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Egypt Still Searching for a Biosafety Framework for Agriculture Biotechnology

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Report Highlights:

On March 5, 2017, the Egyptian Ministry of Environment submitted a new biosafety bill to the cabinet. The bill is currently being revised by the cabinet's Judicial Reform Committee prior to submission to the Parliament of Egypt for ratification. Egypt requires a functional biosafety framework that implements a transparent and clear policy. Without one, Egypt cannot move forward in the area of biotechnology. Egypt imports roughly 8.8 million metric tons (MMT) of corn and 2.0 MMT of soybeans annually, and these are largely sourced from the United States and other markets that openly commercialize genetically-engineered (GE) varieties.

EXECUTIVE SUMMARY

Egypt's agricultural research strategy focuses on optimizing crop returns per unit area, as well as addressing biotic and abiotic stresses. The foregoing strategy is the key driver at major Egyptian research institutions such as the Ministry of Agriculture and Land Reclamation's (MALR) Agriculture Research Center (ARC) and the Desert Research Center (DRC), the Ministry of Higher Education and Scientific Research's National Research Center (NRC), the National Water Research Center (NWRC) of the Ministry of Water Resources and Irrigation (MWRI), and crop improvement research conducted in several universities.

Egypt imports roughly 8.8 million metric tons (MMT) of corn and 2.0 MMT of soybeans annually to meet the feed demand of its expanding poultry and aquaculture sectors. Corn and soybeans are largely sourced from the United States and other markets that openly commercialize genetically-engineered (GE) varieties.

The Government of Egypt permits the import of genetically-engineered product that is approved for and consumed in the country-of-origin, as well as is authorized for export. Currently no genetically-engineered plants or animals are produced in Egypt. The import of GE seed varieties for planting is not authorized. Conventional plant breeding is one of Egypt's strengths; however its continued competitiveness in global agriculture requires the use of innovative technologies.

The commercialization of genetically-engineered yellow corn varieties in Egypt occurred from calendar-years (CY) 2008 through 2012. During this time, 3,800 feddans (approximately 1,596 hectares) were planted with GE corn in the country's newly reclaimed areas. In March of 2012, Minister of Agriculture and Land Reclamation Eng. Reda Ismail issued Decree 378; suspending the registration and commercial planting of GE crops in Egypt. The Minister's decision was prompted by an Egyptian television program that alleged GE corn causes cancer, increased spontaneous abortions, and liver and kidney failure in mice. Since the implementation of Decree 378, no genetically-engineered varieties have been approved for commercialization.

On March 5, 2017, the Egyptian Ministry of Environment submitted a new biosafety bill to the cabinet. The bill is currently being revised by the cabinet's Judicial Reform Committee prior to submission to the Parliament of Egypt for ratification. Egypt requires a functional biosafety framework that implements a transparent and clear policy. Without one, Egypt cannot move forward in the area of biotechnology

Egypt's draft biosafety law in its current form seeks to confirm the safety of both exported and imported genetically-engineered products. The bill aims to establish the conditions to safeguard human health, the environment, and other organisms from any adverse risks arising from the handling and release of GE products into the environment.

The draft biosafety law encourages the safe utilization of genetically-engineered products and tools to the maximum extent possible; while pursuing transparency and collaboration with other countries on the safe use of genetically-engineered products. This bill aims to address GE products' impact on socio-economic considerations and the environment, ensuring the sustainability of local biodiversity. The draft legislation entrenches the consumer's right (through recourse to labeling) to freely choose between GE product and conventional products.

FAS Cairo understands that the draft biosafety law calls for the establishment of a National Biosafety Council, composed of stakeholders from the government and the scientific institutions with responsibility for GE research and development. The scientific community views the current draft legislation in positive terms. The absence of a legal framework impedes field trials, as well as the commercial use of GE crops produced domestically by Egyptian scientists and researchers.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT: A major objective for agricultural biotechnology research in Egypt is the production of plant varieties that are less water consuming. Drought tolerant varieties need also to confer resistance to pest and diseases that cause significant economic losses for local agriculturalists.

The Ministry of Agriculture and Land Reclamation's (MALR) Agriculture Research Center (ARC) and 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 Research Center (ARC):** Within the Agricultural Research Center, the Agricultural Genetic Engineering Research Institute (AGERI) is Egypt's premier biotechnology research organization; whose mandate is to transfer and apply biotech.

Several AGERI cotton, wheat, and maize (i.e., corn) projects have been phased out; results have been published in a number of scientific journals. Most of AGERI's work currently focuses on molecular breeding (of corn and wheat), identifying candidate genes for drought and salinity tolerances, as well as plant regeneration and gene transformation optimization. Project funding comes from the Egyptian Academy of Sciences.

Scientific research conducted by the AGERI encompasses:

- 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

Departments in AGERI include:

- Plant Genetic Transformation
- Plant Molecular Biology
- Microbial Molecular Biology
- Nucleic Acids & Protein Structure
- Bioinformatics & Computer Networking
- Genome Mapping Research

2) The National Research Center (NRC): The National Research Center is a multidisciplinary research organization 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, while rationalizing water consumption systems and improving the properties of the soil.
- Introducing advanced agricultural technologies 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 and supporting technology transfer programs based on needs across different geographical areas in Egypt to provide sustainable agriculture growth.
- Identifying future research needs, priorities and assessment of problems to achieve sustainable productivity.
- Improving nitrogen fixation and enhanced nutrient uptake and use efficiency.
- 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.

b) COMMERCIAL PRODUCTION: All commercial production is stalled due to Ministerial Decree 378 (March 8, 2012). The decree suspends the import registration, cultivation, and commercialization of all genetically-engineered crops in Egypt.

c) EXPORTS: Egypt does not have any commercial GE crop production. It does not export genetically engineered crops to the United States or to any other country.

d) IMPORTS: The Government of Egypt permits the import of genetically-engineered products that are approved for and consumed in the country-of-origin, as well as are authorized for export. Egypt is a net importer of soybeans and corn mainly for feed (see, Figures 1 and 2).

Figure 1: Egypt, Corn Imports by Origin 2013-17

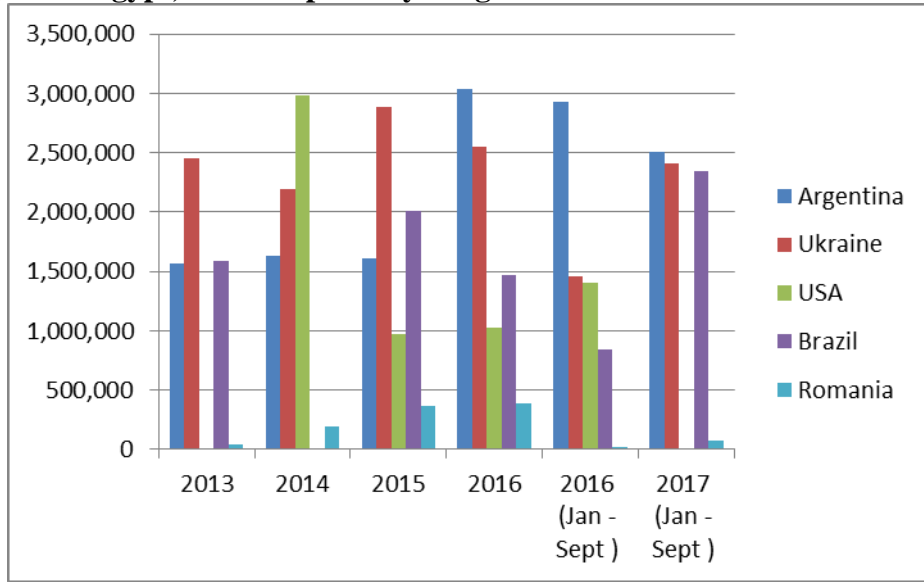
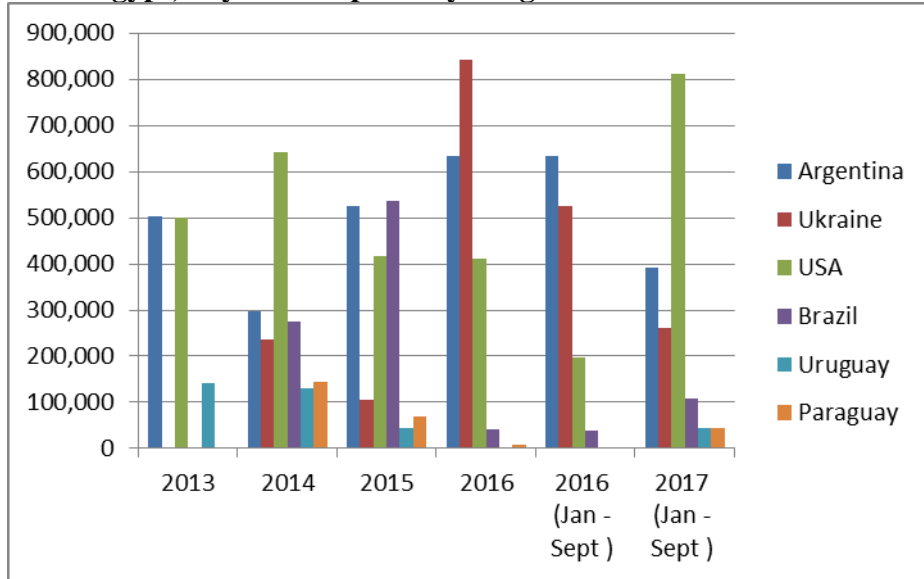


Figure 2: Egypt, Soybean Imports by Origin 2013-17



In calendar year (CY) 2016 Egypt imported 150,000 metric tons (MT) of corn gluten meal; 99.7 percent is U.S.-origin. Similarly, Egypt imported some 135,000 MT of distiller’s dried grains with solubles (DDGS) for feed; 98.6 percent is U.S.-origin. The United States commercializes GE corn and soybean varieties.

e) FOOD AID: Not Applicable.

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

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 (see, Table 1). Oversight for biotechnology currently falls under purview of four different ministries; all count with representation on the National Biosafety Committee (which has not met 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, 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. Consequently, 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 gives the names and qualifications of the 24 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 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 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.

On March 5, 2017 the Egyptian Ministry of Environment submitted a new biosafety bill to the cabinet. The bill is currently being revised by the cabinet's Judicial Reform Committee prior to submission to the Parliament of Egypt for ratification. This committee revises all bills that the government elevates to the parliament; a number of other bills however are of higher priority to the government than biosafety. Chances are slim that the current bill will be enacted; the bill can linger with parliament for up to two years.

The draft biosafety law in its current form emphasizes the safe use and handling of genetically-engineered organisms and their products. It makes no distinction between imports or domestic production or exports prior to environmental release. Article 8 of the draft legislation indicates that the National Biosafety Council (not to be confused with the previous Biosafety Safety Committee established by Decree 85/1995) establishes guidelines and rules governing the import, export, and the release of genetically-engineered products to the environment (i.e., whether release will occur during the research and development phase or during field testing).

It is envisioned that the National Biosafety Council will issue import and export permits for the commercial use of genetically-engineered organisms and products. The council will work with the

Egyptian Organization for Standardization in order to establish a separate standard for genetically-engineered organisms and products. Article 14 of the draft biosafety law states that the data needed as far as authorizing imports will be determined when the executive annex of the law is finalized. At this moment there is no executive annex for this draft legislation.

Egypt relies on corn and soybean imports for its expanding poultry and aquaculture industries; both of these commodities are largely derived from biotechnology. Any disruption in the supply of these commodities will impact domestic food prices, as well as potentially employment and business investment. Egypt requires a functional biosafety framework that implements a transparent and clear policy. Without one, Egypt cannot move forward in the area of biotechnology.

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 majority of field crop varieties and vegetable varieties have been developed by the ARC research institutes. The Agricultural Genetic Engineering Research Institute represents the vehicle within the 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.
- 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 government 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 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 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 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.

The National Biosafety Committee: In 2014, Minister of Agriculture Dr. Adel El-Beltagy, a strong proponent of agricultural biotechnology, issued Ministerial Decree 1495 reestablishing the previous National Biosafety Committee. The committee is comprised of members from a number of Egyptian ministries, aiming to develop policies and procedures to govern the release and commercialization of genetically-engineered crops.

The National Biosafety Committee is meant to 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 obtain approval for their activities. There have been no committee meetings to date.

Other activities of 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: Since the complete suspension of planting and cultivation of GE crops in 2012, no National Biosafety Committee meeting has been held; no new approvals for greenhouse trials, field testing, or for commercial release have been granted. The commercialization of genetically-engineered yellow corn varieties (i.e., resistant to the European corn borer) occurred from calendar-years (CY) 2008 through 2012. During this time, 3,800 feddans (approximately 1,596 hectares) were planted with GE corn in the country's newly reclaimed areas. In March of 2012, Minister of Agriculture and Land

Reclamation Eng. Reda Ismail issued Decree 378; suspending the registration and commercial planting of GE crops in Egypt.

The Minister’s decision was prompted by an Egyptian television program that alleged GE corn causes cancer, increased spontaneous abortions, and liver and kidney failure in mice. Since the implementation of Decree 378, no genetically-engineered varieties have been approved for commercialization. Should the draft biosafety law be enacted, it will remain up to the NBC board to honor prior approvals. We believe that previous field trials/tests that were approved will be utilized as data sources, models, and for risk assessments.

c) STACKED or PYRAMIDED EVENT APPROVALS: There are no current stacked events used in any of the transgenic crops that were produced. For imports of food and feed derived from biotech varieties, the varieties with stacked events that are approved in the country-of-origin are accepted.

d) FIELD TESTING: There is currently no ongoing field testing in Egypt.

Permits Issued By the National Biosafety Committee for GE-Horticultural 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 National Biosafety Committee for GE-Field 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: 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 genetically-engineered crops and conventional crops.

g) LABELING: Egyptian law does not require that biotech crops or products with biotech content to have special labeling. Governmental authorities deal with biotech products as they deal with non-biotech products.

h) MONITORING AND TESTING: Currently no monitoring or testing of GE crops.

i) LOW LEVEL PRESENCE (LLP) 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 National Biosafety Committee 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, data from food and feed safety studies and evidence supporting a determination of low or negligible environmental risk. The applicant provides documents indicating approval of similar genetically-engineered products for release in their country-of-origin.
2. The application form is submitted to the National Biosafety Committee, which, after examination and approval, forwards it to the Seed Registration Committee (SRC) for their approval to proceed with field trials. The Seed Registration Committee from the CASP assigns a team of qualified inspectors drawn from relevant ARC units and/or private certified laboratories to supervise cultivation, ensure adherence to biosafety requirements, confirm the new phenotype, and evaluate agronomic performance.
3. After successful completion of the field trials and the submission of a report to the National Biosafety Committee, the committee 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 Seed Registration Committee.

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 intellectual property (IP) database authority, and plays a key role in technology transfer and intellectual property rights protection. The Egyptian Patent Office 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 the 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 provides these to specialists in order to develop their work and 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.

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. 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 Cartagena Protocol on Biosafety. Egypt is also a member of the World Intellectual 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: Campaigns by European environmental groups against the adoption of biotechnology, as well as the research, development, and commercialization of GE crops has created significant skepticism among Egyptians. There is public opposition to adopting genetically-engineered crops.

Anti-biotech campaigns are very active on social media. These not only advocate misconceptions, but often will lie about the health risks associated with the consumption of food products derived from biotechnology.

Communicating biotechnology to key Egyptian media organization, clarifying the safety of approved products of food and agricultural biotechnology, and helping the media to differentiate between sound science and the strongly-argued yet weakly-substantiated opinion of sectoral advocates that create unsubstantiated fear and apprehension is highly needed.

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.

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

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 genetically-engineered animals.

e) 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. The current draft Biosafety Law being revised by the cabinet's Judicial Reform Committee prior to submission to the parliament for ratification only refers to genetically modified organisms.

b) INNOVATIVE BIOTECHNOLOGIES: Not Applicable.

c) LABELING AND TRACEABILITY: Not Applicable.

d) INTELLECTUAL PROPERTY RIGHTS (IPR): Not Applicable. Egypt's patent office receives applications from various disciplines (including life sciences). Post is unaware of any genetic-engineering being conducted with animals.

e) INTERNATIONAL TREATIES and FORUMS: 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 Organization 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 F: 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. This is not specific to animal products.

c) MARKET STUDIES: Not applicable.