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Report Highlights:

The planting of genetically engineered (GE) crops is currently not authorized and there is no biosafety legal framework in place in Egypt. The absence of a biosafety framework contributes directly to a lack of public awareness, funding, and trust in agricultural biotechnology. In the current environment, there are no prospects for cultivation and production of GE crops for food nor feed in Egypt.

Executive Summary

Agricultural research in Egypt is primarily focused on crop improvement and crop variety development that emphasizes the optimization of returns, as well as addressing biotic and abiotic stress. With limited arable land and water availability for agricultural production, agricultural biotechnology offers several avenues to address crop development and improve climate change resilience, including improvements to drought, heat, and salinity tolerance.

Although Egypt lacks legislation regulating biotechnology, the government permits biotech imports if the country-of-origin also consumes these products. Between 2019 to 2023, Egypt imported roughly 45.3 million MT (MMT) of corn and 18.3 MMT of soybeans to meet the feed demand of its growing poultry, dairy, and aquaculture sectors. Egypt does not require labeling of biotech products. While Egypt sources corn and soybeans derived through genetic engineering (GE), it prohibits the planting of such crops.

In 2008, Egypt was the first Arab country to commercialize GE corn. However, in 2012, Egypt issued a ministerial decree suspending all commercial cultivation of GE crops. Despite the moratorium, agricultural biotechnology research capacity has evolved and expanded through a network of universities and national research institutions that include:

- The Ministry of Agriculture and Land Reclamation's (MALR) Agricultural Research Center's (ARC) Agricultural Genetic Engineering Research Institute (AGERI),
- The Ministry of Higher Education and Scientific Research's (MOHESR) National Research Center (NRC),
- University of Sadat City's Genetic Engineering Biotechnology Research Institute (GEBRI),
- A network of other university research centers and biotechnology departments.

A handful of successful gene editing research projects have been carried out at the ARC and the Faculty of Agriculture at Cairo University to improve drought tolerance in Egyptian wheat cultivars and chickpeas, as well as enhancing biomass quality in sorghum (to improve its value as a forage and biomass crop). These projects included the utilization of the CRISPR/CAS tool for gene editing.

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PART A: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT: Agricultural biotechnology research tools such as marker assisted selection, plant genetic transformation, and tissue culture are currently used to produce field crop varieties that are tolerant to biotic and abiotic stress. MALR's ARC and MOHESR's NRC conduct such research activities utilizing modern biotechnology tools to achieve research goals.

1) The Agricultural Research Center: The Agricultural Genetic Engineering Research Institute (AGERI) is Egypt's main biotechnology research organization under the umbrella of the MALR/ARC. Its mandate is to promote the transfer and application of biotechnology. Scientific research conducted by the AGERI encompasses:

- Plant Molecular Biology
- Microbial Molecular Biology
- Plant Genetic Transformation and Tissue Culture
- Genome Mapping and Marker Assisted Selection
- Nucleic Acids, Proteins Structure
- Bioinformatics

AGERI field crop research primarily focuses on wheat and corn. The wheat program focuses on the establishment of regeneration systems for wheat cultivars, as well as the addition of genes for drought and salinity tolerance. It evaluates transgenic wheat lines in field trials under salt and drought stress conditions.

The corn program focuses on the establishment of *in vitro* regeneration of Egyptian maize (i.e., corn) and sorghum inbred lines; maize and sorghum transformation using genes for drought and salinity stress tolerance; optimization of transient gene expression system; and genetic transformation for production of bio-fortified sorghum.

2) The National Research Center: The National Research Center is a multidisciplinary research body engaged in agricultural research activities. It aims to use new technologies to improve agricultural production. The current research activities at the NRC's Agricultural and Biological Divisions focus on:

- Increasing yields per unit area, as well as improving soil properties.
- Improving water use efficiency in quantity and quality using biotechnology tools.
- Promoting collaborative research with international agricultural research centers.
- Supporting technology transfer programs based on needs across Egypt's geographical areas to provide sustainable agriculture growth.
- Genetic improvement of date palm varieties and the establishment of reliable regeneration and tissue culture systems for domestic date palm varieties.
- Biotech-based production of pharmaceutically bioactive substances and molecules.

- Isolation and testing a variety of *Bacillus thuringiensis* isolates from Egyptian soils for the purpose of biological control.

3) Universities: Biotechnology research activities at Egypt's universities are well established.

Genetic Engineering and Biotechnology Research Institute – University of Sadat City

- The Genetic Engineering and Biotechnology Research Institute (GEBRI), located at the University of Sadat City, is the one of the country's leading research centers in biotechnology. The institute utilizes biotechnology tools to develop crops that can tolerate salinity, drought, and heat, as well as promote water-efficient semi-arid crops (e.g., olives and dates). The institute is developing strategies to tackle the effects of climate change on yields, in addition to expanding the area of germ plasm collection and conservation and using tissue culture for mass propagation of banana and other crops.

Gene Editing Research in Faculty of Agriculture – Cairo University

- The University is supporting the creation of abiotic stress tolerant crops (e.g., wheat) to adapt to Egyptian climate conditions, mitigate problems associated with climate change, and result in favorable agricultural yields. Researchers proposed to utilize precise gene editing techniques to generate drought stress tolerant wheat. The CRISPR (Clustered Regulatory Interspaced Short Palindromic Repeats) system, a sophisticated and effective tool for generating precise genomic changes, was effectively used in this research.

- The University is also using gene editing via CRISPR to develop drought tolerant chickpea varieties. The aim of the research is to utilize the base-editing techniques to generate premature stop mutations using a safe and efficient delivery system to generate drought stress tolerant chickpeas. The CRISPR system will be used to deactivate the Era1 and Sal1 genes in chickpeas. Both Era1 and Sal1 have negative impacts on stomata opening. It is anticipated that mutating the expression of those genes will produce compounds related to stress protection and generate enhanced drought tolerance that does not contain any new genes, potentially expediting the product's commercial release and public acceptance.

b) COMMERCIAL PRODUCTION: Ministerial Decree 378/2012 suspended production and commercialization of GE crops. Cultivation and commercialization are not allowed.

c) EXPORTS: Egypt does not produce nor export GE products.

d) IMPORTS: Egypt permits the importation of GE crops. Imports are permissible if the exporting country-of-origin approves the product for consumption and authorizes its export. Egypt is a net importer of GE soybeans and corn for feed use.

From calendar year (CY) 2019 to 2023, Egypt imported roughly 18.3 MMT of soybeans. Throughout that period, Egypt's main suppliers have been the United States (13.6 MMT), Argentina (1.5 MMT), and Ukraine (1.8 MMT) (see Figure 1). U.S.-origin soybean exports to

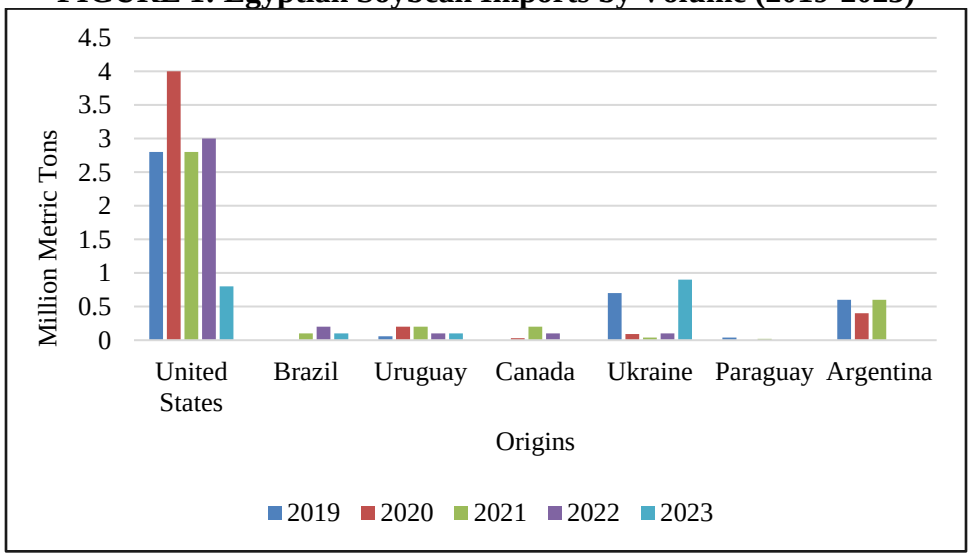
Egypt have risen dramatically in recent years. CY 2020 was a record year for U.S.-origin soybean exports to Egypt – of the 4.7 MMT of Egyptian soybeans imported that year, 4.04 MMT were U.S.-origin soybeans (accounting for nearly 86 percent of total soybeans exported to the Egyptian market).

Egypt is also a net importer of corn. From CY 2019 to 2023, Egypt imported corn from Brazil (15.3 MMT), Argentina (13.5 MMT), Ukraine (13.1 MMT), the United States (2.5 MMT), and the European Union (EU) (2.2 MMT) (see Figure 2).

In addition, Egypt imported U.S. corn gluten meal, corn gluten feed, and dried distillers' grains (DDGs). The United States was the major supplier of these feed commodities to Egypt.

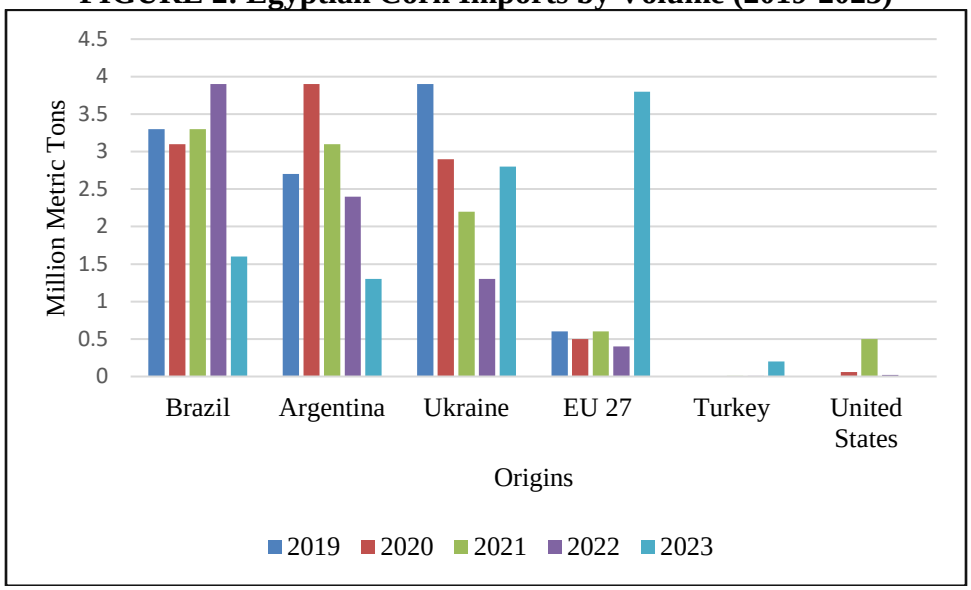
Egypt does not consider non-DNA-containing products derived from GE plants to be GE, since the process of producing such products from the crop removes all the DNA and protein, including the transgene and its protein product.

FIGURE 1: Egyptian Soybean Imports by Volume (2019-2023)



Source: Trade Data Monitor LLC

FIGURE 2: Egyptian Corn Imports by Volume (2019-2023)



Source: Trade Data Monitor LLC

e) FOOD AID: N/A

f) TRADE BARRIERS: Egypt maintains an open market for agricultural commodities and products produced with biotechnology. Imports are permissible if the exporting country-of-origin approves the product for consumption and authorizes its exportation. Imports of biotech seeds for the purpose of cultivation are not permitted due to the aforementioned decree banning cultivation.

PART B: POLICY

a) REGULATORY FRAMEWORK: Egypt's lack of a biosafety framework has led to a promulgation of various decrees dealing with agricultural biotechnology (see Table 1). Biotechnology oversight falls under the purview of four different ministries, all of which have representation on the National Biosafety Committee (which has been dormant since 2014).

TABLE 1: EGYPT, Ministerial Decrees Dealing with Biotechnology

Decree 85 (1995): Established the National Biosafety Committee, assigning it the task of setting regulations and guidelines concerning the safe use of genetic engineering and molecular biology; meant to ensure safety of the environment including human health.
Decree 136 (1995): Established an obligation to obtain a permit from the National Biosafety Committee before using or dealing with any GE product for experimental usage, regardless of the cultivated areas.
Decree 1648 (1998): Established a protocol for the registration of genetically modified seeds. The marketing of GE seed varieties requires approval by the Seed Registration Committee, which receives guidance from the National Biosafety Committee.
Decree 19 (January 2007): Nominated new members to the National Biosafety Committee. Article 1 provides the names and qualifications of the twenty-four members. Article 2 nominates the two officials of the executive secretariat of the National Biosafety Committee. Article 3 restates parts of Decree 85 (1995) and Article 4 underlines that the National Biosafety Committee's authority to call upon outside experts and establish subsidiary committees on special topics.
Decree 767 (June 2006): The Minister of Agriculture established the National Competent Authority for the functions of the Cartagena Protocol on Biosafety. This authority is with the Agricultural Genetic Engineering Research Institute/Agricultural Research Center.
Decree 1495 (September 2014): Reestablished the National Biosafety Committee with new members from the Ministry of Environment, Ministry of Health, Ministry of Scientific Research, industry, a legal advisor, and a representative of the Consumer Protection Agency.

***Ministry of Agriculture and Land Reclamation*:** MALR is the main authority responsible for food cultivation and genetically engineered crops. Three organizations within the ministry play a role in the regulation of agricultural biotechnology:

1) **Agricultural Research Center:** The ARC includes 16 research institutes and support organizations. It has the primary responsibility for crop improvement research, cultivar development, and testing for cereals, fiber materials, oils, legumes, fodder, and sugar in Egypt. The ARC's institutes developed the majority of Egypt's field crop and vegetable varieties.

   The ARC's Agricultural Genetic Engineering Research Institute is responsible for the research and development of agricultural biotechnology. The ARC's Regional Laboratory for Food and Feed oversees food and feed products produced through genetic engineering.

2) **Central Administration for Seed Testing and Certification:** It is the lead agency responsible for seed quality control, seed legislation, and policy enforcement in Egypt. CASC reviews all relevant legislation, updates and prepares rules required to control all seed activities, and works to integrate and harmonize seed legislation. CASC is the designated seed certification authority of Egypt and performs lab and field-testing for certified seed.

3) **Central Administration for Seed Production:** CASP implements the government's seed production policies, advises the ARC on foundation and registered seed requirements, and supervises certified seed production and multiplication.

***Ministry of Environment (MoE)*:** The MoE's role, in tandem with MALR, is to assess the impact of releasing GE crops into the environment. The MOE's Egyptian Environmental Affairs Agency (EEAA) established a biosafety unit in 2013 for this task. The agency ensures that an adequate level of protection exists for the safe transfer, handling, and use of living modified organisms (LMO) that could have an adverse effect on conservation and biological diversity. The MoE uses the same definition for LMOs as defined by the Cartagena Protocol.

***Ministry of Higher Education and State for Scientific Research (MOHESR)*:** MOHESR supervises the Supreme Council of Universities (SCU), which oversees the Sectoral Committee on Biotechnology and Genetic Engineering Education in Egypt. The Ministry is also home to the Academy of Scientific Research and Technology, which is the executing agency for the Ministry's National Strategy and Program for Biotechnology and Genetic Engineering.

The National Biosafety Committee: In 2014, the Minister of Agriculture, Dr. Adel El-Beltagy -- a strong proponent of agricultural biotechnology -- issued Ministerial Decree 1495 reestablishing the NBC. The committee, however, has never met and is currently dormant.

b) APPROVALS/AUTHORIZATIONS: In 2012, the planting and cultivation of GE crops in Egypt was suspended. Since this suspension there have been no new approvals for greenhouse trials, field-testing, or for commercial release. Prior to this, between 2006 and 2010, 41 horticultural crops were approved for greenhouse or open field trials, 20 field crops were approved for greenhouse or open field trials, and one field crop (corn) was approved for commercial cultivation.

c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS: There are no stacked events used in any transgenic crops under development. However, GE varieties with stacked events, approved for consumption in the country-of-origin, are accepted for imports of food and feed.

d) FIELD TESTING: There is no ongoing field-testing in Egypt. The last field trials approved were in 2010.

e) INNOVATIVE BIOTECHNOLOGIES: There is no regulatory policy for innovative biotechnologies such as genome editing using Zinc-finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs), and CRISPR/Cas9. While there is research interest, the lack of funding is often an obstacle.

f) COEXISTENCE: Egypt does not have a policy on coexistence between GE crops and conventional crops.

g) LABELING AND TRACEABILITY: Egyptian law does not require special labeling for biotech crops nor products with GE content. Authorities treat biotech products the same as non-biotech products. There is no voluntary program.

h) MONITORING AND TESTING: There is no GE monitoring and/or testing.

i) LOW LEVEL PRESENCE (LLP) POLICY: Egypt has no low-level presence policy.

j) ADDITIONAL REGULATORY REQUIREMENTS: In 2012, Egypt suspended the planting and cultivation of GE crops. Although there have been no new approvals for greenhouse trials, field-testing, or for commercial release since that time, under the existing regulatory structure there is an approval process for GE crop research and commercialization. However, until there is a law enacted by Egypt's parliament and/or approved by the cabinet, the process is on hold.

There is a low possibility that enactment will occur in the near-term. The current application process is as follows:

1. The applicant completes a permit application form providing details of the genetic material introduced, the process used for inserting it, data from food and feed safety studies, and evidence supporting a determination of low or negligible environmental risk. The applicant also provides documents indicating approval of similar GE products for release in their country-of-origin.

2. The NBC reviews the application. If approved, the application goes to the Seed Registration Committee (SRC) for preliminary approval to proceed with standard field trials. CASP/SRC assigns qualified inspectors (i.e., from ARC units and/or private certified laboratories) to supervise cultivation, ensure adherence to any biosafety requirements, confirm the new phenotype, and evaluate agronomic performance.

3. Following field trials and submission of a report to NBC, which authorizes the applicant to apply to the SRC for approval for the commercial release of the variety. The SRC will supervise for three years (or growing seasons) agronomic performance trials.

k) INTELLECTUAL PROPERTY RIGHTS (IPR): The Egyptian Patent Office (EPO) (Public Law 132/1951) is the national patent registrar. The World Intellectual Property Rights Organization (WIPO) accredits the EPO as a regional intellectual property (IP) database authority; the EPO plays a role in technology transfer and intellectual property rights protection. Since 1971, the EPO and Academy of Scientific Research are in association. Public Law 82/2002 provides coverage of IP issues in the life sciences. Egypt's IPR protections apply to biotech seeds.

The Egyptian Patent Office:

- Registers patent applications for the local and foreign inventions.
- Grants and issues patents protecting Egyptian and foreign inventor rights.
- Collect foreign patent applications, making them accessible to examiners and users.
- Transfers technological information from international patents, providing this to specialists to develop their work and local industries.
- Encourages inventors by helping them participate in exhibitions and compete for recognition and awards.
- Publishes the official patent gazette (monthly) that includes filed, accepted applications, granted patents, and terminated applications.

l) CARTAGENA PROTOCOL RATIFICATION: Egypt ratified the Cartagena Protocol on Biosafety (CPB) in 2003. The biodiversity department of MOE is Egypt's focal point to the CPB's Biosafety Clearinghouse. The clearinghouse is a mechanism set up by the CPB to facilitate information exchange on GE product development and to assist member countries in complying with their obligations under the protocol.

m) INTERNATIONAL TREATIES AND FORUMS: In August of 1994, Egypt joined the Convention on Biological Diversity (CBD). On March 31, 2003, Egypt ratified and joined the Cartagena Protocol on Biosafety. On October 12, 2014, Egypt ratified the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits. It is a member of several international organizations dealing with plant protection and plant health, including the International Plant Protection Convention (IPPC), and Codex Alimentarius (Codex). Egypt is also a member of the World Intellectual Property Organization (WIPO) and signed the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement.

n) RELATED ISSUES: N/A

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: The absence of a biosafety system in Egypt directly contributes to a lack of public awareness and trust in food derived from GE crops. This allows some in the media to overstate misconceptions about biotechnology. A large segment of the Egyptian public uses social media and believes there are significant health risks associated with the consumption of food products derived from GE plants. One-sided reporting by the media on possible health risks associated with planting GE seed varieties and cultivation affects the perception of the public about the technology. The public generally believes that there is a link between GE products and cancer.

Anti-biotech campaigns are active on social media. These often motivate the public misperception about the consumption of food products derived from biotechnology. The food industry has mixed views about biotechnology's risks and benefits. However, Egyptian agri-businesses and food companies exporting to the EU prefer to not advocate for biotechnology products.

b) MARKET ACCEPTANCE /STUDIES: FAS/Cairo is unaware of any recent formal market studies that have evaluated Egyptian public attitudes towards products derived from agricultural biotechnology.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) RESEARCH AND PRODUCT DEVELOPMENT: No GE or cloned animals are under development in Egypt. The ARC does have ongoing biotechnology activities for enhancing livestock, poultry, and fish production, but these are predominantly focused on the development of livestock recombinant vaccines and disease diagnostic kits. Key institutions include:

- The Animal Health Research Institute (AHRI)
- The Veterinary Serum and Vaccine Research Institute (VSVRI)
- The Animal Production Research Institute (APRI) – which conducts research on genetic improvement in cows, buffalo, sheep, goats, and poultry, and disseminates animals with high quality genetics to livestock breeders and small farmers.
- The Central Laboratory for Aquaculture Research (CLAR)

b) COMMERCIAL PRODUCTION: There are no commercially produced GE animals in Egypt.

c) EXPORTS: N/A

d) IMPORTS: There are no regulations applicable to the import of GE or cloned animals in Egypt.

e) TRADE BARRIERS: N/A

PART E: POLICY

a) REGULATORY FRAMEWORK: There is no regulatory framework for the research, production, or importation of GE animals or cloned animals in Egypt.

b) APPROVALS/AUTHORIZATIONS: N/A

c) INNOVATIVE BIOTECHNOLOGIES: There is no regulatory policy for innovative biotechnologies such as genome editing using ZFNs, TALENs, and CRISPR/Cas9. Lack of funding is often an obstacle to using these technologies.

d) LABELING AND TRACEABILITY: N/A

e) ADDITIONAL REGULATORY REQUIREMENTS: None

f) INTELLECTUAL PROPERTY RIGHTS (IPR): There are no IPR issues related to GE or cloned animals at this time in Egypt.

g) INTERNATIONAL TREATIES AND FORUMS: Egypt is a Food and Agriculture Organization and Codex member. It follows World Organization for Animal Health (WOAH) standards and protocols for live animal and beef product imports. Egyptian participation in discussions related to animal biotechnologies, including cloning, within international organizations is limited.

h) RELATED ISSUES: N/A

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: There is public skepticism about biotechnology's benefits. However, FAS/Cairo is not aware of market studies that have researched public or private opinions on GE animals or animal cloning.

b) MARKET ACCEPTANCE/STUDIES: FAS/Cairo is not aware of any recent market studies that have evaluated Egyptian public attitudes towards GE animals.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) COMMERCIAL PRODUCTION: Egypt does not commercially produce food ingredients resulting from microbial biotechnology.

b) EXPORTS: The country does not export GE microbes or any products that contain microbial biotech-derived food ingredients.

c) IMPORTS: There are no regulations applicable to the import of GE microbes or any products that contain microbial biotech-derived food ingredients.

d) TRADE BARRIERS: N/A

PART H: POLICY

a) REGULATORY FRAMEWORK: There is no regulatory framework governing production of microbial biotech-derived food ingredients or processed food products containing microbial biotech derived food ingredients.

b) APPROVALS: N/A

c) INNOVATIVE BIOTECHNOLOGIES: N/A

d) LABELING AND TRACEABILITY: There are no labeling or traceability policies on microbial biotech-derived food ingredients.

e) MONITORING AND TESTING: N/A

f) ADDITIONAL REGULATORY REQUIREMENTS: There are no additional microbial biotech-related regulations.

g) INTELLECTUAL PROPERTY RIGHTS (IPR): There are no known IPR issues related to microbial biotech at this time.

h) RELATED ISSUES: No related issues.

PART I: MARKETING

a) PUBLIC/PRIVATE OPINIONS: FAS/Cairo is not aware of studies that researched public or private opinions of food derived through biotechnology or processed products that uses microbial biotech derived food ingredients.

b) MARKET ACCEPTANCE/STUDIES: FAS/Cairo is not aware of any recent market studies that have evaluated Egyptian public attitudes towards products derived from microbial biotechnology.

Attachments:

No Attachments