Required Report: Required - Public Distribution **Date:** December 14, 2021

Report Number: TW2021-0059

Report Name: Agricultural Biotechnology Annual

Country: Taiwan

Post: Taipei

Report Category: Biotechnology and Other New Production Technologies

Prepared By: Oscar Lin; Erik Syngle

Approved By: Erich Kuss

Report Highlights:

Since the previous report, Taiwan has granted new approvals for imports of genetically engineered (GE) products for processing, food, and feed use. Taiwan has never permitted domestic production of GE crops or animals. In 2020, Taiwan imported close to $1 billion of U.S. GE crops, accounting for 25 percent of total U.S. agricultural exports to the island. Taiwan authorities are still in discussion on how to manage innovative biotechnologies. but do not yet have a public draft or policy for the products of these technologies. However, Taiwan has made some progress on approving the first two microbial biotechnology products, albeit with other requirements for labeling and maximum dietary intake.

Executive Summary:

In 2020, Taiwan imported $3.3 billion of U.S. agricultural products, ranking as the United States' eighth largest agricultural export market. Over 25 percent of this total was comprised of soybeans, corn, and cotton. A high percentage of each of these crops are produced with genetically engineered (GE) varieties. 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 in oil and meal crushing. GE labeling also creates a market niche for close to 5,000 MT of domestically produced soybeans in food utilization (refer to GAIN Report: TW2021-0031).

Researchers in Taiwan have developed GE rice, fruit, vegetables, and ornamental flowers and fish. However, Taiwan authorities have not yet approved any GE crops for domestic cultivation. Infertile GE fluorescent fish, currently undergoing field trials, may be Taiwan's first commercialized biotech product. The promulgated domestic propagation regulation is the "Guidelines for Breeding and Propagation of Transgenic Aquatic Animals and Plants" under the "Fisheries Act". Despite an initial wave of interest and enthusiasm, most researchers have given up working on agricultural biotechnology in Taiwan since regulatory barriers make it almost impossible to commercialize any resulting GE products.

Due to the market launch of products developed via genome editing techniques in exporting countries, Taiwan is now at a familiar juncture with innovative biotechnologies. 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. In 2018, authorities at the Ministry of Science and Technology (MOST) started to fund research projects employing genome editing techniques in human, animal, and plant diseases related studies. Taiwan authorities are currently discussing internally the appropriate public policies necessary to govern these new emerging technologies. Both Taiwan biotechnology regulatory agencies at the Food and Drug Administration (TFDA) and the Council of Agriculture (COA) have conducted studies on risk assessment, risk management, and risk communication for innovative gene editing technologies. However, no policy or draft policy exists publicly as of the publication of this report.

For products derived from microbial biotechnology, on August 15, 2019, TFDA published the "Non-Traditional Food Safety Assessment Guideline for Products Derived from Genetically Modified Microorganisms, which governs products produced by genetically modified microorganisms.

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

TABLE OF CONTENTS

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. PRODUCT DEVELOPMENT: Taiwan is a technologically advanced and highly 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, potato, bitter gourd, tomato, papaya, banana, calla lily, and orchids. Eleven of these domestically developed GE products have applied for and received approval for conducting field trials.

   Field trials for GE white-color oncidium (dancing-lady orchid) were completed by September 27, 2019 (COA Announcement No. AFA1081018487). This is the second domestic plant product to complete a biosafety assessment and is technically eligible to apply for environmental release. However, due to a lack of public acceptance, Taiwan has not accepted any applications nor granted approvals for any GE crops for domestic cultivation. In late 2016, the domestic ring spot virus-resistant GE papaya was the very first product to apply for a food safety assessment from TFDA. Its biosafety assessment had been completed in 2003. As of this report, domestic GE papaya is still under TFDA's review (refer to the TFDA review list).

b. COMMERCIAL PRODUCTION: None. 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 assessment have publicly criticized the current policy on prohibiting domestic cultivation.

c. EXPORTS: None.

d. IMPORTS: Taiwan imported $3.3 billion of U.S. agricultural products in 2020, making it the eighth largest U.S. agricultural export market. Corn, soybean, and cotton and intermediate products accounted for over 25 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.

   Expanded GE labeling requirements instituted 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. Taiwan does occasionally provide food aid shipments of rice 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 the school lunch program. This has further increased confusion amongst the public regarding the safety of GE food.

In response to anti-GE groups' requests, Taiwan has created separate tariff codes for GE versus non-GE and for animal feed versus other use (food use) on soybeans. Anti-GE groups have also requested TFDA to lower the maximum residue level (MRL) for glyphosate on soybeans entering 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 noted that there is no scientific 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 if or when this draft law will be completed for legislative 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.

The specific regulations/laws governed by TFDA are:

- "Regulations Governing the Establishment of the Advisory Committee in Genetically Modified Foods" (2020/06/02)
- "Act Governing Food Safety and Sanitation"(2019/06/12)

The specific regulations/laws governed by COA 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: Two separate agencies, TFDA and COA oversee 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

approvals for 153 products. This includes 60 single biotech events (16 soybean, 22 corn, 15 cotton, six canola, and one sugar beet) and 90 stacked events (12 soybean, 60 corn, 14 cotton, and 7 canola). The list of current TFDA approvals can be found on the TFDA website. TFDA also introduced the new feature of making under review products available to the public. Currently, there are 13 products under TFDA review, including ring spot virus-resistant papaya (the first and only submission of a domestically developed product) and three GM potato events. The sole sugar cane application was withdrawn in July 2021. COA has granted approvals for 127 products, including five GE alfalfa events which are not listed in TFDA approval. In general, COA grants approvals after TFDA does to avoiding market disruptions. COA's approved list is now available on its COA website.

Regulatory reviews are conducted by the respective Genetically Modified Feed or Food Review Committees. Both agencies organize their own review committees following identical rules. The committees are composed of 17-23 experts specializing in biotechnology, microbiology, animal, food nutrition, and/or other related fields. Committee members are subject to 2-year terms. Both agencies reassembled a group of new GE review committees in early 2020, with a one-third member turnover rate to abide by the rules. The committees meet approximately every two months to review GE product premarket registration applications.

c. STACKED or PYRAMIDED EVENT APPROVALS: Starting in May 2008, Taiwan implemented stacked event registration based on 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 the 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, either. COA applies the same rules to review stacked events.

d. FIELD TESTING: Taiwan published field-testing regulations governing GE plants in May 2005. The number of officially granted field trial testing permits has stayed at 11 domestically developed GE events. A ring spot virus-resistant papaya completed field trials in July 2003, before the regulations were published. On September 27, 2019, COA announced the second domestically developed product, white flower oncidium (dancing-lady orchid) which has completed field trials. The announcement states the completion of a biosafety evaluation is not a permission for cultivation and marketing.

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. 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 events must apply to COA for environmental release approval. Taiwan has not granted any approvals for cultivation thus far.

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. Both Taiwan biotechnology regulatory agencies at the Food and Drug Administration (TFDA) and the Council of Agriculture (COA) have conducted studies on risk assessment, risk management, and risk communication for innovative gene editing technologies. However, draft policy for public comment is still forthcoming. The related agencies are also closely following how the United States, Japan, 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. A few academics have devoted gene editing research on biotic and abiotic stresses resistant and ornamental flowers with a hope to establish technology platforms for future development.

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. No regulations on the domestic cultivation of GE crops and animals have been finalized or published.

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

The labeling regulations state that the length and width of the font must not be less than 2 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 GE Food Labeling Q&As (Item No.29 in Chinese). A product can only be labeled as non-GE if there is a commercially available GE-counterparts 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 95 percent in 2020, based on 175 samples. TFDA labeling compliance reports are available in Mandarin on the TFDA website. In addition to meat, dairy, and baby food, in February 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 5 years.

h. MONITORING AND TESTING: TFDA conducts import and regular market surveillance inspections 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 (LLP) POLICY: Taiwan does not have an LLP policy; therefore, the default level is zero. Any unregistered GE product is considered illegal. Unapproved GE products will be destroyed or rejected at the port of entry. Volunteer wheat is a concern for potential LLP detections.

j. ADDITIONAL REGULATORY REQUIREMENTS: A registration is valid for 1 to 5 years, though in most cases registrations are approved for 5 years. Renewal is required 3 months before the expiration date.

k. INTELLECTUAL PROPERTY RIGHTS (IPR): According to Article 24 of the Patent Act (2019/05/01), 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."

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 GE materials in Taiwan. In addition, the regulation governing propagation and production of aquatic plants and animals (fish) also stipulates that aquatic plant and animal GE materials must be submitted to the COA Fishery Administration for a permit for trans-boundary movement.

To date, only a few import/export records for GE materials have been reported for use in confined experiments. COA has established a surveillance program for internal movement of GE materials. The first GE material internal movement surveillance target was GE papaya with batch-by-batch inspection for each commercial papaya seedling transaction.

Anti-GE groups had 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 continues monitoring the spillage conditions and evaluating possible environmental impact.

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: 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 had a noticeable impact on trade. Import of GE products requires a statement of "This shipment of Soybeans (or corn, maize, etc.) may contain genetically modified events as following unique identifier or event names or the similar description", in the shipment's accompanying document, such as packing list or invoice. To claim non-GE products to Customs requires an accompanying Identify Preservation document, or laboratory test reports on all GE events finding below 3 percent of GE content, an organic certificate, or other non-GE certificate, which is recognized by TFDA. Of note, Taiwan allows the import of Crymax (EG-7841), a GE bio-insecticide.

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 over GE food, TFDA has placed additional information on GE products under review on its website.

b. MARKET ACCEPTANCE/STUDIES: On December 31, 2015, Taiwan expanded GE labeling requirements to bulk unpacked products and highly refined products (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 are priced at least 50 percent higher, with locally produced soybeans the highest because of non-GE tofu variety. However, the market has since stabilized, and Taiwan remains a major importer of all types of soybeans. To address the public concern over food consumption safety of GE soybeans, TFDA funded a project 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 was to investigate pesticide residues, content of endogenous allergen, key component analysis, toxicity, and allergenic analysis.

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 soon. 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, Taiwan National University and Academia Sinica also developed a GE fluorescent fish, which has 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 only.

b. COMMERCIAL PRODUCTION: With exception of GE animal vaccines, currently, no GE animals are in commercial production.

c. EXPORTS: None.

d. IMPORTS: Taiwan has paid high attention to GE salmon and TFDA has already developed a GE salmon detection methodology pending for validation.

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

PART E: POLICY

a. REGULATORY FRAMEWORK: 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 (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 December 27, 2019.

b. APPROVALS: Not available; except bio-pesticide 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 new application in food animal breeding, MOST funded a 2-year (2019-2020) research project employing CRISPR/Cas 9 techniques to develop porcine reproductive and respiratory syndrome virus (PRRSv) resistant pig to improve hog production efficiency by deleting a gene sequence.

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). Taiwan has actively participated in OIE activities on diseases prevention. Taiwan also participates in the APEC High Level Policy Dialogue on Agricultural Biotechnology.

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.

CHAPTER 3: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a. COMMERCIAL PRODUCTION:
On March 11, 2021, TFDA approved (link in Chinese) the first domestically developed product, Astaxanthin, for use as a food ingredient. Astaxanthin is produced by fermentation using genetically engineered (GE) *Escherichia coli* strain Ast12 (referred to as *E. coli* Ast12). The approval comes with a daily consumption limit of 2 mg and the following warning: children under 12, pregnant women, breastfeeding women, and those taking drugs related to liver or metabolic diseases should avoid taking it.

On June 16, 2021 TFDA approved (link in Chinese) the second product, 2'-fucosyllactose (referred to as 2'-FL), for use as an additive in infant and follow-up formula with a limit of 1.2 grams/liter. The 2'-FL is developed by a foreign company and is produced by fermentation using GE *Escherichia coli* strain BL21 (DE3) #1540.

On September 15, 2021, TDFA announced draft guidance for *Ganoderma microsporum* globulin-like protein concentrate from GE *Pichia pastoris* Ey72.
The end products from the above approvals no longer contain genetically modified microorganisms or their transgenic fragments.

b. EXPORTS: Thousands of products globally contain food ingredients derived from microbial biotechnology, such as enzymes and processing aids used in cheese, beer, wine, juice, condiments, and processed product production. However, it is difficult to obtain specific information about exports/imports (including from the United States and other major exporting countries in Europe, the Americans, and Asia where food ingredients from microbial biotechnology are produced and used) at this time.

c. IMPORTS: See Paragraph b. above.

d. TRADE BARRIERS: N.A.

PART H: POLICY

a. REGULATORY FRAMEWORK: COA's Department of Animal Industry is responsible for regulating products derived from microbial biotechnology in feed and food use. At the current stage, Taiwan only focuses on regulating products derived from microbial biotechnology but not on GE microorganisms. TFDA makes the rules very clear for the products derived from microbial biotechnology that the final products shall be purified and shall not contain any GE microorganism or its transgenes. The product is regulated as "non-traditional food", which is defined as either produced by using non-traditional (or novel) methodology or no human safe consumption history for 25 years or less. Products defined as non-traditional food require a

safety review before commercialization. Currently, products derived from GE microbial biotechnology will follow the same rules as those of food.

b. APPROVALS: Astaxanthin and 2'-FL have both completed food safety reviews in accordance with the Non-traditional Food Guidelines and were approved in 2021. Below are links to TFDA's announcement and WTO notifications.

   TFDA WTO notifications on Astaxanthin:
   http://tbtims.wto.org/en/ModificationNotifications/View/170981
   https://docs.wto.org/imrd/directdoc.asp?DDFDocuments/t/G/TBTN20/TPKM418A1.DOCX (downloads a document)
   http://spsims.wto.org/en/ModificationNotifications/View/170875
   https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=271793

   TFDA WTO notifications on 2'-FL:
   http://tbtims.wto.org/en/ModificationNotifications/View/172952
   https://docs.wto.org/imrd/directdoc.asp?DDFDocuments/t/G/TBTN20/TPKM447A1.DOCX (downloads a document)
   http://spsims.wto.org/en/ModificationNotifications/View/172915
   https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=274810

c. LABELING AND TRACEBILITY: Labeling follows the same labeling requirement as GE crop products (refer to Chapter 1). It is very similar to highly refined products with the labeling language: "The product is produced by genetically modified microorganism, but ultimately does not contain any genetically modified microorganism and its transgenes." Traceability is not available.

d. MONITORING AND TESTING: N.A.

e. ADDITIONAL REGULATORY REQUIREMENTS: Microbial biotech is regulated under the category of non-traditional food and requires a safety review before commercialization. The web link to TFDA Non-Traditional Food Guideline is here (link in Chinese).

f. INTERLECTURAL PROPERTY RIGHT (IPR): Microorganisms are eligible for IPR protection (refer to Chapter 1).

g. RELATED ISSUES: NONE.

PART I: MARKETING

a. PUBLIC/PRIVATE OPINIONS: There has been very limited public conversation or debate on this issue to date.

b. MARKET ACCEPTANCE/STUDIES: Post is not aware of any studies on market acceptance for GE microbial biotechnology product.

Attachments:

No Attachments