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Food Safety and Sanitation Act Tightens Regulatory Requirements on GE Products

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Report Highlights:

In CY2013, Taiwan was the seventh largest export market for U.S. food and agricultural products, of which genetically engineered (GE) corn, soybeans, and cotton accounted for 29 percent of the total export value US\$3 billion. Still, significant changes are underway as Taiwan authorities seek to tighten the regulatory requirements for GE products, partially in response to anti-GE consumers groups. The February 5, 2014, Food Safety and Sanitation Act (FSSA), for the first time, requires health risk assessment, premarket registration approval, labeling, and traceability of all GE products. On June 20, Taiwan's Food and Drug Administration (TFDA) announced draft text for local comment proposing a 3% threshold for GE food products but exempting highly processed products.

Section I. Executive Summary:

In CY2013, Taiwan was the seventh largest export market for U.S. food and agricultural products, of which GE corn, soybeans, and cotton accounted for 29 percent of the total export value US\$3 billion. As of July 2014, Taiwan granted approval for 31 single biotech events and 38 stacked events of corn and soybean combined. Still, new regulations under the Food Safety and Sanitation Act (FSSA) will likely have a significant impact on GE product imports through expanded labeling, registration, and traceability requirements.

On January 28, Taiwan's Legislative Yuan (LY) passed three readings of a controversial amendment to the FSSA. For the first time, the FSSA specifically requires health risk assessment, labeling, and traceability of GE products in food uses. In drafting the FSSA, Taiwan legislators worked in response to anti-GE activists, motivated by a series of perceived food safety scandals. Taiwan's food safety competent authority at the Ministry of Health and Welfare's (MOHW) Food and Drug Administration (TFDA) is directed to publish revisions of all existing regulations governing GE products.

The complete FSSA text can be found [here](#).

On June 20, TFDA announced draft text for local comment proposing a 3% threshold for GE food products but exempting highly processed products. Taiwan will soon notify the draft labeling regulations to the World Trade Organization (WTO) for member review and comment. The draft labeling regulations propose reducing the current 5% labeling threshold for GE food products to 3%, with food additives subject to the same labeling requirements as food products; anticipated implementation date is January 1, 2016. Labeling requirements for food products sold in bulk will be phased in over three years. Highly processed food products, e.g. cooking oils and corn syrup, of those which contain non-detectable protein or biotech traits residues will remain unchanged, i.e. are exempt from GE labeling requirements.

Taiwan authorities recognize that agricultural biotechnology is a potential tool for addressing food security concerns resulting from climate change and population growth. However, Taiwan regulators remain very cautious about domestic cultivation of biotech crops. Coexistence farming among organic, biotech, and conventional crops is a sensitive topic. The average farm size in Taiwan is just over one hectare and Taiwan's arable land accounts for only about one-fourth of the total land area. As a result, Taiwan's self-sufficiency rate hovers around 30 percent and is amongst the lowest in Asia. The agricultural authority's goal is to raise this rate to 40 percent by 2020 through programs focused on reinvigorating the farming system and rescheduling the (paddy) fallow plans. However, there has not been any indication this would be accomplished through domestic approval of GE product cultivation.

The environmental release for cultivation and marketing of any unapproved biotech product would be in violation of the "Taiwan Plant Varieties and Plant Seeds Act." The "Regulation on Field Trials of Biotech Plants" was promulgated in June 2005, based on Article 52 of the "Plant Varieties and Plant Seeds Act." However, the regulation governing propagation and production of GE crops is still in drafting stage. In other words, field trials may be conducted under a permit scheme but the regulatory system has not provided approval for cultivation.

While there is considerable ongoing biotech research in Taiwan, environmental release for commercial cultivation is unlikely in the near future and only biotech products for non-food or ornamental use are likely

to be approved. Taiwan is expected to approve production of its first biotech product, a fluorescent ornamental fish, in the next few years.

Section II.

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 the implied technology to develop biotech rice, broccoli, potato, bitter melon, tomato, papaya, banana, calla lily, and orchid varieties such as phalaenopsis, and oncidium. Although permits for conducting field trials have been granted for several rice, fruit, and vegetable events, none of these products has gone through the regulatory process for commercial cultivation approval or for food and/or feed approval.
- a. **COMMERCIAL PRODUCTION:** Not applicable. Taiwan is very cautious about coexistence farming among organic, biotech and conventional crops especially given the fact that the average farm size is just over one hectare, and Taiwan's arable land is only about one-fourth of the total land area. While there is considerable ongoing research in Taiwan, commercial cultivation on the island is unlikely in the near future.
- a. **EXPORTS:** Not applicable.
- a. **IMPORTS:** In CY2013, Taiwan was the seventh largest export market for U.S. food and agricultural products of which GE corn, soybeans, and cotton accounted for 29 percent of the total export value US\$3 billion. Taiwan's total agricultural imports from all sources, in CY2013 were valued at US\$14.7 billion. Of this, approved GE soybeans, corn, and cotton combined to account for 20 percent. The United States, Brazil, and Argentina were Taiwan's the top three suppliers of corn and soybeans. The United States, Brazil, and India were Taiwan's top three cotton sources.
- a. **FOOD AID RECIPIENT COUNTRIES:** 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.

PART B: POLICY

- a. **REGULATORY FRAMEWORK:** Taiwan has a U.S.-style interagency coordination approach to regulate biotechnology. TFDA resembles the U.S. FDA and is responsible for food safety assessments including premarket approval and GE labeling and traceability. TFDA conducts mandatory import inspections and market surveillance inspection on all food products including GE products. Although feed ingredients derived from GE products are under the Council of Agriculture's (COA, USDA equivalent agency) portfolio, TFDA is currently the agency that approves GE products for both food and feed use.

COA also administers trans-boundary movement of living modified organisms (LMOs) and bio-safety assessment for environmental release. 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: as follows:

- "[Administrative Regulations for the Field Testing of the Transgenic Plants](#)" (established 2005/06/29 and amended 2012/10/05)
- "[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)

- b. **APPROVALS:** As of July 2014, Taiwan granted registration approvals for a total of 31 single biotech events, including 14 soybean and 17 corn events, as well as 38 stacked events, including 2 two-way stacked soybean events and 36 stacked corn events (13 two-way, 10 three-way, 7 four-way, 5 five-way and 1 six-way). There are a total of 8 discontinued corn events, their registrations expired and respective responsible life science companies had decided not to extend the registrations. New approvals include Stearidonic acid - producing Soybean MON-87769-7, herbicide-tolerant Soybean DAS-68416-4, Double-herbicide-tolerant Soybean Event FG72 and herbicide tolerant Soybean Event SYHT0H2.

The link of current approval list can be found [here](#).

Before the new FSSA, Taiwan's biotech regulatory scope was limited to GE corn and soybeans. However, Now all GE products, e.g. canola, cotton, sugar beet, and alfalfa must be registered and approved by February 5, 2016. Crop Life Taiwan (CLT), an association representing corporate members of life science companies, is concerned that TFDA does not have the regulatory capacity to manage the influx of new applications. For instance, in addition to GE corn and soybeans already in regulatory pipeline, there are 50 some GE products of cotton, canola, sugar beet, and alfalfa events in commercial chains and now required to register to TFDA.

TFDA's Genetically Modified Food Review Panel (GMFRP), is composed of 17 to 23 experts specializing in advanced sciences such as biotechnology, microbiology, food nutrition, etc. GMFRP meets approximately every two months to review GE product premarket registration applications. GMFRP also has a role in supporting communication between committee members, authorities, and industry groups. However, while the GE registration requirements have greatly expanded, the structure of GMFRP has not, thus regulatory backlogs may occur with the increased application numbers. Moreover, GMFRP members are subject to two year terms, thus frequent turnover and an unavoidable learning curve delay progress. Post is investigating risk assessment capacity building for committee members. The FSSA also directs TFDA to establish a separate expert panel to serve as biotech policy advisors to TFDA, a role previously fulfilled by GMFRP. This new panel is anticipated to be organized soon.

Although COA has not yet amended its Feed Control Act to regulate ingredients derived from biotechnology, it is highly likely that the COA will adopt a policy that all the TFDA approved products for food use will also be eligible for animal feed use. As a practical matter, TFDA currently approves biotech events for both food and feed use.

- c. **FIELD TESTING:** Taiwan promulgated its field-testing regulation governing GE plants in May 2005. To date, ten events applied for field testing, of which nine events have been granted permits to conduct field trial testing, but one case on ornamental calla lily event had withdrawn its application and Flowering Locus T *Phalaenopsis equestris* is a new application currently under approval review. However, only one event - a ring spot virus-resistant papaya - completed the field trial in July 2003, before the field trial regulations were promulgated. Upon completion of field trial testing, deregulation and environmental release for cultivation is not automatic, of course. Cultivation requires COA approval and no approvals have, thus far, been granted.

Seven events listed below have completed filed works but 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. Ring spot and leaf distortion mosaic virus-resistant papaya (developed by National Chung Hsing University)
- d. **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 have been already approved in Taiwan. Stacked events not obtained thru conventional breeding are not eligible to apply for premarket approval.
- e. **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.
- f. **COEXISTENCE:** Not applicable. Currently, Taiwan 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. All draft regulations for domestic cultivation are still pending, with the exception of the regulation on propagation and production of aquatic animals and plants, which was promulgated on April 13, 2011 and then revised on May 24, 2012.
- g. **LABELING:** The existing labeling regulations are limited to food products made of GE

soybeans or corn. The labeling threshold level is 5%. The labeling regulations do not apply to products that do not contain pieces of transgene(s) or protein such as cornstarch, corn syrup, corn oil, and soy oil. However, as mentioned, that will change under the proposed FSSA. On June 20, TFDA announced draft text for local comment proposing a 3% threshold for GE food products but exempting highly processed products. Taiwan will soon notify the draft labeling regulations to the World Trade Organization (WTO) for member review and comment. The draft labeling regulations propose reducing the current 5% labeling threshold for GE food products to 3%, with food additives subject to the same labeling requirements as food products; anticipated implementation date is January 1, 2016. Labeling requirements for food products sold in bulk will be phased in over three years. Highly processed food products, e.g. cooking oils and corn syrup, of those which contain non-detectable protein or biotech traits residues will remain unchanged, i.e. are exempt from GE labeling requirements.

Bulk Food Products Phased-in: The draft regulation mandates labeling of bulk food products containing GE materials. Under the draft text, TFDA seeks to a three-part staged implementation.

- January 1, 2016: Mandatory labeling of all GE raw materials (e.g. corn and soybeans) sold by registered commercial companies.
- January 1, 2017: Mandatory labeling of processed GE food products (soybean milk, tofu, etc.) sold by registered commercial companies.
- January 1, 2018: Mandatory labeling of all GE food products sold by small retail outlets, wet markets, street vendors etc.

The draft biotech labeling regulations in Chinese can be found [here](#). Post is monitoring the WTO for notice of this draft regulation for member review and comment.

- h. **TRADE BARRIERS:** Incidences of unapproved GE events in U.S. commodities has resulted in trade barriers. Most recently, the May 2013 discovery of unapproved GE wheat volunteers in Oregon resulted in Taiwan broad testing shipments of U.S. wheat, but no suspensions. (See parts, "b. Approval" and, "m. Monitoring and Testing," for more information. Despite incidences of commingled GE corn such as StarLink and Event 32 corn, there have been no trade disruptions of U.S. GE corn exports to Taiwan. U.S. corn exports to Taiwan are primarily for feed use and draw less attention from the media or local consumers groups. However, the 2006 LibertyLink rice incident did result in Taiwan's suspension of imports of U.S. long grain rice. U.S. long grain rice is remains suspended, though rice is a politically sensitive issue and the suspension has little to do with GE concerns.
- i. **INTELLECTUAL PROPERTY RIGHTS (IPR):** Not applicable. 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."
- j. **CARTAGENA PROTOCOL RATIFICATION:** Not Applicable. 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 on the biotechnology issues. 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 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 recently 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.

- k. **INTERNATIONAL TREATIES/FORA:** Taiwan participates in the Asia Pacific Economic Cooperation activities such as High Level Policy Dialogue for Agricultural Biotechnology.
- l. **RELATED ISSUES:** TFDA will implement traceability requirement for GE products, anticipated on December 31, 2014, in accordance with the FSSA. As there is no domestic commercial production, all imported GE products will be imported under the separate HS codes from their non-GE counterparts. Separate HS codes have yet to be announced. Importers and manufacturers of GE products are therefore responsible for establishing traceability systems for GE products from imports. All records must be kept for 5 years.
- m. **MONITORING AND TESTING:** TFDA conducts mandatory import inspections and regular market surveillance inspection on all food products including GE soybeans and corn and their products. For instance, in response to the May 29, 2013, USDA announcement regarding the discovery of GE wheat volunteers on an Oregon wheat farm, TFDA implemented border inspection for GE material on all imports of U.S. wheat, effective June 4, 2013. Import inspections on U.S. wheat imports soon returned normal testing rate after no positive results were detected.
- n. **LOW LEVEL PRESENCE POLICY:** Not Applicable. Taiwan has no accommodation for low level presence. Any unregistered GE product is considered illegal. Similar to any other illegal product or product determined to be out of compliance with Taiwan's policies, unapproved GE products will be destroyed or rejected at the port of entry.

PART C: MARKETING

- a. **MARKET ACCEPTANCE:** Prior to the FSSA, Taiwan was considered a moderate market for GE products. That is, GE event applications were reviewed in an appropriately timely manner and products were not unnecessarily detained at the border. However, a series of local food safety scandals including mis-labeled rice and adulterated cooking oil created an opportunity for anti-GE activists to push for increased regulations. The island, however, is highly reliant on imports with food self-sufficiency rates amongst the lowest in Asia.
- b. **PUBLIC/PRIVATE OPINIONS:** While highly educated, Taiwan's consumers and authorities

are often overly sensitive to sensationalistic media claims. Taiwan is home to seven round-the-clock TV news networks and approximately twenty online and print newspapers; competition for stories is fierce. Unfortunately, in the absence of local political scandals or natural disasters, media attention may focus on food safety issues, with U.S. agricultural and food exports often a target. Anti-GE groups are often able to find a platform for their message. Recent claims have included the assertion that GE soybeans and corn are not equal to conventional counterparts and are not regularly consumed in the United States. Also, before the beginning of each school term, these groups push for the exclusion of GE products in school lunches (to no avail. To appease these consumers, COA recently promoted the local cultivation of non-GE soybeans, albeit less than 2,200 acres. Still, there are rational players and GE-tolerant reports. For instance, the May 2013 GE wheat incident received minimal attention. Also, an article in *Common Wealth Magazine*, July 2014, pointed out that many common processed foods contain ingredients or products from GE-soybean, corn, or canola, e.g. corn starch in ice cream, soy lecithin in chocolate, soy protein in ham, etc. The author of the article called readers to have thorough understating of GE foods.

- c. **MARKETING STUDIES:** Not applicable.

PART D: CAPACITY BUILDING AND OUTREACH ACTIVITIES

a. **ACTIVITIES:**

- **August 14, 2013 – Safety on GE Corn and Soybeans Discussion Meeting:** U.S Cooperators, Crop Life Taiwan, and AIT/AGR met with Taiwan soy food manufacturers at the Food Industry Research and Development Institute (FIRDI) in Hsinchu to discuss GE food safety and soy food sectors' position on how to address consumer concern on safety of GM foods.
- **September 25, 2013 – Crop Life Taiwan** officially registered with the Ministry of the Interior as an industry association representing corporate members of life science companies.
- **November 1, 2013 - Symposium on Research, Development & Regulation of GM Foods (sponsored by TFDA and conducted by FIRDI):** A seminar co-sponsored by TFDA and FIRDI was held in Taipei, attracting 50 people from Taiwan agencies and academia. Dr. Wayne Parrott, Professor, Crop and Soil Science, University of Georgia spoke on “Recent Development of Biosafety and Food safety on GM Foods.” Dr. Martina Newell-McGloughlin, Professor and Director, UC System-wide Biotechnology Research and Education Program UC Davis spoke on “Regulating the Products of Agricultural Biotechnology” and “Global Development of Agricultural Biotechnology and Food Supply.” Dr. Evert Jacobsen, Professor, Plant Science, Wageningen University and Research Center, Netherlands gave a talk on “Potential of cisgenesis as non-GMO and its importance for breeding classical traits.”
- **April, 2014 – “A Bite of Food Science” (sponsored by TFDA):** TFDA initiated public communication program entitled “A Bite of Food Science.” TFDA joined efforts with a local newspaper, United Daily News, to publish weekly articles on food safety. Consumers seemed appreciative of these informative efforts. However, a June 18 article entitled, “Are GM Foods Carcinogenic? – There Has Been No Scientific Evidence” drew criticism from anti-GMO

groups.

- b. **STRATEGIES AND NEEDS:** Given Taiwan's unique political status, Post would encourage more opportunities for Taiwan's participation in biotech related international fora/discussions or workshops, as appropriate. Such would provide Taiwan authorities and academics more exposure and enhanced familiarity with updated safety assessment technologies and risk management.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: PRODUCTION AND TRADE

- a. **BIOTECHNOLOGY PRODUCT DEVELOPMENT:** The Animal Technology Institute Taiwan 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. GE livestock (to include fowl) for food animals in Taiwan is not foreseen in the near future.

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.

- b. **COMMERCAIL PRODUCTION:** Not applicable. Currently, no GE animals are in commercial production.
- c. **BIOTECHNOLOGY EXPORTS:** Not applicable
- d. **BIOTECHNOLOGY IMPORTS:** Not applicable

PART F: POLICY

- a. **REGULATION:** The Department of Animal Industry of 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 and revised on May 27, 2012; and the "[Management Rules for Breeding and Production of Transgenic Aquatic Animals and Plants](#)," in May 24, 2012 (rules governing aquatic animals and plants are in Chinese).
- b. **LABELING AND TRACEBILITY:** Taiwan regulation requires a traceability labeling system and records must be kept for 5 years.

- c. **TRADE BARRIERS:** Not applicable.
- 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."
- e. **INTERNATIONAL TREATIES/FOR A:** Not applicable.

PART G: MARKETING

- a. **MARKET ACCEPTANCE:** There have been minimal public conversations or debates on this issue.
- b. **PUBLIC/PRIVATE OPINIONS:** Not applicable, but, per consumer's general perception at this time, it seems that biotech products not for food use are easier to be accepted than that for food use by consumers.
- c. **MARKET STUDIES:** Not applicable.

PART H: CAPACITY BUILDING AND OUTREACH

- a. **ACTIVITIES:** Not applicable. The United States and Taiwan engage at an annual "Scientific and Technology" meeting where scientific research proposals are reviewed for potential funding. The results of some of these projects may be relayed to third-market countries as outreach efforts.
- b. **STRATEGIES AND NEEDS:** Not applicable. Unless there is a product set to enter commercial chains, Taiwan is unlikely to devote attention to the issue, resources are dominated by conversations regarding maximum residue levels and domestic food safety issues.