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Prepared By: Oscar Lin

Approved By: Steven Burgoon

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 2023, Taiwan imported close to $930 million of U.S. crops including soybeans, corn, and cotton, accounting for 25 percent of total U.S. agricultural exports to the island. Taiwan authorities are discussing how to manage innovative biotechnologies, but do not yet have a public draft or policy for the products of these technologies. Taiwan continued to make some progress on approving microbial biotechnology products, albeit with other requirements for labeling and maximum dietary intake.

Executive Summary:

In 2023, Taiwan imported $3.7 billion of U.S. agricultural products, ranking as the United States' sixth 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 5,000 MT of domestically produced soybeans in food utilization (refer to GAIN Report: TW2024-0016).

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)(now the National Science and Technology Council (NSTC)) 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 Ministry of Agriculture (MOA) 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. (Note: On August 1, 2023, the Council of Agriculture (COA) was upgraded to the Ministry of Agriculture (MOA). In this report, previous COA actions will be referred to as MOA.)

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 (Item 7)
MOA approval list: https://feed.moa.gov.tw/B0202/index.action

Related GAIN reports from the past year referencing biotechnology:

TW2024-0016 Taiwan: Oilseeds and Products Annual
TW2023-0054 Taiwan: Food and Agricultural Import Regulations and Standards Country Report

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CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a. RESEARCH AND 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 (MOA 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 $3.7 billion of U.S. agricultural products in 2023, making it the sixth 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 sown confusion in the regulatory system for GE food products which TFDA has already deemed safe.

To alleviate pressure from anti-GE groups, Taiwan created separate tariff codes for GE versus non-GE and for animal feeding versus other (including food use) on soybeans and corn. 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. This is widely perceived as an 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 MOA responsibility for regulating GE feed ingredients. In addition to those new duties, MOA also administers trans-boundary movement of "living modified organisms" (LMOs) and bio-safety assessment for environmental release. MOA 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.

With the reorganization of Ministry of Science and Technology (MOST) into National Science and Technology Council (NSTC) in 2022, NSTC now oversees interagency coordination under the Executive Yuan on Taiwan's science and technology policy as well as the biotechnology development regulatory system, including agricultural biotechnology.

The specific regulations/laws governed by TFDA are:

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

In July 2023, TFDA published an updated "Guideline for Food Safety Assessment of Genetically Modified Foods" by combining it with "Guideline for food safety assessment of foods derived from genetically modified plants with stacked traits" and now have placed all food safety assessments for GE products (plant and microbial biotechnology) within TFDA's authority under the same guideline.

The specific regulations/laws governed by MOA are:

- "The Plant Variety and Plant Seed Act" (2018/05/23)
- "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).

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

Legal term (in official language)	Legal Term (in English)	Laws and Regulations where term is used	where term is used Legal Definition (in English)
基因改造	Genetic Modification	Act Governing Food Safety and Sanitation Guideline for Food Safety Assessment of Genetically Modified Foods*	The transferring of genetic materials or implant of live cells or organisms via genetic engineering, molecular biotechnology, or other related technologies to produce genetic recombination, exogenous genetic characteristics, or to suppress certain genes of the recipient. However, this does not include traditional breeding methods or techniques such as the merging, hybridization, mutation, in-vitro fertilization, somaclonal variation, and chromosome doubling of plants of the same species and protoplasts.
基因改造生物	Genetically Modified Organisms, GMO	Guideline for Food Safety Assessment of Genetically Modified Foods*	Changes in the genes of organisms, which are caused by the aforementioned gene modification, rather than natural hybridization or natural recombination
基因改造食品	GM Foods		Foods and food additives that are produced or manufactured from raw materials consisting of or containing genetically modified organisms.
傳統對照食品	Conventional counterpart		A related variety/species, its components and/or products for which there is experience of establishing safety based on common use as food.

* Other definitions including: Host, Vector, Transferred or Introduced or Inserted gene (or Nuclear Acid fragment), Gene products, Gene (or Nuclear Acid fragment) donor, Unintended Effects, Nutrients, Genetically Modified Plants with Nutrition Improvement, Tolerable Upper Intake Levels, Upper Levels, UL , Bioavailability, Acceptable Daily Intake (ADI) and Dietary Exposure Assessment can be found in the Guideline for Food Safety Assessment of Genetically Modified Foods.

b. APPROVALS: Two separate agencies, TFDA and MOA 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 167 products. This includes 70 single biotech events (16 soybean, 28 corn, 16 cotton, 9 canola, and one sugar beet) and 97 stacked events (12 soybean, 61 corn, 17 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 18 products under TFDA review, including ring spot virus-resistant papaya (the first and only submission of a domestically developed product) and three GE potato events. The sole sugar cane application was withdrawn in July 2021. MOA has granted approvals for 172 products, including five GE alfalfa events which are not listed in TFDA approval. In general, MOA grants approvals after TFDA does so to avoid market disruptions. MOA's approved list is now available on MOA's website.

Regulatory reviews are conducted by the Genetically Modified Feed Review Committee, organized by MOA, and the Genetically Modified Food Review Committee, organized by TFDA. 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 2024, 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 individual events already approved in Taiwan; stacked traits not meeting these criteria are ineligible for TFDA or MOA review and approval. Since July 2023, this guideline has been incorporated into the "Guideline for Food Safety Assessment of Genetically Modified Foods." This update also removed agronomic variables as a data requirement (because it was deemed redundant for food safety assessment.)

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, MOA 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 MOA for environmental release approval. Taiwan has not granted any approvals for cultivation thus far.

e. INNOVATIVE BIOTECHNOLOGIES: From 2020 to 2022, TFDA had been 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 Ministry of Agriculture (MOA) 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.53, 2016/01/20). 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 2023, based on 133 samples. TFDA labeling compliance reports are available 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.

MOA's Animal and Plant Health Inspection Agency (APHIA) 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 MOA's Fisheries Agency 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. MOA 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 MOA to establish transportation control measures. In July 2017, MOA began a two-year monitoring project in response to these concerns. MOA 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 (HLPDAB).

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. Imports of GE products require 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.

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. RESEARCH AND PRODUCT DEVELOPMENT: GE animal research in Taiwan is focused on biopharmaceuticals and ornamental fish. Taiwan is unlikely to develop or approve conventional 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 approvals of GE animals including salmon. TFDA has already engaged in studies to develop a methodology for detecting potential GE animals that may enter into Taiwan's food system.

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

PART E: POLICY

a. REGULATORY FRAMEWORK: MOA'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 MOA's 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 "Fisheres 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, NSTC 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. In

2022, TABT team from National Taiwan Ocean University (NTOU) announced the development of a tilapia “NTOU Mighty Tilapia No.1, MT1” utilizing CRISPR/Cas 9 which increase meat yield from 30 to 50 percent. As mentioned in the Plant Section, regulations regarding genome editing are still forthcoming.

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 (HLPDAB).

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 animals.

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:

There are currently four products derived from microbial biotechnology that have received food safety approval, including Astaxanthin and 2'-FL in 2021, Ganoderma microsporum globulin-like protein concentrate in 2022, and trans-Resveratrol in 2023 albeit with other requirements for labeling and maximum dietary intake. Astaxanthin produced by fermentation using genetically engineered (GE) Escherichia coli strain Ast12 was the first domestically developed product. The end products from the above approvals no longer contain genetically modified microorganisms or their transgenic fragments. (See APPROVALS section for more information.)

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: Similar to food products derived from plant biotechnology, TFDA is responsible for regulating products derived from microbial biotechnology in food while MOA is responsible for use in feed.
TFDA makes it clear that in the guidelines that it only addresses safety and nutritional aspects of foods consisting of, or derived from, microorganisms that have a history of safe use as sources of food, which have been modified by modern biotechnology to exhibit new or altered traits. It does not address safety of microorganisms used in agriculture, safety of substances produced by microorganisms that are used as additives or processing aids, specific purported health benefits or probiotic effects that may be attributed to the use of microorganisms in food and risks related to environmental releases of GE microorganisms.
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.

b. APPROVALS:
On March 11, 2021, TFDA approved 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. 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 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 February 7, 2023, TFDA approved to expand 2'-FL use to "Infant formula for special medical purposes".
On February 16, 2022, TFDA approved *Ganoderma microsporum* globulin-like protein concentrate from GE *Pichia pastoris* Ey72.
On June 29, 2023, TFDA approved trans-Resveratrol Produced by Genetically Modified Saccharomyces cerevisiae Strain EFSC4687 as a Food Ingredient with restriction and labeling requirement.
All products above completed food safety reviews in accordance with the Non-traditional Food Guidelines.

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.

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: N.A.

Attachments:

No Attachments