National Biosafety Management Agency

NBMA

FEDERAL REPUBLIC OF NIGERIA

INFORMATION MANUAL

2016

INTRODUCTION

1.1 Background

There are myriads of critical global challenges, which also affect Nigeria. Addressing these challenges requires adoption of out of the box workable measures and safe technologies. Technologies that would foster green economy by reducing and eliminating the factors that contribute to climate change and mitigate the impacts of climate change as well as provide food security for the enhancement of the well-being of citizens are of national priority. Modern biotechnology is globally considered to be among such technologies. Obviously advancements in technology are usually characterized by some potential adverse impacts and 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.

Modern biotechnology is the use of modern scientific techniques including genetic engineering to improve or modify plants, animals and microorganisms.

Biosafety is the adoption of safety measures in minimizing or eliminating potential harmful effects of the practice of modern biotechnology on the environment, biodiversity and human health using policies, laws and guidelines as well as regulations. In order words, Biosafety means safety measures that have been put in place to reduce and eliminate the potential risks resulting from modern biotechnology activities and its products to minimize or eliminate the possible harm/effects to the environment, biodiversity and human health by the use of polices and regulations.

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 negotiated, 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 (LMOs) resulting from modern biotechnology* that may have adverse impact on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focusing on trans-boundary movements of LMOs. Nigeria national Biosafety evolution started with 1st National Biosafety Guidelines developed in 1994 under the then Federal Ministry of Agriculture and subsequently a 2nd National Biosafety Guidelines in 2001, under the Federal Ministry of Environment post the Cartagena Protocol on Biosafety of 2000.

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. The 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 with international requirement, a Biosafety Bill was developed 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 into law.

1.2 Historical perspective

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 with the appointment of its first Director General and Chief Executive Officer, in the person of Dr. Rufus Ebegba to commence full operation of the Agency.

Prior to the Act, national issues of Biosafety were handled by a Special Biosafety Unit in the Federal Ministry of Environment, which was headed by M.P.O. Dore from 1998 to 2007 and Mr. R. A. Usman from 2007 – 2014. In November 2014, Dr. Rufus Ebegba took over the leadership of the Unit on retirement of Mr. Usman. The Unit metamorphosed into the National Biosafety Management Agency on the enactment 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 consists of the former staff of the Special Biosafety Unit.

Presently, the Agency is located at **National Biosafety Management Agency, Umaru Musa Yar'Adua Express Way, (Airport Road), Near City Gate, (National Park Service), Abuja, FCT**. **E-mail Address: nbma@nbma.gov.ng, Telephone:+2348180805451, Website: www.nbma.gov.ng**

2 MANDATE, MISSION, VISION, CORE VALUES, OBJECTIVE, FUNCTIONS AND BENEFITS OF THE NATIONAL BIOSAFETY MANGEMENT AGENCY (NBMA)

2.1 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 mechanisms 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.

2.2 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 regulations and guidelines to ensure safe application and use of products of modern biotechnology.

2.3 Vision

A holistic, responsive and vibrant national biosafety system that offers the best of its potentials in the regulation of modern biotechnology activities in Nigeria, with a view to preventing any adverse impact on the conservation and sustainable of biodiversity taking into account risk to human health.

2.4 Core Values of the Agency

The Core Values are:

- Safety to the environment and human health;
- Respect for human dignity;
- Transparency;
- Integrity
- Professionalism

2.5 Objectives of the Agency shall be:

(a) Establish and strengthen the institutional arrangement on Biosafety matters in Nigeria;

(b) Safeguard human health, biodiversity and the environment from any potential, adverse effect of genetically modified organism including food safety;

(c) Ensure safety in the use of modern biotechnology and provide holistic approach to the regulation of genetically modified organisms;

(d) Provide measures for the case by case assessment of genetically modified organisms and management of risk in order to ensure safety in the use of genetically modified organisms to human health and the environment;

(e) Provide measures for effective public participation, public awareness and access to information in the use and application of modern biotechnology and genetically modified organisms, and

(f) Ensure that the use of the genetically modified organisms does not have adverse impact on socio-economic and cultural interest either at the community or national level.

2.6 Functions

The functions of the NBMA include, to:

i. Develop measures, requirements and criteria for risk assessment, peer review and decision making;

ii. Develop risk management plan and strategy for protecting human health, biological diversity and the environment from potential risks associated with genetically modified organisms (GMOs) and all activities of modern biotechnology;

iii. Receive verify, and review applications for various Biosafety services, granting permits and keeping records of all approvals and unapproved applications;

iv. Carry out laboratory analysis of randomly collected samples of flora and fauna, products or materials, from across the country, for the purposes of determining their genetic composition to ensure compliance with the Act;

v. Carry out environmental and human health risk assessment and risk management of genetically modified organisms;

vi. Carry out actions necessary to ensure compliance with the legal obligations set out in the National Biosafety Management Act (2015), 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;

vii. Take inventory and maintain database of laboratories with physical and human capacities to conduct research in modern biotechnology;

viii. Monitor the activities of Institutional Biosafety Committees and Biosafety officers;

ix. Carry out capacity building activities;

x. Implement the provisions of the Conventions and the Protocols on matters relating to genetically modified organisms;

xi. 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;

xii. Liaise with the Secretariat of the Convention and the Biosafety Clearing House with respect to the administrative functions required under the Protocol;

xiii. Propose, for the approval of the Board, the overall policy guidance on issues of Biosafety in Nigeria;

xiv. Liaises with: United Nations (UN), African Union (AU) and ECOWAS on Biosafety matters;

xv. Partner with other relevant local and international agencies for the speedy realization of the Agency's mandate; and

xvi. Perform other duties as may be necessary for the full discharge of its functions under the Act

2.7 Benefits of the Agency to the Nation

i. Safe adoption of modern biotechnology and utilization of its potential benefits for economic growth, improved agriculture, job and wealth creation, industry growth and sustainable environment under a legal framework;

ii. Minimizing and eliminating risks to human health in the use of GMOs';

iii. Confirmation and harnessing of the potentials of safe modern biotechnology practice;

iv. Protection against any adverse effect of genetically modified organisms (GMOs) on Biological Diversity and the environment;

v. Ensures decisions that would guard against any adverse socio-economic consequences in the use of GMOs;

vi. Reaffirming Nigeria's commitment to the principles of International agreements, treaties (CBD and in particular the Cartagena Protocol on Biosafety (CPB);

vii. Adequate regulation of imported GM products;

viii. Provision of an enabling environment for indigenous and foreign scientists to practice modern biotechnology safely under a robust legal framework;

ix. 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, food security 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, for Nigeria through taxes, permit fees and other charges;

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.

3 STRUCTURE

3.1 OFFICE OF THE DIRECTOR GENERAL/CHIEF EXECUTIVE OFFICER

i. Support staff
ii. Special Units

3.2 Departments of the Agency and their functions:

3.2.1 DEPARTMENT OF ENVIRONMENTAL BIOSAFETY AND COMMERCIAL RELEASE:

Functions:

i. Handles Commercial/General release matters;

ii. Handles Biosafety Risk Assessment and Risk Management of Commercial/General release issues;

iii. Processing of application of Genetically Modified Organisms for Commercial and Open release;

iv. Keep records of all approvals and unapproved applications for commercial and open releases;

v. General Environmental Safety;

vi. Develop measures, requirements and criteria for risk evaluation, peer review and decision-making;

vii. Develop measures and requirements for risk assessment and environmental impact assessment;

viii. Serve as secretariat of relevant review committees

ix. Develop risk management plan and strategy for protecting biological diversity and the environment from potential adverse impacts associated with genetically modified organisms;

x. Monitoring of the environment to determine the effects of genetically modified organisms regulated by the Biosafety Act;

xi. Draft decision documents;

xii. Make recommendation on permits to the DG/CEO for consideration;

xiii. 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) Commercial and Open Release Division (i – v)

ii) Environmental Biosafety Division (vi – xiii)

3.2.2 DEPARTMENT OF BIOSAFETY ENFORCEMENT AND OPERATIONS:

Functions on Matters of:

i. Modern Biotechnology Research Institutions and companies' accreditation and Monitoring for compliance with terms and conditions of accreditation;

ii. Monitor the activities of Institutional Biosafety Committees (IBCs) and Biosafety Officers(BOs);

iii. Processing of Containment and Biosafety Facilities Certification Applications;

iv. Biosafety Risk Assessment and Management in containment facilities and confined field trials;

v. 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;

vi. Carry out and maintain inventory of laboratories with physical and human capacities to conduct research in modern biotechnology and establish guidelines to conduct research.

vii. Processing of the Confined Field Trial applications;

viii. Serves as secretariat of relevant review committees;

ix. Biosafety Risk Assessment and Management in confinement and containment; Draft decision documents;

x. 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.

xi. Biosafety GMOs detection and analysis Lab.

xii. Unintentional Release of GMOs;

xiii. Tracking of GMOs;

xiv. Emergency issues;

xv. General Enforcement;

xvi. 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;

xvii. Relating with law enforcement officers for enforcement;

xviii. 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) Enforcement and Operations Division (i -xviii)

3.2.3 DEPARTMENT OF SOCIO-ECONOMIC AND FOOD SAFETY:

Functions:

i. Socio-Economic, ethical Considerations;

ii. Assessment of socio-economic impacts;

iii. Handles Civil matters;

iv. Develop risk management plan and strategy for protecting human health from potential risks associated with genetically modified organisms;

v. Monitoring of human health to determine the effects of genetically modified organisms regulated by the Biosafety Act

vi. Relates with NAFDAC;

vii. Address issues of Allergenicity, Toxicity;

viii. Address issues of GM food safety;

ix. Liability and Redress matters;

x. Establish safety guidelines for genetically modified foods, feeds and for processing;

xi. Carry out other such duties as may be necessary for the full discharge of the functions of the National Biosafety Management Agency

3.2.4 DEPARTMENT OF ADMINISTRATION AND FINANCE

Functions

i. Compiling and updating of the Agency's nominal rolls;

ii. Processing of promotion matters as they affect staff;

iii. Handling the promotion of both junior and senior officers;

iv. Processing, upgrading/conversion and advancement of officers who acquired relevant additional qualifications to the appropriate posts;

v. Handling disciplinary matters as they affect erring staff;

vi. Handling the constitution of the membership of both the Junior and Senior Staff Committees;

vii. Documenting newly posted staff into the Agency;

viii. Maintaining staff records;

ix. Processing regularization of appointment of staff;

x. Deploying staff within the Agency;

xi. Recruiting junior officers;

xii. Issuing circulars/office notices/instructions as may be directed;

xiii. Handling appeals and petitions by aggrieved staff;

xiv. Preparing yearly Manpower Budget for the Agency;

xv. Identifying staff training needs of the various departments;

xvi. Preparing annual training schedules for consideration;

xvii. Compiling staff list for in-service training at the Federal Training Centres (FTCs) and other training institutions;

xviii. Processing and obtaining approvals for in-service training;

xix. Handling transport matters;

xx. Processing and issuing of staff ID cards;

xxi. Processing all leave matters for staff;

xxii. Allocating office accommodation;

xxiii. Processing pension/gratuity entitlement of staff;

xxiv. Coordinating staff unions and cooperative society matters;

xxv. In charge of all sporting activities;

xxvi. Office maintenance;

xxvii. Processing staff allowances, e.g., first 28 days in lieu of hotel accommodation, transfer allowances, etc;

xxviii. Stores administration;

xxix. In charge of security;

xxx. Advising and guiding the management of the Agency on financial matters;

xxxi. Maintaining the Agency's Accounts with the Central Bank of Nigeria and Commercial Banks;

xxxii. 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);

xxxiii. Rendering timely statement of transcripts, Bank Reconciliation and other financial statements to the office of the Accountant-General of the Federation;

xxxiv. Preparation, implementation and monitoring of Budget;

xxxv. 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. Human Resource (i – xxix)
ii. Finance and Accounts (xxx – xxxiv)

3.2.5 PLANNING, RESEARCH AND STATISTICS DEPARTMENT

Functions:

i. Propose for approval the overall policy guidance on issues of biosafety in Nigeria;

ii. Board matters;

iii. Research and Planning;

iv. Public awareness and enlightenment programs on Biosafety;

v. Serves as the Secretariat of the National Biosafety Committee;

vi. Maintains a database on releases of GMOs in the country;

vii. Carry out capacity building activities;

viii. Biosafety Treaties, Bi-lateral/Multilateral and 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);

ix. Liaise with relevant stakeholders i.e. civil societies on Biosafety matters.

x. Serves as the Secretariat of the National Biosafety Committee

xi. Liaise with the Secretariat of the Convention and the biosafety clearing house with respect to the administrative functions required under the Protocol;

xii. Maintains a database on releases of GMOs in the country;

xiii. Maintains the BCH and National Biosafety Management Agency websites and Biosafety Data Base;

xiv. 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) Planning and Policy Division (I – vii);
ii) Research and Data Base Management Division (viii – xiv)

3.2.6 SPECIAL UNITS:

i. Legal

ii. Internal Audit

iii. Procurement

iv. Press and Protocol

v. Reform/SERVICOM and Anti-Corruption

vi. Stock Verification

vii. Zonal Offices

3.2.7 LEGAL UNIT

The main function of the Legal Unit is to provide legal services to the Agency. The Unit is therefore mandated to represent the Agency in Courts to address legal issues.

3.2.8 INTERNAL AUDIT

The Internal Audit Unit as specified in the Financial Regulations is to provide a complete and continuous audit of the accounts records of revenue and expenditure, plants, allocated stores, and unallocated stores.

Functions

i. Pre-auditing of all payment vouchers. All payment vouchers/payrolls should be subject to 100% pre-payment auditing.
ii. Periodic examination of Accounting Books/Records in all sections of finance and account Division to ensure compliance with financial regulations and treasury circulars;

The Internal Auditor is expected to submit to the Director-General/CEO monthly report which is to be copies to the Accountant-General for the Federation. The key elements of the monthly internal audit report include: -

i. Cash book;
ii. Vote book/liabilities;
iii. Bank reconciliation statement;
iv. Stores
v. Advances
vi. Salaries/IPPIS;
vii. Contracts;
viii. Transcripts; and
ix. Response to audit Query (PAC)

3.2.9 PROCUREMENT UNIT

Functions

I. Coordinating the following procurement activities:

i. Recurrent procurement
ii. Capital procurement
iii. Tenders and Certification
iv. Monitoring of Due Process Compliance
v. Tenders Process and Evaluation
vi. Price Intelligence
vii. Technical/Stand Bid Specification

viii. Technical Audit
ix. Data Base Management
x. Tenders Board and Procurement Planning Committee
xi. Monitoring and Evaluation of Projects

II. Coordination of Store Activities

i. Stock Receipts documentation
ii. Stock issuance

3.2.10. PRESS AND PROTOCOL UNIT:

The major goal of the Press and Protocol Unit is to achieve maximum positive publicity and protocol activities of the Agency.

Functions

i. Formulation and articulation of dynamic and purposeful strategies for effective press coverage and protocol activities of the Agency;

ii. Provision of effective media for the DG/CEO and the entire staff of the Agency;

iii. Writing press releases, press statements, features, articles and distributing same to newspapers, Radio and Television Stations and Website Portal maintained by the Agency;

iv. Organizing media chats for the DG/CEO to update the media on developments in the Agency;

v. Reading of newspapers, newspapers' cuttings, review of newspapers reports and analysis of some topical national issues as they affect the Agency;

vi. Keeping the DG/CEO informed about public opinions and the reactions of the General public and the media to policies, programmes and activities of the Agency;

vii. Use of well captioned action photographs to publicise the activities of the Agency in the print media.

3.2.11 REFORM/SERVICOMAND ANTI-CORRUPTION UNITS

SERVICOM is acronym for Service Compact with all Nigerians and launched in 2004 by the Government of Nigeria to proffer solution to poor service delivery as well as to challenge the Nigerian citizenry or public to learn to demand service from public institution as a matter of right on timely, efficiently, honestly, fairly and transparently basis.

SERVICOM is a tool for strengthening the public service. In order to achieve the purpose of which delivery initiative was adopted, all Ministries, Departments and Agencies were directed to create a SERVICOM Unit to be saddled with responsibilities of driving the initiative on both long and short-term basis. Anti-Corruption programmes and activities of the Agency have been integrated into the Reforms/SERVICOM Unit.

Functions

i. Initiate actions on reform activities of the Agency in line with the Agenda of the government;

ii. Co-coordinating monitoring and evaluating all reform implementation activities of the Agency;

iii. Providing advisory services to change Management programme of the Agency;

iv. Disseminating information in any reform activities Agency;

v. To act as a change driver of the Agency; and

vi. Responsible for driving SERVICOM and Anti-Corruption initiatives to ensure effective and efficient service delivery in the Agency

3.2.12 STOCK VERIFICATION UNIT

In accordance with Financial Regulation 3501, 3503, 3506 and 2507 (c), the Stock Verification Unit is mandated to carry out physical inspection/verification of government Stock by preparing a programme of inspection to cover ALL government stores, Office Equipment/Furniture, Motor Vehicles, Plants and other Moveable assets of government where ever they are at least once a year and submit Report to the permanent Secretary. This entails:

i. Pre-payment of post-payment verification of procurement of Store/moveable Assets, works, series and repairs;

ii. Checking of Payment Vouchers Registers/Invoice control Registers for procurement of Store/moveable Assets, works, repairs and services;

iii. Taking inventories of Office Furniture/Equipment with a view to up-dating the inventory Boards/Records from time to time;

iv. Boarding of unserviceable Stores/Moveable Assets of government, coasting and disposing them off by auctioning or as otherwise recommended;

v. Any other duty assigned by the Director-General/CEO.

3.3.13 ZONAL OFFICES

The Agency in proposing to establish Zonal Offices in the six (6) Geopolitical Zones of Nigeria. The Zonal Offices will assist the Agency to effectively discharge its duties in all parts of the country.

4 ORGANOGRAM

The Organogram of the NBMA is attached as Annex 1

4.1 Personnel

Presently, the NBMA has staff strength of Forty-Four (44). Twenty (20) of the staff members were core staff of the Biosafety Unit while twenty-four (24) were drawn from various Departments of the Ministry of Environment.

5 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:

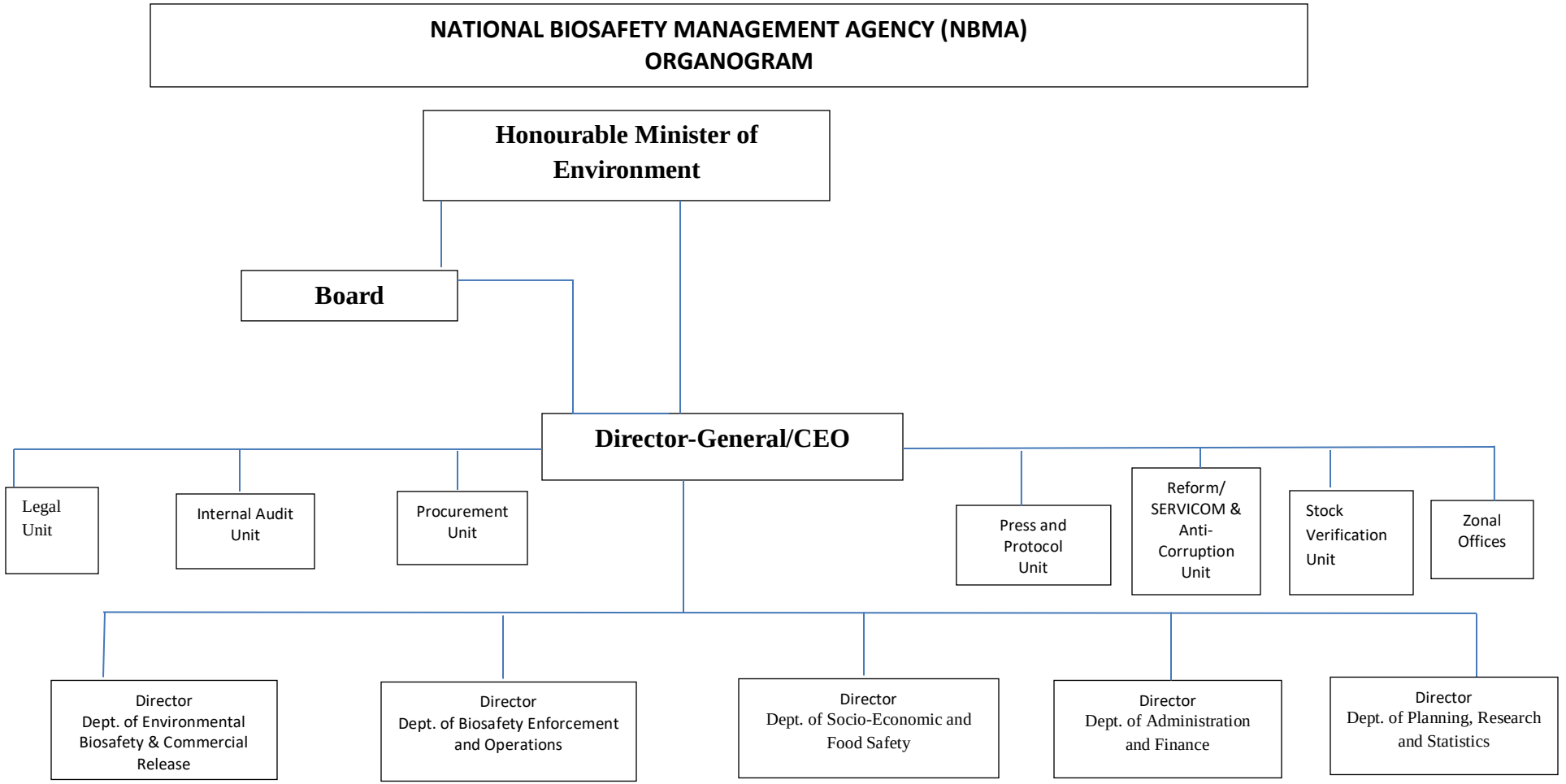
i. National Biosafety Management Agency Act, 2015
ii. Biosafety Policy;
iii. Biosafety Guidelines;
iv. Nigeria Biosafety Application Administration Guidelines
v. Biosafety application forms;
vi. Biosafety Containment Facilities Guidelines;
vii. Accreditation of Institute application form;
viii. Certification of Biosafety Containment Facility form,
ix. Confined Field Trial Monitoring and Inspection Manual,
x. GMOs import/shipment form,
xi. National Biosafety Risk Analysis Framework,
xii. Decision document.
xiii. National Biosafety Communication strategy
xiv. National Biosafety Emergency Response strategy
xv. National Laboratory for GMO detection and analysis
xvi. Cessation Order,
xvii. Revocation Order,

xviii. Biosafety website: www.nbma.gov.ng

xix. Biosafety Regulations:

a. GMOs import, Export and transit,
b. GMOs Packaging, identification and transport,
c. GMOs Commercial release,
d. Biosafety Liability and Redress,
e. GMOs Contained Use and Confined Field trial

ANNEX 1


NATIONAL BIOSAFETY MANAGEMENT AGENCY (NBMA)
ORGANOGRAM
Honourable Minister of Environment
Board
Director-General/CEO
Legal Unit
Internal Audit Unit
Procurement Unit
Press and Protocol Unit
Reform/ SERVICOM & Anti-Corruption Unit
Stock Verification Unit
Zonal Offices
Director Dept. of Environmental Biosafety & Commercial Release
Director Dept. of Biosafety Enforcement and Operations
Director Dept. of Socio-Economic and Food Safety
Director Dept. of Administration and Finance
Director Dept. of Planning, Research and Statistics