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Annual

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Report Highlights:
In April 2015, the GON passed the lingered biosafety bill into law and created the National Biosafety Management Agency (NBMA). The establishment of NBMA provides a regulatory framework, an institutional and administrative mechanism in the application of modern biotechnology in Nigeria. Confined Field Trials (CFTs) were conducted for transgenic cow pea, sorghum and cassava varieties with legal backing for multi-locational on-site trials and eventual release to farmers. As a result, promoting stakeholders do not foresee major challenges with adopting products of agricultural biotechnology in Nigeria.

Section I. Executive Summary:
Nigeria is rich in oil and gas and the largest economy in Africa. Population is over 180 million and GDP estimated at $510 billion in 2014. Agriculture accounts for about 40 percent of GDP and provides employment for about 70 percent of the population, despite its oil boom over the past three decades. Agriculture also remains subsistence-based with 80 percent of output from the aged, poor and rural

farmers.

Nigeria relies on imports to meet a significant amount of the country's food needs. Imports of food and agricultural products exceed $10 billion per year (mostly grains and consumer-oriented foods). Nigeria is largely a bulk commodity market and imports wheat, soybean products, tallow, rice and high value products. U.S. food and agricultural exports averaged $1 billion over the past five years—wheat accounting for nearly 90 percent. In 2014, Nigeria exported mostly rubber and cocoa (valued $80 million) to the United States.

In 2001, Nigeria established the National Biotechnology Development Agency (NABDA) to promote, commercialize and regulate biotechnology products and issues. NABDA had operated without any legislation since its creation. The Biosafety bill lingered in the country's parliament over the last two sessions (6^{th} and 7^{th} sessions) of the country's National Assembly, and stakeholders and lawmakers were unanimous on the importance of passing it into law. In April 2015, Nigeria's biosafety bill was signed into law and resulted in the establishment of National Biosafety Management Agency (NBMA) to regulate the law. This law leans heavily on the precautionary approach and requires certification and mandatory labeling for imports of all biotech products.

NBMA is principally responsible for providing oversight for biotechnology's use and regulating the commercialization of biotechnology products in Nigeria. The Agency has become the focal point and authority on biosafety and approaches agricultural biotechnology as a tool to achieve food security. Nigerian scientists and researchers are now able to move forward from field trials (such as transgenic cow pea, sorghum and cassava varieties) into commercial testing phases for eventual deployment to farmers.

In view of this, Nigerian government officials have publicly announced their interests in commercializing Bt cotton, Bt maize, Herbicide Tolerant (HT) soybeans, and the Super Cassava, which are already approved commercially in South Africa, Burkina Faso and Egypt. Although there has been no official approval for commercialization of biotech products in Nigeria, there is an expectation to lead to increased yield productivity and contribute in ensuring food security and industrial growth especially in the ailing textile industries. GON also expects adoption will promote the quantity and quality of cotton that Nigeria can export to other international countries.

Section II. Author Defined:

Section II. Plant Biotechnology Trade and Production:

PART A. PRODUCTION AND TRADE

a) Product Development

There are three (3) developed genetically engineered crops under Confined Field Trials (CFT) in Nigeria:

1. Bt Cowpea: engineered for resistance to Maruca with one CFT site in the Institute of Agricultural Research, Zaria.
2. Africa Bio-fortified Sorghum (ABS): engineered with improved Vitamin A, Iron and Zinc for

Nutritional enhancement with one CFT site in the Institute of Agricultural Research Zaria. There is also plan for multi-trial location.
3. Cassava: engineered for Mosaic Diseases virus resistance (CMD) and for Brown Streak Disease virus resistance (CBSD)

Research capacity exists at the International Institute for Tropical Agriculture (IITA) and the Government of Nigeria (GON)'s Sheda Science and Technology Complex (SHESTCO) to conduct and apply basic biotechnology research.

b) Commercial Production
Currently, there is no commercialization of biotechnology products; however, with the new National Biosafety Agency Bill into law, Nigerian government officials have publicly noted their interests in the commercialization of certain products, such as cotton, maize, and herbicide-tolerant soybeans. GON is aware that these products are commercialized in other African countries like South Africa, Burkina Faso and Egypt.

c) Exports
Nigeria does not export GE crops

d) Imports
Formally, Nigeria has been importing transgenic seeds only for research and CFT purposes.
e)
e) Food Aid: Nigeria is not a recipient of food aid.

PART B. Plant Biotechnology Policy:

A. Regulatory Framework for Agricultural Biotechnology
In April 2015, the GON signed into law a biosafety bill which established NBMA and seeks to stimulate agricultural biotechnology in the country.

i). Responsible institutions involved in agricultural biotechnology in Nigeria:
The National Biosafety Management Agency (NBMA) was newly created by Nigeria's Federal Ministry of Environment (FME) to be the National Focal Point and the competent Authority for biosafety in Nigeria. It is the regulating body for modern biotechnology activities, e.g. provision of the biosafety/regulation requirements for bringing into the country GE crops for testing and release. FME is the GON's liaison with the Secretariat of the Convention on Biological Diversity for administrative functions required under the Cartagena Protocol on Biosafety. NBMA is also an independent biosafety agency and regulatory body for all biotechnology activities including responsibility for all correspondences with importers, exporters, and applicants on movement of products of modern biotechnology.

NBMA will carry out its roles and responsibilities through the following mechanisms:

• Define modules of practice of modern biotechnology and the handling of its products to ensure safety to the environment and to human health;
• Guide different segments of society in contributing to safe application of modern biotechnology;
• Recognize the complex issues to be addressed by central authorities in the judicious application of modern biotechnology;
• Ensure that modern biotechnology activities and their products are safe for the environment and to human health;
• Base the deliberate release of GE organisms on advance informed agreement;
• Define responsibilities among designated bodies/institutions;
• Confer powers to authorize release of GE organisms and practice of modern biotechnology activities;
• Confers powers to carry out risk assessment/management;
• Define offences and penalty for violation of the act;
• Cover all LMOs, products food/feed and processing; and
• Cover socio-economic consideration in risk assessment and labeling of all GE products;
The Federal Ministry of Agriculture is in charge of formulating agricultural policy as it relates to biotechnology, promoting and facilitating agricultural activities, implementation of the policies and programs of agriculture. It houses all agricultural research institutes in the country.

National Biotechnology Development Agency (NABDA) was established in 2001 in the Ministry of Science and Technology with the mandate for formulating biotechnology policy in Nigeria, acquiring, deploying, promoting and facilitating biotech activities for indigenous and self-reliant national growth. The agency is active in creating awareness for products of biotechnology. NABDA conducts regular workshops for the major stakeholders in biotechnology. For further details see http://www.ofabnigeria.com/

National Food and Drugs Administration Control (NAFDAC) regulates herbicide tolerance in GE events for food and feed.

GON's Sheda Science and Technology Complex (SHESTCO) is a center for research and training in the area of modern biotechnology. It has the mandate to domesticate technologies for the application of modern biotechnology in health, agriculture, and environment.

Universities are also involved in research and development aspects of agricultural biotechnology such as including Confined Field Trials as noted in Part 2(a). Most of them have Institutional Biosafety Committees.

ii). Role and Membership of the National Biosafety Committee (NBC)
The NBC serves as the Competent National Authority for biosafety. The inter-ministerial NBC is responsible for the safe management of biotechnology activities. The Committee has 16 members drawn from the Ministries of Agriculture, Science & Technology, Environment, Commerce, Education, Health (NAFDAC), Industry, Foreign Affairs, Internal Affairs (Nigerian Customs Service), Justice, Nigerian Association of Chambers of Commerce, Industry, Mines and Agriculture (NACCIMA) and other Organized Private Sector. The National Biosafety committee includes Biologists, Physical Scientists and Social Scientists. Furthermore, there are representatives of NGOs distinguished in environmental/conservation matters. The Committee is required to review all applications for the release

of products of bioengineering, make recommendations to the Minister of Environment on whether or not to allow such products, oversee the implementation of the National Biotechnology Program, and any other/s that relate within the Bio-safety Law.

The NBC has also established National Biosafety Technical Sub-committees (NBTS) to focus on interests of sectors such as agriculture, health, industry and the environment. The sub-committees review proposals for research and recommend the conditions under which experiments should be conducted. They are to provide technical advice to the Committee and contribute to its functions in relation to contained use, field trials, release and placement on the market.

Presently, all applications for import, field trials, transit and contained use must be routed through NBMA. The NBC will meet and direct 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 then the decision is conveyed to the applicant by NBMA, which determines the issuance of licenses to carry out events.

NBMA is charged with responsibility for providing regulatory framework, institutional and administrative mechanisms for safety measures in the application of modern biotechnology. This prevents any adverse effect on human health, animals, plants and the environment, and for related matters.

iii). Political factors
GON officials widely support agricultural biotechnology; government transition (change of government after election) could influence this position.

iv) GON draws distinctions between regulatory treatment for the approval of food, feed, processing, and environmental release.

B. Approval of Biotechnology Crops
Now that the biosafety law has been enacted by the National Assembly, NBMA in collaboration with Federal Ministry of Environment, which houses the secretariat of the National Biosafety Committee, has commenced drafting of the operational guidelines. There are distinctions between the regulatory treatment of the approval for food, feed, processing and environmental release. Timeline followed for approvals is 270 days.

C. Field Testing
With the approval of the National Biosafety Committee, the National Root Crops Research Institute, Umudike and Institute of Agricultural Research (IAR), Zaria, carried out earlier mentioned CFTs on transgenic cassava, sorghum and cowpea. The approval was based on the provisions of the National Biosafety Guidelines. The guidelines have a provision for field-testing bio-engineered crops.

i) The cowpea maruca (insect) resistant confined field trials (CFT):
• CFTs have been conducted on the cowpea maruca (insect) resistant. The trial took place on the Research Farm of IAR, Ahmadu Bello University, Zaria. The field trial was to evaluate transgenic events (lines) for their reaction to the legume pod boring insect, Maruca. The trial was replicated four

times.
• Preliminary results show that CFT4 is a very successful trial. The proof of the concept is not in doubt and the data presented showed that the experiment is more than 95% significant in controlling cowpea pod borer (maruca).
• The physical and biological control mechanisms put in place by the institute to mitigate potential environmental risk conformed to established guidelines.
• Four CFTs for this event has been successfully concluded.
• The multi-location trials (a project): is funded by African Agriculture Technology Foundation (AATF), Nairobi and aided by USAID and other donors.

ii) The Africa Bio-fortified Sorghum (ABS) Field Trial in IAR, ABU Zaria
The Africa Bio-fortified Sorghum (ABS) has completed three successful trials. Multi- location CFTs are being carried out in IAR research farm stations. Africa Bio-fortified Sorghum testing for Nutritional Enhancement with Vitamin A, Iron and Zinc.

iii) The Bio-cassava Plus (BC+) Field Trial at Umudike
The CFT for Biocassava Plus is being conducted by the National Root Crop Research Institute, Umudike. The transgenic cassava, named "Super Cassava," which is fortified with vitamin A was developed at the Danforth Center. It was established in October 2009 and is funded by the Bill & Melinda Gates Foundation. Bio-fortified Cassava plus for enhanced nutrition.

NABDA is collaborating with the research institutes in creating awareness among Nigerian cowpea and cassava clientele, while the NBMA will ensure compliance to Nigerian Biosafety guidelines in the conduct of the trial. Internationally, African Agricultural Technology Foundation (AATF) provides funding platform, planning, capacity building and linking with other donors such as USAID; the Network for the Genetic Improvement of Cowpea in Africa leverages scientific input of members for planning and linkage, Program for Biosafety Systems assists in regulatory compliance with capacity building and advice.

D. Stacked events approvals
Additional approval is needed for stacked events. Insect resistance is registered through Federal Ministry of Agriculture. The herbicide needs to be registered differently by National Food and Drugs Administration Control (NAFDAC) which is the regulatory agency for food and drugs. The approved varieties may then be used by farmers.

E. Additional Requirements
Once the variety is approved and released by Varietal Release Committee and deregulated, in case of seeds, no further registration is required. For processed products of GE, registration with Food and Drugs Administration may be required.

F. Coexistence
Nigeria's new biosafety law is silent on coexistence. However, there are provisions for monitoring. Rules and Guidelines will soon be developed by the new NBMA established by the government to

regulate GE Crops.

G. Labeling
The new biosafety law requires the mandatory labeling of all products of agricultural biotechnology in order to protect "consumers' right to know." Although not specific to biotech products, existing labeling regulations are being enforced by NAFDAC, the GON's regulatory body responsible for food product manufacturing, importation, advertisement and distribution in Nigeria. NAFDAC regulations require food labeling to be informative and accurate.

USDA/FAS Lagos has open dialogue with 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 free trade.

H. Trade barriers
Post is not aware of any biotechnology-related trade barriers affecting U.S. exports to Nigeria. However, the mandatory labeling requirement may generally retard market access for GE products.

I. Intellectual property rights (IPR)

J. Cartagena Protocol Ratification
Nigeria signed the Cartagena Protocol on Biosafety in 2000 and its instrument of ratification was signed by the country's President on 30th November, 2002. The protocol came into force in September, 2003. Nigeria, having signed and ratified the protocol, became subject to implementing it. The implementation of the protocol is slow and has had no effect on trade.

K. International treaties/ fora
Nigeria signed the Convention on Biological Diversity in 1992 and ratified the instrument in 1994, and was an active participant in the negotiations leading to the adoption of the Cartagena Protocol. Officials of key biotech agencies such as the Federal Ministry of Environment and NABDA regularly attend meetings of international standard-setting bodies.

L. Related issues

M. Monitoring and Testing
The country recently imposed an Act to regulate the domestication and deployment of GE crops. This Act includes a regulatory framework, as well as institutional, administrative, and monitoring mechanisms. NBMA's main responsibility is to ensure the safe handling, transfer and trans-boundary movement of GE crops, living modified organisms (LMOs).

The Biosafety Law also defines penalties for not complying with its regulations. Failure to obtain approval or proper permits before importing or releasing GE organisms into the environment carry the following stated penalties:

• Individuals can be fined 2.5 million Naira (about $15,000) or imprisonment for a period not less than

five (5) years or both;
• Corporations would pay a fine of at least 5.0 million Naira (about $30,000) and the directors or officers of the body shall each be liable to a fine not less than 2.5 million Naira (about $15,000) or imprisonment for a term not less than five (5) years or to both such find and imprisonment;
• False information results in the same penalty as failure to obtain approval;
Obstruction results in a 2.5 million Naira (about $16,000) fine or imprisonment for not less than three (3) years or both

N. Low Level Presence Policy
Nigeria does not currently have a low level presence policy.

PART C: Marketing

A. Market Acceptance
Generally, most Nigerians are not aware of products of modern agricultural biotechnology and the issues involved. Information and discussions on modern biotechnology have been undertaken largely among GON officials, scientists and researchers. However, there are pockets of consumer rights and environmentalists indicating interests in pursuing activism in Nigeria's biotechnological adoption. Many stakeholders do not consider them a serious challenge considering the already wide availability and consumption of biotechnology food and agricultural products. Farmers are also more interested in improving their yields and increasing income. Nigerian farmers and the general public need to be educated about the technology.

B. Public/Private Opinions
There are active organizations like Friends of the Earth and other NGOs lobbying against the use of GE plants and/or production in the country. The perception varies with the intended use. The non-food crops like cotton are more acceptable. Crops conferred with disease resistance traits are acceptable. Farmers generally accept GE crops. Public attitudes towards biotech industries or research institutions in the country are cordial.

C. Marketing studies
FAS/Lagos is unaware of relevant marketing studies for biotechnology

PART D. Plant Biotechnology Capacity Building and Outreach:

A. Activities
There is an extensive relationship between the United States and Nigeria on agricultural biotechnology. USDA has helped to fund scientists to work on biotechnology at the IITA, under its technical assistance program. FAS/Lagos also utilized the Cochran Fellowship Program to provide U.S.-based training on agricultural biotechnology to Nigerian scientists.

Starting in 2001, the U.S. Government (USG) has also supported Nigeria to establish the Public Biosafety Systems (PBS) guidelines which created provisions for field testing of GE crops.

Since 2004, agricultural biotechnology in Nigeria received a boost with two linked initiatives funded by USAID; namely, the West African Biotechnology Network (WABNET) and Nigeria Agriculture Biotechnology Project (NABP), implemented by IITA. NABP was designed to assist Nigeria in building the framework for decision-making that will facilitate access to the opportunities biotechnology offers and will ensure the safe and effective application of this technology to improve agriculture.

A key element of Nigeria Agriculture Biotechnology Project is to improve implementation of biosafety regulations and enhance public knowledge and acceptance of biotechnology. The project developed collaborative linkages with, and provided facilities to: Nigerian universities/institutes; to NABDA for biotech information dissemination; SHESTCO for training of scientists; National Root Crops Research Institute (NRCRI) for plant genetic transformation; Institute for Agricultural Research (IAR) for tissue culture; and to University of Agriculture, Abeokuta for advanced biotechnology training.

Starting 2005, PBS has worked in Nigeria to support the development of draft biosafety policies and laws, and to provide technical training in biosafety review and regulatory oversight. Nigeria's NABMA is currently leading the drafting of biosafety implementation guidelines.

In early 2009, USAID sponsored a study tour trip for the House Committees members on Agriculture, Environment and Science and Technology to the Philippines GE crop farms. The visits gave the participants practical experience on GE crops, how they are being regulated, and the legislation procedure. These activities have assisted in the eventual enactment of the biosafety law.

The International Food Policy Research Institute (IFPRI) also coordinated through HarvestPlus with other local and international research institutions with presence in Nigeria to develop three new Vitamin A-rich 'yellow-colored' cassava varieties in Nigeria. Funded by the U.S. government through USAID, the cassava would provide more Vitamin A in the diets of over 70 million Nigerians who eat cassava on a daily basis. Vitamin A Deficiency (VAD) is widely prevalent in sub-Saharan Africa – afflicting about 20 percent of pregnant women and approximately 30 percent of children (under five years of age) in Nigeria. VAD can lower immunity and impair vision, which can lead to blindness and even death.

Also, in 2009, Nigeria's NBC endorsed two applications for CFTs of GE crops, one for nutritionally enhanced cassava and one for insect-resistant Bt cowpea. PBS, in collaboration with the AATF worked to facilitate the submission and review by regulatory authorities of the latter CFT application. It also provided material and manpower resources that assisted the country establish biosafety institutions and processes that will guide against the misuse of biotechnology. The support included providing and supporting capacity for the multi-locational CFT and inspections of GE crops which aimed at improving the skills and proficiency of Biosafety Regulators on the conduct of CFT inspection for GE crops, particularly on multi-location trials.

The USG is also supporting OFAB (http://aatf-africa.org/projects-programmes/programmes/open-forum-agricultural-biotechnology-africa-ofab) which also assembles knowledgeable stakeholders to interact and discuss issues regarding biotechnology in Nigeria and the rest of Africa.

Late 2012, the USDA also sponsored Nigerian journalists, filmmakers, actors and some related GON policy makers on a familiarization tour of facilities, institutions, firms, farms, etc. to further expose

them to the application of modern agricultural biotechnology in the United States. The tour is assisting to further the enlightenment of Nigerian stakeholders to agricultural biotechnology.

USG assistance generally takes the following directions:

• Educating policymakers, media personnel, local farmers and stakeholders on how to address the negative perceptions of the public;
• Building awareness to create innovative products and research outputs and demonstrating the economic potential of agricultural biotechnology;
• Securing a reliable information source through multiple Nigerian media sources, i.e. publications, advertisements and broadcasting;
• Creating awareness on the safety of genetically engineered crops to increase its acceptance;
• Educating farmers and grassroots organizations on farming techniques for genetically engineered crops to enhance yield; and
• Building capacity for regulators and plant breeders to effectively cultivate and commercialize GE crops in Nigeria.

B. Strategies and Needs

i) National - USDA's FAS/Lagos and the U.S. Mission Nigeria Biotech Outreach Program will attempt to support Open Forum on Agricultural Biotechnology in Nigeria (OFAB) to organize monthly meetings with key stakeholders. USDA will facilitate discussions and technical workshops where national and international experts speak about the benefits of biotechnology as a tool for climate change mitigation and for enhancing food security in Nigeria.

Other country-specific needs include, but are not limited to, the following:
• Monthly Sensitization workshops, symposiums, farmers' field day;
• "Seeing is Believing" tours in GE commercialized countries;
• Technical trainings on the commercialization of Genetically Engineered crops, Biosafety Risk Assessment/Management, Biosafety application review process, Biosafety Inspection;
• Recruit Volunteers for decentralization of Knowledge and information
• Equip Laboratories for necessary experiments and tests.

ii) Institutional Local research institutions lack capacity in scientific DNA manipulation and laboratory management. FAS/Lagos will continue to support the strengthening of local capacity if funding becomes available.

CHAPTER II: Animal Biotechnology

There are neither nether plans nor regulations for animal biotechnology in Nigeria; it is therefore not included in this report.

Reference Materials
• Nigeria Biosafety Guidelines 2001

- Draft National Biosafety Framework
- National Biosafety Policy
- National Biosafety Management Agency Act, 2015