

**Required Report:** Required - Public Distribution

**Date:** November 25, 2022

**Report Number:** NI2022-0010

**Report Name:** Biotechnology and Other New Production Technologies  
Annual

**Country:** Nigeria

**Post:** Lagos

**Report Category:** Biotechnology and Other New Production Technologies

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**Report Highlights:**

Nigeria has taken an increasingly active role in biotechnology research and development in Africa – spurred by the solid support of the Government of Nigeria (GON). In September 2022, Nigeria hosted regulators from Mozambique and Ethiopia to learn more about Nigeria’s biotechnology regulatory experience.

## ***EXECUTIVE SUMMARY***

Nigeria's biotechnology sector is growing and has great potential to bolster agricultural-led growth. The government has identified biotechnology as one of the vital pillars of agriculture-led development. As a result, Nigerian scientists use advanced technological tools like genetic engineering in crop production to generate economically viable crop yields for farmers. Increasing crop productivity is critical in meeting the country's food security needs - as the country's population increases by 2.6 percent annually.

The agricultural sector is not highly developed; it accounts for around 23 percent of the GDP and employs roughly 35 percent of the population. Climate change is affecting crop yields across the country's agricultural ecosystems. Agriculture in Nigeria is highly vulnerable to climate change and associated shocks due to higher temperatures, prolonged droughts, floods, and other conditions. Biotechnology offers new tools for increasing farm productivity and protecting food crops from climate changes such as heat, floods, and drought.

Currently, Nigeria is a continental leader in biotechnology development and research. The country has hosted several African scientists to learn about ongoing policy and regulatory changes in biotechnological development. In 2001, Nigeria established the National Biotechnology Development Agency (NABDA) to promote, commercialize, and regulate biotechnology products. The country also signed the biosafety bill into law, establishing the National Biosafety Management Agency (NBMA), which assumed biotech regulatory authority from the NABDA in 2015. The NBMA is Nigeria's focal point and authority on biosafety, providing oversight for the use of biotechnology and regulating the commercialization of biotechnology products. In December 2020, the Government of Nigeria, through the NBMA, authorized guidelines on gene editing. Nigeria takes this historic step in becoming the first country in Africa to issue gene editing guidelines.

Meanwhile, the government is advancing and commercializing agricultural biotechnology as a tool to achieve food security. Nigeria officially has two approved commercialized products - its first biotechnology crop, *Bacillus thuringiensis* (Bt) cotton, was commercialized in 2018. and Bt. cowpea (Pod-Borer Resistant Cowpea PBR cowpea; AAT709A) was released for commercialization in January 2019. There are eight (8) crops that are in different developmental stages.

In July 2022, NBMA approved GE wheat imports from Argentina. Nigeria became the latest country to authorize the use of GE wheat in food and feed after Brazil, Colombia, Australia, and New Zealand. Amid this situation, civil society groups are intensifying their anti-GE campaigns. However, anti-GE messaging is not resonating with farmers, who generally have positive attitudes toward biotechnology.

Biotechnology releases in the past reports can be found in:

<https://www.fas.usda.gov/data/nigeria-grain-and-feed-annual-5>

<https://www.fas.usda.gov/data/nigeria-oilseeds-and-products-annual-1>

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## **CHAPTER 1: PLANT BIOTECHNOLOGY**

### **PART A: PRODUCTION AND TRADE**

**a. PRODUCT DEVELOPMENT:** The National Center for Genetic Resources and Biotechnology (NACGRAB) was established in 1987 by the Nigeria Federal Ministry of Science and Technology (FMST) to conduct research, gather data, and disseminate technical information on matters relating to genetic resources conservation, utilization, and biotechnology applications. The central government, backed by Decree 33 of 1987, regulates the seed, livestock, and fisheries industries through the Varietal Release Committees. Nigeria, over the next five years, is seeking to develop and commercialize new genetically engineered (GE) crops:

**i. Herbicide Tolerant Soybeans Project in collaboration with Michigan State University (MSU), USA and National Cereals Research Institute (NCRI), Badeggi, Niger State.**

The field trial aims to evaluate two glyphosate formulations (Roundup Ready MSU lines, E14086 and E14017). Glyphosate-tolerant soybean will be compared to leading Nigerian commercial varieties. Weed management is one of the major problems militating against the large-scale soybean production in Nigeria. The introgression of herbicide tolerance (HT) genes into Nigerian commercial varieties will help to alleviate the struggle and cost of weed management. Effective weed control resulting from the adoption of this technology would boost the soybean yield and productivity in Nigeria.

Objectives:

1. To screen HT soybean varieties with leading Nigerian commercial varieties.
2. To backcross HT soybean with leading Nigerian commercial varieties.
3. To check for stability and efficacy of HT gene against glyphosate in subsequent backcross progenies of soybean.
4. To commercialize and popularize improved HT soybean varieties.

Confined field trial is currently being carried out at National Agricultural Biotechnology Agency (NABDA) field in Abuja.

- ii. Tomato Project:** This project is carried out in collaboration with International Institute of Tropical Agriculture, IITA, Ibadan. There are two components of this project: A) Shelf-life increase; and B) Adoption of GE /NABDA Hybrid Tomato.
- iii. NEWEST Rice:** The rice is stacked with nitrogen-use efficiency, water-use efficiency, and salt tolerance (NEWEST) traits. The project develops and disseminates preferred and locally adapted rice varieties to small-holder farmers across Sub-Saharan Africa (SSA).

The proof-of-concept on NEWEST Rice has been done through select farmers who have worked on introgression and backcrosses projects. The results indicated 10-15% improvement in yield, 30% reduction in nitrogen use, and 15% decrease in total production costs.

Multi-locational trials have been completed and deregulation date is being prepared.

- iv. **Virus Resistant Cassava (VIRCA) Plus Project:** This project is in collaboration between the National Roots Crops Research Institute (NRCRI) in Umudike and the Donald Danforth Plant Science Centre in the United States. The latter completed CFT at Umudike. Multilocational trials is due to commence next year.

Building on the successes of earlier projects, the VIRCA Plus collaboration is addressing these nutritional challenges by developing and delivering two cassava varieties, one for East Africa and the second for Nigeria and other West Africa countries. The Nigerian VIRCA Plus product is a cassava variety with elevated levels of iron and zinc for improved nutrition, as well as disease resistance.

- v. **Africa Biofortified Sorghum (ABS) Project.**

The ABS project seeks to address the following UN Sustainable Development Goals (SDGs):

SDG 1 (No Poverty) seeks to build the resilience of the poor and reduce exposure and vulnerability to climate-related extreme events and other economic, social, and environmental shocks.

SDG 2 (Zero Hunger) seeks to end all forms of malnutrition, including stunting and wasting in children under 5 years of age, and address the nutritional needs of adolescent girls, pregnant and lactating women, and older persons.

SDG 3 (Climate Action) seeks to strengthen resilience and adaptive capacity to climate-related hazards.

In 2004, Africa Harvest Biotech Foundation International (Africa Harvest) formed a consortium to develop bio-fortified African sorghum through the ABS Project. The consortium members include the following - Pioneer-DuPont (now Corteva Agriscience) USA, Institut de l'Environnement et Recherches Agricoles (INERA) -Burkina Faso, Kenya Agricultural and Livestock Research Organisation (KALRO), Institute for Agricultural Research (IAR) - Nigeria, University of Pretoria – South Africa, NABDA – Nigeria, Council for Scientific and Industrial Research (CSIR) - South Africa, African Agricultural Technology Foundation (AATF) - Kenya, and the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT).

The confined field trial is currently suspended due to lack of funding.

#### Project progress

The ABS consortium has successfully sought competitive subsidiary funds and utilized them to deliver vital aspects of the bio-fortified sorghum project from 2011 to 2018.

During this period:

- Sorghum transformation time has been reduced by 60% i.e., from six months to four and the transformation frequency was increased by about 100-fold over previous capabilities.
- Scientific advances have enabled the use of direct and indirect transformation of select farmer preferred native African sorghum varieties.
- Beta ( $\beta$ )-carotene levels and stability in sorghum have been increased to 50-70  $\mu\text{g/g}$ ;  $\beta$ -carotene stability also increased to nearly 10 weeks.
- Efficient bioconversion of bioavailable  $\beta$ -carotene to retinol, which becomes converted to vitamin A, has been demonstrated in a mammalian system.
- In addition, increased bioavailability of iron and zinc through reduction in phytate, without impact on seed germination, has been achieved.
- Multiple stacked constructs and “regulatory-ready” events have been confirmed in at least 2 different popular varieties of sorghum – increased levels of essential nutrients, especially lysine, vitamin A, iron, and zinc.
- Procedures for regulated CFTs and transgenes introgression into local varieties have been developed and trials have been conducted in Nigeria and Kenya.

#### Project goals and objectives

With solid results, in addition to developed events with nutritional transgenes in given sorghum germplasm, the project is moving from the development phase of the final construct to deregulating and subsequent commercializing well-adapted cultivars with improved nutritional traits. Deregulating lead events will pave the way for the commercial use of ABS sorghum in East and West Africa.

#### **vi. Blight Resistance Potatoes**

This project is in collaboration between the National Roots Crops Research Institute (NRCRI) in Jos Station and African Agricultural Technology Foundation (AATF). The latter completed CFT at Umudike.

#### **vii. GE crops Projects:**

- i. Yam seedling multiplication: aeroponics/hydroponics systems, temporary immersion bioreactor systems, and tissue culture systems can generate millions of seedlings that can benefit thousands of farmers through yield increases.
- ii. Biopesticides and biofertilizer production. This requires large scale fermentation equipment from USA.

**b. COMMERCIAL PRODUCTION:** Currently, Bollgard II cotton (Bt cotton) and PBR cowpea have been released for commercialization. Farmers across the country started their cultivation during the 2019 and 2021 planting seasons, respectively.

- i. **Bt Cotton Project-** This collaborative project involves Bayer Agriculture, Nigeria; Mahyco Agriculture Nigeria Private; IAR, Zaria; the NABDA and the National Agricultural Seed Council (NASC) of Nigeria. The project’s goals align with the Federal Government’s vision to revive the cotton sector. 2018 was a landmark year - Nigeria approved the commercial

cultivation of two Bt cotton hybrids (Mahyco C 567 BGII & Mahyco C 571 BGII), after two years of multi-locational trials conducted by the IAR, Zaria.

Adopting Mahyco Bollgard II Hybrid seed has the potential to revive the cotton industry in the country. The released Bollgard II' offers significantly higher yields, superior cotton quality and decreases the cost of pest control while enhancing the farmers' income levels. Reviving cotton farming will also strengthen the country's economy - creating new jobs and supporting the textile sector.

In 2019, the primary objective of Mahyco was to demonstrate the value of its hybrid seed technology to farmers in their fields. During the 2019 wet season, Mahyco distributed more than 2,000 samples through its partners (private and institutional) to select farmers for planting. The company also trained more than 200 on-field farmers on appropriate agronomic practices conducted during various phases of crop growth across 12 states. The training focused on agronomy skills to optimize and sustain yields. In addition, the company conducted seed production training sessions to reduce the impact of diseases, pests, and weeds.

Extension workers conducted more than 70 field training days were conducted during the harvesting time - to increase awareness of the newly released Mahyco Cotton Hybrids. Across targeted states, incremental yield advantage of 3 tons/ha or more was observed (over traditional cotton seed). Around 20,000 farmers have been exposed to the performance of Mahyco Bollgard II cotton hybrids during farmer meetings and field training days. The farmers who have experienced the value of these Mahyco Bollgard II Hybrids are keen to use the seed in the future.

Between 2023-2025, the company plans to meet at least part of the demand with local seed production - expanding substantially by training registered farmers through various partners. By 2025, the objective is to create a significant pool of farmers adept in seed production protocols and at delivering the end product with 99 percent purity. Additionally, a local quality analysis laboratory will assess seed trait purity.

- ii. **Bt Cowpea Project:** On December 15, 2019: The Federal Government of Nigeria approved the registration, naming, and release of a new PBR cowpea variety for commercialization. The National Committee on Naming, Registration and Release of Crop Varieties approved the crop at its 28th meeting in Ibadan on December 12, 2019. Scientists at the IAR, Ahmadu Bello University, Zaria collaborating with several partners including, NABDA under AATF developed the new cowpea variety.

In early 2019, NBMA confirmed the product was safe for humans, livestock, and the environment. This approval paved the way for submission to the National Variety Release Committee to register the crop as the first variety containing the PBR cowpea trait as a commercial crop in Nigeria.

The newly registered Bt cowpea is highly resistant to *Maruca vitrata*, an insect pest that causes up to 90 percent yield loss in severe infestation cases. This new variety is early

maturing (70 - 75 days) with semi-erect growth habit, is insensitive to day-length, and has medium large white seeds. It is also resistant to striga and alectra - two notorious parasitic weeds.

The release of Bt cowpea will allow farmers to reduce the sprays they currently apply to their crop, from 6 to 7 applications to only 2 per cropping season. The latter will increase yield quantity and quality. Bt cowpea will also reduce the 500,000-ton annual shortfall in cowpea production and improve national productivity by 20%.

Researchers found Bt cowpea to have highly stable grains across the test locations during the Multilocational Advanced Yield Trials conducted across Nigeria's agricultural ecologies. The minimum observed average grain yield increase over the conventional cowpea varieties was at least 20 percent (3 tons per hectare), which could be higher depending on severity of the Maruca infestation.

In June 2021, Bt cowpea seeds became available for sale across the country, making Nigeria the first African country to commercialize a genome-edited crop. This development was a significant achievement for Nigerian agricultural biotech research, as well as regulatory organizations and international partners working for several decades to commercialize transgenic cowpea.

#### Product development and commercialization

- An agreement was signed between IAR and National Agricultural Extension and Research Liaison Services (NAERLS) to cover the whole country with demonstration trials in 34 states.
- Three local seed companies were selected and licensed to produce certified commercial seed.
- Capacity strengthening of both seed companies and NASC is underway.
- The launching of the Bt cowpea was held in Kano City. All project partners both local and international collaborators were present.
- Farmers across the country purchased commercial Bt cowpea - the first harvest started in late October/early November 2021. Many farmers got bountiful harvest
- This year the government announced that due to the yield margin of Bt cowpea, farmers will gain higher output and incomes.

#### Way Forward

- Increase the capacities for producing foundation seed.
- Provide each region with a PBR cowpea variety conformed to the local preferences.
- Making the technology sustainable – an active stewardship program is in place with emphasis on insect resistance management.

**c) EXPORTS:** Nigeria does not export GE products.

**d) IMPORTS:** Nigeria permits the import of biotech crops and GE grains for poultry feed and seeds for research purposes. Nigeria authorizes GE crop imports. An approved NBMA-issued GE seed import



permit is required; applications need to be submitted to the Director General at least 270 days prior to the import date. The agency will reject non-complaint shipments and refused their entry into Nigeria. In January 2020, the NBMA published a new guideline for importing GE organisms for food, feed and processing (FFP).

These guidelines serve as step-by-step instructions for importers of GE products intended for FFP - including procedures for obtaining biosafety permits. The guidelines also highlight the roles of all relevant border regulatory agencies that play a role in importing GE products for FFP into Nigeria. In addition, the guidelines also specify the first point of contact (POC) - for applicants who wish to import GE products for FFP. The POC will also provide additional information about the processes – including receipt of an application and the final decision. These regulatory requirements are working tools that guide importing of GE products into Nigeria.

In July 2022, the NBMA approved the importation of genetically engineered (GE) drought- resistant wheat (HB4) from Argentina. The import of GE wheat is mainly for food and processing not for planting.

At the same time, the NBMA also announced a twenty-one (21) day public notice about an application dossier by Trigall Genetics S. A, for importing GE Wheat. The announcement enables the public to make comments that would facilitate informed decisions on the application.

<https://nbma.gov.ng/public-display-of-application-dossier-for-importation-of-genetically-modified-wheat-resistant-to-drought-and-glufosinate-based-herbicides-for-food-processing/>

### **Objective of the Guidelines**

These guidelines aim to assist importers of GE products for FFP in obtaining biosafety permits in line with the federal government’s executive order 1 on “ease of doing business”. These guidelines also help keep stakeholders informed about what is required of them in importing GE products. The executive order ensures strict adherence to accountability and transparency by importers of GE products for FFP. The main objective is to ensure that all GE imports’ actual quality and events match the claims on all accompanying documents.

### **Relevant Legislation and Policies for GE products Imported for FFP**

There are several legislations related to GE imports for FFP into Nigeria. Some of the relevant national policies, laws and regulations include:

**I. National Biosafety Management Agency Act, 2015 (As Amended):** This law provides the regulatory framework, which is the institutional and administrative mechanism for safety measures applying to modern biotechnology in Nigeria. The legislation aims to prevent any potential adverse effects to humans, animals, plants, or the environment.

**II. Plants Quarantine Act 2017:** This law regulates the importing and exporting of plants /plant products and establishes controls for plant pests. Frequently asked questions can be found at <https://naqsportal.net/NAQS-Portal-Frequently-Asked-Questions>

**III. Customs and Excise Management Act 2004 (As Amended):** This act regulates the management and collection of duties of customs and excise and for purposes ancillary thereto.

National Biosafety Regulations, forms and fees can be found at <https://nbma.gov.ng/resources>

**e) FOOD AID:** Nigeria does not provide food aid. It does however receive food aid, including GE corn-soy blend products.

**f) TRADE BARRIERS:** Nigeria maintains an open market for agricultural commodities and products derived through or produced with biotechnology. There are currently no biotechnology-related trade barriers affecting U.S. food and agricultural product exports to Nigeria.

#### ***PART B: POLICY***

**a) REGULATORY FRAMEWORK:** The NBMA is the government institution responsible for regulating GE products in Nigeria. The National Biosafety Committee (NBC) reviews applications. It carries out data analysis of socio-economic considerations of GE crops alongside risk assessment before recommending any products to the agency for approval. The legislation and regulations regarding the approval and release of GE crops, including the National Biosafety Act 2015, National Biosafety Regulations 2017, and National Biosafety Guidelines 2018, can be found at <https://nbma.gov.ng>

## **NIGERIAN INSTITUTIONS INVOLVED IN AGRICULTURAL BIOTECHNOLOGY**

**i. Nigeria Federal Ministry of Environment:** Nigeria's Federal Ministry of Environment (FME) established the NBMA as the national focal point and the competent authority for biosafety in the country. NBMA is the regulating body for modern biotechnology activities. It provides biosafety regulations for bringing GE crops into the country for testing and environmental release. Meanwhile, MFE the Nigerian government's liaison with the Secretariat of the Convention on Biological Diversity – is required under the Cartagena Protocol on Biosafety (CPB).

**ii. National Biosafety Management Agency (NBMA):** The agency is an independent biosafety and regulatory body for all biotechnology activities. The NBMA is responsible for all correspondence with importers, exporters, and applicants regarding movement of products of modern biotechnology.

### **Roles and Responsibilities:**

- Defines modules of practice for modern biotechnology and the handling of its products to ensure safety to the environment and to human health.
- Provides guidance on the safe application of modern biotechnology.
- Recognizes complex issues to be addressed by central authorities on the judicious application of modern biotechnology.
- Ensures that modern biotechnology activities and their products are safe for the environment and to human health.
- Bases the release of GE organisms on advance informed agreement, which aims to establish bottom-up participation and consultation processes.
- Defines responsibilities among designated bodies/institutions.
- Confers powers to authorize release of GE organisms and practice of modern biotechnology activities.
- Confers powers to carry out risk assessment/management.
- Defines offences and penalty for violation of the act.
- Regulates use of all living GE products and products for FFP.
- Addresses socio-economic considerations in risk assessment and labeling of GE products.

The agency is responsible for providing the regulatory framework, institutional and administrative mechanisms for safety measures applying to modern biotechnology.

**iii. Nigeria Federal Ministry of Agriculture and Rural Development (FMARD):** The FMARD formulates agricultural policies relating to biotechnology. The FMARD promotes and facilitates agricultural activities and implements policies and programs. It houses all agricultural research institutions in the country. The National Agricultural Seed Council (NASC) is a FMARD agency, and it is responsible for developing and regulating the seed industry in Nigeria – including transgenic seeds.

**iv. National Biotechnology Development Agency:** The agency was established in 2001 under the Ministry of Science and Technology with the mandate to formulate biotechnology policy in Nigeria and acquire, deploy, promote, and facilitate biotech activities for indigenous and self-reliant national growth. The agency is active in creating awareness for products of biotechnology. It conducts regular workshops

for major biotechnology stakeholders (see Open Forum for Agricultural Biotechnology in Africa – Nigerian Chapter).

**v. National Agency for Food and Drug Administration and Control (NAFDAC):** The NAFDAC oversees all food safety including drugs, chemicals, and related issues. The agency regulates herbicide tolerance to determine maximum residue limits (MRLs) in food and feed products.

**vi. Sheda Science and Technology Complex (SHESTCO):** The Center is a Nigeria government biotechnology research and training facility. It has the mandate to develop and use domestic technologies for the application of biotechnology in health, agriculture, and environment.

**vii. Nigerian National Universities:** Several National Universities are also involved in the research and development aspects of agricultural biotechnology including CFTs. Most of these universities have institutional biosafety committees.

**viii. The National Biosafety Committee (NBC):** The inter-ministerial NBC serves as the competent national authority for biosafety. The NBC is responsible for the safe management of biotechnology activities. The committee has 16 members drawn from the Ministries of Agriculture and Rural Development, Science and Technology, Environment, Commerce, Education, Health (NAFDAC), Industry, Foreign Affairs, Internal Affairs (Nigerian Customs Service), Justice, and the Nigerian Association of Chambers of Commerce, Industry, Mines, and Agriculture (NACCIMA) and other private sector organizations. The NBC includes biologists, physical and social scientists, as well as representatives of environmental and non-governmental conservation organizations (NGOs). The committee must review all applications for the release of bioengineered products. Furthermore, the NBC recommends to the Minister of Environment on whether to approve bioengineered products. It also oversees the implementation of the National Biotechnology Program and addresses any issues that may arise within the NBMA Act.

The NBC established the National Biosafety Technical Subcommittees (NBTS) to focus on the interests of sectors such as agriculture, health, industry, and the environment. The subcommittees review research proposals and recommend experimental conditions. The group also provides technical advice to the NBC and contribute to its functions concerning contained use, field trials, release, and market placement.

Currently, all applications for imported products containing GE for field trials, transit, and contained use must be routed through the NBMA. The NBC acts as a liaison between the relevant NBTS to carry out risk assessment and ensure participation of all relevant stakeholders. Findings of the NBTS are submitted to the NBC and the agreed decision is conveyed to the applicant by the NBMA, which determines the issuance of licenses to carry out activities. The NBMA is responsible for the safe application, use, and handling of GE organisms and their products.

**ix. Open Forum for Agricultural Biotechnology (OFAB):** OFAB is an information platform that holds outreach activities to enhance the understanding and acceptance of GE crops among varied stakeholders - Nigerian government officials, journalists, and scientists. Officials of the Ministries of Agriculture, Environment, and Science and Technology have all participated in OFAB activities.

**b) APPROVALS:** There are distinctions between the regulatory approval for A) food, feed, processing, and B) environmental release. Bt. Cotton, Bt. Cowpea and Tela Maize are currently the only approved crops for environmental release (i.e., cultivation) in Nigeria. On the other hand, the government has approved imported GE corn and soybean varieties for feed and oil processing. The NBC reviews operational guidelines for transgenic crop approvals. The timeline for approvals is usually about 180 days.

**c) STACKED OR PYRAMIDED EVENT APPROVALS:** The approval process and conditions are the same for stacked event approvals as for single trait approvals.

**d) FIELD TESTING:** Field testing and evaluations are allowed.

With the approval of the NBC, the NRCRI-Umudike, IAR-Zaria, and NCRI-Badeggi have carried out CFTs on cassava, cotton, sorghum, cowpea, and rice. The approval is based on the provisions of the National Biosafety Guidelines, which include field-testing of bio-engineered crops.

The NBDA collaborates with the NRCRI-Umudike, IAR-Zaria, and NCRI-Badeggi for creating awareness among Nigerian cowpea and cassava stakeholders, while the NBMA ensures compliance with Nigerian Biosafety Guidelines.

**e) INNOVATIVE BIOTECHNOLOGIES:**

In December 2020, the GON, through the NBMA, authorized guidelines on genome editing. Nigeria became the first African country to issue genome editing guidelines.

Nigeria is a party to the CPB, and per the general provisions in Article 2 of the CPB, “each party shall take necessary and appropriate legal, administrative, and other measures to implement its obligations”. Consequently, the NBMA Act 2015 (as amended) empowers the NBMA to provide safety standards, guidelines, and rules to facilitate the development and implementation of genome editing guidelines.

The Act defines “Genetically Modified Organism (GMO)” as “any organism living or non-living that possesses a novel combination of genetic material obtained using modern biotechnology and gene-editing.

Genome editing provides techniques that enable targeted and precise alteration of the genome with high degree of specificity, thus opening new possibilities in their applications. The techniques include Transcription activator-like Effector Nucleases (TALENs), Zinc Finger Nucleases (ZFNs), Oligonucleotide-Directed Mutagenesis (ODM) and Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR).

Nigeria has determined that genome editing products are subject to appropriate biosafety regulations on a case-by-case basis.

Nigeria adopted an approach to regulate genome-editing and its products. According to the system, a product is classified as genetically engineered if recombinant DNA sequences or the gene edited product has a novel combination of genetic material (e.g., uses a recombinant DNA that remains in the final

product). On the other hand, where genome-editing or the product does not lead to or does not have a new combination of genetic material (e.g., does not use a recombinant DNA or uses a recombinant DNA that is removed in the final product), a non-GE regulatory classification is applied.

For more information on Nigeria’s genome editing policy, see <https://www.fas.usda.gov/data/nigeria-government-nigeria-approved-national-biosafety-guideline-gene-editing>

**f) COEXISTENCE:** Nigeria GE policy is still evolving. A review of 2015 Acts was done in 2019, which incorporated new developments. The NBMA develops rules and guidelines to regulate GE crop cultivation.

**g) LABELING AND TRACEABILITY:** Regulations stipulate that product with four percent GE content should be labeled with statements such as:

- “This product contains genetically modified organisms” whenever there is evidence of the presence of GE products.
- “This product may contain genetically modified organisms” when it cannot be proven that the product does not contain GE ingredients.

The purpose of the labeling is to enable consumers to make informed choices on products purchased. The NBMA Act requires mandatory labeling of all derivatives of agricultural biotechnology to “protect consumers’ right to know. In Nigeria, NAFDAC enforces existing labeling regulations including biotech labelling. The government body regulates food product manufactured, imported, and distributed in Nigeria. NAFDAC regulations require that food labels are informative and accurate. FAS Lagos has an open dialogue with NABDA, NAFDAC, NBMA and other key stakeholders on the operational guidelines of the law - to ensure that mandatory labeling requirements do not obstruct trade.

**h) MONITORING AND TESTING:** The NBMA Act includes monitoring requirements. The NBMA Act also defines penalties for violating the regulations. Failure to obtain approval or proper permits before importing or releasing GE organisms into the environment is subject to the following stated penalties:

- Individuals can be fined Nigerian naira (NGN) 2.5 million or imprisoned for a period not less than five years or both.
- Corporations would pay a fine of at least NGN 5.0 million and the directors or officers of the companies “shall each be liable to a fine not less than NGN 2.5 million or imprisonment for a term not less than five years or to both fines and imprisonment”.
- False information also results in the same penalty as failure to obtain appropriate approval.
- Obstruction can also result in NGN 2.5 million fine or imprisonment for not less than three years or both.

**i) LOW LEVEL PRESENCE (LLP) POLICY:** The tolerance for low level presence of approved events by NBMA in the country of origin that are not yet approved in Nigeria is 4 percent.

**j) ADDITIONAL REGULATORY REQUIREMENTS:** After the NBMA gives GE crop approval, the crop will also need to meet the requirements of other extant laws related to the seed system in Nigeria. Other agencies that regulate new varieties or importation of plants or organisms (i.e., whether they are GE or not) include the Nigeria Agricultural Quarantine Service (NAQC), the National Varietal Release Committee, the NASC, and the NAFDAC.

The NASC and the Varietal Release Committee require additional registration of seeds/traits before commercialization. Once the variety is approved and released by the Varietal Release Committee and deregulated (in the case of seeds), no further registration is required. A NAFDAC-issues registration is required for processed products containing GE product. On the other hand, the Ministry of Agriculture requires registering of occurrences of insects building resistance to GE crops/pesticides. For HT traits, the herbicide needs to be registered differently by the NAFDAC. Farmers can use the approved varieties after registration.

**k) INTELLECTUAL PROPERTY RIGHTS (IPR):** In May 2021, the GON signed into law the Plant Variety Protection Act 2021 to protect plant varieties in Nigeria. President Buhari signed the Bill into law after the House of Representative passed the Bill in December 2020 and their counterparts in the Senate approved the Bill in March 2021.

**l) CARTAGENA PROTOCOL RATIFICATION:** Nigeria signed the CPB in 2000 and its instrument of ratification was signed by the Nigerian President on November 30, 2002. The protocol came into force in September 2003.

**m) INTERNATIONAL TREATIES AND FORUMS:** Nigeria signed the Convention on Biological Diversity in 1992 and ratified the instrument in 1994. Nigeria was active during the negotiations that led to the adoption of the CPB. Officials of key biotech agencies such as the Federal Ministry of Environment, NABDA and NMBA regularly attend meetings of international standard-setting bodies. Regulation of GE products in Nigeria is in line with the provisions of the *Codex Alimentarius* (Codex) guidelines.

**n) RELATED ISSUES:** FAS Lagos is not aware of any biotechnology-related trade barriers affecting U.S.-origin exports to Nigeria. However, the mandatory labeling requirement may restrict market access for GE products.

### ***PART C: MARKETING***

**a) PUBLIC/PRIVATE OPINIONS:** The Nigerian public has mixed opinions about GE food products. To some, these products are very important in promoting food security. Others are concerned about safety and health issues. These mixed messages are due to an information gap or limited understanding of the potential benefits of the technology. Consumers with more knowledge of the technology tend to accept GE crops. According to research, a higher number of the public believe Nigeria should domesticate the technology and build capacity to develop GE crops.

On the other hand, there are civil society groups and environmental activists that campaign against GE crops in Nigeria. However, the availability and consumption of food products derived from biotechnology remains widespread. Farmers are interested in biotechnology because of the technology's

potential to improve farm yields and increase income. Some members of the public take a cautious stance against the safety of GE crops. Strategic risk mitigation communication is required to address the misconceptions. Most Nigerians need to be more aware of products of modern agricultural biotechnology and the issues involved. Information sharing and discussions on modern biotechnology have been undertaken largely between Nigeria government officials, scientists, and researchers.

**b) MARKET ACCEPTANCE/STUDIES:** Nigerian farmers are willing and ready to accept the commercialization of Bt. Cotton and Bt. Cowpea because of the positive monetary benefits they expect from these crops. Over the past decade, Nigeria farmers have accepted GE crops gradually. The Nigerian public has an overall cordial attitude towards the biotech industry and research institutions in the country.

#### Review Article on Biotech Progress in Sub-Sahara Africa

In 2020, a scientific journal, *Frontiers in Plant Science*, published an important peer-reviewed report entitled 'Biosafety Regulatory Reviews and Leeway to Operate: Case Studies from Sub-Sahara Africa'. The article analyzes the increases in adoption and testing of new agricultural technologies such as GE crops, as well as novel regulatory approaches used in biosafety decision-making. It presents case studies for Ghana, Kenya, Malawi, Nigeria, and Uganda to illustrate successes and ongoing challenges, and concludes with policy recommendations for emerging economies.



## CHAPTER 2: ANIMAL BIOTECHNOLOGY

### PART D: Production and Trade

#### a): PRODUCT DEVELOPMENT

The goal of biotechnology intervention in animal agriculture in Nigeria is to sustainably reposition the sector for enhanced productivity and profitability.

Currently, efforts are directed toward preventing the loss of genetic diversity among major species of farm animals in the country. In addition, efforts are being made to develop value added and novel feed ingredients.

The following research teams exist to support comprehensive interventions in the animal agriculture space.

- a. **Animal Genetic Resources (AnGR)** underscores sustainable management through incorporating the FAO's Global Plan of Action (GPAs) for collecting, processing, and preserving genetic resources both "in situ" and "ex situ" including sperm/bio banking. This project is in partnership with the Department of Animal Husbandry Services, Federal Ministry of Agriculture and Rural development and National Advisory Committee on AnGR.
- b. **Assisted Reproductive Techniques (ARTs) in Livestock** – This project focuses on the use of available, adaptive, and accessible reproductive technologies to facilitate the breeding of livestock in the country. With a 5-year Memorandum of Understanding and Memorandum of Association with the Mississippi State University USA, strategies were set out to adapt these technologies across Africa by modelling them in a climate smart animal agriculture context. The focus technologies are artificial insemination, multiple ovulation and embryo transfer, estrous synchronization and local hormone development, and in vitro fertilization.
- c. **Animal Product Bio-Processing and Food Development**- The project emphasizes the use of plant-based and organic preservatives to deliver safe animal products. Quality assurance of animal products and laboratory testing practices are also part of the project management plan.
- d. **Dairy Value Chain Development**- the dairy sector is a priority for the government - partnerships have been developed between several stakeholders across Nigeria – for example, SMAP Farms Ltd, Nigeria Army Farms and Ranches, Salbari Farms - to achieve a sustainable genetic improvement and eventual development of dairy lines in the country. Current efforts have yielded positive results – for example, indigenous cows on partners' farms now produce 15-20 liters of milk per day compared to the unimproved indigenous breeds that produce about 1-1.5 liters per day. The genetic improvement interventions are still ongoing. The project's main goal is to develop an optimally performing Nigeria dairy cow- a collaborative effort largely between the private sector and farmers.

b) COMMERCIAL PRODUCTION: Not applicable

- c) EXPORTS: Not applicable
- d) IMPORTS: Not applicable
- e) TRADE BARRIERS: Not applicable

**PART E: POLICY:**

- a) **REGULATORY FRAMEWORK: Not applicable**
- b) **APPROVALS/AUTHORIZATIONS: Not applicable**
- c) **INNOVATIVE BIOTECHNOLOGIES:**

For more information on Nigeria's genome editing policy, see government approved national biosafety guideline gene editing on <https://nbma.gov.ng>

- d) **LABELING AND TRACEABILITY: Not applicable**
- e) **ADDITIONAL REGULATORY REQUIREMENTS: Not applicable**
- f) **INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable**
- g) **INTERNATIONAL TREATIES and FORUMS: Not applicable**
- h) **RELATED ISSUES:**

**PART F: MARKETING**

- a) **PUBLIC/PRIVATE OPINIONS**
- b) **MARET ACCEPTANCE/STUDIES: Not applicable**

## CHAPTER 3: MICROBIAL BIOTECHNOLOGY

### PART G: PRODUCTION AND TRADE

#### a) COMMERCIAL PRODUCTION

Post is aware of ongoing microbial biotech research in Nigeria to produce biopesticides and clean water from industrial waste.

- i. **Microbial Biotechnology and Derived Products** – in plants and animals, scientists use biotechnology to alter one or more desired characteristics in single-celled microorganisms (i.e., microbes) such as bacteria or fungi. On the other hand, microbial biotech produces ingredients that otherwise occur naturally in bacteria, fungi, plants, or animals but are challenging to extract at scale. Microbial biotech is an efficient and effective alternative to natural extraction. A range of biotech tools can be utilized; although, genetic engineering (GE) using recombinant DNA (rDNA) or transgenics remains predominant.

#### Example of microbial biotech-derived products and their uses

Microbial Biotech-Derived Product	Ingredient Uses(s)	Product Use(s)
Chymosin	Enzyme	Cheese
Protease	Enzyme and additive	Infant formula, Protein supplement, meat extracts (soy sauce, soups, sauces, snacks)
Asparaginases	Enzyme and additive	Baked/Fried foods
Oligosaccharide	Enzyme and additive	Sweetener, fermented and non-Dairy Products
Soy Leghemoglobin “Heme”	Flavoring and Coloring	Flavor/Color
Stevia Glycosides	Seasoning and Flavoring	Sweetener
Vanillin	Seasoning and Flavoring	Flavor and aromatic
Colicin Preparations	Additive	Antimicrobial agent
Biogums, Xanthan Gum	Additive	Geller, thickener, and stabilizer
Vitamin A, B2/Riboflavin, C, D, and E	Vitamin	Fortifier and preservative

- ii. **Animal Feed Bio-resources Development** – This project focuses on leveraging science, technology, and innovation to solve the competition between human and animal food vs the feed value chains – to alleviate a political crisis between herders and farmers. Generally, the situation is a land-use conflict between farmers and herders across Nigeria’s Middle Belt. The spiraling conflict has led to the death of many citizens and the loss of property.

The project explores agricultural and industrial waste through microbial bio-fortification to develop novel feedstuff. In addition, deploying fodder hydroponics systems is critical to this

intervention. Feed testing for quality and safety is a central part of the project's focus area of intervention, including a forage seed development program.

- iii. **Bio-pesticides and Bio-fertilizer production** - This requires large scale fermentation equipment from USA.

#### b) **EXPORTS**

There are neither official statistics nor estimates on exports of microbial biotechnology products. However, Nigeria exports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

#### c) **IMPORTS**

The only microbial biotech-derived food ingredients imported by Nigeria are those traditionally used in producing alcoholic beverages, dairy products, and processed food products. Likewise, Nigeria imports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

**d) TRADE BARRIERS:** Currently, there are no regulations that target the import of GE microbes or their derived products.

### **PART H: POLICY**

a) REGULATORY FRAMEWORK

b) APPROVALS/AUTHORIZATIONS: Not applicable.

c) LABELING and TRACEABILITY: Not applicable.

d) MONITORING AND TESTING: Not applicable.

e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable.

f) INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable.

g) RELATED ISSUES: Not applicable.

### **PART I: MARKETING**

d) PUBLIC/PRIVATE OPINIONS: Not applicable.

e) MARKET ACCEPTANCE/STUDIES: Not applicable.

#### **Attachments:**

No Attachments