

FEDERAL REPUBLIC OF NIGERIA

INFORMATION MANUAL

2018

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INTRODUCTION

The National Biosafety Management Agency (NBMA) was established by the National Biosafety Management Agency Act 2015, to provide a regulatory framework to adequately safe guard human health and the environment from potential adverse effects, while harnessing the potentials of modern biotechnology and its derivatives, for the benefit of Nigeria. The Act came into force on the 18th of April 2015 and subsequent appointment of first Director General and Chief Executive Officer, in the person of Mr. Rufus Ebegba to commence the Agency.

The issues of Biosafety were under a Special Biosafety Unit in the Federal Ministry of Environment to address the issues of Biosafety nationally. From 1998 to 2007 M.P.O Dore headed the Special Biosafety Unit. On the retirement of Mr. Dore in September, 2007, Mr. R.A.Usman took over the headship of the Special Biosafety Unit. In 2014 November 6th Mr. Rufus Ebegba took over headship of the Unit on the retirement of Mr. Usman. The Unit transformed into the National Biosafety Management Agency on the actualization of the National Biosafety Management Agency Act 2015 which gave legal basis for the creation of the National Biosafety Management Agency. Other foundation staff of the Agency consist of the former staff of the Special Biosafety Unit.

The Agency is currently domiciled at the National Parks Service, Airport Road, after City Gate, Abuja,

BACKGROUND

There are myriads of critical global changes which also affect Nigeria. Addressing these challenges requires adoption of out of the box workable measures and safe technologies which include modern biotechnology which Nigeria has adopted. Technologies that would foster green economy, address the factors that contribute to climate change and mitigate the impacts of climate change are of national priority to enhance the wellbeing of citizens. There is also no doubt that advancement in any technology also goes with some potential adverse impacts. Modern biotechnology is not an exception in this regard. It is in this context that Biosafety has become a means of addressing potential adverse impacts of modern technology and genetically modified organisms (GMOs) on the conservation and sustainable use of biodiversity taking into account risks to human health.

In 1992 during the Earth Summit the Convention on Biological Diversity (CBD) was adopted and Nigeria signed it in 1992 and ratified it in 1994. The CBD mandated Parties to negotiate and develop a Protocol on Biosafety. Subsequently the Cartagena Protocol on Biosafety was developed, adopted in 2000 and came into force on the 11th of September 2003. Nigeria signed and ratified the Protocol in 2000 and 2003 respectively. The objective of the Protocol is to

contribute to ensuring an adequate level of protection in the field of *safe transfer, handling and use of Living Modified Organisms (LMO) resulting from modern biotechnology* that may have adverse impact on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on trans-boundary movements of LMOs. The national Biosafety evolution started with 1st National Biosafety Guidelines – 1994 under the Federal Ministry of Agriculture, and subsequently a 2nd National Biosafety Guidelines-2001, under the Federal Ministry of Environment, post the Cartagena Protocol on Biosafety.

The Conference of Parties to the Convention on Biological Diversity, serving as Meeting of Parties (COP-MOP) to the Cartagena Protocol on Biosafety, in 2010, adopted a new protocol known as the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress, which Nigeria signed in 2012. Objective of the supplementary protocol is to contribute to the conservation of and sustainable use of biological diversity, by providing international rules and procedures in the field of liability and redress relating to living modified organisms. In compliance to international requirement, a Biosafety Bill was development and subjected to various stakeholders' review, to address the concerns associated with modern biotechnology and to domesticate both the Cartagena Protocol on Biosafety and the Nagoya-Kuala Lumpur Protocol on Liability and Redress. The Bill, which was passed by the 6th Parliament on 1st June 2011, became time barred and was re-presented to the 7th National Assembly, passed in 2015 and was signed on the 18th of April 2015.

MANDATE

The National Biosafety Management Agency has the mandate to manage Biosafety matters in Nigeria. It is therefore charged with the responsibility of providing regulatory framework, and institutional and administrative mechanism for safety measures in the application of modern biotechnology in Nigeria, with a view to preventing any adverse effects on human health, animals, plants and environment.

MISSION

The Mission of the National Biosafety Management Agency (NBMA) is to promote the basic tenets of biosafety as enunciated in the Cartagena Protocol on Biosafety and enforce Nigeria National Biosafety Management Agency Act 2015 to ensure the safe application and use of products of modern biotechnology.

VISION

The Vision of the National Biosafety Management Agency (NBMA) is to ensure that the practice, processes and procedures of Modern Biotechnology is 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.

OBJECTIVE OF THE AGENCY

The main objective of the NBMA is to ensure adequate level of protection in the field of safe transfer, handling and use of genetically modified organisms resulting from modern biotechnology that may have adverse impacts on conservation and sustainable use of Biodiversity taking into account risks to human health.

FUNCTIONS OF THE NATIONAL BIOSAFETY MANAGEMENT AGENCY

Functions of the NBMA include, to:

- Develop measures, requirements and criteria for risk assessment, peer review and decision making;
- Develop risk management plan and strategy for protecting human health, biological diversity and the environment from potential risks associated with genetically modified organisms (GMO) and all activities of modern biotechnology;
- Accept and verify applications in respect of genetically modified organisms and keep records of all approvals and unapproved applications;
- Carry out laboratory analysis of randomly collected samples of crops, products or materials, from across the country, for the purposes of determining their genetic composition to ensure compliance with the Act;
- Receive biosafety applications and grant permits,
- Carry out risk assessment and risk management of genetically modified organisms on the environment and human health,
- Carry out actions necessary to ensure compliance with the legal obligations set out in the Biosafety Act, including, but not limited to, the inspection of facilities, research activities with genetically modified organisms covered by this Act, collection and analysis of samples of materials covered by the Act, monitoring of human health and the environment to ensure safety of genetically modified organisms regulated by the Act;
- Take inventory and maintain database of laboratories with physical and human capacities to conduct research in modern biotechnology;
- Monitor the activities of institutional committees and Biosafety officers;
- Carry out capacity building activities;
- Implement the provisions of the Conventions and the Protocols on matters relating to genetically modified organisms;
- Render reports to the secretariat of the Convention on the implementation of the Convention and Protocol on matters relating to the use of genetically modified organisms;
- Liaise with the Secretariat of the Convention and the Biosafety Clearing House with respect to the administrative functions required under the Protocol;

- Propose, for the approval of the Board, the overall policy guidance on issues of Biosafety in Nigeria;
- Liaises with: UN, AU and ECOWAS on Biosafety matters
- Partner with other relevant local and international agencies for the speedy realization of the Agency's mandate; and
- Perform other duties as may be necessary for the full discharge of its functions under this Act

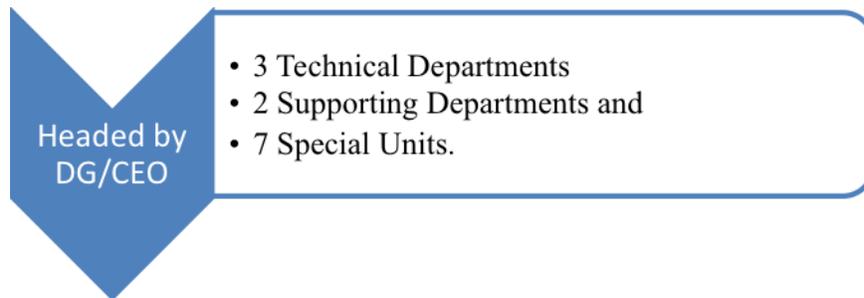
BENEFIT OF THE AGENCY TO THE NATION

- i. safe adoption and benefits from modern biotechnology under a legal framework for economic growth, improved agriculture, job and wealth creation, industry growth and sustainable environment,
- ii. minimization of risks to human health in the use of safe GMOs.
- iii. Confirmation and harnessing the potentials of safe modern biotechnology,
- iv. protection against any adverse effect of genetically modified organisms (GMOs) on biological Diversity and the environment.
- v. Decisions that would guard against any adverse socio-economic consequences in the use of GMOs.
- vi. The reaffirming of Nigeria's commitment to the principles of International agreements, treaties (CBD and in particular the Cartagena Protocol on Biosafety (CPB)).
- vii. The determination in advance when hazards to human health and natural systems will result if any particular GMO is released into the environment. amongst others.
- viii. proper regulation of imported GM products,
- ix. Provision of an enabling environment for indigenous and foreign scientists to practice modern biotechnology safely under a robust legal framework;
- x. Assurance of adequately regulated and safe use of modern biotechnology for:
 - a. Improvement and increased productivity in the agricultural sector that would lead to improved socioeconomic status of Nigerian farmers and enhanced national economic prosperity;
 - b. Foreign investments and earnings from safe modern biotechnology sector;
 - c. Environmental sustainability;
 - d. Jobs/wealth creation arising from various modern biotechnology activities;
 - e. Availability of raw materials for industrial growth, particularly in the Nigerian textile sector;
 - f. Revenue generation and foreign earnings for Nigeria,

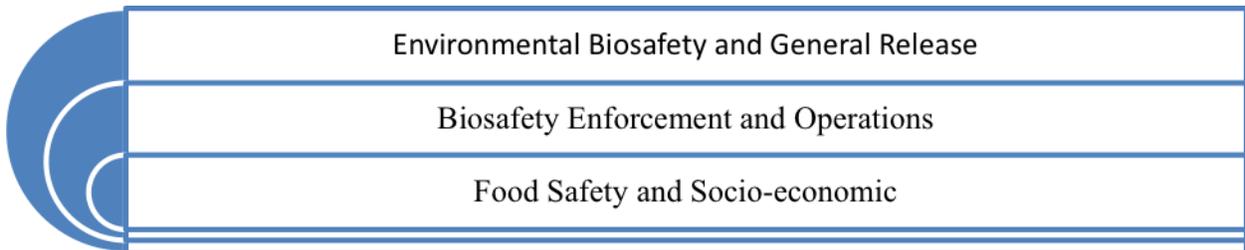
- g. Development of safe plants/organisms that can reduce the impact of climate change and serve in pollution remediation;
- h. Improvement of the medical sector using various plants that abound in the country.

STRUCTURE

The Agency is headed by a Director General/ Chief Executive Officer, has three technical departments, two supporting departments and seven special Units.



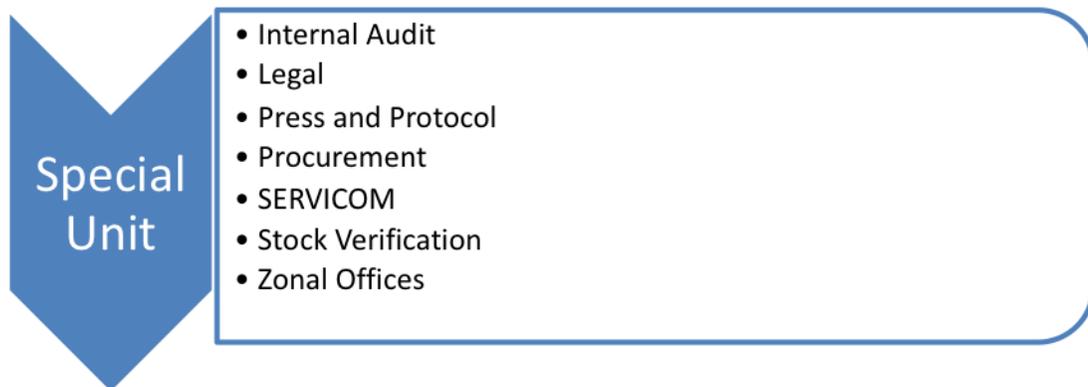
Technical Departments of the Agency



Supporting Departments:



Special Units



FUNCTIONS OF THE DEPARTMENTS

1. Department of Environmental Biosafety and Commercial Release:

- a) Commercial/General release;
- b) Biosafety Risk Assessment and Management of Commercial/General release;
- c) Receipt and processing of application of Genetically Modified Organisms for Commercial and Open release;
- d) Records of all approvals and unapproved applications for commercial and open releases;
- e) General Environmental Safety;
- f) develop measures, requirements and criteria for risk evaluation, peer review and decision-making;
- g) develop measures and requirements for risk assessment and environmental impact assessment;
- h) develop risk management plan and strategy for protecting biological diversity and the environment from potential risks associated with genetically modified organisms;
- i) Monitoring of the environment to determine the effects of genetically modified organisms regulated by the Biosafety Act;
- j) Liability and Redress;
- k) Carry out such other duties as may be necessary for the full discharge of the functions of the National Biosafety Management Agency under the Act.

The Department has two Divisions

- a. Commercial and Open release Division (Functions: Departmental functions a-d)
- b. Environmental Biosafety Division (Functions: Departmental functions e-k)

2. Department of Containment and Confinement:

Functions:

- a) Modern Biotechnology Research Institutions and companies' accreditation and monitoring for compliance to terms and conditions of accreditation;
- b) Monitor the activities of institutional committees and biosafety officers;
- c) Receipt and processing of Containment and Biosafety Facilities Certification Applications;
- d) Biosafety Risk Assessment and Management in containment;
- e) Take samples and carry out laboratory analysis of crops, products or materials for purposes of determining if they contain genetically modified organisms and ensures compliance with the Biosafety Act;
- f) Carry out and maintain inventory of laboratories with physical and human capacities to conduct research in modern biotechnology and establish guidelines to conduct research.
- g) Receipt and processing of the Confined Field Trial applications;
- h) Biosafety Risk Assessment and Management in confinement;
- i) Carry out such other duties as may be necessary for the full discharge of the functions of the National Biosafety Management Agency under the Act.
- j) Biosafety GMOs detection and analysis Lab.

Divisions and their Functions:

- i) Containment Facilities Division (Functions: Departmental functions a-f)
- ii) Confinement Activities Division (Functions: Departmental functions g-J)

3. Department of Biosafety Enforcement and Operations:

Functions:

- (a) Unintentional Release of GMOs;
- (b) Tracking of GMOs;
- (c) Emergency issues;
- (d) General Enforcement;
- (e) Carry out actions necessary to ensure compliance with the legal obligations set forth in the Biosafety Act, including but not limited to the inspection of facilities, conducting activities with genetically modified organisms covered by the Biosafety Act, the collection and analysis of samples of materials covered by the Act;
- (f) Carry out such other duties as may be necessary for the full discharge of the functions of the National Biosafety Management Agency under the Act;

Divisions and their Functions:

- i) Biosafety Operations Division (Functions: Departmental functions a-c)
- ii) Biosafety Enforcement Division (Functions: Departmental functions d-f)

4. Department of Socio-Economic and Food Safety:

Functions:

- (a) Socio-Economic, ethical Considerations;
- (b) Assessment of socio-economic impacts;
- (c) Civil matters;
- (d) Develop risk management plan and strategy for protecting human health from potential risks associated with genetically modified organisms;
- (e) Monitoring of human health to determine the effects of genetically modified organisms regulated by the Biosafety Act
- (f) Relates with NAFDAC;
- (g) Allergenicity, Toxicity;
- (h) GM food safety;
- (i) Establish safety guidelines for genetically modified foods, feeds and for processing.

Divisions and their Functions:

- i) Socio-Economic Division: (Functions: Departmental functions a-c)
- ii) Biosafety Food safety Division:(Functions: Departmental functions d-i)

5. Department of Administration and Finance:

Functions

- a) Compiling and updating of the Agency's nominal rolls;
- b) Processing of promotion matters as they affect staff;
- c) Handling the promotion of both junior and senior officers;
- d) Processing, upgrading/conversion and advancement of officers who acquired relevant additional qualifications to the appropriate posts;
- e) Handling disciplinary matters as they affect erring staff;
- f) Handling the constitution of the membership of both the Junior and Senior Staff Committees;
- g) Documenting newly posted staff into the Agency;
- h) Maintaining staff records;
- i) Processing regularization of appointment of staff;

- j) Deploying staff within the Agency;
- k) Recruiting junior officers;
- l) Issuing circulars/office notices/instructions as may be directed;
- m) Handling appeals and petitions by aggrieved staff;
- n) Preparing yearly Manpower Budget for the Agency;
- o) Identifying staff training needs of the various departments;
- p) Preparing annual training schedules for consideration;
- q) Compiling staff list for in-service training at the Federal Training Centres (FTCs) and other training institutions;
- r) Processing and obtaining approvals for in-service training;
- s) Handling transport matters;
- t) Processing and issuing of staff ID cards;
- u) Processing all leave matters for staff;
- v) Allocating office accommodation;
- w) Processing pension/gratuity entitlement of staff;
- x) Coordinating staff unions and cooperative society matters;
- y) In charge of all sporting activities;
- z) Office maintenance;
- aa) Processing staff allowances, e.g., first 28 days in lieu of hotel accommodation, transfer allowances, etc;
- bb) Stores administration;
- cc) Advising and guiding the management of the Agency on financial matters;
- dd) Maintaining the Agency's Accounts with the Central Bank of Nigeria and Commercial Banks;
- ee) Collection of revenues on behalf of the Federal Government and ensuring same is remitted to the appropriate authorities (i.e the sub-treasurer of the Federation and the Federal Inland Revenue Service);
- ff) Rendering timely statement of transcripts, Bank Reconciliation and other financial statements to the office of the Accountant-General of the Federation;
- gg) Preparation, implementation and monitoring of Budget;
- hh) Liaising with the Federal Ministry of Finance and Office of the Accountant-General of the Federation and the National Assembly on matters relating to the Agency's budget and finance.

Divisions and Their Functions:

- i. Administration - Depts. functions a-aa
- ii. Account - Depts. functions bb-gg

6. Planning, Research and Statistics Department

Functions:

- a) Propose for approval the overall policy guidance on issues of biosafety in Nigeria;

- b) Board matters;
- c) Research and Planning;
- d) Public awareness and enlightenment programs on Biosafety;

- e) Serves as the Secretariat of the National Biosafety Committee;
- f) Maintains a database on releases of GMOs in the country;
- g) Carry out capacity building activities;
- h) Biosafety Treaties, Bi-lateral/Multilateral land Conventions: (Matters on the Convention on Biological Diversity Cartagena Protocol on Biosafety, Supplementary Protocol on Biosafety, the biosafety clearing house, African Union on Biosafety and ECOWAS Biosafety);
- i) Liaise with relevant stakeholders i.e. civil societies on Biosafety matters.
- j) Serves as the Secretariat of the National Biosafety Committee
- k) Liaise with the Secretariat of the Convention and the biosafety clearing house with respect to the administrative functions required under the Protocol;
- l) Maintains a database on releases of GMOs in the country;
- m) Maintain the BCH website and Biosafety Data Base;
- n) Carry out such other duties as may be necessary for the full discharge of the functions of the National Biosafety Management Agency under the Act.

Divisions and Their Functions:

- i) Policy and Planning Division (Functions: Departmental functions a-g;
- ii) Bilateral/Multilateral (Functions: Departmental functions h-n

WHO AND WHAT NBMA REGULATES

1. Who the NBMA Regulates:

The NBMA is mandated to regulate all modern biotechnology practitioners and users of its products as well as service providers. By this definition, the organizations under the regulatory ambit of the Agency cut across multiple sectors of the Nigerian economy. These organizations include:

- Modern Biotechnology Research Institutes,
- Modern Biotechnology Laboratories,
- Modern Biotechnology Companies,
- GM seed/ products companies,
- GMOs Processing/manufacturing companies,
- GMOs stores/facilities,
- Packaging and transport companies, and

- Containment Facilities.

2. What the NBMA Regulates:

The following processes, in so far as they involve the practice of modern biotechnology or the use of its products (such as GMOs), are also under the regulatory ambit of the NBMA. These include:

- GMO/LMO Containment Activities,
- On-Farm demonstrations involving LMOs,
- General Release/Commercialization activities,
- Confined Field Trials (CFT) of LMOs,
- Multi Location Trials (MLT) of GMOs,
- Transboundary movements of GMOs (import, export and transit),
- Unintentional and illegal transboundary movements of GMOs,
- Notification procedures involving GMOs, and
- Decision-making procedures pertaining to the import, export, transit, confined use or commercialization of GMOs.

PERSONNEL

Presently, NBMA has staff strength of over 200 staff of which Twenty were core staff of the Biosafety Unit, some drawn from various departments of the Ministry and other Ministries, Departments and Agencies. Bulk of the staff are newly recruited.

ACHIEVEMENTS

The National Biosafety Management Agency as a former unit and currently has achieved the following:

- Accreditation and certification of facilities of the following Institutes for modern biotechnology activities:**
 - National Root Crops Research Institute, (NRCRI) Umudike;
 - Institute for Agricultural Research, (IAR) Zaria;
 - Federal University of Technology, (FUTA) Akure;
 - National Biotechnology Development Agency (NABDA), Abuja;
 - National Cereal Research Institute (NCRI), Badeggi.
- Approved Confined Field Trials:**

- a. Bio-fortified cassava enhanced with pro-vitamin A, (concluded) – at National Root Crops Research Institute, Umudike
- b. Bio-fortified cassava enhanced with Iron, (concluded) – at National Root Crops Research Institute, Umudike
- c. Cowpea modified for resistance against *Maruca* insect pest currently at multi-locational level- at IAR, (ongoing)
- d. African Biofortified Sorghum: bioavailability of iron, zinc, protein and pro-Vitamin A (on going)- at IAR
- e. GM rice modified for Nitrogen use efficiency, water use efficiency and salt tolerance (ongoing)-at National Cereals Research Institute, Badeggi
- f. Cassava resistant to cassava mosaic virus and brown streak virus disease (ongoing)) - at National Root Crops Research Institute, Umudike

iii. **Operational/Regulatory Instruments:**

The Agency currently has the following biosafety regulatory instruments in place as part of its strength for effective biosafety management in Nigeria:

- National Biosafety Management Agency Act,
- Biosafety Policy;
- Biosafety Guidelines;
- Nigeria Biosafety Application Administration Guidelines
- Biosafety application forms;
- Biosafety Containment Facilities Guidelines;
- Accreditation of Institute application form;
- certification of Biosafety containment Facility form,
- Confined Field Trial Monitoring and Inspection Manual,
- GMOs import/shipment form,
- National Biosafety Risk Analysis Framework,
- Decision document.
- National Biosafety Communication strategy
- National Biosafety Emergency Response strategy
- National Laboratory for GMO detection and analysis
- Cessation Order,
- Revocation Order,

- Biosafety website: www.nbma.gov.ng,
- The following Draft Biosafety regulations developed
 - i. GMOs import, Export and transit,
 - ii. GMOs Packaging, identification and transport,
 - iii. GMOs Commercial release,
 - iv. Biosafety Liability and Redress,
 - v. GMOs Contained Use and Confined Field trial
 - vi. Capacity building of biosafety staff,

ON GOING ACTIVITIES:

The following are some of the ongoing or activities at advanced stages:

- i. Surveying, tracking and profiling of GMOs in Nigeria,
- ii. Enlightenment of the public on Biosafety matters,
- iii. Consultation with sister Regulatory Agencies for partnership,
- iv. Development and reviewing of National Biosafety Regulations and Guidelines,
- v. Capacity building for staff of the Agency,
- vi. Receipt and reviewing of biosafety applications,
- vii. Program to guide against faking of GMOs,
- viii. Updating of the Agency's website,
- ix. Seeking relevant approvals from Office of Accountant General of the Federation, Head of Civil Service of the Federal, Salaries and Wages Commission and Budget

CHALLENGES:

- **Poor Funding:** At inception, the Agency was not given any take-off grant as it is customary done when new MDAs are created. Hence, the Agency has had to contend with poor and inadequate funding to put the Agency in a proper standing.
- **Irregular Political Support:** While we give kudos to the present administration for supporting the Agency, the Agency needs a stable political support to drive the achievement of certain goals and objectives.
- **Inadequate Office Accommodation:** The National Biosafety Management Agency is temporarily being accommodated by the National Packs Service. However, the

space allocated is grossly inadequate to accommodate its over 200 members of staff, five departments and seven units.

- **Insufficient Office furniture, equipment, ICT facilities and back-up Power Supply:** There is inadequate office furniture and facilities such as tables, chairs, computer systems, UPS, extension wires, etc.
- **Inadequate internet facility:** Internet is very important for the workflow and efficiency of any modern organization and as such the Agency needs to be equipped with Internet as the mandate of the Agency involves e-research, e-communication with all biosafety stakeholders including regulatory and developmental partners, and maintenance of database on the use of GMOs in Nigeria as well as the BCH website. For effective handling of these responsibilities, constant internet service is needed.
- **Inadequate Operational uniforms for various sections of the Agency:** Uniforms such as enforcement uniforms and laboratory coats are required in the discharge of the duties of the Agency.
- **Lack of Operational Vehicles for survey**

WAY FORWARD.

- i. Adequate office accommodation,
- ii. Massive education and enlightenment of the public on the need for the safe use of modern biotechnology for national economic growth,
- iii. Adequate funding,
- iv. Mainstreaming of biosafety into national economic programs,
- v. Operationalization of the National Biosafety Laboratory for GMOs detection and analysis,
- vi. Surveying, tracking and profiling of GMOs in Nigeria.
- vii. Approval of dedicated account for the Agency by the Office of the Accountant General of the Federation to address the challenge in the wake of Treasury Single Account Policy,

COMMUNICATION CHANNELS

More information about the Agency can be obtained through the underlisted electronic communication channels among others

- ✓ National Biosafety Management Agency Website: www.nbma.gov.ng
- ✓ Biosafety Clearing house: www.bch.cbd.int (Information exchange mechanism)
- ✓ Social media: facebook: www.facebook.com/biosafetynigeria
- ✓ Twitter: @BiosafetyNig

- ✓ e-mail: biosafetyng@gmail.com, nbma@nbma.gov.ng
- ✓ Television/Radio: (Press briefing/reports and interviews)
- ✓ Telephone +2348180805451

Annex 1

**NATIONAL BIOSAFETY MANAGEMENT AGENCY (NBMA)
ORGANOGRAM**

