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Report Highlights:

Though momentum towards environmental release of the Bt cowpea seems to have slowed down, approval remains inevitable. Dossier on Nitrogen Use Efficient (NUE) rice is ready for submission.

EXECUTIVE SUMMARY

Food and nutrition security has remained a national priority for successive Ghanaian governments. Faced with strong growth in food demand resulting from rapid demographic shifts and changing consumption habits, Ghana imports food from all over the world to help meet its domestic needs. Ghana's major trading partners in Africa include Cote d'Ivoire, Egypt, Kenya, Morocco, Senegal, and South Africa. Food imports from Asia, Australia, Europe, New Zealand, North and South America are also common on the Ghanaian market.

The Government of Ghana (GOG) recognizes the potential of biotechnology as a critical innovation in the quest for national food and nutrition security. The new administration's initiative, "Planting for Food and Jobs," seeks to drastically increase food security and domestic production of key crops such as corn, rice, and soybean. Provision and usage of improved inputs are a crucial part of this initiative. While not explicitly stated in the initiative, biotechnology can be a vital tool in achieving the GOG's goals.

A Legal Instrument (LI) was passed in June 2019 outlining the implementation of the Biosafety Law's provisions. This provides guidelines to some institutions like the Institutional Biosafety Committees and offers procedures for the uptake of the technology from research to commercial release.

There is currently no restriction on importing GE products or products containing GE material, and Ghana currently imports food and feed products that may contain biotechnology elements.

Alcoholic beverages, dairy products, and processed products are imported and exported by Ghana, which may contain microbial biotech-derived food ingredients.

In terms of current commercialization efforts, considerable progress has been made, especially regarding plant biotechnology. There is a high possibility of a commercial release of Bt cowpea in the very near future.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

Ghana continues to build capacity for the development and production of modern agricultural biotechnology crops. According to reliable sources, the approval for environmental release and commercialization of Bt cowpea is imminent. The dossier on Bt cowpea is complete and an application for approval was submitted to the National Biosafety Authority (NBA) for environmental release.

Five applications for research on biotech crops were received by the National Biosafety Committee (NBC), the predecessor of the NBA. Applications for Nutrient Enhanced sweet potato and Nitrogen Use Efficient (NUE) rice were submitted by the Council for Scientific and Industrial Research's (CSIR) Crop Research Institute (CRI). Additionally, the Savanna Agricultural Research Institute (SARI) submitted applications for Bt cowpea, Bt cotton, and insect resistant and herbicide tolerant stacked traits cotton, which the research institution refers to as GM cotton. The NBA also received an application for Nitrogen-Use Efficient, Water-Use Efficient, and Salt Tolerant (NEWEST) rice from the CRI.

The NUE rice's two required regulatory field trials have been completed successfully, and the dossier is ready for submission to the NBA. Lack of funding is preventing the confined field trials for the NEWEST rice. Trials for the Nutrient Enhanced sweet potato, the Bt cotton, and the genetically engineered (GE) cotton have been halted due to lack of funding as well.

b) COMMERCIAL PRODUCTION:

There is no commercial production of biotechnology crops.

c) EXPORTS:

Not applicable.

d) IMPORTS:

Ghana requires prospective importers of GE products to seek approval from the NBA and the Food and Drugs Authority (FDA) before importation. The NBA first gives clearance, and then the FDA for products classified as food per the NBA's issued guidelines. A food safety assessment is required for bioengineered products that contain actively detectable GE traits or those that have not undergone a high degree of processing to denature the foreign DNA. Based on the scope of the Biosafety Act and the recently issued Biosafety Regulations 2019, agricultural products which may contain GE elements such as soybean meal, soybean oil, and processed foods, are freely imported from Argentina, Brazil, the European Union, and the United States. Ghana imports soybean meal from Argentina, Bolivia, Brazil, Europe, India, Paraguay, and the United States. In past years, significant imports of soybean meal have also come from Uruguay, South Africa, and China.

e) FOOD AID:

Ghana has been the recipient of U.S. food assistance under USDA's Food for Progress program. There are no biotechnology-related trade barriers in Ghana.

f) TRADE BARRIERS:

Currently, there are no biotechnology-related trade barriers in Ghana.

PART B: POLICY

a) REGULATORY FRAMEWORK:

The GOG established the NBC in 2002, with a mandate to draft the Biosafety Bill, produce guidelines for the implementation of the Biosafety Law, and prompt the GOG to move forward on biotechnology issues. It consists of officials from government institutions, scientists, farmer organizations, and other stakeholders. In dialogue with the GOG, the NBC drafted the Biosafety Bill in 2004 and produced the National Biosafety Framework and biosafety guidelines.

The NBA has since managed the implementation of the Ghana Biosafety Act 2011 (Act 831). A thirteen-member Board of Directors is in place whose term ends after three years. A Memorandum of Understanding (MoU) was prepared and signed between the NBA and the seven regulatory agencies in November 2016. This would replace the separate bilateral agreements that have been signed between the NBA and each of the regulatory agencies, namely, FDA, Ghana Standard Authority (GSA), Environmental Protection Agency, Customs Services, Plant Protection, and Regulatory Services Directorate, Veterinary Services Directorate, and Local Government. This initiative engenders cooperation among the regulatory agencies. To date, the Local Government remains the only regulatory agency not to have signed the MoU. The lack of cooperation from the Local Government is partly due to a change in leadership and the fact that there is no designated desk for biosafety at the agency. The NBA has finally relocated to its new office, giving it the sense of autonomy as an institution of authority.

i. Responsible Institutions for Implementing the Biosafety Law:

The key institutions tasked with the implementation of the Biosafety Law are:

- The National Biosafety Authority (NBA)
- The Technical Advisory Committee (TAC)
- Institutional Biosafety Committees (IBCs)

The 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, go through this authority. The governing body of the NBA is a Board whose chairman and the President of the Republic appoint members for three-year assignments. The TAC consists of not more than eleven individuals from the

regulatory agencies and the private sector knowledgeable in science and socio-economic matters related to biotechnology. The TAC is the national advisory committee on the issues concerning or related to biotechnology and 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 the Board's recommendations for a period not exceeding three years. The seven regulatory agencies of the GOG responsible for monitoring and enforcement are also represented on the TAC. The IBCs review applications for contained use and field trials.

ii. Role and membership of the NBA:

The National Focal Point on Biosafety in Ghana is MESTI, 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.

The Biosafety Act established the NBA, which is interdisciplinary, to process applications relating to biotechnology products specified under the Act. The NBA ensures adherence to the Cartagena Protocol on Biosafety by implementing the national biosafety guidelines and other regulations. Additionally, the Act provided the NBA's governing board with an advisory committee to provide technical advice. The establishment of the IBCs was also provided under the Act. The Biosafety Act also allows for the development of further guidelines to facilitate the better performance of the 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 the safety of humans and the environment;
- Stop a project through the relevant IBC after establishing that the project is unsafe to humans or the 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 GE product into the environment or import or place it on the market must first obtain a written approval of the NBA. The structure of the NBA's governing body is as follows:

1. An expert in biotechnology and related biological sciences including biosafety, as the Chairperson;
2. The Chairperson of the Technical Advisory Committee established under section 27;
3. One representative of the Ministry responsible for science (MESTI) not below the rank of Director;
4. One representative of the Association of Ghanaian Industries (AGI);
5. One legal practitioner with not less than ten years of experience and has sufficient background knowledge relevant to the subject matter of this Act;
6. One representative from a non-governmental organization (NGO) preferably a farmer-based organization (FBO);
7. Two members from academia that have sufficient background knowledge

- relevant to the subject matter of this Act at least one of whom is a woman;
8. One representative of the Council for Scientific and Industrial Research (CSIR) not below the rank of Director;
 9. One representative of the Ministry of Food and Agriculture (MOFA) not below the rank of Director;
 10. One representative of the Ministry of Health (MOH) not below the rank of Director;
 11. One representative from the Customs Division of the Ghana Revenue Authority (GRA);
 12. The Chief Executive Officer of the NBA.

iii. Assessment of Political Factors:

The Biotechnology and Nuclear Agricultural Research Institute (BNARI) of the Ghana Atomic Energy Commission (GAEC) coordinated the draft Biosafety Framework for Ghana between November 2002 and July 2004. The United Nations Environment Programme/Global Environment Facility (UNEP/GEF) provided financial and technical support for the project. The framework is unique to Ghana and 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 strategies for public awareness and participation.

Before the Ghana Biosafety Law passed, the GOG’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) documents. The GOG ratified the Cartagena Protocol on Biosafety in May 2003. The Ghana Biosafety Act 2011 (Act 831) passed, paving the way forward for the use of GE products. The “precautionary approach and the environmentally sound management of biotechnology” are also factors that were included in drafting the Framework and Biosafety Act. For example, the Act begins by stating that the first objective is “to ensure, under the precautionary principle, an adequate level of protection in the field of safe transfer, handling and use of Genetically Modified Organisms (“GMO”) that may harm the environment.”

In April 2017, President Nana Addo Dankwa Akufo-Addo launched the “Planting for Food and Jobs” program. The President explained that planting for Food and Jobs will be anchored on the pillars that will transform Ghanaian agriculture: the provision of improved seeds, supply of fertilizers, the provision of dedicated extension services, a marketing strategy, and the use of e-agriculture. “The Planting for Food and Jobs program is expected to increase the production of corn by 30 percent; rice by 49 percent; soybean by 25 percent; and sorghum by 28 percent from current production levels,” he added. This initiative seeks to drastically increase domestic production of corn, rice, soybean, sorghum, and select vegetables through improved inputs, extension services, and improved infrastructure. Improved seeds are part of the improved inputs, and while biotechnology is not explicitly mentioned, it can play an essential role in this initiative.

iv. Regulatory Distinction between GE Plant Products with and without DNA in Final Form:

Regulatory distinction exists between GE plant products containing DNA in the final form of the product and those products of GE plants that do not contain DNA in the final form. All GE plant products that contain DNA with an active gene in the final form of the products are deemed as “GMO”. These are first regulated by the NBA before being regulated by the FDA. All GE plant products that do not contain DNA in the final form of the product (oil, sugar, etc.) are not regulated by the NBA.

v. Regulatory Distinction between Living and Non-Living GE Plant Products:

Pre-market approval by the NBA is only required for “Living Modified Organisms (LMOs)” like seeds. Placement of non-living GE products or processed foods (such as meal, cake, etc.) on the market only requires approval from the FDA. Non-living GE products are considered non-“GMOs”. In the case of living GE products, an application for approval to import gets reviewed by the NBA and the relevant regulatory agencies within 180 days. If there is need for the review to go beyond 180 days, the NBA communicates this to the applicant accordingly.

vi. Differences in Regulatory Approval for various GE Plant Products:

The approval process under the Ghana Biosafety Act 2011 (Act 831) is quite similar for food, feed, processing, and environmental release. The NBA via the TAC does the assessment in collaboration with the relevant regulatory agencies. The period of review and the regulatory agencies involved will depend on the type of request as well as the bioengineered product specified in the request. The NBA’s issued guidelines stipulate that for applications requesting introduction into the environment, and import or placement on the market, risk assessment shall be conducted in accordance with Schedule Four (4) of Act 831, and in accordance with the Cartagena Protocol on Biosafety (Annex III). Food safety assessment for applications to place prepackaged bioengineered products on the market shall be conducted in accordance with the Act 831 and current CODEX guidelines for safety assessment of food derived from recombinant DNA organisms.

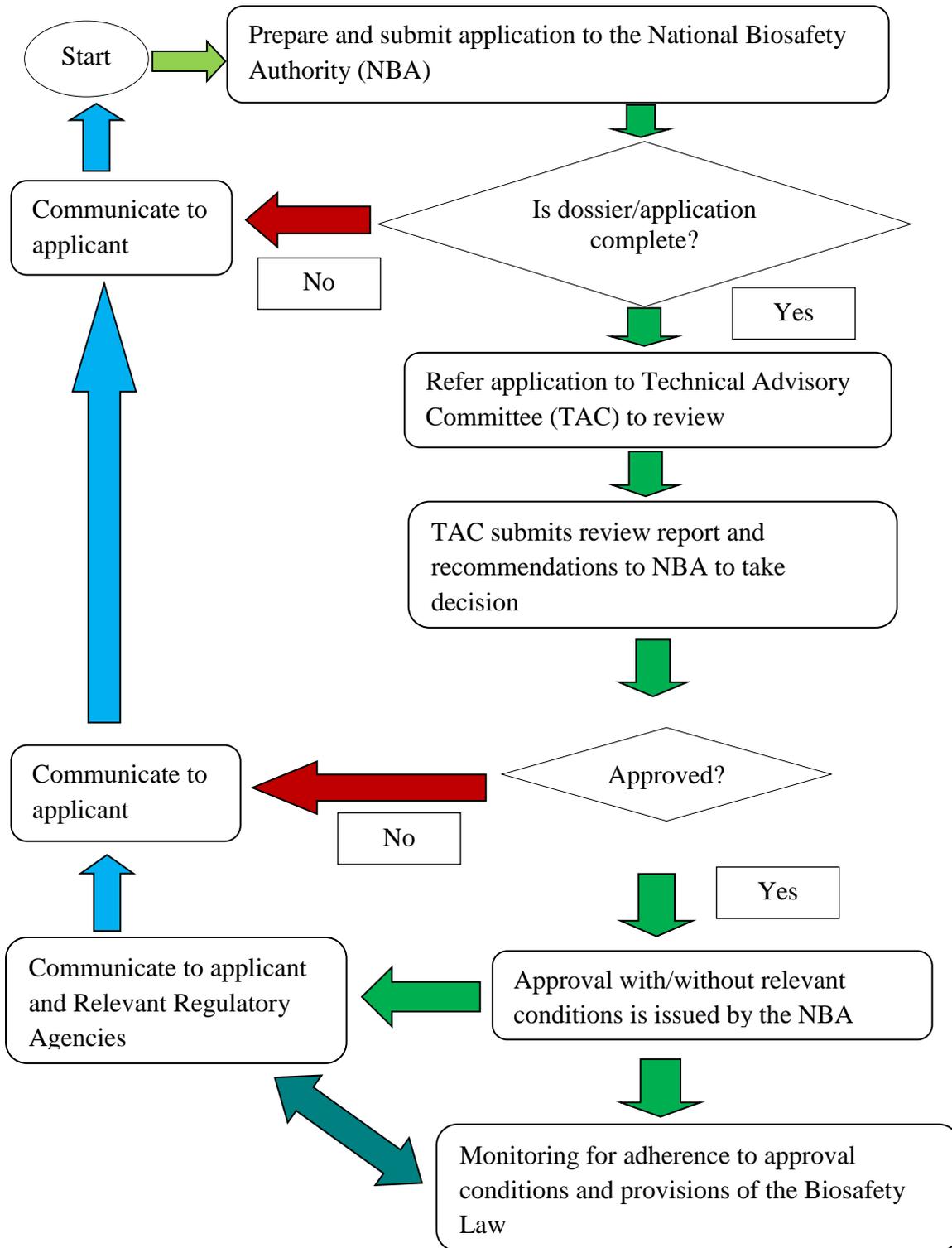
vii. Reference to pertinent Pending Legislations and Regulations:

FAS Accra is not aware of any pending legislation and regulations with the potential to affect US exports.

viii. Timeline for Approvals:

The timeline for the approval of applications is 180 days. Below is the flow chart for the review of biosafety applications:

FLOW CHART FOR BIOSAFETY APPLICATION REVIEW PROCESS IN GHANA



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

ix. Legislation and/or Regulations on Biosafety:

The Regulations on the management of biotechnology (Biosafety) in Ghana, was passed in June 2019. The regulations, L.I. 2383, spell out how provisions in the Biosafety Law will be implemented. It also provides guidelines to some institutions like the IBCs, and the process for moving a product from research to commercial release. Prior to this, the existing guideline (L.I. 1887) only covered up to research.

x. Additional Required Registration for Approved GE Plant Product:

Additional registration is required beyond GE plant approval/authorization depending on the specific product (for example, seed or food). If seed, additional approval is required from the Ministry of Food and Agriculture's National Variety Release and Registration Committee. If food, additional approval is required from the FDA.

xi. Requirement of Re-registration:

This has not been necessitated because the NBA is yet to grant approval to the first submitted application. Re-registration is envisaged as a requirement in the future.

xii. Approvals/Authorizations Durations or Expirations:

Approvals or authorizations last for a period of 10 years.

b) APPROVALS:

At present, no GE crops (industrial crops, food crops, or feed) have been approved or registered in Ghana for open cultivation, import, or export.

c) STACKED OR PYRAMIDED EVENT APPROVALS:

The NBA requires additional approval for stacked events. There is also a need to review approval should there be a sequencing change regarding an already approved GE trait.

d) FIELD TESTING:

Ghana allows field testing, and confined field trials are managed strictly in conformity with issued guidelines by the IBCs and NBA as dictated by the regulation on biosafety (LI 2383). Two field testing exercises are underway: NUE rice (by CRI in the Ashanti Region) and Bt cowpea Cry2AB (by SARI in the Northern Region).

e) INNOVATIVE BIOTECHNOLOGIES:

At present, the Ghana government has not addressed the regulation or non-regulation of genome editing.

f) COEXISTENCE:

The Ghana Biosafety Act 2011 (Act 831) is silent on co-existence. However, cultivation co-existence with non-GE crops (including organic agriculture) is implied.

g) LABELING AND TRACEABILITY:

Though the biosafety legislation does not contain any labeling requirements for biotech or GE food products, or strict liability provisions, labeling is required for packaged foods and feeds in Ghana. The FDA's General Labeling Rules, 1992, (L. I. 1514) stipulate 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.

Also, labels should capture product name, net mass/weight, batch number, expiry date, and country of origin (if imported). A list of ingredients and food additives must be stated. It is mandatory to label any prepackaged food item. General labeling regulations for food products are strictly enforced, but they are not specific to biotechnology products. A national threshold regarding GE content is yet to be established. However, labeling the specific product as GE will be required.

h) MONITORING AND TESTING:

The Ghana Biosafety Act 2011 (Act 831) established a monitoring body for biotechnology products. However, a monitoring program of GE food products is yet to be developed. Equipment has been acquired to establish a "GMO" detection lab on the premises of the GSA, and installation is yet to be completed. This is to help ensure that the importation of GE products, especially living GE products, is complying with the NBA's guidelines. The testing will also ensure that only approved GE events are in circulation. There is no timeline on implementing this monitoring and testing site, but announcements providing further details are anticipated soon.

i) LOW LEVEL PRESENCE (LLP) POLICY:

There is no current LLP policy, but one is under development.

j) ADDITIONAL REGULATORY REQUIREMENTS:

Additional regulatory requirements are needed for commercial release for food by the National Variety Release and Registration Committee (NVRRC) and the FDA, respectively. In the case of seeds, the Plant Protection and Regulatory Service Directorate's (PPRSD) Ghana Seed Inspection Division collaborates with the NVRRC, which makes recommendations to the National Seed Council regarding the official release or otherwise. These additional regulatory requirements call for additional field trials, but the NBA, the PPRSD, and the NVRRC are considering combining the CFT and the data gathering stage of the varietal release process. Nonetheless, these additional regulatory requirements have nothing

to do with the genetic makeup of the product. They are just mandatory requirements for all products, bioengineered or not.

k) 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. Registration fees vary according to the nature of the patent, but local and foreign applications attract the same rate. The Ghanaian system for patent and trademark protection is based on British law, and it was only in 1992 that the patent laws of the UK ceased to apply in Ghana. Local courts offer compensation 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 patent approval, 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 counterfeit, reproduce, export, import, exhibit, perform, or sell any work without the copyright owner's permission. The Biosafety law does not contain any IPR requirements for biotechnology products. Currently, the parliament of Ghana is reviewing a Plant Breeders' Bill, which, when passed into law, will help address intellectual property rights related to plant breeding in general.

l) CARTAGENA PROTOCOL RATIFICATION:

Ghana ratified the Convention on Biological Diversity in August 1994 and the Convention's Cartagena Protocol on Biosafety (CPB) on May 30, 2003. As stated in the National Biosafety Framework for Ghana, the Protocol is in line with the country's constitutional obligations, environmental laws and policies, and the fulfillment of treaty obligations. A law on biosafety has been passed, and regulations have been developed and issued but trade has not been affected in any way.

m) INTERNATIONAL TREATIES and FORUMS:

Ghana has taken a pro-biotechnology position at the CPB, the World Trade Organization (WTO), and Codex, and acknowledges biotechnology and nanotechnology as a means of achieving much-needed development under the science, technology, and innovation policy.

n) RELATED ISSUES:

At the inauguration of a new 13-member Board of Directors of the NBA in Accra on September 25, 2017, Professor Kwabena Frimpong-Boateng, then Minister of Environment, Science, Technology, and Innovation, said since "GMOs" were good technological systems that help improve crop and plant varieties and ensure food security, it was proper that the public was well engaged to help them better

understand and accept biotechnology. The Minister, therefore, urged the NBA Board to educate the public on biotechnology and biosafety issues. This, he said, will help the public understand and embrace biotechnology as a vital tool in socio-economic advancement. He added that such public education on biotechnology, especially on "GMOs", was needed to be carried out by the Board "to help correct the wrong perception created in the minds of the public regarding the technology. Biotechnology is so important, and we can't develop without it", the Minister noted, citing China's embrace of biotechnology research in 1986. (<https://mesti.gov.gh/nba-board-inaugurated/>)

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

A few groups that lobby against the use of agricultural biotechnology maintain an active presence and have filed lawsuits against the commercialization and release of GE products in Ghana; however, it was dismissed in 2015¹. With the imminent commercialization of Bt cowpea, campaigns against the introduction of biotechnology by these groups and individuals in Ghana are expected to increase.

More recently, several stakeholders have engaged the media on issues related to biotechnology to convey accurate, science-based information to Ghanaians concerning GE technologies. This has led to a growing interest in having an honest discussion on biotechnology across the country.

b) MARKET ACCEPTANCE/STUDIES:

In Ghana, many deliberations on biotechnology are done by academia, researchers, and GOG officials from the relevant ministries. All that notwithstanding, producers are eager to adopt GE crops as a means of achieving improved productivity. For instance, after observing the results of the Bt cotton trials, farmers were highly impressed that cotton could be produced with only two insecticide applications per production cycle and demanded that the seeds be made available to them immediately.

Post is not aware of any specific study assessing Ghanaians' acceptance of biotechnology products. However, Post expects that the Ghanaian producer, importer/retailer, and the consumer would accept appropriately regulated biotechnology inputs and products if it guarantees increased yield and income.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

Post is not aware of the development of any bioengineered animal product in Ghana.

¹ <https://www.graphic.com.gh/news/general-news/court-dismisses-injunction-on-commercialising-of-gmos.html>

b) **COMMERCIAL PRODUCTION:**

Not applicable because the focus remains on plant biotechnology for now.

c) **EXPORTS:**

Not applicable because the focus remains on plant biotechnology for now.

d) **IMPORTS:**

Would not be any different from that for plant biotechnology.

e) **TRADE BARRIERS:**

Not applicable because the focus remains on plant biotechnology for now.

PART E: POLICY

a) **REGULATORY FRAMEWORK:**

Same as for plant biotechnology.

b) **APPROVALS:**

Not applicable because the focus remains on plant biotechnology for now.

c) **INNOVATIVE BIOTECHNOLOGIES:**

Not applicable because the focus remains on plant biotechnology for now.

d) **LABELING AND TRACEABILITY:**

Not applicable because the focus remains on plant biotechnology for now.

e) **ADDITIONAL REGULATORY REQUIREMENTS:**

Not applicable because the focus remains on plant biotechnology for now.

f) **INTELLECTUAL PROPERTY RIGHTS (IPR):**

Not applicable because the focus remains on plant biotechnology for now.

g) **INTERNATIONAL TREATIES AND FORUMS:**

Ghana is a member of the World Organization for Animal Health (OIE)

h) **RELATED ISSUES:**

Not applicable because the focus remains on plant biotechnology for now.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

Not applicable because the focus remains on plant biotechnology for now.

b) MARKET ACCEPTANCE/STUDIES:

Not applicable because the focus remains on plant biotechnology for now.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION:

Not applicable

b) EXPORTS:

Ghana exports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.

c) IMPORTS:

The only microbial biotech-derived food ingredients imported by Ghana are those traditionally used in the production of alcoholic beverages, dairy products, and processed products. Likewise, Ghana imports alcoholic beverages, dairy products, and processed products, which may contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS:

Not applicable because the focus remains on plant biotechnology for now.

PART H: POLICY

a) REGULATORY FRAMEWORK:

Same as for plant biotechnology.

b) APPROVALS:

Same as for plant biotechnology.

c) LABELING AND TRACEABILITY:

Same as for plant biotechnology.

d) MONITORING AND TESTING:

Same as for plant biotechnology.

e) ADDITIONAL REGULATORY REQUIREMENTS:

Same as for plant biotechnology.

f) INTELLECTUAL PROPERTY RIGHTS (IPR):

Same as for plant biotechnology.

g) RELATED ISSUES:

Not applicable because the focus remains on plant biotechnology for now.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS:

Not applicable because the focus remains on plant biotechnology for now.

b) MARKET ACCEPTANCE/STUDIES:

Not applicable because the focus remains on plant biotechnology for now.

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Attachments:

No Attachments

Attachments:

No Attachments