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POLICY

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Report Highlights:

As of June 2017, Israel does not have a policy that restricts the use of imported genetically engineered (GE) commodities or derivative products. The existing regulation does not permit local commercial production of GE crops in Israel but allows for their development for research purposes, which is not inconsequential. Israeli regulations also allow GE products to be imported, sold and used for the production of food and pharmaceuticals in Israel. Israel is one of a small handful of countries to have decided not to require regulations for certain products of gene editing. In October 2013, the Israeli Ministry of Health (MOH) announced new draft regulations that, once approved, will codify Israeli policy on GE organisms.

EXECUTIVE SUMMARY

As of June 2017, Israel did not have a policy restricting the use of imported GE commodities or derivative products. Existing Israeli regulation does not permit local commercial production of GE crops for human consumption; however, crops not for human consumption may be produced if approved. Current regulations do allow for production for research purposes. Israeli regulations also allow GE commodities and products to be imported, sold, and used for the production of food, 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 as such and domestic experimental use is limited. Different countries ship grains and oilseeds to Israel and, for commodities like corn and soybeans, a sizable percentage is likely from biotech varieties. The only GE crop that is currently permitted to be grown commercially in Israel is tobacco, which is engineered with human genes and used by the cosmetic and pharmaceutical industry. All other GE crops that are grown in Israel are for R&D purposes only and not grown commercially. No GE animals are produced in Israel or known to be imported. Some GE plants developed in Israel are now being grown in other markets, such as ornamental flowers.

In October 2013, new draft regulation announced by the Israeli Ministry of Health (MOH), called "[Public Health Regulations Food – Novel Foods 5773 – 2013](#)" and was notified to the WTO as G/TBT/N/ISR/710. It is unclear when the new regulation will be implemented. After official approval, the measure will come into effect one year after publication in Israel's Official Gazette. Under the proposed regulation, *novel foods* are defined as products that:

- Contain 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 [Note that this could include gene edited products];
- Contain a GMO or part of one;
- Contain plants, animals, microorganisms, fungi, algae or extracts thereof, and do not contain enzymes that are not proven safe for human consumption in Israel;
- Were 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;
- Are not food additives that were previously approved in the food additive regulation;
- Are not food ingredients that were previously approved in the food ingredient regulation;
- Are not a material production aid or a food flavor.

Under the proposed regulation, novel foods must be registered and go through a risk assessment process before being approved. The link for registration can be found [online](#). If approved, the product must then be registered in order to be manufactured, imported, stored, or sold. Approved and registered novel foods will be on an official list. Additionally, the approved GE products will have to be labeled as

“genetically modified” or, if sold in bulk, signage will have to note the same. Products exempt from labelling are those for which the GE products:

- Do not contain DNA and protein, or
- For which less than 0.9 percent of the product is comprised of ingredients derived from a GE organism.

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 their use; therefore, there are no known problems with marketing GE crops in Israel today.

The National Committee for Transgenic Plants’ most recent committee decision, published in March 2017, confirms 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 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 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 (R&D) 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 research of GE are kept as a company secret until registered. In registration, applicants are required to reveal product details to the NCTP. A partial list of products under research and development is listed in the Field Trials Section.
- 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 is a GE tobacco plant, deemed innocuous as it is not in the food chain. 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 2016, 370,000 MT of soybeans and 1,364,000 MT of corn were imported into Israel, out of which 78,000 MT and 427,000 MT, respectively, came from the US. 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, which could potentially block them from the market. The responsibility for labeling will fall to the local importers and distributors.

PART B: POLICY

- a) **REGULATORY FRAMEWORK:** Currently, the 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 requirements 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 National Committee for Transgenic Plants (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. An example application produced by the NCTP can be found in APPENDIX 1. 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. This laboratory is managed by FAPAS England.

The National Committee for Transgenic Plants' most recent committee decision, published in March 2017, confirms 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 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*. The proposed regulation is still pending and further revision is expected. 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.

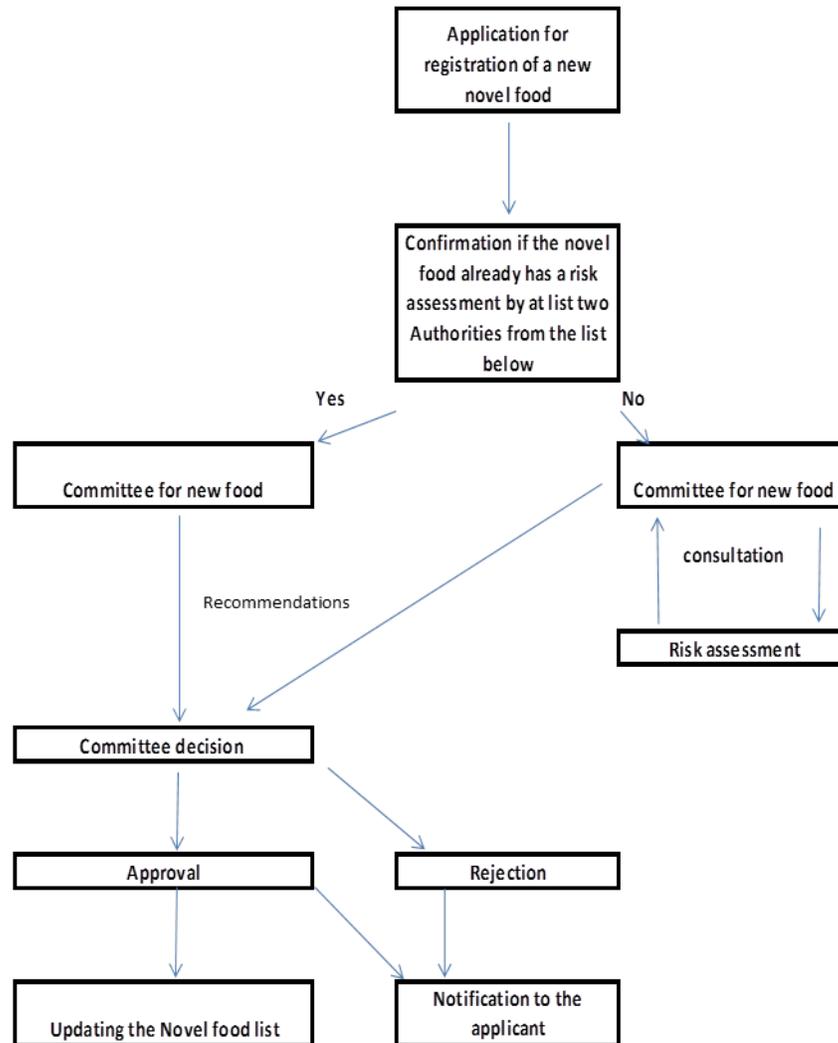
Novel food definition: Under the draft regulation, the scope of the definition "novel food" is limited to food or food ingredients that meet the following requirements:

- 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 aids 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:



The international associations approved by the head of food inspection services for risk assessments currently include:

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

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 done 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:** 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.
- 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 the firms and organizations that have a valid authorization by the NCTP for experiments and trials using GE crops or seeds:

- **Evogene:** Studying resistance for insects, diseases and herbicides and crop enhancement and drought tolerance. They are working with corn, soybean, cotton, banana, castor seeds and canola.
- **CollPlant:** Using GE tobacco plants with human genetics to produce collagen for cosmetic and medical purposes. Some of their products are already in the market while others are at different development and approval stages. They hold the approval of the NCTP to commercially produce in Israel GE tobacco plants under strict regulations. Currently eight producers are growing GE tobacco on a total of 2.5 Hectares. This plant is exceptional and the approval for growing it was given due to the fact that the tobacco is not part of the food chain.
- **Danziger Innovations:** Working with vegetables, woody and ornamental crops. This firm developed ornamental flowers that are now being grown in Kenya using Israeli technology.
- **FuturaGene:** Studying woody biomass and biotic/abiotic stresses.
- **Kaiima:** Improving yield enhancement and biotic/abiotic stresses. They are working with vegetables (mainly tomatoes and peppers) and also grains, such as corn, rice, canola and wheat.
- **Protalix:** They are working on developing recombinant therapeutic proteins for the pharmaceutical markets. They work with carrot and tobacco plants.
- **Rosetta Green:** Working to locate and develop unique genes so as to develop seed strains of crops suitable for biofuels and food. The firm is researching corn, wheat, rice, soybean, cotton, canola and algae.
- **TargetGene:** Studying DNA editing solutions in living organisms and plants.
- **Morflora:** Improving plant disease resistance. They are working with wheat, pepper, grapes, oranges and olives.
- **Plantarche:** No available information regarding their work.
- **Governmental and academic centers:** Also authorized to research GE crops.

- 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.
- 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 organisms. 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 foods.

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 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. That 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 and 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:** N/A
- l) **CARTAGENA PROTOCOL RATIFICATION:** Israel did not sign 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 GMOs.

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 very little 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.
- 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 importing of GE animals and the new draft regulation avoids the subject.
- b) **INNOVATIVE BIOTECHNOLOGIES:** Post is unclear on how gene edited animals may be treated in the future.
- c) **LABELING AND TRACEABILITY:** There is no policy for the traceability and labeling of GE animals.
- d) **INTELLECTUAL PROPERTY RIGHTS:** N/A
- e) **INTERNATIONAL TREATIES and FORUMS:** Israel is a member of Codex Alimentarius and also a member of the World Organization for Animal Health (OIE) but does not actively participate in discussions related to animal biotechnologies.
- f) **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 very limited specific information. 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, and, as yet, no time and money has been invested in market studies and analysis.

APPENDIX 1: APPLICATION FOR GE APPROVAL

משרד החקלאות / Ministry of Agriculture
ועדה ראשית לצמחים מהונדסים (ורצ"מ) /
National Committee for Transgenic Plants (NCTP)

בקשה לרישוי ניסויים בצמחים מהונדסים (צ"מ) * ויבוא

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

(המידע בבקשה ישמש לרישוי ניסויים בלבד בצ"מ, מ"א ויבוא עבורם.
לשחרור לסביבה ולמסחר נדרש מידע ואישור נוספים לבקשה מתאימה נפרדת).
(This information will be used to determine eligibility to receive permit for experiments
with genetically modified plants & microorganisms and their import. For release to
environment permit, additional information will be required)

הועדות המטפלות בבקשה זו רשאיות לספק מידע בלתי מסווג המופיע בבקשה /או הנלווה אליה לכל חוקר
או גורם מוסמך שיבקש זאת ממנה. חוקר המעוניין שמידע מסווג המופיע בבקשה /או הנלווה אליה יסווג
ולא יופץ יציין זאת בעת הגשת הבקשה והועדות המטפלות בה תתייחסנה לכך.

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.

הוראות: יש למלא את כל הפרטים הנדרשים, בעברית ובאנגלית, ולצרף מידע נוסף לפי הרשימה.
Instructions: Complete this form and enclose the supporting information listed.

פרטי הניסוי: מס' (למילוי ע"י ורצ"מ) No. Experiment details:

תאריך Date _____

מטרת הניסוי: _____

Aim of experiment: _____

סוג האישור המבוקש Type of permit requested

* חדש New חידוש Renewal

* לניסויים ברמת מעבדה/חממה/שדה (כולל יבוא) For experiments
In the lab. / greenhouse/ field (including import).

* לייבוא For import

* ומיקרואורגניזמים (מ"א) הקשורים אליהם
** GMO= Genetically Modified Organisms

פרטי המבקש The applicant

שם: Name _____

תואר: Title _____

Address

כתובת המוסד/המחלקה

טלפון/פקס: _____ Telephone/fax

Application details

פרטי הבקשה

שם מדעי: _____ שם מקובל ו/או מסחרי _____
שם הזן: _____

Common or Trade name: _____ Scientific name _____

תאור החומר הגנטי **Description of the genetic material**

פרט: מקור הגנים המוחדרים, מקבל הגנים, דרך העברה (הוקטור), אתר ההחדרה (גרעין/חוץ גרעין) ופרטי התוצר (יש לצרף מפה) להלן: _____

Designation of transformed line:

Phenotype:

Construct; Genotype (promoter; gene; enhancer; terminator):

Selectable marker (promoter; gene; terminator):

המקור לקבלת החומר לנסוי/יבוא * _____ Origin of the regulated article

התחייבות

1. הנני מאשר בזאת שכל המידע בבקשה זאת ובנספחיה הוא למיטב ידיעתי והכרתי מלא, נכון ומדויק.
2. הנני מתחייב לנהוג בעת פעילותי עם צמחים ומ"א מהונדסים לפי כל ההוראות והכללים של נוהל בטיחות מוסדית, ורצ"מ ותנאי הרישוי.
3. הנני מתחייב להודיע לוב"מ על מועד תחילת ותום הניסוי והצעדים שנקטו לשם סיומו והשמדת החומר הביולוגי.

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 biosafety committee & the national committee procedures and the license conditions.
- c. I hereby certify to report to the institutional biosafety committee about the initiation & termination of the experiment and the measures taken for termination & disposal of the biological material.

חתימה: _____ תאריך: _____

Date: _____ Signature: _____

למילוי ע"י יחיד רבי"מ * Complete by the responsible person

Name _____ : שם

Title _____ יו"ר רבי"מ מרכז ולקני : תואר

Address _____ כתובת: מחלקה לחקר תוצרת חקלאית לאחר הקטיף ת.ד. 6 בית דגו

Institute biosafety procedure _____ נוהל הבטיחות במוסד

Name & Aim of the experiment _____ שם הניסוי ומטרות

Date of application received _____ תאריך קבלת הבקשה

Notification of application received _____ הודעה על קבלת הבקשה

Experiment facility checked _____ מתקן הניסוי נבדק

Experiment labeling _____ סימון הניסוי

Emergency measures checked _____ אמצעי החירום נבדקו

Application & attachment details checked _____ פרטי הבקשה והנספחים נבדקו

Signature & Date: _____ חתימה ותאריך:

Application approved _____ /אשור הבקשה במוסד/

application was sent for further review _____ הבקשה נשלחה לרבי"מ לאשור

Comments _____ הערות

Signature & Date: _____ חתימה ותאריך:

הודעה על אשור הניסויים נשלחה לרבי"מ ולחוקר
Notification of application approval was sent to the NCTP & the applicant.

Signature & Date: _____ חתימה ותאריך:

הודעה על תחילת/תום הניסוי נשלחה לרבי"מ
Notification of start/termination of the experiment was sent to the NCTP

Signature & Date: _____ חתימה ותאריך: