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Report Highlights:

Taiwan is the sixth largest agricultural market for the United States and imported almost one billion U.S. dollars of U.S. biotech products in 2005. While trade has not been interrupted, the approval process for new events has been slow due to the requirement for consensus and an academic rather than risk management approach by some regulators. Lack of political support and a strategy for commercializing locally developed events means that several promising products are being wasted, researchers are becoming frustrated, and the support base for biotechnology is weak.

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Executive Summary

Taiwan is the U.S.'s sixth largest agricultural export market. In 2005, the United States exported more than \$2.4 billion of agricultural products to Taiwan, including \$986 million in biotech products. U.S. soybean exports totaled \$430 million, while corn exports were valued at \$556 million. Taiwan is the third largest export market for U.S. corn and fourth largest market for U.S. soybeans.

Taiwan has adopted a fairly rational regulatory environment for products derived from biotechnology. 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.

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.

Although all currently exported corn and all soy varieties have been approved, the slowness of the food safety assessment process for new-to-market events threatens to disrupt trade in the future. Taiwan is considering a new biotech basic law as a regulatory framework to develop biotechnology, but its final draft is still pending. It is not clear if approval of local events requires a new basic law. However, in June 2005, Taiwan implemented import-export and labeling and packaging regulations for transgenic plants, and revised field-testing regulations. Taiwan is also expected to eventually require the registration of all foods, not just corn and soybean events, and is currently reviewing its GM food assessment guidelines. Taiwan is also considering extending its GM food regulation to stacked events and GM microorganisms and their derived products in food.

Although Taiwan's organic food sector continues to expand rapidly, partly driven by labeling requirements, biotech marketing has so far not been a major problem on Taiwan.

Biotechnology Trade and Production

Production

Taiwan does not commercially produce any biotech crops.

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 that growing and/or marketing the unapproved GM papaya on Taiwan is a violation of the Plant Variety and Plant Seeds Act and that violators will be fined one – five million New Taiwan Dollars (NTD).

Development

There are no biotechnology crops under development on Taiwan that are expected to be on the market within the next year. However, several rice, fruit and vegetable varieties will likely enter the market in the next five years.

Imports

Taiwan is the U.S.'s sixth largest agricultural export market. In 2005, the United States exported more than \$2.4 billion of agricultural products to Taiwan, including \$986 million in

biotech products. U.S. soybean exports totaled \$430 million, while corn exports were valued at \$556 million. Taiwan is the third largest export market for U.S. corn and fourth largest market for U.S. soybeans.

Taiwan's import/export regulation of GM plants covers environmental release, not food, feed or processing use (See regulation in reference section.)

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

Taiwan's biotechnology food regulations are based on the Food Sanitation Law, last amended in 2002. However, the law makes no specific mention of biotechnology, which is governed by Department of Health (DOH) regulations.

On Feb. 23, 2001, DOH promulgated regulations on bioengineered food labeling and registration. These regulations applied to soybeans and corn and their products and became effective on January 1, 2003. Currently, no bioengineered soybean and corn may be produced, processed, prepared, packed, and imported or exported unless it has been registered and approved by DOH's Food Sanitation Bureau (FSB).

The Department of Health 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.

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 outside experts who evaluate materials submitted by the life science companies. The committee is drawn mostly from the medical and academic communities. Although the process is often slow and cumbersome, deliberations usually follow sound science.

Although Taiwan is considering a new biotech basic law, it is still in draft form. However, in June 2005, Taiwan implemented import-export and labeling and packaging regulations for transgenic plants, and revised field-testing regulations. These regulations are available on line at <http://law.moj.gov.tw/Eng/Fnews/FnewsList.asp?gid=345000000G>. Taiwan is also expected to eventually require the registration of all biotech foods, not just corn and soybean events, and is currently reviewing its GM food safety assessment guidelines, which are posted online at <http://www.doh.fda.tw.com>. Taiwan is also considering extending its GM food regulation to stacked events and GM microorganisms and their derived products in food.

In December 2005, DOH launched research projects to improve Taiwan's capacity in GM food safety assessment, and to establish a third party food safety consultation service to facilitate

GM food risk communication between DOH, life science companies, GM product developers, and consumers. DOH set a goal of helping local developers meet domestic and international GM food standards. DOH also supports GM food safety assessment research focusing on a particular product or a particular field such as toxicity, allergenicity, composition and analysis, unexpected effects, and/or animal test etc.

Although DOH is mostly left to regulate biotechnology without overt political interference, in the past Taiwan's legislature has considered laws that would seriously impair market access for biotech food in Taiwan. Lawmakers may reintroduce a bill into the Legislative Yuan that would effectively ban foods containing biotech events. First proposed in 2002 and again in 2003, the measure was defeated both times. In addition, a law imposing a "compensatory" tax on all products of biotechnology was introduced in 2002, but did not get out of committee. The tax would have been used to indemnify persons for damages caused by biotechnology, but also would have had a chilling effect on biotechnology investment in Taiwan.

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

As of May 30, 2006

CROP	EVENT	COMPANY	Description
Soybean <i>Glycine max</i> L.	GTS 40-3-2	Monsanto Company	Glyphosate tolerant soybean variety produced by inserting a modified 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) encoding gene from the soil bacterium <i>Agrobacterium tumefaciens</i> .
Corn/Maize <i>Zea mays</i> L.	176	Syngenta Seeds, Inc.	Insect-resistant maize produced by inserting the cry1Ab gene from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> . The genetic modification affords resistance to attack by the European corn borer (ECB).
Corn/Maize <i>Zea mays</i> L.	B16 (DLL25)	Monsanto Company	Glufosinate ammonium herbicide tolerant maize produced by inserting the gene encoding phosphinothricin acetyltransferase (PAT) from <i>Streptomyces hygroscopicus</i> .
Corn/Maize <i>Zea mays</i> L.	BT11 (X4334CBR, X4734CBR)	Syngenta Seeds, Inc.	Insect-resistant and herbicide tolerant maize produced by inserting the cry1Ab gene from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> , and the phosphinothricin N-acetyltransferase (PAT) encoding gene from <i>S. viridochromogenes</i> .
Corn/Maize <i>Zea mays</i> L.	DBT418	Monsanto Company	Insect-resistant and Glufosinate ammonium herbicide tolerant maize

			developed by inserting genes encoding Cry1AC protein from <i>Bacillus thuringiensis</i> subsp <i>kurstaki</i> and phosphinothricin acetyltransferase (PAT) from <i>Streptomyces hygrosopicus</i>
Corn/Maize <i>Zea mays</i> L.	GA21	Monsanto Company	Introduction, by particle bombardment, of a modified 5-enolpyruvyl shikimate-3-phosphate synthase (EPSPS), an enzyme involved in the shikimate biochemical pathway for the production of the aromatic amino acids.
Corn/Maize <i>Zea mays</i> L.	MON810	Monsanto Company	Insect-resistant maize produced by inserting a truncated form of the cry1Ab gene from <i>Bacillus thuringiensis</i> subsp. <i>kurstaki</i> HD-1. The genetic modification affords resistance to attack by the European corn borer (ECB).
Corn/Maize <i>Zea mays</i> L.	MON863	Monsanto Company	Corn root worm resistant maize produced by inserting the cry3Bb1 gene from <i>Bacillus thuringiensis</i> subsp. <i>kumamotoensis</i> .
Corn/Maize <i>Zea mays</i> L.	NK603	Monsanto Company	Introduction, by particle bombardment, of a modified 5-enolpyruvyl shikimate-3-phosphate synthase (EPSPS), an enzyme involved in the shikimate biochemical pathway for the production of the aromatic amino acids.
Corn/Maize <i>Zea mays</i> L.	T25	Bayer CropScience (Aventis CropScience(AgrEvo))	Glufosinate herbicide tolerant maize produced by inserting the phosphinothricin N-acetyltransferase (PAT) encoding gene from the aerobic actinomycete <i>Streptomyces viridochromogenes</i> .
Corn/Maize <i>Zea mays</i> L.	TC1507	Mycogen (c/o Dow AgroSciences); Pioneer (c/o Dupont)	Insect-resistant and Glufosinate ammonium herbicide tolerant maize produced by inserting the cry1F gene from <i>Bacillus thuringiensis</i> var. <i>aizawai</i> and the phosphinothricin N-acetyltransferase encoding gene from <i>Streptomyces viridochromogenes</i> .
Corn/Maize <i>Zea mays</i> L.	DAS-59122-7	Dow AgroSciences & Pioneer(c/o DuPont)	Glyphosate herbicide tolerance and resistance to corn root worm (Coleoptera, <i>Diabrotica</i> sp.). Coleopteran insects western corn rootworm (<i>Diabrotica virgifera</i>), northern corn rootworm (<i>D. barberi</i>), and Mexican corn rootworm (<i>D. virgifera zea</i>) by producing insecticidal proteins (delta-endotoxins). Three novel genes, were introduced into the maize hybrid line Hi-II using <i>Agrobacterium</i> -mediated transformation.

Corn/Maize <i>Zea mays</i> L.	MON88017- 3	Monsanto Company	Glyphosate herbicide tolerance and resistance to corn root worm (Coleoptera, <i>Diabrotica</i> sp.). The transgenic maize line MON 88017 was genetically engineered to resist the western corn rootworm (<i>Diabrotica virgifera</i>) and northern corn rootworm (<i>D. barberi</i>) by producing an insecticidal protein, and to express tolerance to the herbicide glyphosate. Two novel genes, a variant of the <i>cry</i> 3Bb1 gene and <i>cp4 epsps</i> , were introduced into the maize line LH198 using <i>Agrobacterium</i> -mediated transformation.
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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

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. There are six GM plants currently undergoing field testing for biosafety assessment. They are:

1. Sweet rice for processing developed by Academia Sinica
2. Phytase rice developed by Academia Sinica
3. Latoferris rice developed by National Chung Hsing University
4. Delay ripening broccoli developed by Academia Sinica
5. Phytase potatoe developed by Academia Sinica
6. Cucumber mottle mosaic virus resistance tomato developed by Asia Vegetable Research Development Center (AVRDC)
7. Eucalyptus for pulping developed by COA affiliate Taiwan Forestry Research Institute

Plus, there is one 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 its 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 will make a recommendation or propose draft regulations for stacked events by the end of 2006. 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.

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 with certain soybean and corn products on January 1, 2003.

Mandatory bioengineered food labeling took effect on January 1, 2003 for raw soybeans and corn, soybean meal/flour, and corn grit/meal/flour.

Labeling requirements for primary processed soybean and corn food products, such as tofu, soy milk, soy curd, frozen corn, canned corn, soy protein came into effect on January 1, 2004.

Labeling was required for processed soybean and corn food products from January 1, 2005.

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 other food products 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.

Labeling threshold: Taiwan uses a 5 percent tolerance level by weight to determine a product's bioengineered status and for bioengineered food labeling.

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."

These rules are in place primarily because Taiwan authorities support a consumer's right to know. They do not see labeling as a food safety issue.

According a market surveillance inspection result conducted by DOH late 2005, 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. COA's Bureau of Animal and Plant Inspection and Quarantine (BAPHIQ) is the lead agency on the issue and serves as Secretariat of Biotech Interagency Task Force under the cabinet, Executive Yuan's Biotech Industry Guidance Committee.

Trade Barriers

There have been no trade disruptions of U.S. biotech product exports. However, Taiwan's approval process has become increasingly slow. The Genetically Modified Food Safety Advisory Committee (GMFSAC) meetings are delayed because members are academics with heavy outside commitments such as giving lectures and grading exams. In addition, since they are not professional regulators, committee members can lack an understanding of the regulatory process. In addition, the process is slowed further since the committee works on the principle of consensus. The slowness of the food safety assessment process threatens to disrupt trade, and may also delay the introduction of Taiwan-developed products such as biotech rice and vegetables.

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. Post will report any concrete details of the new law as they become available. As the proposed basic biotech law is comprehensive one, its final draft is still pending.

Technology Fees

Taiwan does not commercially plant any 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 of marketing by local producers and slowly increasing consumer awareness of biotech.

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:

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.

November 2005: CropLife Asia invited Dr Bruce Chassy, professor, University of Illinois at Urbana-Champaign, and Dr. Ian Munro, former Health Canada official and consultant of CANTOX Health Sciences International, to visit Taiwan regulators to exchange views on GM food toxicity analysis.

November 2005: A symposium of the TECRO/AIT agricultural science and technology of program took place in Taipei. Many agricultural biotechnology research projects were presented. The symposium also provided U.S. and Taiwan regulators and researchers, who participated in U.S.-Taiwan agricultural Science and technology cooperation programs, with an opportunity to exchange views on development of agricultural biotechnology.

October 2005: John P. Cherry, Director of Eastern Regional Research Center, Agricultural Research Service, U.S. Department of Agriculture broke away from an International Meeting of Biocatalysis and Biotechnology held at National Chung Hsin University to present "an Overview of Technology Transfer Program of USDA/ARS" to COA agricultural researchers, university students and faculty members.

September 2005. Alan McHughen, Professor of University of California-Davis, a public sector educator, scientist and consumer advocate was invited by COA to deliver a presentation on "Tracability" and "Risk Management" of biotech products.

August 2005: Dr. Sujatha Sankula of National Center for Food and Agricultural Policy (NCFAP) led a delegation consisting of Dr. Karim M. Maredia, Professor of Michigan State University-East Lansing and Dr. Bruce Chassy, professor of University of Illinois at Urbana-Champaign to Taiwan. They delivered presentations on the benefits of agricultural biotechnology and biosafety issues in agricultural biotechnology to academia and industry and held a media communication section with local print media. The goal of this seminar was to familiarize Taiwan journalists with agricultural biotechnology issues.

June 2005: Biotech Week. Series of events in Taipei, Tainan and Taichung led by Dr. Kalidas Shetty, U.S. State Department Fellow aimed at facilitating commercialization of Taiwan-developed biotech products, establishing bilateral research linkages and deepening public acceptance of biotech products. Speakers included representatives of three life science companies. Participants included 450 researchers, businesspeople government officials, and general public.

April 2004: Joint U.S. Biotech Regulator Visit to Taiwan. U.S. biotech regulators from EPA, FDA and APHIS visited Taiwan to meet with counterpart Taiwan regulators and held a public seminar on U.S. and Taiwan regulatory system for agricultural biotechnology.

September 2003: Taiwan Media Training Trip to United States. AIT led a delegation of seven Taiwan journalists on an Agricultural Biotechnology Professional Development visit to Washington, DC and St. Louis, MO. The activity aimed to overcome threats to the marketing of U.S. biotech food products by educating the local media on the benefits of agricultural biotechnology as well as its food and environmental safety.

September 2002: Taiwan Media Training Seminar in Taipei. The goal of this seminar was to familiarize Taiwan journalists with agricultural biotechnology issues.

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 in the fall of 2006.

Reference

Useful Websites

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

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" are 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.