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REPORT OUTLINE

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Report Highlights:

Egypt was the first North African country to approve genetically engineered (GE) corn. However an aggressive media campaign led to a decree issued by a former Minister of Agriculture in March 2012 to suspend the planting and commercialization of the yellow corn variety Ajeeb-YG, *Bacillus thuringiensis (Bt.* So for more than two years now, the cultivation and commercialization of genetically engineered crops in Egypt has been on hold. Despite the relatively advanced research and development of useful seed varieties, agricultural biotechnology is often either misconceived or misunderstood. This lack of misunderstanding requires a sustainable effort in risk communication, public awareness and outreach. The ministerial decree of suspending seed variety registration, cultivation and commercialization of genetically engineered crops is still in effect but could be reversed in the near future given new Ministry of Agriculture and Land Reclamation (MALR) leadership.

SECTION I: EXECUTIVE SUMMARY

In Egypt, like any other arid, developing country, the agricultural sector faces daunting challenges exacerbated by climate change, water scarcity, desertification and low agricultural productivity. The rapid increase in population necessitates taking decisive steps to increase food production using available natural resources, research and development capabilities and implementation of appropriate research outcomes.

The strategy for agricultural development in Egypt for 2030 emphasizes the necessity to adopt a number of policies, programs and projects in both horizontal expansion (land reclamation) and vertical expansion (increasing the per-unit productivity of land, water, labor and capital). Productivity increases and cost decreases are crucial to agricultural growth in Egypt. Both require continued attention to the development of plant varieties that are particularly suited to the country's unique agro-ecology, production systems and land tenure situation. While conventional plant breeding was always one of Egypt's strengths, competitiveness in global agriculture necessitates the use of biotechnology as well.

The newly appointed Minister of Agriculture, Professor Adel Al Beltagy, is a key supporter of scientific and agricultural research and fully recognizes the potential benefits of agricultural biotechnology and how it can be used as a tool for crop improvement under Egyptian conditions.
Egypt is a large consumer of imported agricultural biotech commodities such as yellow corn for feed and soybeans for food and feed. Government of Egypt (GoE) policy states that as long as the imported commodity/product is approved and consumed in the countries of origin, it is a safe product to import and consume in the Egyptian market. Mr. Reda Ismail, former Minister of Agriculture, issued Decree #378 on March 8 2012 to suspend the registration of genetically engineered yellow corn variety Ajeeb-YG for planting and cultivation in Egypt, pending a risk assessment by the Ministries of Health and Environment.

Both ministries are represented on the National Biosafety Committee (NBC) which approved the marketing of Ajeeb-YG after six years of greenhouse and small-scale and large-scale field trials.

The Minister’s decision was influenced by a program carried on Egyptian channel that aired over a 3-day period in March 2012 that alleged that the Ajeeb-YG yellow corn caused cancer, abortion, and liver

and kidney failure. The Ajeeb variety incorporates the MON810 event which is approved by the European Food Safety Agency, pertinent US Government agencies, Canada's food safety agency, as well as those of Japan, Australia and a number of other countries. Egypt had planted approximately 3,800 acres of biotech corn. With the Ajeeb-YG variety, farmers were able to achieve yields of 50 to 150 percent higher than using conventional hybrid corn.

Since 1995, regulation of agriculture biotechnology has been under the auspices of the NBC chaired by the MALR Minister, with representatives of the Ministry of Environment, Ministry of Health, Ministry of Scientific Research and other relevant ministries and institutions. However, the Biosafety law, at least in its current draft produced by the Ministry of Environment, would likely prevent agricultural biotechnology product development and marketing in Egypt and could pose a threat to commodity exports to Egypt.

During the past two years, there have been no approvals for greenhouse or field trials and all marketing of new biotech seed varieties has been shelved even though there genetically engineered seed types produced or enhanced by Egyptian scientists and researchers in local research institutions that are ready for commercial release.

For Egypt to move forward in the area of biotechnology, an updated and sound biosafety law and a functional biosafety system implementing a transparent and clear policy is needed. The obvious challenge is to build an effective partnership between ministries that have historically not trusted each other. However, Egyptian scientists and stakeholders hope that the new administration will have a more favorable, science-based approach to biotechnology development in the country.

The case of *Bt* corn in Egypt highlights the importance of building capacity among scientists to better employ various risk communication strategies and better communicate with policy makers, media, and the public. Post is now working to revive the momentum and re-engage stakeholders to support biotechnology communication to demystify biotech, minimize misconception, demonstrate benefits of biotech, provide accurate and balanced information about biotech and create opportunities for intellectual discourse about biotechnology.

U.S. government programs such as the Cochran Fellowship Program and Borlaug Scientific Exchange are used to expand Egyptian scientists and regulators' knowledge of biotechnology and set the stage for a wider acceptance among regulators.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER 1: PLANT BIOTECHNOLOGY

A: PRODUCTION AND TRADE

a) PRODUCT DEVELOPMENT:

Research, development, and capacity building in modern biotechnology continue in Egypt, despite the suspension of planting GE crops in the country. Biotechnology was identified by the government as worthy of special support in the early 1980s, but it was not until a decade later that concrete measures to initiate such support were undertaken. In 1991, a focal point for genetic engineering and biotechnology was established in the Academy of Scientific Research and Technology, a part of the Ministry of Scientific Research. A national strategy for genetic engineering and biotechnology was developed by local experts and policy makers in 1995.
Agricultural biotechnology research capacity has evolved and expanded through a network of universities and national research institutions that included the MALR's Agriculture Research Center (ARC), the National Research Center (NRC) of the Ministry of Scientific Research, genetic engineering and biotechnology centers in universities, of which the most renowned is the Genetic Engineering Research Center (GERC) of the Faculty of Agriculture at Cairo University.

1-The National Research Center (NRC)

This is a multidisciplinary research center that is engaged in some agricultural biotechnology research activities through its agricultural and biological division. The current biotechnology research activities at NRC are focused on biotechnology-based production of pharmaceutically bioactive substances and molecules, transgenic plants resistant to biotic and abiotic stresses and mapping of disease resistance genes. The future plan is to focus on bioethanol and biofuel production, improvement of neglected drought tolerant crops (sorghum, flax and date palm) and effective and better utilization of native valuable genetic resources. Research on producing biological pesticides for pest control to reduce environmental pollution using Egyptian isolates of the bacteria *Bacillus thuringiensis* is also being conducted.

2-The Agricultural Research Center (ARC)

Within the Agricultural Research Center (ARC), the Agricultural Genetic Engineering Research Institute (AGERI) is Egypt's premier biotechnology research organization with a mandate to promote the transfer and application of this technology. AGERI researchers are using transgenic techniques to introduce a range of traits into maize, wheat, cotton, tomato and potato.
In 1992 a cooperative research agreement was reached between AGERI and ABSP (Agricultural Biotechnology for Sustainable Productivity Project) to develop Egypt's agricultural biotechnology research system. Teams of scientists from both Egypt and the United States were established to address specific commodity constraints and policy issues such as biosafety and intellectual property rights, and management and networking within the project.

In collaboration with other institutes within ARC such as the Plant Protection Research Institute (PPRI), Field Crops Research Institute (FCRI), Cotton Research Institute (CRI), Horticulture Research Institute

(HRI), other National Research Centers and Universities, AGERI is conducting research on the following crops:

I. Field Crops

Wheat

Drought stress is a serious problem limiting crop production. Scientists in AGERI have produced drought -tolerant wheat by transferring the barley HVA1 gene into Egyptian bread wheat. During 2009 NBC granted approval for the field testing 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.
Transgenic wheat lines encoding the mannitol-1-phosphate dehydrogenase gene isolated from the bacteria *E.coli* were also produced in AGERI. Salt tolerant transgenic wheat lines were tested under bio-containment greenhouse conditions and small-scale field trials were also conducted by AGERI. Production of wheat resistant to fungal diseases including stem, leaf and yellow rust and powdery mildew also took place in AGERI.

Corn

During the past three years corn research in AGERI has focused on Abiotic stress tolerance. This includes genetic transformation of the Nicotiana Protein Kinase (NPK1) gene which confers osmotic tolerance, and transformation of the gene for salt tolerance, BI-GST. Moreover, work has been done on transformation of the dehydrin gene for the production of Egyptian inbred corn lines with enhanced tolerance to abiotic and environmental stress conditions such as salinity.

Cotton

AGERI, CRI and PPRI have partnered with Monsanto in a project to cross Egyptian long staple cotton varieties with Monsanto's Bollgard II to produce an insect–resistant long staple genetically engineered cotton strain. The new variety would confer resistance to cotton bollworms, pink bollworm and spiny bollworm as well as the cotton leaf worm by expressing the Cry1AC and Cry2Ab B*t* genes which could save the cotton industry millions of dollars.

After the approval by the NBC for field trials, research and development of new long staple cotton varieties, namely Giza 86, 89, 90, 91, 96, started in May 2007 in the Delta and middle Egypt. The new varieties have been cultivated under the supervision of AGERI, CRI and PPRI. The areas planted were two and six acres, respectively.
In 2009, the GE cotton varieties Giza 80,90,85,89 were also planted at AGERI and the bio-containment and screening processes were initiated to ensure that the GE cotton plants contain only the gene of interest. In 2010 CRI requested from the NBC authorization to plant the GE cotton varieties for the production of basic seed and to assess crop yields. NBC granted the approval and the crop was planted on a trial basis.

During the past three years, CRI focused its efforts on seed multiplication in ARC research stations in Giza, middle and Upper Egypt and the Delta while PPRI conducted further research using transgenic

seeds produced by CRI to ensure the efficacy of *Bt* transgenic Egyptian varieties expressing both genes against the insects in various locations.
An assessment of the effects of Egyptian transgenic cotton on a non-target organism was also conducted in 2013. The study concluded that the transgenic cotton varieties do not have any unexpected toxic effects on natural enemy species of cotton pests. Egyptian B*t* cotton varieties are still waiting approval of the NBC for commercialization.

II. Horticultural Crops

Cucurbits

Under the umbrella of the Agricultural Biotechnology Sustainable Productivity project (ABSP-1), researchers at AGERI and the Horticulture Research Institute collaborated to introduce the coat protein gene of the Zucchini Yellow Mosaic Virus (ZYMV) into the squash variety Iskandarany and the melon variety Ananas El-Dokki. Field testing and selection of ZYMV resistant lines was carried out. Bio-containment greenhouse and field evaluation results were submitted to the NBC for commercialization approval between 2005 and 2010.

Strawberry

Developing strawberry plants resistant to viruses transmitted by the white fly using siRNA strategy of strawberry plant resistance to viruses. This research is still in progress. Research also involves the improvement of diagnostic tools for the certification of virus-free strawberry materials.

Tomato

Tomato yellow leaf curl virus (TYLCV) has spread to all of the main vegetable-producing regions of Egypt where it has become the limiting factor for tomato production during the summer and fall, causing up to 100% yield loss.
TYLCV-resistant tomato varieties were engineered through collaboration between Cairo University, AGERI and the Donald Danforth Plant Science Center using the siRNA strategy to block the viral life cycle in the plant and prevent it from spreading. The produced plants acquired virus resistance and subsequently the yield increased. The developed plants will enable the economic production of high quality tomatoes while reducing the need for continuous/increasing dependence on environmentally harmful and increasingly less effective chemical crop protection methods. The tomato varieties are still waiting the approval of the NBC for field trials.

Potato

Development of potatoes resistant to different viruses predominant in Egypt is probably the most effective means to achieve sustainable potato production. The coat protein and replicas gene strategies have been adopted to produce resistance to potato virus Y and for potato leaf roll virus (PLRV). The transgenic lines are in the field-testing stage. The development of potatoes resistant to infestation by the potato tuber moth (PTM) was the result of collaborative research between AGERI and Michigan State University (MSU).
Tubers have been field-tested for seven seasons in the International Potato Center (CIP) regional office in Egypt. Fourteen years after the initiative began, risk assessment trials took place in 2010. AGERI

officials met with stakeholders, farmers, exporters and the media to show them that Egyptian potato exports to Europe will not be affected. Results were submitted to the NBC for approval.

Sweet Potato

Sweet potato is grown in the Delta governorates of Beheira, Kafr El-Sheikh and Menoufia. The area of sweet potato under production has reached 28,000 acres with an average yield 12 tons/acre. The sweet potato feathery mottle virus (SPFMV) is a major constraint to increasing sweet potato production. The focus in AGERI was to improve the deteriorated local variety (Abees) through the production of virus-free stock plants and to develop an efficient system of propagation that can prevent spread of the viral disease. The work also included the development of efficient quantitative system for viral detection in sweet potato fields and sequence analysis of coat protein gene and 3` non coding region of sweet potato feathery mottle virus (SPFMV) isolated from Egypt cultivars.

3-Universities

Biotechnology research activities in the universities became well established during the past decade. The most famous of these centers is the Genetic Engineering Research Center (GERC) of the Faculty of Agriculture at Cairo University. In the GERC several successful research projects were carried out in collaboration with other national and international research institutions. The projects undertaken included the production of drought-tolerant Canola plants, improvement of salt tolerance in tomato, production of transgenic rice resistant to rice blast and stem borers and improving the salt tolerance of wheat.

The Institute of Biotechnology and Genetic Engineering at the University of Sadat City conducts basic research in plant biotechnology with a special emphasis on horticultural crops. In 1993, Al-Azhar University established a Regional Center for Mycology and Biotechnology to develop applications for fungi and biotechnology. Currently it carries out research in different subjects including biosynthesis of new forms of antimicrobial agents, metabolic regulations of mycotoxin production, fungi and allergy and fungal biotechnology, and biodegradations and bio-transformations and enzymes

b) COMMERCIAL PRODUCTION:

Prior to the NBC and seed registration committee (SRC) decisions to approve the commercialization of the Ajeeb-YG corn variety, a series of field trials were conducted during the period of 2002-2007. In 2008 Ajeeb-YG was the first GE crop to be commercialized in the country and the Egyptian government allowed the importation of about 28 tons of transgenic corn seed from South Africa into the Egyptian market. Egypt was the first North African country to permit planting of a biotech crop. The yellow corn variety Ajeeb-YG, is a cross between MON 810 and an Egyptian maize variety with resistance to three corn borer pests, and was developed by Monsanto scientists in South Africa — currently the only African country planting GE crops commercially

In order to be in compliance with decrees and regulations that govern the biosafety framework in Egypt, an Egyptian company, Fine Seeds, was allowed to plant all the seeds in the newly reclaimed areas for the purpose of use as silage. In June 2010 the NBC allowed the same local company to conduct trials with other GE varieties with the same gene. NBC also allowed the company to start the process of registering two corn varieties with SRC.

All of the plantings and field trials were monitored by the NBC. Since Ministerial Decree #378 on March 8, 2012 suspending the registration of Ajeeb-YG for planting and cultivation in Egypt, the NBC has not held a meeting and progress on the approval of GE crops for commercialization has been at a standstill.

c) EXPORT:

With no commercial production of GE crops, Egypt does not export GE crops 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. The government maintains a general import policy of allowing imports of agricultural commodities as long as the imported product is approved and is also consumed in the countries of origin.
For genetically engineered seeds or GE product imports, the applicant must first obtain a permit for importation of the initial seed material from the Supreme Committee for Food Safety (SCFS) under the Ministry of Health. The permit is then presented to the NBC and SRC, after which the seed is imported into the country. From this point forward, the remaining steps in the approval are exactly the same as for genetically engineered organisms (GEOs) developed within Egypt.

e) FOOD AID RECIPIENT COUNTRIES:

Not Applicable

PART B: POLICY

a) REGULATORY FRAMEWORK:

I. Responsible Ministries and their roles in Biotech food policy:

Ministry of Agriculture (MALR):

The Ministry of Agriculture is the main authority responsible for food cultivation and GE crops issues. Within the ministry, the following agencies play a key role in Egypt's seed sector:

1-The Agricultural Research Center (ARC):

ARC has 17 research institutes and support organizations. It has the primary responsibility for crop improvement research, cultivar development and testing throughout the country. 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 agriculture biotechnology.

2- The Central Administration for Seed Testing and Certification (CASC):

CASC, established in 1995, is the agency responsible for seed quality control, seed legislation and policy enforcement. CASC reviews all relevant legislation, updates and prepares rules required to control all seed activities, and works to integrate and harmonize the seed legislative framework. CASC is the designated seed certification authority and performs lab and field testing for certified and uncertified seed.

3- The Central Administration for Seed Production (CASP):

CASP administers and advises ARC on requirements for foundation and registered classes of seeds and plants. CASP is responsible for certified seed multiplication trials at all stages from planting to harvest.

4- Food Safety and control

There are three bodies responsible for food safety and control:

1. The Reference Laboratory for Safety Analysis of Food of Animal Origin (RLSAFAO)
2. The Regional Laboratory for Food and Feed (GLFF);
3. AGERI

To help in achieving this goal AGERI, the third organization playing a role, addresses the public to explain the real benefit of the use of biotechnology applications.

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.
The ministry has the following committees and organizations:

- The Supreme Committee for Food Safety ensures the safety of food production and consumption and controls food import permitting.
- The National Organization for Drug Control and Research oversees pharmaceutical research and controls distribution.
- The Food Safety and Control General Directorate (FSCGD)
- The Central Public Health Laboratories (CPHL)
- The National Nutrition Institute (NNI) Egyptian Standardization organization (ESO)

Ministry of Trade and Industry (MTI):

The ministry executes its activities through the following organizations:

- 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 in the environment. MOE and MALR compete over jurisdiction of biosafety regulatory issues. The NBC is currently housed within MALR, but MOE, under funding from a UNEP-GEF project passed a draft biosafety law in 2007 in an attempt to set up a parallel regulatory framework that would bring the biosafety portfolio under its jurisdiction which has a more EU risk-based approach towards GE crop adoption and commercialization.
Since the MOE is the focal point for the Cartagena Protocol, it was eligible to receive from the Global Environment Facility (GEF) $1 million to conduct activities in Egypt.
There are 4 components under the current GEF project to implement the Cartagena Protocol. These are:

- Regulatory framework
- Handling of requests, performing risk assessments, decision making and exchanging information
- System for follow up and monitoring
- Outreach, public awareness and participation

In 2013 The Egyptian Environmental Affairs Agency (EEAA) of MOE established a biosafety unit under the biodiversity component. The mandate of the new biosafety unit includes:

1. Ensuring adequate level of protection for safe transfer, handling, and use of living modified organisms that may have an adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health and specifically focusing on trans boundary movements and imports and exports of genetically modified organisms.
2. Establishing a database of existing regulatory structures and legislation pertaining to the import and export of GEOs, environmental protection, animal and human health safety, and biotechnology research existing capacity on the national level.

II. The National Biosafety Committee (NBC):

Following its obligations under article 8g of the Convention on Biological Diversity, Egypt was among the first countries to establish regulations for biosafety in 1995. Since 1995, these regulations have been regularly updated and refined, to take into account new developments, such as the commitments stemming from the Cartagena Protocol on Biosafety. Over the years, the domestic regulatory framework for biosafety in Egypt has developed as follows:

Ministerial Decrees under the MALR

- 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 the 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 in a laboratory, greenhouse or open field, regardless of the cultivated areas.
- Decree #1648 (1998), established a protocol for the registration of genetically modified

seed. Consequently, marketing of GE seed variety requires approval by the Seed Registration Committee, which seeks the advice of the NBC.

- Decree #19 (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 subcommittees on special topics.
- With Decree 767 (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.
- These decrees were based on several laws, among others the Law on Agriculture, and consequently the relevant provisions of those laws apply, such as provisions relevant for enforcement, apply to these decrees.

Ministerial Decree under the MOH

Decree #242 (1997) requiring approval from the SCFS for the importation of GEOs intended for food.

Roles and Responsibilities of NBC:

An Egyptian National Biosafety Committee was established in 1995, comprising policy makers and designers, scientific experts in agriculture, health, industry and environment from government and academic research institutes as well as experts from the private sector. The NBC must hold 4 meetings each year to review all the documents submitted.
The purpose of the National Biosafety Committee is to establish policies and procedures to govern the use of modern biotechnology in the country. This includes publishing the National Biosafety Committee guidelines (NBC Guidelines) to be followed at the national level. The committee would also provide technical advice to the regulatory authorities and the institutions responsible for the development of biotechnology in the country.

Activities of NBC:

a) Formulate, implement and update safety codes.
b) Risk assessment and license issuance.
c) Coordination with international and national organizations.
d) Provide training and technical advice.
e) Report at least annually to governmental authorities.

The NBC requested that all institutions conducting recombinant DNA research to establish le an Institutional Biosafety Committee. The NBC specified that all institutional biosafety committees in institutes and universities across Egypt be responsible for the conduct of safe handling procedures governing the work in labs as well as in greenhouse containment facilities**.**

The Institutional Biosafety Committees are responsible for ensuring that the r-DNA research is carried out in full conformity with the provisions of the NBC Guidelines. Additional procedures as deemed necessary to govern the institution research may also be implemented.

b) APPROVALS:

Since the complete suspension of GE crops planting and cultivation in 2012, not a single NBC meeting has been held; hence, no new approvals for either greenhouse or field testing or commercial release.

Application process for imported GE Material

1. Notification for transboundary movement of GE crops or animal feed having a biotech. content would be sent to the country Focal Point (located at MOE) before shipping the GE to Egypt (two the members of the NBC are from the MOE).

2. The applicant request along with all the attached documents should be submitted to the NBC office before the import permit issuance (which is done through the Supreme Committee of Food Safety-MOH). Also, one member of the NBC is the head of this committee.

3. The NBC-secretariat will check all documents and record them into a NBC database and forward copies of the applications to members of the Agricultural Biosafety Sub-committee (ABSC). These copies would be sent ahead of time to allow enough time for ABSC members reviewing the files.

4. The ABSC would be the one to call upon NBC meetings to check applications and requests.

5. Members of the NBC would assign different application (GE seeds or Animal feed) to different agencies or laboratories for trial/experiment preparation.

The path for imported varieties then follows the procedure for varieties produced within Egypt, and the process is as follows:
1. The applicant completes a permit application form providing details of the genetic material introduced, the process used for inserting it, 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 for their preliminary approval to proceed with standard field trials conducted at several locations. The SRC 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 Seed Registration Committee 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.

Permits Issued By the NBC for Horticultural GE Crops during 2006- 2010

	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 during 2006- 2010

	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

c) FIELD TESTING:

Due to the lack of a national law governing the release of GE plants into the Egyptian market, the relevant ministerial decrees will be followed as a comprehensive regulatory regime, which covers the use, transfer, release, and commercialization of GE plants into the environment. The Agricultural Competent Authority (ACA)-NBC will have a monitoring role over applications concerning cross-boundary movement of genetically modified plants and animal feed (containing ingredients produced through biotechnology).

d) STACKED EVENT APPROVALS:

There are no current stacked events used in any of the transgenic crops that were produced. If there are applications for stacked event varieties in the future, the NBC will take a case by case approach on whether to treat the event as novel and requires their approval separate from the approval of each individual event in the stack.

e) ADDITIANAL REQUIREMENTS:

CASC is responsible for handling all issues concerning seed registration, certification and field testing while CASP is responsible for certified seed multiplication and production.

f) COEXISTENCE:

Egypt does not have a policy on coexistence between GE crops and conventional crops. Once GE crops are released for commercialization, there will likely be management practices in place for coexistence with non-GE crops.

g) LABELING:

No decisions on the labeling of GEO-based food products have been made. Egyptian law does not require that biotech crops or products with biotech content have special approval or labeling, and governmental authorities deal with biotech products as they deal with non-biotech products. In addition, there is no approval needed for importing biotech products. Egypt stipulates specific requirements for labeling for imports of food products in general, but there is no special labeling requirement for biotech

packaged or non-packaged products.
The draft biosafety law of 2007 would require labeling for GEOs' products. The Egyptian Standardization Organization (ESO) will be the authority to develop labeling for the GE crop that complies with Cartagena Protocol.

US agricultural exports to Egypt currently face no import restrictions as a result of agricultural biotechnology policy. However, this could change if the Ministry of Environment continues its negative and often confusing rhetoric about the "potential risks" of agricultural biotechnology and the need for Egypt to follow European regulations and standards in this regard. MOE remains a strong advocate of the European regulatory regime but there is a sense of late that there are at least a few, more objective voices within the MOE who would advocate for a more balanced biosafety law that promotes the technology in a positive and science-based manner.

h) TRADE BARRIERS:

Egypt maintains an open market for agricultural commodities and products derived through biotechnology. However, Egypt's current draft biosafety law, if passed by the next parliament to be elected, could present a trade barrier which might potentially affect exports from Argentina, Brazil, Canada and the U.S., among others, to Egypt. While Egypt has established regulations on GE plants, they are at critical point on whether to move forward with the current draft biosafety law or to pursue another round of discussions among stakeholders.
The U.S. in this regard can always provide technical assistance. The adoption of a functional and transparent biosafety system and a comprehensive biotechnology communication strategy to build a strong public awareness campaign would limit opportunities to impact trade between the US and Egypt using the "Potential Risk" card.

i) INTELLECTUAL PROPERTY RIGHTS (IPR):

1-Ministry of Scientific Research

The Egyptian Patent Office (EPO)

The EPO was established in 1951 by Law 132 of that year and has been associated with the Academy of Scientific Research and Technology since 1971. A 2002 law, #82, was published to incorporate coverage of IP issues in life sciences.
The EPO is the sole national office for registering and issuing patents and 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.

Goals of the EPO According to Law

- Register patent applications for the local & foreign inventions.
- Grant and issue patents to protect the ownership rights of the Egyptian & foreign inventors.
- Collect the 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 to participate in exhibitions and compete for recognition and awards.
- Publish (monthly) the official Patent Gazette which includes filed, accepted applications, granted patents and terminated applications.

2-Ministry of Agriculture and Land Reclamation MALR

Agricultural Research Center (ARC)

Technology Management and Commercialization Office (TMCO)

The TMCO was established by Ministerial Decree 3075/2001 and run under direct jurisdiction of the ARC President. The Office runs its activities according to an "Internal Policy for Technology Management and Commercialization (IP Policy)" issued by a Ministerial Decree 1402/2002. The IP Policy specifies the obligations and the responsibilities of the ARC, ARC-Staff and end-user in regards 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:

- 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 royalties' distribution.

- 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.

Agricultural Genetic Engineering Research Institute (AGERI)

AGERI has established an Intellectual Property and Technology Transfer Office. This office serves the scientific community in AGERI and other institutions in ARC.

The office has made significant progress in IPRs' policy and management. It has developed IPR policy for AGERI. The office is also very active in creating awareness and education of ARC scientists in various aspects of IPRs as they relate to agriculture. Moreover, it will play a key role in the development of Material Transfer Agreements (MTAs) and licensing of technologies generated in AGERI and ARC. At the same time, it develops educational materials on IPR management for scientists in Arabic and English languages. Finally, it will serve as a link with the private and public sector in Egypt and abroad.

j) CARTAGENA PROTOCOL RATIFICATION:

Egypt ratified the Cartagena Protocol on Biosafety (CPB) in 2003. 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 of the CPB and shares data with the Biosafety Clearing House, 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.

k) INTERNATIONAL TREATIES/FORA:

Egypt is a member of several international organizations that deal with plant protection and plant health, including the International Plant Protection Convention (IPPC), the Codex Alimentarius (Codex), and the aforementioned CPB. Egypt is also a member of WIPO and signed the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement.

l) RELATED ISSUES:

Egypt adopted the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the CPB in 2013. It gives Egypt flexibility to implement legislative, administrative or judicial rules and procedures relevant to liability and redress.

m) MONITORING AND TESTING:

NBC is responsible for approving imports of GE products, while the Central Administration of Plant Quarantine (CAPQ) monitor and test agricultural commodity and food product imports at ports of entry.

N) LOW LEVEL PRESENCE POLICY:

Egypt has no low-level presence policy.

PART C: MARKETING

a) MARKET ACCEPTANCE:

The current inefficient biosafety system contributed indirectly to a lack of trust between scientists and the media creating misconceptions about biotechnology. If Egypt adopts a more restrictive approach to biotechnology via regulations and legislation, then it will forego and/or pay more for agricultural commodities and food over time. As in other countries around the world, Egyptians do not concern themselves much with the origin of food products or how processing is handled for example. Access to food and pricing are what count.

b) PUBLIC /PRIVATE OPINIONS:

The fear of biotechnology by the public is mainly due to successful anti-biotech campaigns of Greenpeace supported by members of a small organic industry. Some segment of the Egyptian public commonly may believe there are health risks associated with the consumption of food products which have biotech ingredients. Furthermore, one-sided reporting by the media on possible risks associated with planting GE seed varieties and cultivation affects the perception of the public about the technology.

On the other hand, the Egyptian Biotechnology Information Center (EBIC) within the Faculty of Agriculture, Cairo University, plays an important role in raising public awareness about biotechnology and genetic engineering applications and works as a link between scientists and the public by simplifying scientific information to be understandable for all levels of the society, as well as clarifying both benefits and potential risks through reasonable and transparent fora.

c) MARKETNG STUDIES:

Post is unaware of any recent marketing studies that have evaluated Egyptian public attitudes towards products derived from agricultural biotechnology. One market research study conducted by Promar International, Morgan & Myers, & Roper Media and Public Affairs in August 2004 provided a survey about public attitudes towards biotechnology.

Part D: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES:

Over the last decade FAS-Cairo has conducted numerous training programs for policy-makers, academics and journalist training programs. During July 2012 FAS organized a visit of a prominent US expert on legal matters related to biosafety legislation and regulatory frameworks. The purpose of the visit was to provide support to MALR and MOE and other stakeholders as they revised the draft biosafety law and annex in anticipation of its presentation to Parliament for passage and adoption during that time.

The visit involved the following:

- Day 1 – Initial meetings with MOE staff and interested stakeholders from other government offices and the private sector;

- Day 2 and 3 – Work with MOE and MALR staff to educate them about international biosafety obligations, relevant developments on the continent on this topic, and to review the documents (draft law and annex) and provide specific comments on the language and regulatory structure;

- Day 4 – Workshop involving Parliamentarians, government officials and interested stakeholders addressing the need for a biosafety law in Egypt and made two presentations about the importance of biosafety legislation to Egypt and the situation in Africa; and

- Day 5 – Meetings with MOE, USAID, and NBC about the results of the previous four days and the steps needed to continue the process in the next few months.

In April 2014, FAS-Cairo hosted a communication workshop on agricultural biotechnology and an invitational media workshop on communicating food science, and a stakeholder outreach program in Cairo, Egypt. The workshops and outreach program were developed by the International Food Information Council and conducted in collaboration with the Egyptian Biotechnology Information Center (EBIC) in response to the need for diverse risk communication strategies to be implemented to raise public awareness about biotechnology derived products.

Both workshops helped Egyptian officials, scientists and media representatives who are actively engaged in biotechnology, agriculture and food production to better understand and communicate the risks and benefits of agricultural biotechnology.

Key topics presented and discussed at the workshop included:

- Current status of agricultural biotechnology in the USA and key world regions
- Measuring and developing public understanding
- Misconceptions, barriers and opportunities confronting biotechnology in Egypt
- Insights from farmer and practitioner experience in Argentina and India
- The value of consumer attitudinal research
- Using "Food Biotechnology: A Communicator's Guide to Improving Public Understanding"
- Working with conventional and social media
- Involving the public and the private sector locally and globally
- Optimizing access to credible on-line resources
- How to optimize biotechnology communications in Egypt

The invitational media workshop on communicating food science responded to the interests and concerns of key Egyptian media representatives, 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.

Key topics presented and discussed included:

- The challenge of communicating science through the media
- Interpreting scientific studies and food safety evaluations
- Differentiating fact from fiction, informed advice and advocacy
- Responding to the interests and concerns of the public
- The value of consumer attitudinal research
- Guidelines for communicating emerging science on food safety nutrition and health

b) STRATEGIES AND NEEDS:

Egypt needs a public dialogue on the benefits and risks of agricultural biotechnology. Key to a productive dialogue is the availability and circulation of credible studies on the benefits and risks of the technology. A lack of familiarity with the topic also hinders the ability of the media to report on the topic accurately and distribute credible information. The lack of reliable information fueled by activism and exaggerated and misrepresentative media coverage contributed, in part, to elevated, but unfounded public concern about biotechnology, which, in turn, can led to political decisions in 2012 to suspend the approval process for GE crops. Egypt has centers of excellence conducting research in agricultural biotechnology, but they have been reluctant to speak publicly.

Modern communication, such as social media, has proliferated information about agricultural biotechnology; but too often disseminates inaccurate information. A solid and sustained communications drive by scientists and stakeholders – working with and through the media – is needed to build public understanding of agricultural biotechnology, public confidence, and a political climate that would allow the resumption of product development and commercialization of GE crops.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

Part E: PRODUCTION AND TRADE

a) BIOTECHNOLOGY PRODUCT DEVELOPMENT:

No Genetically engineered animals are under development in Egypt. However, ongoing biotechnology activities for enhancing livestock productivity 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.

The aforementioned institutes are within the ARC.

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

c) BIOTECHNOLOGY EXPORTS:
Not applicable.

d) BIOTECHNOLOGY IMPORTS:
Not applicable.

PART F: POLICY

a) REGULATION:

Institutional biosafety committees are effective but on the national level there is almost no policy with respect to animal biotechnology

b) LABELLING AND TRACEABILITY:

Not Applicable

c) TRADE BARRIERS:

Not Applicable

d) INTELLECTUAL PROPERTY RIGHTS (IPR):

Post is unaware of any IPR problems in Egypt as the cultivation of GE Crops is presently suspended.

e) INTERNATIONAL TREATIES /FORA:

Egypt is a member of several international organizations dealing with plant protection and plant health like the European and Mediterranean Plant Protection Organization (EPPO), the Food and Agriculture Organization (FAO) International Plant Protection Convention (IPPC), and Codex. Egypt follows OIE standards and protocols regarding importation of live animals and beef products. Egypt is not actively arguing against animal biotechnology.

PART G: MARKETING

a) MARKET ACCEPTANCE:

Not applicable.

b) PUBLIC/PRIVATE OPINIONS:

Egyptian public opinion is skeptical of benefits from new agricultural technologies, in general.

c) MARKET STUDIES:

Not applicable.

PART H: CAPACITY BUILDING AND OUTREACH

a) ACTIVITIES:

None

b) STRATEGIES AND NEEDS:

As with plant biotechnology, Egypt needs a strong, functioning biosafety regime that can address public concerns through an effective dialogue with the media and the public on the benefits and risks if any of biotechnology research in the animal sector.