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Global Agricultural Information Network

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## Taiwan

### Agricultural Biotechnology Annual

#### 2018 Annual Report

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**Report Highlights:**

Taiwan imported over a billion dollars of U.S. genetically engineered (GE) crops in 2017, accounting for over a third of total U.S. agricultural exports to the island. No GE crops or animals have been approved for domestic production. Taiwan authorities are currently debating how to manage new breeding techniques.

## **Section I. Executive Summary:**

Taiwan imported \$3.3 billion dollars of U.S. agricultural products in 2017, making it the United States' seventh largest agricultural export market. Over a third of this total was comprised of corn, soybeans, and cotton. A high percentage of each of these crops are produced with GE varieties in the United States. Moreover, the United States remains 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.

Researchers in Taiwan have developed GE rice, fruit, vegetables, and ornamental fish. However, Taiwan authorities have not yet approved any GE crops for domestic cultivation. GE fluorescent fish, currently undergoing field trials, may be Taiwan's first commercialized biotech product. Despite an initial wave of interest and enthusiasm, most researchers have given up working on agricultural biotechnology in Taiwan as regulatory barriers make it almost impossible for them to commercialize any products they develop.

Taiwan is now at a similar juncture with newer precision breeding techniques, such as gene editing. Taiwan researchers, professors, and breeders are interested in using these technologies to develop products and plant varieties to meet Taiwan's agricultural needs and challenges if there is a supportive regulatory environment. Taiwan authorities are currently discussing internally the appropriate public policies necessary to manage these new emerging technologies.

## **Section II.**

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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. Taiwan agricultural researchers and public breeders are generally encouraged to take on challenging projects and have good laboratory facilities. On the island, scientists have utilized advanced technology to develop biotech varieties of rice, broccoli, potato, bitter melon, tomato, papaya, banana, calla lily, and orchids. However, 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 FDA for food use in late 2016 and it is being evaluated.

- b. **COMMERCIAL PRODUCTION:** None. 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 \$3.3 billion of U.S. agricultural products in 2017, making it the United States' seventh largest export market. Corn, soybean, and cotton accounted for over a third of this total. Most of these crops are produced with GE seed in the United States. The United States is Taiwan's largest supplier of GE crops, followed by Brazil. Additionally, many processed products from various countries also contain biotech ingredients.

Expanded GE labeling requirements in 2015 drove up demand for imported non-GE soybeans in 2016 and 2017. However, the market appears to have internalized the separate supply chain needs for each type of soybean needed and finished balancing overall demand for GE and non-GE soybeans. Imports of non-GE soybeans were up only two percent in the first half of 2018 compared to the year before. Going forward, Canada is the largest supplier of non-GE soybeans to Taiwan.

- 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](#)). This has further increase confusion amongst the public regarding the safety of GE food.

Some legislators and activist groups have proposed additional actions. 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. Taiwan authorities have 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 inspections on food products.

In February 2015, Taiwan amended the Feed Control Act to give COA responsibility for regulating GE feed ingredients. In addition to those new duties, COA also administers trans-boundary movement of “living modified organisms” (LMOs) and bio-safety assessment for environmental release. COA has worked intermittently to combine existing biotechnology related regulations under a new agricultural biotechnology law. It is unclear when, or if, this draft law will be passed.

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"](#) (2005/06/29)
- ["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"](#) ( 2015/02/04).
- ["The Plant Variety and Plant Seed Act"](#) (2018/05/23)
- ["Regulations of Permission and Inspection on Genetically Modified Feed or Feed Additives"](#) (2016/01/04)

- b. **APPROVALS:** All GE products for food use must be approved by TFDA. In addition, all products for feed use require approval by COA. Products such as corn and soybeans that are used for both food and feed require approval by both TFDA and COA. As of November 9, 2018, TFDA has granted registration approvals for 136 products. This includes 59 single biotech events (16 soybean, 23 corn, 13 cotton, 6 canola, and 1 sugar beet events) and 77 stacked events (11 soybean, 50 corn, 8 cotton and 8 canola stacked events). The list of current TFDA approvals can be found on the [TFDA website](#). COA has granted approvals for an additional three GE alfalfa events for feed use.

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. A group of new GE review committee members started in early 2018.

- c. **STACKED or PYRAMIDED 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 trials, but this occurred in July 2003 before the current field trial 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. The research institute previously drafted proposed guidelines for Zinc Finger Nucleases (ZFN) technology, Oligonucleotide-directed Mutagenesis (ODM), RNA-dependent DNA Methylation (RdDM), and Grafting for TFDA's consideration. Taiwan officials have not yet decided on how to manage any new breeding techniques, as individual techniques or as a group. They are closely following how the United States and other countries are managing these new technologies. Taiwan researchers, professors, and breeders have expressed interest in using these new technologies if there is a supportive regulatory environment.
- 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 (soybean oil, corn starch and syrup, soy sauce, etc.) made from GE raw materials are required to be labeled as GE. “Secondary” products (beverages containing corn syrup, etc.) made with GE primary products are exempted from GE labeling requirements.

The labeling regulations state that the length and width of the font must not be less than two mm and must be differentiated by a 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. A product can only be labeled as non-GE if there is a commercially available GE-version in Taiwan. For instance, papaya is not eligible for non-GE labeling as Taiwan has not approved any varieties of GE-papaya (domestic or imported). TFDA conducts annual retail label inspections to evaluate compliance with GE-labeling rules. Labeling compliance was 98.4 percent in 2017 based on 254 samples. Report are available in Mandarin on the [TFDA website](#).

- 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 REGULATORY REQUIREMENTS: A 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.
- k. INTELLECTUAL PROPERTY RIGHTS (IPR): According to Article 24 of the [Patent Act](#), Taiwan does not grant patent protection for plants or 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."
- 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 definitions in the Regulations Governing Transboundary Movements of LMOs.

COA's Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) is the lead agency for movement of LMOs in Taiwan. 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 approval. In addition, the regulation governing propagation and production of aquatic plants and animals (fish) also stipulates that aquatic plant and animal LMOs 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 use in confined experiments. COA has established a surveillance program for internal movement of LMOs. The first LMO internal movement surveillance target was 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.

- m. **INTERNATIONAL TREATIES AND FORUMS:** 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 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. This rule has not had a noticeable impact on trade. The list of HS codes for GE and non-GE are available [here](#).

### ***PART C: MARKETING***

- a. **PUBLIC/PRIVATE OPINIONS:** Taiwan officials have been reluctant to speak publicly on issues related to biotechnology. As a result, much of the public discussion is dominated by non-governmental organizations and anti-GE activists. 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. COA has not yet announced an implementation date. 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.
- b. **MARKET ACCEPTANCE/STUDIES:** Taiwan expanded GE labeling requirements to bulk products and highly refined products on December 31, 2015 (see GAIN report [TW15016 on Taiwan GE Labeling Requirements](#)). 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 promote non-GE products and sell them at a premium over conventional products. However, the market has since stabilized and Taiwan remains a major importer of all types of soybeans.

## **CHAPTER 2: ANIMAL BIOTECHNOLOGY**

### **PART D: PRODUCTION AND TRADE**

- a. **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.

In one example, 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.

In another example, the Taiwan National University and the Academia Sinica also 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 regulations require labeling and traceability for GE products. Records must be kept for five years.
- d. **INTELLECTUAL 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, "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 has been minimal public conversation or debate 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.
- b. **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.