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Annual

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Report Highlights:
In April 2015, Nigeria signed its biosafety bill and established the National Biosafety Management Agency (NBMA). NBMA functions to regulate the law and provide oversight for utilizing and commercializing biotechnology products for Nigeria's food security. These four genetically-engineered crops are under development and will likely be commercialized within the next five years: Bt Cowpea, Bt Cotton, Africa Bio-fortified Sorghum and Nitrogen Use Efficient, and Water Use Efficient and Salt Tolerant (NEWEST) Rice.

Section I. Executive Summary:

By way of background, Nigeria is Africa's most populous country (of more than 180 million people) and its largest economy. The country depends on proceeds from oil and gas exports for more than 90 percent of its revenue. Despite the oil boom over the past three decades, Nigeria could neither diversify its economy nor grow its agricultural sector. The agricultural sector accounts for about 40 percent of its gross domestic product —providing employment for about 70 percent of the population. Global oil prices have been down by more than 50 percent continuously for more than two years with no indication that they will rise any time soon. As a result, Nigeria is challenged by the recent global oil price decline while the country remains a net importer of food and major agricultural products.

In an effort to strengthen its food security, in 2001, Nigeria established the National Biotechnology Development Agency (NABDA) to promote, commercialize and regulate biotechnology products. NABDA operated without any legislation since its creation. The Biosafety bill lingered in the country's parliament over the 6th and 7th sessions of the country's National Assembly, while stakeholders and lawmakers were unanimous on the importance of passing it into law. Fifteen years later, in April 2015, Nigeria's biosafety bill was signed into law and led to the establishment of the National Biosafety Management Agency (NBMA) to regulate such law. This law leans heavily on the precautionary approach and requires certification and mandatory labeling of all biotech products. NBMA is principally responsible for providing oversight for biotechnology's use and regulating the commercialization of biotechnology products. The Agency has become the focal point and authority on biosafety and approaches agricultural biotechnology as a tool to achieve food security.

Nigerian government officials 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 that commercialization will lead to increased yield productivity and contribute to 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 countries.

Section II. Plant and Animal Biotechnology:

Part A. Production and Trade

a) Product Development

There are four genetically engineered crops (see below) under development that Nigeria is likely to commercialize within the next five years.

Bt Cowpea: The cowpea was developed in Australia but with significant participation of Nigerian scientists. The Bt gene is inserted to resist the Maruca insect that reduces crop productivity by about 60 percent. The research is being carried out in the Institute of Agricultural Research (IAR) Zaria and it is at its multi-locational trial level.

Bt. Cotton: The National Biosafety Management Agency granted Monsanto approval for the

commercial release of the bioengineered cotton and the confined field trial of drought-tolerant corn. The IAR Zaria commenced the multi-locational trials on Bt. Cotton with one site in Zaria and another in NABDA headquarters Abuja.

Africa Bio-fortified Sorghum (ABS): The ABS project is supported by the Bill and Melinda Gates foundation (BMGF) and DuPont Pioneer. It is at confined field trial stage at the IAR Zaria, and the sorghum is modified to have increased levels of Vitamin A, Iron and Zinc.

Nitrogen Use Efficient, Water Use Efficient and Salt Tolerant (NEWEST) Rice: The NEWEST rice project was commissioned in October 2015 at the National Cereal Research Institute, Baddeggi. The project is facilitated by the African Agricultural Technology Foundation (AATF) with the aim of increasing rice productivity in flood prone, poor Nitrogen and saline environment.

NOTE: The confined field trials for Bt maize is yet to start, but approval for research was granted.

b) Commercial Production
Currently, there is no commercialization of biotechnology products; however, with the new National Biosafety law, Nigerian government officials 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 approved in other African countries. GE crops are still at the research phase in Nigeria.

c) Exports
Nigeria does not export any GE crops

d) Imports
Formally, Nigeria has been importing transgenic seeds for research and CFT purposes only. Nigeria has no ban on the import of GE products and cannot ascertain if crops being imported have GE content. NBMA is yet to carry out analysis on GM crops in the country.

e) Food Aid: Nigeria is not a recipient of food aid.

PART B. Plant Biotechnology Policy:

A. Regulatory Framework for Agricultural Biotechnology

The National Biosafety Management Agency is the government institution responsible for regulation of GE products in Nigeria. NBMA seeks to stimulate agricultural biotechnology in the country. The National Biosafety Committee reviews applications and carries out analysis of socio-economic factors and risk assessments of GM crops before making recommendations to the Agency.

i) Responsible institutions involved in agricultural biotechnology in Nigeria:
The National Biosafety Management Agency (NBMA) was 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 and has responsibility for all correspondences with importers, exporters, and applicants on movement of products of modern biotechnology.

The Federal Ministry of Agriculture and Rural Development (FMARD) is in charge of formulating agricultural policy as it relates to biotechnology, promoting and facilitating agricultural activities and implementing 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 and 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 on these activities, 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 including CFTs noted in Part 2(a). Most of them have Institutional Biosafety Committees.

ii). Role and Membership of 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, 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 address any other issues 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 activities.

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

iii). Political factors: GON officials widely support agricultural biotechnology.

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

B. Approval

Currently, no GE crop has been approved for cultivation, import or export in Nigeria. However, operational guidelines for approval have been reviewed by the National Biosafety Committee. There are distinctions between the regulatory treatment of the approval for food, feed, processing and environmental release. The timeline followed for approvals is 270 days.

C. Field Testing

Field testing is allowed in Nigeria. Guidelines and draft regulations are in place.

With the approval of the National Biosafety Committee, the National Root Crops Research Institute (NRCRI)-Umudike, the IAR- Zaria, and the NCRI- Baddeggi in Niger State of Nigeria carried out CFTs on cassava, cotton, sorghum, cowpea and rice. The approval was based on the provisions of the National Biosafety Guidelines- which include field-testing of bio-engineered crops.

i) The cowpea maruca (insect) resistant multi-locational field trials (MFT):

- MFTs 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 and the field trials sites are located in Kano, Zamfara and Zaria.
- Preliminary results show that CFT4 is a very successful trial. The data shows that the experiment is more than 95 percent significant in controlling cowpea pod borer (maruca).
- The physical and biological control mechanisms are put in place by the Institute to mitigate potential environmental risk.
- Four CFTs for this event has been successfully concluded.
- The multi-location trials was 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: This event 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 Bio-cassava Plus is being conducted by the NRCRI, Umudike. The transgenic cassava, named "Super Cassava," is fortified with Vitamin A and was developed at the Danforth Center. It was established in October 2009 and is funded by the Bill & Melinda Gates Foundation.

iv) Nitrogen Use Efficient, Water Use Efficient and Salt Tolerant (NEWEST) Rice field Trial in NCRI, Baddeggi, Niger State. The NEWEST rice project was commissioned in October 2015 and has started its first field trials. The project is coordinated by the African Agricultural Technology Foundation (AATF)-Arcadia Biosciences Inc. provides technical support in product development and Public Intellectual Property Resource for Agriculture (PIPR) donated the plant transformation technology for the project.

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, the 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, and the 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 the National Food and Drugs Administration Control (NAFDAC) as the regulatory agency for food and drugs. The approved varieties may then be used by farmers.

E. Additional Requirements

After GE crop approval is given by NBMA, the crop also needs to meet the requirements of other extant laws related to the seed system in Nigeria. The National Agricultural Seed Council and the varietal Release Committee carries out additional registration of seeds/traits before commercialization. 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

Coexistence policy is evolving. However, there are provisions for monitoring. NBMA developed rules and guidelines to regulate GE Crops.

G. Labeling

Work in progress draft regulation stipulates products with four percent GE content to be labelled GM. The purpose of the proposed labeling is to enable consumers to make informed choices on products purchased. The 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 an 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. Monitoring and Testing

The country has 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; and
- Obstruction results in a 2.5 million Naira (about $16,000) fine or imprisonment for not less than three (3) years or both.

I. Low Level Presence Policy

The Policy on Low Level Presence is evolving. It makes provision for labelling of GM crops as:

- The term "genetically modified organisms" is used wherever there is evidence of the presence of genetically modified organisms; and,
- The phrase "This product may contain genetically modified organisms" is applied where genetically modified organisms in a product cannot be excluded.

J. Additional Regulatory requirements.

There are no additional regulatory requirements as of this report's submission.

K. Intellectual Property Rights (IPR)

The IPR legislation is evolving.

L. 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. Nigeria has signed and ratified the Cartagena Protocol on Biosafety. Towards domesticating the ratified protocol, Nigeria has passed its biosafety bill into law, thus the establishment of the National Biosafety Management Agency

M. 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, 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 guidelines.

N. Related issues

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

PART C: MARKETING

A. Public/Private Opinions

There are Civil Society groups campaigning against GE crops in Nigeria and this has affected the public perception on GE crops. Many stakeholders do not consider them a serious challenge considering the already- wide availability and consumption of biotechnology food and agricultural products.

Separately, farmers are also more interested in improving their yields and increasing income. The Open Forum on Agricultural Biotechnology is campaigning for GE crop production in Nigeria, in partnership with other NGOs e.g. Journalists for Social Development Initiative, Every Woman Initiative Centre, concerned scientists in the universities and research institutes.

The public has expressed concerns on the safety of GM crops, so strategic risk communication is required to address the misconceptions. 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. Nigerian farmers and the general public need to be educated about the technology. Farmers generally accept GE crops. Public attitudes towards biotech industries or research institutions in the country are cordial.

Misconceptions on the benefits of agricultural biotechnology and its potentials to drive development led to a spate of criticisms in Nigeria, Africa and the world at large. Incipient activism against the technology has also raised concerns in recent times. With the aim of building confidence in the Nigerian public, biotechnology practitioners, crop developers and the industry paving way for the use of science and technology in agriculture.

B. Market Acceptance

Nigerian farmers are willing to accept the commercialization of Bt. Cotton because of the benefits they expect. Farmers generally accept GE crops. Public attitudes towards biotech industries or research institutions in the country are cordial. FAS/Lagos is unaware of relevant marketing studies for biotechnology.

CHAPTER II: Animal Biotechnology

There are neither 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- http://www.nbma.gov.ng/?page_id=503
- Agricultural Biotechnology & Biosafety Workshop (ABBW 2016, ABUJA), Communiqué.