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Approved By:
Mark Petry

Prepared By:
Chiou Mey Perng and Andrew Anderson-Sprecher

Report Highlights:
Taiwan imported over a billion dollars of U.S. genetically engineered (GE) crops in 2016, accounting for approximately a third of total U.S. agricultural exports to the island. Anti-GE activists and legislators continue to push for increased restrictions on GE products. While the Legislative Yuan (LY) and regulators have so far rejected proposals to dramatically restrict GE products in Taiwan, the overall policy environment and direction remains challenging.

Section I. Executive Summary:

Taiwan imported $3.34 billion dollars of U.S. agricultural products in 2016, making it the United States' seventh largest agricultural export market. Over a billion dollars of this was comprised of GE corn, soybeans, and cotton. The United States is the largest supplier of GE crops to Taiwan, followed by Brazil. Expanded GE labeling requirements have increased demand for non-GE soybeans, although the total volume remains small compared to conventional soybeans. Canada is the primary exporter of non-GE soybeans to Taiwan.

Researchers in Taiwan have developed GE rice, fruit, vegetables, and ornamental fish. However, Taiwan has not yet approved any GE crops for domestic cultivation due to a lack of public acceptance. GE fluorescent fish, currently under field trial, are likely to be Taiwan's first commercialized biotech product. A Taiwan developer of a ring spot virus-resistant GE papaya variety claims that their GE papaya completed confined and open field trials in 2003, but Taiwan authorities have not confirmed whether the product passed field trials or is eligible to apply for cultivation approval. Regardless, the developer submitted an application for food use premarket approval in late 2016.

In February 2015, Taiwan amended the Feed Control Act to give the Council of Agriculture (COA) responsibility for regulating GE feed ingredients. Previously, all approvals were handled by TFDA. COA has completed its review of GE traits already approved by the Taiwan Food and Drug Administration (TFDA) and has also issued one-year approvals for three GE alfalfa traits. Importantly, there were no trade interruptions during this regulatory transition period.

Anti-GE activists and legislators have been successful in advocating for increased restrictions on GE crops. In 2015, Taiwan increased regulations for GE products, expanded GE labeling requirements, and banned GE products from school lunches. In June 2017, COA notified a new rule creating a separate tariff codes for soybeans for food and feed use. The change was made at the request of anti-GE legislators who hope to ban GE soy from food use. The Legislative Yuan and regulators have so far rejected proposals to dramatically restrict GE products in Taiwan. However, the overall policy environment and direction remains challenging.

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT: Taiwan is a highly technical, very well educated society. On the island, scientists have implied technology to develop biotech rice, broccoli, potato, bitter gourd, tomato, papaya, banana, calla lily, and orchids. Taiwan has not approved any GE crops for domestic cultivation due to a lack of public acceptance. One Taiwan developer reported that its ring spot virus-resistant GE papaya completed field trials in 2003. However, Taiwan regulators have not publically confirmed whether the product passed field trials or is eligible to apply for environment release approval. Nevertheless, the developer submitted a premarket approval application to TFDA for food use in late 2016 and it is being evaluated.

b. COMMERCIAL PRODUCTION: None. While there is ongoing research in Taiwan, commercial cultivation on the island is unlikely in the near future due to public opposition. Taiwan regulators also cite concerns over how to manage coexistence between organic, biotech, and conventional crops given that the average farm size is just over one hectare.

c. EXPORTS: None.

d. IMPORTS: Taiwan imported $3.34 billion of U.S. food and agricultural products in 2016, making it the United States seventh largest export market. GE corn, soybean, and cotton accounted for approximately a third of this total. Many processed products from various countries also contain some biotech ingredients. The United States is Taiwan's largest supplier of GE crops, followed by Brazil.

   Expanded GE labeling requirements has driven up demand for imports of non-GE soybeans. Imports of non-GE soybeans increased 22 percent in 2016, to 72,000 tons. Imports for the first eight months in 2017 are up another 18 percent. Canada is the largest supplier of non-GE

soybeans to Taiwan, enjoying a 60 percent market share. Taiwan established separate tariff codes for GE and non-GE corn and soy in November 2014.

e. FOOD AID: Taiwan is a developed economy and does not receive or require food aid. It does provide some food aid to third countries, but none of the aid consists of GE products.

f. TRADE BARRIERS: The Legislative Yuan amended the School Health Act on December 30, 2015 to ban GE food from the school lunch program (see GAIN report TW15050). Some legislators have also proposed banning GE soy for all food use. On June 14, 2017, Taiwan notified to the WTO (G/SPS/N/TPKM/438) that it plans to create separate tariff codes for soybeans for food and feed use. Anti-GE groups and legislators requested the creation of the new tariff codes. They have also asked TFDA to lower the MRL for glyphosate on food use soybeans from 10 ppm to 0.1 ppm, which is perceived as a thinly veiled effort to block the importation of GE soy for food use. TFDA has so far declined to change the MRL, noting that there is no scientific or food safety basis for making such a change.

PART B: POLICY

a. REGULATORY FRAMEWORK: TFDA is responsible for food safety assessments, including pre-market approval, GE labeling, and traceability. TFDA conducts import inspections and market surveillance inspection on food products.

In February 2015, Taiwan amended the Feed Control Act to give COA responsibility for regulating GE feed ingredients. COA also administers trans-boundary movement of living modified organisms (LMOs) and bio-safety assessment for environmental release. COA is currently drafting a bill to transfer field trial regulatory oversight responsibilities to its central office in order to tighten environmental risk management.

The Ministry of Science and Technology supervises the overall safety of biotechnology laboratory work. The final authority for Taiwan's biotechnology regulatory system resides with the Board of Science and Technology (BOST) under the Executive Yuan. BOST is in charge of interagency coordination at the ministerial level on Taiwan's science and technology policy, including agricultural biotechnology.

The specific regulations governed by COA are:

- "Administrative Regulations for the Field Testing of the Transgenic Plants" (2014/03/05)
- "The Regulations for Packaging and Labeling of Transgenic Plants" (2005/06/29)
- "Regulations for Approving Import/Export of Transgenic Plant" (2005/07/07)
- "Feed Control Act" (Amended 2015/02/04).
- "The Plant Variety and Plant Seed Act" (2010/08/25)
- "Regulations of Permission and Inspection on Genetically Modified Feed or Feed Additives" (2016/01/04)

b. APPROVALS: Taiwan's Act Governing Food Safety and Sanitation, all GE products for food

use must be registered and approved by TFDA. As of November 9, 2017, TFDA has granted registration approvals for 129 products. This includes 58 single biotech events (16 soybean, 23 corn, 13 cotton, 5 canola, and 1 sugar beet events), and 71 stacked events (10 soybean, 45 corn, 12 cotton and 4 canola stacked events). The list of current TFDA approvals can be found on the TFDA website. COA has completed feed safety reviews for biotech events already approved by TFDA. COA also issued one-year approvals for three alfalfa events. The alfalfa registrants have already begun the process of applying for renewal.

Regulatory reviews are conducted by COA and TFDA's Genetically Modified Feed and Food Review Committees. The committees are composed of 17-23 experts specializing in biotechnology, microbiology, animal, food nutrition and/or other related fields. The committees meet approximately every two months to review GE product premarket registration applications. Committee members are subject to two-year terms.

c. STACKED EVENT APPROVALS: Starting from May 2008, Taiwan implemented stacked event registration on the basis of the "Guideline for Food Safety Assessment of Foods Derived from GE plants with Stacked Traits." The guideline applies only to foods produced from GE plants with stacked traits obtained through conventional breeding of single events already approved in Taiwan. The submission of a dossier for any new stacked event will not be accepted by TFDA unless the single events are already approved in Taiwan. Stacked events not obtained through conventional breeding are not eligible to apply for premarket approval.

d. FIELD TESTING: Taiwan promulgated field-testing regulations governing GE plants in May 2005. To date, field trial testing permits have been granted for 11 domestically developed GE events. Only one event - a ring spot virus-resistant papaya – has reportedly completed field trails, but this occurred in July 2003 before the current field trail regulations were promulgated. Cultivation requires COA approval and no approvals have been granted thus far. The seven events listed below have completed field testing but are still pending final biosafety reviews:

1. Sweet rice for processing (Academia Sinica)
2. Lactoferrin rice (National Chung Hsing University)
3. Delay-ripening broccoli (Academia Sinica)
4. Phytase potato (Academia Sinica)
5. Cucumber mottle mosaic virus-resistant tomato (World Vegetable Center)
6. Eucalyptus for pulping (Taiwan Forestry Research Institute)
7. Phytase rice (Academia Sinica)

e. INNOVATIVE BIOTECHNOLOGIES: TFDA is working with a research institute to draft regulatory guidelines for innovative biotechnologies, such as gene editing. Reportedly, a draft guideline on Zinc Finger Nucleases (ZFN) technology, Oligonucleotide-directed Mutagenesis (ODM), RNA-dependent DNA Methylation (RdDM), and Grafting has been completed for the agency's regulatory policy preparedness. Recently, the gene-editing technology clustered regularly interspaced short palindromic repeats (CRISPR)/Cas9, has also been brought up in seminar discussions in Taiwan. However, it's unclear whether Taiwan authorities are supporting CRISPR related research on plant breeding. Nevertheless, marker-assisted selection and other

technologies have been applied broadly in plant breeding programs, according to Taiwan plant breeders.
According to scholars, plant breeders in Taiwan are already using marker-assisted selection.

f. COEXISTENCE: Taiwan does not have a coexistence policy as it does not allow the production of GE crops outside of accredited field trial facilities. However, Taiwan has drafted regulations governing the commercial production of biotech plants, animals, and aquatic plants and animals. Regulations on the propagation and production of aquatic animals and plants were promulgated on April 13, 2011 and then revised on May 24, 2012. No other regulations on the domestic cultivation of GE crops and animals have been finalized.

g. LABELING: Primary products made from GE raw materials, such as soybean oil, corn starch and syrup and soy sauce, are required to be labeled as GE. "Secondary" products made with GE primary products, such as beverages containing corn syrup, are exempted from GE labeling requirements. The length and width of the font must not be less than 2 mm and must be noticeable by different color, font or background. Fines for violating the regulations can range from NT$30,000 (US $1,000) up to NT$3 million (US $100,000). Business licenses can be revoked for serious violations. More information is available on TFDA's website for GM Food Labeling Q&As. Non-GE labeling is only allowed for products for which GE alternatives are commercially available. For instance, coffee is not eligible for non-GE labeling as GE coffee is not commercially available.

h. MONITORING AND TESTING: TFDA conducts import inspections and regular market surveillance inspection on all food products, including GE products. Post is not aware of any recent violations or rejections due to unapproved GE events.

i. LOW LEVEL PRESENCE POLICY: Taiwan does not have a low-level presence policy, therefore, the default level is zero. Any unregistered GE product is considered illegal and unapproved GE products will be destroyed or rejected at the port of entry.

j. ADDITIONAL REGULATRORAY REQUIREMENTS: Registration is valid for one to five years, though in most cases registrations are approved for five years. Renewal is required three months before the expiration date.

d. INTELECTUAL PROPERTY RIGHTS (IPR): According to Article 24 of the Patent Act, Taiwan does not grant patent protection for plants and animals. This article stipulates that "an invention patent shall not be granted in respect of any of the following: animals, plants, and essential biological processes for the production of animals or plants, except processes for producing microorganisms; and that animals and aquatic plants and animals are not protected under this Act."

k. CARTAGENA PROTOCOL RATIFICATION: Given its unique political status, Taiwan cannot sign the Cartagena Protocol on Biosafety. However, Taiwan has implemented some international standards and has incorporated Cartagena guidelines into its Regulations Governing Transboundary Movements of LMOs. COA's Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) is the lead agency. In July 2005, BAPHIQ promulgated the

"Regulations for Approving Import/Export of Transgenic Plant" based on the "Plant Variety and Plant Seed Act". The regulation stipulates that all LMOs must be submitted to BAPHIQ for import/export approvals for environmental release. In addition, the regulation governing propagation and production of aquatic plants and animals (fish) also stipulates that LMOs of aquatic plants and animals must be submitted to the COA Fishery Administration for a permit for trans-boundary movement. To date, only a few import/export records of LMOs have been reported for experimental purposes. COA has established a surveillance program for internal movement of LMOs. The first LMO internal movement surveillance target is GE papaya with batch-by-batch inspection for each commercial papaya seedling transaction, though there is not public information about other surveillance activities in Taiwan.

Anti-GE groups recently raised concerns over GE corn and soybeans spilling into the environment during transportation from the port of entry to feed mills or soybean crushers and urged COA to establish transportation control measures. In July 2017, COA began a two-year monitoring project in response to these concerns. COA is expected to develop regulations governing the transportation of GE crops based on the results of this study.

l. INTERNATIONAL TREATIES and FORUMS: Taiwan participates in Asia Pacific Economic Cooperation (APEC) activities, such as the High Level Policy Dialogue for Agricultural Biotechnology.

m. RELATED ISSUES: On February 5, 2015, TFDA implemented a traceability requirement for food importers of GE raw materials in accordance with the Act Governing Food Safety and Sanitation. Importers and manufacturers of GE products are responsible for establishing traceability systems for GE products. All records must be kept for five years. In November 2014, Taiwan began requiring that GE and non-GE corn and soybeans enter under separate tariff codes. The list of HS codes for GE and non-GE are available here.

PART C: MARKETING

a. PUBLIC/PRIVATE OPINIONS: Anti-GE activists and legislators have been successful in advocating for increased restrictions on GE crops. In 2015, Taiwan increased regulations for GE products, expanded GE labeling requirements, and banned GE products from school lunches. In June 2017, COA notified a new rule creating separate tariff codes for soybeans for food and feed use. The change was made at the urging of anti-GE legislators who hope to ban GE soy from food use. TFDA is working to address consumer concerns by placing additional information on GE approvals on its website. It is also considering implementing a public comment period for GE approvals.

b. **MARKET ACCEPTANCE/STUDIES:** Taiwan expanded GE labeling requirements to bulk products and highly refined products on December 31, 2015 (see GAIN report TW15016). Covered products include tofu and soymilk sold at wet markets, as well as soybean oil. The new labeling requirements have hurt demand for GE soy products. Retailers are increasingly promoting non-GE products, which sell for a large premium over conventional products. Some local soy sauce companies have advertised that they have switched entirely to non-GE soybeans.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

PRODUCT DEVELOPMENT: GE animal research in Taiwan is focused on biopharmaceuticals and ornamental fish. Taiwan is unlikely to develop or approve GE animals for food use in the near future.

The Agricultural Technology Research Institute Division of Animal Technology developed a method for using the mammary gland of transgenic-cloned pigs as a bioreactor to produce coagulation factor IX, and then transferred this technology to a private company for continued research on a treatment for hemophilia. Taiwan National University and the Academia Sinica developed a GE fluorescent fish and transferred production to two private companies. These fluorescent fish are currently undergoing field trial and are likely to be Taiwan's first commercialized biotech product. All of these fluorescent fish are infertile and intended for ornamental use only.

b. COMMERCAIL PRODUCTION: Currently, no GE animals are in commercial production.

c. EXPORTS: None.

d. IMPORTS: None.

e. TRADE BARRIERS: No GE animals have been approved for import.

PART E: POLICY

a. REGULATORY FRAMWORK: COA's Department of Animal Industry is responsible for regulating GE livestock. To date, Taiwan has established only one regulation regarding animal biotechnology: the "Regulations for the Field Trial of Transgenic Breeding Livestock (Fowl) and Bio-safety Assessment" under the Animal Industry Act of November 24, 2010. The COA Fisheries Agency is responsible for aquatic animals and plants. Taiwan has established two regulations guiding biotech fishery products: the "Rules for the Field Trial of Transgenic Aquatic Animals and Plants" and the "Management Rules for Breeding and Production of Transgenic Aquatic Animals and Plants" under the "Fisheries Act" of July 20, 2016.

b. INNOVATIVE BIOTECHNOLOGY: Taiwan has used gene-editing techniques on animals for biopharmaceutical studies, but not for food production.

c. LABELING AND TRACEBILITY: Taiwan regulation require labeling and traceability for GE products. Records must be kept for 5 years.

e. INTELECTUAL PROPERTY RIGHTS (IPR): According to Article 24 of the Patent Act,

Taiwan does not grant patent protection to technology for the development of GE plants and animals. This article stipulates that "an invention patent shall not be granted in respect of any of the following: animals, plants, and essential biological processes for the production of animals or plants, except processes for producing microorganisms; and that animals and aquatic plants and animals are not protected under this Act."

e. INTERNATIONAL TREATIES and FORUMS: Taiwan is a member to the World Organization of Animal Health (OIE). Taiwan has actively participated in OIE activities on diseases prevention. Taiwan also participates in the APEC High Level Policy Dialogue on Agricultural Biotechnology.

f. RELATED ISSUES: None.

PART F: MARKETING

a. PUBLIC/PRIVATE OPINIONS: There have been minimal public conversations or debates on this issue. However, TFDA pays close attention to U.S. FDA statements on GE salmon and the local media reports on any market developments regarding GE salmon.

MARKET ACCEPTANCE: Post is not aware of any studies on consumer acceptance of GE animals in Taiwan for food use. Based on public dialogue and media reports, there appears to be more public acceptance for GE animal-based biopharmaceuticals than GE animals for food use.