

USDA Foreign Agricultural Service

GAIN Report

Global Agricultural Information Network

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY
USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT
POLICY

Required Report - public distribution

Date: 11/29/2018

GAIN Report Number: IS18011

Israel

Agricultural Biotechnology Annual

Israel Agricultural Biotechnology Annual 2018

Approved By:

Ali Abdi, Minister Counselor

Prepared By:

Jessica Sullum Shay, Marketing Specialist, and Bret Tate, Agricultural Attaché

Report Highlights:

As of October 2018, Israel does not have a policy that restricts the use of imported genetically engineered (GE) commodities or derivative products. The existing regulation states that the sale of GE crops is not permitted without a valid Registration Certificate. To date only GE tobacco has received approval. Israel allows development of GE crops for research purposes. Israeli regulations allow foreign-produced GE products to be imported, sold, and used for the production of food and pharmaceuticals in Israel. In March 2017, Israel decided that genome edited plants resulting only in a deletion of nucleotides and no insertion of foreign DNA are not considered transgenic and therefore are not subject to the GE Seed Regulation. In the upcoming year, the Israeli Ministry of Health (MOH) plans to complete the needed legal work on their drafted regulation for novel foods, which includes foods containing GE components.

EXECUTIVE SUMMARY

As of October 2018, Israel does not have a policy restricting the use of imported GE commodities or derivative products. The existing [GE Seed Regulation](#) states that the sale of GE crops is not permitted without a valid Registration Certificate, to date only GE tobacco has received approval. In Israel GE crop production is allowed for research purposes. Israeli regulations allow foreign-produced GE commodities and products to be imported, sold, and used for the production of food and feed, ornamental purposes and pharmaceuticals in Israel. Israel's religious Kashrut authority determined that the use of GE ingredients in food does not affect its kosher status as these ingredients are used in "microscopic" proportions.

Currently, the volume of biotech imports to Israel is not quantified and domestic experimental use is limited. Different countries ship grains and oilseeds to Israel and, for commodities like corn and soybeans, a sizable percentage are likely biotech varieties. The only GE crop that is permitted to be grown commercially in Israel is tobacco, which is engineered with five human genes and used by the cosmetic and pharmaceutical industry. All other GE crops that are grown in Israel are for research and development purposes only and are not grown commercially. No GE animals are produced in Israel or known to be imported. A number of GE plants developed in Israel are now being grown in other markets, such as ornamental flowers.

In October 2013, new draft regulations for novel foods, including food produced using biotechnology, were announced by the Israeli Ministry of Health (MOH). It is unclear when the new regulation will be implemented, but based on conversations with the MOH, the ministry plans to finalize the draft in 2019. After official approval, the measure will come into effect one year after publication in Israel's Official Gazette.

While Israeli scientists usually are supportive of biotechnology, environmental activists have expressed concerns regarding its use. The local media rarely discusses genetic engineering. Most Israelis do not have an opinion regarding the use of GE products. As a result, there are no known problems with marketing GE crops in Israel today.

The National Committee for Transgenic Plants (NCTP) published in March 2017 that genome edited plants resulting only in a deletion of nucleotides and no insertion of foreign DNA are not considered to be transgenic and will not be subjected to the GE Seed Regulation. The applicant must submit data showing that they meet the determined criteria to ensure that foreign DNA sequences were not incorporated into a plant genome. Other genome edited plants, where foreign DNA is incorporated, and their progeny will be subject to regulations and guidelines found in the GE Seed Regulation.

TABLE OF CONTENTS

TABLE OF CONTENTS

| | |
|--------------------------------------|----|
| CHAPTER 1: PLANT BIOTECHNOLOGY..... | 4 |
| PART A: PRODUCTION AND TRADE | 4 |
| PART B: POLICY..... | 5 |
| PART C: MARKETING | 11 |
| CHAPTER 2: ANIMAL BIOTECHNOLOGY..... | 13 |
| PART D: PRODUCTION AND TRADE | 13 |
| PART E: POLICY | 13 |
| PART F: MARKETING..... | 13 |

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** Israel is considered an international center for genetic engineering and research, focusing on improving plant resistance to pests, disease, herbicides, salinity, and drought. Research is conducted by Israeli universities, governmental institutes, and the private sector. Genetic engineering is permitted today in Israel for research and development purposes and it is subject to conditions established by law. The [2005 “Seed Regulation for Plants and Other GE Organisms”](#) (GE Seed Regulation) stipulates the requirements for conducting research in Israel with GE propagation material. All trials have to be approved by a committee of 13 members called the National Committee for Transgenic Plants (NCTP) chaired by the chief scientist of the Ministry of Agriculture (MOAG). The stages and advances made in GE research are kept as a company secret until registered. In registration, applicants are required to reveal product details to the NCTP. The number of NCTP authorized experiments between the years 2013-2017 is presented in the following table. In addition, a partial list of products under research and development is listed in the Field Trials Section.

NCTP Authorized Experiments 2013-2017

| | 2013 | 2014 | 2015 | 2016 | 2017 |
|-------------|------|------|------|------|------|
| Laboratory | 13 | 44 | 12 | 7 | 21 |
| Greenhouse | 27 | 31 | 20 | 13 | 10 |
| Field Trail | 15 | 6 | 8 | 5 | 5 |
| Total | 55 | 81 | 40 | 25 | 36 |

Source: NCTP

In May 2018, the Chief Scientist’s Office at the MOAG published its intent to establish a National Center for Genomic Editing and [funding opportunities](#) for genome editing research projects. The funding was made available for the following areas of research:

- Agricultural product (plants, animals) development through the deletion of genes via existing genome editing tools.
- Development of tissue culture protocols or protocols for any other process that enable the creation of whole plants / animals through genomic imprinting at the cellular level and meet the requirements listed above.
- Development of innovative methods and tools for "enhanced" or "targeted" genome editing.

- b) **COMMERCIAL PRODUCTION:** Currently, commercial production of GE crops, including the use of GE seeds, requires a license from the Plant Protection and Inspection Service (PPIS). The only crop currently approved for sale is the GE tobacco plant grown in confinement for cosmetic and pharmaceutical use. [Note: The GE tobacco is grown in confinement to remain isolated from pathogens and potential vectors.] However, this policy is expected to change within the coming years. It is unknown how or when the policy will change; however, there is pressure on the MOAG and PPIS from private sector interests working with GE crops.
- c) **EXPORTS:** As the Israeli industry uses imported raw materials that include GE components, it is likely that some fraction of Israeli food products exported to the US, or to other countries, contains some biotech content. This is especially likely among those products that rely on imported grain, oilseeds or cotton as inputs. In these cases, Israeli exporters must follow the importing country's regulations regarding GE labeling. If a product includes a GE component and is shipped to a destination that requires specific labeling, the producers will mark it accordingly.
- d) **IMPORTS:** All of the soybeans and corn used in Israel are imported. In 2017, 453,000 MT of soybeans and 1,755,000 MT of corn were imported into Israel, out of which 53,000 MT and 112,000 MT, respectively, came from the U.S. The remainder came from other sources, including South American and Black Sea suppliers. There are no records regarding the percentage of GE varieties amongst these imports.
- e) **FOOD AID:** Israel is not a food aid recipient and is not expected to be in the future.
- f) **TRADE BARRIERS:** Currently, there are no trade barriers regarding GE products. If the proposed novel food regulation is approved, imported GE food products would face labeling requirements. Noncompliance could potentially block them from the market. The responsibility for labeling will fall to the local importers and distributors. The novel food regulation would also institute a pre-market approval process for GE foods.

PART B: POLICY

- a) **REGULATORY FRAMEWORK:** Currently, responsibility for GE research, development, use and approval is shared primarily by the Ministry of Health (MOH) and by the MOAG. The Ministry of Agriculture's Plant Protection and Inspection Services (PPIS) is the competent authority in Israel for enforcement of the [Plant Protection Law of 1956](#), which is the existing legal framework for GE plants. The GE Seed Regulation provides specific regulation regarding research activity, sales, export and import of GE materials.

The MOAG is responsible for all trials of engineered plants, as well as those organisms that are directly related to GE plants. These could include pathogens, pollinators, natural enemies, etc. The MOAG is also responsible for handling, commercializing, importing, and exporting GE propagation material.

Within the legal and regulatory framework mentioned above, three bodies have specific roles. First, the NCTP is an inter-ministerial committee, composed of 13 members. Two members are

from MOAG (the chairperson and deputy), one member from the Ministry of Environment, one member from the MOH, one member from the Ministry of Science, and eight members from academia and the private sector. This committee exists to formulate guidelines for conducting GE trials, publish procedures and application forms for researchers, and serve as an advisor to government and academia on GE issues. The application produced by the NCTP can be found [online](#). Second, field inspection teams from the PPIS enforce NCTP guidance and regulations related to the handling of GE materials. Third, the PPIS Laboratory for Molecular Techniques and Transgenic Plants manages identification of GE seeds, vegetative propagation materials, and processed foods. This laboratory uses a “ring test” to determine the presence of GMOs in a consignment for import or export. For further information, refer to the [PPIS website](#).

The National Committee for Transgenic Plants published in March 2017 the committee’s decision that genome edited plants resulting only in a deletion of nucleotides and no insertion of foreign DNA are not considered to be transgenic and will not be subjected to the GE Seed Regulation. The applicant must submit data showing that they meet the determined criteria to ensure that foreign DNA sequences were not incorporated into a plant genome. Other genome edited plants, where foreign DNA is incorporated, and their progeny will be subject to regulations and guidelines found in the GE Seed Regulation.

Future Regulation

In October 2013, the Israeli Food Control Services (FCS), which is a part of MOH, notified the WTO of draft regulation on *novel foods*, notification G/TBT/N/ISR/710. The proposed regulation is still pending and further revision is expected. Based on conversations with the MOH, the ministry plans on finalizing the draft regulation in 2019. The draft regulation entitled [“Public Health Regulations Food – Novel Foods 5773 – 2013”](#) includes the following key provisions:

- Registration of novel foods through a risk assessment process;
- Prohibition on processing, importing, storing or selling unregistered novel foods;
- The creation of an official novel food list, which is updated periodically;
- Labeling instruction for food items containing GE ingredients.

Novel food definition: Under the draft regulation, the scope of the definition “novel food” is limited to food or food ingredients that meet the following requirements:

- Contains a new primary structure at the molecular level or which has been modified in its primary structure at the molecular level and is not yet proven safe for human consumption in Israel;
- Contains a GMO or part of one;
- Contains plants, animals, microorganisms, fungi or algae or extracted from one of these and does not contain enzymes that are not proven safe for human consumption in Israel;
- Was manufactured in a new process, except for cleaning and disinfecting, and that the process created a change in the formulation of the food or in its ingredients that made a

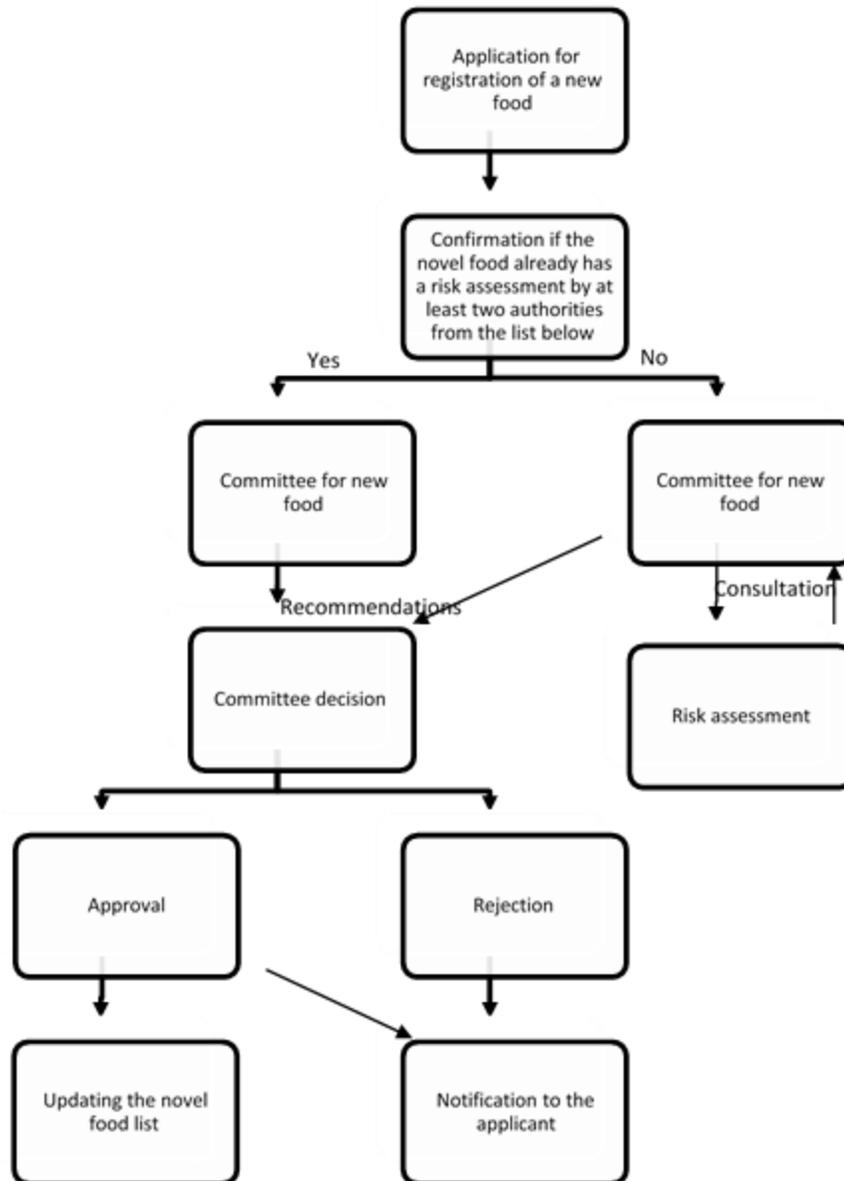
change in its nutritional values, the body metabolism or the level of unwanted ingredients in the food;

- Is not a food additive that was previously approved in the food additive regulation;
- Is not a food ingredient that was previously approved in the food ingredient regulation;
- Is not a material production aid or a food flavor.

According to the draft regulations, manufacturers and importers are required to submit an application for registration to the Novel Food Committee of the Food Control Service, for any novel food which is not already on the approved list of novel foods. New-to-market products must undergo a risk assessment prior to approval. Once a product is approved, it will be registered and added to the official list of approved products. The link for registration can be found [online](#). Only by following these steps can the product be commercialized.

For importation of food items that include a GE ingredient already approved and on the novel food list, the importer will have to apply for an import permit. The importer must attach to the application a declaration from the supplier or manufacturer that the food item in question is GE, as well as the name or variety of the GE organism as listed in the list of approved novel foods.

The process of registration of a new novel food is as follows:



A new risk assessment will not be required for a novel food if it has already been reviewed by at least two of the international associations approved by the head of food inspection services for risk assessments, which currently include:

- The European Union – European Food Safety Authority (EFSA)
- United States – Food and Drug Administration (FDA)
- Canada - Health Canada
- Australia and New Zealand – Australia and New Zealand Food Authority (ANZFA) and– Food Standards Australia New Zealand (FSANZ)
- Japan - Department of Food Safety – Ministry of Health, Labor and Welfare (MHLW)
- Specialist Committees of the CODEX ALIMENTARIUS (including FAO and WHO)

As most GE traits currently in production worldwide have been approved by the above regulatory agencies, they would have a streamlined review process in Israel under the new regulation.

The timeline for approval of novel foods varies according to the risk assessments that have been done. If the food has two or more approvals from the certifiers listed above, the application may be completed in as little as six months. If the product is new-to-market, approval could take up to 12 months. All novel foods are required to undergo the same process, regardless of their final use.

- b) **APPROVALS:** Thus far, only GE tobacco has been approved in Israel. The NCTP has granted a number of approvals for field trials (see Field Testing below). Israel does not currently require event-by-event pre-market approval for GE imports intended for use as food, feed or processing. However, this would change under the proposed novel foods regulation. An up-to-date list of approved novel foods can be found [online](#). Post is not aware of how products already on the market, but not listed as novel foods will be treated.
- c) **STACKED EVENT APPROVALS:** If a plant is genetically engineered for more than one trait, each trait must be approved separately. After approval, each trait will then be listed separately on the approved list. The current novel food registration process does not address the issue of stacked events.
- d) **FIELD TESTING:** Field experiments of plants produced through biotechnology began in Israel about 20 years ago. All of the experiments have to be authorized by the NCTP, based on a complete, detailed application and consultation with experts. The experiments are under the regulatory supervision of the PPIS.

The following outlines a partial list of firms and organizations that have received authorization by the NCTP for experiments and trials using GE crops or seeds:

| Company | Research | Crop Type | Comment |
|----------------------|--|--|--|
| Evogene | Insect, disease and herbicide resistant crops, crop enhancement and drought tolerance | Corn, soybean, cotton, banana, castor seeds and canola | |
| CollPlant | Uses GE tobacco plants with human genetics to produce collagen for cosmetic and medical purposes | Tobacco | Tobacco is not part of the food chain and therefore was approved. Some of their products are in the market while others are in different development and approval stages |
| Danziger Innovations | | Vegetable and ornamental crops | The firm developed ornamental flowers that will be grown in Kenya using Israeli technology |

| | | | |
|-----------------------------------|--|--|---|
| FuturaGene | Woody biomass and biotic/abiotic stresses | | |
| Kaiima | Yield enhancement and biotic/abiotic stresses | Vegetables (mainly tomatoes and peppers) and also grains, such as corn, rice, canola and wheat | |
| Protalix | Recombinant therapeutic proteins for the pharmaceutical markets | Carrot and tobacco plants | |
| Rosetta Green | Unique genes to develop seed strains of crops suitable for biofuels and food | Corn, wheat, rice, soybean, cotton, canola and algae | |
| TargetGene | DNA editing solutions in living organisms and plants | | |
| Morflora | Improving plant disease resistance | Wheat, pepper, grapes, oranges and olives | |
| Plantarche | | | No available information regarding their work |
| Governmental and academic centers | | | |

- e) **INNOVATIVE BIOTECHNOLOGIES:** [Please see Part B: POLICY a) Regulatory Framework] Israel maintains that plants that are the result of targeted mutagenesis using genome editing technologies that do not incorporate any foreign DNA into the genome will not be considered as transgenic. The Commission also confirmed that cucumber plants resistant to viruses, developed with genome editing are not considered transgenic. In May 2018, the State of Israel published its intent to establish a National Center for Genomic Editing and funding opportunities for genome editing research projects for agricultural products, which include plants and animals.
- f) **COEXISTENCE:** There are no written regulations regarding coexistence. The NCTP has to approve the application to work with GE products and it will solicit the opinion of the National Committee for Experiments (NCE). If the NCE has a doubt regarding the experiment or its location (proximity to other crops), it may ask for external expert opinions prior to approval.

- g) **LABELING:** Currently, Israel has no governmental policy on the labeling of GE products. Under the draft regulation “Public Health Regulations (Food) – Novel Foods 5773 – 2013”, mandatory labeling of food items that contain GE ingredients could be implemented. According to the Israeli MOH, the mandatory labeling is not for deterrence or warning, but to address consumers’ rights regarding access to information about food.

Under the proposed regulation, the following product categories will be exempt from labeling:

- Products not containing DNA or protein
- Products with less than 0.9 percent of the product being comprised of GE ingredients.

According to this definition, highly refined foods, such as oils, would not require special labeling, as the refining removes proteins from the product. When the new labeling regulations are approved, exporters of food items to Israel will have to declare if the products contain ingredients derived from GE crops. Animal feed will be exempt from the labeling requirements. Sellers will also have to place a sign beside GE products that are sold in bulk.

- h) **MONITORING AND TESTING:** Israel does not have a system for testing and controlling the entry of GE products into the country; therefore, currently, products containing GE organisms are allowed to enter the country. Exporters that produce food items from imported raw materials for export would be subject to the destination country’s regulations. This would include any labeling or testing requirements.
- i) **LOW LEVEL PRESENCE POLICY:** N/A
- j) **ADDITIONAL REGULATORY REQUIREMENTS:** GE seeds and plants are not commercially planted or grown in Israel for human consumption. GE products, as other novel foods, would face the regulatory hurdles explained above. It is worth noting that some novel foods, such as red grape cells, are currently approved for human consumption in Israel under very specific conditions.
- k) **INTELLECTUAL PROPERTY RIGHTS:** Israel is a signatory of the TRIPs Agreement and member of the UPOV.
- l) **CARTAGENA PROTOCOL RATIFICATION:** Israel is not signatory to the Cartagena Protocol. The Israeli ministry in charge of biosafety is the Ministry of Economy.
- m) **INTERNATIONAL TREATIES/FORA:** Israel is not actively participating in discussions related to GE plant or seed varieties with international organizations.
- n) **RELATED ISSUES:** N/A

PART C: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:** In the past, some environmental activists expressed concerns regarding the safety and the potential harm that could result from the use of GE crops. One fear is that GE seeds will “leak” into the wild and cross-pollinate wild plants causing new unwanted varieties. In spite of these minority opinions, Israeli consumers will buy products containing GE.

As in other countries, many Israeli scientists and researchers working with GE crops favor the technology as a way to supply global food markets when faced with shortages, plant disease, and environmental stress.

- b) **MARKET ACCEPTANCE/STUDIES:** Israeli consumer awareness regarding biotechnology is relatively low. There is hardly any reference in the local media to the issue. The Israel public is currently unconcerned with the issue.

Post is not aware of any Israeli marketing studies on GE crops, seeds or food products containing them.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** There is some very limited research on animal genetic engineering in Israel using human or animal cells. Most of this work is focused on repairing human tissue. Researchers and companies do not publicize specific information regarding these studies. In May 2018, the State of Israel published its intent to establish a National Center for Genomic Editing and funding opportunities for genome editing research projects for agricultural products, which include plants and animals. [Please see Chapter 1 Part A: PRODUCTION AND TRADE a) PRODUCT DEVELOPMENT]
- b) **COMMERCIAL PRODUCTION:** There is no commercial production of GE animals in Israel, nor is any expected in the near future.
- c) **EXPORTS:** No GE animals or organs are exported from Israel.
- d) **IMPORTS:** No GE animals are imported by Israel.
- e) **TRADE BARRIERS:** Any prospective GE animals would be subject to the same sanitary requirements as non-GE animals. There are no existing barriers to trade specifically targeting GE animals.

PART E: POLICY

- a) **REGULATORY FRAMEWORK:** The ministry in charge of experiments and regulation of GE animal production is the MOAG's veterinary branch. All requests for such experiments would have to pass through them for evaluation and approval. There is no regulation regarding the importing of GE animals and the new draft regulation avoids the subject.
- b) **APPROVALS:** N/A
- c) **INNOVATIVE BIOTECHNOLOGIES:** Post is unclear on how gene edited animals may be treated in the future.
- d) **LABELING AND TRACEABILITY:** There is no policy for the traceability and labeling of GE animals.
- e) **INTELLECTUAL PROPERTY RIGHTS:** Israel is a signatory of the TRIPs agreement.
- f) **INTERNATIONAL TREATIES and FORUMS:** Israel is a member of Codex Alimentarius and a member of the World Organization for Animal Health (OIE), but does not actively participate in discussions related to animal biotechnologies.
- g) **RELATED ISSUES:** GE animals are not a topic of concern in Israel, and there is no legislation or regulation related to the development, trials, commercial use, imports or exports of GE or cloned animals. The ministry in charge of this subject is the MOAG through its veterinary services.

PART F: MARKETING

- a) **PUBLIC/PRIVATE OPINIONS:** Genetically engineered animals are not being discussed by the public or the private sector. The media rarely reports on the topic and, in fact, many Israelis do not actually understand what a GE animal is. There is general knowledge from international media that cloning exists (i.e. Dolly the sheep), but specific information is very limited. Future concerns regarding GE animal products will likely focus more on kosher issues than on the source of the animal.
- b) **MARKET ACCEPTANCE/STUDIES:** N/A. It is not on the agenda of the public or private sector, therefore no time and money has been invested in market studies and analysis.