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Israel’s Agricultural Biotechnology Regulations Remain Unchanged

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Report Highlights:

As of October 2019, there are no changes in Israel’s policy towards plant and animal biotechnology compared to 2018. Israel does not have a policy restricting the use of imported genetically engineered (GE) commodities or derivative products. GE crop production is permissible for research purposes. Regulations permit GE commodities and products to be imported, sold, and used for food and feed, as well as for ornamental purposes and pharmaceutical use.

EXECUTIVE SUMMARY

As of October 2019, Israel does not have a policy restricting the use of imported genetically engineered (GE) commodities or derivative products. Israel's [2005 "Seed Regulation for Plants and Other GE Organisms"](#) (GE Seed Regulation) states that the sale of GE crops is not permissible without a valid Registration Certificate, this however, is not being currently enforced. Only GE tobacco has received official approval.

In Israel, GE crop production is allowed for research purposes. Regulations allow GE commodities and products to be imported, sold, and used for food and feed production, as well as for ornamental and pharmaceutical uses. 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 biotechnology (biotech) imports to Israel is not quantified and domestic experimental use is limited. Different countries ship grains and oilseeds to Israel, and a sizable percentage are 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 only for research and development purposes and are not grown commercially. Some genetically engineered plants, such as ornamental flowers, developed in Israel are grown in other markets. No GE animals are produced or imported by Israel.

In October 2013, new draft regulations for novel foods, including food produced using biotechnology, were announced by Israel's Ministry of Health (MOH). It is unclear when the new regulation will be implemented. Due to the political situation related to forming a new government, there is no time frame for the discussion on that topic. After official approval, the measure will come into effect one year following 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. There are no known problems with marketing GE crops in Israel.

In March 2017, the National Committee for Transgenic Plants published a decision stating that genome edited plants resulting only in a deletion of nucleotides and with no insertion of foreign deoxyribonucleic acid (DNA), are not considered to be transgenic and will not be subjected to the GE Seed Regulation. The applicant must, however, 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.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** Israel is an international center for genetic engineering (GE) and research, focusing on improving plant resistance to pests, disease, herbicides, salinity, and drought. Israeli universities, governmental institutes, and the private sector conduct research. Genetic engineering is permitted today in Israel for research and development purposes, subject to conditions established by law.

Israel's [2005 "Seed Regulation for Plants and Other GE Organisms"](#) (GE Seed Regulation) stipulates requirements for conducting research with GE propagation material. All trials are approved by a 13-member National Committee for Transgenic Plants (NCTP), that is chaired by the Ministry of Agriculture's (MOAG) Chief Scientist.

The stages and advances made in GE research are kept as a company secret until registration. During registration, applicants are required to reveal product details to the National Committee for Transgenic Plants. The number of NCTP authorized experiments between the years 2013-17 is presented in the following table. In addition, a partial list of products under research and development is listed in the Field Trials Section.

ISRAEL: National Committee for Transgenic Plants - Authorized Experiments, 2013-17

	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 and FAS Tel Aviv office research.

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

- 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 processes that enable the creation of whole plant and/or animals through genomic imprinting at the cellular level and meet the aforesaid requirements.
- 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: Genetically engineered tobacco is grown in confinement, isolating it from potential pathogens and vectors.] FAS Tel Aviv (Post) anticipates that the GE Seed Regulation policy will change within the coming years. It remains 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 United States and or to other countries contains some biotechnology (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 must mark it accordingly.
- d) **IMPORTS:** Israel imports all soybeans and corn used in food and feed manufacturing – both of which are mainly genetically engineered. In 2018, Israel imported some 439,500 metric tons (MT) of soybeans and 1.6 million MT of corn, of which 98,200 MT and 47,600 MT, respectively, came from the United States. Other supplier origins include South America and the Black Sea. There is no information available specifying the percentage of GE varieties included within these imports.
- e) **FOOD AID:** Israel is not a food aid recipient and is not expected to one be in the future. Israel is not a food aid donor.
- 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. 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 between the Ministries of Agriculture and Health (MOH). The Ministry of Agriculture's Plant Protection and Inspection Service is the competent national authority 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 Ministry of Agriculture is responsible for all trials of genetically engineered plants, as well as those organisms that are directly related to GE plants. These could include pathogens, pollinators, natural enemies, and the like. The Ministry of Agriculture is also responsible for overseeing handling, commercializing, importing, and exporting of GE propagation material.

Within Israel's legal and regulatory framework, there are three bodies that have specific roles.

- 1) **The National Committee for Transgenic Plants:** The 13-member NCTP is an inter-ministerial committee. Two members are from the MOAG (the chairperson and deputy), one member from the Ministry of Environment (MOE), one member from the MOH, one member from the Ministry of Science (MOS), 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.
- 2) **The Plant Protection and Inspection Service – Field Inspection Teams:** Field inspection teams from the PPIS enforce the NCTP guidance and regulations related to the handling of GE materials.
- 3) **The Plant Protection and Inspection Service – Laboratory for Molecular Techniques and Transgenic Plants:** The lab manages the identification of GE seeds, vegetative propagation materials, and processed foods. This laboratory uses a “ring test” to determine the presence of GE content in a consignment for import or export. For further information, refer to the [PPIS website](#).

In March 2017, the National Committee for Transgenic Plants published the decision that genome edited plants resulting only in a deletion of nucleotides and with no insertion of foreign deoxyribonucleic acid (DNA), are not considered to be transgenic and will not be subjected to the GE Seed Regulation. The applicant must, however, 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. For more information, see the NCTP Coordinator [presentation on Israel's transgenic plants regulation](#).

Future Regulation

In October 2013, the Israeli Food Control Services (FCS), which is a part of the Ministry of Health, notified the World Trade Organization (WTO) of the draft regulation on novel foods, notification G/TBT/N/ISR/710. The proposed regulation is pending, with further revision expected. The draft regulation entitled [“Public Health Regulations Food – Novel Foods 5773 – 2013”](#) key provisions are:

- 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 “genetically modified organism” 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 used as a material production aid or a food flavoring.

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 the import of food items that include a GE ingredient/component 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.

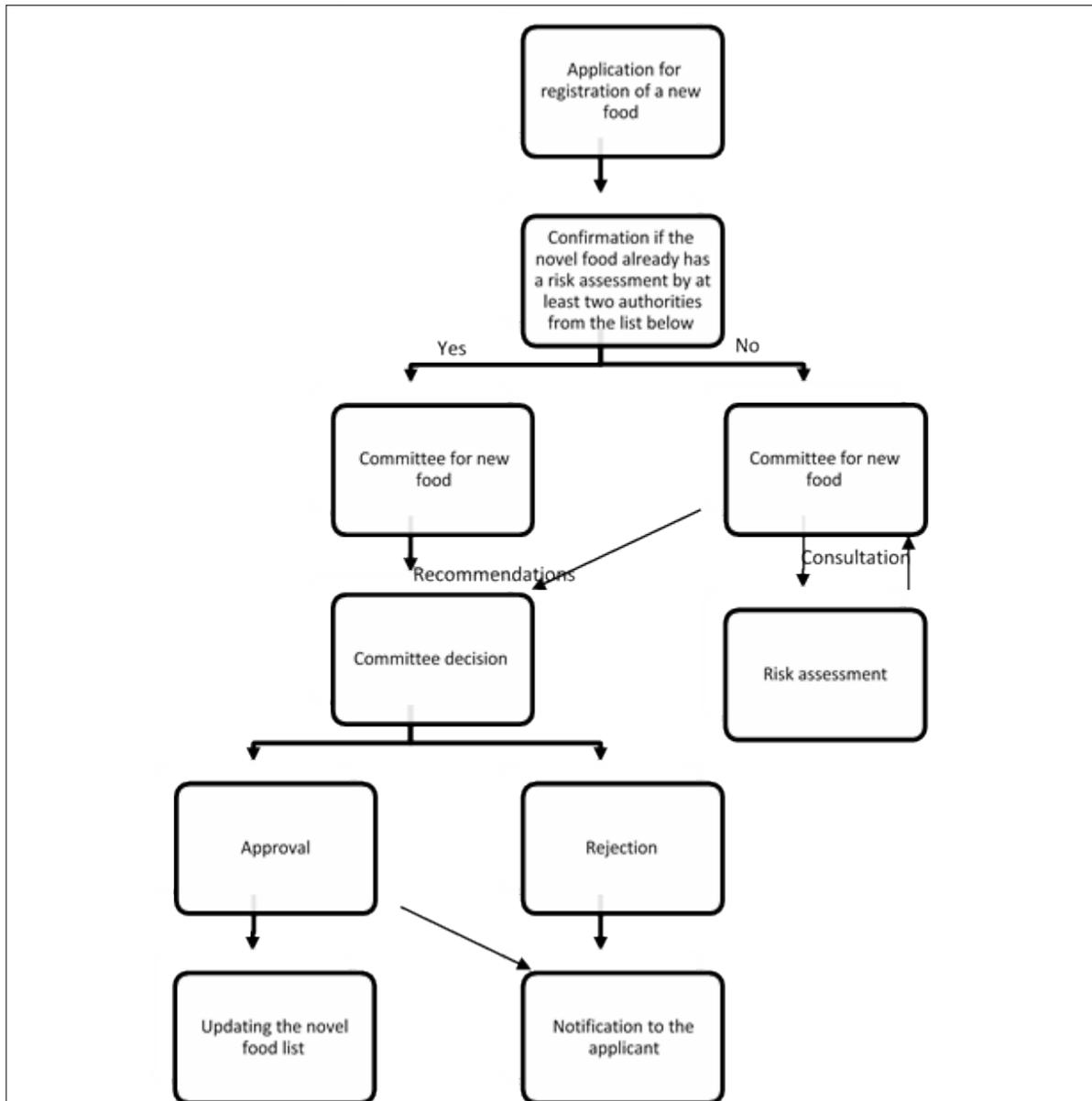
A new risk assessment will not be required for a novel food if it has already been reviewed by at least two of the international associations approved by the head of Food Control Service for risk assessments, which include:

- 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 – Ministry of Health, Labor and Welfare/Department of Food Safety
- Specialist Committees of the *Codex Alimentarius* (including the Food and Agricultural Organization and the World Health Organization).

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

The approval timeline for 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.

ISRAEL: New Novel Food Registration Process



Source: FAS Tel Aviv office research.

- b) APPROVALS:** To date, only GE tobacco to date has been approved in Israel. The National Committee for Transgenic Plants has nonetheless granted approvals for field trials of other crops (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. Experiments must be authorized by the NCTP, based on a complete, detailed application, and consultation with experts. The experiments are under the regulatory supervision of the Plant Protection and Inspection Service.

ISRAEL: Select Firms and Organizations Authorized by the National Committee for Transgenic Plants to Conduct GE Crops/Seeds Experiments and Field Trials (*)

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 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 to 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 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			

NOTE (*): Readers are reminded that Israel does not require this information to be public at the research stage.
Source: NCTP and FAS Tel Aviv office research.

- e) **INNOVATIVE BIOTECHNOLOGIES:** [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. On 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 National Committee for Transgenic Plants must approve the application to work with GE products; it will also solicit the opinion of the National Committee for Experiments (NCE). If the NCE has a doubt regarding the experiment or its location (i.e., 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 Ministry of Health, mandatory labeling is not a deterrence or warning; it exists 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 since 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 component are permissible. Exporters that produce food items from imported raw materials for export would be subject to the destination country’s regulations. That would include any labeling and testing requirements.
- i) **LOW LEVEL PRESENCE POLICY:** N/A
- j) **ADDITIONAL REGULATORY REQUIREMENTS:** Genetically engineered seeds and plants are not commercially planted or grown in Israel for human consumption. Genetically engineered product, as other novel foods, would face regulatory hurdles. Some novel foods, such as red grape cells, are approved for human consumption in Israel under very specific conditions.

- k) **INTELLECTUAL PROPERTY RIGHTS:** Israel is a signatory of the Agreement on Trade-Related Aspects of International Property Rights (TRIPS Agreement) and a member of the International Union for the Protection of New Plant Varieties (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 does not actively participate 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. Despite such (minority) opinions, Israeli consumers continue to routinely purchase GE content products.

As in other countries, many Israeli scientists and researchers working with GE crops favor the technology. Seeing it as a means of supplying global food markets when faced with shortages, plant disease, and environmental stresses.

- 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 Israeli public is currently unconcerned with the issue.

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

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

- a) **PRODUCT DEVELOPMENT:** There is 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. On May 2018, 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 [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 term.
- c) **EXPORTS:** Israel does not export GE animals or offal.
- d) **IMPORTS:** Israel does not import GE animals.
- 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 of Agriculture's Veterinary Branch is responsible for GE animal production experimentation and regulation. All requests for experiments need to pass through it for evaluation and approval. There is no regulation regarding the import of GE animals, the new draft regulation avoids the subject.
- b) **APPROVALS:** N/A
- c) **INNOVATIVE BIOTECHNOLOGIES:** It 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). It however does not actively participate in discussions related to animal biotechnologies.

g) RELATED ISSUES: Genetically engineered 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 of Agriculture's Veterinary Branch is the lead agency.

PART F: MARKETING

a) PUBLIC/PRIVATE OPINIONS: Genetically engineered animals are not being discussed by the public or the private sectors. 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 obtained from the international media that cloning exists (e.g., Dolly the sheep), but specific information remains 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: This is not on the public or private sectors' agenda. No time and or money is being invested in market studies and analysis. Post is unaware of any work in this field.

Attachments:

No Attachments