

NBMA PIONEER L

(28th MAY, 2015



OUR STAFF, OUR STRENGTH

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	National Biosafety Management Agency NBMA

1.0 BACKGROUND TO THE NATIONAL BIOSAFETY MANAGEMENT AGENCY (NBMA)

1.1 Organizational Overview

- Nigeria adopted the use of biotechnology as a means of harnessing technology to enhance food security, accelerate economic development and ensure environmental sustainability through the approval of the National Biotechnology Policy in 2001, and the establishment of the National Biotechnology Development Agency and several Research Institutes. However, there are potential adverse effects associated with its adoption. To address this, Nigeria, led by the Federal Ministry of Agriculture, developed its 1st National Biosafety Guidelines in 1994 and reviewed it in 2001. This was followed by the signing and ratification of the Cartagena Protocol on Biosafety (CPB) in 2001 and 2003 respectively. Between 2002 and 2006, the National Biosafety Framework (NBF) (National Biosafety Policy, draft Biosafety Bill and some guidelines) for ensuring national biosafety system in Nigeria was developed. Parties to CPB are expected to domesticate the Protocol in their countries. Hence in 2015, after about thirteen years of legislative process, the Biosafety bill was enacted giving rise to the National Biosafety Management Act, 2015.
- Accordingly, the National Biosafety Management Agency (NBMA) was established by the NBMA Act, 2015 to be the National Competent Authority on Biosafety and National Focal Point to the CPB. The NBMA Act, 2015 is to domesticate the CPB to which Nigeria is a party. Prior to the passage of the Act, Biosafety issues were handled by a Special Biosafety Unit in the Federal Ministry of Environment. It was headed by M.P.O Dore from 1998 to 2008 and R.A. Usman from 2008-2014. Dr. Rufus Ebegba became head of the Unit in November 2014 when Mr. Usman retired.
- The NBMA Act, 2015 came into force on 18th April, 2015 and the Biosafety Unit transformed into the National Biosafety Management Agency still under the Federal Ministry of Environment. With the appointment of Dr. Ebegba as its pioneer Director-General/Chief Executive Officer on the 28th of May, 2015 to commence the operationalization of the Agency.

1.2 Mandate of NBMA

• As stated in the NBMA Act, 2015, the Agency's mandate is to provide "regulatory framework, institutional and administrative mechanism for safety measures in the application of Modern Biotechnology in Nigeria with the view to preventing any adverse effect on human health, animals, plants, and environment".

• In 2019, the mandate of the Agency was expanded to include regulating emerging modern biotechnologies such as gene drive, gene editing, synthetic biology and putting measures in place to ensure biosecurity in Nigeria.

1.3 Vision

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, animals, plants and the environment. It is also to put in place measures to ensure biosecurity in Nigeria.

1.4 Mission:

To promote the basic tenets of biosafety as enunciated in the CPB and enforce Nigeria National Biosafety Management Agency Act, 2015 (as amended).

1.5 NBMA's Anthem

On the 15th of May, 2022, the DG/CEO made a call for a draft submission of NBMA Anthem by NBMA staff, thereafter several submissions were received. After a vigorous selection process, the anthem composed by Victoria Ladi of the Procurement Unit presented below was adopted as NBMA Anthem on the 24th of July, 2022:



We're committed to safeguarding Human Health, Biodiversity and Environment

With integrity and service to our nation Nigeria.

1.6 Scope of NBMA's Regulation:

The NBMA regulate all institutions, facilities, farms, places and processes involved in the practice of emerging modern biotechnology and the use of its products (such as GMOs) as well as decision-making procedures pertaining to the import, export, transit, confined use or commercialization of GMOs.

1.7 Functions of the Agency

The functions of the NBMA are to implement the provisions of the NBMA Act, 2015 (as amended), which include:

- Proposing the overall policy guidance on issues of Biosafety in Nigeria
- Implementing the provisions of the Convention on Biological Diversity (CBD), CPB, and Kuala Lumpur Protocol on Liability and Redress, on matters relating to GMOs
- Rendering reports to the Secretariat of the Convention on the implementation of the Convention in Nigeria
- Developing measures and criteria for risk assessment, peer review and decision making
- Developing risk management plan and strategy for protecting human health, biological diversity and the environment from potential risks associated with modern biotechnology
- Accepting, verifying and processing applications in respect of GMOs for permit and record-keeping of all approved and unapproved applications
- Carrying out laboratory analysis of living materials and products to ascertain their genetic contents and to ensure compliance with the NBMA Act
- Embarking on activities required to ensure compliance with the NBMA Act, including but not limited to, inspection of GMO research facilities, collection and analysis of GM products and suspects, monitoring of human health and the environment to determine the effects of GMOs regulated by the Act
- Liaising with the Secretariat of the Convention and the Biosafety Clearing House (BCH) with respect to the administrative functions required under the Protocol
- Monitoring the activities of Institutional Biosafety Committees (IBCs) and Biosafety Officers
- Conducting capacity building for Biosafety Officers, Stakeholders and the general public, including the media on the regulation of modern biotechnology
- Building partnerships with relevant stakeholders at local and international levels
- Putting in place measures to ensure biosecurity and
- Performing other duties as may be necessary in carrying out its mandate under the law.

1.8 Responsibility of the Director-General/Chief Executive Officer

According to the NBMA Act, the DG/CEO of the Agency shall be responsible for:

- the day-to-day administration of the Agency;
- the execution of the policies of the Agency; and
- performing other functions as the Board or Minister may from time-to-time assign.

1.9 Organizational Chart

The NBMA is headed by the Director General/CEO and is presently made up of four (4) technical departments, two (2) supporting departments, ten (10) Special Units, six zonal offices and two state offices.

These are:

Technical Departments

- Environmental Biosafety and Commercial Release
- Socio-economic and Food Safety ii.
- **Biosafety Enforcement and Operations** iii.
- **Biosecurity** iv.

Supporting Departments

- Administration and Finance
- ii. Planning, Research and Statistics

Special Units

- i. Anti-Corruption and Transparency
- ii. **General Services**
- iii. Intelligence
- iv. **Internal Audit**
- ٧. Legal
- vi. **Press**
- vii. Protocol
- Procurement viii.
- SERVICOM ix.
- Store (Stock Verification)

National

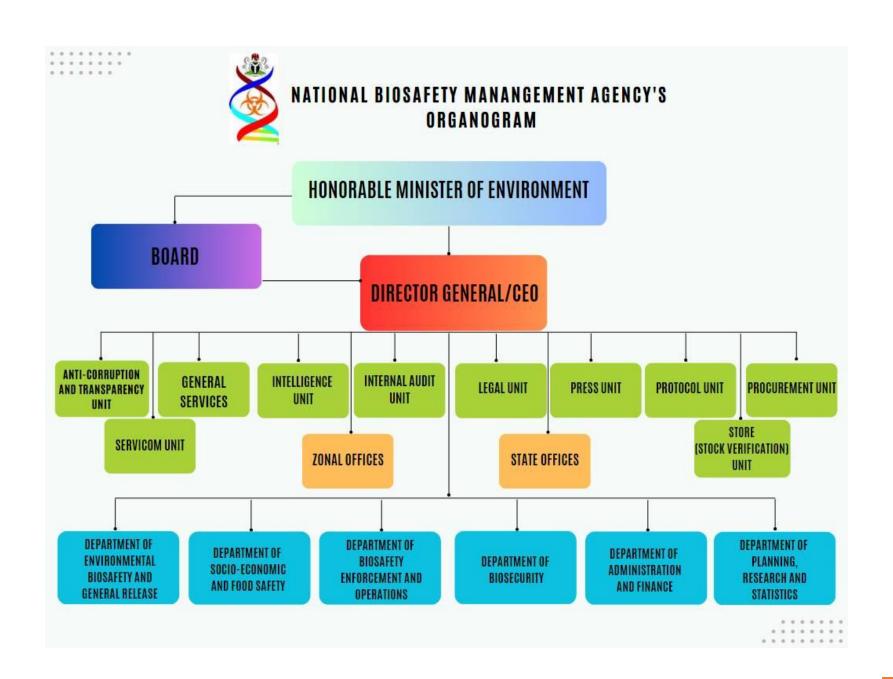
Zonal Offices

- North Fact Zaral (Co. 1977) i.
- ii. North-East Zonal office in Gombe, Gombe state,
- North-West Zonal Office in Katsina, Katsina state, iii.
- South-East Zonal office in Abakiliki, Ebonyi state iv.
- South-South Zonal office in Asaba, Delta state, ٧.
- South-West Zonal office in Lagos Island (TBS), Lagos state, vi.

State Offices

- Makurdi, Benue State i.
- Jos, Plateau State ii.





1.10 NBMA Board

In line with Part IV section 10 of the NBMA Act, 2015 (as amended), the Agency's Board consists of:

- a. Chairman, appointed by the President
- b. The Director-General of the Agency as the only Permanent member
- c. A representative not below the rank of a Director from each Ministry responsible for:
 - i. Environment;
 - ii. Agriculture;
 - iii. Science and Technology;
 - iv. Trade and Investment;
 - v. Health;
 - vi. Nigeria Customs Service;
 - vii. National Agency for Food and Drug Administration and Control (NAFDAC)
 - viii. National Biotechnology Development Agency (NABDA)
 - ix. One representative each of:
 - Conservation Non-Governmental Organizations (NGOs)
 - Organized private sector;
 - ➤ Biotechnology Society of Nigeria (BSN)
- D. The Legal Adviser of the Agency as Secretary of the Board

1.11 Senior Management Composition

- Director-General/CEO
- Heads of Departments
- The Legal Adviser

1.12 Management Composition

- Director-General/CEO
- Heads of Departments
- The Legal Adviser
- Officers on CONRAISS 12 and above

2.0 SCORE CARD

2.1 Proper Positioning and Mainstreaming of the Agency

The Agency has been properly positioned and mainstreamed in the National Administrative Structure. This is through obtaining approvals for:

- > Self-accounting status,
- > Agency's structure and Staff recruitment
- > Budget code,

- > E-payment platform account from Central Bank of Nigeria,
- Appropriate salary structure for the Agency's staff,
- Agency's organizational structure,
- > Establishment status,
- > Opening of Agency's Procurement Portal with BPP,
- Budget and Accounting Classification Codes obtained,
- > Account under the Treasury Single Account (TSA) obtained, and
- > Domiciliary Account with Central Bank of Nigeria
- Personnel Budget
- > Staff registration to National Health Insurance Scheme (NHIS)
- > NBMA's Condition of Service
- NBMA's Scheme of Service
- National Housing Fund and
- Staff Pension Fund

2.2 Establishment of Biosafety Institutional Structures

One of the provisions of the NBMA Act, 2015 (as amended) is to establish Biosafety Institutional Structures. Hence the underlisted institutions are in place:

A. National Biosafety Management Agency (NBMA)

B. Institutional Biosafety Committees (IBC)

All institutions in Nigeria, both private and public (which plan to undertake modern biotechnology research and/or development), shall each establish an Institutional Biosafety Committee (IBC), which will be responsible to, and cooperate with the NBMA. The Committee is to ensure that the application of modern biotechnology is carried out in line with the NBMA's operational instruments. The NBMA has successfully inaugurated IBCs in all the institutions that have so far been accredited to carry out modern biotechnology activities. They are as follow:

- Federal University of Technology, (FUTA), Akure;
- Institute for Agricultural Research, (IAR), Zaria
- International Institute of Tropical Agriculture (IITA), Ibadan
- National Biotechnology Development Agency (NABDA), Abuja;
- National Cereals Research Institute (NCRI), Badeggi
- National Root Crops Research Institute, (NRCRI), Umudike;
- Bayero University, Kano
- University of Calabar

C. National Biosafety Committee (NBC) and a National Biosafety Technical Sub-Committee (NBTC)

On receipt of biosafety applications, ad hoc NBC and NBTC are constituted, made up of experts drawn from the academia, research institutes, MDAs and

other relevant fields, to carry out in-depth risk assessment review of each application and advise the Agency on Issuing/Re-Issuing of Biosafety Permits. The DG/CEO puts their recommendation into consideration in deciding whether or not to give approval but is not duty bond to adopt their recommendation. In a situation where the Agency is not convinced, the DG/CEO may reconstitute another NBC and NBTC or seek the opinion of other authorities to reassess the application before taking a final decision.



Figure 1: NBC and NBTS in session

2.3 Biosafety Operational and Implementing Instruments in Place

To ensure effective implementation of the NBMA Act, the National Biosafety Policy and several regulatory and operational instruments were developed and approved, and are constantly reviewed in line with global best practices to keep abreast with advancements in modern biotechnology.

These instruments include:

A. INTERNATIONAL AGREEMENTS

In line with Nigeria's obligation to international agreements, NBMA implements the following international treaties (signed and ratified) on behalf of Nigeria:

- i. Convention on Biological Diversity as it relates to Biosafety issues
- ii. Cartagena Protocol on Biosafety
- iii. Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety

B. FUNDAMENTAL INSTRUMENTS

i. Act

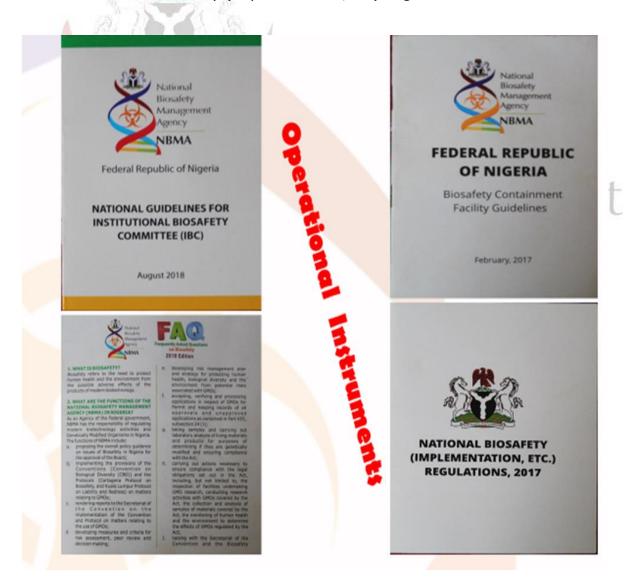
NBMA Act, 2015 (as amended in 2019)

ii. Policies

- National Biosafety Policy, 2017 approved by the Federal Executive Council on the 21st of December, 2017
- National Biosecurity Policy and Action Plan 2022-2026 approved by the Federal Executive Council on the 23rd of December, 2021

iii. Regulations

National Biosafety (Implementation, etc) Regulations 2017



B. STRATEGIES/FRAMEWORKS

i. National Biosafety Risk Analysis Framework

- ii. National Biosafety Emergency Response Strategy
- iii. National Biosafety Communication Strategy

C. MANUALS

- i. Biosafety Laboratory Manual
- ii. National Biosafety Administrative Manual
- iii. Biosafety Information Manual
- iv. National Biosafety Application Processing Manual
- v. National Manual for National Technical Working Group (NTWG) on Biosecurity 2022
- vi. Working Manual of the National Advisory Council on Biosecurity 2022

D. GUIDELINES

- i. Guidelines on Biosafety for Nigeria 1994
- ii. National Biosafety Guidelines 2001
- iii. National Biosafety Containment Facilities Guidelines, 2017
- iv. National Biosafety Guidelines for Institutional Biosafety Committees (IBCs), 2018
- v. National Biosafety Inspection Guidelines, 2018. *This has 11 inspection forms and 1 checklist as annextures*
- vi. National Biosafety Guidelines on Gene Editing, 2020
- vii. National Biosafety Guidelines for Risk Assessment and Risk Management of GM Plants with Stacked Genes
- viii. National Biosafety Guidelines on Importation of GMO for FFP
- ix. National Biosafety Guidelines for the Certification of Containment Facilities
- x. National Biosafety Guidelines on Food Safety
- xi. National Biosafety Guidelines on Genetically Modified Fish

NB- apart from the National Biosafety Guidelines 1994 and 2001, all others were developed by NBMA

E. FREQUENTLY ASKED QUESTIONS ON BIOSAFETY (FAQs)

FAQ Frequently Asked Questions

F. FEES FOR VARIOUS BIOSAFETY PERMITS IN NIGERIA

G. APPLICATION FORMS

- i. Application Form for Accreditation of Institution for Modern Biotechnology Activity
- ii. Application Form for Certification of Biosafety Physical Containment Facility
- iii. Application Form for Confined Field Trial for GMO
- iv. Application Form for General and Commercial Release
- v. Application Form for Importation/Exportation of GMO for Food, Feed and Processing (FFP)
- vi. Application Form for Authorization of GMO for FFP for Biotechnology Developers

vii. Application form for Genetically Modified Organism Gene Registration

H. CHECKLIST

- i. Checklist for the Completeness of Application Dossier
- ii. Application Checklist for Physical Containment facility
- iii. Inspection Checklist for Physical Biosafety Containment Facility

I. FORMS

a. Inspection Forms

*All I-FM 001 - 012 are incorporated in the National Biosafety Inspection Guidelines as annextures

- i. Planting Inspection Form of GMO under CFT
- ii. Growth/flowering-Stage Inspection form of GMO under CFT
- iii. Facility Inspection Form
- iv. Shipping and Storage Inspection Form for GMO
- v. General Inspection Form of GMO under CFT
- vi. Confined Field Trial Protocol Inspection Form
- vii. Confined Field Trial Termination and Harvest Inspection Form
- viii. Trial Post Harvest Inspection form
- ix. Trial Record Review and Exit Meeting Inspection Form
- x. Unintended Release and Non-Compliance Inspection Form
- xi. Inspection Report Form
- xii. GMO Survey-Analysis Form

b. No Conflict-of-Interest Form

This form is to be completed by members of NBC/NBTC before commencement of biosafety risk assessment review meetings)

- J. BIOSAFETY DECISION DOCUMENT Template
- K. BIOSAFETY PERMIT CERTIFICATE Template
- L. BIOSAFETY ORDERS (Templates)

Cessation Order Revocation Order

2.4 A Critical Mass of Biosafety Officers in Place

The initial staff of the NBMA were twenty-seven (27) in number seconded from the Biosafety Unit of the Forestry department, Federal Ministry of Environment and a few others from other MDAs. Today the Agency has a critical mass of over 397 well trained, vibrant and robust biosafety officers and other staff manning various departments and units. This is achieved through having in place effective Capacity Building Programmes such as:

• short Biosafety and Biosecurity courses both nationally and internationally

- masters' programmes in Biosafety (which is the highest qualification at the global level) and in related fields
- daily inhouse training rotated among the Departments and Units anchored by staff of the Agency to keep abreast with developments in the sector
- seminars,
- workshops and
- field trips/study tours

There are also regular training programmes for various stakeholders from other MDAs like lawyers, media, policymakers and other sectoral related regulatory agencies to enhance national biosafety mainstreaming.



Figure 2: International training on Biosafety Risk Assessment



Figure 3: International training on Biosafety Risk Assessment

2.5 Synergy among Stakeholders and Signing of MOUs

The Agency has established synergy with several international and national bodies and persons relevant to the sector for effective biosafety and biosecurity regulation. NBMA went further to sign MoUs with nine relevant regulatory MDAs listed below to further its collaborative drive.

- Federal Competition and Consumer Protection Commission (FCCPC)
- Federal Ministry of Agriculture and Rural Development through its Veterinary and Pest Control Department
- Federal University of Petroleum Resources, Effurun, Delta state (The Agency is currently in the process of establishing of a Centre of Excellence for Biosafety and Biosecurity to be domiciled at the University)
- National Agency for Food and Drug Administration and Control (NAFDAC),
- National Agricultural Seed Council (NASC),
- National Varietal Release Committee (NVRC),
- Nigeria Agricultural Quarantine Service (NAQS),
- Nigerian Customs Services (NCS) and
- Standard Organization of Nigeria (SON)



Figure 4: Signing of MoU Ceremonies

Parties resolved to collaborate with each other in activities such as importation, transportation, storage, handling, commercialization and safe use of Genetically Modified Organisms (GMOs) to protect human health and the environment. Both parties recognized that their mutual collaboration for the purpose of protecting consumers is vital and consistent with their respective mandates.

Key International Partners

- Africa Agricultural Technology Foundation (AATF)
- African Union Development Agency, (AUDA-NEPAD);
- Argentine Embassy/Argentine National Advisory Commission of Agricultural Technology (CONABIA),
- Danforth Plant Science Center
- Food and Agricultural Organization (FAO)
- International Food Policy Research Institute (IFPRI)
- International Centre for Genetic Engineering and Biotechnology (ICGEB)
- International Institute of Tropical Agriculture (IITA) Ibadan
- International Service for the Acquisition of Agri- Biotech Applications (ISAAA);
- Michigan State University (MSU);
- Missouri State University (USA)
- Office of the Gene Technology Regulator, Australia (OGTR),
- Open Forum on Agricultural Biotechnology (OFAB)
- Program for Biosafety Systems (PBS);
- United Nations Environment Programme/ Global Environment Facility (UNEP/GEF)
- United Nations Industrial Development Organization (UNIDO)
- United States Agency for International Development (USAID)
- United States Department for Agriculture (USDA),
- World Health Organization (WHO)
- Sandia Lab USA
- Health Security Partners USA

Some of the fall out of these Synergies and MoUs include:

- Development of the Biosafety regulatory instruments
- The successful detection of 96,000 MT unauthorized GM Maize in 2017 at the Lagos border been imported by WACOT Nigeria Limited from Argentina and its repatriation
- Review and validation of the National Biosecurity Policy and Action Plan 2022-2026
- Capacity strengthening of NBMA Staff
- Support for the Agency's participation in Multilateral Environmental Meetings (COP, COP-MOP)

2.6 Nationwide Survey/Surveillance, Tracking and Profiling of GMOs

Nation-wide survey and tracking of GMO-suspects in supermarkets, open markets and farms are periodically carried out to ensure that only authorized and safe GMOs are in

circulation, in line with the mandate of the Agency. This is to ensure that Nigeria is not used as a dumping ground for unapproved GMOs. Thus, guaranteeing reduction in the potential negative socio-economic consequences in the application of modern biotechnology and the use of its products thereof (GMOs).



Figure 5: Distribution of survey forms and sample collection in Benue State, Nigeria and distribution of questionnaire and visit to grand cereals in Plateau State

2.7 **Biosafety Enlightenment Programmes**

In view of the fact that the sector is shrouded with some concerns and strong controversies which limit its adoption for economic advancement and acceptance by stakeholders, the NBMA carries out several public engagement and enlightenment programmes for effective awareness and feedback. This is through vibrant communication channels such as electronic media, print media, television and radio programmes, social media, conferences and workshops within available resources to effectively educate and enlighten the public. This is to ensure that the issue of Biosafety is demystified and stakeholders are able to make informed choices as to whether or not to consume GMO products.









Television News

Interviews

DISCUSSANTS AT AN EXPERT MEETING ON BIOTECHNOLOGY AND BIOSAFETY - GENETICALLY MODIFIED ORGANISMS(GMOS):





ational

Figure 6: Stakeholder's sensitization and experts' discussions on Biosafety

These include among others:

A. Electronic Communication

- ✓ National Biosafety Management Agency Website: www.nbma.gov.ng
- ✓ Biosafety Clearing house: www.bch.cbd.int (Biosafety information exchange mechanism)
- ✓ Social media: Facebook: www.facebook.com/biosafetynigeria and Twitter: @Biosafetynigeria and Twitter: @Biosafetynigeria and Twitter: www.facebook.com/biosafetynigeria and <a
- ✓ E-mail: biosafetyng@gmail.com, nbma@nbma.gov.ng
- ✓ Television/Radio: (Press briefing/reports, Media chats & interviews)
- ✓ Telephone: +2348180805451

B. Print Communication including Bi-annual Biosafety Magazine, Brochure, Flyers, Newsletters, News bulletins and Policy briefs

C. Annual National Biosafety Conference

D. Others are through Seminars and Workshops

Specifically, the Agency has carried out over 30 and 50 television and radio appearances respectively, 3 regional media sensitizations, 5 legal sensitization workshops and 10 other stakeholders' enlightenment programmes. Others are 17 media chats and 6 annual Biosafety Conferences in collaboration with Universities and MDAs.

2.8 GMO Detection and Analysis Laboratory with Global Standard Equipment

There is established, Nigeria's first GMO Detection and Analysis Laboratory equipped with standard machines and Genetically Modified Organism (GMO) detection kits as well as GM food testing kits for rapid detection. Prior to this, GM foods and grains flooded the country's markets unapproved and untested. With a well-equipped GM laboratory, the NBMA is able to test GM grains and foods to ensure they pose no risk to human health or the environment before they are allowed into the country. It also developed detection protocols for gene edited products and stacked gene traits.



Figure 7: NBMA's GM Detection and Analysis Laboratory



Figure 8: Senate Committee on Environment actively listening to the Head of the Lab during a visit to the Lab



Figure 9: Senate Committee on Environment visit to the Lab and Analysis of GMOs



Figure 10: Visit of the Honourable Minister of Environment to the National GMO Detection and Analysis lab

2.9 Training of University Students and National Youth Corp Members

NBMA has become a training hub for local and international University Students on GMO Detection and Analysis. Over 900 undergraduate students (Industrial Training students) have been trained on basic molecular biology techniques and GMO Detection and Analysis. Others trained are:

- Staff of National Quarantine Service (NAQS)
- > Staff of Kano State Ministry of Science and Technology
- NYSC Corps members
- Supervision of a post-graduate project of a student of the National Defence Academy (NDA), Kaduna

The staff of the Agency have also been invited to act as resource persons at several other local and foreign capacity building programmes.

Below was how one of the Year 4 IT students captured her experience in the GM detection and Analysis laboratory in her social media account

"I work at the NBMA. Generally, the Agency is committed to ensure regulation of Modern Biotechnology and its products (GM) so it does not cause harm to humans and environment. I have been taught mostly theory throughout my stay in the university, seeing laboratory equipment and machines and having the opportunity to operate and use them is like seeing pure gold and using it. That feeling when you are not only told the functions of machine but you have the opportunity to handle it. Sincerely, the feeling is out of this world. Now, I can carry out some important practicals single-handedly with full confidence."



Figure 11: Training session on going and surprise visit by the DG/CEO during one of the training sessions

2.10. Biosafety Risk Assessment and Issuance of Biosafety Permit

Following Biosafety Applications and necessary in-house procedures, ad hoc National Biosafety Committees and National Technical Biosafety Subcommittees consisting of experts on a case-by-case basis are constituted to carry out Biosafety risk assessment review and advise the Agency accordingly. After careful consideration of the report of the in-depth biosafety risk assessment review conducted, the Agency through the DG/CEO grants Biosafety Permits to deserving applicants to foster improved and safe seeds for national food security. Since inception, the Agency has accredited institutions that have met the requirements set forth for accreditation. It has also certified Containment Facilities (CF) for different purposes and granted various Permits for commercial release and importation of GM crops such as maize and soybeans for feed and food processing.



Figure 12: Risk assessment in progress by adhoc National Biosafety Committee

These are among others:

A. Accreditation of Biotechnology Institutions

- Federal University of Technology (FUTA), Akure;
- Institute for Agricultural Research (IAR), Zaria;
- International Institute of Tropical Agriculture (IITA), Ibadan;
- National Biotechnology Development Agency (NABDA), Abuja;
- National Cereals Research Institute (NCRI), Badeggi;
- National Root Crops Research Institute (NRCRI), Umudike;
- Bayero University, Kano; and
- University of Calabar.

All the containment facilities in the above institutions have been certified.

B. Confined Field Trials

- Bio-fortified cassava enhanced with pro-vitamin A (concluded) at National Root Crops Research Institute, Umudike.
- Bio-fortified cassava enhanced with Iron (concluded) at National Root Crops Research Institute, Umudike.
- GM Cassava (AMY3 RNAi Transgenic lines) for delay in post-harvest deterioration (ongoing) at International Institute of Tropical Agriculture (IITA)
- Cassava Clone trial for increased starch yield, IITA Ibadan
- TELA maize modified for resistance against stem borer insect pest and for drought tolerance, IAR Zaria
- Transgenic Cassava modified for increased storage root yield, IITA Ibadan
- GM cassava modified to express elevated levels of Iron and Zinc in the storage roots and high resistance to cassava brown streak virus, NRCRI Umudike

- Africa Biofortified Sorghum modified for bioavailability of iron, zinc, protein and pro-vitamin A (terminated) at IAR.
- GM rice for Nitrogen use efficiency, water use efficiency and salt tolerance at National Cereals Research Institute, Badeggi (terminated)
- GM Maize modified for insect resistance and herbicide tolerance, Monsanto Agriculture Nigeria Ltd (now acquired by Bayer CropScience LLC) (yet to commence)
- GM Cowpea (Cry2Ab Gene) for Efficacy Testing, IAR, Zaria (concluded)
- GM Soybean (Cry2Ab Gene) for Efficacy Testing, IAR, Zaria (Yet to commence)
- GM Soybean modified for tolerance to herbicides, NABDA, Abuja (Yet to commence)
- GM Potato Modified for Resistance to Late Blight disease, NRCRI Umudike

C Permit for Commercial Release

- Bt Cotton (Bollgard) modified for insect resistance Monsanto Agriculture Nigeria Ltd. (now acquired by Bayer CropScience LLC) (recently approved and released by National Varietal Release Committee) for commercial/general release.
- Bt Cowpea modified for pest resistance (Maruca vitrata) granted to IAR
- TELA Maize modified for herbicide tolerance and resistance to army fall worm
- Hybrid Cotton containing Cry1Ac and Cry2Ab genes for resistance to Bollworms granted to Fiyah Global Concept Ltd.
- POD Borer-resistant cowpea containing Cry2AB Gene that confers resistance to the POD Borer, Maruca Vitrata (AAT-Ø245F-3)

D Permit for Importation of GM Crops for Food, Feed or Processing:

- Importation of GM Maize for feed processing to CHI Farms Ltd.
- Importation of GM Maize for feed processing to Flour Mills Nigeria Plc. (Golden Agri Inputs Ltd.)
- Importation of GM Maize for feed Processing to WACOT Nig. Ltd.
- Importation of GM Soybean for feed processing to Agboola Farms Ltd
- Importation of GM Soybean for feed processing to CHI Farms Ltd
- Importation of GM Soybean for feed processing to Elephant Group Ltd.
- Importation of GM Soybean for production of edible oil to ROM Oil Mills Ltd.

2.11 Biosafety Enforcement Compliance Visits

To ensure that the operators of modern biotechnology only apply the technology for the purpose for which approval is given and to ensure compliance to terms of approvals in line with NBMA, Act 2015 (as Amended) and regulations, the Agency carries out inspection and monitoring of accredited biotechnology institutes for compliance with laid down regulations. Some institutions inspected were:

• International Institute of Tropical Agriculture (IITA), Ibadan: the purpose was to inspect the CFT for commencement of harvest and data collection of the transgenic cassava CFT research on-going at the Institute.

- Crown Flour Mill's GMO Storage Facilities: Storage facilities were inspected to ascertain level of compliance with terms of approval given to them by NBMA for import of GM grains
- CFT sites in NABDA, NCRI, NRCRI, etc

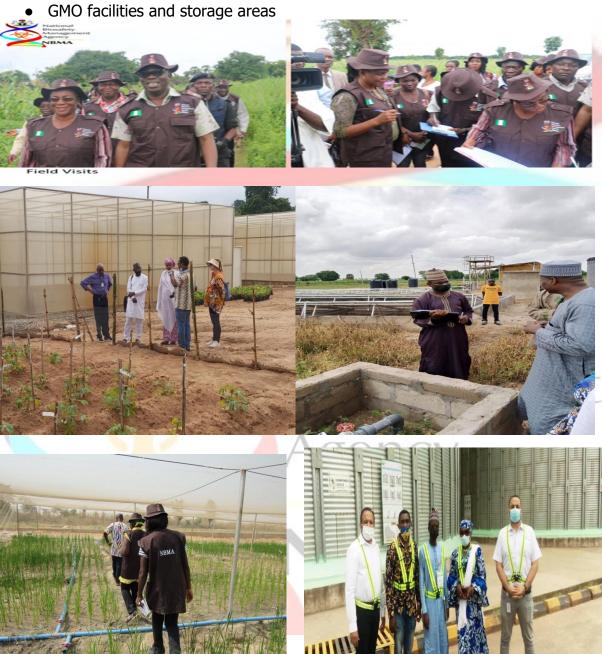


Figure 13: Biosafety inspection compliance visits

2.12 Documentation of Approved and Unapproved GMOs

There exist a register of Biosafety applications and approvals in the office of the DG/CEO where details of biosafety applications and Permits are documented. There also exists a register in the laboratory where list of samples collected and analyzed are documented.

2.13 Rendition of Reports

In line with the NBMA Act 2015 (as amended), the Agency's annual reports and audited accounts as at when due have been submitted to the President from 2016-2021. In line with other government circulars, monthly and quarterly audit reports have been duly submitted to the Offices of the Accountant-General and Auditor-General of the Federation as well as to the National Budget Office from 2016-2021. Other reports submitted to the Offices of the Auditor-General and Accountant-General of the Federation were complete and continuous audit (reports) of the accounts and records of revenue and expenditure, assets, allocated and unallocated, where applicable and other activities which add value to the Agency. The 2022 annual and general reports to the President are being developed.

2.14 Measures in Place to ensure Biosecurity in Nigeria

- Approval for a National Biosecurity Policy and Action Plan (2022-2026)
 by the Federal Executive Council:
- Following the development of a draft National Biosecurity Policy and Action Plan (NBP & AP) (2022-2026) and its presentation to Stakeholders, the Agency, under the auspices of the Federal Ministry of Environment, collaborated and coordinated several review meetings for the draft policy. The meetings of the NBP &AP had in attendance about 105 MDAs, state governments, civil society groups, academic institutions, professional associations and international partners participating. On 23rd December 2021, the Policy was approved by the Federal Executive Council (FEC). The NBP & AP aims to foster the integration and harmonization of Biosecurity strategies that will be implemented through One-Health approach for prevention, early detection, rapid response to biothreats and recovery from biosecurity incidence. The policy also aims to ensure synergy among stakeholders involved in biosecurity for effective and efficient operations.



Figure 14: Presentation of the Validated National Biosecurity Policy and Action Plan 2022-2026 by the Honourable Minister of State for Environment to Stakeholders



Figure 15: Presentation of a copy of the National Biosecurity Policy and Action Plan 2022-2026 to the Honourable Minister of Environment

Other provisions for the effective implementation of NBP&AP include:

- a. National Advisory Council on Biosecurity chaired by the office of the NSA
- b. A Working Manual for the National Advisory Council on Biosecurity
- c. A National Technical Working Group on Biosecurity chaired on rotational basis by the Permanent Secretaries of the Federal Ministry of Environment, Agriculture and Health
- d. A Directional manual for the national technical working group on Biosecurity
- e. National Register of Technical and Supporting institutions for Biosecurity
- f. NBMA Desk officers for the different thematic areas of the NBP&AP

2.15 Commitment to the Principles of International Agreements and Treaties

To fulfil Nigeria's obligation to the Convention on Biological Diversity (CBD) and Cartagena Protocol on Biosafety (CPB) which she is party to:

- a. NBMA paid its financial obligation to the UN,
- b. Updates the Biosafety Clearing House as at when due, and
- c. Attends and participates actively at meetings of COP and COP-MOP where Biosafety issues favourable to Nigeria's economy and its environment are strongly projected.

2.16 Nigeria's Participation at the Global Biosafety Space

As a result of Nigeria's active participation at the global biosafety space such as at the Conference of the Parties (COP) to the CBD meeting of the Conference of the Parties serving as the Meeting of the Parties (COP-MOP) to the CPB and her achievements, Nigeria is being looked upon to lead other African countries on issues of biosafety. Hence:

- The Director-General/CEO of NBMA was appointed the pioneer Chairman of the Steering Committee of the West African Biosafety Regulators Forum (WABRF), the pioneer chair of West Africa Biosafety Regulators Forum and Africa Biosafety Regulators Forum.
- Nigeria hosted and chaired the meeting of the National Experts from Ministries/National institutions as well as the Ministers responsible for Biosafety from fourteen ECOWAS, UEMOA and CILSS member states at the ECOWAS Commission in Abuja from 14th -17th May, 2019. This was to review the preliminary draft Regional Biosafety Regulations by Biosafety Experts. The technical meeting was declared opened by the HMEnv and was chaired by Ms Chinyere Nzeduru (Fmr. Director Environmental Biosafety and General Release, NBMA) on behalf of Dr. Rufus Ebegba, the DG/CEO, NBMA who was unavoidably absent. The draft document was presented and technically adopted subject to the different amendments by experts taking into account the preliminary draft Regional Biosafety Regulations for ECOWAS, CILSS region.

The meeting of Ministers in charge of Biosafety was held on the 17th May, 2019 and was chaired by the Honourable Minister ably represented by the Permanent Secretary who declared the meeting opened. The Ministers considered and approved the conclusions and recommendations of the Experts meeting concerning the sole agenda item, that is consideration of the preliminary draft Regulation on Biosafety in ECOWAS and CILSS regions.



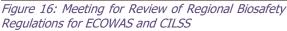






Figure 17: Regulatory Leaders at the Meeting for Review of Regional Biosafety Regulations for ECOWAS and CILSS

2.17 Digitizing NBMA Work process, document and permit process

In line with the Executive order 1 on ease of doing business, the Agency started the process of integrating its permit process into the Nigeria Customs Single one window as well as digitizing its work process by developing a zero draft Digital transformation Framework, the Framework is currently undergoing reviews.

3.0 OFFICE SPACE AND LAND FOR NBMA'S HEADQUARTERS IN FCT ACQUIRED

At the inception, the Agency obtained a temporary office space at the Department of Forestry, Federal Ministry of Environment, Utako, Abuja. As the staff strength increased, she sought for and obtained a bigger temporary space at National Parks Headquarters where it is currently occupying.

However, the National Parks had written to the Ministry requesting that we vacate their premises. Hence the need to facilitate the construction of NBMA's permanent HQ in the plot of land acquired by the Agency located along Umaru Musa Yar'adua Express way, Airport Road, Abuja.

4.0 OUTCOME OF ACHIEVEMENTS:

A. To the International Biosafety Community

i. Other African countries look up to Nigeria for leadership in Biosafety, as a result Nigeria was nominated to serve as the pioneer Chair of the West African Biosafety Regulators' Forum, African Biosafety Regulators Forum and serve as the first Vice-Chair of the West African Integrated Vector Management Forum.

- ii. Other Countries' Biosafety Authorities, particularly African Union member states, visit Nigeria to understudy the Nigerian Biosafety System.
- iii. Nigeria is also a member of the African Biosafety Negotiators Forum for COP-MOP and other UN environmental multilateral issues, particularly in Biosafety and Biodiversity.

B. Scientists, Universities and Researchers

- i. Avenue is being provided to harness the potentials of modern biotechnology practitioners and reduce brain drain in the sector;
- ii. Conducive environment for the practice of modern biotechnology by universities, research institutes and biotechnology concerns.

C. Economy

- i. Biosafety approvals have led to increased confidence in the sector by investors, researchers, farmers and consumers with overall increased benefit to the economy
- ii. Approvals have added to stimulating and enhancing socio-economic development, industrial environment, health, green economy etc.
- iii. Improved food security by provision of better seeds adaptable to adverse climate conditions, and pests and diseases
- iv. Increase in crop yields per planted area through reduced pest damage and increased gain in profit among farmers due to reduced use of agro-chemicals
- v. Creation of direct and indirect job and wealth, and increased GDP growth
- vi. Increased presence as global trade player resulting in increased foreign earning
- vii. Enabler and enhancer of bioeconomy and green economy

D. Industries

i. Availability of safe, reliable, more affordable and better-quality raw materials resulting in revamping of industries (e.g., textile)

E. Farmers

- Reduction in pesticides and agro-chemical use and their attendant costs and effects
- ii. Increase in yields and early maturation of their crops
- iii. Increased shelf life of crops
- iv. Improved protection from insect/pest and disease
- v. Increased tolerance to heat, drought and other environmental stressors
- vi. Healthier and more productive farmers
- vii. Increase in farmers' income
- viii. Reduction in communal clashes
- ix. Improved social relationship between farmers and their spouses
- x. Increased farmers empowerment leading to increase in their socio-status, education of their family members and overall contribution to the economy
- xi. Enhanced crops that are adaptable to critical environmental condition

xii. Making unproductive soil available for productive agricultural uses

F. Consumers

- i. Assurance of safe, nutritious and more affordable food and environment leading to healthier society, increased disposable income and happier people
- ii. Reduction in the depletion of natural resources resulting in reduced communal clashes
- iii. Increased nutritional food value by provision of biofortified crops
- iv. Enhanced the capacity of consumers to make informed choo

G. Environment

- i. Ensures biodiversity conservation and sustainable use of biological resources
- ii. Reduction in greenhouse gases emission from agricultural practices thereby mitigating the effects of global warming and climate change
- iii. Reduction in agricultural activities' negative impact on the land
- iv. Conservation of soil fertility, natural resources and energy
- v. Minimization in the use of toxic herbicides and fertilizers
- vi. Reduction in the impact of climate change

H. Foreign and local investors

i. Investors and other stakeholders now have confidence in the sector thus leading to increased foreign and local investments in the sector as well as increased foreign exchange. This is evident in the ever-increasing number of investors seeking certification, authorization and permits to practice, import and or use the products of modern biotechnology.

I Socio-economic Status

The fall out of these activities are employment generation/job creation, availability of safe raw materials for the food and feed industries, increased productivity and income for farmers, and overall socio-economic improvement of Nigerians.

J Recognition of NBMA's Professionalism

i. Nigeria Customs Service presented an Award to NBMA during its International Customs Day as a mark of outstanding achievement in the discharge of its mandate





Figure 18 & 19: NBMA receives world customs merit award & the Federal Minister Of Environment commending NBMA over award

ii. The FMEny also commended the DG/CEO for excellent negotiations on behalf of Africa during COP-MOP meetings

H. The Agency's Legacy thus Far

- Nigeria is benefiting from safe modern biotechnology under a legal, technical and administrative framework for economic growth, improved agriculture, job and wealth creation, industrial growth and sustainable environment as operators now have confidence in the sector;
- Potential risks to human health from modern biotechnology practice and the use of GMOs are at their barest minimum;
- Dumping of unapproved GMOs into Nigeria is now at its barest minimum,
- Avenue is being provided to ensure safety in the application of modern biotechnology and to harness its potentials;
- Negative socio-economic consequences of GMOs are being guarded against;

- Confidence is being built in the practice of modern biotechnology, the use and handling of GMOs and GM products;
- Nigeria's commitment to the principles of international Agreements and Treaties to Convention on Biological Diversity (CBD) and Cartagena Protocol on Biosafety (CPB) is reaffirmed;
- Proper regulation for imported GM products, so that Nigeria will not be a dumping ground for GMOs;
- Other African Countries look up to Nigeria for leadership in Biosafety
- Annual National Biosafety and Biosecurity Conferences instituted
- National Policies and Guidelines on Biosafety and Biosecurity developed
- Well-trained staff of the NBMA on issues of Biosafety and Biosecurity in place
- Well-articulated biosafety communication strategy in place

5.0 SUMMARY OF LITIGATION, MEDIA, AND/OR PARLIAMENTARY ISSUES

5.1 Case Between Health of Mother Earth Foundation (HOMEF) & 16 Others Vs NBMA Anor.

On the 13th of September 2017, the after mentioned REGISTERED TRUSTESS OF HEALTH OF MOTHER EARTH FOUNDATION (HOMEF) & 16 other NGOs filed Suit No: FHC/ABJ/CS/846/2017 at the Federal High Court Division against the Agency, Monsanto, 2 Federal Ministries, 2 Federal Agencies and the Attorney-General of the Federation; challenging the grant of a Biosafety Permits to Monsanto by the Agency, which, according to them, was issued on a public holiday. They came by way of originating summons asking the court to interpret a particular section of a statute - whether a Permit issued on a public holiday followed due process and does not amount to administrative rascality.

On the surface of their pleadings, they asked the court for the following reliefs:

- An order of the honorable court setting aside the Permit granted to Monsanto for fundamental breach.
- Revocation of the NBMA Act 2015.

In response to the plaintiffs originating summons and affidavit, the Defendants filed a preliminary objection on grounds that the matter is statute barred having been filed out of the stipulated 3 months in line with Section 2 of the Public Protection Act (POPA).

NBMA and 6 other co-defendants also filed a counter-affidavit supported with written addresses of all the defendants.

The matter was decided based on the preliminary objections filed by NBMA and 6 other Defendants. The preliminary objection was upheld and the matter was struck out accordingly.

Been dissatisfied with the ruling of the court, the plaintiffs in 2018, (this time around as Applicants) went to the same court of concurrent jurisdiction with similar facts and

subject as above but different mode of action "Enforcement of Fundamental Human Rights".

The matter was considered and judgement was entered in favor of NBMA by Justice D. U. Okoraofor of the Federal High court 6, Abuja on 20th July, 2022.

5.2 Radio Propaganda

In 2019, the Human Rights Radio Station in its popular Brekete Family programme consistently targeted and laid false and inciting comments against the National Biosafety Management Agency (NBMA). These serious negative comments were all targeted at running down the office and putting the Agency in a bad light before Nigerians. The video trended on their YouTube channel for a long time. The posture of the Radio Station against the NBMA was biased and misinforming.

Consequently, the NBMA wrote to the Nigeria Broadcasting Commission (NBC), Department of State Service (DSS) and the Inspector General of Police to caution the station and the presenter of the programme, Ahmed Isah, to stop misinforming Nigerians, creating fear in the public and to avoid tarnishing government's efforts towards ensuring that products of modern biotechnology are safe for humans and the environment. Thereafter, the media propaganda was stopped.

5.3 Social Media Propaganda

There were also social media propaganda smearing the Agency with the toga of corruption without substantiation, all in attempt to achieve malicious aims.

5.4 Call for the amendment of the NBMA Act

A Bill was brought before the Senate in 2022 without the knowledge of NBMA for an Act to amend some provisions of NBMA Act 2015 as amended in 2019. The proponent of the proposed 2022 amendment to the National Biosafety Management Agency Act, 2015 claimed among others that there is deficiency in the area of conservation of biodiversity, protection of human health and the precautionary principal approach among others. After proper analysis of the existing NBMA Act by NBMA Staff, relevant MDAs and other stakeholders, it was found that the claim of deficiency raised was untrue as all the issues raised are contained in the Act and therefore the proposed amendment was considered not necessary. After series of public hearings and enlightenment programmes, the issue was laid to rest.

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