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Taiwan

Agricultural Biotechnology Annual

Trade Stable Despite Uncertainty on Biotechnology Policy Direction

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Report Highlights:
Taiwan imported over $3.15 billion dollars of agricultural products from the United States in 2015, roughly one billion of which consisted of genetically engineered (GE) crops such as corn, soybeans and cotton. It imports a similar amount of GE crops from Brazil. Some legislators in Taiwan's Legislative Yuan continue to advocate for restrictions on trade in GE crops despite the importance of imports, including GE crops, in meeting Taiwan's demand for food and feed.

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Section I: Executive Summary

Taiwan imported over $3.15 billion dollars of agricultural products from the United States in 2015, roughly one billion of which consisted of GE crops such as corn, soybeans and cotton. It imports a similar amount of GE crops from Brazil. Some legislators in Taiwan's Legislative Yuan continue to advocate for restrictions on trade in GE crops despite the importance of imports, including GE crops, in meeting Taiwan's demand for food and feed. Taiwan does not produce or export any biotech crops.

The February 5, 2014, Act Governing Food Safety and Sanitation (FSSA) for the first time, require a health risk assessment, pre-market registration approval, labeling, and traceability of all GE products. Prior to this amendment, Taiwan's regulatory scope only covered corn and soybeans. Taiwan implemented a three percent GE threshold and expanded requirements to highly processed products which are primarily made of GE raw materials, such as oils and starches, where transgenic fragments or proteins may not be detected. GE and non-GE products are now required to go through Customs clearance under separate HS codes.

On February 4, 2015, Taiwan amended the Feed Control Act (FCA) under which the Council of Agriculture (COA) became the new competent authority for registration and approval of GE products for animal feed use. This authority currently rests with the Taiwan Food and Drug Administration (TFDA). The FCA amendment provides a two-year grace period; all GE products for feed use are required to register with COA and secure approval by February, 2017. Seed developers have already submitted dossiers to COA for almost all GE events previously approved by TFDA that now require COA approval for feed use. Post does not anticipate any trade disruptions in these previously approved events.

Taiwan authorities recognize that agricultural biotechnology is a potential tool for addressing food security concerns. However, Taiwan regulators remain very cautious about domestic cultivation of biotech crops due to public skepticism and opposition from anti-biotech activists and some legislators. Environmental release for commercial cultivation is unlikely in the foreseeable future and only biotech products for non-food or ornamental use are likely to be approved.

Section II: Plant and Animal Biotechnology

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: Production and Trade

a) PRODUCT DEVELOPMENT

Taiwan is a highly technical and well educated society. On the island, scientists have the implied technology to develop biotech rice, broccoli, potato, bitter gourd, tomato, papaya, banana, calla lily, and orchid varieties such as phalaenopsis and oncidium. Although permits for conducting field trials were granted for several rice, fruit, and vegetable events, none of these products have gone through the regulatory process for commercial cultivation, food, or feed approval.

b) COMMERCIAL PRODUCTION

Not applicable. While there is considerable ongoing research in Taiwan, commercial cultivation of biotech food or feed crops is unlikely in the foreseeable future.

c) EXPORTS

Not applicable. Taiwan does not produce or export any biotech crops.

d) IMPORTS

Taiwan imported over $3.15 billion dollars of agricultural products from the United States in 2015, roughly one billion of which consisted of GE crops such as corn, soybeans and cotton. Taiwan imports a similar amount of GE crops from Brazil.

e) FOOD AID

Not applicable. Given its ample domestic supply of staple rice and its overall economic strength, Taiwan is not currently and is not likely to become a food aid recipient under existing economic conditions. All food aid provided by Taiwan to other countries is non-GE.

PART B: Policy

a) REGULATORY FRAMEWORK

Taiwan has a U.S.-style interagency coordination approach to regulate biotechnology. TFDA is responsible for food safety assessments, including pre-market approval and GE labeling and traceability. TFDA conducts import inspections and market surveillance inspection on food products, including GE products.

Feed ingredients derived from GE products are regulated by COA. Under the FCA of February 4, 2015, all GE products for feed use are required to register with COA and secure approval by February, 2017. Before this date all TFDA approved GE products are allowed for both food and feed use. 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 move current field trial regulatory oversights to its central office to tighten environmental risk management.

The Ministry of Science and Technology (MOST) was established in March 2014 under the Executive Yuan (EY). MOST 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 EY. The BOST office 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 (established 2005/06/29 and amended 2014/03/05)

- The Regulations for Packaging and Labeling of Transgenic Plants (established 2005/06/29)

- Regulations for Approving Import/Export of Transgenic Plant (established 2005/07/07)

- Feed Control Act (Amended 2015/02/04) governing approval registration for feed use.

- Regulations of Permission and Inspection on Genetically Modified Feed or Feed Additives (promulgated 01/04/2016)

b) APPROVALS

Under the FSSA, all GE products for food use must be registered with TFDA and granted approval by February 5, 2016. As of November 16, 2016, TFDA has granted registration approvals for 118 products, including all products currently sold in the market. Approvals are valid for five years, after which they need to be renewed. *The current TFDA approval list can be found here.*

Seed developers have already submitted dossiers to COA for almost all GE events previously approved by TFDA that now require COA approval for feed use. Post does not anticipate any trade disruptions in these previously approved events.

TFDA has a Genetically Modified Food Review Panel (GMFRP) composed of 17-23 experts specializing in areas such as biotechnology, microbiology, and food nutrition. COA established a Genetically Modified Feed Review Panel in spring 2016. The TFDA and COA GMFRPs meet approximately every two months to review applications. The panels also play a role in supporting communication between committee members, authorities, and industry groups. GMFRP members are appointed for two year terms.

c) STACKED EVENT APPROVALS

Taiwan implemented stacked event registration in May 2008. Stacked events developed through conventional breeding of single trait varieties are subject to a "bridging review" of its component single trait events. Stacked events developed through genetic engineering are subject to a full package review as a new registration application. Bridging reviews generally take eight to ten months, while a full package review generally takes around 18 months to complete.

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. Flowering Locus T Phalaenopsis equstris is a new application currently under review. However, only one event - a ring spot virus-resistant papaya – has completed field trails, and this occurred in July 2003 before the field trail regulations were promulgated. Two GE events, Phytase rice and virus-resistant papaya, completed field testing but were not granted final approval. 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 (developed by Academia Sinica)
2. Lactoferrin 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-resistant tomato (developed by the World Vegetable Center)
6. Eucalyptus for pulping (developed by COA-affiliate Taiwan Forestry Research Institute)
7. Phytase rice (originally developed by Academia Sinica and transferred to a private company, The Gene Company)

e) INNOVATIVE BIOTECHNOLOGIES

COA stopped funding agricultural biotechnology research several years ago and has also stopped accepting applications for field testing. Since then research in all types of agricultural biotechnology has been limited.

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.

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 mandatory import inspections and regular market surveillance inspection on all food products, including GE products. TFDA tested U.S. wheat shipments following reports of a limited

number of GE wheat volunteer plants in Washington State, but did not detect any GE wheat. Anti-biotech activists in Taiwan recently cited 2014 TFDA glyphosate testing results to advocate for tighter controls on GE imports, although all the testing results were below Taiwan's current MRL for glyphosate in soybeans.

i) LOW LEVEL PRESENCE (LLP) POLICY

Taiwan does not have an LLP policy. Any unregistered GE product is considered illegal and unapproved GE products will be destroyed or rejected at the port of entry.

j) ADDITIONAL REQUIREMENTS

TFDA registration is valid for one to five years, though in most cases registration is approved for five years. Renewal is required before three months of expiration date.

k) INTELLECTUAL PROPERTY RIGHTS (IPR)

Taiwan does not grant patent protection to technology for development of GE plants and animals based on Article 24 of the Patent Act.

l) 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 this area. In July 2005, BAPHIQ promulgated the "Regulations for Approving Import/Export of Transgenic Plant" on the basis of 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 COA's 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. 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.

m) INTERNATIONAL TREATIES AND FORA

Taiwan participates in Asia Pacific Economic Cooperation (APEC) activities such as the High Level Policy Dialogue for Agricultural Biotechnology.

n) RELATED ISSUES

On February 5, 2015, TFDA implemented traceability requirement for food importers of GE raw materials in accordance with the FSSA. All imported GE products are required to enter under separate HS codes from their non-GE counterparts. Separate HS codes for corn and soybeans (and products thereof) were first mandated on November 1, 2014. Importers and manufacturers of GE products are responsible for establishing traceability systems for GE products from imports. All records must be kept for five years. The list of HS code for GE and non-GE is available here.

PART C: Marketing

a) PUBLIC/PRIVATE OPINIONS
Prior to the FSSA Amendment of February 4, 2014, Taiwan was considered a moderately open market for GE products. GE event applications were reviewed in a timely manner and products were not unnecessarily detained at the border. Retailers offered both GE and non-GE options for popular soybean-based foods. A series of local food safety scandals in recent years, including mislabeled rice and adulterated cooking oil, created public anxiety over food safety and provided an opportunity for anti-GE activists to push for increased regulations. Non-GE labels and products are now becoming dominant in many supermarkets. Sales of GE rapeseed oil have decreased substantially. Imports of non-GE soybeans and rapeseed oil are increasing as a result. Local production of non-GE soybeans is also growing, although it remains small due to limited arable land and high production costs.

b) MARKET ACCEPTANCE/STUDIES
Taiwan's domestic policy process, particularly regarding food safety, is highly susceptible to public influence, including from the highly saturated and active media market. Small consumer groups, media outlets, and individual university professors and legislators can have great influence on legislation and regulations. This has resulted in increased restrictions on biotechnology that are not always science based.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART D: Production and Trade

a) PRODUCT DEVELOPMENT
The Animal Technology Institute Taiwan (now reorganized as the Agricultural Technology Research Institute) successfully transferred technology, which uses the mammary gland of transgenic-cloned pigs as a bioreactor to produce coagulation factor IX, to a private company for continued development for hemophilia treatment. Taiwan's research focus is on biopharmaceutical uses, using biotech animals as molecular ranches.

Taiwan National University and the Academia Sinica transferred ownership of GE fluorescent fish production to two private companies. These fluorescent fish are currently under field trial and are likely to be Taiwan's first commercialized biotech product. All of these fluorescent fish are infertile and are intended for ornamental use only.

GE livestock for food animals in Taiwan is not foreseen in the near future. Currently, no GE animals are in commercial production. Taiwan does not import or export GE animals. Researchers in Taiwan developed GE ornamental fish, but they are not currently traded due to regulatory challenges.

b) COMMERCAIL PRODUCTION
Not applicable. Currently, no GE animals are in commercial production.

c) BIOTECHNOLOGY EXPORTS

Not applicable.

d) BIOTECHNOLOGY IMPORTS
Not applicable.

PART E: Policy

a) REGULATORY FRAMEWORK
The Department of Animal Industry under COA is responsible for regulating GE livestock. To date, Taiwan has established only one regulation regarding animal biotechnology, "Regulations for the Field Trial of Transgenic Breeding Livestock (Fowl) and Bio-safety Assessment" in November 2002. The agency responsible for aquatic animals and plants is the Fisheries Agency of COA. Taiwan has established two regulations guiding biotech fishery products, the" Rules for the Field Trial of Transgenic Aquatic Animals and Plants," which was first promulgated in April 2009 with the most recent version of January 27, 2016; and the "Management Rules for Breeding and Production of Transgenic Aquatic Animals and Plants," of May 24, 2012.

b) INNOVATIVE TECHNOLOGIES
Taiwan has not issued regulations specific to gene editing in animals.

c) LABELING AND TRACEABILITY
Taiwan regulations require a traceability labeling system and for records to be kept for 5 years.

d) INTELLECTUAL PROPERTY RIGHTS (IPR)
Taiwan does not grant patent protection to technology for development of GE plants and animals based on Article 24 of the Patent Act. 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."

f) RELATED ISSUES
No additional information.

PART F: Marketing

a) PUBLIC/PRIVATE OPINIONS
GE livestock for food animals in Taiwan is not foreseen in the near future due to lack of public acceptance. Currently, no GE animals are in commercial production. Taiwan does not import or export GE animals.

b) MARKET ACCEPTANCE STUDIES
None**.**