USDA Foreign Agricultural Service
GAIN Report
Global Agricultural Information Network

Required Report - public distribution

Date: 10/11/2018
GAIN Report Number: EG18023

Egypt

Agricultural Biotechnology Annual 2018

Egypt Needs a Biosafety Framework for Agricultural Biotechnology

Approved By:
Ali Abdi, Minister-Counselor

Prepared By:

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

Report Highlights:
The lack of an enacted biosafety law has led to promulgation of various decrees dealing with agricultural biotechnology. Oversight falls under the purview of four different ministries. The absence of a legal framework impedes field trials, as well as the commercial use of GE crops developed domestically by Egyptian scientists and researchers. The absence of a biosafety system contributes directly to the lack of public awareness and trust in biotechnology; allowing the media to sensationalize misconceptions about biotechnology.

EXECUTIVE SUMMARY

Despite Egypt's landmass of nearly 1 million square kilometers, only five percent of the area supports habitation while overlapping with cultivated areas. Less than four percent of the land area is arable. Water availability for human consumption and agricultural production is a major concern. Scientific and technological advances in agricultural production and biotechnology offer the possibility of economic development and crop improvement.

Although Egypt lacks legislation regulating biotechnology, the government permits biotech imports so long as country-of-origin also consumes these products. FAS Cairo (Post) projects that Egypt will import 9 million metric tons (MMT) of corn and 3.5 MMT of soybeans in calendar year (CY) 2018 to meet the feed demand of its growing poultry and aquaculture sectors (see, GAIN-EGYPT No. EG18020 – Grain and Feed Update 2018). Egypt does not require labeling of biotech products. It sources corn and soybeans derived through GE, but prohibits planting of such crops.

Egypt in 2008 was the first Arab country to commercialize a biotechnology corn crop (incorporating *Bacillus thuringiensis* (Bt) spores, providing the crop with an insect resistance trait). In March 2012, the Minister of Agriculture however suspended the planting of MON 810 due to an anti-genetically engineered (GE) products media campaign. Ministerial Decree 378/2012 suspends the registration, cultivation, and commercialization of all genetically engineered crops.

The major objective of agricultural biotechnology 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.

The lack of an enacted biosafety law has led to promulgation of various decrees dealing with agricultural biotechnology. 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 the area of agricultural biotechnology. The absence of a legal framework impedes field trials, innovation, as well as the commercial use of GE crops produced domestically by Egyptian scientists and researchers. Egypt is a party to the Cartagena Protocol on Biosafety (CPB).

TABLE OF CONTENTS

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 National Research Center (NRC) lead research activities utilizing modern biotechnology tools to achieve research goals.

1) The Agricultural Genetic Engineering Research Institute (AGERI): The Agricultural Genetic Engineering Research Institute (AGERI) is Egypt's main biotechnology research organization. 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:

- Molecular Biology
- Microbial Molecular Biology
- Molecular Entomology
- Plant Tissue Culture and Transformation
- Genome Mapping and Marker Assisted Selection
- Structural and Functional Genomics
- Proteomics
- Bioinformatics
- Molecular Virology
- Gene Silencing
- Immunology/ELISA and Virus Diagnosis
- Departments in AGERI include:
    - Plant Genetic Transformation
    - Plant Molecular Biology
    - Microbial Molecular Biology
    - Nucleic Acids and Protein Structure
    - Bioinformatics and Computer Networking
    - Genome Mapping Research

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 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 (NRC):** The National Research Center is a multidisciplinary research body engaged in agricultural research activities through its agricultural and biological division with the aim of using new technologies to improve agricultural production. The current research activities at the NRC's Agricultural and Biological Division 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 utilization of available resources and reduction of soil and water pollution by improving the efficiency of water use in quantity and quality.
- Promoting collaborative research programs with international agricultural research centers. The center supports technology transfer programs based on needs across different geographical areas in Egypt to provide sustainable agriculture growth.
- Enhanced technologies for date palm propagation, conservation, and the genetic improvement of date palm varieties.
- Biotechnology-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 different nanoparticles on plant growth and their 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 is well established. The leading research center is the Genetic Engineering and Biotechnology Research Institute (GEBRI) located at the Sadat City University. 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 also developing strategies to tackle the effects of climate change on yields, in addition to expanding the area of germ plasm collections and conservation.

The Genetic Engineering Research Center (GERC) at Cairo University's Faculty of Agriculture has had several successful research projects. These include production of drought tolerant canola plants, improvement to salt tolerance in tomatoes and wheat.

b) COMMERCIAL PRODUCTION: Egypt in 2008 was the first Arab country to commercialize a biotech corn crop. In March 2012, the Minister of Agriculture however, suspended the planting of MON 810 due to an anti-genetically engineered (GE) products media campaign. Ministerial Decree 378/2012 suspends the import registration of GE seeds, their cultivation, and commercialization and prohibits greenhouse and field trails.

c) EXPORTS: Egypt does not produce or export GE products.

d) IMPORTS: Egypt permits the import of biotech crops. Imports are permissible if the export country-of-origin approves the product for consumption and authorizes its export. Egypt is a net

importer of agricultural commodities. Major imports include soybeans for food and feed, as well as yellow corn, corn gluten meal, and distiller's dried grains with solubles (DDGS) for feed.

- **Corn:** Yellow corn shipments in calendar year (CY) 2018 (January-August) total 6 million metric tons (MMT) or 750,000 metric tons (MT) per month. Egypt's top three suppliers in 2018 are Argentina (2.1 MMT), Ukraine (2.1 MMT), and the United States (1.1 million metric tons).
- **Distiller's Dried Grains with Solubles Imports:** Egypt's DDGS imports through July 2018 total 91,500 MT; Post anticipates imports of 160,000 MT in 2018. Imports in CY 2017 were 173,600 MT, up 40,600 MT or 31 percent higher compared to 2016. In 2017, the United States accounted for 98.8 percent of Egypt's DDGS imports. Local DDGS prices are EGP 4,900/MT ($302.50 per metric ton).
- **Corn Gluten Meal:** Egypt's imports of corn gluten meal through July 2018 total 70,000 MT; FAS Cairo (Post) anticipates imports of 120,000 MT by the end of calendar year 2018. Imports in CY 2017 were 115,000 MT, down 33,000 MT or off by 22 percent compared to 2016. The beef/dairy livestock, poultry, and aquaculture feed manufacturing sector are heavy users of corn gluten meal. Prices for corn gluten meal are EGP 12,700/MT ($711.40 per metric ton).
- **Soybeans:** In 2017, Egypt's largest soybean suppliers remained the United States (1.1 MMT), Ukraine (511,000 MT), Argentina (507,500 MT), and Brazil (110,000 MT). Egypt's total imports of soybeans through, 2018 amount to 2.8 million metric tons. The United States had the largest share with 2.45 MMT or 87.5 percent of total imports.

e) FOOD AID: Not Applicable.

f) TRADE BARRIERS: Egypt maintains an open market for agricultural commodities and products derived through, or 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: Ministerial Decrees Dealing with Biotechnology

Decree 85 (1995): Established the National Biosafety Committee, and gave 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 located in 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):** Consists of 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 have developed the majority of the 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 national 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)

The Food Safety and Control General Directorate, along with the Central Public Health Laboratories and the National Nutrition Institute conduct studies on the impact of GE crops or products produced from these crops on human health. They have representation on the National Biosafety committee.

***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) (responsible for all food imports and has representation on the National Biosafety committee)

***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 Egyptian Environmental Affairs Agency (EEAA) of the MOE established a biosafety unit in 2013 for this task.

The Egyptian Environmental Affairs 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 (MHE): The Ministry oversees the Supreme Council of Universities (SCU), which is in charge of 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 is comprised of members from a number of Egyptian ministries with the aim of developing policies and procedures to govern the release and commercialization of genetically engineered crops.

The committee provides technical advice to the regulatory authorities and the institutions responsible for conducting transgenic research. The committee requires that all institutions conducting transgenic research or field trials go through an application procedure and obtain approval for their activities.

Other activities of the National Biosafety Committee include:

- Formulating, implementation and updating safety codes
- Risk assessment and license issuance
- Coordination with international and national organizations
- Providing training and technical advice

b) APPROVALS: In 2012, the planting and cultivation of GE crops was suspended. Since this suspension there have been no new approvals for greenhouse trials, field-testing, or for commercial release. See GAIN - EGYPT – Biotechnology Annual 2014 for previous listed approvals.

c) STACKED or PYRAMIDED EVENT APPROVALS: Currently, there are no stacked events used in any transgenic crops. 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.

Permits Issued By the NBC for Horticultural GE Crops, 2006-10

	tomato	squash	melon	cantaloupe	cucumber	potato	TOTAL
Greenhouse Trials	1	8	2	3	1	7	22
Open Field Trials	2	8	1	-	1	7	19
Commercialized	-	-	-	-	-	-	-
TOTAL	3	16	3	3	2	14	41

Permits Issued By the NBC for Field GE Crops, 2006-10

	Cotton	Corn	Wheat	Rice	TOTAL
Greenhouse Trials	2	2	4	1	9
Open Field Trials	2	6	5	-	13
Commercialized	-	1	-	-	1
TOTAL	4	7	9	1	21

e) INNOVATIVE BIOTECHNOLOGIES: There is no regulatory policy for innovative biotechnologies such as genome editing using ZFNs, TALENs, and CRISPR/Cas9.

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

g) LABELING: 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. The policy of recognizing country-of-origin approvals prevents LLP issues from occurring.

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, the existing regulatory structure is still in place but not operational. The approval process for GE propagative material requires:

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 submit an application 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. The Egyptian Patent Office and the Academy of Scientific Research and Technology have been in association since 1971. Public Law 82/2002 provides coverage of IP issues in the life sciences.

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 these 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: Egypt ratified the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits (October 12, 2014). It is a member of international plant protection and plant health organizations, including the International Plant Protection Convention (IPPC), *Codex Alimentarius* (Codex), and the Cartagena Protocol on Biosafety. It is a member of the WIPO and signed the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS).

n) RELATED ISSUES: Not applicable.

PART C: MARKETING

a) PUBLIC/PRIVATE OPINIONS: The absence of a biosafety system contributes directly to lack of public awareness and trust in biotechnology; allowing the media to sensationalize misconceptions about biotechnology. Campaigns by European environmental groups against the adoption of biotechnology in Europe have also not been helpful. The public generally believes that there is a linkage between biotech products and cancer. One-sided media reporting on possible risks associated with GE crops skews public perception of the technology, fostering opposition to the adoption of GE crops.

Anti-biotech campaigns are very active on social media. These generate misconceptions, and often lie about the health risks associated with 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 has ongoing biotechnology activities for enhancing livestock, poultry, and fish production. Namely the 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: Not applicable.

d) IMPORTS: There are no regulations applicable to the import of GE animals. Imports of GE animals are not permissible.

e) TRADE BARRIERS: Not applicable.

PART E: POLICY

a) REGULATORY FRAMEWORK: None.

b) INNOVATIVE BIOTECHNOLOGIES: Genetic research in animals using biotech tools or molecular breeding tools to enhance production resistance to diseases carried out according to research goals or targets of the Egyptian institutes. There is no ongoing GE research to produce GE animals.

c) LABELING AND TRACEABILITY: Not applicable.

d) INTELLECTUAL PROPERTY RIGHTS (IPR): Not applicable.

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

f) RELATED ISSUES: Not Applicable.

PART F: MARKETING

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

b) MARKET ACCEPTANCE/ STUDIES: Not applicable.