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Annual

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Report Highlights:
Despite a protracted legal suit against the release into the environment and commercialization of GE products on the Ghanaian market, positive strides have been notched. A thirteen-member board of directors of the National Biosafety Authority was inaugurated in February 2015, and a substantive Chief Executive Officer has now been appointed. Also, Cabinet approved the Regulations on Biosafety Law in April 2015. Reliable sources note that there is the possibility of getting either Bt Cowpea or GM cotton commercialized within the next three years.

Section I. Executive Summary:

U.S. food exports to Ghana consist primarily of wheat, rice, poultry, and other consumer oriented food products. Trade Data from the U.S. Census Bureau showed that the value of US agricultural exports to Ghana in CY 2014 was $129.9 million, a 29% decrease in value as compared to that recorded in CY2013 ($183 million), which was an all-time high in total value of U.S. agricultural exports to Ghana. U.S. exports of soybean meal, prepared food and dog & cat food in CY 2014, all reached record high in values of $8.9 million, $2.1 million and $400,000, respectively. This is also an indication of growth in export values of 269.9%, 167.9% and 74.6%, respectively, over the values recorded in CY 2013. Reliable sources note that there is the prospect of getting either Bt Cowpea or GM cotton commercialized within the next three years.

The President of the Republic of Ghana signed the Ghana Biosafety Act, 2011 (Act 831) in December 2011 following the passage of the Biosafety Law by the Ghanaian Parliament, on June 21, 2011. This Act (Act 831) established the National Biosafety Authority as the administrative body responsible for all issues related to Biotechnology in Ghana. The board is expected to approve the development, transfer, handling and use of GEs in accordance with the Biosafety Act 2011 (Act 831) and direct the operations of the authority, among others. Cabinet approved the Biotechnology regulations in April 2015.

Currently, Ghana imports processed products from South America, Europe and the United States that may contain biotechnology elements. Barring recent concerns raised on the export of seeds to Ghana, there is no discrimination of any sort directed at the existing U.S. agricultural trade interests, namely food exports to Ghana.

There has been an appointment of a substantive Chief Executive Officer of the NBA, and its governing body, a thirteen-member Board was inaugurated in February 2015. There has also been increased stakeholder education on biotechnology and biosafety alongside several outreaches to students and farmers across all ten (10) regions of Ghana. It is expected that more stakeholder engagements will be done for the upcoming year, especially on *Risk Communication*.

SECTION II PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:
Ghana now has the capacity for the development and production of modern agricultural biotechnology crops. There is the prospect of getting either Bt Cowpea or GM cotton commercialized within the next three years.

With the passage of the Ghana Biosafety Act, 2011 (Act 831), some confined field trials using modern agricultural biotechnology methods are being carried out by research institutes and universities in Ghana.

So far a total of five (5) applications have been received for research on biotech crops in Ghana. These were received by the National Biosafety Committee, which is the predecessor of the National Biosafety Authority. The applications were received for Nutrient Enhanced Sweet Potato (CRI); Nitrogen Use Efficient, Water Efficient, Salt Tolerant Rice (CRI); Bt Cowpea (SARI); Bt Cotton (SARI) and later GM Cotton (Dual trait) (SARI).

All the trials, except Sweet Potato and Bt Cotton, are still ongoing. The sweet potato trial never received enough funding to be carried out. The Bt Cotton trial was replaced by the GM Cotton trial, with the former (Bt Cotton) focusing on a single trait (insect resistance) and the latter (GM Cotton) combining this trait with another trait, namely herbicide tolerance.

b) COMMERCIAL PRODUCTION: Ghana does not commercially produce any biotechnology crops.

c) EXPORTS: Not applicable

d) IMPORTS: Ghana officially does not import bioengineered products. Agricultural products such as soybean meal, soybean oil and processed foods are freely imported from the United States, the European Union, Argentina and Brazil that may contain biotechnology elements.

e) FOOD AID: There are no U.S. food aid programs currently in Ghana.

PART B: POLICY

a) REGULATORY FRAMEWORK:

The GOG established the National Biosafety Committee in 2002 whose mandate was to draft the Biosafety Bill, produce guidelines for the implementation of the biosafety law and to prompt the GOG to move forward on biotechnology issues. It is made up of officials of government institutions, scientists, farmer organizations, and other stakeholders. It is a Working Committee that continuously dialoged with the GOG for the passage of the Biosafety law. It drafted the Biosafety Bill in 2004 and produced the National Biosafety framework and biosafety guidelines.
A National Biosafety Authority (NBA) has now been established to manage the implementation of the Ghana Biosafety Act 2011 (Act 831). A thirteen-member Board of Directors of the NBA has been inaugurated, and the Chief Executive Officer's position of the Authority has also been filled.

i. <u>Responsible Institutions for Implementing the Biosafety Bill:</u>
The key institutions tasked with the implementation of the Biosafety Bill are:
The National Biosafety Authority (NBA);
The Technical Advisory Committee (TAC); and
Institutional Biosafety Committees (IBC).

NBA is the designated national authority on all issues related to modern agricultural biotechnology in Ghana. All applications, except for contained use and field trials, will have to go through this Authority. The governing body of the NBA is a Board whose chairman and members are appointed by the President for a period of three years.

TAC consists of not more than eleven individuals from the regulatory agencies and from the private

sector who are knowledgeable in science and socio-economic matters related to biotechnology. TAC is the national advisory committee on matters concerning or related to biotechnology and will undertakes risk assessments of applications at the request of the Board. The Ministry of Environment, Science, Technology and Innovation (MESTI) appoints the members based on recommendations by the Board for a period not exceeding five years. IBC reviews applications for contained use and field trials. The regulatory agencies of the Government of Ghana responsible for monitoring and enforcement are also represented on the TAC. They include:

- The Food and Drugs Authority (FDA)– Food safety and related matters
- Plant Protection and Regulatory Services/MOFA – Plant health and related matters
- Veterinary Services Department/MOFA – Animal health and related matters
- Environmental Protection Agency – Environmental releases and related matters
- Customs, Excise and Preventive Services – Border handling of biotechnology products in collaboration with agencies listed above.

ii. Role and membership of the National Biosafety Authority (NBA):

The National Focal Point on Biosafety in Ghana is the Ministry of Environment, Science, Technology and Innovation (MESTI). MESTI is responsible for liaising with the Secretariat of the Convention on Biological Diversity for the administrative functions required under the Cartagena Protocol on Biosafety. The Ghana Biosafety Regulatory System is a coordinated framework, and the Biosafety Act established the National Biosafety Authority (NBA), which is interdisciplinary in nature, to process applications relating to biotechnology substances under the Act. The NBA ensures adherence to the Cartagena Protocol on Biosafety through implementation of the national biosafety guidelines and other regulations. Additionally, the Act makes provision for a governing Council, the Board, to have a technical advisory committee that will provide advice to the Board. Establishment of an Institutional Biosafety Committee (IBC) is also provided under the Act. The Biosafety Act also provides for issuance of further guidelines to facilitate better performance of the National Biosafety Authority (NBA).

The NBA has the powers as stated under section 39 of the Biosafety Act 2011 (Act 831) to draft and adopt regulations or guidelines to ensure safety of humans and the environment; stop a project through the relevant IBC after establishing that further continuation of the project is unsafe to the personnel, community and environment; and approve deregulation of all regulated materials for free movement and commercial release on the recommendation of relevant IBCs. The Act states that a person or organization intending to introduce a bioengineered product into the environment or import or place a bioengineered product on the market must first obtain the written approval of the NBA. Composition of the governing body of the National Biosafety Authority is as follows:

1. An expert in biotechnology and related biological sciences including biosafety, as Chairman;
2. The Chairman of the Technical Advisory Committee;
3. The Chief Director, or the representative of the Ministry of Environment, Science, Technology and Innovation;
4. One representative, Association of Ghanaian Industries (AGI);
5. One legal practitioner of not less than ten years of experience;
6. One representative of non-governmental organizations (NGO);

7. One member from Academia;
8. One member from the Council for Scientific and Industrial Research;
9. One member from the Ministry of Food and Agriculture;
10. One member from Ministry of Health;
11. Customs Division of the Ghana Revenue Authority;
12. The Chief Executive Officer, National Biosafety Authority.

Assessment of Political Factors:

The Biotechnology and Nuclear Agricultural Research Institute (BNARI) of the Ghana Atomic Energy Commission (GAEC) coordinated the project to draft a Biosafety Framework for Ghana between November 2002 and July 2004. UNEP/GEF provided financial and technical support for the project. The framework is unique to Ghana but it is modeled after the UNEP/GEF blueprint which includes: a government policy on biosafety, a regulatory regime, a system to handle requests for authorizations (including risk assessment, decision-making) and administrative functions, systems for 'follow up' (such as enforcement and monitoring for environmental effects), and systems for public awareness and participation. The text of the Framework and draft Biosafety Bill is available at the UNEP/GEF website: (www.UNEP.ORG).

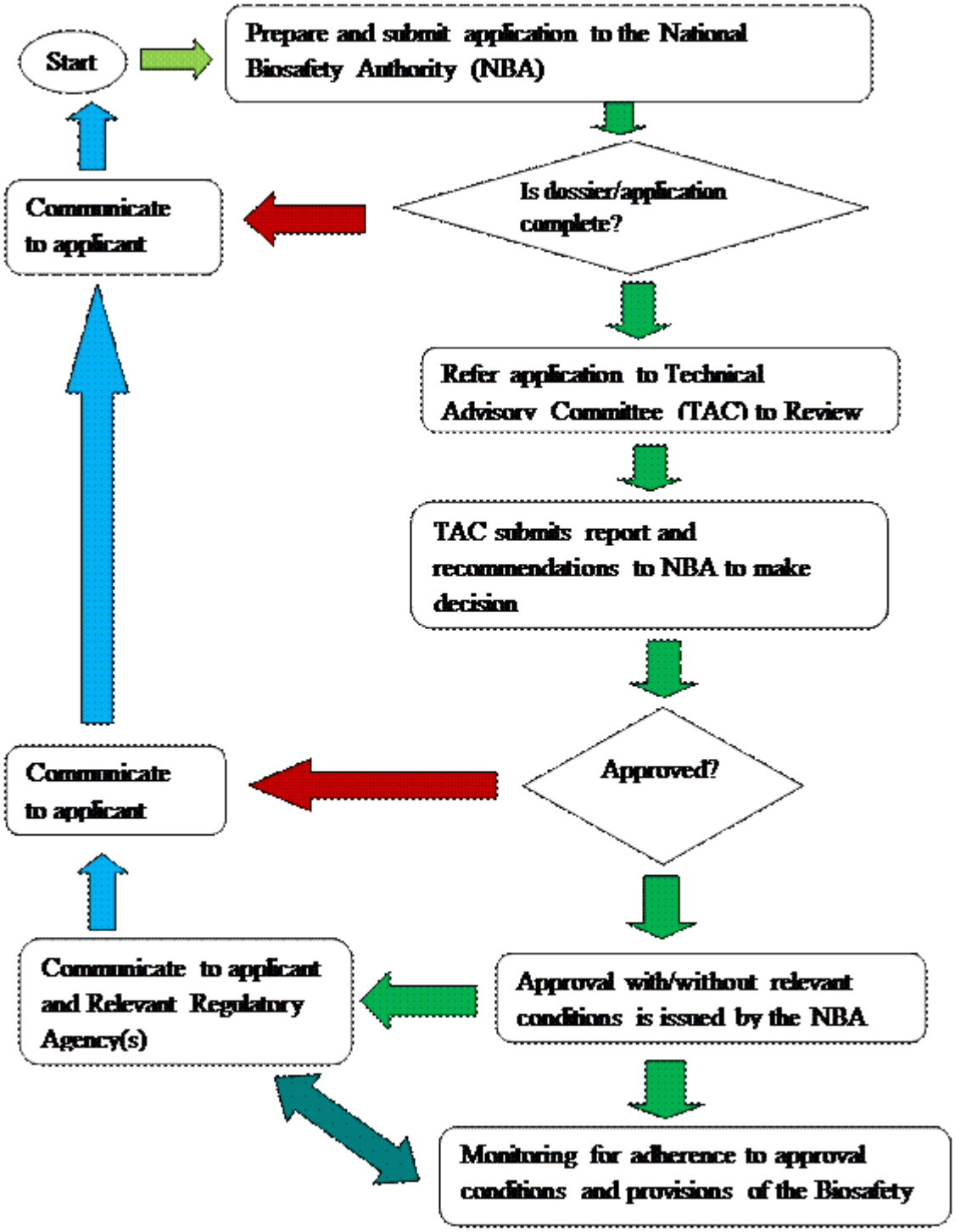
Before the Ghana biosafety law was passed the Ghanaian's position on biotechnology was guided by other principles stated in the National Science and Technology Policy (2000), the Constitution (Art 36, 41) and the Ghana Poverty Reduction Strategy (GPRS). However, at the same time the GOG ratified the Cartagena Protocol on Biosafety in May 2003. The Ghana biosafety Act 2011 (Act 831) has been passed and appears favorable to the use and acceptance of biotechnology. Therefore, the "precautionary approach and the environmentally sound management of biotechnology" are also factors that were strongly considered in drafting the Framework and Biosafety Act. For example, the Act begins by stating that the first objective is "to ensure, in accordance with the precautionary principle, an adequate level of protection in the field of safe transfer, handling and use of Genetically Modified Organisms (GMO) that may have an adverse effect on the environment."

iv. Distinctions between Regulatory Treatment of Approval:
The Ghana Biosafety Act 2011 (Act 831) approval process is the same for food, feed, processing and environmental release.

v. Reference to Pending Legislations and Regulations:
FAS Accra is not aware of any pending legislation and regulations with the potential to affect US exports. The process of drafting implementing regulations has been slow because of change in administration.

vi. Timeline for Approvals:
The Ghana Biosafety Act 2011 (Act 831) does not contain any timeline for the approval of biotech or bio engineered food products. Timeline for approval is dependent on the application submitted to the NBA. Below is the flow chart for the review of biosafety applications:

FLOW CHAT FOR BIOSAFETY APPLICATION REVIEW PROCESS IN GHANA



Source: Ministry of Environment, Science, Technology and Innovation (MESTI)

vii. Regulations on Biosafety: The Regulations on the management of Biotechnology (Biosafety) in Ghana received the approval of cabinet in April 2015. Further deliberation is ongoing between the

MESTI and the office of the Attorney General and Minister of Justice, prior to having it laid before parliament for 21 days after which the regulation comes into full force and effect.

b) APPROVALS:
At the present, no biotechnology crops (industrial crops, food crops, or feed) have been approved or registered for cultivation, import or export in Ghana.

c) FIELD TESTING:
Three field testing are underway; rice (by the Crop Research Institute-CRI) in the Ashanti Region, which has now been moved from the field to on-station; Bt cowpea and GM cotton (by the Savanna Agricultural Research Institute-SARI) in the North.

d) STACKED EVENTS:
The NBA requires additional approval for stacked events. There is also need for review of approval should there be sequencing change regarding an already approved GE trait.

e) ADDITIONAL REQUIREMENTS:
The Ghana Biosafety Act 2011 (Act 831) does not specify any additional product/seed registration or re-registration.

f) COEXISTENCE:
The Ghana Biosafety Act 2011 (Act 831) does not currently address co-existence.

g) LABELING:
The Biosafety legislation does not contain any labeling requirements for biotech or genetically modified food products, or strict liability provisions. Ghana requires labeling for packaged foods and feeds. The Food and Drugs Authority (FDA) General Labeling Rules, 1992, (L. I. 1514) stipulates that food labeling be informative and accurate. Labeling of packaged and prepackaged products is for purposes of health, food safety and need to know. The minimum labeling requirements are that labeling should be clear, concise and in English; should have product name, net mass/weight, batch number and expiry date; list of ingredients and food additives must be stated. It is mandatory to label any prepackaged food item that has nutritional composition. General labeling regulations for food products are strictly enforced, but they are not specific to biotechnology products.

h) TRADE BARRIERS:
FAS/Accra is not aware of any biotechnology-related trade barriers affecting U.S. exports to Ghana.

i) INTELLECTUAL PROPERTY RIGHTS (IPR):
Ghana is a member of the World Intellectual Property Organization (WIPO), the Universal Copyright Convention (UCC) and the African Regional Industrial Property Organization (ARIPO). Manufacturers and traders are strongly advised to patent their inventions and register their trademarks in Ghana, and to do so through a patent or trademark agent. Fees for registration vary according to the nature of the patent, but local and foreign applications pay the same rate. The Ghanaian system for patent and trademark protection is based on British law, and it was only in 1992 that UK patent laws ceased to apply in Ghana. Local courts offer redress when infringements occur, though few cases have been filed in recent years.

The Copyright Act was passed in 1961 and the Trademark Act in 1965 (amended in 2004). The Copyright Administration in Ghana is responsible for patents, copyright and trademarks. Registration of a trademark permits the holder to have the exclusive right to use the registered mark for a specific product or group of products. Upon approval of a patent, the applicant is given the exclusive right to make, export, import, sell, use a product or apply a patented process.
The Copyright Act of 1965 (amended in 1970 and 2005) makes it a criminal offense to make counterfeit, reproduce, export, import, exhibit, perform, or sell any work without the permission of the copyright owner. The Biosafety law does not contain any IPR requirements for biotechnology food products.

j) CARTEGENA PROTOCOL RATIFICATION:
Ghana ratified the Convention on Biological Diversity on August 1994 and the Convention's Cartegena Protocol on Biosafety on May 30, 2003. As stated in the National Biosafety Framework for Ghana, the Protocol is in consonance with the Ghana Constitutional obligations, Ghana environmental law and policy and the fulfillment of Ghana's treaty obligations. FAS/Accra is not aware of any significant impact on trade.

k) INTERNATIONAL TREATIES/FORA: FAS/Accra is not aware of any position pertaining to biotechnology that Ghana may have taken in International Treaties, Conventions or Fora.

l) RELATED ISSUES: Not applicable

m) MONITORING AND TESTING:
The Ghana Biosafety Act 2011 (Act 831) makes provision for the establishment of a monitoring body for biotechnology products. However, a monitoring program of genetically engineered food products is yet to be developed. FAS Accra is not aware of any active testing for genetically engineered products.

n) LOW LEVEL PRESENCE POLICY: FAS/Accra is not aware of any Low level Presence Policy.

PART C: MARKETING

a) MARKET ACCEPTANCE:
In Ghana, the majority of people are not aware of modern agricultural biotechnology products and the issues involved. The academia, researchers and GOG officials are mostly the stakeholders in biotechnology discussions. Very few farmer representatives are involved in biotechnology fora. Most food producers would accept biotechnology if it guarantees increased yields. Post's discussions with representatives of some local Farmer-Based Organizations (FBOs) revealed that farmer organizations have been involved in the development of the Biosafety Framework for Ghana. Their major concerns, regarding public awareness, participation and decision-making have been included in the biosafety guidelines, and it is their expectation that these concerns will be addressed during the implementation phase.

b) PUBLIC/PRIVATE OPINIONS:
There continue to be campaigns against the introduction of biotechnology by anti-GM groups and individuals in Ghana. These have increasingly linked the Plant Breeders Bill, which is still before parliament, to the introduction of Genetically Engineered (GE) food products into Ghana. However, the Ghana Biosafety Act 2011(Act 831) that allows the introduction of GE crops in Ghana was passed in

2011. Some groups have made coordinated attempts to confuse the general public over what the Plant Breeders' Bill really seeks to achieve. The anti-GM activists include, but not limited to, the Food Sovereignty Ghana (FSG), Friends of the Earth, and Centre for Indigenous Knowledge and Organizational Development Ghana (CIKOD).

Most local Ghanaians have little or no knowledge and understanding of modern biotechnology and rely on opinion leaders (especially in the media) to understand issues of such nature. This has left huge gaps for the anti-GM groups to exploit by misinforming the public on issues of genetic engineering. This misinformation campaign has led to several bodies calling for government to exercise caution with the introduction of GE products; such bodies include; the Ghana Health Service (GHS), Ghana Catholic Bishops' Conference, and Ghana Export Promotion Council. For a while, the anti-GM campaign seemed to be gaining ground in the public domain. However, in recent times, several individuals and groups have waged vigorous counter campaigns in the media to send the right information to Ghanaians and to reverse the growing anti-GM sentiments in the country.

Following earlier comments by FSG that they represented the concerns of farmers in Ghana, Program for Biosafety Systems, Ghana (PBS-Ghana) together with the Open Forum on Agricultural Biotechnology in Africa (OFAB) organized the Ghana National Association of Farmers and Fishermen (GNAFF), the mother body of all farmers and fishermen in Ghana to state their support for the continued research into biotechnology solutions. (http://graphic.com.gh/news/general-news/14098-gnaff-supports-adoption-of-gm-food.html)

A thirteen-member Board of Directors for the NBA has been inaugurated in the face of protracted legal case, which has the National Biosafety Committee, National Biosafety Authority, Ministry of Food and Agriculture, Attorney General's department, and the Ghana National Association of Farmers and Fishermen as defendants, and the Food Sovereignty Ghana, the CPP (a political party), the Vegetarian Association of Ghana (VegGhana), and Kanyan Akuafuo Kuo (KAK) a farmer-group from the Brong Ahafo Region of Ghana as Plaintiffs.

Swearing in the members, the Minister of Environment, Science, Technology and Innovation (MESTI) publicly noted that the event was part of steps to legalize biosafety for the country to take decisions on modern biotechnology, based on risk assessment and other considerations. And that, the government sees great potential in modern biotechnology, hence its presence in the National Science, Technology and Innovation Policy as one to be adopted for Ghana's socio-economic development. Furthermore, the government recognizes the potential adverse effects that the technology could have on the environment and health of the people and had therefore adopted biosafety as the decision-making mechanism for the management of the technology. It was disclosed that the inauguration climaxed 16 years of effort by successive governments to put in place appropriate and transparent decision-making mechanisms for modern biotechnology for the benefit of all Ghanaians.

The newly inaugurated board has the immediate tasks of completing its office at the Ghana Atomic Energy Commission, determining fees for biosafety applications, establishing an Appeals Tribunal, establishing Memorandum of Understanding between the Authority and Regulatory Agencies, and educating the public.

PBS in collaboration with OFAB and the African Biosafety Network of Expertise (ABNE) has had

other farmer groups to come out publicly in support of biotechnology in Ghana. They also intend to buy space in key print media to highlight the benefits of GM technology, assist key farmer-groups to take favorable positions on the introduction of GM, identify well-informed individuals who will promptly respond to issues of GM on radio and in the newspapers.

c) MARKETING STUDIES:
Information and discussions of modern biotechnology have been ongoing among GOG officials, scientists and researchers. Post is not aware of any specific study assessing Ghanaians' acceptance of biotechnology products. However, Post expects that the Ghanaian producer, importer, retailer and consumer would accept biotechnology products provided these guarantee increased yield and income.

Part D: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES:
Ghana is clearly moving forward on biosafety and biotechnology with the passage of the Biosafety Act 2011 (Act 831) in December 2011. Ghana could benefit from capacity building outreach programs that would support science-based regulatory efforts and provide accurate information to the broader public on the positive benefits of biotechnology.

USDA has funded biotechnology training over the last few years via the Norman Borlaug Fellowship and Cochran Fellowship programs. In addition, USAID, through the Global Program for Biosafety Systems (PBS), has been promoting the judicious use of modern biotechnology in Ghana to increase agricultural productivity with linkages to regional and global markets. The biotechnology outreach program for 2014 was successfully implemented with very positive results.

USDA-FAS/Accra forwarded nominations as recommended candidates for the 2016 International Visitor Leadership Program. Another team of Ghanaian delegation is being facilitated to participate in the 2015 Agricultural Biotechnology and Biosafety course at the Michigan State University.

b) STRATEGIES AND NEEDS:
In order to facilitate the GOG's effort to move forward on biotechnology regulation, there is the need to continue to boost awareness among government officials, academia, and other stakeholders especially farmers. Capacity building and training is required for the personnel of the Ministries of Food and Agriculture, Environment, Science and Technology, and other officials to be able to develop a biosafety protocol. Technical assistance may also be welcome in setting up the National Regulatory Authority office and secretariat and conducting outreach and awareness raising activities among potential applicants, farmers, agribusinesses, and other stakeholders regarding the regulatory system and application process.

Post also encourages partnering with Ghanaian counterparts in the discussion of biotechnology in international fora. Ghanaian leadership in opinion and rulemaking in Africa would be helpful in supporting a science-based dialogue with African and regional audiences.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: Not applicable
b) COMMERCIAL PRODUCTION: Not applicable

c) EXPORTS: Not applicable
d) IMPORTS: Not applicable

PART F: POLICY
a) REGULATION: Not applicable
b) LABELLING AND TRACEABILITY: Not applicable
c) TRADE BARRIERS: Not applicable
d) INTELLECTUAL PROPERTY: Not applicable
e) INTERNATIONAL TREATIES/FORA: Not applicable

PART G: MARKETING
a) MARKET ACCEPTANCE: Not applicable
b) PUBLIC/PRIVATE OPINIONS: Not applicable
c) MARKET STUDIES: Not applicable

PART H: CAPACITY BUILDING AND OUTREACH
a) ACTIVITIES: Not applicable
b) STRATEGIES AND NEEDS: Not applicable

Reference Materials

1. National Biosafety Framework Document [ISBN: 9988-8275-4-7]
2. National Biosafety Guidelines [Part I-Introduction to biosafety Guidelines] [ISBN: 9988-8275-0-4]
3. National Biosafety Guidelines [Part II-Biosafety Guidelines for laboratory and field work] [ISBN: 9988-8274-3-1]
4. National Biosafety Guidelines [Part III-Biosafety Guidelines for movement of regulated materials and commercial releases][ISBN: 9988-8274-8-2]
5. Risk Assessment Guidelines [ISBN: 9988-8275-1-2]
6. Public Participation Guidelines [ISBN: 9988-8275-2-0]
7. Administrative Guidelines [ISBN: 9988-8275-3-9]