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AGRICULTURAL BIOTECHNOLOGY ANNUAL

Annual Report

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Report Highlights:

In February 2009, Nigeria's Biosafety bill was introduced to the National Assembly for consideration and passage into law. The bill has gone through its first and second readings and a public hearing will commence soon. The bill leans heavily on the precautionary approach and requires certification and mandatory labeling for imports of all products of biotechnology. This could negatively impact the importation of products derived through agricultural biotechnology. Post is collaborating with major stakeholders to ensure that these provisions are modified before the bill is passed into law. The Nigeria Biosafety Committee has approved two new applications for the field testing of transgenic cow pea and cassava varieties.

Section I. Executive Summary:

Nigeria, Africa's most populous nation (146 million), is a food deficit country. Formally a net food exporter, Nigeria's subsistence agriculture can no longer supply the needs of its growing population. According to trade sources, Nigeria imported about \$3 billion worth of agricultural commodities in 2008. Nigeria is largely a bulk commodity market and imports wheat, soybean products, tallow, rice and high value products. In MY 2008/09, U.S. agricultural exports to Nigeria surpassed \$1 billion, primarily wheat. Nigeria was the second largest buyer of U.S. wheat in the world in 2008/09.

Nigeria's draft biosafety bill was finally presented to the National Assembly (Congress) as a private bill for consideration and passage into law. Efforts to put in place a regulatory framework for the practice of biotechnology have been in the works since the 1990s, with the Federal Ministry of Environment providing the lead. Although the Government of Nigeria (GON) signed and ratified the Cartagena Protocol on Biosafety in 1991 as a mark of interest in the technology, very little was done to create the needed regulatory environment. The process leading to the presentation of the bill has been extremely slow. The enactment of biosafety laws in South Africa, Mali, Burkina Faso and Kenya bolstered Nigeria's interest to move the process forward.

Current status of the biosafety bill:

- The Biosafety bill has gone through the first and second readings at the House of Representatives.
- It is been taken as a private bill to the Chairman, House Committee on Agriculture, Honorable Makanjuola Gbenga Peter.
- In May 2009, a study tour trip was organized by USAID Reforms Project to Philippines GM crop farms for member of the House Committees on Agriculture, Environment and Science and Technology. The goal of this trip was to have a practical experience on GMOs and how they are being regulated as well as the legislation procedure. This trip was very successful.
- A public hearing of the bill will follow at a date will be fixed soon.

Major stakeholders in the country have urged Congress to expedite action on the bill in order for the country to benefit from the technology. When passed into law, it will provide the necessary regulatory framework for the practice of biotechnology. At the first reading of the bill held recently, Hon. Gbenga Makanjuola, Chairman House Committee on Agriculture noted that "the potentials of biotechnology are immense, as it can enhance food security, wealth creation and environmental sustainability". He further said that "the vision of Nigeria's biosafety is to ensure that the practice of modern biotechnology is undertaken within the scope of a regulatory system that will guarantee its safe application, protect Nigeria's biodiversity and minimize or eliminate

its risk to human health and the environment, and that all hands must be on deck by relevant stakeholders, by lending support to biosafety in this country."

The African Union has developed a biosafety model law as part of the overall efforts to encourage member countries to adopt the technology. The Economic Community of West African States is also developing common biosafety regulation/laws for the sub-region. Risk assessment /management, proof of safety before approval and the equivalence of GMOs with their conventional equivalent, cost and environmental impact are some of the issues that make the common approach important.

Nigeria's biosafety bill calls for the establishment the Biosafety Department under the National Biodiversity Management Agency. The Department is expected to be the focal point and authority on Biosafety in the country. The objectives of the Department are stated in the biosafety bill as follows:

- establish and strengthen the institutional arrangements on biosafety matters in Nigeria;
- safeguard human health and the environment from any potential adverse effect of genetically modified organism including food safety;
- ensure safety in the use of modern biosafety and provide holistic approach to the regulation of modified organisms to avoid risk based on the precautionary principle;
- provide measures for the case-by-case assessment of genetically modified organisms and management of risk in order to ensure safety in the use of genetically modified organisms to human health and the environment;
- provide measures for the effective public participation, public awareness, access to information and consensus building in the use and application of modern biotechnology and genetically modified organisms; and
- Ensure that use of the genetically modified organisms does not have adverse impact on socio-economic and cultural interest either at the community or national level.

However, the current draft bill contains some clauses that could negatively impact the importation of products derived through agricultural biotechnology. Section 9 (functions of the national biosafety committee) mandates the committee to assess and recommend approval of applications submitted for the import/export, transfer, and transit of GMO products. In addition, Part V (Notification and Authorization) clearly states that importation/exportation and movement of GMO products requires prior approval from the biosafety agency (when established) or the ministry of environment. Also, the bill requires mandatory labeling of products derived through agricultural biotechnology.

In the meantime, National Biosafety Committee has approved two applications for field trials of transgenic crops. The Institute for Agricultural Research, ABU Zaria received approval to conduct a field trial of transgenic cow pea resistant to Maruca, while the National Root Crop Research Institute Umudike has received approval to conduct contained field trials of biotech cassava variety. The transgenic cassava ("Super Cassava") which is fortified with vitamin A was developed at the Danforth Center. The National Biosafety Guidelines adopted by the GON made provision for field-testing bio-engineered crops.

Section II. Biotechnology Trade and Production:

A. Commercial Production of Biotechnology Crops

Nigeria does not currently produce any biotechnology crops commercially. A recent meeting organized by the NABDA, recommended that Nigeria should commence the commercialization of GM crops starting with crops with high industrial uses. With the commencement of commercial production of biotech cotton in neighboring Burkina Faso, Nigerian farmers have indicated strong interest in conducting field trials.

B. Biotechnology Research Efforts

Capacity exists at the International Institute for Tropical Agriculture (IITA) and to some extent at the GON's Sheda Science and Technology Complex (SHESTCO), to conduct and apply biotechnology research. Sustained research using modern agricultural biotechnology methods in Nigeria is being conducted at the IITA. The institute is doing preliminary work on bioengineered cowpea. IITA also collaborates with the National Root Crops Research Institute (NRCRI) on biotech cassava research.

C. Biotechnology Crops under Development

There is no biotechnology crop under development in Nigeria that will be on the market in the near future.

D. Imports of Biotechnology Crops/Products

Agricultural products such as soybeans, soybean meal, soybean oil and processed food are freely imported from the U.S., EU, Brazil and Argentina and may contain biotech ingredients. Corn was imported from the U.S. until an import ban implemented in 2005 to protect local producers. This ban has recently been overturned and corn is again expected to be imported into Nigeria.

E. Food Aid

Nigeria has been a food aid recipient, with rice, soybean meal and skim milk powder having been monetized under USDA food aid programs in the past few years. No issues have arisen as a result of biotechnology and food aid. Nigeria is no longer a recipient of USDA food aid programs.

F. Production of Biotechnology Crops Developed Outside the United States

At present, Nigeria does not produce biotechnology crops.

Section III. New Technologies:

There are no new technologies in use in Nigeria that go beyond biotechnology such as: the

genetic engineering of agriculturally-relevant animals, animal cloning, plants that produce pharmaceuticals, etc.

Section IV. Biotechnology Policy:

A. Regulatory Framework for Agricultural Biotechnology

I. Responsible institutions involved in agricultural biotechnology in Nigeria:

National Focal Point--Federal Ministry of Environment
National Biosafety Authority (NBA) -Proposed
The National Biosafety Committee (NBC)
National Biosafety Technical Sub-Committee
Institutional Biosafety Committees
National Biotechnology Development Agency (NBDA)

The <u>Federal Ministry of Environment</u> is the national focal point on Biosafety in Nigeria. This Ministry is the GON's liaison with the Secretariat of the Convention on Biological Biodiversity for administrative functions required under the Cartagena Protocol on Biosafety. The National Focal point is responsible for all correspondences with importers, exporters and applicants on movement of products of modern biotechnology. Pending the passage of the National Biosafety Bill the Minister of Environment acts for the National Biosafety Agency (NBA).

The Ministry of Environment has developed a National Biosafety Framework (NBF) to provide guidance on the implementation of Nigeria's Biotechnology program. This framework is a combination of policy, legal, administrative and technical instruments that will regulate all biotechnological work. It is also intended to ensure the safe transfer, handling and use of biotech materials that may have adverse effects on the conservation and sustainable use of biological diversity. The Framework is meant to provide a one-stop clearinghouse in the NBC.

The Framework also require the establishment of Institutional Biosafety Committees (IBC) by all institutions in Nigeria, both private and public (e.g. research institutes, universities, international research centers etc.), which plan to undertake biotechnology research and/or development. The IBC shall consult and seek approvals from the NBC and implement recommendations from NBC among others.

ii) Role and Membership of the Biosafety Committee (NBC)

The <u>NBC</u> serves as the Competent National Authority for biosafety in Nigeria. The NBC is responsible for the safe management of biotechnology activities, including research, development, introduction and the use of LMOs/GMOs. 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, and NACCIMA/Organized Private Sector. The NBC will also include a Biologist, a

Physical Scientist, a Social Scientist and a Representative of NGOs distinguished in environmental/conservation matters. The NBC is required to review all applications for the release of products of bioengineering and make recommendations to the Minister of Environment on whether or not to allow such products. The NBC oversees the implementation of the National Biotechnology Program, consistent with the Biosafety Law.

The NBC has also established National Biosafety Technical Sub-committees (NBTS) to focus on sectoral interests 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 NBC and contribute to its functions in relation to contained use, field trials, release and placement on the market.

All applications for import, field trials, transit and contained use must be routed through the registrar of the NBA. 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. The NBC takes a decision, which is then conveyed to the applicant by the Registrar of the NBA. A license to carry out event is issued by the Registrar of NBA.

The National Biotechnology Development Agency (NBDA) was established in 2001 in the Ministry of Science and Technology to promote the development of biotechnology in Nigeria. The agency is active in creating awareness for products of biotechnology. NBDA conducts regular workshops for the major stakeholders in biotechnology.

iii) Political factors

The Nigerian government appreciates the potential of biotechnology to improve agricultural productivity. The national biotechnology policy document states that the GON "supports biotechnology because of its immense potential to more rapidly contribute to sustainable food security and economic growth". The government established the National Biotechnology Development Agency to create awareness of the technology. The field trial of biotech cowpea is part of the approved prioritized research work of the Institute for Agricultural Research and approved by the government. GON officials participated actively in the research work plan meeting in which aspects of the project were discussed, indicating its commitment.

B. Approval of Biotechnology Crops

At present, no law exists to approve biotechnology crops for food, processing and feed.

C. Field Testing

In 2001, the GON adopted the National Biosafety Guidelines. The guidelines have a provision for field-testing bio-engineered crops. The National Biosafety Committee has granted approval to the National Root Crops Research Institute, Umudike and Institute of Agricultural Research (IAR), Zaria to carry out Confined Field Trials on transgenic cassava and cowpea, respectively:

I. The maruca - resistant cowpea field trial at IAR Zaria

This biotech event was developed by CSIRO Plant Industry Laboratory at Canberra Australia. The trial will be sited on the Research Farm of the Institute of Agricultural Research, Ahmadu Bello University, Zaria. Preparations have reached an advanced stage for planting to commence during the fourth week of July 2009. The field trial will evaluate transgenic events (lines) for their reaction to the legume pod boring insect, Maruca. This leg of the trial will last approximately 5 months to December 09. However, the trial will be repeated in 2010. A line will be considered resistant if it does not sustain damage by the insect. In addition, effect of environment, agronomic performance such as plant morphology, maturity and yield will be assessed. The trial will be replicated four times.

Current status

- Approval for the trial has been given by the Federal Ministry of Environment.
- The confined field has been inspected by the Regulators and is proven to be of international standard, therefore it is ready for the field trial.
- Confined Field Trial Training was held recently in Abuja to equip the Principal Investigators, Trial Managers, Technical personnel, Government Officials engaged in the planning, conducting and overseeing confined field trials of GM plants.
- A risk communication workshop organized by Africa Agriculture Technology
 Foundation (AATF) and the Program for Biosafety Systems (PBS) was held in June
 2009 in Nigeria with the main objective of equipping the principal Investigators (from
 Ghana, Burkina Faso and Nigeria), Trial Managers, Government Officials and
 Stakeholders on how to communicate about GMOs and risk management to different
 audiences.
- Application for the importation of seeds has been submitted to the National Agricultural Plant Quarantine Service.

II. The Transgenic Cassava field Trial at Umudike

The National Root Crop Research Institute, Umudike has received approval to conduct contained field trials of biotech cassava variety. The transgenic cassava (Super Cassava), which is fortified with vitamin A was developed at the Danforth Center.

Current Status

- The transgenic seedlings have been imported into the Country.
- They are undergoing acclimatization after which they will be taken to the field for confined field trials

National Biotechnology Development Agency (NABDA) is collaborating with the institutes in creating awareness among Nigerian cowpea clientele, while the Biosafety Office of the Federal Ministry of Environment ensures compliance to Nigerian Biosafety guidelines in the conduct of the trial. Internationally, the AATF provides funding platform, planning, capacity building and linking with other donors such as the USAID; the Network for the Genetic Improvement of Cowpea in Africa leverages scientific input of members for planning and linkage, the PBS assists in regulatory compliance capacity building and advice.

D. Participation in Meetings of International Standard-Setting Organizations

Nigeria signed the convention on biosafety 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.

E. Stacked events

The NBC does not require additional approval for stacked events

F. Review and Approval Process for Biotech Products for Planting and Import

At present, no laws exist to approve biotech products for planting and imports. However, the National Biosafety Guidelines adopted by the GON in 2001 has provision for field-testing bioengineered crops.

G. Coexistence

Nigeria's proposed biosafety bill is silent on co-coexistence. However, there are provisions for monitoring in the draft bill. The relevant portion of the bill states, "for the purpose of biosafety, monitoring shall be used as a tool to ensure that the concerns expressed by stakeholders are addressed, ensure compliance with the terms of approval, confirm claims and trace the fate of LMOs/GMOs".)

H. Labeling

The National Agency for Food and Drug Administration and Control (NAFDAC) is the GON's regulatory body responsible for food product manufacturing, importation, advertisement and distribution in Nigeria. The NAFDAC was established to protect and promote public health by ensuring the wholesomeness, quality, and safety of food and drugs consumed in Nigeria. NAFDAC regulations require food labeling to be informative and accurate. The minimum labeling requirements include net content, specifying essential ingredients in metric weight for solids, semi-solids and aerosols, and metric volume for liquids. Ingredients must be listed by their common names in order of their prominence by weight. The regulations are being strictly enforced, but they are not specific to products of biotechnology. The draft biosafety bill, however, requires the mandatory labeling of all products of agricultural biotechnology in order to protect "consumers right to know."

I. Biosafety Protocol

The GON signed and ratified the Convention on Biological Diversity in 1994 and the Cartagena Protocol on Biosafety in November 2002. Nigeria, having signed and ratified the protocol, is now under obligation to implement it. The implementation of the protocol is slow and has had no effect on trade.

J. Biotechnology-Related Trade Barriers

We are not aware of any biotechnology-related trade barriers affecting U.S. exports to Nigeria and products such as U.S. soybean meal have been imported without problems.

K. Pending Legislation

The Ministry of Environment has prepared a draft biosafety bill. The draft bill advocates mandatory labeling of all products of agricultural biotechnology to protect "consumers' right to know." If the bill were enforced once passed, it would likely affect exports of U.S. food products to Nigeria.

L. Technology Fees

Nigeria does not have any technology fees for bio-engineered crops; neither does it have legislation in place to collect such fees.

Section V. 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. Nigerian farmers and the general public will need to be educated about the technology.

Wheat importers in Nigeria favor the precautionary approach to biotechnology. They have learned about bio-engineered food products primarily from the U.S. - EU debate over biotechnology. Overall, Nigerian wheat importers have expressed the opinion that the U.S. should not introduce bio-engineered wheat into the market until all long-term health concerns are resolved. Nigeria in one of the largest export markets for U.S. wheat.

B. Focus Group Survey

The results of a focus group survey on the attitude of the public to biotechnology revealed that about 40 percent of respondents would not mind consuming bio-engineered food products. Many respondents especially among those with little education were ignorant of biotechnology and its potential usefulness. While some respondents did express concern about the long-term health effects of consuming such products, these concerns seem to be overshadowed by their basic need for affordable food. The survey also revealed a marked preference for biotech products developed locally to those that are imported.

Another national survey on public awareness of agricultural biotechnology in Nigeria was conducted in May 2004, preparatory to the launch of the Nigeria Agriculture and Biotechnology Project (NABP). Survey results suggest that the Nigerian public is only marginally aware of biotechnology. Those who are aware have heard something about biotechnology through stories in the news media. Most Nigerians do not have a clear understanding of biotechnology and

many still confuse the technology with conventional breeding techniques. Nigerians are also not very knowledgeable about national and international policy issues relating to biotechnology. However, Nigerians are interested in the innovation and wish that it could be utilized to address the persisting problems of poverty in the country and one-third of respondents stated that they would be willing to eat genetically engineered (GE) food if given the opportunity.

Following close collaboration by FAS/Lagos with key government Ministries and a series of workshops conducted by USAID funded NAPB for civil servants, policy makers, legislators and for the members of the media, the level of awareness of issues relating to agricultural biotechnology has improved somewhat. Most newspaper articles are well balanced and are devoid of misconceptions about biotechnology.

A number of anti GMO NGOs are active in the country.

Section VI. Capacity Building and Outreach:

A. U.S. Government or USDA Funded Outreach activities

Over the last five years, the USDA has helped to fund scientists to work on biotechnology at the IITA, under its technical assistance program. In addition, the Agricultural Affairs Office in Lagos utilized the Cochran Fellowship Program to provide training in agricultural biotechnology in the U.S. for four Nigerian scientists during the same period. In 2005, Agricultural Affairs Office in Lagos also nominated a journalist to participate in a biotechnology seminar sponsored by the US Grains Council.

In 2004, agricultural biotechnology in Nigeria received a boost with the launch of two linked initiatives funded by the USAID. These are the West African Biotechnology Network (WABNET) and the Nigeria Agricultural Biotechnology Project (NABP), implemented by CGIAR's International Institute for Tropical Agriculture (IITA), in close collaboration with Tuskegee University. The 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 the project is to improve implementation of bio-safety regulations; and, enhance public knowledge and acceptance of biotechnology.

The project developed collaborative linkages with and provided facilities to some Nigerian universities/institutes to facilitate implementation; National Biotechnology Development Agency (NABDA) for biotech information dissemination; Sheda Science & Technology Complex (SHESTCO) for training of scientists; National Root Crops Research Institute (NRCRI) for plant genetic transformation; Institute for Agricultural Research (IAR) for tissue culture and University of Agriculture, Abeokuta for advanced biotechnology training.

In May 2009, USAID sponsored a study tour trip to Philippines GM crop farms for the House Committees members on Agriculture, Environment and Science and Technology to have a practical experience on GMOs and how they are being regulated as well as the legislation procedure. This trip was reported to be highly successful.

B. Country Specific Needs

In order to assist the GON in its efforts to fast-track the creation of an enabling environment for biotechnology, Post would like to arrange an activity for high-ranking, policy level officers from the presidency, Ministry of environment, Agriculture, Science and Technology, Legislature, and academia. Nigerian policy-makers lack accurate information about the benefits of agricultural biotechnology and would benefit from this orientation to bolster their knowledge. The orientation program will highlight how products derived from agricultural biotechnology are considered in the U.S. food safety regulatory system. The proposed program is targeted for individuals and institutions that will play vital roles in the passage of the biosafety bill into law and its implementation. It is anticipated that the group will return to Nigeria with a renewed determination to move forward the process of creating an enabling regulatory environment for biotechnology.

Capacity building training is required for the personnel of the Ministry of Environment to be able to develop a biosafety protocol. SHESTCO requires up-to-date laboratory facilities to act as a national center of excellence that will be able to conduct research and assessment tests.

Section VII. Author Defined:

Copies of the following documents are available in the Agricultural Affairs office.:

Nigeria Biosafety Guidelines 2001 Draft Nigeria Biosafety Bill 2006 Draft National Biosafety Framework National Biosafety Policy

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