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Taiwan

Biotechnology

Local Stagnation and Smooth Approvals

2007

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Report Highlights:

While Taiwan has been following a science based approach to approving new events on imported products, promising locally developed events languish in laboratories. This is partly due to the fact that events are being developed by research institutions and the teams necessary to construct dossiers do not exist. It is also due to the uncertain political environment that an approved event would face. Some attention is also being focused on Taiwan's potential role as an exporter of biotechnology, but this will require an industrial structure similar to that required for commercializing an event within Taiwan.

Includes PSD Changes: No
Includes Trade Matrix: No
Annual Report
Taipei [TW1]
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Executive Summary

Taiwan has adopted a fairly rational regulatory environment for imported products derived from biotechnology. Product reviews for corn and soybean events are relatively smooth, but no food safety assessments have been completed for a locally developed event. Nine events have been approved for field testing, two events have completed field testing, and trials continue on the remaining seven. A ring spot resistant papaya has conditionally passed field trials. Rules controlling the cultivation of biotech crops are still under development.

Taiwan is the U.S.'s sixth largest agricultural export market. In 2006, the United States exported more than \$2.5 billion of agricultural, fish and forest products to Taiwan, of which biotech products worth over one billion USD. U.S. soybean exports totaled \$565 million, while corn exports were valued at \$473 million. Taiwan is the third largest export market for U.S. corn and fourth largest market for U.S. soybeans.

Taiwan's Department of Health (DOH) is the lead agency in granting approval to biotech products intended for food use while the Council of Agriculture (COA) regulates events intended for agricultural use. COA also regulates the field testing and environmental releases of new biotech products.

According to Taiwan's current biotech regulations, prior market approval for biotech soybean and corn imports is required for food, feed or processing use (FFP use). Import approval is also required for all GM plants for environmental release or cultivation. Biotech food labeling for certain corn and soy products and approval of all corn and soy events became mandatory on January 1, 2003. At the same time, Taiwan began a four-year phase in of mandatory labeling of bioengineered (GM) food, beginning with selected soybean and corn products.

Biotechnology Trade and Production

Production

Taiwan's commercialization policy may switch to focus on biotechnology export, but Taiwan researchers will face the same difficulties in commercializing crops in other markets that they face in Taiwan. In spite of several promising events in laboratories and in field trials, Taiwan has yet to legally commercialize a biotech crop. Some of the reasons for this are political, and others are purely practical. The researchers in Taiwan academic institutions have no experience putting an event through a regulatory process. Regulations for controlling the cultivation of biotech crops are still under development.

Reportedly, a ring spot resistance GM papaya, which conditionally completed its field-testing in July 2003, has leaked out to commercial orchards from the developer's laboratory. Taiwan has found GM papaya in the market places from its GM food market surveillance inspection results. COA has clarified its biotech production position that growing and/or marketing the unapproved GM papaya on Taiwan is a violation of the Plant Variety and Plant Seeds Act to the farm community and that violators will be fined one to five million New Taiwan Dollars (NTD). COA has also established GM papaya screening testing points at nursery farms.

Taiwan produced papaya has been allowed to entry the Japan market since February 2005. Taiwan exported 36 tons of papaya, valued at \$172,000 to Japan in 2006. Despite the tiny papaya trade to Japan, Taiwan government has been extremely careful about its biotech papaya commercialization as Japan has been the largest export market for Taiwan agricultural products and biotech engineered papaya has yet to be allowed entry into Japan.

Reportedly, the ring-spot resistant papaya is the same variety as the one exported to Japan market.

Development

There are no biotechnology crops under development on Taiwan that are expected to be on the market soon. However, several rice, fruit and vegetable varieties are on field trails. In addition to crop events, several pharmaceutical applications on GM animals are in field trails. Taiwan has established public field trails facilities under the Council of Agriculture (COA) affiliated research institutes for crop and animal, while infrastructure for fishery trials are under construction. COA celebrated in late April 2007 its grand opening of GM plants field trial facilities in Taiwan Agriculture Research Institute (TARI) located in central Taiwan.

Imports

Taiwan is the U.S.'s sixth largest agricultural export market. In 2006, the United States exported more than \$2.5 billion of agricultural, fish and forest products to Taiwan, of which biotech products worth over one billion USD. U.S. soybean exports totaled \$565 million, while corn exports were valued at \$473 million. Taiwan is the third largest export market for U.S. corn and fourth largest market for U.S. soybeans.

According to Taiwan's current biotech regulation, it requires prior market approval for GM soybeans and corn imports for food, feed or processing use (FFP use) and requires import approval for all GM plants for environmental release or cultivation.

Food Aid

Taiwan is not a food aid recipient nor is it likely to be one in the near future.

Production of Non-U.S. Approved Varieties

Taiwan does not produce commercial quantities of biotechnology crops that were developed outside of the United States but have not passed through the U.S. regulatory system. Taiwan is field-testing varieties that have not passed through the U.S. regulatory system.

Biotechnology Policy

Regulatory Framework

The proposed Biotech Basic Law is no longer, at least for now, being considered, and Taiwan is moving toward a U.S. style interagency approach. DOH is responsible for food safety risk assessment while the Council of Agriculture (COA) has oversight on events to be used in livestock and crop production or aquaculture. COA is also responsible for the environmental risk assessment for new events. The Bureau of Standards, Metrology, and Inspection (BSMI) under the Ministry of Economic Affairs is responsible for import inspection. BSMI currently assists DOH in monitoring grain and oilseed shipments for the presence of biotech events. BSMI takes samples at the ports of entry for DOH's subsidiary agency, the Bureau of Food and Drug Analysis (BFDA) to conduct monitory import inspections on biotech soybean and corn events. BFDA also conducts market surveillance testing for all biotech food products, not limited to corn and soybeans and compliment of biotech labeling regulation. National Science Council (NSC) supervises safety laboratory works in biotechnology. The top authority of Taiwan biotechnology regulatory system is held by an appointed minister without portfolio, the convener of the advisory committee for GM products special task force and the Science and Technology Advisory Group (STAG) under Executive Yuan serves as Secretariat to the interagency advisory GM products special task force.

The announcement of draft revision of biotech food safety evaluation guidelines is scheduled in mid-year, and the guidelines on stacked traits will be announced following, anticipated the

second half of the year. Early reports are that the revised guidelines are similar to Codex and if there is no interaction between stacked events and the events have already been approved additional reviews will not be required. Reportedly, the new draft guideline on stacked events approval is similar to the one implemented in Mexico and Japan. By the end of 2008 DOH expects to extend its regulatory regime to biotech crops other than corn and soybeans. DOH has also funded a Consultative Center for local crop developers to go to for help in going through the food safety regulatory process. On the other hand, DOH is establishing laboratory chains for running tests to build capacity for food safety evaluation submission for locally developed biotech products.

The current Taiwan agricultural biotechnology regulations are only applied to soybeans, corn and products of soybean and corn. No bioengineered soybeans or corn may be produced, processed, prepared, packed, and imported or exported unless they are registered and approved by DOH Food Safety Bureau (FSB). Taiwan has approved 15 of the most widely commercialized bioengineered corn and soybean events. See appendix table for a list of these 15 biotech varieties as of June 27, 2007. For update list please visit a web link at: <http://food.doh.gov.tw/chinese/info/gmo5.htm>

Taiwan implemented regulations for LMOs under the terms of its amended Plant Variety and Plant Seed Act, which went into effect June 9, 2005. Its related regulations and rulings can be found at:

<http://law.moj.gov.tw/eng/fnews/Fnmore.asp?lawType=c>. (This web link is built for browsing entire Taiwan regulations or regulatory environment, not limited for agricultural biotechnology.)

The “Rules for Approving Import/Export Transgenic Plants” were announced on July 7, 2005. Commodities for food, feed and processing use have been excluded from the ruling and are not required to apply for additional approval registration to the Taiwan authority at the Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ). The web link is at:

<http://www.baphiq.gov.tw/ct.asp?xItem=9693&ctNode=1811&mp=1> (only Chinese version is available online. See appendix for unofficial English translation.)

GM Food Approval Process

To gain DOH food safety approval, a biotech event must be reviewed by the Genetically Modified Food Safety Advisory Committee (GMFSAC), which is composed of 16 outside experts who evaluate dossier submitted by the life science companies. The committee is drawn mostly from the medical and academic communities, of which recruited committee members account for above one-half of the entire committee. The three-year term of the current committee began January 2007. The current committee is more efficient in terms of number of events granted approvals in recent months compared to the previous committees (see the list of approval events as of June 27, 2007). This is because the majority of committee members have built up biotech food safety assessment experience in the fields of food toxicity and allergenicity, which are of concerns of food safety in most of submissions.

On the other hand, DOH is adopting international standards of Codex and is revising its Guidelines for Food Safety Assessment. Reportedly, the to-be published for comments revised Guidelines will classify submissions for approval into three classes associated to degree of easiness of review process in terms of granting a approval; easy case - no allergenicity and/or toxicity concerns, moderate case - have allergenicity and/or toxicity concerns, and difficult case - new cases which are different from all submitted and reviewed cases. DOH has also drafted Guidance for Industry or Researchers for Dossier Submission to

assist the biotech industry or researchers in going thru regulatory approval process. The Guidance for Industry for Submission is anticipated in 2008.

Approvals

Below is a list of all biotech products approved on Taiwan for food, feed and processing (FFP). No product has been approved for environmental release (planting). Although COA has not yet amended its feed control act to adopt food or feed ingredients derived with biotechnology, it is likely to follow a policy of approving products for food and feed use after the Starlink incident. As a practical matter, and unofficially, DOH currently approves biotech events for both food and feed use.

Table: Taiwan Approved Biotech Products

Current Approvals of Genetically Modified Foods in Taiwan

Update: 27 June 2007

UNIQUE IDENTIFIER	PRODUCT	NAME	EVENT	APPLICANT	DATE OF APPROVAL	NOTE
MON-04032-6	Soybean	Glyphosate tolerant Roundup Ready Soybean	40-3-2 (RRS)	Monsanto Far East Ltd., Taiwan Branch	July 22 , 2002	Expiration: July 22, 2012
MON-00810-6	Corn	Insect-resistant YieldGard Corn	MON810	Monsanto Far East Ltd., Taiwan Branch	October 15 , 2002	Expiration: October 15, 2007
MON-00021-9	Corn	Glyphosate tolerant Roundup Ready Corn	GA21	Monsanto Far East Ltd., Taiwan Branch	July 22 , 2003	Expiration: July 22,2008
MON-00603-6	Corn	Glyphosate tolerant Roundup Ready Corn	NK603	Monsanto Far East Ltd., Taiwan Branch	April 11 , 2003	Expiration: April 11, 2008
SYN-BT011-1	Corn	Insect-resistant & Glufosinate tolerant corn	Bt11	Syngenta Taiwan Ltd.	June 2 , 2004	Expiration: June 2 , 2008
SYN-EV176-9	Corn	Insect-resistant & Glufosinate tolerant corn	Event176	Syngenta Taiwan Ltd.	June 2 , 2004	Expiration: June 2 , 2008
ACS-ZM003-2	Corn	Glufosinate tolerant corn	T25	Bayer CropScience	August 16, 2002	Expiration: August 16, 2012

DAS-01507-1	Corn	Insect-resistant & Glufosinate tolerant corn	TC1507	DuPont Taiwan	November 17, 2003	Expiration: Nov. 17, 2008
DKB-89614-9	Corn	Insect-resistant & Glufosinate tolerant corn	DBT418	Monsanto Far East Ltd., Taiwan Branch	October 16, 2003	Expiration: October 16, 2008
DKB-89790-5	Corn	Glufosinate tolerant corn	DLL25	Monsanto Far East Ltd., Taiwan Branch	October 20, 2003	Expiration: October 20, 2008
MON-00863-5	Corn	Insect-resistant, YieldGard Rootworm Corn	MON863	Monsanto Far East Ltd., Taiwan Branch	October 16, 2003	Expiration: October 16, 2008
DAS-59122-7	Corn	Insect-resistant & Glufosinate tolerant corn B.t Cry34/35Ab1	59122	DuPont Taiwan	December 21, 2005	Expiration: December 21, 2010
MON-88017-3	Corn	YieldGard Rootworm/ Roundup Ready Corn	MON88017	Monsanto Far East Ltd., Taiwan Branch	March 20, 2006	Expiration: March 20, 2011
REN-00038 -3	Corn	Lysine Maize	LY038	Monsanto Far East Ltd., Taiwan Branch	November 20, 2006	Expiration: November 20, 2011
ACS-GM005-3	Soybean	Glufosinate tolerant Soybean	A2704-12	Bayer CropScience	May 1, 2007	Expiration: May 1, 2012

Note: Taiwan event approvals last for five years. These products are approved only for FFP and not for planting.

Field Testing

In 1998 COA approved guidelines for field-testing of new crop and livestock events. More detailed regulations were published in November 2002, "Regulation for the Field Trial of Transgenic Breeding Livestock (Fowl) and the Bio-Safety Assessment," and June 2005, "The Administrative Regulations for the Field Testing of the Transgenic Plants". Field-testing regulations for aquaculture are still missing. However, the December 2002 edition of the Fisheries Act, Article 69, states that all transgenic fish shall be approved and have completed field-testing prior to commercialization.

On April 21, 2004, Taiwan amended its Plant Variety and Plant Seed Act by adding a new regulation for bioengineered seeds. Imported planting seed varieties are required to pre-register and approve with the Council of Agriculture (COA). Enforcement rules were available and effective on July 7, 2005. GM planting seeds for exportation shall be also compliant to the enforcement rules.

GM Plants

Nine events were granted approval for running field testing for biosafety assessment, and their testing results are as follows.

Two events completed field testing, one conditionally passed and the other didn't pass biosafety assessment. In July 2003, Taiwan conditionally approved a GM ring spot virus resistant papaya. In June 2006, Taiwan disapproved one phytase rice variety developed by a private company, GeneTaiwan Co.

Seven events currently undergoing field testing for biosafety assessment.

1. Sweet rice for processing developed by Academia Sinica
2. Latoferris rice developed by National Chung Hsing University
3. Delay ripening broccoli developed by Academia Sinica
4. Phytase potato developed by Academia Sinica
5. Cucumber mottle mosaic virus resistance tomato developed by Asia Vegetable Research Development Center (AVRDC)
6. Eucalyptus for pulping developed by COA affiliate Taiwan Forestry Research Institute
7. New developed ring spot and leaf distortion mosaic virus resistance papaya applied for field-testing.

Livestock

Gene cloned and transgenic pigs, cows and goats for biopharmaceutical uses have been or are being developed, but none of them have undergone field-testing. Taiwan is currently establishing Standard Operation Practices (SOP) for field-testing.

Stacked Events

Taiwan is still developing its position on stacked events. DOH contracted out a research project to a state-and-industry funded institute, Food Industry Research and Development Institute (FIRDI) to review other economies' regulations on stacked events. FIRDI completed its study by the end of 2006 and made a recommendation and proposed draft regulations for stacked events for DOH consideration. Developed countries' regulations on transgenic animals, microorganisms and second-generation biotech products are also being reviewed by FIRDI.

Non-Biotech Coexistence

Taiwan does not yet have a policy on coexistence between biotechnology and non-biotechnology crops. Its interest in co-existence is arising. As Taiwan doesn't have its coexistence policy, no biotech crop will be released for planting at the present time. One of the chief problems is an unrealistic demand from some quarters for no gene flow.

Labeling

Taiwan's bioengineered food safety approval and labeling regulation took effect on January 1, 2003. Mandatory labeling of bioengineered food was phased in over a two to four year period. Beginning in January 2005, all food made of biotech soybean or corn is required to label. The tolerance level is 5 percent.

The labeling regulations do not apply to products that do not contain pieces of transgene(s) or protein such cornstarch, corn syrup, corn oil, soy oil, and soy sauce. However, labeling may be introduced for food made of non soy and corn ingredients in the future.

On all biotech food labels, the Chinese character size should not be smaller than 2x2 mm. The label should be put adjacent to soybean or corn in the finished products ingredients list or in other easily visible place on the package. There is no standard required format. Note: Soybean or corn food products that are not packaged for retail sale are not subject to the GM food labeling requirement – this includes the large volume of products sold in wet markets and restaurants.

Soybean and corn food products made of non-GM materials can be labeled Non-GM or Not-GM Soybean and while corn food products made of non-bioengineered materials may be voluntarily labeled non-Genetically-Modified. The implementation date for voluntary Non-GM food labeling was January 1, 2001. If there is no biotech alternative available, a product may not be labeled “Non-GM”. DOH has actually forced the re-labeling of such products as “Non-GMO Coffee.”

According a market surveillance inspection result conducted by DOH annually, about 95 percent of food on the market was compliance Taiwan biotech food labeling regulation.

Biosafety Protocol

Taiwan cannot sign the Cartagena Protocol on Biosafety because it is not internationally recognized as a sovereign state. However, in the past, Taiwan has unilaterally implemented some international agreements and is expected to incorporate Cartagena guidelines into its import-export regulation governing biotech products for seeds and planting (see appendix). COA's Bureau of Animal and Plant Inspection and Quarantine (BAPHIQ) is the lead agency on the issue.

Trade Barriers unlikely

There have been no trade disruptions of U.S. biotech product exports. Taiwan's approval process has become increasingly efficient since the third GMFSE Committee is formed and acting in January 2007. The Genetically Modified Food Safety Advisory Committee (GMFSAC) meetings are delayed some times because members are academics with heavy outside commitments such as giving lectures and grading exams. But the committee has mostly overcome the meeting schedule problem and has enhanced communications among committee members and government and industry. Delays of locally developed products such as biotech rice and vegetables are due primarily lacks of capacity for run lab works and compiling data and capability for writing dossiers for food safety assessment and the lack of a favorable political environment.

Pending Legislation

The Executive Yuan (Cabinet) is currently reviewing an interagency-proposed comprehensive biotech basic law covering agricultural and pharmaceutical biotechnology development. The law may also cover areas such as intellectual property rights, the biosafety protocol, as well as food and environmental safety. The law will serve as regulatory framework for all regulations that govern biotechnology. As the proposed basic biotech law is comprehensive one, its final draft is still pending. The current system is similar to the U.S. interagency system.

Technology Fees

While there is likely some illegal cultivation of biotech papaya, Taiwan does not commercially plant any other biotech crops.

Marketing

Consumers

With exception of organic food consumers who are generally skeptical about biotech foods, most consumers are not aware of biotech food. In general, they continue to purchase food in bulk from traditional wet markets and eat traditional Chinese breakfasts with made with biotech soymilk. Despite this, consumption of processed non-biotech food such as soymilk and tofu is gradually increasing because local food companies use non-GM promotion as a marketing tool to create imagine that non-GM is better or value food.

Producers/Importers

As current labeling regulation governs soy or corn food products, some food packers are now promoting foods made of non-GM corn or soybeans. The food producers, who make products in bulk without labeling, generally ignore existence of biotechnology and emphasize their traditional business. Local wheat millers have also warned that they will reject GM wheat while Taiwan feed millers mostly pay attention to trade issues such as biotech product approvals and/or prevention of import disruptions.

Retailers

Except specialty organic food retailing, most of retailing stores stay neutral and provide diversity brands or types food products, both non-biotech and biotech. As of reporting date, there is no country specific study on the marketing on biotech food available.

Capacity Building and Outreach

Taiwan's substantial agricultural research infrastructure, sound legal system, favorable climate and very strong information technology base have been contributed to its ability to develop a world-class biotech sector. In addition, a science-based regulatory system and relative lack of anti-biotech protectionist interests has given the public confidence in the safety of biotech foods.

The primary focus is to build upon these strengths by enhancing Taiwan's regulatory capacity and explaining the benefits of biotechnology to the public. AIT has focused heavily on regulatory cooperation, creating linkages between the biotech sectors on Taiwan and in the United States and working with the media.

Past Activities

AIT Taipei has been actively engaged in a series of U.S. Government and USDA-funded capacity building and outreach activities related to agricultural biotechnology. In reverse chronological order, major activities include:

September 2007: AIT, National Taiwan University, and the Council of Agriculture, and several regional agriculture institutions cosponsored a biotechnology training course for government officials and regulators from across Southeast Asia.

September 2006: AIT and CroLife Taiwan cosponsored a Workshop on Safety Assessment of Transgenic Crops at National Taiwan University to promote science-based safety assessment for GM crops. Dr. Alan McHughen, Dr. Robyn Rose and Dr. James Maryanski were invited to Taiwan to conduct the workshop.

June 2006: CropLife Asia invited Dr. James H. Maryanski, a former regulatory official with the U.S. Food and Drug Administration (FDA), currently manages a consulting business that provides expert advice on issues related to food safety for food crops and products developed using modern biotechnology (bioengineered or GM foods), to visit Taiwan. Dr. Maryanski

delivered a speech and talk on "International Standards of the safety of food derived from Modern Technology" to students and faculty members of National Taiwan University.

March 2006: Ms. Madelyn Spirnak, the State Department Senior Supervisor for Agricultural Biotechnology, visited Taiwan on her way to Thailand. Ms. Spirnak met with Taiwan regulators, officials and consumer foundation representatives to discuss the benefits of agricultural biotechnology and the adoption and development of biotechnology in other countries.

February 2006. Willy De Greef, a plant biologist with extensive experience in tropical crop breeding in Congo, Malawi and Cameroon, and in technology transfer related to agricultural biotechnology was invited by COA thru USGC's Taiwan office. He delivered presentations on "Risk Assessment and Management" and from "R&D to the Market" to Taiwan researchers and regulators to improve the commercialization of research. Planning commercialization at the beginning stage of laboratory work is a key to adoption.

In addition to AIT-led efforts, the U.S. Grain Council, American Soybean Association offices and CropLife Asia have very active biotech programs on Taiwan.

USGC continued supporting local media reporters attending Bio Conference held in the United States in the spring and supporting Taiwan officials attending its International Agricultural Biotechnology Information Conference in the fall each year to facilitate biotechnology communication.

In addition to seminars, there will be workshops on environmental and food safety assessment and a communication program for media and academia as budget is available.

Reference

Useful Websites

<http://law.moj.gov.tw>
<http://www.doh.gov.tw>
<http://www.coa.gov.tw>

Appendix: Rules Governing Approval Import/Export Transgenic Plants

MEASURE ON IMPORT/EXPORT PERMIT OF TRANSGENIC PLANT

Promulgated July 7, 2005

Council of Agriculture #0941490342

Article 1

The Measure is developed based on the first Clause Article 52 of "The Act of Plant Variety and Plant Seed" (referred as "the Act" hereafter.)

Article 2

Transgenic plants referred to in this Measure are categorized into two types based on their claimed purpose of use:

1. For propagation or planting use.
2. For testing or research and development use in laboratories.

(Note: Clauses under Article 2 stated in the previous draft Measure “For direct use as food or feed, or for processing (FFP)” & “For registration approval for FFP for government agency use” is removed. The draft Articles associated to these two Clauses have been removed from the Measure.)

Article 3

For the import of transgenic plant for propagation or planting use based on Clause 1 Article 2 of the Measure, the importer shall file a letter of application to the central competent agency. The application submission shall include the following information and accompany documents. The importer can only start the import process after the import permit is granted.

Required information:

1. Name, phone and address of the importer;
2. The production country, export country and departure port;
3. Name and quantity of the transgenic plant to be imported; and
4. Purpose and use of the imported transgenic plant.

Required accompanying documents:

1. The approval documents as stated in Clause 2 Article 52 under the Act;
2. Origin of the host plant and information of the host transgenic plant’s botanical characteristics, propagation and pollination etc.;
3. Origin of the donor of transgene(s) and information on characteristics and function of the transgene(s);
4. Packaging method and labeling; and
5. Transportation routes, methods and the safety handling measures to be taken during transportation in both the domestic and abroad.

Article 4

For imports of transgenic plants for testing or research and development use in laboratories according to Clause 2, Article 2 of the Measure, the importer should file a letter of application to the central competent agency. The application submission shall include the following information and accompany documents. The importer can only start the import process after the import permit is granted.

Required information:

1. Name, phone and address of the importer;
2. The production country, export country and departure port;
3. Name and quantity of the transgenic plant to be imported; and
4. Purpose and use of the imported transgenic plant.

Required accompanying documents:

1. Origin of the host plant and information of the host transgenic plant’s botanical characteristics, propagation and pollination etc.;
2. Origin of the donor of transgene(s) and information on characteristics and function of the transgene(s);
3. Location and a miniature map of the testing or research and development institution or laboratories;
4. Diagram of facilities and equipments in the testing or research and development institution;
5. Plan of staffing involved in the testing, or research and development;
6. Organization of a biosafety committee and the list of the committee members;
7. Safety control plan for the imported transgenic plant;

8. Packaging method and labeling; and
9. Transportation routes, methods and the safety handling measures to be taken during transportation in both the domestic and abroad.

The biosafety committee stated in Clause 6 under Article 4 of the Measure shall comprise of four to eight members who are experts in biotechnology, crop breeding, biodiversity, plant protection or related fields.

Article 5

For export of transgenic plants, the exporter shall file a letter of application with required information and accompanying documents specified below, to the central competent agency. The applicant can only start the export process after the export permit is granted.

Required information:

1. Name, address and phone number of the exporter;
2. Name and quantity of the transgenic plant to be exported; and
3. Purpose and use of the exported transgenic plant.

Required accompanying documents:

1. Origin of the host plant and information on the host plant's botanical characteristics, propagation and pollination etc.;
2. Origin of the donor of the transgene(s) and information on characteristics and function of the transgene(s);
3. Packaging method and labeling;
4. Transportation routes, methods and the safety handling measures to be taken during transportation in both the domestic and abroad; and
5. Import approval issued by the import country.

Article 6

In order to verify the nature of imported transgenic plants, the central competent agency shall take samples free of charge from the imported goods during entrance. The importer of the transgenic plants shall not deny such request.

Article 7

The central competent agency shall grant confidentiality to exporters or importers of transgenic plants who request to the central competent agency for protection of the confidential information about their business as described important parts in the production method of the transgenic plant.

Article 8

For the application for export or import permit of transgenic plants, the central competent agency shall make a final decision for approval or rejection by the following deadlines.

1. For a paper reviewing application case, the central competent agency shall conclude the application case regardless approval or rejection within 60 days starting from the effective application date. If the central competent agency cannot conclude the application case, the approval or rejection deadline shall be allowed to extend for once and only one time.
2. For an application case that requires sample testing in addition to paper reviewing, the approval or rejection deadline is 270 days starting from the effective application date.

Article 9

The central competent agency will announce and publish the format of application forms and other required accompanying documents.

Article 10

This measure will take into effect from the date it is promulgated.

Taiwan's GM Food Registration Procedures

To register a biotech food in Taiwan, petitioners must follow the GM Food Registration Regulation, which is outlined below:

GM Food Registration Regulation

- Definition of Genetic Modified Technique

Genetic modification technique is a technique that applies genetic engineering or molecular biology to transfer or insert genetic material into a living cell or organism resulted in genetic modification of the cell or organism. The technique does not include conventional breeding, cell and protoplast fusion, hybridization, mutagenesis, in vitro fertilization, somatic mutations, and chromosome amplification.

- The applicant is required to submit the following information to DOH to register a GM food:

1. The completed registration form.
2. Background information about the applicant.
3. Data on characteristics of the GM food being registered.
4. Synopsis of the GM food's safety assessment.
5. Food safety assessment report on the GM food.
6. Literature list (references and relevant research papers) on the GM food

A one-kilogram sample is required along with an application fee of NT\$100,000, or approximately U.S. \$3,025.

Note: (1) the registration form is available on the DOH website at <http://food.doh.gov.tw>

- With exception of the B5-food safety assessment report and B6-literature, all submitted information must be in Chinese. It has to be typed using specified computer software, font style and size. The DOH requires submitted information both in hard copy and on a 1.44 MB, 3.5" diskette. It has to be printed in A4 size paper.

- If the original information for B1-B4 is in languages other than Chinese, it must then be translated into Chinese by a translation agency or translator registered/recognized by the Taiwan authorities.

- The GM food labeling regulation took effect on January 1, 2003. As of that date all GM soybean and corn foods may not be produced, processed, prepared, packed, and imported or exported, unless they are approved by DOH.

Comment: According to DOH's Food Safety Bureau (FSB), Taiwan's Bioengineered Food Safety Assessment Methods are similar to those used in Japan and U.S. The FSB has also expressed a willingness to accept a Food Safety Assessment package that is submitted to and accepted by advanced countries. End Comment.