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Nigeria Approves the Commercial Release of Bt. Pod-Borer Resistant Cowpea

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Report Highlights:

Nigeria approves in January 2019, the commercial release of Pod-Borer Resistant Cowpea (PBR-Cowpea) event AAT709A. It also approves Bt. Cotton for commercialization; a pilot group of one thousand farmers now has access to biotech cottonseeds through the MAHYCO Seed Company Nigeria. On July, 27 2018, the National Center for Genetic Resources and Biotechnology (NACGRAB) commercialized two varieties of Bollgard II hybrid developed by MAHYCO (India) and Monsanto (now Bayer): MRC 7377 BGII (MAHYCO C 567 BGII) and MRC 7361 BGII (MAHYCO C 571 BGII). Africa Bio-fortified Sorghum and Nitrogen-and Water-use Efficient and Salt Tolerant (NEWEST) rice are at different stages of field and confined field trials.

EXECUTIVE SUMMARY

Nigeria with an estimated nominal gross domestic product (GDP) of \$444 billion in calendar year (CY) 2019 (January-December) is Africa's largest economy. It is a major oil producer, with a population of 203.5 million (Central Intelligence Agency – July 2018, estimate) growing at 2.54 percent per annum. Nigeria's GDP has averaged at ~\$500 billion over the last five years. Earnings from crude oil and gas exports contribute more than 80 percent of the country's total revenue. The agricultural sector is underdeveloped, accounting for around 20 percent of GDP and employing roughly 70 percent of the population.

Over the decades, successive governments have initiated policies to grow Nigeria's agricultural sector, but the country remains a net importer of food and agricultural products (~\$7 billion per annum). Lack of infrastructure, absence of effective policy formulation and implementation, insecurity, as well as negative impacts of climate change, continues to impede Nigeria's agricultural growth.

In 2001, Nigeria established the National Biotechnology Development Agency (NABDA) to promote, commercialize, and regulate biotechnology products. The country also signed the biosafety bill into law—establishing the National Biosafety Management Agency (NBMA), assuming biotech regulatory authority from the NABDA in 2015. The National Biosafety Management Agency is Nigeria's focal point and authority on biosafety, providing oversight for the use biotechnology and regulating the commercialization of biotechnology products. However, the law leans heavily on the precautionary approach and requires certification and mandatory labeling for imports of all biotechnology products.

The Nigeria government has publicly announced its interests in commercializing agricultural biotechnology as a tool to achieve food security in the country. Nigeria officially approved its first biotechnology crop, *Bacillus thuringiensis* (Bt.) cotton, for commercialization in 2018. Nigeria approves in January 2019, the commercial release of Pod-Borer Resistant Cowpea (PBR-Cowpea) event AAT709A. Other crops such as Africa Bio-fortified Sorghum and Nitrogen- and Water-Use Efficient and Salt Tolerant (NEWEST) rice are at different stages of confined field trials in the country.

Nigeria's biosafety law requires mandatory labeling of products containing genetically engineered (GE) products or ingredients exceeding four percent. Certain civil society groups and environmental activists have emerged and are intensifying their anti-GE campaigns. These are major limitations to commercialization of biotechnology. Farmers' positive attitude towards biotechnology need to be leveraged to develop more effective strategic risk communication to address the anti-GE misconceptions and steer Nigerians towards embracing the benefits of modern agricultural biotechnology.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** The [National Center for Genetic Resources and Biotechnology](#) (NACGRAB) was established in 1987 by the Nigeria [Federal Ministry of Science and Technology](#) (FMST) to conduct research, gather data, and disseminate technological information on matters relating to genetic resources conservation, utilization, and biotechnology applications. The Center, backed by Decree 33 of 1987, regulates the seed, livestock, and fisheries industries through its Varietal Release Committees. Nigeria over the next five years is seeking to develop and commercialize new genetically engineered (GE) crops:
- i. **Bt. Cowpea:** Nigerian scientist contributed significantly to the development of drought tolerant cowpea (black-eye pea) with Australia. In 1987, Purdue University started the research in partnership with the [Network for Genetic Improvement of Cowpea for Africa](#) (NGICA) and the [Commonwealth Scientific and Industrial Research Organization](#) (CSIRO) in Australia, the [U.S. Agency for International Development](#) (USAID), the [African Agricultural Technology Foundation](#) (AATF), the [Danforth Plant Science Center](#), and the [Rockefeller Foundation](#). The *Bacillus thuringiensis* (Bt.) gene was donated royalty free by [Monsanto \(now Bayer\)](#); the gene has been inserted into the cowpea to resist infestation by the Maruca Pod-Borer (*Maruca vitrata*), an insect that reduces yields by over 60 percent. The research carried out by the [Institute of Agricultural Research-Zaria](#) (IAR-Zaria) is finalized, and a dossier generated. In October 2018, the application for the deregulation and commercialization for Bt. Cowpea was submitted to the [National Biosafety Management Agency](#) (NBMA). Nigeria approves in January 2019, the commercial release of [Pod-Borer Resistant Cowpea \(PBR-Cowpea\) event AAT709A](#).
 - ii. **Bt. Cotton:** On July, 27 2018, the NACGRAB registered and released two varieties of Bollgard II hybrid cotton - MRC 7377 BGII (MAHYCO C 567 BGII) and MRC 7361 BGII (MAHYCO C 571 BGII). Expectations are that these varieties will enhance local cotton production, and revamp the national textile industry. [Maharashtra Hybrid Seeds Co - MAHYCO](#) (India) and Monsanto (now Bayer) developed the varieties. The Institute of Agricultural Research-Zaria conducted agronomic performance trials on the Bt. Cotton varieties over the course of two seasons on-station and on-farmers' fields; with yields coming at 4.1 metric tons (MT) and 4.4 MT respectively. Bt. Cotton is approved for commercialization, farmers are able to access biotechnology (biotech) cotton seeds made available through the MAHYCO Seed Company of Nigeria. One thousand Nigerian cotton farmers will participate in the first year rollout of the new biotech cotton seed varieties.
 - iii. **Africa Bio-fortified Sorghum:** Initial support for the development of Africa Bio-fortified Sorghum (ABS) comes from the [Bill and Melinda Gates Foundation](#) (BMGF). Presently, [DuPont Pioneer \(now Corteva\)](#) is supporting development. Confined field trials at the IAR-Zaria are ongoing. The seed is modified for increased levels of vitamin A, iron, and zinc; DuPont Pioneer (Corteva) owns the variety. Nigerian collaborating partners include the [National Biotechnology Development Agency](#) (NABDA) and the Agricultural Research Council of Nigeria (ARCN).

- iv. **Nitrogen- and Water-Use Efficient and Salt-Tolerant Rice:** [Arcadia Biosciences](#) is providing the Nitrogen- and Water-use Efficient and Salt Tolerant (NEWEST) rice technology. Other participating partners include USAID, the [International Center for Tropical Agriculture \(CIAT\)](#), and the African Agricultural Technology Foundation. Nigeria's NEWEST rice project was commissioned in October 2015, at the [National Cereal Research Institute-Badeggi](#) (NCRI) (i.e., the national partnering institute). The African Agricultural Technology Foundation manages project development, aiming to increase rice productivity in flooded, drought-prone, nitrogen-deficient, and saline environments. The project's goal is to develop and disseminate to sub-Saharan smallholder farmers preferred, locally adapted rice varieties with enhanced nitrogen- and water-use efficiency and salt tolerance. To date the NCRI, has successfully introduced a single nitrogen-use efficient gene; two seasons of confined field trials have been undertaken. Plans to develop a triple stacked variety with all NEWEST genes are ongoing. A rain-out shelter belt is already constructed, and is ready to commence drought tolerance trials
- v. **Experimental Research on Genetically Modified Cassava:** The [International Institute of Tropical Agriculture](#) (IITA) is conducting confined field trials in collaboration with [ETH Plant Biotechnology Lab](#) (Switzerland) on GE Cassava (AMY3 RNAi Transgenic lines). The National Biosafety Management Agency approves the field trials in 2017. This research is in response to one of Africa's biggest agricultural challenges, high postharvest losses due to the starch-rich root's rapid deterioration following harvest. The trait enhances the root starch's shelf-life, bettering the prolongation of starch quality.

PROJECTS NIGERIA IS PLANNING TO DEVELOP

- i. **Drought-Tolerant Corn:** Although the NBMA approved Monsanto's application for confined field trials of Bt. Corn in 2016, field trials have not commenced. The National Biosafety Management Agency approved field trials for stacked herbicide tolerant Bt. maize (NK603 (HT) and MON 89034 (IR) X NK603 (HT)). The [WEMA project](#) (drought and insect tolerance) applications are pending.
- ii. **Herbicide-Tolerant Soybeans:** The National Biosafety Management Agency has granted the NABDA a confined field trial permit for Roundup Ready HT soybeans. The [Nigerian Agricultural Quarantine Service](#) (NAQS) has now issued the corresponding import permit.
- iii. **Virus Resistant and Nutritionally Enhanced Cassava (VIRCA Plus):** This project is yet to commence at the [National Root Crops Research Institute-Umudike](#) (NRCRI) in collaboration with the Danforth Plant Science Center. The VIRCA Plus project aims to develop cassava with resistance to two viral plant diseases: the Cassava Brown Streak Disease (CBSD), which destroys the edible roots even when the rest of the plant looks healthy; and Cassava Mosaic Disease (CMD), which can stunt or kill the plants outright. These two diseases are often found together in the same field and can devastate entire crops. Both diseases are spread by white flies (which cannot be controlled with pesticides), as well as by infected cassava stems that are unknowingly shared among farmers.

- b) **COMMERCIAL PRODUCTION:** Nigeria is commencing the commercial production of biotechnology crops. Bollgard II cotton has been released for commercialization. Planting by a pilot group of one thousand farmers through a Nigerian government program will commence with the next planting season. The commercial approval and cultivation is for fiber, feed, and food.
- c) **EXPORTS:** Nigeria does not export GE products.
- d) **IMPORTS:** Nigeria permits the import of biotech crops. There is no ban on the import of GE products; it counts with the capability to ascertain the presence of GE traits. The country authorizes the import of GE grains for poultry feed, as well seeds for research purposes. GE grains are imported in large quantities. An import permit, approved by the NBMA is required; applications need to be submitted to the Director General at least 270 days prior to the import date. Non-compliant shipments will be rejected, and refused entry into Nigeria. Importers are required to obtain from the NBMA the corresponding GE seed import permit prior to shipment.
- e) **FOOD AID:** Nigeria does not provide food aid. It does however receive food aid, including GE corn-soy blend products.
- f) **TRADE BARRIERS:** Nigeria maintains an open market for agricultural commodities and products derived through, or produced with biotechnology. There are currently no biotechnology-related trade barriers affecting U.S. food and agricultural product exports to Nigeria.

PART B: POLICY

- a) **REGULATORY FRAMEWORK:** The National Biosafety Management Agency is the government institution responsible for regulating GE products in Nigeria. The National Biosafety Committee reviews application and carries out data analysis of socio-economic considerations of GE crops alongside risk assessment before recommending any products to the agency for approval. The provisions for the legislation and regulations regarding the approval and release of GE crops, including the [National Biosafety Act 2015](#), National Biosafety Regulations 2017, and National Biosafety Guidelines 2018, can be found at www.nbma.gov.ng.

NIGERIAN INSTITUTIONS INVOLVED IN AGRICULTURAL BIOTECHNOLOGY

- i. ***Nigeria Federal Ministry of Environment:*** Nigeria's [Federal Ministry of Environment](#) (FME) established the National Biosafety Management Agency as the national focal point and the competent authority for biosafety in the country. It is the regulating body for modern biotechnology activities. It provides biosafety regulation requirements for bringing into the country GE crops for testing and environmental release. The Ministry is the Nigeria government's liaison with the [Secretariat of the Convention on Biological Diversity](#) for administrative functions required under the Cartagena Protocol on Biosafety.
- ii. ***National Biosafety Management Agency:*** The agency is an independent biosafety and regulatory body for all biotechnology activities; the NBMA is responsible for all correspondence with importers, exporters, and applicants regarding movement of products of modern biotechnology.

Roles and Responsibilities:

- Defines modules of practice for modern biotechnology and the handling of its products to ensure safety to the environment and to human health;
- Provides guidance on safe application of modern biotechnology;
- Recognizes complex issues to be addressed by central authorities on the judicious application of modern biotechnology;
- Ensures that modern biotechnology activities and their products are safe for the environment and to human health;
- Bases the release of GE organisms on advance informed agreement;
- Defines responsibilities among designated bodies/institutions;
- Confers powers to authorize release of GE organisms and practice of modern biotechnology activities;
- Confers powers to carry out risk assessment/management;
- Defines offences and penalty for violation of the act;
- Covers all living modified organisms (LMOs), products food/feed and processing;
- Addresses socio-economic considerations in risk assessment and labeling of GE products.

The agency is responsible for providing the regulatory framework, institutional and administrative mechanisms for safety measures in the application of modern biotechnology. Its key objective is to prevent any adverse effect on human health, animals, plants and the environment.

- iii. ***Nigeria Federal Ministry of Agriculture and Rural Development:*** The [Ministry of Agriculture and Rural Development](#) (FMARD) is in charge of formulating agricultural policy relating to biotechnology, promoting and facilitating agricultural activities, and implementing policies and programs. It houses all agricultural research institutions in the country.
- iv. ***National Biotechnology Development Agency:*** The agency was established in 2001 under the Ministry of Science and Technology with the mandate to formulate biotechnology policy in Nigeria and acquire, deploy, promote, and facilitate biotech activities for indigenous and

self-reliant national growth. The agency is active in creating awareness for products of biotechnology. It conducts regular workshops for major biotechnology stakeholders (see [Open Forum for Agricultural Biotechnology in Africa – Nigerian Chapter](#)).

- v. ***National Agency for Food and Drug Administration and Control (NAFDAC)***: The agency regulates herbicide tolerance to determine the maximum residue limits (MRL) in GE events for food and feed. The [NAFDAC](#) is in charge of all food safety including drugs, chemicals, and related issues.
- vi. ***Sheda Science and Technology Complex (SHESTCO)***: The center is a Nigeria government biotechnology research and training facility. It has the mandate to develop and use domestic technologies for the application of biotechnology in health, agriculture, and environment.
- vii. ***Nigeria National Universities***: A number of national universities are also involved in research and development aspects of agricultural biotechnology including confined field trials. Most of these count with institutional biosafety committees.
- viii. ***The National Biosafety Committee (NBC)***: The inter-ministerial NBC serves as the competent national authority for biosafety. The National Biosafety Committee is responsible for the safe management of biotechnology activities. The committee has 16 members drawn from the Ministries of Agriculture and Rural Development, Science and Technology, Environment, Commerce, Education, Health (NAFDAC), Industry, Foreign Affairs, Internal Affairs (Nigerian Customs Service), Justice, and the [Nigerian Association of Chambers of Commerce, Industry, Mines, and Agriculture \(NACCIMA\)](#) and other private sector organizations. The National Biosafety Committee includes biologists, physical and social scientists, as well as representatives of environmental and conservation non-governmental organizations (NGO). The committee is required to review all applications for the release of products of bioengineering, make recommendations to the Minister of Environment on whether or not to approve such products. It also oversees the implementation of the National Biotechnology Program and addresses any issues that may arise within the Biosafety Law.

The National Biosafety Committee established the National Biosafety Technical Subcommittees (NBTS) to focus on interests of sectors such as agriculture, health, industry and the environment. The subcommittees review proposals for research and recommend the conditions under which experiments should be conducted. They provide technical advice to the NBC and contribute to its functions in relation to contained use, field trials, release, and market placement.

Presently, all applications for imported products containing GE for field trials, transit, and contained use must be routed through the National Biosafety Management Agency. The committee acts as liaison between the relevant NBTS to carry out risk assessment and ensure participation of all relevant stakeholders. Findings of the NBTS are submitted to the NBC and the agreed decision is conveyed to the applicant by the NBMA, which determines the issuance of licenses to carry out activities. The National Biosafety Management Agency is responsible for the safe application, use, and handling of GE organisms and their products.

- ix. *Open Forum for Agricultural Biotechnology:*** Nigeria government officials are supportive of agricultural biotechnology. The Open Forum for Agricultural Biotechnology holds sensitization activities to enhance the understanding and acceptance of GE crops. The forum is also building the capacity of journalists to effectively report science-based information. It engages policymakers including those from the Ministers of Agriculture, Environment, and Science and Technology.
- b) APPROVALS:** There are distinctions between the regulatory treatment of the approval for food, feed, processing, and environmental release. Bt. cotton is currently the only approved crop for environmental release (i.e., cultivation) in Nigeria, but imported GE corn and soybean varieties have been approved for feed and oil processing. Operational guidelines for approval are reviewed by the National Biosafety Committee. The timeline for approvals is usually about 180 days.
- c) STACKED OR PYRAMIDED EVENT APPROVALS:** The approval process and conditions are the same as for single trait approvals.
- d) FIELD TESTING:** Field testing and evaluations are allowed.

With the approval of the National Biosafety Committee, the [National Root Crops Research Institute-Umudike](#) (NRCRI-Umudike), IAR-Zaria, and NCRI-Badeggi have carried out confined field trials on cassava, cotton, sorghum, cowpea, and rice. The approval is based on the provisions of the National Biosafety Guidelines, which include field-testing of bio-engineered crops.

The National Biotechnology Development Agency collaborates with the NRCRI-Umudike, IAR-Zaria, and NCRI-Badeggi for creating awareness among Nigerian cowpea and cassava clientele, while the NBMA ensures compliance with Nigerian Biosafety Guidelines. Internationally the African Agricultural Technology Foundation (AATF) provides the funding platform, planning, capacity building and linking with donors. The Network for the Genetic Improvement of Cowpea in Africa leverages scientific input of members for planning and linkages. The Program for Biosafety Systems assists in regulatory compliance with capacity building and advice.

- e) INNOVATIVE BIOTECHNOLOGIES:** The National Biosafety Management Agency Act of 2015 remains current. It does not however apply at present to gene editing, but it is being considered. Anticipations are that incorporation will occur in the Act's next amendment.
- f) COEXISTENCE:** Policy is evolving. The National Biosafety Management Agency develops rules and guidelines to regulate GE crop cultivation.
- g) LABELING AND TRACEABILITY:** Regulations stipulate that products with four percent GE content should be labeled with statements such as:
- This product contains “genetically modified organisms” wherever there is evidence of the presence of genetically modified organisms;

- The words “This product may contain genetically modified organisms” where the presence of GE component in a product cannot be excluded due to inconclusive evidence of any presence of GE content.

The purpose of the labeling is to enable consumers to make informed choices on products purchased. The biosafety law requires mandatory labeling of all products of agricultural biotechnology in order to protect “consumers’ right to know.” Although not specific to biotech products, existing labeling regulations are being enforced by NAFDAC, the government’s regulatory body responsible for food product manufacturing, importation, advertisement and distribution in Nigeria. The NAFDAC regulations require food labeling to be informative and accurate. FAS Lagos (Post) has an open dialogue with the NABDA, NAFDAC, NBMA and other key stakeholders on the operational guidelines of the law to ensure that the requirement of mandatory labeling does not obstruct free trade.

h) MONITORING AND TESTING: The National Biosafety Management Act includes a regulatory framework, as well as institutional, administrative, and monitoring mechanisms. The biosafety law also defines penalties for not complying with the regulations. Failure to obtain approval or proper permits before importing or releasing GE organisms into the environment is subject to the following stated penalties:

- Individuals can be fined Nigerian naira (NGN) 2.5 million (~\$6,900) or imprisoned for a period not less than five years or both, (NGN 360.33 = \$1.00);
- Corporations would pay a fine of at least NGN 5.0 million (~\$13,700) and the directors or officers of the body shall each be liable to a fine not less than NGN 2.5 million (~\$6,900) or imprisonment for a term not less than five years or to both fines and imprisonment;
- False information also results in the same penalty as failure to obtain approval;
- Obstruction results in a NGN 2.5 million (~\$6,900) fine or imprisonment for not less than three years or both.

i) LOW LEVEL PRESENCE POLICY (LLP) POLICY: The tolerance for low level presence of approved events in the country of origin that are not yet approved in Nigeria is four percent.

j) ADDITIONAL REGULATORY REQUIREMENTS: After GE crop approval is given by the NBMA, the crop will also need to meet the requirements of other extant laws related to the seed system in Nigeria. Other agencies, which regulate new varieties or importation of plants or organisms (whether or not they are GE) include: the Nigeria Agricultural Quarantine Service, the National Varietal Release Committee, the National Agricultural Seed Council, and the National Agency for Food and Drug Administration and Control.

The National Agricultural Seed Council and the Varietal Release Committee will carry out additional registration of seeds/traits before commercialization. Once the variety is approved and released by the Varietal Release Committee and deregulated (in case of seeds), no further registration is required. For processed products containing GE products, registration with the NAFDAC may be required.

Insect resistance is registered through the Nigeria Federal Ministry of Agriculture and Rural Development. For herbicide tolerance traits, the herbicide needs to be registered differently by the NAFDAC as the regulatory agency for food and drugs. Farmers may use the approved varieties after registration.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): Legislation is evolving.

l) CARTAGENA PROTOCOL RATIFICATION: Nigeria signed the Cartagena Protocol on Biosafety in 2000 and its instrument of ratification was signed by the Nigerian President on November 30, 2002. The protocol came into force in September 2003.

m) INTERNATIONAL TREATIES AND FORA: Nigeria signed the Convention on Biological Diversity in 1992 and ratified the instrument in 1994. It was an active participant in the negotiations that led to the adoption of the Cartagena Protocol. Officials of key biotech agencies such as the Federal Ministry of Environment, NABDA and NMBA regularly attend meetings of international standard-setting bodies. Regulation of GE products in Nigeria is in line with the provisions of the *Codex Alimentarius* (Codex) guidelines.

n) RELATED ISSUES: FAS Lagos is not aware of any biotechnology-related trade barriers affecting U.S.-origin exports to Nigeria. However, the mandatory labeling requirement may restrict market access for GE products.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: The Nigerian public has a mixed opinion about GE food products. To some, it is very important in promoting food security. Others are concerned about safety and health issues. This opinion is often due to an information gap or limited understanding of the potential benefits of the technology. People with more knowledge of the technology tend to accept it. On research, a higher number of the public believe Nigeria should domesticate the technology and build capacity to develop GE crops.

There are civil society groups and environmental activists campaigning against GE crops in Nigeria. Stakeholders however do not consider them a serious challenge considering the already wide availability and consumption of biotechnology food products. Farmers are also more interested in improving their yields and increasing income.

Some members of the public have expressed concerns on the safety of GE crops. Strategic risk mitigation communication is required to address the misconceptions. Most Nigerians need to be more aware of products of modern agricultural biotechnology and the issues involved. Information sharing and discussions on modern biotechnology have been undertaken largely between Nigeria government officials, scientists and researchers. Nigerian farmers and the general public however need continuous education on the technology.

- b) MARKET ACCEPTANCE/STUDIES:** Nigerian farmers are willing to accept the commercialization of Bt. cotton because of the positive monetary benefits they expect from it. Farmers generally accept GE crops. Public attitudes towards biotech industries or research institutions in the country are cordial.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** None.
- b) **COMMERCIAL PRODUCTION:** None.
- c) **EXPORTS:** None.
- d) **IMPORTS:** None.
- e) **TRADE BARRIERS:** None.

PART E: POLICY

- a) **REGULATORY FRAMEWORK:** Current regulations are drafted for living modified organisms (LMO), these apply to animal products.
- b) **APPROVALS:** None.
- c) **INNOVATIVE BIOTECHNOLOGIES:** None.
- d) **LABELING AND TRACEABILITY:** See Plant Biotechnology.
- e) **INTELLECTUAL PROPERTY RIGHTS (IPR):** See Plant Biotechnology.
- f) **INTERNATIONAL TREATIES AND FORA:** Nigeria is a member of the World Trade Organization (WTO), the World Animal Health Organization (OIE), and *Codex Alimentarius* (Codex).
- g) **RELATED ISSUES:** None.

PART F: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:** The Public has a mixed opinion about genetically engineered food products. To some, it is very important in promoting food security. Others are concerned about safety and health issues. This opinion is often due to an information gap or limited understanding of the potential benefits of the technology.
- b) **MARKET ACCEPTANCE/STUDIES:** Not applicable.