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Agricultural Biotechnology Annual

Annual Report

Approved By:
Ron Verdonk (Minister-Counselor)
Prepared By:
Gilad Shachar and Rachel Trego

Report Highlights:
This report describes the trade and production of genetically engineered (GE) plant and animal products, and related government policies in Israel.

Section I. Executive Summary:

As of July 2014, 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. 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 for comments by other members. The scope of the definition "novel food" is limited to food for human consumption only. The following are the major requirements introduced by the proposed regulations:

- Registration of novel foods which 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

According to the Israeli Ministry of Health, genetically engineered food is defined as food that contains an ingredient produced through biotechnology. Regulation 12 of the Israeli Novel Foods regulation describes the terms for exemptions from mandatory labeling. Products would be exempt from being specifically labelled when the ingredient 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 new regulation has not been approved yet by the Israeli Government and FAS Tel Aviv estimates the new regulations will be approved by the end of 2015. Once approved by the Israeli Government, the new regulation will come into effect one year after the publication in Israel Official Gazette.

Israeli law permits the development and growth of genetically engineered organisms for research purposes in accordance with requirements established by subsidiary legislation. Although genetically engineered seed and crop production is not permitted for commercial purposes, GE products may be imported, sold, and used in the production of food and pharmaceuticals in Israel. While Israeli scientists usually support the development of biotechnology, environmental activists have expressed concerns regarding what they see as potential harm resulting from their use. 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 only used in “microscopic” proportions.

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, and the focus is on the development of seeds and improving plant resistance to pests, disease, and herbicides. Research is conducted by Israeli universities, government research institutions and the private sector. Israeli seed regulations from 2005 outline the parameters for conducting biotechnology research in Israel, which must be approved by the National Committee for Transgenic Plants.

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 2-4 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 comes from the private industry.

C) Exports: Due to the fact that the local industry uses imported raw materials that may include a biotech component, 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 that are imported into Israel are from biotech varieties. In 2013, 363,000 tons of soybeans were imported into Israel, of which 102,000 tons were imported from the U.S and the rest from Brazil, Argentina and Paraguay. It can be estimated that upwards of 90% of the soybeans are biotech varieties. In addition, in 2013, 1.26 million tons of corn for feed was imported to Israel. It is likely that almost all this corn was from biotech varieties. Other imported processed food imported into Israel may contain biotech ingredients. Currently, importers are not required to declare which of their products have a percentage of 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 (MOAG) and the Ministry of Health in accordance with regulations established by these ministries based on their respective authorities.

The Israeli Food Control Services (FCS), which is part of the Ministry of Health, notified in October 2013 the new proposed regulations on "novel food" through the WTO which also relates to food from GE organisms.

New draft regulations have been announced by Israel's Ministry of Health called "Public Health Regulations (Food) (Novel foods) 5773 - 2013". These are the major requirements introduced in the regulations:

- Registration of novel foods (regulations 2 and 4 through 6);
- Prohibition on the processing, importation, storage or sale of novel food unless it is registered on the official list of permitted novel foods (regulations 3);
- Labeling of pre-packaged food with biotech ingredients, fruits and vegetables (regulations 10 through 12).

According to the draft Novel Food Regulations, manufacturers and importers are required to submit an application to the Novel Food Committee in the Food Control Service for the approval of a novel food which contains a biotech ingredient not found on the approved list. The novel food committee assesses the safety of the novel food on a case-by-case basis.

The safety criteria for the assessment of novel foods outlined in the current procedure document were derived from internationally established scientific principles and guidelines developed through the work of international organizations, such as the FAO, WHO and the Codex Alimentarius Commission.

Clarification – only biotech ingredients found on the approved biotech ingredient list can legally enter the food supply in Israel.

The list - The novel foods list will be updated with every additional novel food that is authorized in Israel.

Novel food definition - The scope of the definition of novel food is limited to food for human consumption only.

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, that was approved as a novel food.

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, about which there is insufficient experience in Israel regarding their safe consumption by humans. – That means a plant, fungus, algae etc. 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.

No commercial biotech crop cultivation or seed production is allowed in Israel; however Israel allows importation of biotech food and agricultural products and allows biotech research under specific guidelines.

The Seed Regulations (Genetically Modified Plants and Organisms) 5765– 2005 were 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 with transgenic plants and organisms that are involved in the life cycle of plants in accordance with the regulations. In addition, MOAG handles 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 was done in Israel please refer to the Field Testing paragraph in this report.

The Seed Regulations prohibit any experimentation with plants that have undergone a change by means of genetic modification without a permit issued by the Director of the PPIS. The regulations authorize the Director to grant experiment permits and to stipulate conditions and restrictions for their issue, including conditions for destroying plant material, organisms or regulated articles used during the experiment and requiring that testing be conducted in laboratories that have been 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 for its function and that all necessary means have been taken to prevent all risk to humans, animals and to plants; and to prevent unacceptable negative impacts on the environment;
(2) Field trial only, after consultation with the National Committee for Transgenic Plants.

The regulations authorize the Director to exempt applicants from needing to obtain an experiment permit if he or she is satisfied that 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 with the instructions prescribed by 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 thirteen committee members are appointed by the Minister of Agriculture and Rural Development and include the following persons:
(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 of the public from among the scientific and research community who have backgrounds in life sciences, nature or environmental protection, and from seed producers and variety breeders.

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 level), potatoes, eucalyptus, flowers, soybeans, cotton, corn, strawberries and bananas. Experiments are conducted at Israeli universities, field test plots and greenhouses. Monsanto financed a number of trials.

All the experiments were authorized by the National Committee for Transgenetic Plants, based on the contents of a complete, detailed application and after consultation with appropriate experts.

These 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 Institute	Project Title	Size of Experimental Plot
Hazera genetics	Herbicides and insects 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 (1998)	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 using crop rotations	0.5 ha
	Glyphosate-based weed management practices in Roundup Ready corn	0.3 ha

Source: Israeli Plant and Protection Services

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

Labeling: Currently, Israel has no declared government policy on the labeling of biotech organisms. Some consumer groups have advocated for biotech ingredient labeling that will enable them to choose and consume food that conforms to their beliefs and ideology. In the proposed regulations, labeling novel ingredients, including biotech organisms, is mandatory.

According to the Israeli Ministry of Health, labeling food with biotech ingredients is not for deterrence or warning but fulfills the public's right to receive complete information about the food it consumes and for the purposes of risk management.

Regulation 12 describes the terms for exemptions from mandatory labeling.
Products would be exempt from being specifically labelled **when the ingredient 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.

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 a "genetically modified" label.

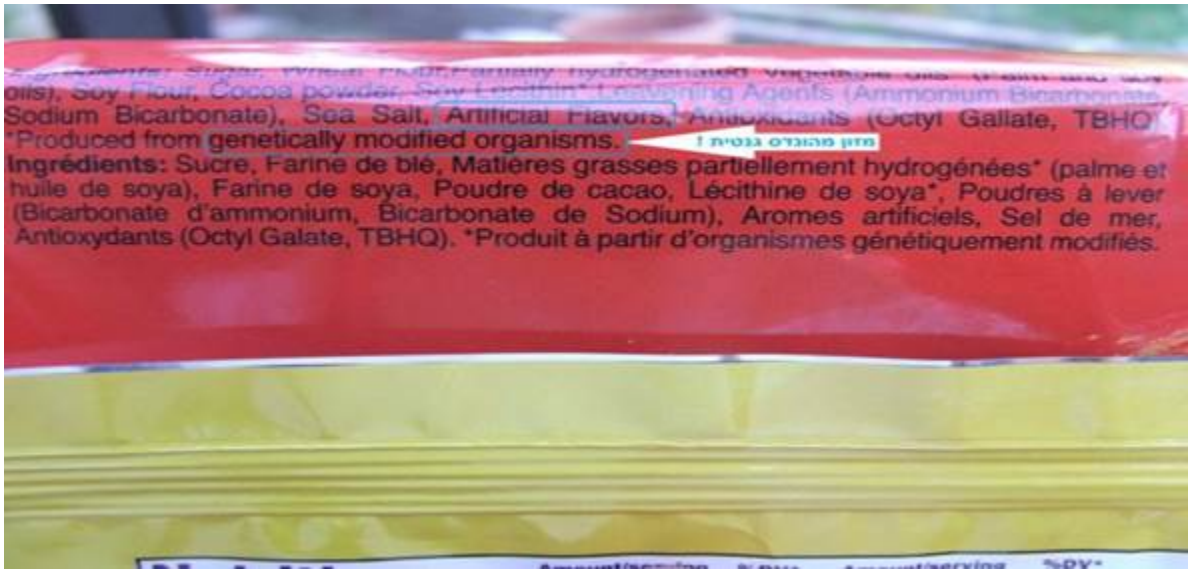
Clarification – only GMOs found in the approved GMO list can legally enter the food supply in Israel. Ingredients derived from those crops produced through that contain DNA or protein require a "genetically modified" label.

When the new labeling regulations will be 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, then the exporter and/or local producer will have to declare if it contains biotech ingredients.

Two pictures of Israeli food products containing biotech ingredients that were exported to the EU were published on the internet at the following address:

Israeli Onion Soup:

Israeli waffles:



G. Trade Barriers – Due to the fact that there is no biotech policy there are no trade barriers for food products with a biotech content in Israel. However, since Israel is in an advanced stage of approving a biotech policy including registration of imported biotech crops and labeling, varieties that will not be included in that list will not be able to enter Israel, until the FCS conducts a risk assessment for that product.

H. 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: N/A

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 for biotech products.

N. Low Level Presence Policy: N/A

PART C: Marketing

A. MARKET ACCEPTANCE: Recently Israeli consumer awareness of biotech products has increased, but they can't readily tell which food products they consume contain biotech ingredients. The commercial sector and the research community are keen to start the production of biotech crops and seeds in Israel.

B. PUBLIC/PRIVATE OPINIONS: Environmental activists have expressed concerns regarding the quality and the potential harm that they believe would result from the use of biotech seed varieties. 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 ecological effects of the breeding of 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 use 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 had full control over all the variables in the gene transfer. As for the risk of contamination . . . [i]f you put a virus into GMO, it will spread. But we safeguard it, there are expert committees that approve GMO, and one thing is certain: If someone wanted to insert a virus genome, or there was a 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 had 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 the products of biotechnology 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, announced that its Apple K Kosher Certification Program would no longer accept applications for products that contain biotech ingredients .[25]
According to a press release issued by the NFC:

While according to the strict letter of Kosher food law a GMO food ingredient is not prohibited, in our view it is not natural. Additionally, there is a Torah (religious)-based law to ‘guard your health’. GMOs are the number-one growing concern among health-conscious consumers and for businesses in the natural and organic food market, as well as in the conventional food industry..”

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: N/A

B. Strategies and Needs: Post highly recommends that American seed companies and U.S. agriculture commodity associations with biotech crops work with FAS/Tel Aviv to submit a list and safety files of the GE crops to the Israeli Food Control Services. In addition, since the new Israeli “Novel Foods” regulations should come into effect by the end of 2015, U.S. food and agricultural companies should follow these new regulations once they are approved.

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 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.

In 2009, Israeli scientists transplanted embryonic pancreatic tissue from pigs to monkeys to combat type 1 diabetes. As a result, the researchers were able to reverse the primate's insulin deficiency, MIT reported. They said the key to their breakthrough was the embryonic tissue's ability to grow into a new pancreas that uses blood vessels from the host animal. The host blood vessels are not subject to the risky immune reaction that has always impeded xenotransplants of mature pancreatic material. Yair Reisner of the Weizmann Institute, who led the research, claimed that the results, published in the journal PNAS, could offer a viable replacement therapy for sufferers of type 1 diabetes, which destroys the pancreas.

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. ACTIVITES: N/A

STRATEGIES AND NEEDS: Since the Israeli Veterinary Services have 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.