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Report Highlights:

Taiwan uses a science-based process for evaluating and granting approval for imports of genetically engineered (GE) products for processing, food, and feed use. No GE crops or animals have been approved for domestic production. In 2018, Taiwan imported over $1.6 billion of U.S. genetically engineered (GE) crops, accounting for 42 percent of total U.S. agricultural exports to the island. Taiwan authorities are currently debating how to regulate innovative biotechnologies.

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Executive Summary:

In 2018, Taiwan imported $3.9 billion of U.S. agricultural products and was the United States' eighth largest agricultural export market. Over forty percent 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 created market segments for non-GE soybeans for food utilization, although the total volume remains small compared to commodity soybeans used in oil and meal crushing.

Researchers in Taiwan have developed GE rice, fruit, vegetables, ornamental flowers, and fish. However, Taiwan authorities have not yet approved any GE crops for domestic cultivation or animals for human consumption. GE infertile fluorescent fish targeting the hobbyist aquarium market are currently undergoing field trials and may be Taiwan's first commercialized biotech product. This is partially because the only domestic Taiwan regulation for promulgation of a GE product is the "Guidelines for Breeding and Propagation of Transgenic Aquatic Animals and Plants" under the "Fisheries Act" of July 20, 2016. However, there are currently no regulations in Taiwan governing the commercial release for domestically developed GE products. Despite an initial wave of interest and enthusiasm, most researchers have given up working on agricultural biotechnology in Taiwan as regulatory barriers including a lack of commercial regulations make it almost impossible for them to bring-to-market any genetically engineered (GE) product for food use that is developed.

Due to new products developed via gene editing techniques in exporting countries, Taiwan is now considering whether or how to regulate innovative biotechnologies like new breeding techniques (NBTs). Taiwan researchers, professors, and breeders are interested in using innovative biotechnologies to develop products and plant varieties that meet Taiwan's agricultural and biomedical needs and challenges, but only if there is a supportive regulatory environment. In 2018, the Taiwan authorities at the Ministry of Science and Technology (MOST) started funding research projects employing gene editing techniques in human, animal, and plant disease related studies. Taiwan authorities are currently discussing internally the appropriate public policies necessary to govern these new emerging technologies. Taiwan's two biotech regulatory agencies, the Food and Drug Administration (TFDA) and the Council of Agriculture (COA), have conducted internal research and external reviews of international studies that include safety assessments, risk management, and communication for innovative biotechnologies.

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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 developed GE varieties of rice, broccoli, potatoes, bitter gourd, tomatoes, papaya, banana, calla lily, and orchids. Of these products, 11 varieties have applied for and been granted approval for field trials.

According to the September 27, 2019 COA Announcement No. AFA1081018487, the GE white color oncidium orchid has completed field trials. This is the second domestic product which had completed a biosafety assessment and is technically eligible to apply for environmental release. However, Taiwan has not accepted any application nor granted approval to any GE crops for domestic cultivation due to a lack of public acceptance. In 2003, domestic ring spot virus-resistant GE papaya completed the first-ever biosafety assessment. In late 2016, GE papaya applied for a food safety assessment with TFDA. However, as of this report, domestic GE papaya is still under review by TFDA (refer to TFDA under review list HERE or to Attachment 1).

b. **COMMERCIAL PRODUCTION:** There is no commercial production of GE products in Taiwan. Commercial cultivation on the island is unlikely soon 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. The developers of the first two domestic GE products which passed biosafety assessments have publicly criticized

the current policy of a de facto ban on domestic cultivation. Resistance by Taiwan authorities have yet to establish a regulatory environment that allows for products that have cleared field trials to commercialize.

c. **EXPORTS:** Due to no domestic commercial production, Taiwan does not export unprocessed GE products or commodities. However, any domestically produced processed product in Taiwan for export could have authorized GE-content and, if so, it would be labeled according to rules described in Part B Section g, LABELING AND TRACEABILITY. It would be up to this exporter to understand both Taiwan's regulations, as well as those of any third country market.

d. **IMPORTS:** Taiwan imported $3.9 billion of U.S. agricultural products in 2018, ranking as the eighth largest U.S. agricultural export market. Corn, soybeans, cotton, and intermediate products accounted for over forty percent 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. Brazil and other key suppliers also have high levels of GE adoption in these same crops. Nonetheless, expanded GE labeling requirements in 2015 drove up demand for imported non-GE soybeans.

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

f. **TRADE BARRIERS:** Article 23 of the December 30, 2015 amendment to the School Health Act prohibited GE food from being served in Taiwan's school lunch program. The amendment has further increased confusion amongst the public regarding the safety of GE food.

In response to anti-GE groups' lobbying efforts, in 2014, Taiwan created separate tariff codes for GE versus non-GE and for feed versus others use (see Part C Section b MARKET ACCEPTANCE/STUDIES). So far, this separate HS code requirement has not been trade-prohibitive to GE products (see Part B Section n, RELATED ISSUES).

Anti-GE groups have also requested that TFDA lower the MRL for glyphosate on soybeans entering the food chain 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 publicly noted in mass media that there is no scientific basis for making such a change. At the same time, Taiwan authorities are not able to establish the MRL level for glyphosate on oats and small grains due to similar anti-GE activism over glyphosate tolerance. Due to the lapse in an MRL on glyphosate, U.S. oats have been blocked out of the Taiwan market since 2013. Taiwan used to account for 26 percent of all U.S. rolled oats exports at a peak of $4.4 million in 2009.

PART B: POLICY

a. **REGULATORY FRAMEWORK:** TFDA is responsible for food safety assessments, including pre-market approval, GE labeling, and traceability. TFDA also 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 completed for legislation discussion.

The Taiwan authorities at MOST supervise 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 oversees interagency coordination at the ministerial level on Taiwan's science and technology policy, including agricultural biotechnology.

Regulatory reviews are conducted by the respective Genetically Modified Feed or Food Review Committees. Both agencies organize their own review committees following an identical set of rules. The committees are composed of 17-23 experts specializing in biotechnology, microbiology, animal health, human nutrition and/or other related fields. Committee members are subject to 2-year terms. Both agencies will assemble a group of new GE review committees in early 2020, with one third of committee seats turning over. The committees meet approximately every 2-months to review GE products premarket registration applications.

After completion of a final biosafety review, domestic cultivation requires an additional application to COA for environmental release approval. So far, Taiwan authorities have not granted any approvals for cultivation of GE products that have passed field testing.

The specific regulations/laws governing TFDA's work in this area are:

- "Regulations Governing the Establishment of the Advisory Committee in Genetically Modified Foods" (2014/09/03)
- "Act Governing Food Safety and Sanitation"(2019/06/12)

The specific regulations/laws governing COA's work in this area are:

- "The 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" (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:** TFDA and COA are in charge of premarket approvals for food and feed use, respectively. Products such as corn and soybeans that are used for both food and feed require approval by both agencies.

As of this report, TFDA has granted registration approval for 149 GE products. This includes 61 single biotech events (16 soybean, 23 corn, 15 cotton, 6 canola, and 1 sugar beet events) and 88 stacked events (12 soybean, 58 corn, 13 cotton and 5 canola stacked events). The list of current TFDA approvals can be found on its WEBSITE. TFDA has also begun to publicly announce products under review. Currently, there are nine products under TFDA review, including the first and only submission of a domestically developed product (ring spot virus-resistant papaya), one biotech sugar cane variety, and three GE potato varietals.

COA has granted approvals for 151 products. In addition to five GE alfalfa events for feed use only, there are three products (one corn and two cotton events) in the TFDA approval list pending COA's approval. In general, COA grants approvals after TFDA does to avoid market disruptions. COA's approval list is now available on its WEBSITE.

Below are web links to approval lists:
TFDA approval list: https://www.fda.gov.tw/tc/siteContent.aspx?sid=2197
TFDA under reviewing list: https://www.fda.gov.tw/tc/site.aspx?sid=1510
COA approval list: https://permit.coa.gov.tw/Feed/B0202/index.action

c. **STACKED or PYRAMIDED EVENT APPROVALS:** Starting from May 2008, Taiwan implemented stacked event registration under the domestic rule the "Guideline for Food Safety Assessment of Foods Derived from GE plants with Stacked Traits." The guideline applies only to GE plant products 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 have already been approved in Taiwan. Stacked events not obtained through conventional breeding (breeding stacks) are not eligible to apply for premarket approval. So far, this policy has not resulted in any issues with approving stacked events. COA applies the same rules to review stacked events as TFDA. TFDA is experienced and efficient in conducting stacked trait reviews, while COA is currently slower in the review process but appear to be catching up.

d. **FIELD TESTING:** Taiwan promulgated field-testing regulations governing GE plants in May 2005. Eleven domestically developed GE events have been officially granted field trial testing permits. A ring spot virus-resistant papaya completed field trails in July 2003, before the regulations were promulgated. On September 27, 2019, COA announced that a second domestically developed product, white color Oncidium orchid (Dancing-Doll Orchid), had

completed field trials. The announcement stated the completion of a biosafety evaluation does not grant permission for cultivation or commercialization.

The seven events listed below have completed field testing but are still pending final biosafety review (developer/submitter):

1. Sweet rice for processing (Academia Sinica)
2. Lactoferrin rice (National Chung Hsing University)
3. Delayed-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)

After completion of a final biosafety review, domestic cultivation requires an additional application to COA for environmental release approval. So far, Taiwan authorities have not granted any approvals for cultivation of GE products that have passed field testing.

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, but these were ultimately not adopted as the techniques were overtaken. Taiwan officials have not yet decided on how to manage innovative biotechnologies. The related agencies 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 innovative biotechnologies if there is a supportive regulatory environment. A few academics are researching gene editing of ornamental flowers for biotic and abiotic stress resistance with the hope of establishing platforms for the technology pending a positive 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. There are no regulations on the domestic cultivation of GE crops or animals.

g. **LABELING AND TRACEBILITY:** Raw materials and primary products made from GE product inputs (such as soybean oil, corn starch and syrup, soy sauce, etc.) are required to be labeled as genetically engineered. "Secondary" products made with GE primary products without DNA residues or protein (such as beverages containing corn syrup, etc.) are exempted from GE labeling requirements.

(本產品不含基因改造成分，
但為基因改造黃豆加工製成)

Translated from Chinese label: **"This product is made of GM soybeans, but do not contain any transgenic materials."**

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 than is present on the product packaging. Fines for violating the regulations can range from NT$30,000 (USD $1,000) up to NT$3 million (USD $100,000). Business licenses can be revoked for serious violations. More information is available on TFDA's WEBSITE under GM Food Labeling Q&A's.
A product can only be labeled as non-GE if there is a commercially available GE counterpart 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 96.6 percent in 2018, based on 232 samples. TFDA labeling compliance reports are available in Mandarin on the TFDA WEBSITE.

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.

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

i. **LOW LEVEL PRESENCE (LLP) POLICY:** Taiwan does not have an LLP 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. The Biotech industry largely avoids asynchronous approvals with Taiwan by withholding products until they are approved in other major East Asian markets.

j. **ADDITIONAL REGULATRORAY REQUIREMENTS:** A registration is valid for one to five years, though in most cases registrations are approved for five years. Renewal is required 3-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 language into its definitions in the Regulations Governing Transboundary Movements of living modified organisms (LMOs).

COA's Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ) is the lead agency for the movement of GE plants and animals in Taiwan. In addition, the regulation governing propagation and production of aquatic plants and animals (fish) also stipulates that GE aquatic plants and animals must be submitted to the COA Fishery Administration for a permit for trans-boundary movement.

To date, there are only a few import/export records of GE plans or animals, all used in limited and contained experimentation. COA has established a surveillance program for internal movement of GE plans and animals. The first internal movement surveillance target was 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. In July 2017, COA began a two-year monitoring project in response to these concerns. COA may 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, and World Trade Organization (ascended 2002).

n. **RELATED ISSUES:** In November 2014, Taiwan began requiring that GE and non-GE raw materials, such as corn and soybeans enter under separate tariff codes. This rule has not been trade prohibitive. The list of GE and non-GE HS codes is available HERE (also refer to Attachment 2). Import of GE products requires that a statement by the exporter on letterhead and a list of traits contained in the shipment accompany the official export documents. The statement reads, "This shipment of Soybeans (or corn, maize, etc.) may contain genetically

modified events as following unique identifier or event names or the similar description." Non-GE products are required to have an Identify Preservation document, organic certificate, other non-GE certificate, or laboratory test report (protein testing and qualitative and quantitative DNA testing) for GE content in the shipment. Products are only allowed to be imported as non-GE if they contain less than 3 percent GE content.

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 May 2019, Taiwan implemented 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. Due to consumers' concern about GE food, TFDA has placed additional information on GE products under review on its website.

b. **MARKET ACCEPTANCE/STUDIES:** Taiwan expanded GE labeling requirements to bulk, unpacked loose, and highly refined products on December 31, 2015 (see GAIN report TW15016 on Taiwan GE Labeling Requirements). The stringent labeling requirements have hurt demand for GE soy products. Retailers promote non-GE products and sell them at a premium over conventional products. Soy based products with Identify Preserved origin labeling are priced at least 50 percent higher, with locally produced soybeans considered the highest premium product (used in non-GE tofu production). However, since the market has stabilized since these changes have been implemented, Taiwan remains a major importer of all types of soybeans. In order to address the public concern over food consumption safety of GE soybeans, TFDA has funded a 3-year project that started in 2017 to conduct its own safety assessment on GE soybeans sold on the local market. Locally produced organic soybeans are used for comparison. The project is designed to compare pesticide residues, content of endogenous allergens, key component analysis, and toxicity.

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 foreseeable 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 developed a GE fluorescent fish variety, and then transferred production to two private companies. These fluorescent fish are currently undergoing field trials and are likely to be Taiwan's first commercialized biotech product. All these fluorescent fish are infertile and intended for ornamental use and sale to hobbyist aquariums.

b. **COMMERCAIL PRODUCTION:** Currently, with the exception of GE animal vaccines, no GE animals are in commercial production.

c. **EXPORTS:** None.

d. **IMPORTS:** Taiwan allowed import of the biopesticide Crymax, GE EG-7841 strain. Additionally, Taiwan has paid significant attention to GE salmon. TFDA has already developed a GE salmon detection methodology, pending validation.

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 Biosafety Assessment (2002/11/15)", in accordance with the ANIMAL INDUSTRY ACT of November 24, 2010. The COA Fisheries Agency is responsible for governance of aquatic animals and plants. Taiwan has established two regulations guiding biotech fishery products: the "Guidelines for the Field Trial of Transgenic Aquatic Animals and Plants" and the "Guidelines for Breeding and Propagation of Transgenic Aquatic Animals and Plants" under the "Fisheries Act" of July 20, 2016.

b. **APPROVALS:** None, except biopesticides and animal vaccines.

c. **INNOVATIVE BIOTECHNOLOGIES:** Taiwan has used gene editing techniques on animals for biopharmaceutical and gene therapy related studies. In an example of a new application in food animal breeding, MOST funded a two-year (2019-2020) research project employing

CRISPR/Cas 9 techniques to develop porcine reproductive and respiratory syndrome virus (PRRSv) resistant pigs to improve hog production efficiency by deleting the exogene.

d. **LABELING AND TRACEBILITY:** Taiwan regulations require labeling and traceability for GE products. Records must be kept for five years.

e. **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."

f. **INTERNATIONAL TREATIES and FORUMS:** Taiwan is a member to the World Organization of Animal Health (OIE) and World Trade Organization. Taiwan has actively participated in OIE activities on disease prevention. Taiwan also participates in the APEC High Level Policy Dialogue on Agricultural Biotechnology. Taiwan is not a member of the Food and Agriculture Organization of the United Nations or of Codex.

g. **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 STUDIES:** 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.

Attachments:

No Attachments