

Required Report: Required - Public Distribution

Date: November 14,2019

Report Number: EG2019-0020

Report Name: Agricultural Biotechnology Annual 2019

Egypt Lacks Biosafety Framework for the Commercialization of GE Crops

Country: Egypt

Post: Cairo

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Mariano J. Beillard, Senior Regional Agricultural Attaché and Ahmed Wally, Agricultural Specialist

Approved By: Ali Abdi, Minister-Counselor for Agricultural Affairs

Report Highlights:

The major objective of agricultural research in Egypt is the production of plant varieties that consume less water and that are higher yielding to benefit small scale farmers. The planting of genetically engineered (GE) crops is currently not authorized and there is no biosafety legal framework in place governing the release of GE crops to the environment and commercialization. The absence of a biosafety system contributes directly to a lack of public awareness and trust in agricultural biotechnology, allowing the media to exaggerate misconceptions about the technology.

EXECUTIVE SUMMARY

The major objective of agricultural research in Egypt is the production of plant varieties that consume less water and that are higher yielding. It supports agricultural development through applied research with the goal of increasing food per unit area. Egypt seeks to rationalize water consumption systems and improve the properties of the soil.

In 2012, Egypt issued a ministerial decree suspending all commercial cultivation of genetically engineered (GE) crops. Despite the moratorium, biotechnology (biotech) research and development continue in Egypt. 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), the National Research Center (NRC), University of Sadat City's Genetic Engineering Biotechnology Research Institute (GEBRI), as well as a web of other university research centers and biotechnology departments.

Although Egypt lacks legislation regulating biotechnology, the government permits biotech imports so long as country-of-origin also consumes these products. Egypt imported some 9 million metric tons (MT) of corn and 3.5 million MT of soybeans in calendar year (CY) 2018 (January-December) to meet the growing feed demand of its poultry and aqua sectors. Although Egypt sources GE corn and soybeans from various origins, it forbids the planting of such crops.

The lack of a ratified biosafety law has led to proclamation of various decrees dealing with GE crops. Oversight falls under purview of four different ministries; all count with representation on the National Biosafety Committee, which has not met since 2014. The country requires a practical biosafety framework that adopts a clear policy. Without one, Egypt cannot move forward in conducting large scale field trials and the commercial planting of GE crops.

TABLE OF CONTENTS

CHAPTER1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

PART B: POLICY

PART C: MARKETING

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

PART E: POLICY

PART F: MARKETING

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) **PRODUCT DEVELOPMENT:** The major objective of agricultural biotechnology research in Egypt is the production of plant varieties that consume less water and that are higher yielding. The Ministry of Agriculture and Land Reclamation's (MALR) Agriculture Research Center (ARC), along with the Ministry of Higher Education and Scientific Research's (MOHESR) National Research Center (NRC) lead research activities utilizing modern biotechnology tools to achieve research goals.

1) The Agricultural Research Center (ARC): The Agricultural Genetic Engineering Research Institute (AGERI) is Egypt's main biotechnology research organization under the umbrella of the Agricultural Research center. It forms part of the of the MALR's Agricultural Research Center. Its mandate is to promote the transfer and the 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

In terms of field crops, the AGERI is primarily focusing on wheat and corn research. 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.

Training Courses: International and regional training courses and workshops are constantly being organized by AGERI to provide an opportunity for researchers from Africa and the Middle East to gain experience in the use of advanced Molecular Biology Technologies. Short-term courses (one-to-two weeks) are organized throughout the year for university and research center undergraduate and graduate students. These trainings are coordinated by AGERI experts, and include modules on:

- Molecular Marker Techniques and Fingerprinting
- Plant Genetic Transformation Techniques & Tissue culture

- Microbial Molecular Biology
- Introduction to Genomics
- Biosafety of GE Organisms
- Biotechnological Techniques
- DNA sequencing
- Introduction to Bioinformatics
- GE Detection
- Bioinformatics

2) The National Research Center (NRC): 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:

- Supporting agricultural development through applied research with the goal of increasing food per unit area. It seeks to rationalize water consumption systems and improve the properties of the soil.
- Introducing advanced agricultural technologies such as biotechnology and nanotechnology to maximize the use of resources and reduce soil and water pollution by improving the efficiency of water use in quantity and quality.
- Promoting collaborative research with international agricultural research centers. The center supports technology transfer programs based on needs across Egypt's geographical areas to provide sustainable agriculture growth.
- Enhanced technologies for date palm propagation, conservation, and the genetic improvement of 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.
- Studying the effect of nanoparticles on plant growth and metabolic functions, as well as the utilization of nanoparticles in plant tissue culture and the interaction between nanoparticles and plant responses including element uptake.

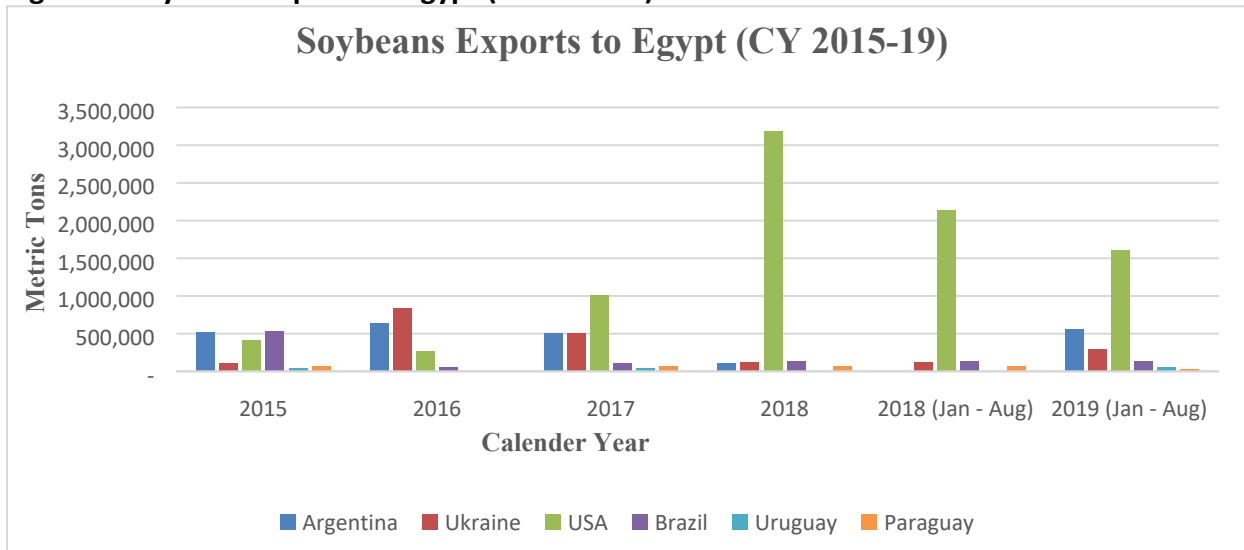
3) Universities: Biotechnology research activities at Egypt's universities are well established. The Genetic Engineering and Biotechnology Research Institute (GEBRI) located at the University of Sadat City, is the country's leading research center. It utilizes biotechnology tools to develop crops that 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.

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 or export GE products.

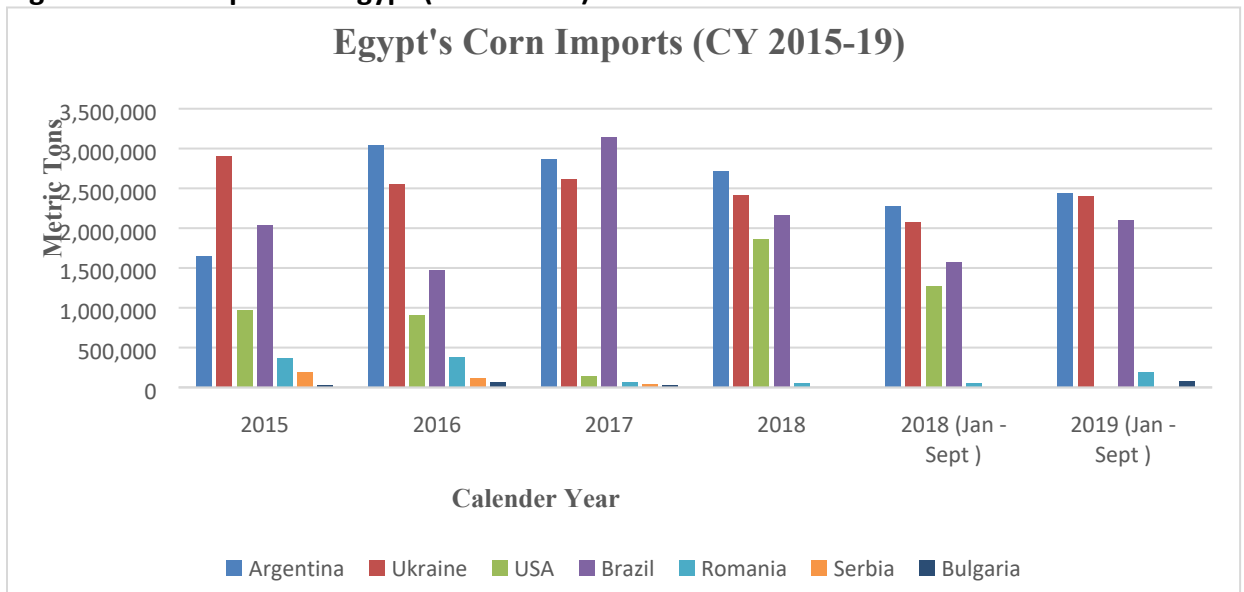
d) **IMPORTS:** Egypt permits the import of GE products. Imports are permissible if the export country-of-origin approves the product for consumption and authorizes its export. Egypt is a net importer of soybeans for food and feed and yellow corn for feed use.

Figure 1: Soybeans Exports to Egypt (CY 2015-19)



NOTE: U.S. soybean exports to Egypt reached record levels in CY 2018 due to U.S.-China trade tensions. Egyptian traders turned to the highly efficient and affordable U.S. producer for record volumes of soybeans.

Figure 2: Corn Exports to Egypt (CY 2015-19)



NOTE: U.S. Corn exports to Egypt decreased in CY 2019 due to market conditions.

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 export country-of-origin approves the product for consumption and authorizes its export.

PART B: POLICY

a) **REGULATORY FRAMEWORK:** Egypt's lack of a biosafety law has led to promulgation of various decrees dealing with agricultural biotechnology (Table 1). Biotechnology oversight falls under purview of four different ministries; all count with 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 genetically engineered 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 genetically engineered seed varieties requires approval by the Seed Registration Committee, which receives guidance from the National Biosafety Committee.
Decree 19 (January 2007): Nominated new members of 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, legal advisor, and a representative of the Consumer Protection Agency.

Ministry of Agriculture and Land Reclamation (MALR): The Ministry of Agriculture 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 (ARC):** Counts with 17 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. The Agricultural Research Center's institutes developed the majority of Egypt's field crop and vegetable varieties. The Agricultural Genetic Engineering Research Institute is responsible for the research and development of agricultural biotechnology. The Regional Laboratory for Food and Feed oversees food and feed products produced through genetic engineering.

- 2) Central Administration for Seed Testing and Certification (CASC):** It is the lead agency responsible for seed quality control, seed legislation, and policy enforcement. The Central Administration for Seed Testing and Certification reviews all relevant legislation, updates and prepares rules required to control all seed activities, and works to integrate and harmonize seed legislation. The Central Administration for Seed Testing and Certification is the designated seed certification authority and performs lab and field-testing for certified seed.
- 3) Central Administration for Seed Production (CASP):** It 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 Health (MOH): The Ministry of Health is responsible for maintaining and improving the overall health of the population. Its responsibilities include approving all food products for sale in Egypt, supervising food quality, regulating the use of preservatives in foods, and ensures that products have expiration dates.

Within the ministry, the following committees and organizations have a role in biotech agriculture and food production:

- The Supreme Committee for Food Safety (ensures the safety of food production and consumption and controls food import permitting)
- The Food Safety and Control General Directorate (FSCGD)
- The Central Public Health Laboratories (CPHL)
- The National Nutrition Institute (NNI)

Ministry of Trade and Industry (MTI): The ministry plays a role in the control of imported products and the creation of food standards; including genetically engineered products. The two primary organizations involved are:

- The Egyptian Organization for Standardization and Quality Control (EOS) (sets the standards for food and industrial products whether imported or locally produced)
- The General Organization for Export and Import Control Authority (GOEIC)

Ministry of Environment (MOE): The ministry's role, in tandem with the MALR, is to assess the impacts of releasing GE crops into the environment. The Ministry of Environment'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 that could have an adverse effect on conservation and biological diversity.

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

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

- b) APPROVALS:** With the 2012 suspension of the planting and cultivation of GE crops, no approvals for greenhouse trials, field-testing, or commercial release have been issued (see [GAIN-EGYPT \(EG-18023\) Egypt Biotechnology Annual 2018 – Egypt Needs a Biosafety Framework for Agricultural Biotechnology](#)).
- c) STACKED or PYRAMIDED EVENT APPROVALS:** There are no stacked events used in any transgenic crops under development. For imports of food and feed derived from biotech varieties, the varieties with stacked events approved in the country-of-origin are accepted.
- d) FIELD TESTING:** There is no ongoing field-testing in Egypt (see [GAIN-EGYPT \(EG-18023\) Egypt Biotechnology Annual 2018 – Egypt Needs a Biosafety Framework for Agricultural Biotechnology](#)).
- e) INNOVATIVE BIOTECHNOLOGIES:** There is no regulatory policy for innovative biotechnologies such as genome editing using ZFNs, TALENs, and CRISPR/Cas9. There is researcher interest, but the lack of funding is 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 or products with GE content. Authorities treat biotech products as they treat non-biotech products.
- 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, the planting and cultivation of GE crops was suspended. Although there have been no new approvals for greenhouse trials, field-testing, or for commercial release since then, under the existing regulatory structure there is an approval process for GE crop research and commercialization, which is on hold. Until there is a law, enacted by Egypt's parliament and or approved by the cabinet, the following process is on hold. There is scant possibility in the near-term that enactment will occur.

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 National Biosafety Committee reviews the application. If approved, the application goes to the Seed Registration Committee (SRC) for preliminary approval to proceed with standard field trials. The Seed Registration Committee from the CASP 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 the National Biosafety Committee, the NBC authorizes the applicant to apply to the SRC for approval for the commercial release of the variety. The Seed Registration Committee 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 in 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 the 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: 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), *Codex Alimentarius* (Codex), and the Cartagena Protocol on Biosafety. Egypt is a member of the 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 contributes directly to lack of public awareness and trust in food derived from GE crops; allowing the media to overstate misconceptions about biotechnology. A large segment of the Egyptian public using social media 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 linkage between GE products and cancer.

Anti-biotech campaigns are very 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. Egyptian agri-businesses and food companies exporting to Europe prefer not to advocate for biotechnology products.

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

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: No genetically engineered (GE) animals are under development. The Agricultural Research Center does have ongoing biotechnology activities for enhancing livestock, poultry, and fish production, mainly development of livestock recombinant vaccines and disease diagnostic kits. Key institutions are:

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

b) COMMERCIAL PRODUCTION: There is no GE approved animal production.

c) EXPORTS: N/A

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

e) TRADE BARRIERS: N/A

PART E: POLICY

a) REGULATORY FRAMEWORK: None. GE animals are not permissible.

b) INNOVATIVE BIOTECHNOLOGIES: N/A

c) LABELING AND TRACEABILITY: N/A

d) INTELLECTUAL PROPERTY RIGHTS (IPR): None. GE animals are not permissible.

e) INTERNATIONAL TREATIES and FORUMS: Egypt is a Food and Agriculture Organization and Codex *Alimentarius* member. It follows World Organization for Animal Health standards and protocols for live animal and beef product imports. Egypt does not support GE animal production.

f) RELATED ISSUES: N/A

PART F: MARKETING

a) **PUBLIC/PRIVATE OPINIONS:** There is skepticism about biotechnology's benefits.

b) **MARKET ACCEPTANCE/ STUDIES:** N/A

Attachments:

No Attachments