participation

Participation means the ability of the public to share and take part in the decision making process on issues of Biosafety and biotechnology Public participation in the area of biotechnology varies from country to country but must be initiated by the government, which creates the enabling environment by supporting the initiative in order for participation to occur, education and awareness raising must take place through the provision of information to the public.

4.1 The Need for Public Participation in National Biosafety Framework in Nigeria

Public participation is a process of encouraging all interested and affected parties to contribute to solving social problems, setting priorities, designing strategies, increasing ownership and taking on responsibilities for action. Active public participation and involvement both as target audience and as viable channels of information are crucial elements of the National Biosafety Framework. The problem which surrounds Public Participation in awareness and decision making programme such as the National Biosafety Framework is how to arouse public interest in the programme and sustain it on a long-term basis in order to make desired changes.

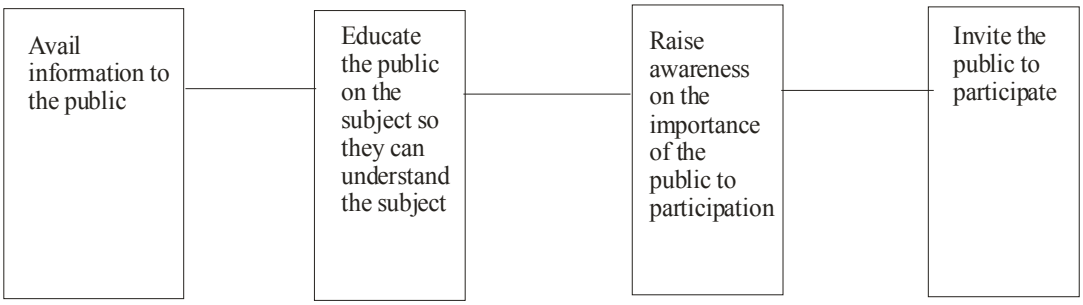
Participation in a National Biosafety Framework aims to encourage the public and interested stakeholders to be aware of, and contribute to the research, development, implementation and monitoring of the policy framework. The experience of both industrialized and developing countries show that the free flow of information constitutes

a powerful development intervention that helps to move societies from an information-poor environment to an information-rich one, thus making more transparent the opportunities for development at all levels and the possible obstacle to progress. The public participation and awareness package for the Biosafety Framework will aim at supporting this move towards the free and timely flow of information within the context of the overall (NBF) programme objectives.

Public Participation demands that relevant tools and methods of sensitization are designed to encourage consultation, debate and discussion to elicit contributions from the public around key issues on a given subject matter. The results of participation will depend on the participants, the processes and the tools that are used to facilitate accord.

The Participation Process

Figure I



4.2 Goals and objectives of Public Participation and Awareness in Biosafety Framework

The goals and objectives of the public participation and awareness component of the Biosafety framework shall include the following:

(i) Recognition of the public as a lawful collaborator
(ii) Provision of timely, accurate and consistent information on the principles and advances in Biosafety through credible sources
(iii) Raising awareness amongst the various stakeholders on issues relating to Biosafety.
(iv) Documentation and dissemination of relevant information to as wide an audience as possible
(v) Encouragement of public presentations and open debate
(vi) Acknowledge that the issues are multi-disciplinary, not limited to science only.

To achieve the goals set above the main policy thrust

(i) Open disclosure of notifications / applications for any subject covered under the Biosafety Act or policy. This would be through the medium of publication in three relevant newspapers detailing the full content of the application, the nature, of the GMOs. The choice of site of display of the notification dossier or request would be guided by the nature of request, the geographic coverage of the event and any other considerations that

would enchance public participation including location where the notification event is expected to take place. The full copy of the notification / dossier shall be open to public view and made accessible in the following places:

- Federal Ministry of Environment Abuja
- National Biosafety Agency
  * State Ministries of Agriculture and Environment
  * LGA Headquarters
  * Nearest University (ies)
  * National Biosafety Clearing House (NBCH) website

(ii) Request for written comments to be sent to the National Biosafety Agency. This written request may be deposited at the designated government points which may vary from one event to another but may include: designated Federal Ministry of Environment and National Biosafety Agency offices, or offices of government agencies listed as members of NBC. The writing shall be done within 21 days of publication.

(iii) The public shall be allowed to participation in any open hearing that may be called for in the course of discussions / hearings on the notification

(iv) At least one Public Hearing will take place in the general geographic area where a notification / application for an event is scheduled to take place and accredited stakeholders representing organized shall be allowed to participate

4.3 Specific Goals of Public Participation

The specific goals of public participation in Biosafety decision making are:

(i) Create sustenance of a dynamic information network that will ensure that the capacity for informed decision-making and reduction of risks associated with the use of modern biotechnology products to avoid adverse impact on human environment.
(ii) Strengthening of institutional capacity for development of effective communication strategies for public participation and education.
(iii) Adoption of a sufficiently broad package of information that will ensure various levels of stakeholder views in decision-making are considered.
(iv) Increase credibility and integrity of the laid down procedures
(v) Reduce disagreements and promote transparency in the regulatory process,
(vi) Provide a means for public to air their voice and understand the issues.
(vii) Overcoming prejudices and perceptions

4.4 What is the Purpose of Public Participation?

The purpose of public participation is to involve local stakeholders in activities and decision making issues that concern them and keep them updated on relevant issues. It also enables those who will be involved to learn, create and take ownership of the project before implementation. The aim of participation is to build partnerships, address individual and group concerns, so that it is possible to harness the collective energy and potential of all stakeholders both in developing and implementing a country's National Biosafety Framework.

Participation by stakeholders in the development of the NBF would help to:

- Promote sustainability through a process of policy development and decision-making that involves all sectors of society, and not just government agencies, thus helping to develop a sense of ownership amongst the public as stakeholders;
- Facilitate determination of baseline conditions in-country with respect to biotechnology and Biosafety by sharing information with relevant stakeholders.
- Validate/verify information available to ensure a transparent process.
- Build capacity for information gathering, sharing and data analysis amongst stakeholders.
- Identify country priorities, problems and needs through the analysis of information.
- Identify potential risks and constraints so that these can be properly managed or factored into decisions making.
- Identify and proffer solutions to possible social, economic, cultural and environmental impacts of GMOs.
- Promote improved decision-making based on sound information and use of available national resources and expertise, thus helping to minimise risks and possible adverse effects;

Promote transparency and accountability of the government's decision-making processes for GMOs, helping to build trust in the government and promote public commitment to biosafety

In order to promote participation, a government has to provide an enabling environment that will support participation by all stakeholders. The necessary conditions can be created through applying the following four pillars of public participation:

4.5 Who Would Be Responsible For Public Information And Participation Process?

An institution that enjoys credibility among the public should be well equipped to provide the public with information and participation programs. This institution should be well equipped to provide the public with information on the activities of Biosafety and biotechnology, such as consumers, scientific, environmental, educational or ecological organizations The credibility of the institution is dependant on their perceived image and track record through which they can prove their trustworthiness eg C & B consumer and biotechnology of Netherlands and GMO information bureau of Poland have been known to provide correct scientific information on biotechnology for the wider public and in particular for media and are a trusted sources of information.

4.6 Who Can Be Involved In The Public Information And Participation Process?

* The leader must be aware of community issues and must be able to translate technical information into terms that lay people can easily understand
* Public relations team
* Policy staff members to review material for consistency with the agency's mission and other activities

* People skilled in graphic design and production are key to well prepared information materials

5.0 Biosafety Clearing House (BCH)

5.1 Background

The Biosafety Clearing-House (BCH) is an information exchange mechanism established by the Cartagena Protocol on Biosafety to assist Parties to implement its provisions and to facilitate sharing of information on, and experience with, living modified organisms (LMOs). It is one of the cornerstones of the Protocol on Biosafety requirements.

5.2 Mandate BCH

Article 20, paragraph 1, of the Biosafety Protocol established a Biosafety Clearing-House (BCH) as part of the clearing-house mechanism of the Convention on Biological Diversity, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

5.3 Clearing-House Mechanism Mission

- Promote and facilitate technical and scientific cooperation, within and between countries

- Develop a global mechanism for exchanging and integrating information on biodiversity

- Develop the necessary human and technological network.

The BCH is essential for the successful implementation of the Protocol. It assists Parties and other stakeholders in different ways in the implementation of the Protocol. For example, it provides a "one-stop shop" where users can readily access or contribute relevant biosafety-related information. This would assist Governments to make informed decisions regarding the importation or release of LMOs. Information in the BCH is owned and updated by the users themselves, this ensuring its timeliness and accuracy.

5.4 Development of the Biosafety Clearing-House

The Biosafety Clearing-House was implemented in a phased manner, beginning with a pilot phase, following the recommendation of the first meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP). In decision BS-I/3 on Information-sharing and the Biosafety Clearing-House (27 February 2004), the first

meeting of the Parties to the Protocol approved the transition of the pilot phase of the Biosafety Clearing-House to the fully operational phase.

6.0 Stakeholders Role

6.1 Stakeholder identification for Biosafety Public Awareness(PA)

In designing a PA programme for Biosafety, cognizance has to be taken of the constitutional provision for conservation, the roles expected to be played by the three tiers of our federal structure, state of development of biotechnology in Nigeria, the potential for commercial application and its implications, existing regulatory mechanisms, government policy on modern biotechnology, agriculture and environment. Stakeholder identification would thus be a proper first step in determining special groups with interests and mandates that will form the fulcrum of use of awareness. Broadly put, the following groups identifiable:

- **Environmental Policy/Decision makers in Government**

  - Legislators.

    This group of stakeholders are responsible for the formulation and passage of laws on all matters. With agriculture and conservation falling on the concurrent list of the constitution of the federal republic of Nigeria, virtually any state may legislate on biosafety in particular as it affects conservation. Secondly, agriculture as currently practiced is largely through the aegis of the Agricultural Development Projects. Legislating on biosafety will thus be a challenge which federal and state governments may have to face as modern biotechnology makes its debut into the fields. It is thus necessary for legislators at the federal and state levels to be properly made aware and educated on the issues surrounding biotechnology and biosafety before harm is done by feeding improper information to this class of stakeholders.

  - The Judiciary

    The courts as arbiters in disputes may have the final say in cases which may arise, and have arisen in the use of Genetically Modified Organisms.

  - Public servants

    Public servants have responsibility for formulating policy and may be involved in initiation of laws by virtue of being in the executive arm of government. Parastatals are also used as agents of development and are particularly important in biotechnology and agricultural research. In this context, three agencies, National Biosafety Agency, National Biotechnology Development Agency (NABDA) and Sheda Science and Technology Complex (SHESTCO) as well as departments in the Ministries of Environment, Agriculture, Science and Technology, Health, Trade, Commerce and Industry are important stakeholders who need to be carried along. In such ministries and agencies, there should be wide-spread dissemination of biosafety issues and need not be restricted to the departments and desk officers.

Other public servant groups who may be involved in one way or another, and should be aware and properly educated include Customs and police officers involved in aspects of detection and apprehension.

- Policy implementers
  This is a diverse group of government establishments, including Customs and Universities.
- The organized private sector (OPS), including industrialists, commercial agriculturalists, chambers of industry, agriculture, and related organizations, Manufacturers Association of Nigeria. Since transboundary movements will be made largely by this sector, the need to educate and inform the operators of this sector cannot be over-emphasized. The activities include transport, agriculture, industrial manufacturing, fisheries and mining among others.

- NGOs/CBOs, Consumer Organisations

Numerous NGOs exist in Nigeria. Some have already taken advert space in newspapers on the subject of use of GMOs. This is an important segment of stakeholders that have to be carried aboard in the public awareness and education work in biosafety so that the citizenry can make informed decisions.
NGOs which work in environment, governance, social welfare, poverty alleviation education, youth and women affairs are relevant here. Characteristically, NGOs define their mission, mandate and style of operation, spheres of operation and geographical spread. Some of these have strong affiliations with NGOs outside Nigeria while others are strong locally. The positions they may take may be influenced or dictated by their relationship with these third parties.

- Research/Academic and Educational Institutions

To the extent that these institutions provide instructional materials on environmental matters to a wide range of audiences, they are important targets for the transmission of biosafety awareness and education information.

- Community Change Agents/Opinion Leaders

It is axiomatic that most developmental processes leading to environmental degradation take place in the local communities. Ordinarily, these include erosion, deforestation, over-cropping and biodiversity loss. Community change agents (CCA) are critical to understanding and dissemination of awareness and education on the issues of biosafety. Traditional modes of involving local people could be used to handle the public awareness (PA) issues on Biosafety.

- Professional Bodies/ Associations

These bodies in Nigeria's context include labour unions, Nigeria Union of Journalists (NUJ), Nigeria Medical Association (NMA) etc.

- Ruralites (small holder farmers, pastoralists, fishermen, hunters and gatherers)

These groups of stakeholders are important and need special focus. In many instances, their language competence is restricted to local dialects and those spoken regionally. To reach them demands interpretation of scientific facts into Nigerian languages. This is usually a challenge in many attempts at introducing new products and technologies. The success that has been achieved in many circumstances lends

credence to the adaptiveness and willingness to learn new ways of doing things by the rural folk.

- Others consisting essentially of the youth and children, urban informal sector workers.
- Donor agencies are important stakeholders and they can participate in influencing strategic directions in many national policy initiatives through a diverse channels open to them. They are also a sources of funding. Their participation give credibility to project development processes and outcomes especially if the issue falls within the purview of their interests. The donor agencies may be UN specialized bodies or representative of foreign governments. It is important to let these donors know the status of policies on these issues as they are usually in a position to attract resources, both human and otherwise to development schemes

6.2 Working with the Media /Appropriate Media Programmes

The public participation and awareness package for the Biosafety framework will aim at supporting the production of free and timely flow of information within the context of the overall programme objectives. This requires working with the media and adopting appropriate media programmes.

A key problem to be addressed by the public participation activities is the articulation of an appropriate mix of media methodology that is most likely to maximize the potential for effective Biosafety public awareness-raising.

Another problem is the reduction of complex terminology and related concepts to a level that the diversified public with different interests and orientation can easily understand. There may be need to tone down the language so that the *problem* of penetrating the illiterate masses at the grassroots will not constitute a monumental impediment. There would be the need to translate core messages into the major language as well as the use of Pidgin English.

Viable media channels include:

i) Print: books, journals, newspapers, newsletters, specialist publications (e.g. calendars) posters and handbills in English and major vernacular languages including Pidgin English.
ii) Electronic; radio, television
iii) Conferences, seminars, workshops, lectures, formal/informal environmental education and training
iv) Use of traditional system of gathering and sharing information at the grassroots and rural centers e.g. town criers, announcement at age grade meetings and town meetings, religious gatherings as well as market squares
v) Recognition of Traditional rulers and Youth/Age grade leaders in information dissemination.

6.3 Use of Media

- Use national and state level media to relay information about Biosafety issues.

To effectively use media to disseminate Biosafety information, the following are necessary:

Identifying electronic sources of information and publication of websites dealing with a variety of issues and opinions about biosafety

- improving the quality and accessibility of the information released to the media
- holding workshops with journalists to identify problems and potential solutions

- Use of multimedia approach such as enter-education or other creative and theatre performance methods to help raise awareness and convey information in an accessible, engaging and entertaining way.
- Use of official bulletin to disseminate information.
- Translation of messages to the major vernacular languages.

To work effectively with the media there will be the need to invite media representatives to workshops or conferences aimed at educating journalists on the subject matter of biosafety and some elements of Biotechnology. Educating the media in this way will give journalists a good knowledge base of the subject of Biosafety which will ensure an informed and accurate report of Biosafety related matters.

Effective communication of Biosafety messages for raising public awareness and ensuring public participation include imaginative use of multi-media approaches.
The most important aspect being:

- Promoting public awareness activities through traditional and modern mass media including NGO participation structures to keep them informed about Biosafety issues.
- Educating the media
- Keeping the media informed
- Making news without creating panic but help build confidence.
- Involving the journalists in packaging information for publication..

6.4 Key Actions on Information and Education

Activities aimed at raising awareness should include the following:

i) National participatory workshops involving government agencies, parastatals, research institutes, farmers' unions, NGOs, the private sector and consumer representatives. The aim is to improve understanding of the different views held by various stakeholders about the safe use of GMOs through education and awareness resulting from a public debate. The debate would help to highlight both areas of consensus and disagreement between different stakeholders, and assist in building trust and respect between different stakeholder groups with differing views;

ii) Involving different stakeholders n the preparation and documentation and review of a national framework to ensure an inclusive process that involves all stakeholders so that different social and religious views can be taken into account in developing a common vision and purpose for the NBF;

iii) Establishment of a dedicated website that will constantly be updated with news on Biosafety. The site should provide space for the interested public to contribute to changes required.

iv) Bearing in mind that a good percentage of the population live in rural areas where electricity is not available, efforts should be made to provide self-winding radios if radio publicity will get to the grassroots.

6.5 Information and Publication

Access to Information - effective participation is dependent on all stakeholders having access to relevant information so that they are able to make decisions based on sound and up-to-date information. Article 23 requires Parties to the Cartagena Protocol to endeavour to ensure that public awareness and education

encompass access to information on GMOs. Parties are also committed to encourage and make easier the flow of information on GMO transfers, handling and use to the public. In this regard, Parties must respect "confidential information in accordance with Article 21".

To achieve this, Government is obliged to:

- publish GMO release consents in public journals and factual books
- produce brochures and handbills on Biosafety (English and Vernacular)
- sponsor feature articles on National newspapers (with wide circulation) and discussion sessions on TV and Radio
- encourage television public opinion debates and other audience participatory programmes in both TV and Radio.

6.6 Education of School Children.

To increase the awareness of school children and improve their knowledge base on the advantages and disadvantages of the use of GMOs, information resources should be provided to schools including teachers. This process should be driven by the National Biosafety Agency(NBA). This approach has the merit of supporting a new generation of citizens who are well informed to grapple with the issues of Biosafety. To this effect, Government should through the NBA:

- Promote school curriculum reviews that integrate information on Biotechnology and Biosafety.
- Promote co-curricular activities that integrate Biosafety messages e.g. Young Farmers Club, Young Scientists Club, Home Economics Associations etc.
- Support training and re-training of teachers through seminars, workshop, in-service training to update their knowledge base in modern Biotechnology and Biosafety using integration /infusion approach into already existing curricula.
- Other activities to sensitize and stimulate school children including organization of quiz, essays, debates, school contests on relevant aspects of Biosafety.

6.7 Training and Education.

i) All stakeholders need the necessary skills and tools to enable them to participate, both in terms of their right to participate in decision-making, and in terms of their responsibility to contribute to the development and implementation of the NBF. The responsibility to participate depends on how their contribution is valued, and whether the public participates on their own terms. This requires capacity building for the public so that they are involved in decision making, as well as for government officials so that they are able to listen to, and make use of, the contributions from the public. Capacity building would therefore include training for scientists and officials convening meetings so that they learn about how to engage different publics on their own terms and to respect different types of knowledge.

ii) Government should support public participation activities covering formal and non-formal education in Biosafety and specifically, training activities targeted at:

- laboratory technicians

- personnel at entry ports e.g. Monitoring /Biosafety Enforcement Officers,Customs, NDLEA, Police, NAFDAC etc.
- permit applicants, importers, relevant industrial sector trade groups
- national Biosafety inspectorate
- education of legislators in Biosafety regulatory requirements

7.0 Different Public participation Methods

* Open house
* Public hearing
* Public meetings
* Retreats
* Workshops
* Focus Group
* Polls, Surveys, questionnaire

8.0 Institutional Arrangements

A viable national mechanism for Biosafety management requires establishment of National Biosafety Agency, co-operation, co-ordination and regular consultation through the establishment of effective institutions and linkages. For this purpose, government will:

- Encourage research linkages in Nigerian tertiary institution on Biotechnology and Biosafety issues.
- Enhance co-operation among all tiers of government on Biosafety planning, monitoring and enforcement.
- Provide systematic and periodic briefing for the public on Biosafety issues and legislation
- Ensure appropriate funding of organs such as NBA and its specialised subsidiary bodies

9.0 Legal Arrangement

The legal framework as a national Biosafety policy should be designed as an instrument that recognizes the need to achieve balance between development and socio-economic considerations. To ensure this, action shall be taken to:

(a) Periodically evaluate existing legislation with a view to ensuring their adequacy and effective implementation
(b) Streamline all legislation and regulations relating to Biosafety.
(c) Make public existing legislation relationship to Biosa fety.
(d) Sensitize the general public through appropriate awareness packages on their expected role in the successful implementation of the NBF.

10.0 Key challenges of participation in Biosafety

In the context of Biosafety, participation can help to de-mystify biotechnologies. This sometimes results in a greater acceptance by a skeptical and worried public.

However, one should be aware that it is sometimes falsely assumed that public participation or consultation will necessarily create a consensus. Participation can also bring a number of diverse views and perspectives into the debate. There are also barriers to effective public participation on Biosafety issues. These include:

- Inadequate knowledge of Biosafety and other related laws
- Lack of familiarity with Biosafety and modern biotechnology
- Prejudice
- Transparency and accountability - .is a cardinal pillar of public participation. This requires that the process and structures of decision-making have to be transparent, i.e. the way in which decisions are made, and who makes the decision, have to be

public knowledge. Also the results of decisions taken should be public knowledge as specified in Article 23.

- Effective participation is only possible when sufficient time is allowed within the decision-making processes of government for consultation with the relevant stakeholders. This requires a balance between enabling participation and ensuring that decisions and actions are taken in a cost-effective and efficient manner. It is not possible for government to consult all members of the community on every decision on Biosafety. The government therefore has to select those mechanisms that are culturally appropriate and allow for effective participation by the relevant stakeholders in decision-making, implementation and monitoring.

The emphasis on participation and consultation is based on the idea that the involvement of stakeholders is critical to the effectiveness of any regulatory framework. It is also acknowledged that without increasing public consent or approval, decisions by governments to allow the commercial growing of GM crops would create an insecure and uncertain foundation for the successful development of GM produce. Most fundamentally, people have a right to be informed and consulted about decisions that have a direct impact upon their lives especially through the food they eat.

11.0 Monitoring and Evaluation

An Evaluation is an assessment or measurement which is helpful in answering the major questions – what needs to be done and how well?

In keeping with the goals and objectives of the public participation and awareness component of the implementation of Biosafety, there shall be established a national Biosafety monitoring and evaluation network.

The responsibilities here shall include:

(i) Evaluating the impact of public awareness-raising efforts around Biosafety issues.
(ii) Conducting a survey to establish whether changes in awareness, knowledge and perceptions has occurred as a result of the various public awareness packages.
(iii) Monitoring and enforcement of Biosafety quality standards and regulations.

11.1 When is an evaluation done?

Before a communication plan

- To find out the public's opinion
- To find out the information needs

- To assess the public level of understanding on the subject
- To determine the communication requirement of the public

After the communication plan

- To find out if the objectives of the campaign were achieved
- To measure the success of the communication plan
- To learn from the successes and failures for next time planning.

11.2 Evaluation methods

Table II

Survey and questionnaires	Finding out specific information from the public To asses how effective the message was
Focus groups	Obtaining insight information, as they comprise of people with common attributes
Opinion polls	Useful to know about the attitudes and opinions of the public
Letters to the organization	Can be useful to know what people think and also the direction the debate may be taking
Phone ins	Gathering opinions
Hits on the website	Information about the number of people who are interested in the subject
Letters of inquiry	Level of understanding of the message as well as the frame of mind of the public
Workshop	Consulting on issues that are complex and contentious