



REGULATORY REQUIREMENTS FOR GM PRODUCTS IN NIGERIA

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NIGERIA AT A GLANCE

Population: 150million

Area: Over 927,000sq.km in the West African Sub-region

Agric Crops: Corn, Soybeans, Rice, Cassava, Yam,
Banana, Cow pea

Petroleum Products

Various plants/Animal Species

INTRODUCTION

In 1992 at the First Earth summit in Rio, Brazil where the issues of Environment and Sustainable Development were highlighted, Nigeria from that period recognized the science of the 21st century as a tool that provides opportunities in various sectors of economy and also its commitment to global initiatives such as CBD, CPB adopted modern biotechnology, for the attainment of various sustainable development goals.

INTRODUCTION CONT'D

- Nigeria joined the league of nations that took precautionary safety measures by signing and ratifying the Cartagena Protocol on Biosafety in 2000 and 2003 respectively.
- Nigeria has also signed the Nagoya-Kuala Lumpur supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety in 2012.
- Nigeria Successfully completed the UNEP-GEF Development of NBF project (2002-2006).
- Nigeria Commenced the UNEP-GEF NBF Implementation Project in June 2011 and it is currently on going.

VISION

- The National Biosafety Office is to ensure that the practice, process and procedures of modern biotechnology are undertaken within the limits of regulatory systems that guarantee the safe use, protects Nigerian biodiversity and providing minimum risks to human health and the environment.

MISSION

- Promoting the basic tenets of biosafety as enunciated in the Cartagena Protocol on Biosafety and enforce National Biosafety Regulatory Regimes to ensure the safe application and use of products of the technology.

OBJECTIVES OF THE BIOSAFETY IN NIGERIA

- **To assist Nigeria through capacity building activities to address identified gaps in legal, technical and administrative measures in ensuring compliance to the Cartagena Protocol on Biosafety.**
- **Articles 19 (3) and 8g of the CBD are provisions that relate directly to the LMOs/GMOs which consequently gave rise to negotiations of the CPB under the CBD. Article 8(g) requires parties/members to the Protocol to regulate**

OBJECTIVES OF THE BIOSAFETY IN NIGERIA CONT'D

- Manage or control risks associated with LMOs/GMOs resulting from the biotechnology that are likely to have impacts on:
Conservation, Sustainable use of biological diversity and human health.

The issue: Biosafety

- Highly contentious
- “Promises” to make significant contributions to the following:

OBJECTIVES OF THE BIOSAFETY IN NIGERIA CONT'D

- Better health care
- Enhanced food security through sustainable agricultural practice
- Improve supply of portable water
- More efficient industrial developmental processes for raw material transformation

INSTITUTIONAL STRUCTURE

- The Federal Ministry of Environment is the National Competent Authority On Biosafety in Nigeria prior to the establishment of Nigeria Biosafety Management Agency whereby all functions hitherto being performed by the FMENV will be transferred to the Agency. This agency will also be working in partnership with other MDAs for the safe management of modern biotechnology activities and the use of the products from the technology.

FUNDAMENTAL PRINCIPLES

- The establishment of the necessary legal instrument and procedures to guide the implementation of the protocol in sound scientific, economic, social, cultural and ethical considerations
- Protecting her biodiversity for sustainable development
- Minimizing risks to human health and the environment that may arise from the unregulated exploitation, development, use and transboundary movement of modern biotechnology products.

FUNDAMENTAL PRINCIPLES CONT'D

- Developing national capacity for Biosafety
- Reaffirming the country's commitment to the principles of WTO, agreements/other agreements of which the country has acceded to
- Reaffirming Nigeria's commitment to the goals, objectives of the BCD as obtained in Articles 3, 8, 14, 15, 16 and 19. especially in the sovereign rights to control/manage risks associated with LMOs/GMOs assessment of environmental impact, access to genetic resources, etc

FUNDAMENTAL PRINCIPLES

CONT'D

- Nigeria shall continue to work in tandem with other regional, sub-regional and international bodies to ensure the safe use of modern biotechnology.
- Development of necessary human and infrastructural capacity to
- Manage the regulatory systems
- Having effective control of transboundary movement of LMOs/GMOs and products of modern biotechnology through information exchange established under the BCH mechanism

FUNDAMENTAL PRINCIPLES CONT'D

- Provide an institutional framework for National decision-making process and linkage with International Community

EMERGING BIOSAFETY ACT

The Biosafety Act is divided into the following parts:

- Functions of the Executing Agency
- Establishment/composition of National Biosafety Committee (NBC)
- Establishment and composition of National Biosafety Sub-Technical Committee (NBTS)

EMERGING BIOSAFETY ACT

CONT'D

- Notification and Authorization
- Risk Assessment and Risk Management
- First, Second, Third and fourth schedules
- Offences, enforcement, powers, etc
- Miscellaneous provisions.

EMERGING BIOSAFETY ACT CONT'D

- All LMOs/GMOs and practices of modern biotechnology laboratories, confirmed environment up to commercial release of LMOs
- Current and future applications of modern biotechnology in agriculture, human/veterinary medicine, industry, environment management, bioremediation and waste management.
- Regulatory systems for CFT, Containment facilities, import/export, labeling, Risk Assessment/Risk Management, Commercial release (placing on market)

EMERGING BIOSAFETY ACT CONT'D

Research and development in modern
biotechnology

PROCESSING OF BIOSAFETY APPLICATION

- Receive, Acknowledgement of application,
- National Biosafety Committee (NBC) meets to review application and constitutes National Biosafety Technical Sub-committee (NBTS),
- NBTS reviews application in details and submits recommendation to NBC,
- Public participation: the public view may be required.

PROCESSING OF BIOSAFETY APPLICATION CONT'D

- Honourable Minister of Environment/Director-General of Agency takes decision on application,
- Approved permit issued
- Decision document is prepared by the Biosafety Office and sent to applicant within 270 days of receipt of application, after which the Biosafety Unit inspects the facility periodically
- Decision posted into the Biosafety Clearing House

BIOSAFETY REGULATORY INSTRUMENTS IN PLACE

- Develop Risk Management plans and strategy for protecting human health, biological diversity/environment from potential risks associated with GMOs.
- Certification and accreditation of laboratories for GM exercises among others.
- Institutional Biosafety Committee (IBC): It's the committee responsible for biosafety matters at the level of institutions that deal in Modern Biotechnology research and development.

BIOSAFETY REGULATORY INSTRUMENTS IN PLACE

- Biosafety application form;
- Biosafety containment facilities guidelines;
- Biosafety Inspection Guidelines;
- GMOs import/shipment form;
- National biosafety Risk analysis Framework;
- Decision document;
- Nigeria Biosafety Application Administration Guidelines;
- IBC Guidelines.

SECTORAL LINKAGES FOR DECISION MAKING PROCESS

- Policy on Biotechnology
- Policy on environment
- Policy on Agriculture
- Policy on Health
- Policy on Science and Technology
- Policy on Trade, etc.

ACHIEVEMENTS

- Identification of research institutes (RI), Agencies, Universities in Nigeria that have the personnel and infrastructure Genetic Engineering (GE). These are institutes of Agricultural Research (IAR), ABU Zaria, and National Root Crops Research Institute (NRCRI) Umudike, National Biotechnology Development Agency, (NABDA), Abuja.

ACHIEVEMENTS CONT'D

- Certification and accreditation of the two institutes
- Granting of approval/permits to IAR and NRCRI for the confined Field Trials on:
 - Pro-vitamin A enriched transgenic cassava (NRCRI)
 - Maruca resistant transgenic cowpea (IAR) using the existing guidelines aforementioned.
 - Iron enriched transgenic cassava.

ACHIEVEMENTS CONT'D

PUBLICATIONS

- Nigeria Biosafety System pamphlets,
- Nigeria Biosafety Risk Analysis Framework;
- Nigeria National Biosafety Containment Facility Guidelines;
- Biosafety Application Form;
- Biosafety Institutional Accreditation Form;
- Biosafety Containment Facility Certification Form;
- Biosafety Containment Facility Guidelines;

ACHIEVEMENTS CONT'D

- Biosafety Application Form
- Biosafety Institutional Accreditation Form
- Biosafety Containment Facility Certification Form
- Biosafety Containment Facility Guidelines
- Confined Field Trial Monitoring Manual
- Genetically Modified Organisms Shipment Inspection Form

ACHIEVEMENTS CONT'D

- Confined Field Trial Monitoring Manual;
- Genetically Modified Organisms Shipment Inspection Form;
- Biosafety Decision Document Format
- Biosafety Risk Assessment Framework (on going)
- Training of the Unit staff through workshops/seminars by collaborating with development partners.

ACHIEVEMENTS CONT'D

- BCH is updated .

<http://ng.biosafetyclearinghouse.net>



EXPECTATIONS

- Fully functional and responsive regulatory regime in line with Cartagena Protocol and national needs and priorities;
- Functional national system for handling request, perform risk assessment, detect GMOs, decision-making, perform administrative tasks;
- Functional national system for “follow-up”, namely monitoring of environmental effects and enforcement; and
- Functional national system for public awareness, education, participation and access to information.

SOME THOUGHTS ABOUT LEVELS OF REGULATION

Over regulation:

- Can be expensive and technically demanding.
- Diverts regulatory attention from serious health problems to address more minor ones.
- Can discourage innovation and lead to loss of useful products.
- Only large multinational companies can afford it.
- Only large profitable projects are possible; local and small markets are ignored as unprofitable.
- Imports may be “unfairly” excluded leading to trade disputes

Regulation is appropriate where risks exist that are not controlled in other ways but the level should be proportional to the risks.

SOME THOUGHTS ABOUT LEVELS OF REGULATIONS CONT'D

Under – regulation could lead to:

- Illness, injury, and environmental problems
- Lack of public confidence in the technology
- Exports to more stringent countries could be impacted.

CONCLUSION

- Biosafety regulation in Nigeria is intended to ensure adequate protection for the environment and human health in the deployment of modern biotechnology and its products for national development through proper funding, adequate capacity building in human and material resources.

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- THANK YOU FOR YOUR ATTENTION