Required Report: Required - Public Distribution **Date:** October 27,2020

Report Number: GH2020-0012

Report Name: Agricultural Biotechnology Annual

Country: Ghana

Post: Accra

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

Submission of the application for environmental release of Ghana's first genetically engineered (GE) product, Bt cowpea, to the National Biosafety Authority (NBA) for approval is still pending, and the dossier for Nitrogen Use Efficient (NUE) rice is expected to be complete by the second quarter of 2021.

EXECUTIVE SUMMARY

Food and nutrition security have 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 need. 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 key 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 maize, rice, and soybean. Provision and usage of improved inputs is a key part of this initiative, and biotechnology, while not explicitly stated in the initiative, can be a key tool in achieving the GOG's goals. In terms of current commercialization efforts, appreciable progress has been made, especially regarding plant biotechnology. There is high possibility of a commercial release of Bt cowpea in the very near future.

A Legal Instrument (L.I.) 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 the importation of GE products or products containing GE material, and Ghana currently imports food and feed products from elsewhere in Africa, Asia, Australia, Europe, South and North America that may contain biotechnology elements.

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PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:
Ghana continues to build its 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 very imminent. The dossier on Bt cowpea is now complete, and submission of an application to the National Biosafety Authority (NBA) for environmental release approval is planned for October 2020.

Five applications for research on biotech crops were received by the National Biosafety Committee (NBC), predecessor of the NBA. Applications for Nutrient Enhanced sweet potato, and for Nitrogen Use Efficient (NUE) rice was 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 application for Nitrogen-Use Efficient, Water-Use Efficient and Salt Tolerant (NEWEST) rice from the CRI.

A dossier has now been built for Bt cowpea. The first of two required regulatory field trials for the NUE rice has been completed successfully, and the second and last trial is underway. Funding is precluding the confined field trials for the NEWEST rice. Trials for the Nutrient Enhanced sweet potato, the Bt cotton and the IR-HT cotton have been halted due to lack of funding.

b) COMMERCIAL PRODUCTION: There is no commercial production of biotechnology crops.

c) EXPORTS: Not applicable

d) IMPORTS:
Ghana requires prospective importers of bioengineered products to notify the NBA, and then obtain approval from the FDA prior to importation. Clearance is first given by the NBA, and then the FDA in the case of products that are classified as food per the NBA's issued guidelines. 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 that are not considered as living modified organisms (LMOs), such as soybean meal, soybean oil and processed foods, are freely imported from Argentina, Brazil, the European Union and the United States, which may contain biotechnology elements. 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, and there has not been any barrier that impedes importation of GE food aid.

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 to prompt the GOG to move forward on biotechnology issues. It consisted of officials from government institutions, scientists, farmer organizations, and other stakeholders. The committee, in dialogue with the GOG, drafted the Biosafety Bill in 2004 and produced the National Biosafety Framework and biosafety guidelines.

The NBA has since been established to manage the implementation of the Ghana Biosafety Act 2011 (Act 831). A thirteen-member Board of Directors is in place, with its membership to be reconstituted after a three-year mandate. The current mandate ends in 2020. A common Memorandum of Understanding (MoU) was prepared and was expected to have been signed between the NBA and the seven regulatory agencies by the end of November 2016. This would replace the separate bilateral agreements that have been signed between the NBA and each of the regulatory agencies, namely; Food and Drugs Authority (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, Local Government remains the only regulatory agency not to have signed the MoU. This lack of cooperation by the Local Government is partly due to a change in their 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 that it craved as an institution of authority. Membership of an Appeals Tribunal that will address concerns by the public before issues are taken to the High Court has been approved by the NBA's Board.

i. <u>Responsible Institutions for Implementing the Biosafety Law:</u>
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)

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 members are appointed by the President of the Republic for a period of three years.

The 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 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 three years. The seven regulatory agencies of the Government of Ghana 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, which 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. The Biosafety Act established the NBA, which is interdisciplinary in nature, to process applications relating to biotechnology products specified 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 made provision for the NBA's governing board to have an advisory committee to provide technical advice. Establishment of the IBCs was also provided under the Act. The Biosafety Act also provides for issuance of further guidelines to facilitate 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 safety of humans and the environment;
- Stop a project through the relevant IBC after establishing that continuing 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 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 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 of not less than ten years standing, who has a sufficient background knowledge relevant to the subject matter of this Act;
6. One representative of non-governmental organizations (NGOs) preferably a farmer-based organization (FBO);
7. Two members from the academia who are persons with a 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 project to draft a Biosafety Framework for Ghana between November 2002 and July 2004. United Nations Environment Programme/Global Environment Facility (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.

Before the Ghana Biosafety Law was 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) has been passed and is favorable to the use and acceptance of biotechnology. 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."

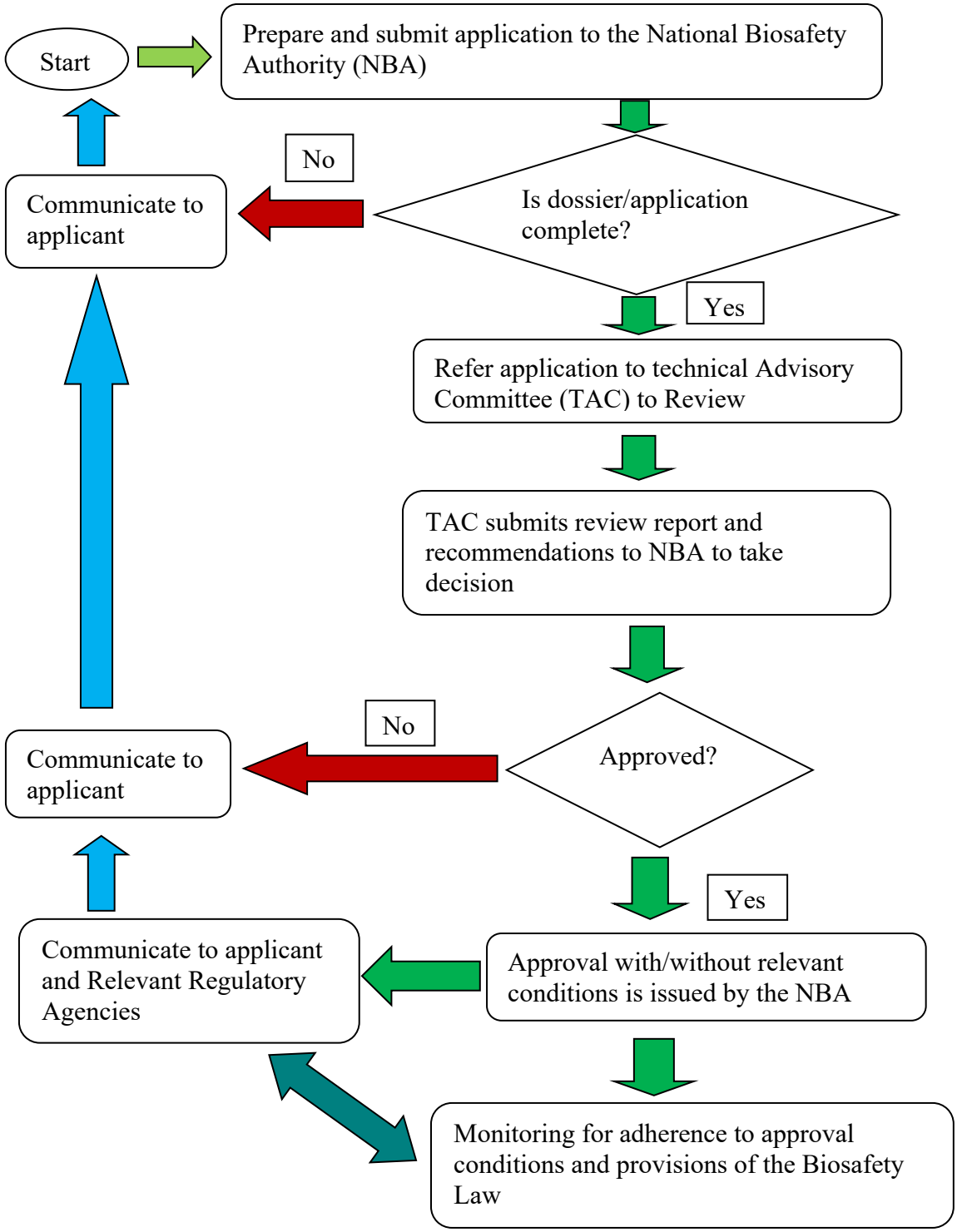
In April 2017, President Nana Addo Dankwa Akufo-Addo launched the "Planting for Food and Jobs" program. Planting for Food and Jobs, the President explained, will be anchored on the pillars that will transform Ghanaian agriculture; the provision of improved seeds, the supply of fertilizers, the provision 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 maize by 30 percent; rice by 49 percent; soybean by 25 percent; and sorghum by 28 percent from current production levels," he added. This initiative is seeking to drastically increase domestic production of maize, rice, soybean, sorghum and select vegetables by means of 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 important role in this initiative.

iv. Distinctions between Regulatory Treatment of Approval:
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. Again, per the guidelines, food safety assessment for applications to place prepackaged bioengineered products on the market shall be conducted in accordance with the current CODEX guidelines for safety assessment of food derived from recombinant DNA organisms. Pre-market approval by the NBA is only required for LMOs like seeds. Placement of non-LMO processed foods on the market only require approval from the FDA. In the case of LMOs, an application for approval to import gets reviewed by the NBA and the relevant regulatory agencies within 180 days. If there is the need for the review to go beyond 180 days, the NBA communicates this to the applicant accordingly.

v. 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 CHART FOR BIOSAFETY APPLICATION REVIEW PROCESS IN GHANA



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

vi. 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.

b) APPROVALS:
At present, no biotechnology crops (industrial crops, food crops, or feed) have been officially 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 need for review of approval should there be 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 to the IBCs and NBA as dictated by the regulations on biosafety (L.I. 2383). Two field testing exercises are currently underway, namely; 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 products 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, beyond which labeling the specific product as GE will be required.

h) 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 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 currently happening at the GSA lab. This is envisaged to help ensure that importation of bioengineered products, especially LMOs, is complying with the NBA's guidelines. The testing will also

ensure that only approved GE events are in circulation. There is currently no timeline on the implementation of this monitoring and testing but announcements providing further details are anticipated in the near future.

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 and clearance for food by the National Variety Release and Registration Committee (NVRRC) and the FDA, respectively. And 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 requirement 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. Fees for registration 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 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 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 products. There is currently before the parliament of Ghana a Plant Breeders' Bill, which when passed into law, will help to address intellectual property rights related 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 consonance 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, 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 key 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. (http://mesti.gov.gh/nba-board-inaugurated/)

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS:
A few anti-GE groups maintain active presence, especially Food Sovereignty Ghana (FSG), which had a lawsuit against the commercialization and release of GE products in Ghana dismissed in 2015.[1] With the imminent commercialization of Bt cowpea, campaigns against the introduction of biotechnology by anti-GE groups and individuals in Ghana are expected to be revived.

More recently, several stakeholders have engaged the media on issues related to biotechnology in an effort to convey accurate, science-based information to Ghanaians with regard to GE technologies. This has led to a growing interest in having an impartial discussion on the topic of 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. 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 and GE 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 consumer would accept duly deregulated biotechnology inputs and/or products if it guarantees increased yield and income, lower cost of import and handling, and affordability.

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

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.

b) COMMERCIAL PRODUCTION: Not applicable

c) EXPORTS: Not applicable

d) IMPORTS: Would not be any different from that for plant biotechnology.

e) TRADE BARRIERS: Not applicable

PART E: POLICY

a) REGULATORY FRAMEWORK: Same as promulgated for plant biotechnology.

b) APPROVALS: Not applicable

c) INNOVATIVE BIOTECHNOLOGIES: Not applicable

d) LABELING AND TRACEABILITY: Not applicable

e) ADDITIONAL REGULATORY REQUIREMENTS: Not applicable

f) INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable

g) INTERNATIONAL TREATIES AND FORUMS: Ghana is a member of the World Organisation for Animal Health (OIE)

h) RELATED ISSUES: Not applicable

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Not applicable

b) MARKET ACCEPTANCE/STUDIES: Not applicable

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

PART H: POLICY

a) REGULATORY FRAMEWORK: Same as promulgated for plant biotechnology.

b) APPROVALS: Would not be any different from that 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

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Not applicable

b) MARKET ACCEPTANCE/STUDIES: Not applicable

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Attachments:

No Attachments