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Report Highlights:
As of July 2015, Israel does not have a policy that restricts the use of imported biotech commodities or derivative products. Existing regulations do not permit local commercial production of biotech crops in Israel but allows their growth for research purposes. Israeli regulations also allow biotech products to be imported, sold, and used in the production of food and pharmaceuticals in Israel. In October, 2013 new draft regulations announced by Israel's Ministry of Health called "Public Health Regulations (Food) (Novel foods) 5773 - 2013" (G/TBT/N/ISR/710) were notified to the WTO, with the US, Canada and other countries submitting comments. The draft regulation has not been approved by the Israeli Government; FAS/Tel Aviv expects that it will be approved in 2016. Once approved, the labeling regulation will come into effect one year after the publication in Israel's Official Gazette; however, imported biotech products must be noted on the import permit once the regulation is published in the Gazette.

Section I. Executive Summary:

As of June 2015, Israel does not have a policy that restricts the use of imported biotech commodities or derivative products. Existing regulations do not permit local commercial production of biotech crops in Israel but allows their growth for research purposes. Israeli regulations also allow biotech products to be imported, sold, and used in the production of food and pharmaceuticals in Israel. Israel's religious kashrut authority has determined that the use of biotech ingredients in food does not affect its kosher status as these ingredients are used in "microscopic" proportions.

In October, 2013 new draft regulations announced by Israel's Ministry of Health called "Public Health Regulations (Food) (Novel foods) 5773 - 2013" (G/TBT/N/ISR/710) were notified to the WTO, with the US, Canada and other countries submitting comments. The scope of the definition "novel food" is limited to food for human consumption, and must meet the following requirements:

- Novel foods must go through a risk assessment process before being approved.
- Prohibition of the manufacture, importation, storage or sale of a novel food unless it is registered in the official list of permitted novel foods.
- Labeling of genetically modified pre-packaged food, fruits and vegetables

Products are exempt from labelling when the product containing a biotech ingredient:

1. Does not contain DNA and protein or
2. Less than 0.9% of the product is comprised of ingredients derived from a biotech crop.

The draft regulation has not been approved by the Israeli Government; FAS/Tel Aviv expects that it will be approved in 2016. Once approved, the labeling regulation will come into effect one year after the publication in Israel's Official Gazette; however, imported biotech products must be noted on the import permit once the regulation is published in the Gazette.

While Israeli scientists usually are supportive of biotechnology, environmental activists have expressed concerns regarding their use.

Section II. Author Defined:

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

A) Product Development: Genetic engineering is permitted in Israel for research purposes, subject to conditions established by law. Israel is considered an international center for genetic engineering research, focusing on improving plant resistance to pests, disease, and herbicides. Research is conducted by Israeli universities, government research institutions and the private sector. Israeli seed regulations of 2005 stipulate the requirements for conducting biotechnology research in Israel, approved by the National Committee for Transgenic Plants.

Rosetta Green, an Israeli agro-biotechnology company based in Rehovot, Israel, has modified plants so that these are able to withstand prolonged periods of severe drought, as well as high salinity. The company aims to develop new plant varieties resistant to harsh conditions, while maintaining high yields. It experimented on genetically modified tobacco plants, irrigating them with seawater instead of freshwater, which successfully grew under these conditions. The company's CEO stated: "This experiment is another step in the company's progress towards production of improved plants that will provide farmers with excellent yields even in drought conditions, and allow the growth of crops in wide areas that are currently unsuitable due to soil salinity and weather conditions." As to the pricing of their crops, the company explains that their business model relies on licensing their technology to large seed companies who will be responsible for their commercialization.

Israel's Evogene company is applying biotechnology to improve crop quality and productivity. Through its PointHit platform, the biotech firm is using big data to analyze molecules in weeds and identify key plant macro-molecules responsible for the essential biological processes in weeds. By targeting those processes, Evogene, or the companies that license its platform, will develop more effective herbicides.

The cutting-edge technology has caught Monsanto's eye, the world's leading biotech company, as it is now a major investor in Evogene. In Dec 2013, Evogene held an IPO on the New York Stock Exchange, raising $74 million with a valuation of $365 million, followed by an additional $10.6 million from its book runners, bringing its total money raised to over $84 million.

B) Commercial Production: Currently, commercial production of biotech crops, including the use of biotechnology for seed production, is not allowed in Israel. However, this policy is expected to change in the next two-four years as the Israeli Ministry of Agriculture is currently discussing this issue, and the Israeli Plant and Protection Services (PPIS) supports the commercial production of biotech crops in Israel. The pressure to allow the domestic production of biotech plants and seeds is coming from the private industry.

C) Exports: Due to the fact that the local industry uses imported raw materials that may include biotech components, it is likely that a fraction of Israeli food products exported to the U.S. or other countries

contain some biotech ingredients. Exports of Israeli food products to the EU, which contain more than 0.9 percent of biotech components, must be labeled according to EU biotech regulations.

D) Imports: Most of the soybeans and corn imported into Israel are from biotech varieties. In 2014, 290,000 tons of soybeans were imported into Israel, of which 96,000 tons were U.S origin and the rest from Brazil, Argentina and Paraguay. It is estimated that upwards of 90 percent of the soybeans come from biotech varieties. In 2014, 1.7 million tons of corn for feed was imported by Israel, of which 0.4 million tons came from the U.S and the rest from Ukraine, Russia, Brazil, Argentina, Moldova and Romania. It is likely that most of the U.S., Brazil and Argentina corn is from biotech varieties, which totals about 0.5 million tons or 30 percent of total corn imports. Other imported processed food imported into Israel may contain biotech ingredients. Currently, importers are not required to declare biotech content.

E) Food Aid Recipient Countries: Israel is not a food aid recipient and will not be a recipient in the future.

PART B. POLICY

A. Regulatory Framework: Responsibilities for GMO research, development, and use are shared by the Ministry of Agriculture and Rural Development (MOAG) and the Ministry of Health in accordance with regulations established by these ministries based on their respective authorities.

In October 2013, the Israeli Food Control Services (FCS), which is part of the Ministry of Health, notified proposed draft regulations on "novel foods" to the WTO.

The draft regulations called "Public Health Regulations (Food) (Novel foods) 5773 - 2013", have the following key provisions:

- Registration of novel foods through a risk assessment process.
- Prohibition of processing, importing, storing, or selling novel foods unless the food is registered on the official novel food list.
- The Official Novel Food List - The novel foods list will be updated with every additional novel food that is authorized in Israel.
- Labeling of pre-packaged foods that contain biotech ingredients, fruits and/or vegetables.

According to the draft regulations, manufacturers and importers are required to submit an application to the Novel Food Committee of the Food Control Service for the approval of a novel food, if the product contains a biotech ingredient not found on the official novel food list. The committee will assess the safety of a novel food on a case-by-case basis. The current GM events approved by the Ministry of Health will forego this process once the law is in effect, and they will automatically be added to the Official Novel Food List.

Novel food definition - The scope of the definition of novel food is limited to food for human consumption. It is a food product or food ingredient, except if it is a food supplement, ingredient of a food supplement, food additive, taste and scent substance of production enhancing substances, which pertains to one of the following groups:

1. Has a primary new structure at the molecular level or underwent a deliberate modification in its primary structure at the molecular level. – This refers to a new molecule that hadn't been used for food before February 2006, as defined under the Novel Food Procedure, a related document. For example the sugar, Isomaltulose.

2. Contains an ingredient derived from a commodity produced through biotechnology.

3. Contains plants, animals, microorganisms, fungi or algae or part of them, excluding enzymes, of which there is insufficient experience in Israel regarding their safe consumption by humans. – That means a plant, fungus, algae, or other organism that is not listed in the Israeli database as approved for human consumption. For example the *Hoodia parviflora* plant that was approved as novel food.

4. Underwent a production process which has not been used widely in Israel for the food type in question, excluding a cleansing and disinfection process, and this process causes a modification in the food composition, its structure, or its ingredients which affected its nutritional value, its metabolism, or the level of unwanted substances in the food. For example, red grape cells (RGC) that are grown in bioreactors as a cell culture and those cells contain a higher level of Resveratrol and less sugar than the same grapes grown in the field.

The Seed Regulations (Genetically Modified Plants and Organisms) 5765– 2005 issued in 2005 by the MOAG based on general authorities provided under the Seeds Law, 5716-1956, and the Plant Protection Law, 5716-1956.

MOAG oversees all experimentation of transgenic plants and organisms involved in the life cycle of plants in accordance with the regulations. In addition, MOAG regulates the importation and exportation, handling, and commercialization of genetically modified propagation material.

MOAG's activities in these areas are managed by the following bodies:

1. The Plant Protection and Inspection Service (PPIS);
2. The National Committee for Transgenic Plants (NCTP); and
3. The Authorized Institutional Representative

For a list of the biotechnology field testing that has been done in Israel, please refer to the Field Testing paragraph in this report.

The Seed Regulations prohibit any experimentation with plants that have undergone genetic modification without a permit issued by the Director of the PPIS. The Director grants experiment permits and stipulates the conditions for their issue, including the destruction of all material used during the experiment, as well as requiring that all testing be conducted in laboratories approved by the Director. The Director may refuse to issue a permit for experiments that are to be carried out in a:
(1) Containment facility, unless the applicant proves that the containment facility is appropriate and that all necessary means have been taken to prevent risks to humans, animals and plants; and to prevent unacceptable negative impacts on the environment;

(2) Field trial only, after consultation with the National Committee for Transgenic Plants (NCTP).

The regulations authorize the Director to exempt applicants from obtaining a permit if the experiment will be conducted in a laboratory equipped with an autoclave facility, and its operator and safety officer have ensured that "all experiment residues are destroyed in an incinerator or sterilized with material that the Director has approved."

According to the regulations, the role of the NCTP is to advise the Director, in accordance to the regulations, and "to determine if genetically modified plants or organisms or their sale, pose any risk to humans or animals or have unacceptable negative impacts on the environment."

The NCTP is made up of thirteen members, which are appointed by the Minister of Agriculture and Rural Development and include the following:
(1) Two representatives from the Ministry; one of whom will act as chairman of the committee, and the second as deputy chairman;
(2) One representative from a list submitted by the Minister of the Environment;
(3) One representative from a list submitted by the Minister of Health;
(4) One representative from a list submitted by the Minister for Science, Culture and Sport;
(5) Eight representatives from the public, which must include members of the scientific and research community with a background in life sciences, nature or environmental protection; and members from the seed and plant breeding industries.

Effective Israeli laws which cover GE plant testing and GE seed regulations

Annex 1: Application for permit to experiment with transgenic plants, GMO and their import

Annex 2: Seed Regulations (Genetically Modified Plants and Organisms) - 2005

B. Approvals: N/A

C. Field Testing: Field experiments of plants produced through biotechnology began in Israel about 20 years ago. To date, experiments have been conducted on tomatoes (increasing lycopene levels), potatoes, eucalyptus, flowers, soybeans, cotton, corn, strawberries and bananas. Experiments are conducted at Israeli universities, field test plots and greenhouses.

All the experiments have been authorized by the National Committee for Transgenetic Plants, based on the contents of a complete, detailed application and after consultation with appropriate experts.The experiments were under the regulatory supervision of the Plant Protection and Inspection Services (PPIS) staff.

It is prohibited to conduct field trials for biotechnology crops near seed fields, organic or commercial

fields. In order to conduct an experiment, an application must be submitted to the Plant Protection and Inspection Services of Israel (PPIS), the competent authority (see Annex 1).

Table 1 – Recent Biotechnology Field Trials for Plants Conducted in Israel

Name of the Institution Conducting Trials	**Project Title**	**Size of Experimental Plot**
Hazera genetics	Herbicides and insect resistance in Cotton	1 ha
Evogene	Tolerance to abiotic stress and nitrogen use efficiency in tomato	0.2 ha
Hazera Genetics	Improvements in tolerance to abiotic stress (drought, salinity) in tomato	0.1 ha
Eucalyptop Ltd	Increased growth rate in Eucalyptus in Wasps' Resistance varieties	1 ha
Weizmann Institute	Mutants selection in Tomato	0.1 ha
Evogene	Tolerance to abiotic stress (drought) in Corn	1.6 ha
Evogene	Tolerance to abiotic stress in canola	0.05 ha
Evogene	Improvements in tolerance to abiotic stress (drought, salinity) in tomato	0.1 ha
Danziger Nurser	Study the effect of anthocyanins gene on *Gypsophila* flower color	$5m^2$
Dept of Genetics, The Volcani Center ARO	Fruit set under temperature stress in tomato	0.1 ha
CBD Technologies	Increased growth rate in potato	0.02 ha
CBD Technologies	Increased growth rate in Eucalyptus	1 ha
Field and Garden Crops, Agricultural Research Organization, The Volcani Center	Starch synthesis reduction in strawberry leaves.	0.05 ha
Rahan Meristem	Banana plants with improved fruit shelf life	0.3 ha
RH Smith Institute of Plant Sciences and Genetics in Agriculture Faculty of Agricultural, Food and Environmental Sciences The Hebrew University	Glyphosate-based weed management practices in Roundup Ready cotton	0.3 ha
	Efficacy of purple nutsedge (*Cyperus rotundus*) control	0.5 ha

	using crop rotations	
	Glyphosate-based weed management practices in Roundup Ready corn	0.3 ha

Source: Israeli Plant and Protection Services

Sample application for field trial permit by the Ministry of Agriculture:

Ministry of Agriculture

NCTP))National Committee for Transgenic Plants

Application for permit to experiment with transgenic plants, GMO ** & their import

(This information will be used to determine eligibility to receive permit only for experiments with genetically modified plants & microorganisms and their import. For release to environment and commercialization permit, additional information is required in a separate form)

Any information that the applicant does not want to disclose for competitive reasons can be claimed as confidential information. Applicants should submit a written justification to support each claim, which will be considered.

Instructions: Complete this form and enclose the supporting information listed.

Experiment details: No.

_____Date_____

Aim of experiment:____

Type of permit requested

- **New** **Renewal**

- **For experiments**
- **In the lab. / Greenhouse/ field (including import)*****
- **For import**

**** GMO= Genetically Modified Organisms**

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The applicant details

Name _____

Title_____

Address _____

Telephone/fax_____

E-mail_____

Application details

Common or Trade name: _____ scientific name _____

Description of the genetic material____

Designation of transformed line:____
Phenotype:_____
Construct; Genotype (promoter; gene; enhancer; terminator) (Please add map):____

Selectable marker (promoter; gene; terminator):_____

Origin of the regulated article_____

Containment - means: Refer to research proposal or specify here____

Location of the experiment facility (map), marking, isolation, confinement, sanitation; biosafety procedure_____

Monitoring - specify the means you will use to follow gene transfer, phenotypic & genetic stability, during and after the field trial____

Comments (similar experiment abroad)____

Permit class definition_____

exempt / not exempt_____

(* For exempt only)
State why you believe this case falls within the requested exempt definition____

Duration of Permit required_____

Commitment

a. I hereby certify that the information in this application and all attachments is complete and accurate to the best of my knowledge and belief.

b. I hereby certify that during the conduct of the experiment I will follow the institutional bio-safety committee & the national committee procedures and the license conditions.

c. I hereby certify to report to the institutional bio-safety committee about the initiation & termination of the experiment and the measures taken for termination & disposal of the biological material.

d. I hereby declare that the risk assessment submitted in this application and its attachments was prepared to the best of my knowledge and information sources available. I hereby certify to report to the NCTP of relevant new information and to follow the NCTP procedures required according to the risk assessment submitted.

Date: _____ Signature: _____.

End of Permit.

D. Stacked Event Approvals: Stacked events in GE field testing are subject to the approval of the Plant and Protection Services. No commercial plants and seed growing are allowed in Israel; therefore stacked event approval is not applicable to commercial GE production.

E. Additional Requirements: N/A

F. Coexistence: N/A

G. Labeling: Currently, Israel has no declared government policy on the labeling of biotech organisms. But under draft regulation "Public Health Regulations (Food) (Novel foods) 5773 - 2013", if approved, will require for the mandatory labeling of novel foods that contain biotech ingredients. According to the Israeli Ministry of Health, mandatory labeling is not for deterrence

or warning but fulfills the public's right to receive complete information about the food it consumes.

Exemptions from mandatory labeling are the following:

1. Does not contain DNA and protein.
2. Less than 0.9% of the product is comprised of ingredients derived from a biotech crop.

According to this definition, highly refined foods, such as oils, in which the refining processes have the effect of removing DNA and protein, food additives derived from crops produced through biotechnology that do not carry DNA or protein, and processing aids derived from these same crops would not require labeling.

When the new labeling regulations are approved, foreign exporters will have to declare if the products contain ingredients derived from crops produced through biotechnology. Feedstuffs will be exempt from the biotech labeling requirements. However, if the commodity will be used for food processing, the local producer will have to declare if the end product contains biotech ingredients.

Figure 1: Activists protest inside a supermarket in the city of Holon, demanding the labeling of baby formulas that, according to them, contain genetically modified organisms (GMO), November 26, 2103.

H. **Trade Barriers –** There are no trade barriers for food products with biotech content in Israel. However, if "Public Health Regulations (Food) (Novel foods) 5773 - 2013" is approved, products derived from biotech events not approved in Israel will not be able to enter Israel until a risk assessment is conducted for that event.

I. **Intellectual Property Rights (IPR) –** N/A

J. Cartagena Protocol: Israel did not sign the Cartagena Protocol on Biosafety and is unlikely to do so.

K. International Treaties: Israel is not actively participating in discussions related to biotech plant varieties or seeds with international organizations.

L. Related Issues:

M. Monitoring and Testing: Israel does not have a system for testing and controlling the entry of biotech products into Israel; therefore, currently, biotech products are allowed to enter Israel. When Israel approves its biotech policy, the Government of Israel will likely adopt a testing system.

N. Low Level Presence Policy: N/A

PART C: Marketing

A. MARKET ACCEPTANCE: Israeli consumer awareness of biotech products has increased, and we assume most consumers are unaware of food products that contain biotech components. The commercial sector and the research community are keen to start the production of biotech crops in Israel.

B. PUBLIC/PRIVATE OPINIONS: Environmental activists have expressed concerns regarding the safety and the potential environmental harm that they believe could result from the use of biotech crops. Activists argue that "GM seeds produce sterile crops, so cross-pollination with wild plants could bring rapid extinction to those wild varieties." They have also expressed concerns about the long-term environmental effects of breeding biotech seed varieties with other plants.

Israeli scientists, however, generally support the development of agricultural biotechnology. According to Professor Gad Galili of the Weizmann Institute of Science in Rehovot, the development of genetically engineered crops can address "the global shortage of staple foods." In response to concerns regarding the long-term impact of biotechnology, he opined that "although scientists do not know the long-term effects of genetically modified organisms' consumption they were safer than conventionally interbred ones because scientists have full control over the variables in the gene transfer." As for the risk of contamination, he stated " if you put a virus into GMO, it will spread. But we safeguard the technology, and there are expert committees that approve GMO, and one thing is certain: If someone wanted to insert a virus genome, or there was contamination risk, it would not be approved."

C. Religious Concerns

Concerns have been raised both in Israel and among Jewish communities around the world regarding whether products that include biotech components are Kosher and thus fulfill strict Jewish dietary standards. The *Epoch Times* has reported that the religious kashrut authority –which certifies products

as Kosher– in Israel has ruled that genetic engineering "does not affect kosher status" because genetic material is "microscopic."

But there are Jewish groups that dispute this decision and consider biotech products a violation of the biblical prohibition against "kilayim," mixed breeding both in crops and in livestock. Those believing biotech products cannot be labeled kosher quote the well-respected 13th century Kabbalist Rabbi Moshe ben Nachman (known as "the Ramban"), who said mankind should not disturb the fundamental nature of creation.

In the United States, the Natural Food Certifiers (NFC) Organization, in a press release, announced that its Apple K Kosher Certification Program would no longer accept applications for products that contain biotech ingredients.

D) MARKETING STUDIES: Post is not aware of any Israeli marketing studies on GE crops, seeds or food products.

Part D: Capacity Building and Outreach

A. ACTIVITES: The U.S. Embassy and FAS/TEL AVIV were awarded $5,000 under a Department of State sponsored FY 2015 AG BIOTECH OUTREACH. Post will bring two speakers for a 2-day workshop in Israel, educating relevant decision-makers from the Israeli government and private sector on U.S biotechnology policy, commercial benefits, and risk communication to counter the negative perception of biotechnology in Israel. Speakers will discuss policy, regulatory and food safety issues. The activity will likely be held in October of 2015 in Tel Aviv.

B. Strategies and Needs: Since the new Israeli Biotech law should be approved in the next 12 months by the Israeli Government, it is good timing to conduct an educational seminar in Israel for both Israeli public and private sectors.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: PRODUCTION AND TRADE

GE animals are currently not a topic in Israel and no legislation and regulations related to the development/testing, commercial use and/or import of bio-engineered or cloned animal products are in place. The ministry in charge of this subject is the Veterinary Services, which is a part of the Ministry of Agriculture.

A. BIOTECHNOLOGY PRODUCT DEVELOPMENT: There is some very limited genetic engineering of animals (mainly insects) in Israel which is done by universities (mainly the Weizmann Institute), and which are under development for use as sources of scarce cells and organs for transplantation into humans and other animals.

A team from the Weizmann Institute has demonstrated for the first time how tissues transplanted from pig embryos might, in the future, be able to induce the human body to produce blood-clotting proteins for hemophilia patients (http://www.israel21c.org/did-you-know-israel-facts/).

B. COMMERCIAL PRODUCTION: There is no commercial production of GE animals in Israel. Post is not aware of any foods from GE animals in Israel.

C. BIOTECHNOLOGY EXPORTS: No exports of GE animals from Israel.

D. BIOTECHNOLOGY IMPORTS: There are no imports of GE animal for agricultural purposes to Israel.

PART F: POLICY

A. REGULATION: In order to perform GE testing on animals in Israel, an application must be submitted to the Israeli Veterinary Services and a committee at the Veterinary Services will evaluate the request.

B. LABELING AND TRACEABILITY: There is no policy for the traceability and labeling of GE animals.

C. TRADE BARRIERS: Currently there are not GE-related barriers in Israel on GE animals. However, although there are no barriers, no GE animals are imported into Israel both for commercial and for research.

D. INTELLECTUAL PROPERTY RIGHTS (IPR) – N/A

E. INTERNATIONAL TREATIES: Israel is a member of Codex Alimentarius and is also a member of the World Organization for Animal Health (OIE), but does not actively participate in discussions related to animal biotechnologies.

PART G: MARKETING

A. MARKET ACCEPTENCE: There is a very little awareness of GE animals among the Israeli public.

B. PUBLIC/PRIVATE OPINIONS: Animal biotechnology currently does not exist on the political agenda, and there is currently almost no lobbying in favor or against the use of livestock cloning. However, if the issue should arise, it is estimated that public views on cloning will be similar to those regarding biotech crops.

C. MARKET STUDIES: Post is not aware of any Israeli marketing studies on GE animals or clones.

PART H: CAPACITY BUILDING AND OUTREACH

A. ACTIVITIES: None planned.

B. STRATEGIES AND NEEDS: Since the Israeli Veterinary Services has limited knowledge and awareness of GE animals and U.S. policy, Post recommends that the appropriate U.S. agencies share information on this issue with the Israeli Veterinary Services.