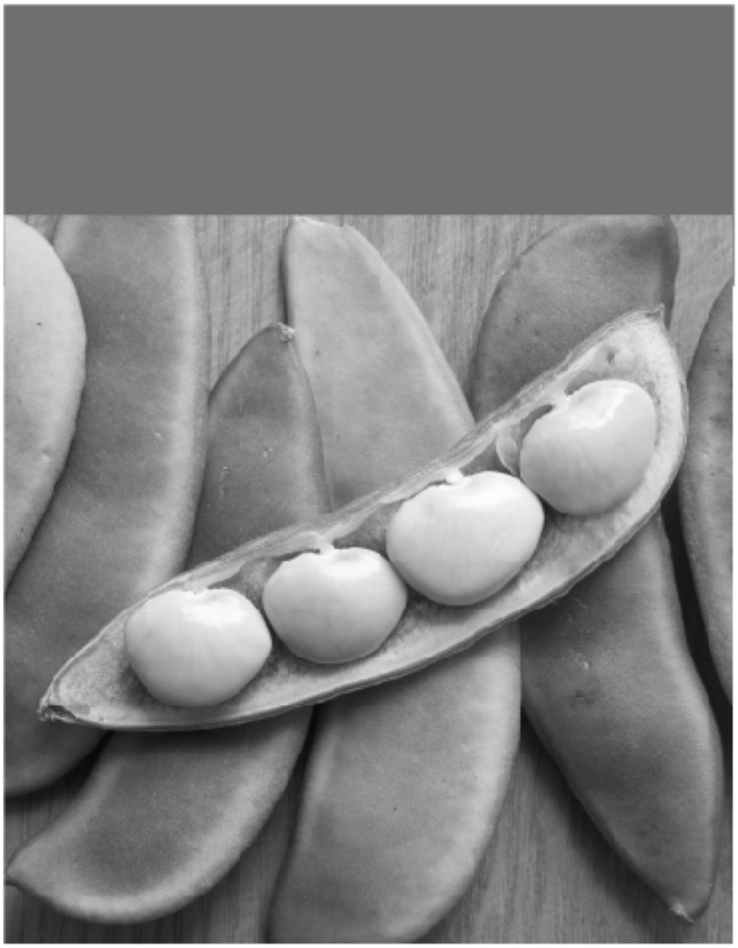
# THE STATE OF BIOSAFETY IN NIGERIA

A Report by Health of Mother Earth Foundation

HOMEF
HEALTH OF MOTHER EARTH FOUNDATION



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# CONTENTS

# LIST OF ABBREVIATIONS /ACRONYMS

AI Artificial Intelligence
AIA Advance Informed Agreement
ARMG Antibiotic Resistant Marker Gene
AU Africa Union
BCH Biosafety Clearing House
BSE Bovine spongiform encephalopathy
BSC Biosafety Cabinet
BSL Biosafety Level
Bt Bacillus thuringiensis
CaMV Cauliflower Mosaic Virus
CBD Convention on Biological Diversity
CBSD Cassava Brown Streak Disease
CPB Cartagena Protocol on Biosafety
CRISPR Clustered Regularly Interspaced Short Palindromic Repeats
DBT Department of Biotechnology
DNA Deoxyribonucleic acid
DSMB Data and Safety Monitoring Board
EA Environmental Audits
EFSA European Food Safety Authority
EIA Environmental Impact Assessment
EPA Environmental Protection Agency
FAO Food and Agriculture Organization
FEC Friable embryogenic callus
FM Frascati Manual
GDP Gross Domestic Product
GE Genetic Engineering
GEI Gene-Environment Interaction
GHS Global Health Security
GM Genetically Modified
GMOs Genetically Modified Organisms
GMT Good Microbiology Techniques
HOMEF Health of Mother Earth Foundation
IBSC Institutional Bio-safety Committees
LMOs Living Modified Organisms
MDAs Ministries, Departments and Agencies
MoEF&CC Ministry of Environment, Forest and Climate Change
NABDA National Biotechnology Development Agency
NAFDAC National Agency for Food and Drug Administration and Control

| | |
|---|---|
| NBMA | National Biosafety Management Agency |
| NESREA | National Environmental Standards and Regulations Enforcement Agency |
| NHREC | National Health Research Ethics Committee |
| NRIC | National Research and Innovation Council |
| NRIF | National Research and Innovation Fund |
| OECD | Organization for Economic Co-operation and Development |
| PCB | Polychlorinated biphenyls |
| SBCC | State Biotechnology Coordination Committees |
| S & T | Science and Technology |
| SOP | Standard Operating of Procedures |
| R & D | Research and Development |
| rDNA | Recombinant Deoxyribonucleic Acid |
| RDAC | Recombinant DNA Advisory Committee |
| RCGM | Review Committee on Genetic Manipulation |
| R&I | Research and Innovation |
| UNDP | United Nations Development Programme |
| VBM | Valuable Biological Materials |


Image: Babawale Obayanju

# EXECUTIVE SUMMARY

The term, Biosafety encompasses the actions, systems and policies that protect humans from exposure to harmful biological agents. Biosafety is an important consideration when individuals may or will handle high risk, highly transmissible and highly lethal biological agents.

This report focuses on GMOs biosafety which entails food/feed and environmental safety. Also, the report touches, in a general sense, the relation of biosafety to containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogen/toxins and their accidental release in laboratory research.
The report analyses the use of GMOs including their official and illegal releases, the implementation of the principles of biosafety, and the level of public awareness on the subject. The biosafety regulatory system in Nigeria is also reviewed, revealing its strengths and weaknesses. The report concludes with factful and necessary recommendations to the Nigerian government and the scientific community to address identified weaknesses and ensure food sovereignty, climate resilience and economic stability.
In today's agricultural sector, there is an increased campaign for the adoption of genetic engineering technology in crop breeding and animal production. This has heightened biosafety concerns in most developing countries including Nigeria as to the safety of the public and the environment. Africa is particularly targeted and Nigeria is seen as a cardinal entry point.

Consumers are deeply concerned about this development particularly because of weaknesses in biosafety practices by administrators, policy makers, researchers, producers and users of GMOs. Strict compliance to biosafety guidelines is still a huge challenge although there have been official releases of GMOs for commercial uses in Nigeria.
The National Biosafety Management Agency (NBMA) established in 2015 is the national biosafety regulatory authority in Nigeria. However, instead of functioning as an unbiased regulatory body, the agency promotes openly, the development and deployment of the technology often times with disregard for the opinion of the public. There have been a frenzy of approvals for introduction of GMOs into Nigeria for commercial placement, food and feed processing or for field trial.

As of November 2020, according to information available on the Biosafety Clearing House, NBMA has issued nineteen permits for introduction of GMOs into the country - eight (8) for field trials, nine (9) for direct use as food and/or feed processing and two (2) for commercial release. GM Cowpea (beans) and GM Cotton were approved for market placement in 2019. After scientific assessment and critical review of applications for permit, objections have been sent to the NBMA by concerned citizens but these objections have continuously disregarded.

Contrary to the assurance by the Agency that there are no GMOs in Nigeria, market shelf survey carried out by HOMEF between 2018 and 2020 have revealed the presence of over 30 different products containing genetically modified ingredients and/or produced with genetic engineering. The question of who is checking the importation of these processed foods with genetically modified ingredients is left unanswered. The result of the survey strengthens the assertion that labelling of GMOs in Nigeria will not protect our people from the impacts of GMOs as many of our people do not read labels and more so, some of the inscriptions are so tiny that they can easily be missed. Generally, labelling is nearly impossible to effect in Nigeria because of our socio-economic system and the manner in which food is sold and consumed.

The NBMA Act 2015 which mandated the setup of the Agency has several fundamental flaws that make it impossible to protect the interests of the public and avert the negative implications of GMOs on our health, economy and environment. The gaps include lack of access to information, no provision for adequate stakeholder engagement or consultation and participation, defective provision for liability and redress, subjective decision-making; and skewed provisions for appeals and reviews. The law is full with use of slack terms such as “may” rather than “shall” therefore bestowing enormous discretionary power on the Agency. These loopholes create room for abuse of administrative powers and make allowance for gross injustice against the people of Nigeria and the environment.

Another major flaw in the NBMA Act is the composition of the board of the Agency. The agency has on its board, major promoters of modern biotechnology including the National Biotechnology Development Agency (NABDA) whose mandate is to promote modern biotechnology and the release of their products into the environment. This gives room for conflict of interest and possible regulatory capture. The Act also made provisions for representation of Industry, Trade and Investment and the Biotechnology Society of Nigeria on the governing board of NBMA whereas farmers (small scale farmers) who are the major food producers in the country are not adequately represented.
In 2019, the scope of the NBMA Act, 2015 was broadened to include applications of genome editing, gene drives and synthetic biology as regulated technologies along with GMOs. The amendment which was received with mixed reactions by many Nigerian civil society groups brought the new tools and technologies under the purview of a dysfunctional regulatory agency. One major challenge is that it paves the way for the possible regulation of genome editing innovations with the same lax framework currently used for GMOs.

It is recommended that the NBMA Act be swiftly reviewed to close the existing gaps. HOMEF has drafted a review of the Act. It will be helpful for the government to take up that review and duly consider the recommendations made.

Although there have been many historical breakthroughs in the area of synthetic biology that represent a shift in biology research from the exploration of life to the creation of organisms with desired phenotypic characteristics, its potential biosafety, biosecurity, and related ethical risks have also emerged in recent years as the technology becomes less

expensive, more mature, and more accessible. In addition to these are the problems of allergies, antibiotic resistance, carcinogens, and pathogenicity or toxicity among human-health–related risks; and changes to or depletion of the environment; competition with native species, horizontal gene transfer, and pathogenicity or toxicity as environmental risks. Currently, the increasing biosecurity risk of synthetic biology is the possibility of bioterrorism via the dual-use synthetic biology technology.

Scientific innovations have a plethora of ethical and moral dilemmas that necessitate ethical action and normative analysis. Most times it is difficult to determine clearly at what point the negatives of innovation begin to overshadow the good that it brings. For this reason, evaluating the relationship between ethics and scientific innovation is imperative.
The proper environment for research is not yet prevalent in Nigeria. It is recommended that more efforts should be made towards increasing and strengthening of the theoretical and practical based training to enhance the quality and quantity of the critical mass of science and technology (S&T) experts needed to promote research and maintain an endogenous science and technology base for the advancement of research and development (R&D) agenda in Nigeria.

The need for strengthened mechanisms and institutional structures to ensure the effective and holistic implementation of biosafety regulatory protocols and management of Nigeria's local bio-resources in all applicable sectors cannot be over emphasized. Policies guiding vulnerability studies, biosafety risk assessment, biosafety risk mitigation measures, biosecurity threat assessment, bio-risk management and determination of risk acceptance and resource rights of the indigenous people should be formulated and implemented uncompromisingly as a way of safeguarding our people and communities for the future.

# 1. BACKGROUND

The issue of biosafety is one of increasing concern and requires continuous review/assessments especially as modern biotechnology advances speedily in various levels and spheres of life. Scientific advancements and innovations have been of great benefits to humankind and hold potential for the future, but they also present diverse risks, which should be critically and proactively examined to ensure that the innovations serve the interests of the people, are safe, sustainable and ethically/culturally appropriate.

GMOs are organisms that have had their genetic material-deoxyribonucleic acid (DNA) altered or modified in some way through genetic engineering. In first generation genetic engineering, scientists remove one or more genes from DNA of an organism, such as bacterium, virus, animal or plant and recombine them into the DNA of another organism. For instance, genetic scientists have transferred genes from a bacterium known as Bacillus thuringiensis (Bt) into the DNA of crops. Recently, gene editing techniques allow for an organism's genetic sequence to be edited within itself.

Nigeria is a key actor when it comes to GMOs Biosafety. She signed the Cartagena Protocol on Biosafety in May 2000 and ratified it in October 2003 in commitment to Global Biodiversity Management. However, the questions remain of the implementation of the principles of biosafety, of the continuous assessment of the implications of products of genetically modified organisms on the people/environment and of the level of awareness of the public on the subject.

The review of the state of biosafety in Nigeria is particularly expedient as the livelihood and wellbeing of its over 200 million population is dependent on it. Agriculture forms the base of the Nigerian economy and provides the main source of livelihood for most Nigerians[1]. Approximately 70 percent of the population engages in agricultural production[2] which contributes significantly to the nation's GDP (21.65%[3] in 2018).

With Nigeria's increasing population, more than 67% of people are said to live below the poverty line of 1 USD a day according to the Nigerian National Bureau of Statistics. Life expectancy stands at 55.6 years for females and 53.4 years for males and ranks at an abysmal number 177 on the global life expectancy scale by the World Health Organisation. Climate change on the other hand stands as a big threat to agricultural productivity and to environmental and economic stability.

The present government has singled out agriculture as a viable alternative to oil revenue, leading to a 15.19 billion Naira increase in budget allocation between 2017 and 2018[4].

It is understood that agriculture holds great potential in the nation's economic growth and that more has to be done in other to ensure availability and access to food by the growing population. However, the questions remain: what system of agriculture? What system of agriculture would ensure food sovereignty and climate resilience? In the over 2 decades since the introduction of GMOs globally and over half a decade since their introduction in Nigeria, what has been the implications? Is the industrial system of agriculture, often characterized by the use of genetically modified seeds, heavy use of chemicals and dependence on fossil fuel energy, the solution or are there alternatives?

HOMEF conducted the research and produced this report through:

- Assessment of the implications of GMOs on the livelihoods of farmers and on environment health.
- Assessment of the existing legislation related to biosafety (The National Biosafety Management Agency Act 2015, amended in 2019) and implementation.
- Evaluating existing measures and capacity to detect, control, and prevent the natural, accidental, or deliberate spread of genetically modified organisms (GMOs) in Nigeria.
- Consultation with experts on biosafety and bioethics

# II. BIOSAFETY: PRINCIPLES AND IMPLEMENTATION

Biosafety is a term that encompasses the actions, systems and policies that protect humans from exposure to harmful biological agents[5]. Biosafety is an important consideration when individuals may or will handle high risk, highly transmissible and highly lethal – biological agents.

The World Health Organization in its Safety Manual 3 defined biosafety as the term used to describe the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens (biological agents), toxins, or their accidental release. At laboratory level biosafety precedence is personnel health and safety, and environment with a goal to reduce or eliminate exposure of individuals and the environment to potentially hazardous biological agents[6]. Therefore, biosafety entails the application of broad based safety precautions not only to reduce a laboratory worker's risk of exposure to a potentially infectious (biological agent) but to equally limit contamination of the work environment and ultimately the community. Bottom-line, biosafety is risk containment (Figure 1).

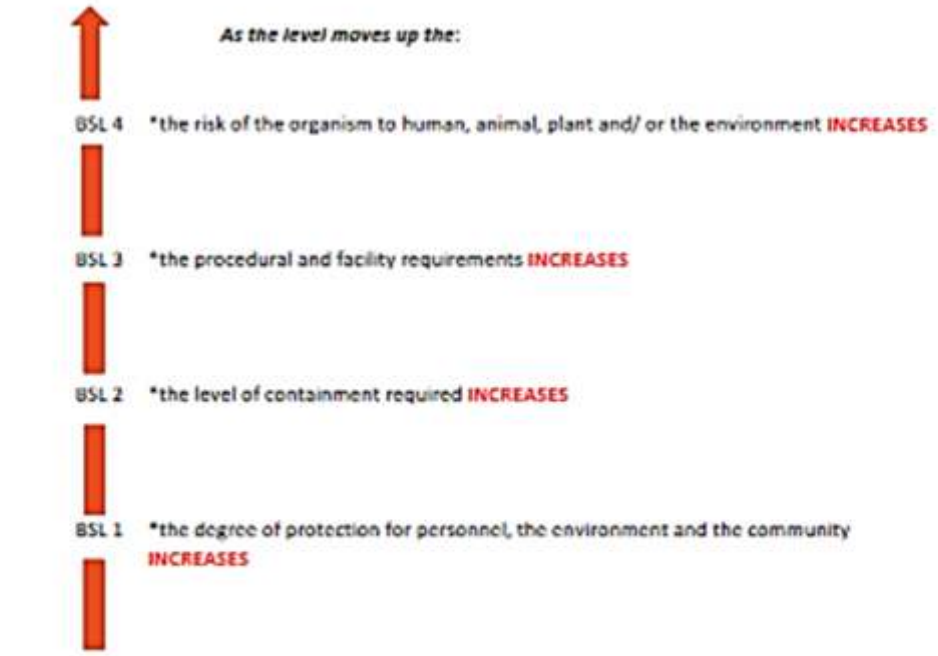



**FIGURE 1: BIOSAFETY LEVEL ACCORDING TO INCREASING NEED TO PROTECT HUMAN AND ANIMAL HEALTH AND ENVIRONMENT FROM THE POSSIBLE ADVERSE EFFECTS.**

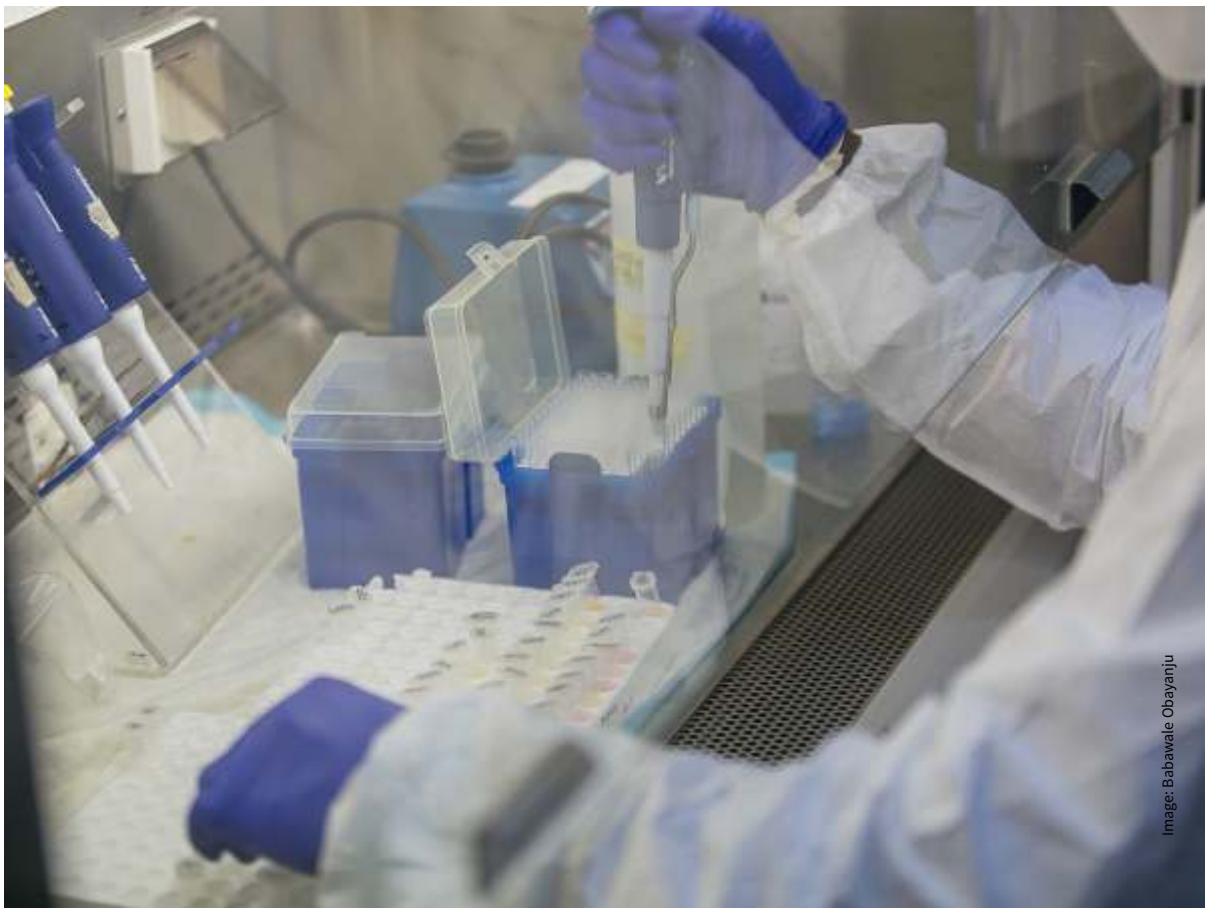


Image: Babawale Obayanju

Biosafety is related and relevant to several fields of human endeavour[8]. In ecology, biosafety refers to imported life forms not indigenous to the region. Biosafety in agriculture is concerned with the reduction of the risk of alien viral or transgenic genes, or prion such as Bovine spongiform encephalopathy (BSE) or Madcow Disease, reducing the risk of food bacterial contamination. Biosafety has a very wide application in medicine. From issues of organ or tissues of biological origin to genetic therapy products, viruses, levels of laboratory containment protocols (Biosafety Level - BSL: 1,2,3,4) in rising order of danger. In Chemistry, Biosafety helps to deal with the issues of substances such as nitrate in water, polychlorinated biphenyls (PCB) levels affecting fertility. Even in Exobiology, Biosafety is relevant in NASA policy for containing alien microbes that may exist in space. Biosafety is vital to promoting safe laboratory practices and procedures; proper use of containment equipment and facilities; providing advice on laboratory design and risk assessment of experiments involving infectious agents, rDNA in-vitro and in-vivo in academic and universities research[12,9].

The principle of Biosafety defines and presents information on methods used to provide biosafety in facilities where potentially infectious agents are used as shown in Table 1,[10,11]. These include:

- Containment
- Biological safety cabinets
- Personal protection equipment
- The facility as primary barrier
- Secondary barriers

| RISK GROUP | BIOSAFETY LEVEL (BSL) | LABORATORY TYPE | LABORATORY PRACTICE | SAFETY EQUIPMENT |
|---|---|---|---|---|
| 1 | Basic BSL - 1 | Basic teaching and research | Good microbiology techniques (GMT) | None, open bench work |
| 2 | Basic BSL - 2 | Diagnostic services and research | GMT + protective clothing biohazard Sign | Open bench plus bio – safety cabinet (BSC) for potential aerosols |
| 3 | Containment BSL - 3 | Special diagnostic services and research | As BSL -2 plus special clothing controlled access directional airflow | Biosafety cabinet and/or other primary devices for all activities |
| 4 | Maximum Containment BSL - 4 | Dangerous pathogen units | As BSL -3 plus airlock entry, shower exit and special waste disposal | Class -3 BSC or positive pressure suites in conjunction with class -2 BSCs, double ended autoclave trough the wall and filtered air |

Biohazards are hazardous agents of biological origin such as microorganisms, toxins, and allergens derived from those organisms; genetically modified organisms and allergens and toxins derived from higher plants, transgenic plants, animals and insects that have the capacity to produce deleterious effects on humans[11],. Managing these biohazards requires the proper mixed application of engineered containment and administrative controls and is referred to as biosafety or biohazard control. Biosafety delineates the containment conditions under which biological agents can be safely manipulated.

Biosafety is a containment endeavour used to protect against harmful incidents by the prevention of large-scale loss of biological integrity, focusing generally on ecology and human health[12]. Many laboratories and handlers of biohazards materials employ risk management assessment and enforcement process subjected to regular reviews of strict guidelines and protocols to ensure biosafety. Failure to follow these standard biosafety guidelines and protocols due mainly to human error, negligence or poor compliance to techniques can lead to increased risk of unnecessary exposure and compromise the best safeguards set in place for protection.

In a broad sense, “biosafety” is the totality of a nation's ability to effectively coordinate activities that mitigate biological threats, prevent and control major emerging infectious diseases. It also protects against biological weapon attacks, prevents bioterrorism attacks, prevents biotechnology abuse, ensures laboratory biosafety, protects its special biological resources, and prevents the invasion of its territory by alien organisms.

The need for robust biosafety implementation is now at an all-time high than ever in history because the spatiotemporal, internal and external risk factors are more than ever before broader and more intricate.

**Biosafety and Biosecurity/Bioterrorism**

Biosafety describes the development and implementation of administrative policies, containment principles, technologies, work practices, facility design, and safety equipment to prevent unintentional exposure to pathogens and toxins, or their accidental release[10,19]. On the other hand, biosecurity refers to institutional and personal security measures designed to prevent the loss, theft, misuse, diversion or intentional release and misuse of pathogens and toxins or critical relevant information[18]. Biosecurity is based upon the development and execution of a sound biosafety programme. Good biosafety practices reinforce and strengthen biosecurity systems.

Biosafety is usually regulated by national work environment safety laws. Conversely, biosecurity processes involve consultation with law enforcement officials and security experts. In simple terms, biosafety is risk assessment to ensure working safely - keeps bad bugs away from people, while biosecurity consists of threat assessment to keep the work secure - keeps bad people away from bugs.

Granted, there is no single, universally accepted definition of bioterrorism, it rightly refers to the unlawful use, or threatened use, of microorganisms or toxins derived from living organisms to produce death or disease in humans, animals, or plants[13,14,15]. Bioterrorism is a form of terrorism where there is the intentional release of biological agents (bacteria, viruses, or other germs). The act is intended to create fear and intimidate governments or societies in the pursuit of political, religious, or ideological goals. Those who intentionally use biological agents often have capacity to manipulate both the agents and the environment[16]. Biological weapons have been used many times in warfare throughout history. In some instance, there could be a surreptitious use of extant infrastructure in the delivery of the agent or a simple manipulation of the environment might be used to introduce a new deleterious agent. Biological warfare agents that are often highly pathogenic and infectious agents such as Bacillus anthracis, Brucella species, Clostridium botulinum, Yersinia pestis, Francisella tularensis, Tula virus, and Ebola virus may be used[17].

The effect of biological weapon attack is usually not immediately visible at the attack scene. Because biological weapons are naturally occurring diseases, the impact of their initial release may appear to be a natural outbreak of the disease. What is more, the harmful effects of biological weapons have strong situational dependence. Different pathogens, different attack methods, different social and natural environments, and other conditions result in different paths of risk evolution and different risk levels, which increases the difficulty of national biological defense. Advances in preparedness has helped to enhance national biological defense capabilities against bioterrorism.

Most developed countries, now have specially trained emergency personnel, emergency supplies, medicines and vaccines, treatment equipment, monitoring and early warning systems, and on-site disposal, recovery, and reconstruction as part of preparedness and countermeasures to prevent attacks and mitigate their effects[18].

**Biosafety Principles in Agriculture**

The Food and Agriculture Organization (FAO), an international agricultural flagship authority, defined biosafety as the avoidance of risk to human health and safety, and to the conservation of the environment, as a result of the use for research and commerce of infectious or genetically modified organisms. In food and agricultural regulatory systems, the United Nations through its relevant organ, the FAO, uses biosecurity to handle issues relating to sanitary, phytosanitary (pests and pathogens), and zoosanitary (animals) as a measure that is applied in food and agriculture regulation.

The issues encompassed in biosecurity have traditionally been dealt with through animal health safety laws, animal and plant quarantine and pesticide regulations. Within the agricultural community, biosecurity policy and regulatory framework details the process of managing biological risks associated with agriculture and food safety, animal life and health, plant life and health. Biosecurity is the strategic and integrated day-to-day practices that help to minimize the intentional and unintentional exposure of food crops, livestock, poultry, and aquatic life to diseases and toxin[18]. According to the FAO, three key factors form the basis for the increased necessity for the institution of biosecurity measure in the agriculture namely:

I. Protection of agricultural production systems, and those dependent on the systems, such as producers and others dependent on agriculture.
II. To protect human health and consumers' confidence in agriculture
III. To protect the environment and promote sustainable agricultural production.

Biosafety is a matter of public health and certainly requires public awareness on the rules, regulations, monitoring bodies, etcetera. To ensure biological safety at the grassroots, researchers must have top notch knowledge of biosafety and take the responsibility to create the awareness. Recognizing the need of biosafety in genetic engineering (GE) research and development activities, an international multilateral agreement on biosafety “the Cartagena Protocol on Biosafety (CPB)” was adopted by 167 parties, including 165 United Nations countries (inclusive of Nigeria), Niue, and the European Union.

The Protocol entered into force on 11 September 2003, and its main objectives are: (i) to set up the procedures for safe trans-boundary movement of living modified organisms, and (ii) harmonize principles and methodology for risk assessment and establish a mechanism for information sharing through the Biosafety Clearing House (BCH). The Cartagena Protocol on Biosafety is a legally binding protocol to the Convention on Biological Diversity (CBD). Pursuant to the foregoing objectives, every research work in the area of Genetic

Engineering (GE) and GMOs requires prior approval from the appropriate in-country regulatory authorities[19].

In today's agricultural sector, there is an increased targeted campaign for the adoption of Genetic Engineering technology crop breeding and animal production. This has heightened biosafety concerns in most developing countries including Nigeria to ensure safety of the public and the environment[20].

Consumers are deeply worried by this development particularly because of perceived inconsistencies in biosafety practices by administrators, and policy makers, researchers, producers and users of genetically modified organisms (GMOs) in Nigeria. Globally, biosafety regulatory policies and regulatory bodies are precedent conditions for research and development of GMOs.

However, strict compliance to biosafety guidelines is still a huge challenge in Nigeria. Though there have been several alleged and official releases of GMOs in Nigeria and its environs for commercial uses, in most instances, compliance to the stringent biosafety and biosecurity rules in the processes were said to be suspect.

By and large, Biosecurity best practices are based upon the development and execution of a sound biosafety program. It is therefore imperative that those who handle agents of high public health and agricultural importance, or agents of commercial value take seriously the implementation of the stringent biosecurity measures put in place for their operations. Biocontainment standards appropriate for working with agriculture pathogens at the right biosafety Levels must be adopted in agriculture. When studying agriculture pathogens (even in the laboratory), any of the appropriate four proposed biosafety levels can be used with the additional criteria of BSL-3-Ag reserved for studying high consequence pathogens in loose-housed animals where the room becomes the primary containment.

To avoid jeopardy and interference with agricultural study (including laboratory based operations) requires a familiarity with microbiology and the materials that requires protection. This will help promote free exchange of research materials, and information through a combined approach that will ensure the protection of pathogens and other sensitive biological material at biosafety levels commensurate with identified risks.



**Assessment of Measures to Ensure Biosafety and Biosecurity in the Use of Agricultural Biotechnology in Nigeria.**

Biosafety and biosecurity is the summation of practices that demonstrates a nation's capacity and capability to maintain and protect its own safety interests and to effectively respond to biological threats and related factors. Following the rapidly developing field of biotechnology, biosafety and biosecurity as a public health matter has gained increased awareness in Nigeria. Although biotechnology is said to be as old as man, the old techniques which involved the use of whole organisms for the benefit of man has overtime evolved to become integrated with many disciplines such as nanotechnology, information technology, precision electronics, optoelectronic engineering, and micro-manufacturing.

This has not only entirely changed the mode of research adopted by traditional life sciences, but has accentuated the development and maturation of biosafety policy, regulations and technology[21].

Due to the risks associated with biotechnology techniques, measures had to be put in place to reduce and where possible eliminate potential risks. This brought about The National Biosafety Management Agency Act.

The relationship between biosafety and biotechnology can be divided into two segments. First, for appropriate biotechnology applications to be transferred in a safe and effective way, biosafety regulatory mechanisms have to be put in place. Second, the saving and protection of biodiversity is a complex venture or effort that requires, on one hand, protecting natural habitats (for example from the invasion of alien species), and on the other hand, easing pressure on the land and by extension from the natural habitats. It is the latter that is directly related to the sustainability issue and agricultural production and productivity.

The whole process of biotechnology, biosafety and set up of biosafety law has raised lots of concerns especially in countries in Africa, Nigeria inclusive with regards to GMOs associated with food and agriculture.

In Nigeria, the National Biosafety Management Agency (NBMA) established in 2015 is the national biosafety regulatory authority. The mission of the National Biosafety Management Agency is to promote the basic tenets of biosafety as enunciated in the Cartagena Protocol on Biosafety, and enforce the Nigeria National Biosafety Management Agency Act 2015 to ensure the safe application and use of products of modern biotechnology[22].

The NBMA Act 2015 has several fundamental flaws such as: lack of access to information, no provision for stakeholder engagement or consultation and participation, defective provision for liability and redress, no provision on labelling and the right to know, subjective decision-making; and skewed provisions for appeals and reviews. The law is froth with use of lax terms such as “may” rather than “shall”); thus, - endowing the Agency with enormous discretionary power.

The standard of liability and redress in Section 41 subsection (1) of the NBMA Act 2015 is fault-based liability not strict liability. There is no mention of liability and redress in case damage arises from the release of GMOs into the environment whereas Nigeria signed the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress and in line with the precautionary approach. The NBMA Act 2015 provision on liability requires a higher burden of proof, and could make it difficult for liability to be established.”

The National Biotechnology Development Agency (NABDA) was empowered by the NBMA Act but with the conflicting mandate to regulate and as well promote modern biotechnology activities and release of their products into the environment.

Here is the worrisome reverse, with the mandate of NABDA in mind, Section 10 (1) (d) of the NBMA Act 2015 provided for representation of NABDA, amongst other interests such as Industry, Trade and investment and the Biotechnology Society of Nigeria on the governing board of NBMA. Why should NABDA be part of the Governing Board, when it is really their mandate to promote modern biotechnology and their products that the NBMA law is aiming to regulate?

Incontrovertibly, this sets the stage for duplicitous conflict of interest. Moreover, Industry, Trade and Investments, Biotech Agency and Biotech Society people are not the best of regulators.

Notwithstanding the existence of biosafety legal frameworks especially the Nigeria National Biosafety Management Agency Act 2015 amongst others, measures put in place to monitor and assess biosafety and biosecurity in agriculture in Nigeria continue to pose a major challenge.
There are serious concerns that the National Biosafety Management Agency does not ensure the strict compliance with biosafety law with regard to release of GMO products into the Nigerian environment. Recently, the NBMA (amendment) Act, 2019 broadened the scope of the Act to include “biosecurity” concerns, and applications of genome editing, gene drives and synthetic biology as regulated technologies along with GMOs.

The amendments received with mixed reactions by many Nigerian civil society groups brought the new tools and technologies under the purview of a dysfunctional regulatory agency. One major challenge is that it paves the way for the possible regulation of genome editing innovations with the same lax NBMA framework currently used for GMOs. There is a real possibility of Nigeria becoming a dumping ground or an open testing laboratory for risky technologies that are not allowed elsewhere .

The seemingly unbridled official and surreptitious releases and commercialization of GMOs in Nigeria has become a matter of fierce public concern and debate.  Palpable misgivings are expressed by many Nigerians over GMOs safety not just for human consumption but also for the environment and their economic impact on farmers as well, especially the small scale farmers. The debate continues to rage over the application of genetically modified crops in the Nigeria agricultural and food system.

The foremost cause of apprehensions over the scope of biosafety regulation in the country includes, the lack of appropriate and coordinated mechanisms established to ensure that Nigerians are not inadvertently ill-exposed to genetically modified agro seeds (foreign and local), foods, diagnostics, vaccines and drugs, modified organisms for bioremediation, and other essentials of life. Biosafety is multi-sectorial and multidisciplinary in application, but the lack of synergy and synchrony in biosafety responsibilities among and between the various ministries, departments and agencies (MDAs) remains a major challenge to biosafety regulation in Nigeria.

In India, biosafety regulation including for GMO monitoring is jointly carried out by the following MDA's with related mandates to regulate all activities related to GMOs and products derived from GMOs in India:

The Recombinant DNA Advisory Committee (RDAC), The Review Committee on Genetic Manipulation (RCGM), The Genetic Engineering Appraisal Committee (GEAC), Institutional Bio-safety Committees (IBSC), State Biotechnology Coordination Committees (SBCC) and District Level Committees (DLC). Government of India through multi-tiered regulatory framework assesses and ensures biosafety of GM crops work is governed by Rules: 1989 under the provisions of the Environment Protection Act (EPA), 1986 through the Ministry of Environment, Forest and Climate Change (MoEF&CC) and Department of Biotechnology (DBT) of Ministry of Science and Technology[24].

In the regulatory cascade, the India Ministry of Health (1 Department and 1 Res. Council), and Ministry of Food and Food Supply are also not left out in the regulatory chain.

Similarly, in Nigeria, without prejudice to the NBMA mandate or its amendment Act, 2019, the Medical Laboratory Science Council of Nigeria[25] is the national authority that make regulations on all matters that pertain to biosafety and biosecurity in the laboratories. NBMA's scope of regulation is limited to the application of genetically modified organisms and the regulation of the application of modern biotechnology as it applies to agricultural development and food security. Pursuant to the National Environmental Standards and Regulations Enforcement Agency (NESREA) Establishment Act, 2007, biosafety regulation related to environmental safety is under its jurisdiction.

NESREA has the responsibility for the protection and development of the environment, biodiversity conservation (permits relating to issues on access to Genetic Resources) and sustainable development of Nigeria's natural resources in general and environmental technology including coordination and liaison with relevant stakeholders within and outside Nigeria on matters of enforcement of environmental standards, regulations, rules, laws, policies and guidelines[27].

The National Agency for Food and Drug Administration and Control (NAFDAC) established by Act Cap N.1 LFN 2004 is charged with biosafety regulatory issues related to food and drugs. Added to these MDAs are over 124 universities across Nigeria, most of which have departments of biological sciences, medicine, biotechnology, veterinary science and agriculture.

There are also about 42 research institutions of biosciences which are wide spread and which cover many communities and bio-resources in Nigeria.


These universities and the research institutes represent a grossly under-utilized repository of local competence for evolving a functional strategy for an effective biosafety programme and for safeguarding local bio-resources. In spite of the multiplicities and duplicities of these biosafety related statutory agencies in Nigeria, inappropriate and inadequate biosafety regulatory conditions abound because some of these ministries and agencies that have one or more biosafety responsibilities do not even have biosafety officers. Disappointingly, because of these existing regulatory slipshod, Nigerian communities are currently vulnerable to unchecked entry of genetically modified organisms (GMOs) especially in agro seeds and foods, vaccines and drugs, and other essentials of life[28].

Biosafety presents new opportunities for international cooperation and global governance[29,30],. The biotechnology investments are in genetically modified agro seeds and local foods, vaccines and drugs, and modified organisms for bioremediation. ,

There are indications that these products of biotechnology could have adverse effects on human, plant and animal health, biological diversity and the environment[31].

Nigeria lacks the capacity to compete and make significant contributions in the already established and fast evolving market of bio-opportunities. Accordingly, there is urgent need to safeguard our bio-resources against predatory advances of profit seeking multinationals.

Considering that Nigeria is richly endowed with diverse biodiversity, some of which are unique to our ecosystems, it will be catastrophic if beclouded by purported economic benefits, the country surrenders to the possible long term health and environmental costs of modern biotechnology in Agriculture.

Essentially, biosafety regulations and programmes are complementary to biosecurity and require systematic processes involving monitoring and warning, detection traceability, prevention and control, diagnosis and treatment, emergency measures, and other technical and defense aspects. Presently, Nigeria's priorities are mostly waste management, oil spills, forest management, and occasionally Environmental Impact Assessment (EIA) and Environmental audits.

Even the handling of some of these are arguably unsatisfactory. Biological risk assessment is a legal obligation in many countries that have biosafety regulations[32]. It is unfortunate that in Nigeria universal risk management is scarcely integral to most of the development and evaluation of modified organisms in a systematic fashion, for example from the laboratory, through stages of field-testing, to commercialization. The number and forms of these stages are not fixed, but depends on the outcome of biological risk and biosecurity threat assessment at the different stages.

According to the 2019 Global Health Security (GHS) Index[33], Nigeria had a zero country score for biosafety. Against this backdrop, Nigerian government must commit to the protection of her people and territory from harmful incidents by the prevention of large-scale loss of biological integrity, focusing generally on ecology and human health.

The need for rejigged mechanisms and institutional structures to ensure the effective and holistic implementation of biosafety regulatory protocols and management of Nigeria's local bio-resources in all applicable sectors cannot be over emphasized.

Policies guiding vulnerability studies, biosafety risk assessment, biosafety risk mitigation measures, biosecurity threat assessment, bio-risk management and determination of risk acceptance and resource rights of the indigenous people should be formulated and implemented uncompromisingly as a way of safeguarding our people and communities for the future.

# III. ETHICS IN SCIENTIFIC RESEARCH AND DEVELOPMENT (BIOSAFETY IN CONTEXT)

“What Science believed and Technology made possible must first be judged for its safety and benefit to the “whole stream of life”[34].

Definition of Ethics and Morality
Ethics - (from the Ancient Greek "ethikos", meaning "arising from habit") can be defined as: a method, procedure, or perspective, or norms of conduct that distinguishes between acceptable and unacceptable, right or wrong, good or evil behaviour and responsibility[35]. It is the ideals, values or standards that people use to determine whether their actions are good or bad. Ethics are relatively easy to follow guidelines that dictates the working of our social system towards the application of morality. Ethics are communal, relating more to a group, community or society.

As set of codes, ethics are professional standards that help address anything that affects others. It is a broad field of study divided into three major areas namely[36]:

- Meta-ethics (the study of the concept of ethics),
- Normative ethics (the study of how to determine ethical values), and
- Applied ethics (the study of the use of ethical values).

Ethics is seen as an inquiry into the moral worth of human conducts and endeavor. As an inquiry, it touches every facet of life where one can point to one human conduct or the other. Accordingly, ethics and its norms are applicable to science and scientific creative activities. The ultimate aim of ethics is to provide standards that can be used to make distinction between those of our actions that are good and those that are bad, between those that are right and those that are wrong, between those that are acceptable and those that are not acceptable, and between those that are commendable and those that are not commendable.

Many philosophers in the quest to determine what is the appropriate moral standards have identified the following three ethical theories that can serve as guides for making moral decisions:

- The consequence of the action can help determine the right standards
- The intention of the person performing the action and
- The nature of the action

Morality refers to the concept of human ethics which pertains to matters of good and evil, right or wrong, applied within three contexts: individual conscience; systems of principles and judgments[42].

Morality is often considered as moral values, shared within a cultural, religious, secular, humanist or philosophical community; serving as codes of behavior or conduct. In a way, morality is in sync with ethics. While morality is abstract in understanding, ethics is defined and in the form of written code.

Morality is concerned with the ethical queries on the moral outcome of a specific situation. Morality therefore is better understood as an assimilation of beliefs about the essentials to lead a 'good' life which within an environment are considered adopted code of conduct or a set of agreed upon rules for what is 'right' and 'wrong'.

Ethics and morals are colloquially used to mean roughly the same thing but they are not synonyms. Generally, morals mean accepted norms that govern practical behavior primarily toward our fellow humans, wherever and whenever they live[37]. Morals define an individual's character informed by choice, believe or religion. It is the basic marker of behaviour. In its modern definition, morals include norms also with respect to nature. On the other hand, ethics is a moral philosophy that describe the subject as well as comparing and critically reflecting different moralities. Ethics in science relates to how certain standards affect science and if scientific research are conducted with regard for ethics[38]. It similarly highlights ethical issues associated with the outcome of science considering the fact that science may be taken as an end in itself which ought not to be limited in anyway. Ethics and science universally interrogates four pertinent issues namely: the use of humans for scientific research, the implication of scientific research for the environment, the use of animal for research and the need to avoid falsification of results about data gathering and plagiarism.
Most concourse on ethics, scientific research and development science relating to ethical concerns, has traditionally focused primarily on the protection of research subjects. Mistakenly, biosafety is not seen as part of ethical framework but as a branch of occupational health and is therefore ignored. Biosafety is not just a personal requirement but fundamentally it is a collective of activities that ensure biological safety for a clean and safe environment. In today's world with the increased adoption of molecular tools and techniques in life science research and development activities, biosafety issues have become important to ensure biological safety for the public and the environment[39].

Therefore, ethical framework for evaluating biosafety risks of scientific experiments and research will be invaluable in the mitigation of the risk of accidental release from a laboratory which could lead to extensive or even global spread of a virulent pathogen[40]. Biosafety and laboratory biosecurity promotes safe and secure working practices that help prevent unintentional exposure to pathogens and toxins, or their accidental release, as well as to protect, control and account for valuable biological materials (VBM) within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release (Sharif and Kimani, 2019).

Reasonably, ethical principles should apply to any class of scientific experiments and research where biosafety risks threaten public health[41]. There is no doubt that scientific processes and products may have negative consequences.

In order to limit these potential untoward outcomes, ethics seeks to limit extreme pursuit of scientific knowledge that has little or no regard for human values. Ethical appraisal helps achieve this by developing standards that ought to be followed in science and scientific research to ensure that the transformation brought about by science must be positive and not negative or destructive.

If ethics is divorced from scientific knowledge truth will be lost and there will be lots of fabrications, falsifications of, and tampering with research data[43]. Consequentially, the ultimate goal of science and scientific research will be defeated.

Some scholars including Davis Resnik have identified what is now known as secondary ethical principles to include: Honesty (strive for honesty in all scientific communications), Objectivity (avoidance of bias in experimental design, and other aspects of research), Integrity (Keep your promises and agreements), Carefulness (avoid careless errors and negligence; carefully and critically examine your own work and the work of your peers), Openness (share data, results, ideas, tools, resources and being open to criticism and new ideas), Respect for Intellectual Property (honor patents, copyrights, and other forms of intellectual property, acknowledgements or credit for all contributions to research and never plagiarize), Confidentiality (protect confidential communications), Responsible Publication (in order to advance research and scholarship), Mentorship (educate, mentor, and advise students), Respect for colleagues (treat them fairly), Social Responsibility (promote social good and prevent or mitigate social harms through research, public education, and advocacy), Non-Discrimination (avoid discrimination on the basis of sex, race, ethnicity, or other factors not related to scientific competence and integrity), Competence (sustained professional competence and expertise through lifelong education and learning), Legality (obey relevant laws and institutional and governmental policies) Animal Care (respect and care for animals when using them in research), and Human Subjects Protection[44].

An important and widely acknowledged duty of the individual scientist is to follow good research practices and conduct research responsibly. Good scientific practice in research is recognized as essential for the integrity of research, to nurture confidence within the research community and with the society. Generally, good research practices include the conscientious avoidance of research misconduct (fabrication, falsification or plagiarism); policies for handling misconduct, conflicts of interests, data management, authorship, peer review and collaborative research; and policies regarding the protection of human and animal subjects[45].

Another important responsibility of individual researchers is to consider the possible future implications of their work and, as far as possible, undertake such an evaluation as part of the research risk assessment.

Some challenges are associated with this topic[46]. First, enabling individual researchers to exercise such a responsibility requires raising their awareness about those potential risks. Second, scientists may not have the expertise to undertake such assessment, let alone the possible conflicts of interest that may arise.

Studies have shown that currently life scientists in general lack much awareness on this topic. It is argued that awareness-raising will not make scientists able to predict the future with certainty.

Therefore, the expectation is simply that scientists, to the best of their ability, make informed reflective judgements taking the likelihood and magnitude of reasonably foreseeable harms and benefits of research into account about whether or not, or the extent to which, precaution is necessary.

The ability of scientists to make such judgements could, meanwhile, be enhanced via relevant education regarding bio-risks, biosafety and laboratory biosecurity, and ethics[47,48].

**Ethics and Scientific Innovations: The Issues Related to Biosafety and Biosecurity**

"As our nation invests in science and innovation and pursues advances in biomedical research and health care, it's imperative that we do so in a responsible manner." - President Barack Obama.

Science and technology obviously exceeds the understanding of many but must be done right. Ethics questions about scientific innovation is usually not a binary yes or no, or even now or later. It questions to what extent and under what conditions and who decides[49]. Ethics promotes thorough analysis of the actual and potential consequences of an innovation in the short, medium, and long terms.

As today's technology is approaching the man-machine and man-animal boundaries, and the society may be leaping into humanity-defining innovation without the equivalent of a constitutional convention to decide who should have the authority to decide whether, when, and how these innovations are released into society**50**. Scientific integrity relates to issues such as falsification, fabrication, plagiarism, and authorship disputes that are relevant to all scientific disciplines. However, in light of several high-profile biosafety and biosecurity incidents at laboratories in recent years, there has been an effort within the life sciences to develop a culture of responsibility specifically focused on laboratory safety and dual-use research issues[51,52].

We have had many historical breakthroughs in the area of synthetic biology that represent a research shift in biology research from the exploration of life to the creation of an organism with a desired phenotype.

Synthetic biology is commonly defined as a multidisciplinary research area that combines biology with chemistry, mathematics, computer science, and engineering and focuses on engineering of biological systems by modifying, designing, and de novo constructing biological components with new functions. Notwithstanding the acclaimed contributions of synthetic biology to basic life science research, human health, environmental protection, and even economic growth, its potential biosafety, biosecurity, and related ethical risks have also emerged in recent years as the technology becomes less expensive, more mature, and more accessible.

In addition to these are the problems of allergies, antibiotic resistance, carcinogens, and pathogenicity or toxicity among human-health–related risks; and changes to or depletion of the environment; competition with native species, horizontal gene transfer, and pathogenicity or toxicity as environmental risks[55]. Currently, the increasing biosecurity risks of synthetic biology is the possibility of bioterrorism via the dual-use synthetic-biology technology[56].

Increasingly, the people and companies with the technological or scientific ability to create new products or innovations are de facto making policy decisions that affect human safety and society. Human society must not slide into the lassitude of technological prowess or scientific brilliance determining and making decisions that may affect all humanity in profound ways. Without sparing thoughts for who bears responsibility for its untoward potential risks and unforeseen uses, who gets to control innovation remains a central question of our time. For instance, the National Academies of Science, Engineering, and Medicine recently issued a report recommending that the ethical framework applied to gene therapy also be used when considering CRISPR applications[55];[57].

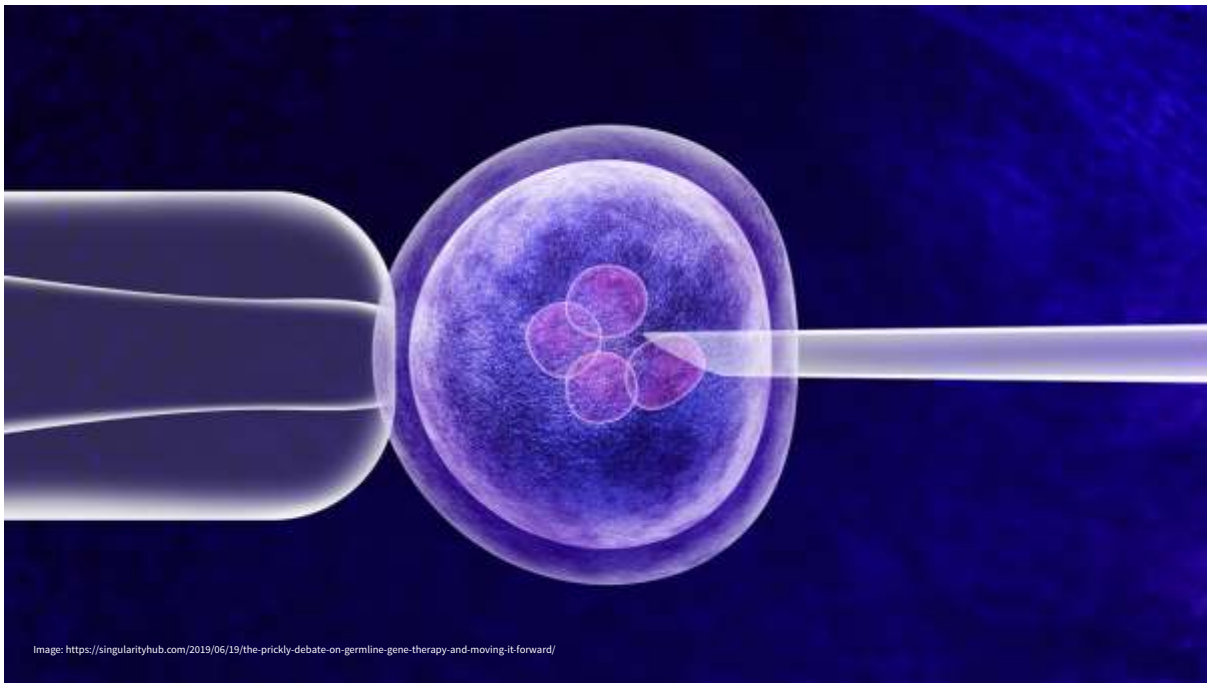


Image: https://singularityhub.com/2019/06/19/the-prickly-debate-on-germline-gene-therapy-and-moving-it-forward/

Their recommendation in effect begs the question whether their scientific brilliance should legitimize them as decision-makers for all of us.

For a more responsible use of technology a broader societal conversation that includes consumers, experts, and regulators should precede certain innovations. Other ways involve integrating ethics earlier and more rigorously into decision-making, improved disclosure, and the institutionalization of the necessary checks and balances.

Scientific innovations are froth with a plethora of ethical and moral dilemmas that necessitate ethical action and normative analysis. Most times it is difficult to have a clear cut determination of the point where the negatives of innovation tend to overshadow the good that it brings[57]. For this reason, evaluating the relationship between ethics and scientific innovation has always been a challenging task especially for policy-makers.

This is because emerging scientific notions, technologies and innovations such as artificial intelligence (AI), gene editing (in plants and animals using the CRISPR - Clustered Regularly Interspaced Short Palindromic Repeats), nanonotechnologies, synthetic biology, animal testing, human trials, emerging information technologies, autonomous machines, weapons and military (R&D), space colonization (such as Martian colonization) have continued to disrupt ethical categories, and traditional ethical norms, such as autonomy and human responsibility (English, 2019).

In all these adventures, the protection of human life must be given priority above all else. No matter the perceived or actual benefits of any given innovation it is not worth compromising on the ethics of the science and technology behind such innovation.

Intentionally, or unintentionally, scientists can sometimes make pathogens more virulent or more transmissible (Gibson et al., 2010). Dual-use research policies require that research be ethical and that the benefits gained from the research outweigh the risks[58]. Disappointingly, the 2019 global health security index score for dual-use research and culture of responsible science in Nigeria is a rock-bottom zero (GHS index, 2019).

The country is therefore in a dire need of a strong culture of responsibility as an effective tool in mitigating many of the risks of life sciences research.

Ethics seeks to limit extreme pursuit of scientific knowledge that has little or no regard for human values. In a traditional technological setting, ethics is mostly seen as a constraining procedural requirement of a legal nature that needs to be met at the outset of the scientific research leading up to the innovations[58].

As new technology-related ethical challenges continue to arise, the need to rejig ethical requirements so as to make them stricter and enhanced by policy contexts that promote concepts such as ethics by design and responsible innovation cannot be over stressed.

Ethics ensures accountability of scientific innovators to the public, and seeks to avoid situations where persons doing science people would do as it pleases them. Without ethics human life and the interest of the larger society can become endangered by scientists and innovators in attempts to meet one challenge or the other confronting people.

Ethics must be embedded in technology because how people think about technologies matters. Technology as major contributor to modern economic growth and development, shapes people, and the people shape technologies.

The complexities in the relationship between people and technology impacts research agendas, investment flows, business models and the content of education systems. Two widespread perspective of technologies exist among current business leaders and senior policy makers. One of the views considers technologies as mere tools that are intrinsically and unquestionably aligned with greater opportunity while the second views technologies as being inevitable and out of human control.

None of these views is ideal and holistic. The absence of a more critical comprehension of technologies, and their moral role in society, reduces our ability to make informed decisions about the development and application of powerful new approaches, particularly with those technologies that blur the lines between human and technological capabilities, such as machine learning, biotechnologies, neurotechnologies, and virtual and augmented reality.
A more balanced and empowering appreciation of technologies is that which see technology as how we engage using our capabilities to interpret, transform and make meaning of the world around us. Technologies are distinct from human beings but affect how people order their lives, interact with one another and see themselves[60]. Beyond simple objects and processes, technologies are deeply socially constructed, culturally situated and reflective of societal values.

This more distinctive view of technologies and hence scientific innovations is key and strategic and as well has implications for successful governance of technologies especially through ethical protocols.

**Promoting Ethical Research and Development in Nigeria**

Research is an undertaking intended to extend knowledge through a powered systematic, methodological study/inquiry with clear social/scientific objectives, validity and value that appraises basic facts around an identified problem in order to find solutions based on these facts for purposes of development[61]. Primarily, the purpose of research is to birth discoveries and proffer meaningful answers to questions aimed at solving societal challenges[62]. Ethical research denotes adherence to norms in research and is central to attaining the aims of the research, such as knowledge, truth, and avoidance of error.

These norms are essential elements in research and development because of their ability to bring about development or underdevelopment. Ethics help to ensure the quality and integrity of research, prohibits fabrication, falsification, or misrepresenting research data while promoting the truth and minimizing errors. Ethical research promotes a variety of important moral and social values, such as social responsibility, human rights, animal welfare, compliance with the law, and public health and safety[63]. Through ethical research researchers are held accountable and gain the requisite public trust.

Though most societies do have laws and legal rules that govern behaviour, ethics and law are not the same. Ethical norms are to a certain degree broader and more informal than laws. A given action may be legal but unethical or illegal but ethical. For this reason, ethical concepts and principles can be considered more a collective and relevant to criticize, evaluate, propose, or interpret laws. This explains why all people recognize some common ethical norms but interpret, apply, and balance them in different ways in light of their own values and life experiences[72].

In Nigeria, the National Health Research Ethics Committee (NHREC) inaugurated in 2005 which replaced the erstwhile moribund Health Research Ethics Committee is the apex body responsible for the provision of and ensuring adherence to guidelines that govern ethical research practice in Nigeria[64]. Amongst its other numerous mandate, the NHREC set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials. NHREC is saddled with the responsibility to promote ethical research in Nigeria. To determine which research should be approved, NHREC is guided in their judgement and consensus by its own set of codes that helps balances the various principles of ethical research.

Research is the basic tool for development, and is inherently associated with certain risks and sometimes, even a country may be exploited or be exposed to grievous harm therefrom. According to UNDP, human development enlarges peoples' choices. Since development is concerned with choices and differing conceptions of value (the good life) systemic ethical regulation of research helps to ensure that it is conducted in a manner that will maximize the benefits of research while limiting its potential harms and avoiding exploitation[65].



Research is an adventure with inevitable risks and involves a great deal of cooperation and coordination among many different people in different disciplines and institutions. Ethical standards help entrench the values that are essential for collaborative work, such as trust, accountability, mutual respect, and fairness (UW,2021).

Nigeria as a nation is in dire need of scientific and technological breakthroughs with a clear cut philosophy for national development (Odia, 2013).

Providentially the country has strong potentials for sustainable growth and development because it is enormously endowed with teeming skilled humans and extensively rich natural resources[66].

To achieve this lofty ideal, the country must pursue a well-defined, strengthened independent, systemic and institutional operation devoid of the politicization, interference, manipulative interests. Regrettably, the country's desired goal and benefits associated with research and development remains a mirage because both the government and its people are yet to get their acts right in research and development.

As opined by UNESCO in 2010, it is the responsibility of government to help spread the benefits of innovation through policies that encourage growth in the areas of science, technology and innovation. Nigerian scientists claim that until certain bottlenecks hindering research in the country are removed research and development will continue to remain at very low levels. Some of these bottlenecks includes those attributable to, Nigerian political leaders, policy makers and implementers, at all levels who are yet to key into research and development that can help move the nation forward in a way to yields higher human development indices. Constraints hindering ethical research and development in Nigeria are innumerable.

These includes inadequate infrastructure, lack of trained manpower, poor institutional capacity, poor funding, low level of public education and awareness, and near absence of a dual-research and culture of responsible science. The problems militating against ethical research in Nigeria are daunting, but are not all together insurmountable.

In 2007, the Africa Union (AU), resolved that member countries should dedicate a minimum of one per cent of the nation's GDP to R&D purposes. The Nigerian National Science, Technology and Innovation Policy and the Nigeria National Research and Innovation Fund (NRIF) are laudable initiatives put in place in compliance with Africa Union (AU) 2007 resolution (UNESCO, 2010).

A legal framework through a legislative enactment will help to consolidate these thrusts of government to ensure sustained funding through government appropriation which can be augmented with Internally Generated Revenues (IGRs) from research and development related agencies, private sector and international organizations.

Promoting research and development in Nigeria requires concerted S&T efforts along identified national priorities and goals. Nigerian MDAs with bias for research and development must commit to the facilitation of the acquisition of adaptable knowledge needs for reproducible technologies for the growth of a virile innovative system. In addition, government must support the establishment and strengthening of relevant organizations, institutions and structures for effective coordination and management of the much needed S&T activities that will promote research and development in Nigeria.


Image: https://thecitizenng.com

# IV. MODERN BIOTECHNOLOGY IN FOOD AND AGRICULTURE IN NIGERIA

The journey with GMOs in Nigeria formally began with the signing into law of the NBMA Act in 2015. The first approvals were for importation of GM maize for field trial and Bt cotton for commercial release in 2016. Since then, Nigeria has turned out to be the gaping hole through which GMOs are dumped, threatening the entire continent. Besides the crops approved for field testing, commercial release, or use for food and feed processing, several products pass on to our market shelves through the porous hands of regulatory agencies. One of the cases with grave implications for biosafety administration in Nigeria is the one that hit headline news in October 2017 that unauthorised genetically modified maize worth about $9.8 million had been impounded at Lagos sea ports.

Nigerians were thrilled by the vigilance of the regulatory agency and officers of the Nigerian Customs Service to intercept the illegal imports by WACOT Ltd. Another company implicated in the illegal importation of the GM maize is the Olam Group, a conglomerate that deals mostly in rice, including the widely sold Mama's Pride brand[67].

The Director General of the National Biosafety Management Agency (NBMA), stated in a press conference held in Abuja on September 13, 2017 that the Agency got notice of the importation through an intelligence report and had set in motion necessary machineries to track the importers and bring them to book.According to the National Biosafety Management Agency (NBMA) Act 2015, “Any person, institution or body who

otherwise carry out a contained field trial, multi-locational trial or commercial release of genetically modified organism shall apply to the Director General of the Agency not less than 270 days to the date of import, export, transit or the commencement of such activity."

The Federal Executive Council was notified of the decision to repatriate the illegal genetically modified maize to Argentina, its country of origin and also the National Assembly held a public hearing on the illegal importation. However, hopes that biosafety is important to the government were dashed[68] because the noise over the impounding of the illegal GM Maize turned out to be nothing other than mere noise. Why do we say this?

Barely a week after the NBMA announced that together with the Nigerian Customs Service they would ensure the repatriation of the illegal GM maize, the same NBMA issued a public advertisement, announcing the application for importation of GM maize by WACOT Ltd.The announcement stated: "In accordance with the National Biosafety Management Agency Act, 2015, requiring public display of any Biosafety application, for permit to intentionally release genetically modified organisms (GMOs), for comments from interested members of the public, the National Biosafety Management Agency (NBMA) hereby announces a twenty- one (21) day display of an application dossier submitted by WACOT Ltd for the importation of genetically modified maize for feed processing. The display is with effect from 22nd November to 12th of December 2017 to enable the public to make input that would facilitate informed decision on the application."That application was approved by NBMA and the applicant received permit for the impounded illegal import and to further import genetically modified maize at will into Nigeria over the next three years. The NBMA permitted release of the maize that the Federal Executive Council and Nigerians at large had been told were to be repatriated and against the law which states that such application must be made 270 days before the importation of such products.

**Permits Granted For Importation of GMOs Between 2015 and 2020**

According to information on the Biosafety Clearing House, as of November 2020, the NBMA has issued (8) confined field trial permits, Nine(9) importation permits for direct use as food and/or for feed processing and two (2) commercial release permits.Staple crops such as cassava, maize and cowpea are targeted, and the public is yet to see any evidence that any application has been turned down in Nigeria.

There is also no evidence that objections to advertised applications sent by consumers and the general public are considered. While research shows no comparative advantage of genetically modified crops over natural and conventional varieties, the myth continues to be peddled that because they are engineered in the laboratory, they have higher yields and are more nutritious. The false arguments are backed by years of colonial brainwashing that whatever big industry and big capital present must be accepted without question.

In 2016 NBMA signed the permits for importation for GM cotton and maize just one month and a few days after the applications were opened to the public for comments. This was done in spite of factual objections prepared and signed by over 80 civil society groups. It is instructive to note that the approval for Bt Cotton was granted just after the same cotton c onstruct had failed in the neighboring Burkina Faso. NBMA states that it was "convinced that there are no known adverse impacts to the conservation and sustainable use of biodiversity taking into account risk to human health." However, the Bt cotton application submitted in Nigeria by Monsanto is a replica of the Bt Cotton application that it had submitted in Malawi in 2014 which was rejected on scientific, legal and socio-economic \ grounds.

**List of GMOs Approved by NBMA Until November 2020**

| S/N | Name of Crop | Company | Purpose | Date |
|---|---|---|---|---|
| 1. | Cassava (stacked with beta carotene trait to increase vitamin A level) | The National Root Crop Research Institute | Field trial | January 2009 |
| 2. | Maize( NK603 and MON 89034 x NK603) for insect resistance and herbicide tolerance | Monsanto Agriculture Nigeria Limited | Field Trial | May 2016 |
| 3. | Cotton(MON15985) for lepidopteran insect pest resistance. | Monsanto Agriculture Nigeria Limited | Commercial Release/Market Placement | May 2016 |
| 4. | Cassava( AMY3 RNAi Transgenic lines)-post-harvest starch reduction | International Institute of Tropical Agriculture | Field Trial | September 2017 |
| 5. | Maize | WACOT Nigeria Limited | For Feed and Processing | December 2017 |
| 6. | Soy Bean- modified for herbicide tolerance | National Biotechnology Development Agency | Field Trial | May, 2018 |
| 7. | Soy Bean | Agboola Farms Limited | Feed Processing | June 2018 |
| 8. | Maize | Flour Mill Nigeria Plc | Feed Processing | June 2018 |
| 9. | Soy Beans | Rom Oil Mills Limited | Processing of Edible Oil | August 2018 |
| 10. | Soy Beans | CHI Farms Limited | Poultry Feed Processing | August 2018 |

| | | | | |
|---|---|---|---|---|
| 11. | Cowpea (Cry2Ab Gene) modified for resistance to lepidopteran pests | Institute of Agricultural Research, Zaria, Kaduna | Field Trial | September 2018 |
| 12. | Soy Beans | Elephant Group | Feed Processing | September 2018 |
| 13. | Maize | CHI Farms LTD | Feed Processing | October 2018 |
| 14. | Cowpea (PBR) -genetically modified for lepidopteran insect pest | Institute of Agricultural Research, Zaria | Commercial Release | January 2019 |
| 15. | Cassava modified for increased starch yield of the storage root | International Institute of Tropical Agricuture | Field Trial | February 2019 |
| 16. | Cassava for elevated levels of zinc and iron | National Root Crops Research Institute | Field Trial | July 2019 |
| 17. | Maize modified for resistance to stem borer insect and for drought tolerance –WEMA | Institute of Agricultural Research, Zaria | Field Trial | November 2019 |
| 18. | Maize Events-3272 and MZIR093-Pest and disease resistant; Herbicide tolerant; Biofuel Production. | Syngenta South Africa (pty) limited | Food, feed and processing | December 2019 |
| 19. | Soybean-Herbicide Tolerance | Syngenta South Africa (pty) limited | Food, feed and processing | December 2019 |

## Objections to Applications for Introduction of GMOs into Nigeria

After rigorous research by scientists and review by various groups of experts, objections have been sent on applications for introduction of GMOs into Nigeria. There is no evidence that these objections which represent the opinion of millions of Nigerians have been considered.
Here are summaries of objections sent respectively against the applications for GM Maize - (1) NK603 AND (2) MON89034 X NK603; Cotton - MON+15985 and Cassava genetically modified to express elevated levels of Iron and Zinc in the storage roots and high resistance to cassava brown streak disease (CBSD).

### A. Summary of Objections to the GM Maize Application (1) NK603 AND (2) MON89034 X NK603 Maize in Nigeria)

A thorough and rigorous independent scientific assessment of this application has been impossible due to the omission of detailed information relevant to purpose in particular on insect pest resistance. The information on gene flow was also scanty. Other important information, such as the description of the detailed genetic modification of the single events NK603 and combined event MON89034 x NK603 and resultant phenotypic modifications, were not provided as Monsanto provided only scanty information on page 10 of her application on phenotypic changes.
Throughout the application, Monsanto asserted that NK603 and MON 89034 × NK603 are equivalent to conventional maize.
The theory of 'equivalence' is a worn out argument that has been discredited by independent science, including in a joint South Africa – Norway biosafety project published in 2011. (See SANBI (2011)[69].
“The genetic modifications used to generate NK603 and MON 89034 were not meant to alter the reproductive biology of maize. MON89034 x NK603 was obtained by traditional breeding and therefore no new genetic modification was used.”

The above is Monsanto's assertion on page 10 of the application, ignoring completely the unintended consequences that may arise from the effect of the events and gene interactions (epistasis). The lack of attention to the potential unintended consequences of the interactions appears to also conform to the claim that because MON 89034 × NK603 was produced by the conventional breeding of single GM varieties, safety assessment of these individual parent varieties, and not MON 89034 × NK603 itself is satisfactory for risk assessment.

However, the best practice is for such stacked GM plants to be themselves subject to risk assessment, as exemplified in the Cartagena Protocol on Biosafety 'Guidance for Risk Assessment of Living Modified Organisms and in various jurisdictions, including the European Union.
This is due to the potential unintended effects of “subsequent conventional breeding of the recombinant DNA plant” as highlighted by the Codex Alimentarius Commission in its Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.

There is a dearth of information regarding the description of the GM maize varieties throughout the application. For example, no reference was made to southern blot analysis, this is not shown anywhere in the application, not allowing for independent verification.

No mention is made of other characterization techniques, such as polymerase chain reaction(PCR). Numerous studies have noted that a combination of Southern blotting and polymerase chain reaction (PCR) should be used in GMO risk assessment.

This was not done.

The conclusion of safety to humans of these proteins was based upon the following considerations:
“The proteins have a demonstrated history of safe use; the proteins have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals;

The proteins do not exert any acute toxic effects to mammals. In addition, the rapid digestibility in simulated digestive fluids provide additional assurance for their safety. It is therefore highly unlikely that CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins would cause any toxic effects on human or animal health. (Page 13)
The CP4 EPSPS, Cry1A.105 and Cry2Ab2 proteins were also assessed for their potential allergenicity according to the recommendations of Codex Alimentarius Commission (page 13).

The proteins are from non-allergenic sources, lack structural similarity to known allergens, are rapidly digested in simulated gastric fluid, and constitute a very small portion of the total protein present in the grain of NK603 or MON 89034 x NK603. Taken together these data lead to the conclusion that these proteins are unlikely to have any allergenic potential, and NK603 and MON 89034 x NK603 are as safe as conventional maize regarding the risk for allergenicity (page 13 of application).”

The above shows that evidence of the lack of risk to human and animal health is totally scanty. In fact, it is almost non-existent as reliability is placed on history not on empirical evidence from any study carried out by the applicant, as details are not provided. Vague reference is made to an animal feeding study, but no information is given to the study's duration, the number of animals used, or any information about control groups or the control group's diets.

“None of the genetic elements inherited from MON 89034 and NK603 encode toxic, allergenic or other proteins harmful to men or the environment (except for the targeted insect pests), or influence the reproduction, survivability, persistence or dissemination of the host plant.

Cry1A.105 and Cry2Ab2 proteins are toxic to certain lepidopteran insect pests but have been demonstrated not toxic to mammals and non-target organisms”
'The proteins have no structural similarity to known toxins or other biologically active proteins that could cause adverse effects in humans or animals”

It is claimed on page 12 of the application as above that the Bt proteins present in these GM maize varieties have “no structural similarities to known toxin or other biologically active proteins that could cause adverse effects in humans or animals, and that the Bt proteins themselves are not toxic to humans, animals or non-target organisms”.
This claim is not true at present. We cite multiple peer-reviewed articles that undermine these assertions, including a recent study in which pigs (their digestive systems are closer to that of man) fed GM maize and soya suffered severe stomach inflammation compared to pigs fed the non-GM equivalents (Carman et al. 2013).

No discussion of the potential risks to human and animal health and the environment from glyphosate is made in the application, even though this GM maize variety has been engineered for the express purpose of being sprayed with this chemical as seen below: “to evaluate the selectivity of two glyphosate formulations when applied to MON 89034 × NK603 compared to an unsprayed hand weeded treatment; to evaluate the weed efficacy of two glyphosate formulations when applied on MON 89034 × NK603 in comparison to a local standard and hand weeding” page 14 of Monsanto application.

Two out of the four trial purposes are on glyphosate selectivity yet no information on environmental or health effects of glyphosate is provided.
We cite a number of studies that show that this technology has increased herbicide use and that glyphosate is associated with so many health risks, including evidence from the USA

Image: www.africamash.com

and Europe that glyphosate has found its way into public water resources, and has been detected in people's urine. We note that glyphosate has been classified as a “probable human carcinogen” by the WHO due to the health risks.

Monsanto's application on page 12 claims that the “CP4 EPSPS, Cry1A.105 and Cry2Ab2, proteins exhibit toxicity towards certain lepidopteran insects but not toxic to mammals and non-target organisms”. A number of peer-reviewed articles that contradict these claims are referenced. No mention at all is made of any environmental risk from glyphosate nor the rapid emergence of insect populations resistant to Bt crops, and weed species resistant to glyphosate.

Monsanto does not adequately nor specifically describe measures to prevent crosspollination during field trials, other than to say that adequate temporal and/or spatial isolation measures will be provided and that the trial sites will be allowed to have physical barriers of 5 m fallow and 6 border rows with conventional maize as buffer zone.

This is inadequate as the trial sites cover all Nigerian agro-ecological zones and dire consequences are expected in the event of contamination. Contamination of Nigerian maize crops could impact negatively on farmer's livelihoods and the national maize market including maize products in Nigeria.

We cite peer-reviewed sound scientific records to prove that 5 m is too short a distance. It cannot prevent gene flow. Should the GM maize events be eventually approved for commercial use, there are potentials implications for our farmers that will need to be seriously considered, even at this early stage. The oft-repeated claim that small-scale farmers will benefit from the adoption of GM seeds is not borne out by independent research.

For example, small-scale farmers will not be allowed to share seeds as in traditional Nigerian settings. Stacked GM maize seed varieties, such as MON89034 x NK603, are typically more expensive than their single trait counterparts.

If the adoption of single and then stacked GM maize seed in Nigeria expands, our traditional and native hybrids will be eroded and eventually lost and dependence will be placed on Monsanto seeds making Nigerian farmers subservient to corporate interests.

Experience from South Africa has shown this to be so. Maize seed prices in South Africa have continued to rise, prompting concern among commercial agricultural organizations.

Small scale farmers do not have nearly as much representation, however, expert testimony to the Competition Tribunal in 2011 in South Africa stated that maize seed price increases would make it impossible for small scale and subsistence farmers to continue farming (SANBI, 2011).

Finally, there is a clear notable lack of capacity within Nigeria to adequately monitor the potential human and environmental risks of GM crops and their associated herbicides.

NBMA may claim to the contrary but we will challenge a public display as we have records of all laboratories in Nigeria and their REAL capabilities. There is also virtually no testing of any food material and products in Nigeria presently for residues of glyphosate or other pesticides, or to monitor their presence in the environment or our water resources.

It is unacceptable for government oversight to lag so far behind research, development and administration, while continuing to allow ever more controversial and complex events into our food chain and environment. Our authorities can and must set the pace to ensure safety. This application has failed to adequately show that NK603 and MON89034 x NK603 are safe for human, animal and environmental health.
Our submission points to a number of areas of scientific uncertainty that pose serious risks and require further research.

The Precautionary Principle both obliges the NBMA and accords it the right to halt the introduction of these events into our environment until this research has been satisfactorily carried out. In addition, we do not believe that single or stacking genes to deal with insect and herbicide resistance is a reasonable response to these problems.

It is clear that this strategy will lead to a cycle of further stacking, further resistance and increased use of agrochemicals to deal with the problem. We show that alternative weed and insect management systems exist and are proving to be effective while in no way undermining agricultural yield.

Our biodiversity is our strength.

About 75% of Nigerians depend on it for survival. Introduction of these GM crops will not just lower their quality but eventually eliminate them. In all areas of the country where glyphosate has been applied for the past three years spear grasses no longer exist, for example (Aguoru, et al. 2015). In several rural communities in Nigeria including the Director General of NBMA's village it is a raw material for the well cherished traditional thatched houses. Caution, adequate care and accountable actions must prevail.

## B. Summary of the Civil Society Objection to Monsanto's Application for the General Release of MON+15985 Cotton in Nigeria

Several main areas of concern were identified regarding the objection to the release of GMOs in the cotton zone of Nigeria, or more specifically, the requested approval of Monsanto's MON 15985 “Bollgard II” variety of Bt cotton. These areas of concern have been extensively laid out in this submission and are summarized as follows:

**Socio-Economic Concerns**

- The application by Monsanto has not sufficiently addressed the needs and concerns of other equally important actors in farming, such as the organic growers; protection of Nigeria's biodiversity and natural resources; promotion of sustainable agriculture and economic development for the benefit of both the present and future generations; promotion of gender equality and equity in biotechnology undertakings; promotion of traditional crops, animal genotypes and indigenous knowledge.

- No cost benefit analysis has been carried out to support Monsanto's claims that this technology will benefit cotton farmers in the northern cotton zone and indeed the entire cotton zones of Nigeria. Experiences from Burkina Faso and South Africa have shown that the technology brings a high risk of indebtedness due to the exorbitant cost of the seed. Farmers must further risk the loss of markets where trading partners will not accept GM crops and traders might face increased costs and obstacles when transporting cotton seed that will be subject to the provisions of the Cartagena Protocol. Private-public partnerships that the Government of Nigeria may have entered into that do not allow the cultivation of GM cotton are also threatened by the introduction of Bt cotton.

There is no clarity regarding liability and redress for farmers whose crops fail or who lose markets due to GM contamination. Furthermore, Monsanto has not clearly stated how they intend to control the spread of these Bt cotton seeds beyond Zaria and surrounding towns, despite being fully aware that the seed market in Nigeria is highly mobile.

**Technical & Administrative Concerns**

- The original notice placed by NBMA in the Leadership newspaper, calling for a 21-day period of public comment, included two display centres– one in Abuja and one in Zaria. For a country of 36 states and Abuja which is treated as a separate state, this is woefully inadequate. This indicates that effectively NBMA has given only two addresses for over 160 million Nigerians and for the 36 states even when Federal Ministry of Environment to which NBMA belongs has offices in the 36 states of the federation yet NBMA chooses not to use them, depriving Nigerians from full access to information.

The inclusion of the dossier on the website of NBMA was also inadequate given that many Nigerians do not have access to the Internet. In addition, the legal understanding regarding how to as not been tested in that regard.

remedy the situations of grievances is yet to be clearly understood arising from the fact that the Biosafety Act of 2015 is still new and has not been tested in that regard. The Act also has a lot gaps. Moreover, we are not aware that NBMA has developed regulations arising from the Act for effective operation and implementation.

We also put on record that the application was speedily uploaded onto the website after we had complained that it was not available on the website. We also note the inconsistencies and contradictions in the Public Notice of the application regarding the deadline for submission in the advertisement that was placed in the Newspaper on 25 February. Two different display dates are mentioned in the same advert: 29 February-28 March and 22 February–15 March. We have also not been able to resolve the puzzle as to why the deadline mentioned in the notice took effect from 22 February but the advert was published on 25 February.

We are really alarmed that the application is for an environmental release and placing on the market. This is coming so close after the dismal failures of Bt cotton in Burkina Faso. We are shocked to learn that it is already at the commercial release stage, when our Biosafety Act has only recently entered into force. What legislation was used to authorize the field trials in the first place?

The National Biosafety Technical Committee has evident technical capacity gaps that should be fully addressed before it can be deemed technically ready to assess an application of such specifications (being the first of its kind in Nigeria and for commercial release) and there are concerns regarding government capacity to monitor GM cotton for the development of insect resistance once it is released into the environment.

We request that the field trial data be made available to us to review, and record our disappointment that the application does not refer to any of the specific field trial data! From Nigeria. Public access to local field trial data on the use of MON 15985 in Nigeria, has remained inaccessible and out of the public domain. This is the case also for Zaria locality where approval for release is sought.

- **Molecular Concerns**
-
- MON 15985 contains genes referred to as cry2Ab2 and cry1Ac, which produce Bt toxins. These genes have been synthetically manufactured with no history of safe use in nature.
- The insertion of the aadA antibiotic resistant marker gene (ARMG) causes concerns regarding the potential transfer of antibiotic resistance to other living organisms. This concern, which is dismissed by the applicant, has been raised by a scientific panel of the European Food Safety Authority (EFSA) stating that this particular ARMG should be restricted to field trial purposes and should not be presenting GM plants to be placed on the market.
- No information is included in the application regarding the specific locations and genetic context of where the insertions took place, or of specific primers necessary for the detection of the genetic insertions.

- There are several unexplained inconsistencies in the application with regard to the 'Southern Blot' and PCR tests used for molecular characterization, but no satisfactory clarification or explanation is made of these. Only general reference is made to ELISA.
- The applicant fails to provide information on the identification of novel production of ribonucleic acid (RNA) variants, a known occurrence with the terminator (NOS 3') used in MON 15985. The RNA variants have the potential to produce novel proteins with potential toxic or allergenic effects.
- MON 15985 also contains the 35S promoter from the cauliflower mosaic virus (CaMV). Recent scientific research has raised concerns regarding the consequences of a potential overlap between 35S and a viral gene VI. Such an overlap has not been tested for, nor ruled out, by the applicant.

**Safety Assessment**

- There are no baseline data regarding the quantity, spread and use of cotton seed meal/cakes/oil used for human or animal consumption in Nigeria, and therefore no foundation for the assessment of food and feed safety.
- The applicant states that the safety of newly produced proteins can be determined through the assessment of these proteins on an individual basis, but fails to take into account any combinatorial or cumulative effects. Therefore, safety tests should be conducted on the whole plant and not individual toxins.
- One component of the allergenic assessment of MON15985 is based on comparison of its sequence similarity with an 8-amino acid segment in assessing allergenicity. Research has also shown that when assessed using a 6-amino acid segment, both Cry1Ac and Cry2Ab toxins have shown similarities to known allergenic proteins. Further evidence is required to show that the two toxins, both separate and combined, will not cause allergenic effects.

Environmental Risk Assessment

- The treatment of the potential effects on non-target organisms (organisms other than the target pests) in the application is very superficial and is contrary to what has been demonstrated in the literature. No data is provided on the tests used to confirm the claim of no adverse effects, neither is there a demonstration that the specificity of ecological functional groups that are unique to Nigeria has been taken into account.
- Scientific models exist for assessing the environmental risks of the Bt toxins in a broader context of testing parameters, including the direct and indirect, cumulative and interactive effects. Such assessment models have been used in Kenya, Brazil and Vietnam and would yield more meaningful results if also applied in Nigeria.
- The ways in which organisms can come into contact with the Bt toxins of MON 15985 are referred to a “exposure pathways”, and despite being very diverse are given very little attention in the application. Methods of exposure and potential transfer of toxicity include: consumption of lower-order organisms by higher order organisms through the food web, wind dispersal of GM pollen, washing of plant matter into aquatic ecosystems, leaching of transgenic materials into the soil, leaching from root systems through fecal matter or through the release of decaying plant and animal matter. These exposure pathways should be described and understood in order to determine whether or not and to what degree non-target organisms come into contact with the plant and the Bt toxins.
- Secondary Pests and Insect Resistance
- Secondary pests are populations of insects that can become a serious problem following changes in management practices or disruption of control by a natural enemy. The issue of secondary pests occurring, following the reduction in the target pest, is not considered at all in the application. Problems arising with secondary pest populations subsequent to the use of Bt crops have already been identified in several countries. Should secondary pests replace the target pests, this may necessitate increasing spraying of pesticides.
- Strategies for risk management and monitoring of GM crops are important and necessary according to the “Guidance on Risk Assessment of Living Modified Organisms” developed under the Cartagena Protocol on Biosafety, to which Nigeria is a party. Unfortunately, this application concludes that as no significant risks were identified compared to conventional cotton, therefore no risk management, i.e. post-commercial monitoring, beyond insect resistance management, is necessary. There is only a vague mention in the Fourth Schedule (page 3) of activities that will delay development of resistance.
- Insect resistance to Bt toxins has been documented in various parts of the world, including in Africa. Insect resistance to Bollgard I has already rendered it ineffective in several countries, and as such it is not marketed commercially anymore; hence the applicant's request for the approval of Bollgard II in Nigeria. Bollgard III, incorporating a third

toxin, is already seeking application for use in some countries.

- The use of two toxin Bt crops is thought to be able to delay resistance development, however, several assumptions for the success of such a "pyramid" strategy have not been borne out. The possibility of insects developing resistance to MON 15985, despite it containing two toxins, cannot be excluded, nor can the possibility of cross.

**C Summary of Objections to the application for field trial of Cassava Genetically Modified To Express Elevated Levels Of Iron And Zinc In The Storage Roots And High Resistance To Cassava Brown Streak Disease (CBSD) In Nigeria**

*Section 1- Administrative Information*
We note that genetic engineering of mineral content in staple crops poses serious concern and has the inherent disadvantage of over-expression of multiple genes (De Steur et al., 2015). The applicant did not provide information relating to the several gene orchestrated processes from mineral uptake by the roots to transport throughout the plant to accumulation in edible tissues (cassava storage roots). The unintended outcome and hence potential harm of these complex genetic interplay remain unknown.

It has been recognised by the UN's International Conference on Nutrition that there is need to move from over-emphasis on food fortification strategies, including biofortification, toward a permanent solution, i.e. diet diversification through locally available foods.
Nigeria should shift towards developing and implementing key strategies for food and dietary diversification at the community and household levels.


Image : www.demandafrica.com

Agroecology is an important and viable alternative which addresses this need.

**Previous Applications or Approvals**

The fact that the commercial release of this GM cassava has not been authorised before in any jurisdiction, raises much concern.

The lack of relevant scientific information and knowledge regarding the extent of potential adverse effects, call for the Precautionary Principle referenced in the Cartagena Protocol to be triggered. Addressing uncertainty is a key element of that Protocol.
The National Biosafety Management Agency should note that recently in Africa, many countries such as Zimbabwe also conducted CFTs on GM cassava as orphan crops but such research in these countries has been discontinued and abandoned at laboratory stage for being futile.

**Section 2-Plant Information**
There is a high possibility of gene flow from the genetically modified cassava and this portends great threat to biodiversity and loss of the indigenous varieties of the crop.

Although cassava cultivars are propagated exclusively by stem cuttings, there could be movement of material from the site through flooding, animal feeding, several species of wasp (mainly polistes spp) and honey bees (Apis melfera) pollinators of cassava, ant dispersal of cassava seeds or unlawful harvest.

Tendency and Weediness: we note that the ability of cassava to establish and maintain volunteer growth can be a veritable feature that can further cause contamination.

Toxicity and Allergenicity: The possibility that the cassava plant from the experimental field trial will be consumed is very high. It will be almost impossible to rule out surreptitious acquisition of the stem-cutting and the likelihood of unlawful harvest by locals who had always accessed improved cassava varieties from NRCRI, Umudike the CFT site. This is a serious concern as the transgenic cassava is said to have some allergen properties.

**Section 2.2-Modified Plant Information**

Intended Phenotypic Changes to the Plant: The adopted modification technology is undeclared. All commonly used genetic transformation systems in cassava rely on the induction of somatic embryogenesis (Beyene et al., 2016).
The culture of rapidly dividing, highly disorganized callus tissues, such as the Friable embryogenic callus (FEC) used in cassava transformation systems, is known to induce changes at the genetic and epigenetic levels (Kaeppler et al., 2000; Ma et al., 2015; Miguel and Marum, 2011).

Obviously, there will be significant alteration and /or loss of nutrient following this modification and this application has not substantiated anything to the contrary.
Source of Genetic Material: No molecular information is provided by the applicant.Has the applicant checked to see if the introduced genes or sequences are as they say?


**Section 4- General Confinement**

Flood and pollinators such as honeybees (Apis mellifera) will most likely cause adventitious contamination. Again, the honeybees (Apis mellifera) population in this region may suffer some sort of adversity as a result the undue exposure to this novel genetic construct.

**Section 5- Material Confinement**

The procedure stated for the packaging and labelling for transport of the experimental plant to the trial site are not referenced to any standard biosafety protocol.

# WHAT'S ON OUR PLATES?
## REPORT ON MARKET SHELF SURVEY FOR PRODUCTS OF GENETICALLY MODIFIED ORGANISMS IN NIGERIA[70,71]

The need for close surveillance on our market shelves cannot be over stressed. The NBMA stated repeatedly that there are no products of GMOs in our markets but after the careful survey carried out by HOMEF in two consecutive years: 2018-2019(as at the time of writing this report), it is clear that we have a long way to go in terms of GMOs regulation or safety. The survey has been carried out in 12 States in Nigeria and up to 10 supermarkets/malls were visited in the capital city of each state. The survey identified food products which are clearly labeled as:

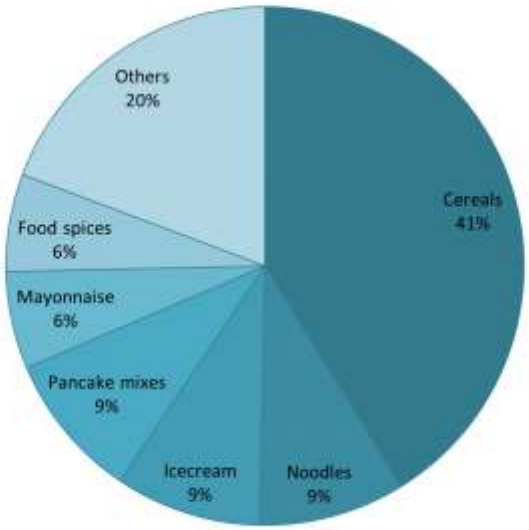
I. being produced with genetic engineering/genetic modification
II. containing genetically modified ingredients

The survey was carried out repeatedly in Lagos, Port Harcourt, Abuja, Kano, Benin City, Ibadan, and Enugu and once in Warri, Uyo, Katsina, Onitsha.
In 2019, the survey revealed about 27 new products that are said to contain genetically modified ingredients or produced with genetic engineering, apart from those (30) already identified in 2018. The total number of products of genetic engineering/genetically modified ingredients seen are about 57 which are spread across supermarkets and stores in the various states surveyed. The products include vegetable oils, cereals, ice cream, chocolates, food spices, mayonnaise/salad cream, cake mixes etc. and are mostly imports from USA, South Africa, China and India. Genetically modified ingredients were mostly corn and soy.

The survey also took note of herbicides sold in markets across the nation which contain glyphosate, which in addition to being linked with cancer, is implicated in the destruction of biodiversity as seen in the reduced population of bees. Up to 34 different glyphosate-containing herbicides were identified in the markets. Some of the herbicides spread across several Nigerian agrochemical markets that are seen to contain glyphosate as an active ingredient are: Roundup Turbo, Force Up, Glycel Glyphosate, Uproot, Weed Pro, Glyspring, Royasate, Glyphotex, Relisate, Top-G-Sate, Rake Out, Sunsate etc.
Less products were seen in some cities in 2019 and this is linked with the closure of border in the period before the survey was conducted.

Generally it was difficult to get data in some places as shop owners were apprehensive and disallowed the process.
Overall, the open markets were less tolerant and objected to pictures of items being taken in their shops.

4.1. Groups of products seen to be genetically modified or having genetically modifed ingredients




Several products were seen to have the inscription "modified" on some of their ingredients e.g. modified starch, modified corn flour or potato starch. While we cannot conclusively say that the inscription refers to genetic modification, there is a high probability of this. A number of persons have indicated[72] that they get allergenic reactions to modified starches, for example.

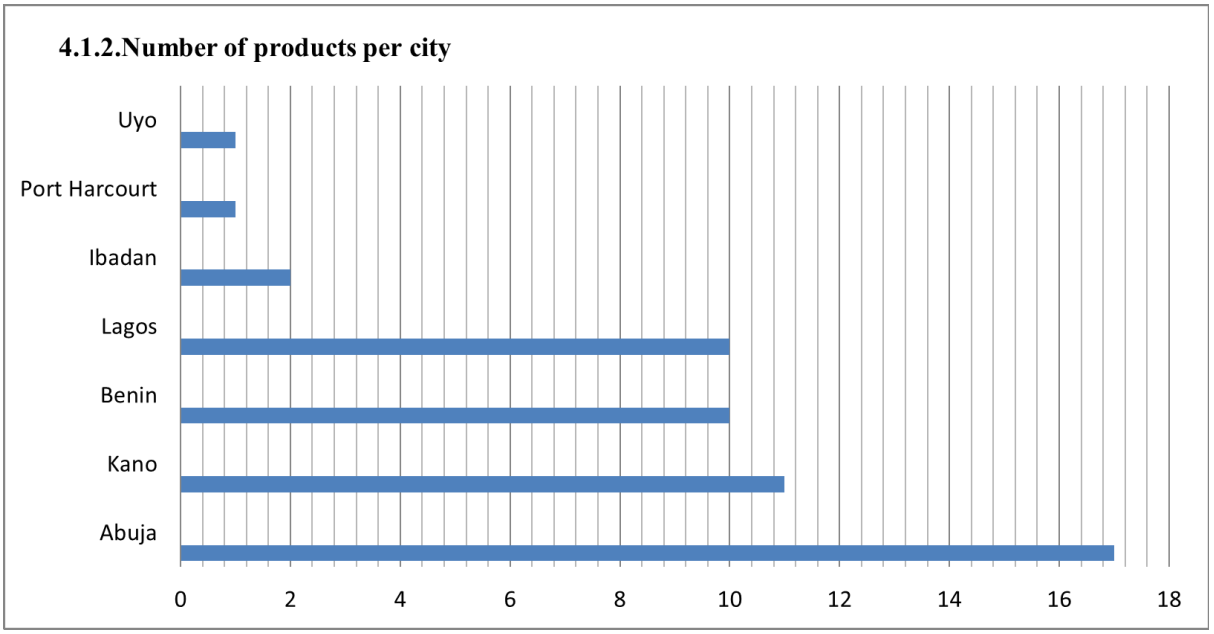
Other ingredients which were noted and are suspected to be linked with genetic modification include: soy lecithin, maltodextrin and aspartame.

**4.2. Number of genetically modified products seen per city**

In each of the cities, many of the products were replicated in more than one shop and some of them were

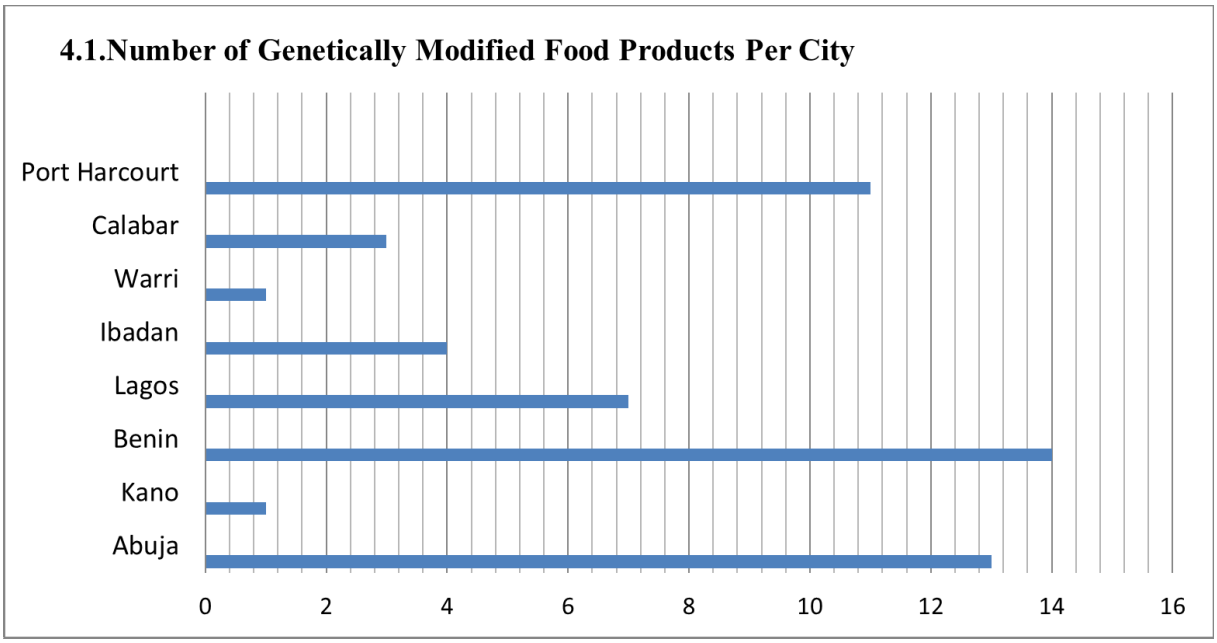
| S/N | City | Number of GM Products Seen |
|---|---|---|
| 1 | Abuja | 17 |
| 2 | Kano | 11 |
| 3 | Benin | 10 |
| 4 | Lagos | 10 |
| 5 | Ibadan | 2 |
| 6 | Uyo | 1 |
| 7 | Port Harcourt | 1 |

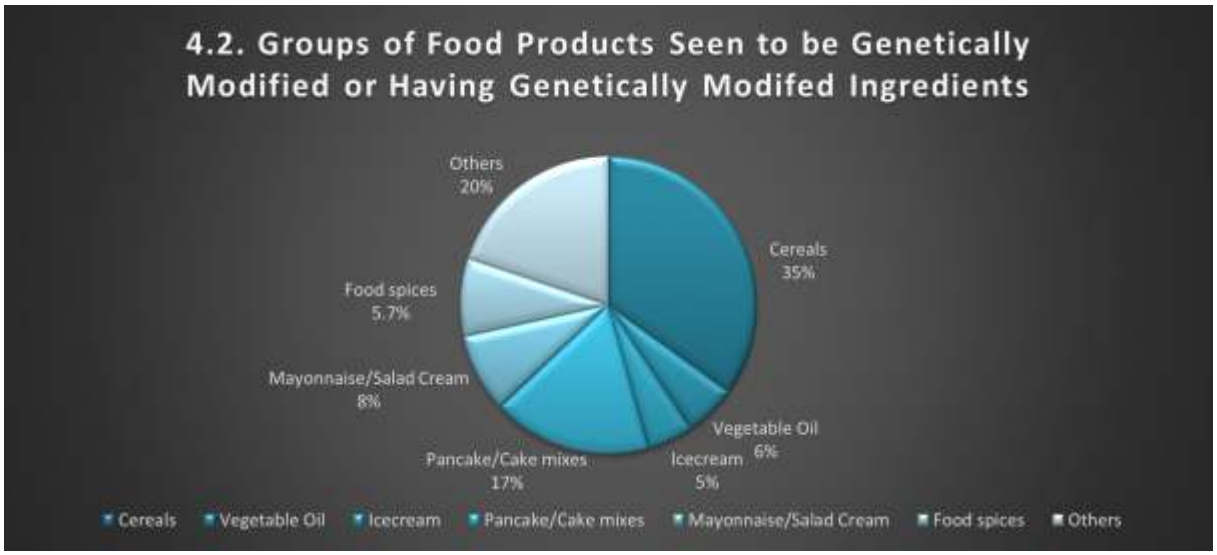
in different flavours (counted once). Also, similar products were identified in more than one city.




Result of Survey in 2019
Number of Genetically Modified Food Products Seen Per City

| S/N | City | Number of GM Products |
|---|---|---|
| 1 | Abuja | 13 |
| 2 | Port Harcourt | 11 |
| 3 | Benin | 14 |
| 4 | Lagos | 7 |
| 5 | Ibadan | 4 |
| 6 | Calabar | 3 |
| 7 | Kano | 1 |
| 8 | Enugu | 1 |
| 9 | Warri | 1 |




- **Implication of GMOs on Biodiversity/Environment and Agriculture in Nigeria**

In Nigeria, it is difficult to immediately trace the implications of GMOs for human/animal health. However, studies have recently shown links between consumption of GMOs and allergic disorders, cancers, and birth defects all of which are on the increase in Nigeria over the past decade since the introduction of GMOs in Nigeria.

Current in-vitro experiments on the Bt Maize (for example) developed by Monsanto have revealed that protein produced by the Cry1Ab gene has toxic effects[73] on human liver cells. Researchers in Italy in November 2008 resolved that the consumption of the Bt maize induced alterations in intestinal and peripheral immune response in mice.

Another study[74] with different investigative process showed that effects (seen in blood cells, adrenal glands, kidney weights etc.) linked with the Bt maize are generally detected after about 4 months of consumption. Additional long-term (up to 2 years) animal feeding studies were recommended.

Besides the short-lived risk assessments which are believed to be mostly concerned with the interactions of the genetic constructs with natural varieties, Nigeria has not conducted long term tests or studies on the implications of GMOs on the health of its population. Scientists generally observe unexpected impacts in and from genetically modified crops and we are faced with intergenerational consequences.

GMOs have serious implications for biodiversity and for the environment in general. Cultivation of the genetically modified variety of cowpea (Bt Cowpea), for example will bring about an irrevocable contamination of the natural and indigenous varieties which have been nurtured over the years by farmers.

Study[75] of pollinator characteristics of the natural West African wild cowpea populations shows that the Bt-gene can pass from the genetically modified lines to non-modified lines resulting to natural cowpea and indeed other plants taking up the resistance trait and causing ecological imbalance.

GMOs do not necessarily yield higher than natural crops. They promote monocultures which in addition to reducing nutritional diversity and ecosystem resilience, leads to land grabbing and thus displace and impoverish small scale farmers. Also, GMOs depend on toxic agrochemicals that degrade soils and ecosystems. Mostly, crops are genetically modified to withstand the use of chemicals (which are manufactured by the same companies producing the modified seeds), such as Monsanto's Roundup Ready which is all over the Nigerian market.

The weeds these chemicals try to kill have however been known to build resistance and become super weeds, requiring higher doses of the lethal constructs. These chemicals do not only kill weeds, they kill other beneficial organisms in the soil and in waters where they may be washed into.
Roundup Ready has glyphosate as a major component and this is carcinogenic.

Thousands of cases have been instituted against Monsanto (and Bayer who bought the company) over the deadly health effects suffered by users of the chemical. As revealed in the market survey, that chemical is in several products all over our markets, complete with NAFDAC numbers.

One of the landmark cases against Monsanto is that of a man named DeWayne Johnson for whom the jury in California ruled that $289.2m[76] later reduced to $7.8m be paid in damages by Monsanto. This ruling by the court and many others against Monsanto are based on the fact that the company failed to warn citizens in the United States of the cancerous effects of the use of the chemical.

Following that case, a jury awarded $2 billion in damages against the company for cancer suffered by a couple who were exposed to the herbicide[77].

Court findings suggested that the presence of glyphosate, a major ingredient in the herbicide, roundup, in food supply has link to increased level of more severe cases of non-alcoholic fatty liver disease (NAFLD) in the USA. In the course of the legal tussle, lawyers showed members of the jury heaps of materials said to show how the manufacturers of the herbicide are manipulating scientific literature, ghost-writing scientific review papers and getting them published and cited as authoritative by policy making agencies like the Environmental Protection Agency (EPA) of that country

On the other hand, some of the GMOs, such as Bt cotton and Bt beans, are designed to kill target pests. They are created by genetically altering their genome to express a microbial protein from the bacterium Bacillus thuringiensis. It is argued that the bacterium is found in soils, is safe and should be no cause for concern but the truth is that the naturally occurring Bacillus thuringiensis is not exactly the same as the one genetically engineered[78]. The natural Bacillus thuringiensis has a shorter half life when exposed to sunlight, but the biotech variant persists with implications and consequences, including for our gut organisms.

Bt Cotton was trumpeted as dramatically reducing the use of pesticides on the crop as they were supposed to kill the target bollworm pests. The crop has failed to kill off bollworms in India and farmers have had to use more pesticides and suffered economic woes as a result of the failure. Cotton farmers in Burkina Faso complained of this failure, besides the fact of poor-quality fibers. It is that failure that is being celebrated in Nigeria with the release of the Bt Cotton here.

For the Nigerian economy, GMOs have significant implications. Presently, the country operates a largely informal system of Agriculture where farmers are free to exchange, save and reuse seeds. Small holder farmers contribute the most (up to 70%) to Nigeria's Agricultural output and therefore they require support in terms of infrastructure, extension service and policies for increased productivity and resilience.

Genetically modified crops favor industrial agriculture and disregards the rights of small scale farmers. Many of the GM constructs come with patent rights that restricts farmers from sharing or reusing seeds, forcing them to purchase seeds and the accompanying chemicals in every planting season.

In the case of the Bt Cowpea, crop diversity (income diversity) is affected as the small-scale farmers usually intercrop cowpea with other cereals, mostly staple crops such as maize, millet and sorghum. The high cost of the seeds and these chemicals threatens the economic resilience of Nigerian farmers. Currently, Nigeria's cowpea is under a ban from the EU (one of our major international cowpea market) because of poor quality and residual chemicals issue. It remains a question as to where the export market for our Bt Cowpea will be[79].

# V. INTERNATIONAL PROTOCOL ON BIOSAFETY

- **The Cartagena Protocol**

The international protocol on biosafety refer to provisions put in place to provide uniform international requirements for ensuring the safe transport and use of products of modern biotechnology. The Protocol offers a framework to guide countries in setting up regulatory systems for products of biotechnology at national level.

The Biosafety Protocol has its roots in of the Convention on Biological Diversity (CBD), - a multilateral treaty for protecting biodiversity - especially Article 19.3 which obliged Parties to the CBD to consider the need for and modalities of a protocol setting out appropriate procedures in the field of the safe handling and use of any living modified organism (LMO)/genetically modified organism (GMO) that may have adverse effect on biodiversity[80].

The international protocol, known as the Cartagena Protocol on Biosafety was adopted on 29, January 2000 as a supplementary agreement to the CBD and it entered into force on 11, September 2003[81]. The Cartagena Protocol recognises for the 1st time in international law that GMOs are inherently different from other naturally occurring organisms and carry special risks and hazards and therefore need to be regulated internationally. It recognises that GMOs may have biodiversity, human health and socio-economic impacts; and that these impacts must be risk assessed[82].

The CBD has three main objectives: conservation of biological diversity, sustainable use of its components and fair and equitable sharing of the benefits arising from the use of the genetic resources. The Cartagena Protocol is one of the tools for implementing the CBD, particularly with regard to regulation, management or risk control associated with transfer, handling and use of LMOs (GMOs) that may have adverse effects on the conservation and sustainable use of biodiversity.

The Protocol established a Biosafety Clearing-House (BCH) to facilitate the exchange of information on LMOs/GMOs and to assist countries in the implementation of the Protocol. It established an advance informed agreement (AIA) procedure to make sure that countries are provided with necessary information to help in decision making before approving the import of such organisms into their territory. The Protocol contains the precautionary principle as an essential component and reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development.

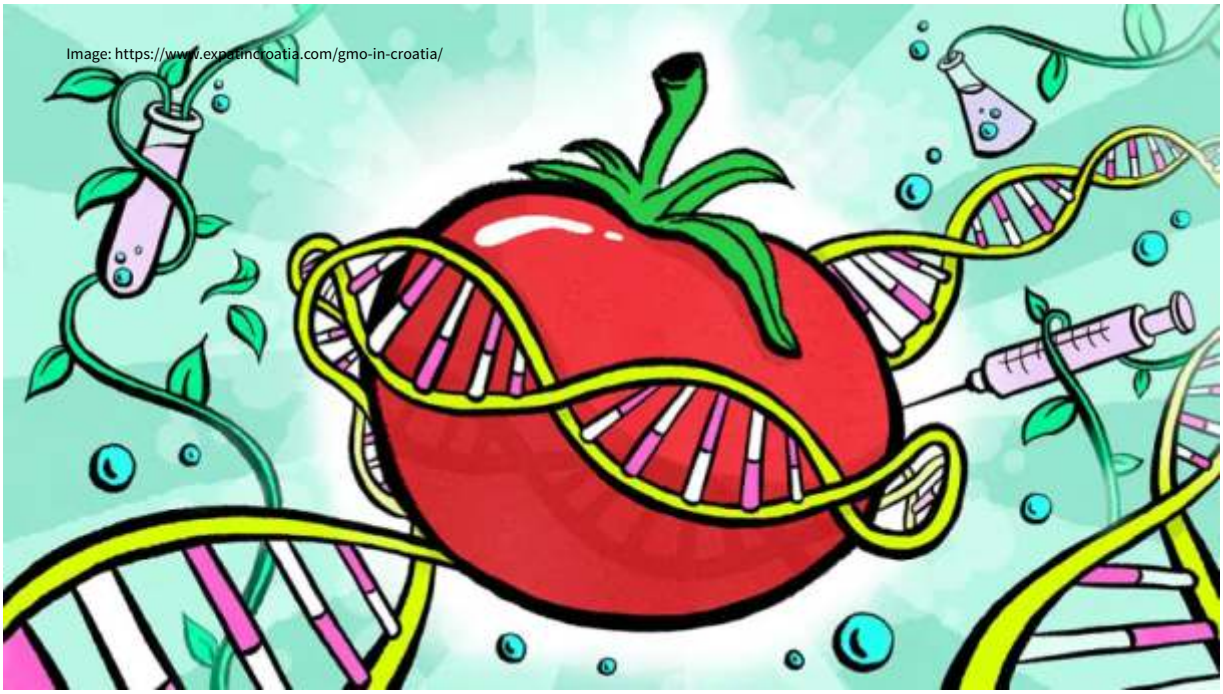
Nigeria is the 111th of the 170 countries that have signed the Cartagena Protocol on Biosafety. While Nigeria signed the Cartagena Protocol on May 24, 2000, the instrument of ratification (rtf)/acceptance (acs) was deposited on July 15, 2003 and the Protocol entered into force in Nigeria on October 13, 2003[84].

**The Precautionary Principle on Biosafety**

The precautionary approach states that where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation[85]. The Precautionary Principle calls for the examination of a wider range of harms including social and economic ones than traditional risk analysis. It points to the need to examine not only single, linear risk but also complex interaction among multiple factors, and the broadest possible range of harmful effects.

The Precautionary Principle is found at five places in the Cartagena Protocol: (i) in the preamble, which states that nations undertake the Protocol reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development; (ii) in Article 1, which declares that the objective of the treaty should be interpreted in accordance with the precautionary approach; (iii) in Article 8 (6), which deals with the decision-making procedure for importing LMOs/GMOs intended for introduction into the environment; (iv) in Article 10 (8), which concerns LMOs/GMOs intended for direct use as food or feed, or for processing; and (v) in Annex II, which elaborates the elements of a proper risk assessment of LMOs/GMOs in Article 15. The Cartagena Protocol contains a strong version of the Precautionary Principle that can be categorised as an operational definition. The Protocol also incorporates the Precautionary Principle into a party's decision-making process under the Advance Informed Agreement (AIA) procedure and gives members the ability to take trade-restrictive action to prevent potential adverse effects of LMOs/GMOs on biodiversity and human health.

For instance, Article 10 (6) of the Protocol provides that: *"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question ... in order to avoid or minimize such potential adverse effects."*[86]




The Precautionary Principle is based on a willingness to take precautions in advance of formal scientific proof, to refrain from actions that might harm the health or the environment, and to shift the burden of proving the safety onto those who want to carry out the action. In this process, issues including the cost effectiveness of the planned action as well as of the non-action, the intrinsic value of biodiversity, and concerns for future generation can be taken into account[87]

There are concerns that Nigeria's National Biosafety Management Agency (NBMA) Act 2015, amended in 2019 does not give priority to the Precautionary Principle, hence the frenzy of approval for products of GMOs with a disregard for the health, environmental and socio-economic implications.

# VI.REGULATORY FRAMEWORK: ASSESSING THE EXISTING LEGISLATION AND REGULATION ON BIOSAFETY IN NIGERIA - THE NATIONAL BIOSAFETY MANAGEMENT AGENCY (NBMA) ACT 2015

**Introduction**

Biosafety remains a controversial subject of discussion globally. The laws and regulations on biosafety to a large extent are still insufficient to ensure biosafety.

Nigeria's journey to the regulatory framework on biosafety started with the signing of the Convention to Biological Diversity on the 13th of June 1992 and ratifying same on 29th of August 1994. Subsequently, Nigeria signed and ratified the Cartagena Protocol, a supplementary to the Convention on Biological Diversity on the 24th of May 2000 and October 13th 2003 respectively.

Although these acts made Nigeria a party to these treaties, the implication was that the treaties did not transform into Nigeria's laws as they were yet to be domesticated.

Hence before 2015, there was no explicit regulation on Biosafety enforceable within Nigeria. However, it could be argued that a community reading of Sections 14, 20, 33 and 34 of the 1999 constitution of the Federal Republic of Nigeria (as amended 2011)[88] could be interpreted to include issues relating to biosafety with regards to the use and transboundary movement of Genetically Modified Organisms. That notwithstanding, failure to formally domesticate the convention and protocol by legislative intervention left gaps in the Nigerian legal system with regards to the use of Genetically Modified Organism and also did not show sufficient commitment of the Nigerian government in transforming these treaties into domestic laws.

**Regulatory Framework in Nigeria**

Shortly before transition of power from the former President Goodluck Johnathan's administration to the Muhammadu Buhari's administration in 2015, the then President Johnathan signed into law a number of bills amongst which was the National Biosafety management agency Act 2015 also known as the Biosafety Act 2015.

The purpose of the Biosafety Act is for the establishment of the National Biosafety Management Agency[89], whose objectives as provided in Section 2 of the Biosafety Act are:

"The objectives of the Agency shall be to:
(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."

The Act domesticated by reference the Convention on Biological Diversity and the Cartagena Protocol. See Section 3 (b) of the Biosafety Act which provides one of the functions of the agency to wit:
***(b) implement the provisions of the Conventions and the Protocols on matters relating to genetically modified organisms***
***The interpretation section of the Biosafety Act, Section 43 defines convention to mean "the Convention on Biological Diversity" and Protocol to mean "Cartagena Protocol on Biosafety to the Convention on Biological Diversity"***

A treaty is said to be domesticated by reference where the implementing statute transform a treaty into the domestic law merely by reference either to nomine or generally. According to Prof Akin Oyebode, The main question raised by this method (of domestication of treaties) concerns whether or not and to what extent courts can depart form the text of the implementing statute in case of ambiguity or mistake in its wordings[90].

The Board in exercising powers conferred on it by sections 41 of the National Biosafety Management Agency Act, 2015 ("the Act") made the National Biosafety (Implementation, Etc.) Regulations, 2017. Section 1 of the Regulation provides: The objectives of these Regulations include, to-
***(a) complement and enhance the provisions of the Act;***
***(b) provide details of regulatory and supervisory requirements necessary to promote and aid the efficient and profitable implementation of the provisions of the Act ; and***
***(c) facilitate the attainment of the goals for which the Agency is established in Nigeria***

The signing into law of the Biosafety Act 2015 and the domestication by reference of the convention and protocol seeks to fill the gaps in the legal system with regards to Genetically Modified Organism and provides regulation of the use thereof. However, within the Biosafety Act itself, are loop holes that can create room for abuse of administrative powers and make allowance for gross injustice against the people of Nigeria.

In order to fully appreciate the thoughts in this report, it will be important to look briefly at the Convention and Protocol as well as the principles to ensure Biosafety. Thereafter the particular sections of the Biosafety Act will be examined vis a-vis the objectives of the Convention and Protocol as well as the principles.

**Convention on Biological Diversity**

The Convention on Biological Diversity (CBD), known informally as the Biodiversity Convention, is a multilateral treaty. Paragraphs 8 and 9 of the preamble states:

***"Noting that it is vital to anticipate, prevent and attack the causes of significant reduction or loss of biological diversity at source,***
***"Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat."***

The Convention outlines three main goals in Article 1 of the convention including: the conservation of biological diversity (or biodiversity); the sustainable use of its components; and the fair and equitable sharing of benefits arising from genetic resources.

In other words, its objective is to develop national strategies for the conservation and sustainable use of biological diversity. It is often seen as the key document regarding sustainable development[92].

As of 2016, the Convention had 196 parties, which includes 195 states and the European Union. All UN member states—with the exception of the United States—have ratified the treaty. Non-UN member states that have ratified are the Cook Islands, Niue, and the State of Palestine.

The Holy See and the states with limited recognition are non-parties. The US has signed but not ratified the treaty, and has not announced plans to ratify it[93].

**Cartagena Protocol to the Convention on Biodiversity**

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. It was adopted on 29 January 2000 and entered into force on 11 September 2003[94].

The Protocol contains reference to a precautionary approach and reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development. The Protocol also establishes a Biosafety Clearing-House to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol.

**Core Principles of Biosafety**

The general principle for biosafety is the Precautionary Principle. The precautionary principle was defined in

Principle 15 of the Rio Declaration which was referenced in Objective 1 of the Cartagena Protocol.

Objective 1 of the Cartagena Protocol provides that

***"In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."***

The referred principle 15 of the Rio Declaration states

***"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation"***

Hence from these it can be deduced that the elements to precautionary principle are:

1. Anticipatory action: Duty to prevent harm
2. Right to know: access to relevant information from the applicant.
3. Alternative assessment: a full range of alternatives must be examined.
4. Full cost accounting: the cost involved in deployment of the technology and cost of containment in event of any adverse effect
5. Participatory decision process: which must be democratic and in accordance with the rule of law

The precautionary approach entails risk assessment, risk management and risk communication.

**Assessment of the Legislation and the Regulation**

This report is focused on the areas that could create issues in the implementation of the legislation and the regulation such as: constitutionality of the method of domestication; wide discretionary powers and public participation; agency structure and possible conflict of interest; liability and redress; room for regulatory capture; and right of appeal.

**Constitutionality of the Method of Domestication**

While by virtue of Section 3(b) of the Biosafety Act 2015, the act domesticates the convention and protocol by reference, it can be also be argued that it is inconsistent with the provisions of section 12 of the 1999 constitution. Section 12 provides:

***No treaty between the Federation and any other country shall have the force of law except to the extent to which any such treaty has been enacted into law by the National Assembly***

The question is if domestication by reference is constitutional. This may create a legal limitation in the implementation of biosafety norms domestically[95].

In the Supreme Court case of General Sani Abacha & 3ors V Chief Gani Fawehinmi[96], the court held that no treaty can be said to come into effect in Nigeria unless the provisions of such treaty have been enacted into law by the Nigerian Government through the National Assembly. According to Justice Uwaifo, JSC
"Where we have an international treaty of this nature, it only becomes binding when enacted into law by our National Assembly… it is only such law that breathes life into such a treaty in Nigeria"
This has left the onerous burden of interpreting the biosafety norms contained in the convention and the protocol referred on the courts.

According to Prof. Oyebode[97], the main question raised by this method (of domestication of treaties) concerns whether or not and to what extent courts can depart form the text of the implementing statute in case of ambiguity or mistake in its wordings. However, considering the operating word used in section 3, which is "Shall", there is a mandatory obligation on the Biosafety agency to at all time implement the provisions of the Convention and the Protocol, although potential debates could have been avoided if the Convention and Protocol were domesticated by enactment in line with section 12 of the 1999 constitution of the Federal Republic of Nigeria as amended (2011).

**Wide Discretionary Powers and Public Participation**
Discretion is important in every administrative process as it allows innovative and creative decisions.

However, discretion without boundaries would tamper with the fundamental rights of the people.
According to Justice Douglas of the United States Supreme Court:
"Where discretion is absolute, man has always suffered … Absolute discretion … is more destructive of freedom than any of man's other inventions"[98] And further:
"Absolute discretion, like corruption, marks the beginning of the end of liberty.[99]"

The actions of public authorities therefore are viewed through the prism of rule of law in general and fundamental rights guaranteed in the Constitution in particular[100].
The drafters of the Biosafety Act 2015 gave wide discretionary powers to the Biosafety Agency especially with regards to public participation.

Section 25 of the National Biosafety Management Act provides
**"(1) The Agency shall upon the receipt of the application and the accompanying information under section 23 of this Act, display copies of such application and relevant information at such places and for such period as the AGENCY MAY, from time to time determine to enable the general public and relevant government ministries and agencies study and make comments on the application and relevant information within 21 days.**
**(2) THE AGENCY MAY, prior to the**

**national and one local newspapers, the national Biosafety clearing house or such other news media as the agency may from time to time determine, giving summary of the application and brief information on the place, duration and time for the display"**

Public participation in the decision making process of administrative agencies is part and parcel of democracy that ensures accountability and transparency. Furthermore, access to information in informing the public of any application is also a key element.

The issue with section 25 as cited above is that excess power is granted to the agency to determine the way the public access information. First, the agency can decide where to display the information. Considering the size of Nigeria both geographically and population it's unwise to leave this at the discretion of the agency.

The Act should specify the places where this information should be displayed and it should be wide enough for the reach of every Nigerian. Secondly, the period to display is also left to the discretion of the agency. Again, the Act should specify this and give a good time frame. Thirdly, publication should be made mandatory. Newspaper publication is a good means to make the public aware of an application.

Publication should be made mandatory and if the issue is the burden of cost, then the applicants should bear the burden of cost. Whichever way, publication should not be made a discretionary issue. Lastly, nothing is said about what happens to comments that oppose the application. The Act should make provision for this in line with the principles of rule of law and precautionary measures. There must be an obligation to properly respond to comments especially if such comments are objections. The Act should make provisions for this.

**Agency Structure and Possible Conflict of Interest**

Section 10 includes the National Biotechnology Development Agency (NABDA) in the governing Board of the Biosafety agency. The mandate of NABDA is "Promotion, coordination, and deployment of cutting-edge biotechnology research & development, processes, and products for the socio-economic well-being of the nation". So the promoters of the technology are part of the board of the regulators. It is irrelevant that the agencies are both government agencies. For the purpose of transparency that should not be so. The appointment of members of the NBTC is done by the agency. Hence in the risk assessment process it is possible for NABDA to influence the outcome of the risk assessment.

Section 32 of the Biosafety Act 2015 which provides:
***No person, shall be involved in a risk assessment review by the Agency in respect of a subject matter in which:***
***(a) he has direct or indirect interest of any kind; or***
***(b) there is likely to be conflict of interest as a result of his participation in the risk assessment process.***
Section 10 should be reviewed to exclude promoters of the GMO in the governing board of NBMA.

**Room for Regulatory Capture**

Regulatory capture is a corruption of authority that occurs when a political entity, policymaker, or regulatory agency is co-opted to serve the commercial, ideological, or political interests of a minor constituency, such as a particular geographic area, industry, profession, or ideological group.

When regulatory capture occurs, a special interest is prioritized over the general interests of the public, leading to a net loss for society. Government agencies suffering regulatory capture are called "captured agencies.

Section 18 of the Biosafety Act is dangerous and can lead to regulatory capture. It provides:
***(1) The Agency may, accept gifts of land, money or other property or things from within and outside Nigeria, on such terms and conditions, if any as may be specified by person or organization offering the gift.***
***(2) The Agency shall not accept any gift if the terms and conditions attached by person or organization offering the gift are inconsistent with its functions under the Act.***

**Liability and Redress**
The standard of liability and redress used in section 41(1) a) is fault- based.
***41. (1) The Board may, on the recommendation of the management of the Agency, make regulations generally for carrying into effect the provisions of this Act:***
***(a) handling, transporting, packaging; fault-based liability and redress for damages from the activities of modern biotechnology and genetically modified organisms. Liability and Redress for a damage that occurs as a result of an activity under this ACT is subject to applicable laws; and…***

Fault based is a type of liability where the Plaintiff or the person asserting a wrong must prove that the alleged doer-of-the-wrong's conduct was either negligent or intentional. In this case, a person conducting GMO related activity is liable for damage when such a person is at fault or acted negligently, as against strict liability wherein a person conducting GMO related activity becomes liable, irrespective of any fault or negligence. Strict liability is the opposite of the fault based liability[101].

The burden is placed on the person conducting a GMO related activity to prove that it is not his/her fault or he/she did not act negligently. It imposes liability on a party without a need to prove the fault of the party. This is consistent with the principle of precautionary measure.

Without an effective liability regime for holding proponents of GMO related activities liable for their actions, room will be given for Regulatory capture. We recommend a standard of strict liability.

**Right of Appeal**

Every affected party in any proceeding whether administrative or judicial should have a right of appeal over any decision given. The Biosafety Act seems to restrict the parties to administrative process of the Biosafety Agency to just the Applicant alone.

***Section 30 (1) of the Biosafety Act states:***
***Any applicant who is aggrieved by any decision of the Agency under sections 24 and 25 of this Act may appeal to the Board to reconsider that decision, stating his grounds of appeal, including any additional information***

This seems to deny any other interested party the locus standi to appeal against any decision of the Biosafety Agency. This is against **section 36 (2) of the 1999 constitution of the Federal Republic of Nigeria** which provides:

> ***Without prejudice to the foregoing provisions of this section, a law shall not be invalidated by reason only that it confers on any government or authority power to determine questions arising in the administration of a law that affects or may affect the civil rights and obligations of any person if such law -***
> ***(a) provides for an opportunity for the persons whose rights and obligations may be affected to make representations to the administering authority before that authority makes the decision affecting that person; and***
> ***(b) contains no provision making the determination of the administering authority final and conclusive***

Section 30 (1) offends the provision of Section 36 (2) (a) of the 1999 Constitution. It also is not consistent with the principle of precautionary measures contained in the convention and protocol.

This should be amended to include every person affected by a decision of the Biosafety agency.

The coming into law of the Biosafety Act 2015 is a mile stone in fulfilling Nigeria's obligation to the Convention on Biological Diversity as well as the Cartagena Protocol.

However, what good is the law when what it leaves room and loop holes that encourages what it seeks to protect against? Hence, the Biosafety Act should be amended to fill the gaps above. Also, litigation in these areas should be encouraged in order to get the Courts involved in bridging gaps and clearing ambiguities that the Biosafety Act 2015 has created.

HOMEF has filed a suit[102] against NBMA, NABDA, Monsanto Agricultural Nigeria Limited and others with regards to permits for introduction of Genetically Modified Organisms (GMOs) – Maize and Cotton - into Nigeria. The case was mentioned at the Federal High Court, Abuja, on 20 January 2021 with both parties present and ready for hearing but the court excused the proceeding for lack of time.
The case seeks a declaration that the Bt cotton (MON 15985) and maize (1) NK603 & (2) MON89Q34 x NK603 supplied by Monsanto and approved by the NBMA for commercial release and confined field trial respectively in Nigeria contravene the fundamental rights to life and human dignity of Nigerians.These rights are guaranteed under Section 33 and 34 of the 1999 Constitution (As Amended) and Article 4, 5, 16 and 24 of the African Charter on Human and Peoples' Rights (Ratification And Enforcement) Act.

Also, the case seeks a declaration that the continuous refusal by NBMA and Monsanto to provide scientific evidence to dispel fears of the applicants as contained in the Exhibits presented in court infringes on the fundamental rights of the applicants as guaranteed under the Nigerian Constitution and aforementioned Act.

The case was first filed in the Federal High Court of Justice, Abuja in 2017 but was struck out, not for lack of merit or Cause of Action but for technical reasons. The case was, however, resumed in 2018 as a matter of fundamental human rights and has been rescheduled for hearing at the Federal High Court of Nigeria on 17 May 2021 after several shifts on hearing dates. It is hoped that justice will be served soon and the rights of the people of Nigeria and of the environment upheld.

# VII. CONCLUSION

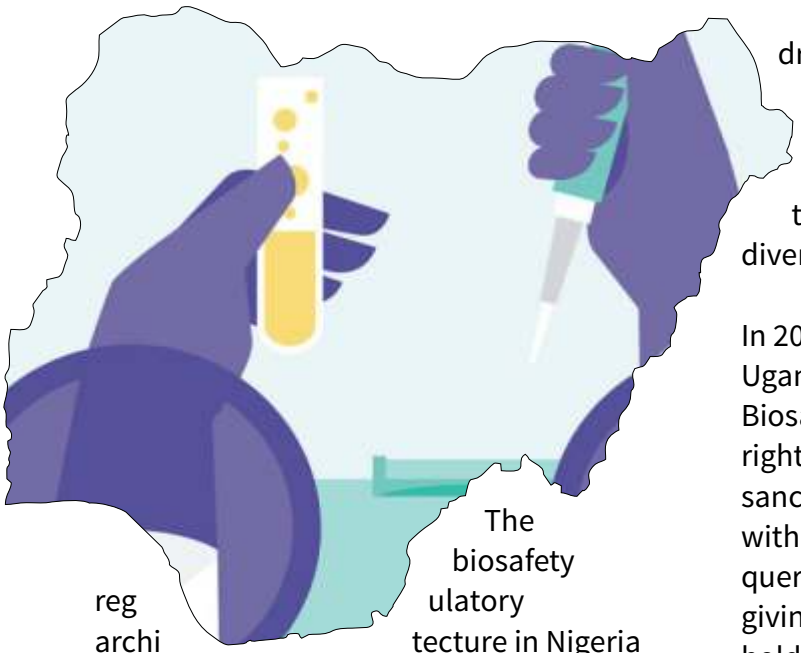
The potential health, socio-economic, cultural and ethical impacts of GMOs are enormous and diminish the positive impacts of small holder farmers who are feeding the country; promoting cultural practices, community well-being, traditional crops and varieties; reducing rural unemployment; engendering trade; raising the quality of life of indigenous peoples; and re-affirming food security.

The concern about Genetically Modified Organisms is not only about their safety for consumers. We are equally concerned about the more damaging systematic appropriation of the rights to seeds by transnational corporations that deprives farmers of their traditional rights to seeds, in favor of patents by these corporations.

Nigeria's fertile land guarantees the nation food sovereignty. By food sovereignty we mean the situation where all people at all time have access to food that is healthy, nutritious, culturally appropriate and which is produced using ecologically sound measure. Food sovereignty promotes the rights of food producers to and consumers to define and control what they eat and how that is produced.
Consequently, hunger in Nigeria is due to bad governance, poor infrastructure for preservation and distribution of food and lack of adequate all-round support to small holder farmers who constitute over 70% of the farmers in Nigeria. Our Government needs to invest more in agriculture and wield support for farmers producing food using ecologically sound methods.

Nigerians should be worried about the prevalence of the herbicide, Roundup and other glyphosate containing chemicals in our markets. Monsanto-Bayer claims that the chemical is safe when applied as prescribed by them including by being suited up as though you were headed for a space flight. With lax industrial practices, our farmers are not following those prescriptions. Even with the best adherence to the prescriptions in the USA, the results are that farmers and others that are exposed to the poison are not safe.

We have had fair warning that things can go deeply wrong if humans continue to toy with the genetic makeup of living organisms – especially in efforts to concentrate power and profit. This is evident in the outbreak and spread of pandemics such as COVID-19. We must desist from interfering with Nature. When humans engineer crops to make them act as pesticides, Nature offers super pests or superbugs. When toxic herbicides are produced to kill all other crops except the ones genetically engineered to withstand them, Nature responds by offering superweeds.



The biosafety regulatory architecture in Nigeria needs an overhaul to close the fundamental gaps it has and protect the people. We have a biosafety regulatory agency that disrespects the voices of the people, ignores national interests and blatantly promotes the interests of biotech corporations and marketers.

The relationship between National Biosafety Agency (NBMA), National Biotechnology Development Agency (NABDA) and Monsanto is rife with conflict of interest against the Nigerian people. This is highlighted in the fact that NABDA (a major promoter of GMOs in Nigeria) sits on the Board of NBMA, and as a co-applicant with Monsanto got approval for the application for commercial release of Bt Cotton in Nigeria.

It is instructive for our policy makers to learn from the experience of Burkina Faso and a host of other countries that are rejecting the GMOs and the false gospel of agricultural development.

In 2002 Zambia in the face of a severe drought rejected genetically modified corn as food aid, insisting that it must be milled. This radical stand was taken because they understood the implication of GMOs on genetic diversity.

In 2019, the President Yoweri Museveni of Uganda turned down the nation's Biosafety Bill for issues related to patent rights of indigenous farmers and sanctions for scientists who mix GMOs with indigenous crops and animals. He queried that “this law apparently talks of giving monopoly of patent rights to its holder and forgets about the communities that developed the original material,” although genetic engineering may make it possible to add additional qualities – such as drought resistance, quick maturity, disease resistance

The Ugandan president noted that the bill ignored the roles of the local farmers who had preserved the original seeds over the years and cautioned that “to be on the safe side, GMO seeds should never be randomly mixed with our indigenous seeds just in case they turn out to have a problem.”

In 2020, with a bold headline, “National well-being wins over foreign interests as gov't ditches GMOs”, a report announced that the government of Ghana, through the Minister of Food and Agriculture was terminating the imposition of GMOs on farmers in the country. The minister was paraphrased to have said that “the nation has capable scientists who could use traditional breeding methods to produce high yielding varieties and disease resistant plants for cultivation by farmers and no need for GMOs in the next 100 years in Ghana.”

Early in 2021, the Minister of Agriculture in Tanzania, Prof Adolf Mkenda, announced t[103]he cancellation of research trials involving genetically modified organisms (GMOs) in the country and the decision to put in place extra biosafety scrutiny of imported genetically modified (GM) seed. The decision was taken by the Minister in order to conserve the country's genetic resources and local seed[104].

In the global north, GMOs have been permitted under the condition that they are labeled. It is clear that because of our socio-cultural setup it is impossible to effectively label GMOs in Nigeria. For the Bt Cowpea that has been approved for commercial release, we know that no one will use GMO labeling on their products so citizens can make a choice between eating akara or moi moi made from this variety of beans.

Our people will eat cottonseed cakes and oils without the slightest inkling that they are consuming GMOs. The market shelf survey for GMOs revealed the presence of several products containing genetically modified organisms or made with genetic engineering. The question remains as to if these products pass through the approval processes before they are being sold to our people.

Although this report focuses on the basic genetic modification of crops, we keep an eye on new extremes biotechnologies that have emerged; on genetic engineering techniques such as gene editing that do not involve transference of genetic materials between species. Whereas the first generation GMOs tried to reduce the need to weed frequently or to kill off pests, the new variants, among other things, are essentially extinction GMOs.


Products like ogi made from Bt corn will not be labeled by the market woman. The roasted corn sold by the roadside will not realistically be labeled.

They are prone to being weaponised and introduce traits with unpredictable and dire consequences for the future.

Our government has recently approved guidelines on gene editing. This move, although on the surface should be applauded, is actually a rigged pathway to make our environment the test ground for the risky and needless experimentation.  From our experience with genetically modified food crops in Nigeria, having the provisions in place to regulate the release of such organisms is equivalent to express permits for their introduction as the agency responsible for this regulation acts more like a promoter of the technology than a regulator. Nigeria must show leadership in the protection of African biodiversity and not allow an agency of government run amok with whatever technologies promoters suggest to it. Requests by HOMEF for a copy of the guideline has been met with silence.

The COVID-19 pandemic has taught us lessons on the importance of preserving biodiversity; of building local economies and of strengthening resilience at grassroots levels. We are presented with an opportunity to make radical changes with our food systems to enable optimum productivity as well as ecological restoration. It is time for our government to wake up to the threats tobiosafety in Nigeria and strengthen the regulatory architecture to protect the interest of our people against the forces of colonialism.

# VIII. RECOMMENDATIONS

Based on the findings of the research into the state of biosafety in Nigeria as outlined in the different sections above, the following recommendations are made to encourage policy review and actions to preserve genetic diversity, human and environmental health as well as ensure economic resilience.

1. Biosafety is multi-sectorial and multidisciplinary in application. There should be synergy and synchrony in biosafety responsibilities among and between the various ministries, departments and agencies (MDAs) for effective regulation in Nigeria.
2. The National Biosafety Management Agency (NBMA) Act 2015 and as amended in 2019 should be urgently reviewed to close the existing gaps and to ensure it protects the interests of the Nigerian people. HOMEF has drafted a review of the Act[105]. This should be taken up by the National Assembly.
3. Section 10 of the Act should be reviewed to exclude promoters of GMOs in the governing board of NBMA.
4. The Act should specify the places where information about application for GMOs permits should be displayed and this should be wide enough for the reach of every Nigerian. Secondly, publication of such applications should be made mandatory.
5. The fault based liability clause in the Act should be replaced with a standard of strict liability. Without an effective liability regime for holding proponents of GMO related activities liable for their actions, room will be given for Regulatory capture.
6. There must be an obligation to properly respond to comments/objections to applications for GMOs permits. The Act should make provision for this in line with the principles of rule of law and precautionary measures.
7. Section 30 (1) of the Act offends the provision of Section 36 (2) (a) of the 1999 Constitution. It also is not consistent with the principle of precautionary measures contained in the convention and protocol. This should be amended to include every person affected by a decision of the Biosafety agency.
8. Litigation should be encouraged in order to get the Courts involved in bridging gaps and clearing ambiguities that the Biosafety Act 2015 has created.
9. Ethical principles should be applied to every class of scientific experiments and research where biosafety risks threaten public health since there is no doubt that scientific processes and products may have negative consequences.
10. Scientists should make informed reflective judgments, taking the likelihood and magnitude of reasonably foreseeable harms and benefits of research into account. The ability of scientists to make such judgement should be enhanced through relevant education regarding bio-risks, biosafety and laboratory biosecurity, and ethics.

11. As new technology-related ethical challenges continue to arise, ethical requirements should be readjusted to make them stricter and enhanced by policy contexts that promote responsible innovation.
12. More efforts should be made towards increasing and strengthening theoretical and practical based training to enhance the quality and quantity of scientific research in Nigeria which responds to the real needs of the people.
13. The Convention on Biological Diversity and the Cartagena Protocol should be domesticated by enactment in line with section 12 of the 1999 constitution of the Federal Republic of Nigeria as amended (2011). This will eliminate legal limitation in the implementation of biosafety norms in Nigeria.
14. Permits already granted for importation and use of GMOs in Nigeria should be withdrawn to avert the intended and unintended implications for our health, environment and economy.
15. Nigeria has vast human and natural resources. With adequate support for our small scale farmers in terms of infrastructure, timely credit schemes, extension service, access to land and irrigation services etc., Nigeria can increase productivity, reduce waste and strength our local economy.
16. Agroecology is central to achieving food sovereignty. As a system of agriculture that nourishes agroecosystems, is less dependent on fossil fuel energy, respects grassroots farmers knowledge and participation and uses divers ecological practices, Agroecology has the potential to optimally improve food productivity and help with mitigation and resilience to climate change.
17. The government should discourage the use of inorganic fertilisers, pesticides and herbicides especially Roundup Ready and the glyphosate containing formulations which have dire implications for human health and ecosystem balance.
18. Long term, independent risk assessment covering environmental, health and economic impacts including animal studies should be carried out on GMOs. We cannot rely on data from the same actors promoting GMOs.
19. Nigeria should critically examine emerging technologies promoted either for food or climate change. Solutions which destroy biodiversity and put local economies and grassroots people at a disadvantage are no solutions at all.
20. Research institutes in Nigeria should be adequately funded to encourage local innovations/solutions.

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Section 14(principle of democracy and social justice: partici pation of the people in the governmental process) and section 20 (safety of environment) read together with sections 36 and 33 & 34 respectively. African charter on peoples and human rights Act, Articles 4(life), 5(human dignity), 7(fair hearing), 24(environment)

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# ABOUT HOMEF

Health of Mother Earth Foundation (HOMEF) is an ecological think tank and advocacy Organization founded in the year 2011, with head office in Benin City and branches in Abuja (Nigeria), Juba (South Sudan) and Lome (Togo). Nigeria is our base but Africa is our focus.

HOMEF works to bridge the yawning gap between policy/decisions made by governments and the actual needs at the grassroots. Our main thrust is examining the roots of exploitation of resources, peoples and nations. We nurture movements for the recovery of memory, dignity and harmonious living with Mother Earth.
We recognise that global crises have systemic roots and the current paradigm of development and growth based on competition will lead to the critical destruction of biodiversity and continued destructive extraction of natural resources as well as dependency on risky technologies.

HOMEF believes in the rights of Mother Earth, the need to equip communities to push back oppression and the need for justice for the environment, our food systems and natural cycles at every level of policy engagement. We believe in contextual solutions over externally generated and imposed ideas and we are firmly rooted in the ideals of solidarity and dignity.

Our core values are: justice and equity in all circumstances; people and the planet in harmony and free from exploitation; dignity; solidarity and knowledge. HOMEF uses the platform of sustainability academy, community dialogues and workshops, ecological defence, popular direct actions and litigation as tools in the struggles for environmental and food justice.

Our work includes collaborations with community people, policy makers, media, students, the academia, farmers/fisher folks across Nigeria and Africa.

HOMEF
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# SOME OTHER PUBLICATIONS BY HOMEF

- Eco-Instigator (quarterly journal)
- Threat to Fisheries in the Gulf of Guinea
- Assessing Clean Drinking Water Availability in Juba, South Sudan
- Resource Democracy
- Living in Fear-Juan Lopez Villar
- Community Dialogue Guide (Oil/Gas)
- Community Dialogue Guide (Forest)
- Community Dialogue Guide (FishNet)
- Not on our Plates: Nigeria Does Not Need GM Food
- Community Dialogue Guide (Food and Farming Systems)
- Oil Politics: Echoes of Ecological Wars-Nnimmo Bassey
- Community Guide to Environmental Monitoring and Reporting
- Oil, Power and a Sign of Hope-Klaus Steiglitz with Sabine Pamperrien
- Nigeria's Biosafety Management Agency Act 2015: In Whose Interest?
- Resistance to the Military-Corporate Wedlock in Nigeria and Beyond-Nnimmo Bassey (With TNI)
- To Mint an Illusion: Economic + Poverty Growth in an Extractive Rentier State - Nnimmo Bassey and Patrick Bond
- Beyond Oil: Reimaging Development in the Niger Delta-Ken Henshaw, Ify Malo, Irikefe V. Dafe, Nnimmo Bassey
- Who Benefits from Corona – A Breakfast with Mr. Gates (2020)
- Blue Economy Blues – HOMEF introduction to the Blue Economy (2020)
- Threat to Fisheries in the Gulf of Guinea (2020)
- A guide to Aquatic Ecosystem Monitoring, Reporting, Organizing & Advocacy (2020)