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Report Highlights:
On October 20, 2016, the Egyptian Ministry of Environment (MOE) submitted a new draft biosafety bill to the cabinet. The bill is currently being cleared by the cabinet's Judicial Reform Committee before submission to the Parliament for ratification.

Section I. Executive Summary:

The current strategy for agricultural development in Egypt emphasizes the necessity of applying biotechnology to address biotic and abiotic stresses facing Egyptian Agriculture, as well as optimizing crop returns per unit of land and water consumed. These goals are the key drivers of major research institutions such as the Ministry of Agriculture and Land Reclamation's (MALR) Agriculture Research Center (ARC), the Ministry of Higher Education and Scientific Research's National Research Center (NRC).

Egypt is a large consumer of imported yellow corn for animal feed, as well as soybeans for food and feed use. These products are sourced from the US and other markets that openly commercialize GE seed varieties. According to the Government of Egypt policy as long as the imported product is approved and is also consumed in the countries of origin, it is allowed to be exported to Egypt. No GE plants or animals are produced in Egypt and no GE seed varieties may be imported for planting.

Field tests of GE plant varieties in Egypt were ongoing until 2012. In March of 2012 the Minister of Agriculture issued Decree 378 suspending the registration of genetically engineered crops, for planting and cultivation in Egypt. Since the implementation of Decree 378, no GE varieties have been approved for commercialization.

Since 1995, regulation of agricultural biotechnology has been under the auspices of the National Biosafety Committee, chaired by the Minister of Agriculture, and with representatives of key ministries, scientific institutions, and academia. However, a biosafety law and a functional biosafety system have not been implemented. The lack of a legal framework is an impediment to trials or commercial use of GE crops produced domestically by Egyptian scientists and researchers.

A draft biosafety law, originally drafted in 2007, was introduced to the cabinet on December 28, 2014. After a number of iterations and legal discussions within the executive branch, the Ministry of Environment (MOE) submitted the law to the Cabinet on October 20, 2016. That version is currently being cleared by the Cabinet's Judicial Reform committee before its submission to Parliament for ratification.

Stakeholders need to understand that some of Egypt's challenges such as water scarcity, climate change, and biotic and abiotic stressors can be partially addressed by the safe use of agricultural biotechnology. If stakeholders are influenced by misperceptions, Egypt will continue to lag in biotechnology development and be subject to increasing imports to meet its food needs. Its cotton industry, once famous and highly productive, is lagging behind other countries in Africa that were able to capitalize on new technologies and have benefited vastly from GE technology.

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Chapter 1: Plant Biotechnology

PART A: PRODUCTION AND TRADE

a) Product Development: One of the major objectives for agricultural biotechnology research in Egypt is the production of transgenic plants conferring resistance to biotic stresses resulting from insects, viruses, bacteria, and abiotic stresses such as drought, salinity and high temperatures. Both of these factors lead to economic losses in the crops cultivated in Egypt.

Despite the moratorium on the commercialization of GE crops in the country, agricultural biotechnology research capacity has evolved and expanded through a network of universities and national research institutions. These organizations continue research to address Egyptian agricultural challenges. Institutions such as the Agricultural Research Center (ARC) and the National Research Center (NRC) are at the forefront of implementing a variety of research activities that utilize modern biotechnology tools to achieve their research objectives.

The Agricultural Research Centre):
Within the ARC, the Agricultural Genetic Engineering Research Institute (AGERI) is Egypt's premier biotechnology research organization with a mandate to promote the transfer and the application of biotechnology. AGERI's goals are to develop drought and salt tolerant crops, as well as pest and disease resistance traits; to expand and diversify the pool of highly qualified trained professionals in biotechnology; and to broaden the cooperation in biotechnology research with public and private sectors. Scientific research domains in AGERI are:

- Molecular Biology
- Microbial Molecular Biology
- Molecular Entomology
- Plant Tissue Culture & Transformation
- Genome Mapping & Marker Assisted Selection
- Structural and Functional Genomics
- Proteomics
- Bioinformatics
- Molecular Virology
- Gene Silencing
- Immunology / ELISA & Virus Diagnosis

It collaborates extensively with the Plant Protection Research Institute (PPRI), Field Crops Research Institute (FCRI), Cotton Research Institute (CRI), Horticulture Research Institute (HRI), and other national research centers and universities.

In terms of field crops, AGERI is focusing on wheat and corn research. The wheat program focuses on the establishment of regeneration systems for wheat cultivars, the addition of genes for drought and salinity tolerance, and the evaluation of transgenic wheat lines in field trials under salt and drought

stress. Scientists in AGERI have produced drought-tolerant wheat by transferring the barley HVA1 gene into wheat varieties. In 2009, the National Biosafety Committee (NBC) approved the field trails of transgenic wheat lines. Currently, the new lines have been incorporated in the national wheat-breeding program of ARC for further field testing and seed multiplication.

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.

In terms of horticultural crops, AGERI is focused on tomato production. Tomato yellow leaf curl virus (TYLCV) has spread to all of the main vegetable-producing regions of Egypt. It has become the limiting factor for tomato production. In some cases, the virus causes up to 100 percent yield loss.

Tomato varieties resistant to TYLCV have been engineered in collaboration between Cairo University, AGERI, and the Donald Danforth Plant Science Center. These varieties use the siRNA strategy to block the viral life cycle in the plant and prevent it from spreading, thus acquiring viral resistance. If successful, the plants will enable the economic production of high quality tomatoes while reducing the need for chemical protection methods. The tomato varieties are still waiting NBC approval to conduct field trials.

The National Research Center (NRC)
The National Research Center is a multidisciplinary research organization engaged in agricultural biotechnology research activities through its agricultural and biological division. The current biotechnology research activities at NRC are focused on:

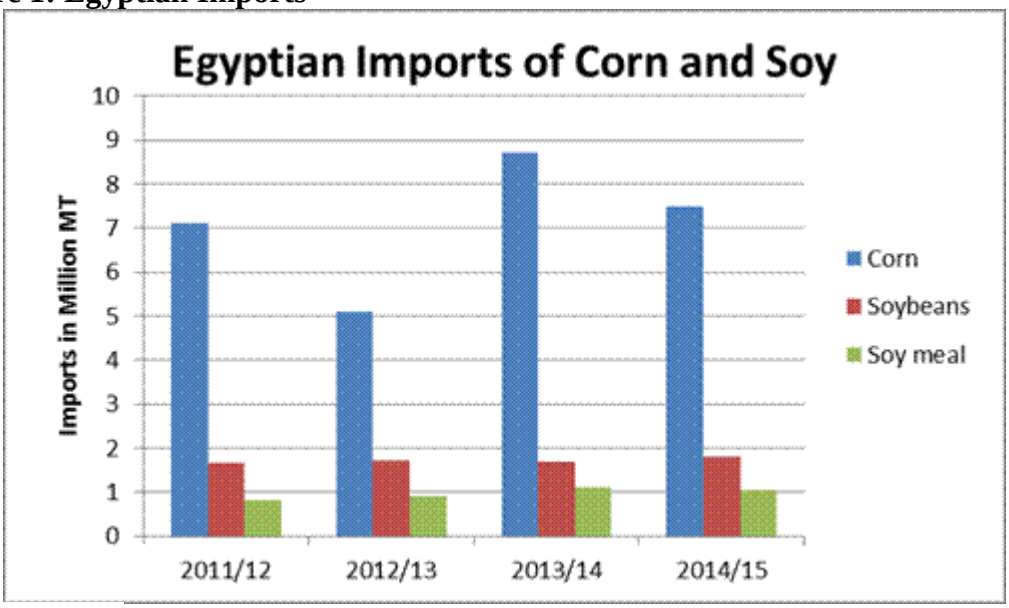
- Delivering resistance to biotic stresses (insect pests and diseases) and tolerance to abiotic stresses (drought, salinity and high temperatures)
- Increased productivity, improved quality, and gene mapping associated with yield.
- Improved nitrogen fixation and enhanced nutrient uptake and use efficiency
- Improved fermentation technology
- Enhanced technologies for date palm propagation, conservation and 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

b) Commercial Production: All commercial production is currently stalled due to Ministerial Decree 378, issued on March 8, 2012. This decree suspended import registration, cultivation, and commercialization of all GE crops in Egypt.

c) Export: With no commercial production of GE crops, Egypt does not export to the United States or any other country.

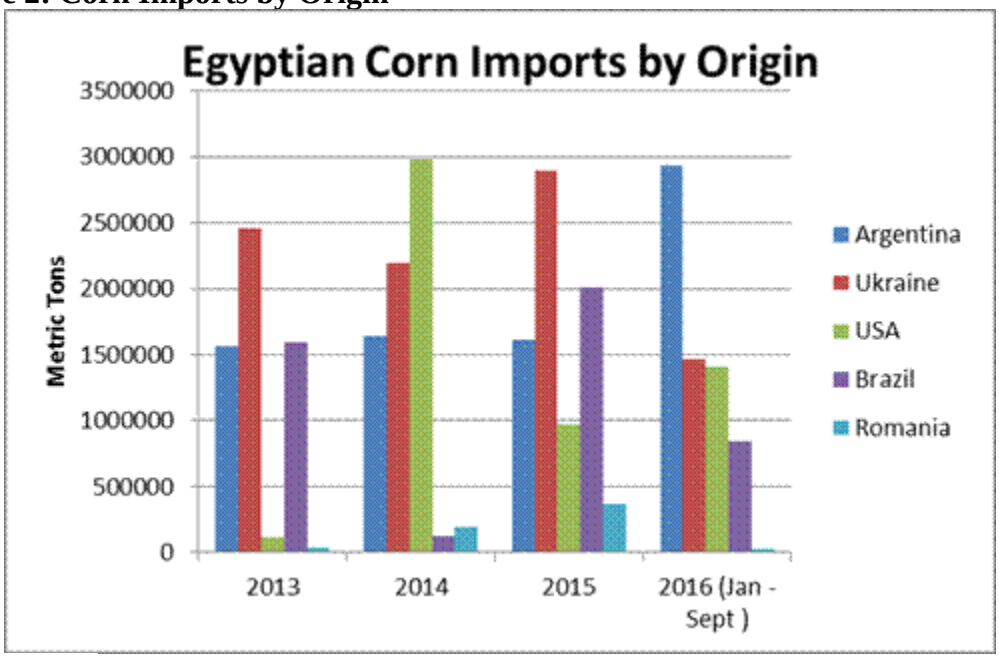
d) Imports: Egypt is a net importer of agricultural commodities including soybeans for food and feed and yellow corn for feed (see Figures 1-3). With the exception of Ukraine, countries exporting to Egypt produce primarily GE corn and soybeans. The Egyptian government maintains a general import policy of allowing imports of agricultural commodities, as long as the imported product is approved and consumed in the country of origin.

Figure 1: Egyptian Imports



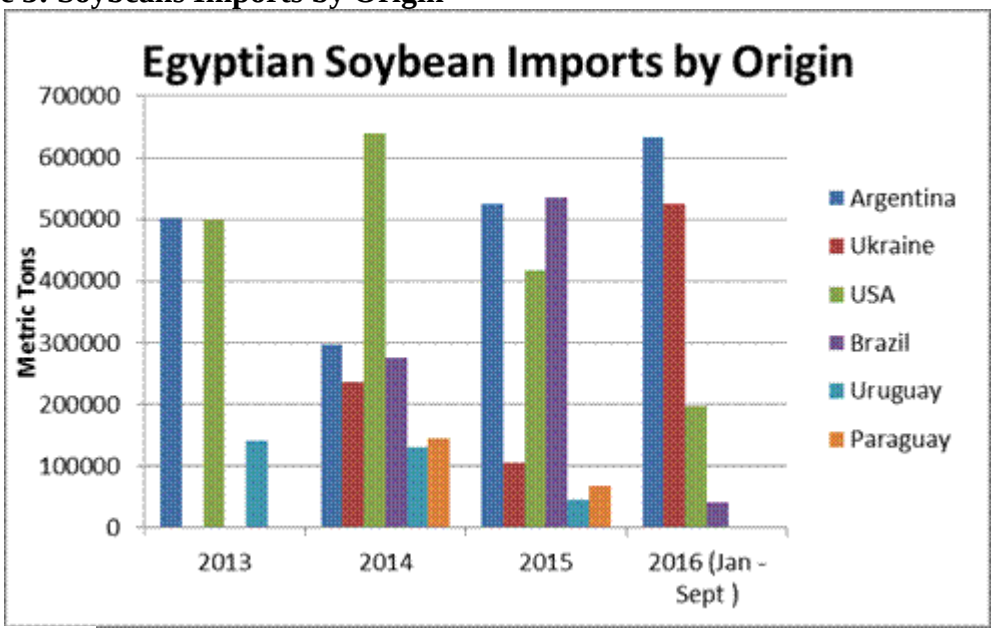
Source: USDA

Figure 2: Corn Imports by Origin



Source: GTA

Figure 3: Soybeans Imports by Origin



Source: GTA

e) Food Aid: Not Applicable

f) Trade Barriers: Egypt maintains an open market for agricultural commodities and products derived through, or produced with biotechnology.

Agricultural exports to Egypt from the US currently face no import restrictions as a result of agricultural biotechnology policy. It would be untenable for Egypt to impose trade restrictions on biotechnology, as it relies close to 100 percent on soybean imports and 60 percent of corn imports to meet its needs.

PART B: POLICY

a) Regulatory Framework: Due to Egypt's lack of a biosafety law, various ministers have issued decrees to deal with agricultural biotechnology. Table 1, below outlines the decrees.

Table 1: Ministerial Decrees Dealing with Biotechnology

Decree 85 (1995): Established the National Biosafety Committee (NBC), and gave it the task of setting regulations and guidelines concerning the safe use of genetic engineering and molecular biology, to ensure safety of the environment including human health.
Decree 136 (1995): Established an obligation to obtain a permit from the NBC 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. Consequently, marketing of GE seed varieties requires approval by the Seed Registration Committee, which receives guidance from the NBC.
Decree 19 (January 2007): Nominated new members of the NBC. Article 1 gives the names and qualifications of the 24 members. Article 2 nominates the two officials of the executive secretariat of the NBC. Article 3 restates parts of Decree 85 (1995) and Article 4 underlines that the NBC can call upon outside experts and can 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 AGERI/ARC.
Decree 1495 (September 2014): Reestablished the National Biosafety Committee NBC with new members from the Ministry of Environment (MOE), Ministry of Health (MOH), Ministry of Scientific Research (MOSR), industry, legal advisor, and a representative of the Consumer Protection Agency.

Due to the piecemeal nature of Egyptian policy on agricultural biotechnology, oversight for biotechnology falls to four different ministries, all with representation in the National Biosafety Committee. The role of each is described below.

Ministry of Agriculture (MALR): The Ministry of Agriculture is the main authority responsible for food cultivation and GE crops issues. Three organizations within the ministry play a role in the regulation of agricultural biotechnology.

First, the Agricultural Research Center has 17 research institutes and support organizations. It has the primary responsibility for crop improvement research, cultivar development, and testing throughout the country. The ARC supervises national field crop breeding programs for cereals, fiber materials, oils, legumes, fodder, and sugar. The majority of field crop varieties and, to a lesser extent, vegetable varieties have been developed by the ARC research institutes. AGERI represents the vehicle within ARC for the research and development of agricultural biotechnology. Additionally, the Regional Laboratory for Food and Feed oversees food and feed products produced using genetic engineering.

Second, the Central Administration for Seed Testing and Certification (CASC) is the agency responsible for seed quality control, seed legislation and policy enforcement. The 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 and performs lab and field testing for certified seed.

Third, the Central Administration for Seed Production (CASP) implements government seed production policies, advises ARC on foundation and registered seed requirements, and supervises certified seed production and multiplication.

Ministry of Health (MOH): The Ministry of Health is charged with 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 ensuring that products are labeled properly with expiration dates.

Within the ministry, the following committees and organizations are relevant to 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 GE 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 MOE's role, in tandem with 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 EEAA 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. They are required to take into account risks to human health, trans-boundary movements, as well as imports and exports of genetically modified organisms. The EEAA is further charged with establishing a database of regulation and legislation pertaining to the import and export of GE organisms. This database is still in development.

The National Biosafety Committee (NBC): In 2014, former Minister of Agriculture, Dr. Adel El-Beltagy, issued Ministerial Decree 1495 to reestablish the NBC. The committee is comprised of members from many Egyptian ministries. It is designed to put in place policies and procedures to govern the release and commercialization GE crops. The committee would also provide 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 get approval for their activities.

Other activities of NBC 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: Since the complete suspension of planting and cultivation GE crops in 2012, no NBC meeting has been held; hence, no new approvals for greenhouse trials, field testing, or for commercial release have been granted.

c) Stacked or Pyramided Event Approvals: There are no current stacked events used in any of the transgenic crops that were produced. If applications for stacked events are submitted, the NBC will take a case by case approach on whether to treat the event as novel and require their approval separate from the approval of each individual event in the stack. For imports of food and feed derived from biotech varieties, the varieties with stacked events that are approved in the country of origin will be accepted.

d) Field Testing: There is currently no ongoing field testing in Egypt.

e) Innovative Biotechnologies: Egypt does not have a regulatory policy on the use of 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: No decisions on the labeling of genetically engineered organisms or GE based food products have been made. Egyptian law does not require that biotech crops or products with biotech content have special labeling. Governmental authorities deal with biotech products as they deal with non-biotech products.

h) Monitoring and Testing: Currently no monitoring and testing of GE crops is taking place.

i) Low Level Presence Policy: Egypt has no low-level presence policy.

j) Additional Regulatory Requirements: Since the complete suspension of GE crop planting and cultivation in 2012, no NBC meeting has been held; hence, no new approvals for greenhouse trials, field testing, or for commercial release have been granted. However, under the existing regulatory structure, the approval process for GE propagative material is as follows:

1. The applicant completes a permit application form providing details of the genetic material introduced, the process used for inserting it, and other relevant information. The applicant also provides data from food and feed safety studies and evidence supporting a determination of low or negligible environmental risk. Where applicable, the applicant provides documents indicating approval of similar GEOs for release in their country of origin.
2. The application form is submitted to the NBC, which, after examination and approval, forwards it to the Seed Registration Committee (SRC) for their preliminary approval to proceed with standard field trials. The Seed Registration Committee from CASP assigns a team of qualified inspectors drawn from relevant 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. The NBC has the right to confirm the nature of the genetic modification by taking samples from the field for molecular analysis.
4. After successful completion of the field trials and submission of a report to the NBC, the NBC

authorizes the applicant to submit an application to the SRC for final approval to commercially release the new variety. Pending this, three years or seasons of agronomic performance trials are conducted under the supervision of the SRC.

k) Intellectual Property Rights (IPR): The Egyptian Patent Office (EPO) is the sole national office for registering and issuing patents. The office is accredited by the World Intellectual Property Rights Organization (WIPO) as a regional IP database authority, and plays a key role in technology transfer and IPR protection. The EPO was established in 1951 by Public Law 132 and has been associated with the Academy of Scientific Research and Technology since 1971. In 2002, Public Law 82 was published to incorporate coverage of IP issues in life sciences.

Goals of the Egyptian Patent Office

- Register patent applications for the local and foreign inventions.
- Grant and issue patents to protect the ownership rights of the Egyptian and foreign inventors.
- Collect foreign patent applications and arrange them to be easily accessible to examiners and users.
- Transfer technological information from patents granted internationally and provide it to specialists in order to develop their work and develop local industries.
- Encourage inventors by helping them participate in exhibitions and compete for recognition and awards.
- Publish (monthly) the official Patent Gazette that includes filed, accepted applications, granted patents and terminated applications.

Specific to agricultural technologies, MALR's ARC operates an office to oversee intellectual property protections as they pertain to agriculture. The Technology Management and Commercialization Office (TMCO) was established in 2001 and is under the jurisdiction of the ARC President. The Office runs its activities according to an "Internal Policy for Technology Management and Commercialization (IP Policy)". The IP Policy specifies the obligations and the responsibilities of the ARC, ARC staff and end-users with regard to intellectual property (IP) protection and technology transfer.

The office also has access to other legal consultants and expertise in the areas of marketing, promotion, and plant variety protection. A *Trustee Committee* has been established to pursue and oversee implementation of the office's mission.

Services of the TMCO:

- To provide legal and professional services for all ARC staff to protect their innovations under the executive regulations of the Intellectual Property Law 82/2002.
- Negotiation, execution and follow up of licensing agreements to ensure technology proper application and distribution of royalties.
- Provide all technical documents for ARC staff in the form of full patent text, database, and electronic connection with counterpart IPR strategic offices around the world.
- Provide legal support in completing/submission of intellectual property protection documents on behalf of the inventor or the breeder.
- Run awareness programs to improve ARC staff-knowledge of intellectual properties, ARC internal IP policy and related international conventions.
- Evaluation of ARC generated technologies to determine the marketability of each technology and its market niche.

l) Cartagena Protocol Ratification: Egypt ratified the Cartagena Protocol on Biosafety (CPB) in 2003. Since the signing of the protocol, no enabling regulation has been put into place. The international regulatory agreement requires countries to address environmental safety and human health by ensuring safe handling, transport, and use of GE products. The biodiversity department of the MOE is Egypt's focal point to the CPB's Biosafety Clearing House. The clearinghouse is a mechanism set up by 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/Fora: On October 12, 2014 Egypt ratified the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits. Egypt is a member of several international organizations that deal with plant protection and plant health, including the International Plant Protection Convention (IPPC), *Codex Alimentarius* (Codex), and the aforementioned CPB. Egypt is also a member of the World International Property Organization and signed the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement.

n) Related Issues: Not Applicable

PART C: MARKETING

a) Public/Private Opinions: As in other countries around the world, Egyptians do not concern themselves much with the origin of food products or how processing is handled. Access to food and pricing is paramount. However, campaigns by environmental groups in Europe against the adoption of biotech crops have created some obstacles to the development and adoption of GE crops in Egypt. Fear of biotechnology by a segment of the public could create further obstacles to adoption.

This segment of the Egyptian public believes that there are health risks associated with the consumption of food products derived from biotechnology. Furthermore, one-sided reporting by the media on possible health and environmental risks associated with planting GE seed varieties and cultivation affects the public perception of the technology. The media is affected by the advocacy of European environmental groups regarding the use of biotechnology.

Scientists and public officials from research centers of MALR and the Ministry of Higher Education and Scientific Research are mostly pro-biotechnology and fully understand the benefits of biotechnology. These proponents see biotechnology as a way to solve many of the challenges facing Egyptian agriculture. The food industry has mixed views about biotechnology risks and benefits. Agri-businesses and food companies exporting to Europe prefer not to advocate for biotechnology products.

On the other hand, the Egyptian Biotechnology Information Center (EBIC) within the Faculty of Agriculture at Cairo University plays an important role in educating the public about biotechnology. They simplify scientific information to and disseminate it to all levels of society, as well as clarifying both benefits and potential risks through reasonable and transparent fora.

b) Marketing Studies: Post 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 animals are under development in Egypt. However, ongoing biotechnology activities for enhancing livestock productivity continue within the ARC. These activities include development of livestock recombinant vaccines and disease diagnostic kits. The key institutions involved in this type of research are:

- 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.

b) Commercial Production: No genetically engineered animals have been approved in Egypt for any use.

c) Exports: Not applicable.

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

c) Trade Barriers: Not Applicable.

PART E: POLICY

a) Regulatory Framework: There is currently no policy with respect to animal biotechnology. All existing regulations are designed for plant products.

b) Innovative Biotechnologies: Not Applicable.

c) Labeling and Traceability: Not Applicable.

d) Intellectual Property Rights (IPR): Not Applicable.

e) International Treaties/Fora: Egypt is a member of several international organizations dealing with animal health and protection, such as the Food and Agriculture Organization (FAO), and *Codex Alimentarius*. Egypt follows World Organisation for Animal Health (OIE) standards and protocols regarding importation of live animals and beef products. Egypt is not actively arguing against animal biotechnology.

f) Related Issues: Not Applicable.

PART G: MARKETING

a) Market Acceptance: Egyptian consumers have limited knowledge regarding GE animal events. There is no information regarding market acceptance of these products.

b) Public/Private Opinions: Egyptian public opinion is skeptical of benefits from new biotechnologies, in general. This is not specific to animal products.

c) Market Studies: Not applicable.