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Prepared By: Ebenezer Boluwade, Agricultural Specialist USDA/FAS, Lagos

Approved By: Gerald Smith

Report Highlights:

Nigeria continues to deliver notable achievements in biotechnology research and development – spurred by strong support of the Government of Nigeria (GON). In December 2020, Nigeria became the first African country to issue gene editing guidelines. Meanwhile, the planting of insect resistant cowpea and cotton are ongoing across the country. Recently, transgenic corn received National Biosafety Management Agency (NBMA) approval for confined field trials (CFTs).

EXECUTIVE SUMMARY

Nigeria is Africa's largest economy, and a major oil producer with a current population of over 212 million people. Nigeria's Gross Domestic Product (GDP) grew by five per cent, year-on-year, in the second quarter of 2021 according to the National Bureau of Statistics. The five per cent (**\$1.81trn**) increase marks three consecutive quarters of growth following the negative growth rates recorded in the second and third quarters of 2020. Nigeria relies on imports to meet its food and agricultural product needs (mostly wheat, rice, poultry, fish, food services, consumer-oriented foods, etc.)—worth about \$10 billion annually. Europe, Asia, the United States, South America, and South Africa are major sources for agricultural imports.

The agricultural sector is not highly developed; it accounts for around 23 percent of GDP and employs roughly 35 percent of the population. Over the decades, successive governments have initiated policies to grow Nigeria's agricultural sector, but the country remains a net importer of food and agricultural products. Lack of infrastructure, absence of effective policy formulation and implementation, insecurity, as well as the negative impacts of climate change, continue to impede Nigeria's agricultural growth. Climate change is affecting crop yields across the country's Northern states. Agriculture in Nigeria is highly vulnerable to climate change and associated occurrences of higher temperatures, prolonged droughts, floods, and other conditions. Biotechnology offers new tools for increasing agricultural productivity and protecting food crops from climate changes such as heat, floods, and drought.

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 assumes 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. However, the law leans heavily on the precautionary approach and requires certification and mandatory labeling for imports of all biotechnology products.

Currently, the government is advancing and commercializing agricultural biotechnology as a tool to achieve food security in the country. Nigeria officially approved its first biotechnology crop, *Bacillus thuringiensis* (Bt) cotton, for commercialization in 2018. Next, Nigeria approved the commercial release of Pod-Borer Resistant Cowpea (PBR cowpea; AAT709A) in January 2019. Towards the end of 2020, the NBMA authorized guidelines on gene editing. On October 8, 2020, the NBMA approved the cultivation of TELA maize (drought and insect tolerant). The permit was issued to the Nigerian Institute for Agricultural Research (IAR). With this release, the IAR was permitted to conduct multi-location trials to evaluate the yield and adaptability of the TELA hybrids. The IAR will seek another approval by the National Variety Release Committee before making the seeds commercially available to farmers for planting at the start of the 2023 crop season.

There are various factors that may limit commercialization of biotechnology in Nigeria. Nigeria's NBMA Act requires mandatory labeling of products containing genetically engineered (GE) products or ingredients exceeding 4 percent. Furthermore, civil society groups are intensifying their anti-GE campaigns. However, anti-GE messaging does not resonate with farmers, who generally have positive attitudes towards biotechnology. The situation could even be better if effective risk communication strategies are implemented to address misconceptions surrounding genetic engineering. Robust risk

communication and best practices could steer Nigerians towards embracing the benefits of modern agricultural biotechnology.

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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 technological 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 purpose of this field trial is to evaluate two glyphosate formulations (Roundup Ready MSU lines, E14086 and E14017). Applied glyphosate tolerant soybean will be compared to leading Nigerian commercial varieties. Weed management is one of the major problems militating against large scale production of soybean in Nigeria. Introgression of herbicide tolerance (HT) genes into Nigerian commercial varieties will help to alleviate the drudgery 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.
- 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.

The expected benefits of NEWEST variety to the country are numerous – including yield increases of at least 20% over the conventional varieties, a 10% reduction in Nigeria’s rice deficit, and 20% reduction in nitrogen run-off and emissions. Additionally, farmers will be able to grow NEWEST Rice on abandoned land that is no longer suitable for producing other rice varieties.

- 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.

Cassava grows well in conditions of drought and low soil fertility – this situation is prevalent in many African countries. However, plant viral diseases can destroy up to 100 percent of a cassava crop yield, threatening livelihoods and leading to hunger. Although it is an excellent source of calories, cassava does not contain significant levels of key nutrients to meet minimum daily requirements - especially for women and children. For example, in Nigeria, 75% of preschool children and 67% of pregnant women are anemic. Vitamin A deficiency affects almost 30% of preschool children, according to the [World Health Organization](#).

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.

Further development of VIRCA Plus cassava varieties high in iron and zinc is taking place in collaboration with the NRCRI, Nigeria. The team works with national government regulators, who will review safety data as part of the approval process before VIRCA Plus varieties can be made available to farmers. National research institutes are expected to make VIRCA varieties accessible and available to farmers through a program – functioning in a similar way to the casava existing program across the country.

- 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, a consortium was formed by Africa Harvest Biotech Foundation International (Africa Harvest) to develop a 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 consortium received its initial funding from the Bill and Melinda Gates Foundation (BMGF) to implement the ABS project. The project also received supplemental funding from the Howard Buffet Foundation, Corteva, and an anonymous donor.

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 (β)-carotene levels and stability in sorghum have been increased to 50-70 $\mu\text{g/g}$; β -carotene stability also increased to nearly 10 weeks.
- Efficient bioconversion of bioavailable β -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 development phase of the final construct to deregulation and subsequent commercialization of well-adapted cultivars with improved nutritional traits. Deregulation of the lead events will pave the way for commercial utilization of ABS sorghum in East and West Africa.

vi. 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 is a collaborative project involving Bayer Agriculture, Nigeria; Mahyco Agriculture Nigeria Private; IAR, Zaria; the NABDA and the National Agricultural Seed Council (NASC) of Nigeria. The goals of the project align with the Federal Government's vision to revive the cotton sector. In fact, 2018 is a landmark year - Nigeria approved 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.

Adoption of Mahyco Bollgard II Hybrid seed has the potential of reviving the cotton industry in the country. The released 'Mahyco Cotton Hybrids of Bollgard II' offer significantly higher yields, superior cotton quality and decrease the cost of pest control, thereby enhancing the income level of farmers. Reviving cotton farming will also strengthen the economy of the country by creating new jobs and supporting the textile sector.

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

More than 70 field days were conducted during the harvesting time - to increase the awareness of the newly released Mahyco Cotton Hybrids. Across targeted states an 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, in various phases of interactions from farmer meetings to field days. The farmers who have experienced the value of these Mahyco Bollgard II Hybrids are keen in accessing the seed for their use next year.

Between 2023-2025, the company is planning to meet at least part of the demand with local seed production, which will be expanded substantially by training registered farmers through various partners. By 2025, the objective is to create a significant pool of farmers who are adept in seed production protocols and at delivering the end product with 99 percent purity.

Additionally, a quality analysis laboratory will be established locally to 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 approval was granted by the National Committee on Naming, Registration and Release of Crop Varieties at its 28th meeting, which was held in Ibadan on December 12, 2019. The new cowpea variety, Bt cowpea, was developed by scientists at the IAR, Ahmadu Bello University, Zaria and in collaboration with several partners including NABDA under coordination of the AATF.

In early 2019, NBMA confirmed the product was safe for human, 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 number of sprays they currently apply to their crop, from 6 to 7 applications to only 2 per cropping season. The latter will result in an increase in yield quantity and quality. Bt cowpea will also reduce the 500,000 ton annual shortfall in cowpea production and improve national productivity by 20%.

During the Multilocal Advanced Yield Trials conducted across Nigeria's agro-ecologies, researchers found Bt cowpea to have highly stable grain yield across the test locations. The minimum observed average grain yield increase over the conventional cowpea varieties was at least 20 percent (3 tons per hectare), and this 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 major achievement for Nigerian agricultural biotech research, as well as regulatory organizations and international partners that have been 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.

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 import of biotech crops and GE grains for poultry feed, as well as seeds for research purposes. GE crops are imported in large quantities. A GE seed import permit approved by NBMA is required; applications need to be submitted to the Director General at least 270 days prior to the import date. Non-complaint shipments will be rejected and refused entry into Nigeria. In January 2020, the NBMA published new guideline for the importation of GE organisms for food, feed and/or processing (FFP).

These Guidelines serve as a step-by-step guide for importers of GE products intended for FFP, including procedures for obtaining biosafety permits. The guidelines also state the roles of all relevant border regulatory agencies with regards to the importation of GE products for FFP into Nigeria. Additionally, 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 information about the processes - from the receipt of an application to when the decision(s) is taken and communicated to the applicant. These regulatory requirements are working tools that guide the import of GE products into Nigeria.

Objective of the Guidelines

The objective of these guidelines is 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 to keep stakeholders informed about what is required of them in importing GE products. The executive order is aimed at ensuring strict adherence to accountability and transparency by importers of GE products for FFP. The main objective is to ensure that the actual quality, events, and quantity of all GE imports match the claims on all accompanying documents.

Relevant Legislation and Policies for GE products Imported for FFP

There are several pieces of legislation that are relevant to importing GE products 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.

III. Customs and Excise Management Act 2004 (As Amended): This is an act to regulate 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 www.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 and carries out data analysis of socio-economic considerations of GE crops alongside risk assessment before recommending any products to the agency for approval. The provisions for 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 www.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. It is the regulating body for modern biotechnology activities. It provides biosafety regulation requirements for bringing GE crops into the country for testing and environmental release. The Ministry is the Nigerian government's liaison with the Secretariat of the Convention on Biological Diversity - 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 NASC is a FMARD agency, and it is responsible for the overall development and regulation of 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 conservation non-governmental organizations (NGO). The committee is required to review all applications for the release of products of bioengineering, make recommendations to the Minister of Environment on whether to approve such 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 interests of sectors such as agriculture, health, industry, and the environment. The subcommittees review proposals for research and recommend the conditions under which experiments should be conducted. They provide technical advice to the NBC and contribute to its functions in relation to 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 sensitization 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, but imported GE corn and soybean varieties have been approved for feed and oil processing. Operational guidelines for approval are reviewed by the NBC. 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 in accordance with 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” as “a type of genetic engineering in which DNA is inserted, deleted, modified or replaced in the genome of a living organism”. Genome editing provides techniques that enable targeted and precise alteration of the genome with a 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 products of genome editing are subject to appropriate biosafety regulations on a case-by-case basis.

Nigeria adopted an approach to regulate genome editing and products such that where the genome editing requires the use of 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), the product will be classified as a “GMO” and will be regulated as such. 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> or visit www.nbma.gov.ng

f) COEXISTENCE: Nigeria GE policy is still evolving. A review to 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 products of agricultural biotechnology to “protect consumers’ right to know.” Although not specific to biotech products, existing labeling regulations are being enforced by NAFDAC, the government’s regulatory body responsible for food product manufacturing, importation, advertisement, and distribution in Nigeria. The NAFDAC regulations require food labeling to be informative and accurate. FAS Lagos has an open dialogue with the NABDA, NAFDAC, NBMA and other key stakeholders on the operational guidelines of the law to ensure that the requirement of mandatory labeling does not obstruct trade.

h) MONITORING AND TESTING: The NBMA Act includes monitoring requirements. The NBMA Act also defines penalties for not complying with 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 GE crop approval is given by the NBMA, the crop will also need to meet the requirements of other extant laws related to the seed system in Nigeria. Other agencies, which regulate new varieties or importation of plants or organisms (whether they are GE or not) include: the Nigeria Agricultural Quarantine Service, the National Varietal Release Committee, the NASC, and the NAFDAC.

The NASC and the Varietal Release Committee will carry out additional registration of seeds/traits before commercialization. Once the variety is approved and released by the Varietal Release Committee and deregulated (in case of seeds), no further registration is required. For processed products containing GE products, registration with the NAFDAC may be required. Occurrences of insects building resistance to GE crops/pesticides are registered through FMARD. For HT traits, the herbicide needs to be registered differently by the NAFDAC as the regulatory agency for food and drugs. Farmers may 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. It was an active participant in 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 a mixed opinion about GE food products. To some, these products are very important in promoting food security. Others are concerned about safety and health issues. This opinion is often due to an information gap or limited understanding of the potential benefits of the technology. People with more knowledge of the technology tend to accept it. According to research, a higher number of the public believe Nigeria should domesticate the technology and build capacity to develop GE crops.

While there are civil society groups and environmental activists campaigning against GE crops in Nigeria, the availability and consumption of biotechnology food products remains widespread. Farmers interested in this technology's potential to improve their yields and increase their income. Some members of the public have expressed concerns on 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. Public attitudes towards biotech industries or research institutions in the country are cordial.

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. Additionally, 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)** sustainable management through domestication of 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 Department of Animal Husbandry services, Federal Ministry of Agriculture and Rural development and National Advisory Committee on AnGR (www.angr.org.ng).
- 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 domesticate these technologies in Africa by modelling them with the context of climate smart animal agriculture. 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 emphasis here is on the use of plant-based and organic preservatives to deliver safe animal products. The quality assurance of animal product and testing laboratories comes under this project.
- d. **Dairy Value Chain Development**- Due to the renewed national aspirations in this important sub sector, partnerships have been developed between several stakeholders in Nigeria's dairy industry - 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. The present effort has yielded results, as 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 on-going. The goal of this project is to get 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 <https://fas.usda.gov/data/nigeria> government approved national biosafety guideline gene editing or www.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) MARKET ACCEPTANCE/STUDIES: Not applicable

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION

Post is aware of microbial biotech product development in Nigeria for biopesticides and biopesticide production and ongoing research into industrial waste recovery.

- i. **Microbial Biotechnology and Derived Products** – Like with plants and animals, biotechnology (biotech) can be utilized to alter one or more desired characteristics in single-celled microorganisms (microbes) such as bacteria or fungi. 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 is focusing on leveraging science technology and innovation to solve the competition between the human and animal food vs the feed value chains - leading to a political crisis between herders and farmers. Generally, the crisis is a land-use conflict between farmers and herders across the country's Middle Belt. The spiraling conflict has led to the death of many residents and citizens of the country and avoidable loss of property.

The project explores agricultural and industrial waste through microbial bio-fortification to develop novel feedstuff from waste material. Additionally, deploying fodder hydroponics systems is critical to this intervention. Feed testing for quality and safety is equally part of the project's focus area of intervention, which also includes 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 the production of alcoholic beverages, dairy products, and processed products. Likewise, Nigeria imports alcoholic beverages, dairy products, and processed products that may contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS: There are currently no regulations that apply specifically to 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