



**Federal Ministry of Environment**

# **NATIONAL BIOSAFETY POLICY**

**FEBRUARY, 2017**

## **1.0 PREAMBLE AND INTRODUCTION**

Biotechnology refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific uses. It has been used to describe the use of biology in industrial

processes such as agriculture, brewing and drug development. Traditional applications include plant and animal breeding, brewing beer with yeast and cheese making with bacteria and meristem plant production through tissue culture. Modern biotechnology as an advanced form of biotechnology is defined as the ability to alter life-forms through applying *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or the fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Through Modern Biotechnology research, new genetically modified plant or animal life forms are continually being developed for use in agriculture, horticulture, the food industry, medical research, the pharmaceutical industry etc. While these Genetically Modified Organisms (GMOs) have the potential to advance human development, the potential risks attendant to their use must be carefully identified and managed. These potential risks include possible threats to biodiversity, risks to human, plant and animal health as well as the socio-economic consequences of introducing GMOs and their derivatives into the environment or the marketplace. The process of managing these risks can be referred to as Biosafety.

This new aspect of biotechnology creates enormous opportunities for agricultural modernisation, industrialisation production and environmental protection. The application of modern biotechnology can therefore, be very instrumental in realizing Nigeria's development potential especially in Agriculture, health and environment management.

At the 1992 Earth Summit in Rio de Janeiro, Brazil, world leaders agreed on a comprehensive strategy for "sustainable development" - meeting our needs for health, environment and biodiversity while ensuring that we leave a healthy and viable world for future generations. One of the key agreements adopted at Rio was **Convention on Biological Diversity (CBD)**, which establishes three main goals: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising from the use of genetic resources.

The potential benefits, notwithstanding, there are concerns that the products of modern 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 modern biotechnology. As a result of these concerns the **Cartagena Protocol on Biosafety (CPB)** was adopted in Montreal on the 29th

January 2000 at an extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity. The Cartagena Protocol on Biosafety makes provisions to regulate, manage or control risks associated with transfer, handling and use of organisms and derived products resulting from modern biotechnology that may have adverse effects on conservation and sustainable use of biological diversity, taking into account risks to human health, focusing on their trans-boundary movement.

Nigeria signed the Convention on Biological Diversity in 1992 and ratified it in 1994. With regards to the Cartagena Protocol on Biosafety, Nigeria signed this Protocol in the year 2000 and subsequently ratified it in 2003. As a signatory to the CBD and CPB, Nigeria is obliged to implement the articles of the CPB and develop its own national regulatory framework for the safe transfer, handling, use and release of **Genetically Modified Organisms (GMOs)** and products resulting from modern biotechnology.

In fulfilling these international obligations, the Nigerian government signed into Law the National Biosafety Management Agency Act, 2015 on the 18<sup>th</sup> of April 2015. This Act established the National Biosafety Management Agency, charged with the responsibility of providing regulatory framework, institutional and administrative mechanism for safety measures in the application of modern biotechnology and the use and handling of GMOs in Nigeria. This is with a view to preventing any adverse effect on human health, animal, plant and the environment.

This document constitutes the National Biosafety Policy for Nigeria. It is the product of deliberations by a range of Government Ministries, Departments and Agencies (MDAs) and non-governmental agencies, as well as consultations with other relevant stakeholders. It sets out objectives, strategies and implementation procedures for a range of government-led activities, which together create the framework for a national biosafety regime. It addresses the safe use, transportation, storage and handling of GMOs – including requirements for trans-boundary movement – and sets a policy framework for supporting research and public education on modern biotechnology. The policy is designed to meet not only international obligations, specifically those set out in the Cartagena Protocol on Biosafety, but also the peculiar needs and requirements of Nigeria as it seeks to benefit from the advantages of the technology.

This policy is to be read and implemented in conjunction with a range of complementary national laws and policies, including the National Biosafety

Management Agency Act 2015, which creates a wider regulatory framework for modern biotechnology industry.

The formulation of this revised policy was spearheaded by National Biosafety Management Agency, charged with the responsibility for coordinating the formulation of biosafety policies and their integration into national development processes.

## 2.0 Legislative and Policy Environment

There are several pieces of legislation that currently affect some aspects of biosafety. The following national policies, laws and regulations are relevant.

### 2.1 Laws

- I. **National Biosafety Management Agency Act, 2015:** This law provides regulatory framework, institutional and administrative mechanism for safety measures in the application of modern biotechnology in Nigeria with a view to preventing any potential adverse effect on human health, animal, plant and the environment.
- II. **The Plants (Quarantine) Act:** This law regulates the importation and exportation of plant species and establishes control on plant pests.
- III. **National Agricultural Seeds Act 1992:** This law charges the National Agricultural Seeds Council with the overall development and regulation of the national seed industry.
- IV. **National Agency for Food and Drug Administration and Control (NAFDAC) Act CAPN1 Laws of Federation:** it mandates NAFDAC to regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of food, drugs, cosmetics, chemicals, detergents, medical devices and packaged water (known as regulated products).
- V. **Customs and Excise Management Act:** An Act to regulate the management and collection of duties of customs and excise and for purposes ancillary thereto.

### 2.2 Policies

- I. **National Policy on Biotechnology:** This policy focuses primarily on all aspects of biotechnology, including research and development activities.
- II. **National Policy on Environment:** This policy identifies key sectors requiring integration of environmental concerns and sustainability with development. It presents specific guidelines for achieving sustainable development in the following fourteen sectors of Nigeria's economy: Human Population; Land Use and Soil Conservation; Water Resources Management; Biodiversity Conservation including Forestry, Wildlife and Protected Natural Areas; Marine and Coastal Area Resources; Sanitation and Waste Management; Toxic and Hazardous Substances; Mining and Mineral Resources; Agricultural Chemicals; Energy Production; Air Pollution; Noise in the Working Environment; Settlements; Recreational Space, Green Belts, Monuments, and Cultural Property.
- III. **National Policy on Agriculture:** Seeks to work with stakeholders to build an agricultural business economy capable of delivering sustained prosperity by meeting domestic food security goals, generating exports and supporting sustainable income and job growth.
- IV. **National Policy on Health:** To strengthen the national health system such that it will be able to provide effective, efficient quality, accessible and affordable health services that will improve the health status of Nigerians through the achievement of the health-related Sustainable Development Goals (SDGs).
- V. **National Policy on Science and Technology:** To build a strong Science, Technology and Innovation capability and capacity needed to evolve a modern economy.
- VI. **National Policy on Trade:** To encourage the production and distribution of goods and services to satisfy domestic and international markets for the purpose of achieving and accelerating economic growth and development.

### 3.0 Current Institutional Arrangements

The National Biosafety Management Agency is the Competent National Authority with direct oversight on biosafety issues. There are several government MDAs, Professional Associations and NGOs that are represented on the Governing Board of the Agency.

- I. Federal Ministry of Environment
- II. Federal Ministry of Agriculture and Rural Development
- III. Federal Ministry of Science and Technology
- IV. Federal Ministry of Industry, Trade and Investment

- V. Federal Ministry of Health
- VI. Nigeria Customs Service
- VII. National Agency for Food and Drugs Administration and Control
- VIII. National Biotechnology Development Agency
- IX. Biotechnology Society of Nigeria and
- X. One representative each of conservation Non-Governmental Organization (NGOs) and organized private sectors.

#### **4.0 SCOPE**

This policy provides the framework to protect the natural resources of Nigeria and the health of the people living in the country from the potential adverse effects that may arise from the development and application of GMOs and its derived products. This will be achieved by:

- I. Regulating, evaluating and monitoring the development and use of GMOs in Nigeria;
- II. Establishing criteria for assessing potential risks associated with GMO use;
- III. Developing the capacity in Nigeria to effectively manage and mitigate such potential risks;
- IV. Promoting the establishment of collaborative links with regional countries and institutions on biosafety;
- V. Establishing mechanisms for assessing the benefits to be derived from GMO use; and
- VI. Ensuring that public education, participation and consultation is critical in the implementation of this policy.

#### **5.0 FUNDAMENTAL PRINCIPLES**

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

- I. The policy shall at all times be consistent with the national aims and objectives guiding sustainable development as provided for in the Nigerian Constitution, 1999 (as amended), Convention on Biological Diversity and National Biosafety Management Agency Act.
- II. Nigeria has 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 potential adverse effects on such resources.

- III. The National Biosafety Management Agency Act 2015, together with the Convention on Biological Diversity (CBD) and the United Nations Conference on Environment and Development (UNCED), provide for the regulation of trans-boundary movement of Living Modified Organisms (LMOs) which may cause harm to biodiversity or human health.
- IV. Nigeria shall endeavor 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.
- V. The import, export, use, commercialization, trans-boundary movement, etc. of modern biotechnology products and practices must fully conform to relevant existing national laws.
- VI. The safe use of modern biotechnology and its products is regulated by the National Biosafety Management Agency, whose decision-making process must be transparent, scientifically sound and fully cognizant of environmental, public health, socio-economic and cultural considerations.
- VII. The Precautionary Principle is applied.
- VIII. 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 the National Biosafety Management Agency Act 2015 and any other national legislations 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 Government shall provide the desired assistance and advice to ensure equitable negotiation and conclusion of such a contractual agreement.
- IX. Nigeria shall cooperate with other countries in the sub-region and Africa as a whole to ensure the safe practice and use of modern biotechnology, its applications and products within its borders.
- X. Nigeria shall not permit or authorize the importation and Trans-boundary movement and/or use of modern biotechnology products and procedures which do not meet minimum safety standards as provided for in the National Biosafety Management Agency Act, regulated by the National Biosafety Management Agency and specified in this policy document and other established legislation.
- XI. The Agency shall carry out risk assessments on GMOs as appropriate before approval.

## 6.0 POLICY FRAMEWORK

### I. Policy Statement

The Biosafety Policy reflects the commitment of the Government of Nigeria in ensuring appropriate levels of protection in the safe use of modern biotechnology based on **the precautionary principle** and in accordance with other national policies, within the framework of sustainable development of the country for the benefit of present and future generations of Nigerians. All matters related to the handling and/or use of GMOs and its products in Nigeria shall be in accordance with the goal and objectives as expressed in this policy.

### II. Policy Goals

To ensure an appropriate level of protection of human, animal and plant health and life in the development and application of modern biotechnology, while ensuring the well-being of the country of Nigeria.

### III. Policy Objectives

The main objectives of the National Biosafety Policy are:

1. Implementation of effective regulation and management of the production, release, commercialization, importation, exportation and trans-boundary movement of GMOs, in order to ensure that there will be no adverse effects of modern biotechnology on human health, the environment, food security, biodiversity or existing agricultural activities and markets in keeping with international standards;
2. Ensuring that the possible negative effects of GMOs on human health and biodiversity are prevented, minimized and/or eliminated;
3. Regulation of GMO-labelling;
4. Provision of an institutional framework for national decision-making process on biosafety, networking, monitoring of modern biotechnology Research and Development (R&D), and international cooperation in all matters relating to biosafety;
5. Facilitation of public awareness and participation in biosafety policy implementation and transparency in decision-making process;
6. Increasing the capacity of national institutions to implement and monitor national framework for biosafety.



7. Supporting and facilitating capacity building in Biosafety, with particular reference to regulatory management, risk assessment, risk management, risk mitigation and risk communication, including the development of a roster of experts in biosafety.

#### IV. Policy Principles

1. Recognizing the importance of protecting its people, environment and biodiversity while promoting sustainable social and economic development of Nigeria;
2. Recognizing the human health, environmental and socio-economic risks that may be incurred from the unregulated exploitation, development, use, trans-boundary movement or trade in modern biotechnology and its products for agriculture, health, waste management, food, feed and other purposes.
3. Realizing the need for developing Nigeria's own capabilities in biosafety through research, development and training;
4. Recognizing that it is the responsibility of the Government of Nigeria to ensure the safety of her citizens and environment from the potential risks arising from the use of modern biotechnology and its products;
5. Recognizing that GMOs have the potential to adversely affect and disrupting indigenous ecosystems - (germplasm, landraces, seed sources, agricultural crops, agricultural production practices) through gene-transfer;
6. Recognizing that there are existing traditional alternative methods that can be used for sustainable agricultural practices;
7. Recognizing that GMOs may have potential benefits with respect to food security and pharmaceuticals;
8. Recognizing the importance of enhancing the capacity of Nigerians (scientists, policy makers, government operatives, regulators, civil society groups and other stakeholders) to cope with the nature and scale of the known and potential risks associated with the products of modern biotechnology.
9. Reaffirming Nigeria's commitment to the Principles of the Declaration on Environment and Development, especially in Rio de Janeiro (1992):
  - a. Liability and redress as well as compensation for damage, including that occasioned by trans-boundary movements, incidents and processes (Principle 13) and

- b. 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)
10. Reaffirming Nigeria’s Commitment to the Principles of the World Trade Organization (WTO) Agreements, especially those related to Technical Barriers to Trade (TBT)
11. Reaffirming Nigeria’s commitment to the principles, goals and objectives of the CBD, especially:
  - a. Article 3 (Principle of Sovereign Rights and Responsibilities)
  - b. Article 8g (control of risks associated with Genetically Modified Organisms – GMOs)
  - c. Article 14 (assessment and minimization of environmental impact)
  - d. Article 15 (access to genetic resources)
  - e. Article 16 (access and transfer of technology)
  - f. Article 19 (handling of technology and distribution of benefits)

**Nigeria shall ensure that:**

- I. The Biosafety Act and Regulations are based on the precautionary principle and the Advanced Informed Agreements (AIA).
- II. The production, use, import, export, sale, or trans-boundary movements of modern biotechnology applications, practices and products conform fully to all relevant national legislations and international agreements and obligations to which Nigeria is signatory. This will include a mechanism to ensure the traceability of GMOs and their products.
- III. Adequate regulations and procedures are established to address national food security needs in the event of an emergency.
- IV. Public awareness, education and participation in the decision-making processes are made essential for ensuring the ethical and judicious use of modern biotechnology applications, practices and products for socio-economic development, without jeopardizing the environment, indigenous cultures and practices, biodiversity or human health.
- V. Risk assessment and management of GMOs used in Food, Feed and Processing (FFP) shall be carried out according to National Biosafety Act

and Regulations. Decisions shall be based on evaluation of the risks that may result from a biotechnology products, applications or procedures.

- VI. Recognition and respect for intellectual property rights with respect to GMOs and their products, will only be granted if it contributes to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and is done in a manner that is conducive to social and economic welfare, and to a balance of rights and obligations (Article 7 of the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS).
- VII. Obligations under the CBD treaty shall provide for a mechanism that will allow fair and equitable sharing of the benefits arising from the commercial and other utilization of genetic resources. Access to genetic resources and traditional knowledge for such commercial purpose must fulfill the stated requirements and have the prior informed consent of the Government Ministry responsible for biological resources and the consent of any communities involved, with both government and community sharing the proceeds derived from the commercial exploitation of the material or knowledge concerned. Intellectual property rights can only be obtained if the aforementioned requirements are met.
- VIII. Persons involved in the use or sale of GMO or its derived products shall ensure that consumers are fully informed of the nature of the technology or product. Data resulting from safety tests/research on the technology or product, (for agricultural biotechnology, human genetic testing, manipulations or applications, for example), shall be fully disclosed and made public.
- IX. Decisions on biosafety issues shall not favor commercial considerations over public health, environment and safety.
- X. Labeling of genetically modified products using international norms shall be mandatory so that the consumer may make an informed choice.
- XI. National safety guidelines and implementation practices shall be adopted by industries using modern biotechnology or their products. The guidelines will cover all related aspects such as material handling, equipment, storage, waste disposal, laboratory safety, etc.
- XII. Modern biotechnology laboratories and/or analytical GMO laboratories established shall obtain certification from the National Biosafety Management Agency (NBMA).

- XIII. Priorities in Human Resource Development in Biosafety shall be determined, ranked and implemented.
- XIV. Public awareness of modern biotechnology in relation to assessment of potential risks/benefits/alternatives and management techniques shall be enhanced, involving the community at large, including policy makers, legislators, administrators, the private sector and modern biotechnology industry.
- XV. Research into the risks to the environment and human health that can be caused by modern biotechnology shall be supported.
- XVI. A comprehensive regime for liability as well as for adequate and prompt compensation (redress) for damage resulting from the transfer, handling or use (including illegal trafficking) of a GMO or its products under the jurisdiction of Nigeria shall be provided for. This regime shall be consistent with the “polluter pays” principle and shall cover property damage, economic damage (including socio-economic damage to the communities) damage to biodiversity, preventive measures, injury or disease and the cost of the reinstatement or remediation of an impaired environment.
- XVII. Permit Holder of GMOs or biosafety containment facilities should ensure safety to the ecosystem and human health.
- XVIII. No GMOs without permit shall be allowed in Nigeria.
- XIX. This policy is supported by legislation.

## **7.0 IMPLEMENTATION STRATEGIES**

The approach to the implementation of this policy will be multi-sectoral, involving the collaboration and input of relevant MDAs. The implementing agency is the NBMA with the responsibility of coordination, monitoring and enforcement of safety of modern biotechnology and GMOs.

Other specific implementation functions will be integrated into the related mandates of a range of government entities. Organisations that benefit from government funding and/or regulation, in particular universities and research entities will also be involved in implementing the relevant biosafety strategies.

The strategies for implementing each objective are set out as follows:

**7.1 Objective 1:** Implementation of effective regulation and management of the importation, exportation and trans-boundary movement of GMOs in order to ensure that there will be no adverse effect on human health, the environment, food security,

biodiversity or existing agricultural activities and markets in keeping with International standards.

### **Overview**

The Cartagena Protocol provides global standards for regulating the trans-boundary movement of GMOs. The implementation of its provisions facilitates synchrony between the local regulatory environment and that which exists in other markets/jurisdictions. In the identification of strategies to fulfill this objective, aspects of the Cartagena Protocol related to the following areas will be applied:

- I. Trans-boundary movement of GMOs
- II. Notification and authorisation procedures
- III. Decision-making procedures
- IV. Unintentional and illegal trans-boundary movement
- V. GMOs in transit
- VI. Information sharing

### **Procedures**

- I. The NBMA is the policy authority that establishes procedures for regulating the trade and trans-boundary movement of GMOs and may expand or amend the policy and procedures from time to time.
- II. The NBMA will monitor and keep under review procedures for regulating general release, containment and confinement and trans-boundary movement of GMOs, including but not limited to the procedures set forth below.
- III. Prior to the first intentional trans-boundary movement (i.e. exportation or importation) of a GMO, the following requirements must be fulfilled, in keeping with the 'Advance Informed Agreement' (AIA) requirements under the Cartagena Protocol:
  1. The exporter shall submit written notification to the National Competent Authority of the destination country. The written notification shall be in the format required by the country of destination, and shall contain all the information required by the NBMA Act, 2015.
  2. For a product being exported from Nigeria, the information given in a notification must be verified by the NBMA prior to submission to the country of destination.

3. For products being imported to Nigeria, the 'competent national authority' for receiving and reviewing notifications shall be the NBMA.
  4. Having received a notification from a prospective importer, the NBMA will acknowledge receipt in writing within 90 days, stating:
    - a. The date of receipt;
    - b. Whether the notification contains the required information;
    - c. The decision-making procedure for consenting to or prohibiting the importation of the GMO:
  5. Within 270 days of acknowledging such notification, the NBMA shall submit its written decision, which may fall within any of the following categories:
    - a. Approval which can be a permit or authorisation including, where applicable, requirements, guidelines or timelines.
    - b. Prohibition of the importation of the GMOs, stating reasons.
    - c. A request for additional information.
    - d. An extension of the review period by a stated number of days.
  6. The NBMA shall determine the range of factors to be considered in reviewing applications for various biosafety permits, in line with the NBMA Act, 2015. Conditions may be imposed to mitigate or control potential risks.
- IV. Subsequent trans-boundary movement or release of GMOs must be in compliance with the provisions of this policy, as well as the conditions (if any) imposed on its approval.
- V. Notwithstanding any statement made in this policy or in a grant of approval or waiver, the NBMA retains the right to suspend or prohibit the further release or importation of any GMO on any of the following grounds:
1. New scientific evidence has revealed potential harm that was not known at the time of permit.
  2. The Permit Holder's persistent non-compliance with conditions of permit.
  3. The Permit Holder's failure to give full and frank disclosure in the notification.
  4. The Permit Holder's attempt to import or release additional GMOs without NBMA permit.

In every such case, the NBMA shall notify the affected Permit Holder(s), giving reasons for the decision.

- VI. The permit procedures governing GMOs in transit shall comply with Biosafety transit regulation.
- VII. All decisions made under these procedures shall be recorded by the NBMA, which shall perform the function of a national Biosafety information clearing-house. The NBMA shall, in compliance with the Cartagena Protocol, forward relevant information to the international Biosafety Clearing-House, in such format as is required.

**7.2 Objective 2:** Ensure that the possible negative effects of GMOs on human health and biodiversity are effectively managed.

### **Overview**

The potential adverse effects that GMOs may have on biodiversity and natural ecosystems must be identified, evaluated and risks mitigated. Such evaluations will take into account the possible effects of use or exposure on human health and will reflect the standards and guidelines developed by international organisations. The management of risks is related not only to the external trade and trans-boundary movement of GMOs, but to activities within the local modern biotechnology industry.

In addition to the biodiversity impact of introducing a GMO into the environment, changes caused by such an introduction may have strong effects on communities and industries. These effects may be of great consequence and should guide the framework for introducing a GMO into the environment and/or market.

In order to manage the interface between GMOs and the human and physical environment, safety procedures must be observed by every organisation whose personnel come into physical contact with GMOs. These should include general guidelines applicable across different industries, as well as specific procedures tailored to each individual organisation.

### **Procedure**

This policy objective will be implemented under three main headings:

- I. Risk Assessment
- II. Assessment of Socio-Economic Impact
- III. Promotion of Safe Practices

## **1. Risk Assessment**

- a. The NBMA will develop, and continually update, risk assessment procedures applicable to the importation, use, handling, research and development of GMOs. Risk assessment procedures will be developed and implemented in a scientifically sound manner and will reflect international standards, particularly those set out in the Cartagena Protocol and the Biosafety Act, 2015.
- b. A risk assessment shall be undertaken by the NBMA prior to granting any approval related to the release, use, handling or trans-boundary movement of a GMO.
- c. Risk assessments may also be undertaken at any time on the subject matter of modern biotechnology research being conducted by locally-based tertiary or scientific institutions. Notwithstanding the existence or outcomes of previous assessments, a risk assessment should always be conducted immediately prior to the first release of a GMO into the environment.
- d. In making its determination in relation to granting any permit related to the use, handling or trans-boundary movement of a GMO, the NBMA will weigh the outcomes of a risk assessment against:
  - i. The relative impact of potential risks associated with similar, non-modified organisms; and
  - ii. The socio-economic impact that is likely to result from the introduction of the GMO into the environment.
- e. The cost of conducting a risk assessment shall be borne by the party whose products, research or systems are being assessed.
- f. The NBMA may conduct a new risk assessment if in doubt of the risk assessment submitted by the applicant. This risk assessment may on the approval of the NBMA be conducted by any competent public or private entity.
- g. Where there is insufficient information to carry out a thorough assessment of risks, the NBMA will request for additional information from the applicant and stop the clock until information is provided.

## **2. Assessment of Socio-Economic Impact**



- a. The NBMA shall restrict, prohibit or attach conditions to the use or introduction of a GMO into the environment and/or market where it appears that such use or introduction is likely to result in significant, adverse socio-economic impact.
- b. The NBMA shall set parameters for the socio-economic impact assessment of a GMO. In so doing, the NBMA shall be guided by, among other factors, the extent to which the use or introduction of the GMO poses a threat.
- c. Any organisation, community or person(s) claiming the adverse potential or actual effects of the use or introduction of a GMO shall make a submission to the NBMA.

### **3. Promotion of Safe Practices**

- a. The NBMA may develop relevant guidelines and regulations for the development and implementation of internal safety procedures for public or private organisations engaged in modern biotechnology research or the use, transportation, storage or handling of GMOs.
- b. Every publicly funded programme engaged in modern biotechnology research or whose personnel are engaged in the use, transportation, storage or handling of GMOs shall develop and implement internal safety procedures. Programmes to which this section is applicable shall include but not limited to the following:
  - i. Tertiary institutions receiving government grants or subventions;
  - ii. MDAs in which personnel are directly exposed to GMOs.
- c. As a precondition to the approval of grants, incentives or other forms of state support to private organisations or the entry into public-private partnership with any tertiary or scientific research institution, such organisations or institutions shall be required to develop internal safety procedures reflecting the guidelines developed by the NBMA.
- d. Safety procedures should, among other things, provide for the accurate labelling and identification of GMOs and should endeavour to limit the possibility of accidental introduction of the GMO into the environment.

Safety procedures must also set guidelines for their monitoring, enforcement and compliance management.

### 7.3 Objective 3: Regulate the labelling of GMOs.

#### Overview

In keeping with the requirement for safe use and handling of GMOs, as well as the requirement of keeping the public informed on the nature and characteristics of GMOs to which it is exposed, standards for the labelling of GMOs must be carefully developed and monitored. Such information is important, not only for GMOs being introduced to the market, but also for GMOs being stored, transported or displayed for research or information purposes, as well as GMOs being brought into the country for aid relief.

#### Procedures

- I. The NBMA may in collaboration with relevant MDAs put in place from time to time standards for the labelling and identification of GMOs. In developing these standards, the NBMA will take into account the labelling and packaging requirements under the Cartagena Protocol and domestic laws, as well as those proffered by other international bodies. The NBMA may from time to time consult with relevant MDAs to keep such standards updated and relevant.
- II. At a minimum, the standards for labelling GMOs will include the following requirements:
  1. All GMOs, whether in storage, in contained use, being transported, on the market, on display or which may otherwise be exposed to the public, should be clearly marked with language to the effect that it:
    - a. Contains or may contain Genetically Modified Organisms
    - b. This information should be included in labels, packaging and signage, as well as in documentation accompanying the GMO.
  2. Labels, packaging and signage for GMOs being stored, transported, displayed or distributed should also contain the following information:
    - a. The identity and relevant traits or characteristics of the GMO;
    - b. Instructions for safe use, storage, transportation or handling;
    - c. Instructions for preventing the unintentional release of the GMO into the environment; and
    - d. The name and contact information of the owner, distributor, importer, exporter, any party having custody of or responsibility

for the GMO or any party authorised to give further information on the GMO.

3. A GMO that is being imported or exported should also be labelled with a declaration that the trans-boundary movement of the GMO is in compliance with the standards of the Cartagena Protocol and domestic laws.
4. All labels, packaging and signage for GMOs shall be:
  - a. In English;
  - b. Written or typed in a clear, legible font; and
  - c. Conspicuously placed.

**7.4 Objective 4:** Facilitate public awareness and participation in biosafety policy implementation and transparency in decision-making.

#### **Overview**

As one of the principles on which any national biosafety regime is based, the responsibility for informing the public on biosafety and modern biotechnology must be executed through ongoing and multi-sectoral initiatives. In keeping with the policy of the Government of Nigeria to integrate public consultations on all major policy decisions, the participation of the public in biosafety policy and decision-making will also be accommodated to ensure transparency.

#### **Procedures**

- I. The NBMA, in collaboration with other stakeholders, may develop relevant public awareness and communication strategy on Biosafety, which shall include but not limited to:
  1. Frequently Asked Questions (FAQs), brochures and other easily distributed materials explaining the characteristics and principles of biosafety and biosafety policy in simplified language.
  2. Publication of this Biosafety Policy and related information in booklet format, to facilitate wide distribution throughout the public sector and among tertiary and scientific organizations engaged in modern biotechnology research.
  3. Documentation of all forms, standards, guidelines and protocols related to biosafety and modern biotechnology, for print and electronic access by the public.

4. Stakeholder awareness-building fora, to be conducted Nationwide.
  5. Personnel training sessions to be conducted within all public and private entities that will have direct input in the implementation of this Biosafety Policy.
- II. The relevant MDAs will, where necessary, incorporate relevant information from this Biosafety Policy in their public education materials or activities.
  - III. The NBMA may advocate for the inclusion of information on modern biotechnology and this Biosafety Policy in:
    1. The public enlightenment campaign of all public and private entities involved in public awareness building on issues related to science, the environment, agriculture and consumer protection.
    2. The curricula of vocational or tertiary institutions conducting training in the science, environmental or agricultural fields

**7.5 Objective 5:** Increase the capacity of national institutions to implement and monitor a national framework for biosafety. Also, to support and facilitate capacity building in Biosafety, with particular reference to regulatory management, risk assessment, risk management, and risk communication, including the development of a roster of experts in biosafety.

### **Overview**

The effective implementation of this policy will require the upgrading of technology and human resources in all government entities involved in the process. This will require the commitment of the heads of such ministries and agencies to build internal capacity, to the extent of available resources. While several agencies may integrate this policy into existing operations through adjustments to procedures and training of staff, investment in equipment and technology is required for other responsibilities. In particular, the capacity to detect GMOs in food, plant, animal and other products that are being imported, or which are the subject of research, will require such investment.

### **Procedures**

- I. The NBMA will include in its annual plan and programmes strategies to support and facilitate biosafety through capacity development, knowledge transfer and the acquisition of technological resources and equipment, requisite to its mandate.

- II. The implementation of this policy requires the capacity to test for genetically modified foods, seeds, plants, animals and similar products which are being used for various purposes.
- III. The NBMA may in conjunction with relevant agencies build the capacity for such testing, through the acquisition of equipment and the training of staff.
- IV. The NBMA will maintain a database of all projects and initiatives involving modern biotechnology research or the use of GMOs.

## **8.0 PERFORMANCE INDICATORS**

The biosafety regulatory framework is in accordance with national, regional and international requirements.

- I. All activities with GMOs are conducted in accordance with the goals, objectives and principles of this policy and the provisions of the Biosafety Act, 2015.
- II. There is an increased public consultation, awareness, education and participation in the biosafety regulatory framework.
- III. There is an increased capacity in the field of GMOs especially with regard to risk assessment, risk management and risk communication.
- IV. An updated database of current biosafety issues in other countries, especially countries in the region is established.
- V. An effective monitoring mechanism of GMO use in Nigeria is established.
- VI. There is an increased public awareness of emerging biosafety issues.
- VII. There is periodic dissemination of information on the state of biosafety in Nigeria.
- VIII. Adequate number of trained personnel.
- IX. Proper labeling regime in place.
- X. Effective coordination among relevant stakeholders.