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# **Report Name:** Agricultural Biotechnology Annual

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**Report Highlights:**

Thailand has yet to finalize its Biodiversity Act. Since December 4, 2022, the Thai Food and Drug Administration has enforced two notifications regarding GE (termed “Genetically Modified” or GM) food imports, production and labeling.

**Executive Summary**

Since February 2022, Thailand's Council of State has been reviewing the text of the draft Biodiversity Act after the Cabinet had approved the draft bill on principle. After the Council of State approves the bill, it will go to the National Assembly of Thailand for approval. The remaining legislative process to finalize the bill may take up more than a year. In parallel with the ongoing legislative process for the Biodiversity Act, the Department of Agriculture (DOA) Ministry of Agriculture and Cooperatives (MOAC) is drafting own notification to regulate genetically engineered (GE) plant cultivation.

In January 2023, the Thai Food and Drug Administration (TFDA) updated its website in Thai to include GE food requirements related to import documentation, safety assessment and labeling. From December 2022, Thailand has implemented two "GM" notifications regarding GE food and labeling (see Thailand Update its Implementation on "GM" Food Regulations and Food and Agricultural Import Regulations and Standards Country Report in Section VII. Other Specific Standards: 7.15 Genetically Modified Foods (GMFs), published on June 30, 2023).

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## CHAPTER 1: PLANT BIOTECHNOLOGY

## PART A: PRODUCTION AND TRADE

a. RESEARCH AND PRODUCT DEVELOPMENT: In 2003, the Thai government issued a blanket ban on field trials with genetically engineered (GE) crops after public opposition. In 2007, the Cabinet permitted GE crop field trials in Thailand under certain restrictions, but there have been no GE crop field trials in Thailand since the 2003 ban.

b. COMMERCIAL PRODUCTION: Thailand has a de facto ban on GE crop cultivation due to strong objection from activist groups, though there is an existing biosafety law related to conducting field trial cultivation. There are no developments toward extending field trial cultivation to commercial-scale production.

c. EXPORTS: Thailand does not officially export GE products since there is no legal domestic cultivation of GE crops. However, Thailand imports GE soybeans to crush for cooking oil production, which the government does not treat as GE.

d. IMPORTS: Thailand limits the importation of GE products to soybeans, corn, and distiller's dried grains with solubles (DDGS) (solely imported from the United States) for feed and industrial uses, processed food, and cotton lint. Roughly 95 percent of total soybean imports and 85-90 percent of cotton imports in 2022 came from GE plants. The Thai Customs Department reported Thailand's 2022 total imports at $2.03 billion of soybeans and $535 million of cotton. DDGS, cotton, and soybean imports from the United States totaled $502 million in the same year.

e. FOOD AID: Thailand is not a food aid recipient and does not provide food aid on a regular basis. Thailand has occasionally donated rice for disaster relief to neighboring countries.

f. TRADE BARRIERS: Since December 2022, Thailand began enforcing two new genetically modified (GM[1]) food regulations, which may delay or disrupt trade flow of all processed foods containing GM organisms and microorganisms into Thailand. The TFDA requires documentation that specifies the GM events of imports match the approved GM events in the Positive List (Appendix 1) or Temporary Approval List (Appendix 6) of the Ministry of Public Health (MOPH) Ministerial Regulation No. 431 Re: Food Derived from Genetically Modified Organisms (GMOs) (see attachment). However, according to TFDA website on updating the implementation on GM food regulations, the food products that use plants, animals, and microorganisms that are edited, trimmed, modified, or altered genetic material or incorporated new genetic material from modern biotechnology as food or food ingredients and were registered with the TFDA and imported or sold in Thailand before December 4, 2022, are exempted from providing additional import documents for Thai FDA inspection at the port of entry.

[1] Specifically denoted in the Thai notifications as "GM" when referring to GE (genetically engineered)

## PART B: POLICY

a. REGULATORY FRAMEWORK: The six main government agencies involved in the regulation of agricultural biotechnology are the: 1) the Department of Agriculture (DOA) of the Ministry of Agriculture and Cooperatives (MOAC) regulates imported GE seed for planting, conducts GE research and development, and carries out risk assessments; 2) MOAC's Department of Fisheries oversees imported GE aquatic animals; 3) MOAC's Department of Livestock Development regulates imported GE livestock animals; 4) the National Center for Genetic Engineering and Biotechnology (BIOTEC) of the Ministry of Higher Education, Science, Research and Innovation (MHESI) conducts GE crop research and development, including DNA technology laboratory development, technical advice and research funding; 5) the Ministry of Natural Resources and Environment (MONRE) drafted the National Biodiversity Act Law and serves as the national focal point for the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (CPB); and 6) MOPH's TFDA regulates and monitors the use of GE food, including labeling and imports of GE-contained food products. In addition, the National Bureau of Agricultural Commodity and Food Standards (ACFS) under MOAC represents the Thai Government in negotiating all SPS issues in international organizations (e.g., WTO, Codex, OIE, etc.), including the safety of GE products.

   The National Biosafety Committee (NBC) in the Ministry of Science and Technology is the coordination body to develop national biosafety guidelines, to oversee imports of living organisms, and to review and direct research methodologies. The NBC worked with the Institutional Biosafety Committee (IBC) to achieve its mandate, which is a working group comprised of various institutions, mainly universities and government agencies, that conduct GE research and development projects. IBC is primarily responsible for controlling and monitoring GE projects to ensure they comply with national biosafety guidelines. The IBC must report project proposals and project evaluations to NBC. However, the NBC is no longer active due to a lack of real field trial activities. The Technical Biosafety Committee (TBC), an ad hoc technical advisor of BIOTEC, is conducting the review of biosafety issues for GE plants and animals. In 2010, the TBC signed a memorandum of understanding (MOU) with the TFDA to conduct food safety assessments for all GE organisms (i.e., plant, animal, and microorganism). The MOU divides every 5-year increment into phases. The MOU is currently in its third phase from 2021 to 2025, which extended the scope of work to cover safety assessments on food contained genetic materials which are modified or obtained from modern biotechnology as defined by the Cartagena Protocol. The TBC's main roles and responsibilities are:

   1) to provide technical advice and consultations to various organizations on biosafety as it relates to modern biotechnology in accordance with international standards and guidelines;
   2) to provide standards and guidelines for biosafety assessments; and
   3) to strengthen capacity building of the IBC.

Table 1. Legal Definitions

| **Legal Term (in official language)** | **Legal Term (in English)** | **Laws and Regulations Where Term is Used** | **Legal Definition (in English)** |
|---|---|---|---|
| สิ่งมีชีวิตดัดแปรพันธุกรรม | Living Modified Organism (LMO) | Draft Biodiversity Act | Any living organism that possesses a novel combination of genetic material obtained by the use of modern biotechnology or other methods as prescribed by the responsible minister per the committee's advice. |
| สิ่งมีชีวิตดัดแปรพันธุกรรม | Genetically Modified Organism (GMO) | MOPH Ministerial Notification No. 431 Re: Food derived from Modern Biotechnology | The organism whose genetic materials are modified and obtained by the use of modern biotechnology |
| สิ่งมีชีวิต | Organism | MOPH Ministerial Notification No. 431 Re: Food derived from Modern Biotechnology | The biological unit that can be transferred or transcript or multiplied by their own and including sterile biological units, viruses and viroids |
| เทคโนโลยีชีวภาพสมัยใหม่ | Modern Biotechnology | MOPH Ministerial Notification No. 431 Re: Food derived from Modern Biotechnology | (1) in vitro nucleic acid techniques including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, that overcome |

| | | | |
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| | | | natural reproduction and that are not techniques used in conventional breeding and variety selection; or<br><br>(2) Fusion of cells beyond the taxonomic family, that overcome natural reproduction and that are not techniques used in conventional breeding and variety selection |
| พืชดัดแปรพันธุกรรมแบบรวมยีน | Genetically modified crops with stacked events | MOPH Ministerial Notification No. 431 Re: Food derived from Modern Biotechnology | Genetically modified plant which is obtained from conventional breeding of parental lines which are genetically modified plants. |
| สิ่งมีชีวิตดัดแปรพันธุกรรม | Genetically Modified Organism (GMO) | MOPH Ministerial Notification No.432 Re: Labeling of Food Derived from GMO | The organism whose genetic materials are modified and obtained by the use of modern biotechnology |
| อาหารที่ได้จากสิ่งมีชีวิตดัดแปรพันธุกรรม | Food derived from Genetically Modified Organisms | MOPH Ministerial Notification No.432 Re: Labeling of Food derived from GMO | (1) Plants, animals, and microorganisms that contain modified or altered genetic materials or that combined new genetic materials |

| | | | |
|---|---|---|---|
| | | | via modern biotechnology, and are for consumption as food<br><br>(2) Food Products that use (1) as a food ingredient or produce from (1).<br>(3) Products from (1) used as a food ingredient or used as food additives or used as nutrient |

In 2021, MONRE submitted to the Cabinet a draft Biodiversity Act, which addressed research, field trial, and commercialization for genetically modified plant, animal, and microorganisms. The Cabinet approved the bill in principle on February 22, 2022. Since then, the Office of the Council of State has been reviewing the draft bill. The draft bill will then need to pass the hearings and gain approval from the National Assembly of Thailand. The King of Thailand will make the final approval before the bill becomes law.

The draft Biodiversity Act represents a more than 10-year process to develop a law governing biodiversity. The latest push to finalize biodiversity legislation stemmed from the National Strategy developed in 2018. The National Strategy provided guidelines on promoting economic development while also managing the sustainability of Thailand's national resources. The National Reform Plan in Natural Resources and Environment (NRP) was published in the Royal Gazette in April 2018 in response to the National Strategy and stated that the drafting of a comprehensive biodiversity law must be initiated by 2020.

Thailand is also adopting the economic growth model known as Thailand 4.0, which mandates agriculture and biotechnology as one of the growth engines. One of the projects initiated under Thailand 4.0 is the Agriculture 4.0 project. The Agriculture 4.0 project's objective is to improve crop productivity using innovative biotechnologies for more efficient farming while reducing negative impacts on the environment and society. The project aligns with the national agenda of the Bio-Circular-Green Economy (BCG), which aims to modernize Thailand's agricultural sector through:

- Strategy 1: Promote sustainability of biological resources through balancing conservation and utilization.
- Strategy 2: Strengthen communities and grassroots economies by employing resource capital, creativity, technology, biodiversity, and cultural diversity to create value to products and services, enabling communities to move up the value chain.

- Strategy 3: Upgrade and promote sustainable competitiveness of Thai BCG industries with knowledge, technology, and innovation focusing on green manufacturing.
- Strategy 4: Build resilience to global changes.

The draft Biosafety Act's definition of biosafety covers environmental safety, human health safety, and sustainable biodiversity. There is concern that the bill's broad definition of a living modified organism may lead Thailand to treat gene-edited products as GMOs and impeded the future of gene editing field trials and commercialization in Thailand.

The draft Biodiversity Act's definition of biosafety covers access to biological resources, the fair and equitable sharing of benefits arising from utilization of biodiversity, living modified organisms (LMOs), and control of potential effects on biodiversity. The draft legislation adopted the Cartagena Protocol on Biosafety provisions on the control of potential effects of LMOs. In addition, the draft uses the precautionary principle on the control and approval of LMOs to avoid the criticism leveled by anti-biotech NGOs at the 2015 Biosafety Act.

The draft legislation stipulates that only LMOs on the Release List will be allowed into the environment. Applicants wishing to add an LMO to the Release List must submit an application with a biosafety risk assessment report to the competent authority. Permission from the competent authority is required in order to import, export, transfer, commence contained use activity, and field trials. In addition, the owner of both domestically developed and imported LMOs must comply with ministerial regulations as well if undertaking importation, exportation, transportation, packaging, classification, or usage in a controlled environment and in the field (a biosafety assessment is required before environmental release). The draft legislation also stipulates that any person who possess LMOs that appear to be unsafe, harmful, or able to cause adverse effect to the environment, human or animal health, or socio-economy must dispose or destroy the LMOs at his/her own expense.

On December 4, 2022, TFDA began to MOPH Ministerial Notification No. 431 Re: Food Derived from Genetically Modified Organisms (GMOs) also known as Mandatory Safety Assessment Regulation (unofficial English translation attached to this report):

i. The notification covers all food products derived from genetically modified organisms and contains the definitions referenced in Table 1.
ii. The import, production and/or commercialization of food derived from "GM organisms" would be allowed for:
    (1) Food derived from "GM organisms/events" that are on the list of approved organisms (see Annex I for the positive list as of October 2023).
    (2) Food derived from GM organisms on the Temporary Approval list (TAL; see Appendix 6 of the MOPH Regulation No. 431) for 5 years from December 4, 2022.
        a) To list an event in the TAL, developers of GM plant organisms and GM microorganisms have to present an associated food safety approval from at least 5 OECD countries. The TFDA advises developers to submit the dossiers of TAL events within the first 3 years of implementation so that the Technical Biotechnology Committee at BIOTEC can perform the risk assessment. The Committee usually completes a risk assessment between 4 and 12 months.

Following a BIOTEC safety assessment, the developer has to submit the reference materials, method of analysis, or other related information to the Department of Medical Science (DMsC). Both the safety assessment report and confirmation document from DMsC must be summitted to the TFDA to ensure the events receive approval and are listed in the positive list before the 5-year grace period expires. From December 4, 2027, TFDA will only allow the importation of GM food itemized in the positive list.

(3) TFDA requires each shipment of imported GM grain/products with approved events listed in the positive list or TAL to be accompanied with one of the following:

- analytical report issued by a government laboratory from the country of origin, a government laboratory in Thailand or a private laboratory accredited by the Thai government;
- certificate of analysis for a specific silo/batch issued by a government laboratory from the country of origin, a government laboratory in Thailand or a private laboratory accredited by the Thai government;
- phytosanitary certificate specifying the event trait or the OECD unique identifier of GM plants or the absence of any unauthorized traits;
- identity preservation;
- invoice or packing list specifying event trait or OECD unique identifier if food derived from GM organisms; and
- a self-verified document issued by the manufacturer or exporter stating, "This shipment of (name of plant or animal or microorganism) may contain genetically modified events as following…." OR other statement with a similar meaning including the contact information of the importing party; or
- a self-verified document of the manufacturer or exporter with a written statement that states the shipment "adheres to MOPH Ministerial Notification No. 431."

b. APPROVALS/AUTHORIZATIONS: Thailand has not approved any GE crops for cultivation. The Department of Agriculture is drafting biosafety regulations aligned with the draft Biodiversity Act to enforce imported GE seed cultivation for lab testing and field trial to commercialization including conducting risk assessments. The BIOTEC's Biosafety Guideline for GE crops in contained/confined use for research and development (R&D) purposes specifies that IBC approval requirement. The guideline also includes genome editing technology and synthetic biology in the definition of modern biotechnology (see https://www.biotec.or.th/biosafety/images/document/G01-Biosafety%20Guideline.pdf for the original Thai).

Imports of GE crops are limited to corn, soybeans, and cotton for feed and industrial use. According to the MOPH Ministerial Regulation No. 431, the importation, manufacturing, and commercialization of "GM food derived from GM plant organism" must pass a "GM food safety assessment" as promulgated in Appendix 2 of the regulation.
The positive list and temporary approval list of "GM plants" are available at Appendix 1 and 6, respectively, at

https://food.fda.moph.go.th/media.php?id=50944131010147942 4&name=P431_E.pdf

BIOTEC is responsible for conducting the food safety assessment for food derived from GM plants and has published the Guideline for Food Safety Assessment of Food Derived from Recombinant-DNA Plants based on the CODEX principles of substantial equivalence and conventional counterpart with four key considerations of molecular biology, nutrition, toxicology, and allergenicity. The guideline in Thai is at https://www.biotec.or.th/biosafety/index.php/guideline. The TFDA provides an exemption from in-country submission and food safety assessment if the Joint WHO/FAO Scientific Advice Bodies or WHO Expert Advisory Panels and Committees have approved the "GM food derived from GM plant organisms."

c. STACKED or PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS: No GE crops with stacked or pyramided events have been approved for cultivation. According to the MOPH Ministerial Regulation No. 431, the importation, manufacturing, and commercialization of "GM food derived from GM plant stacked events" must pass a "GM food safety assessment" as promulgated in Appendix 2 of the regulation. BIOTEC published its guidelines for food safety assessments of GE conventional stacked events classifying GE crops into the following three categories:

**Category 1**: Transgene exerts no effects on the host metabolic systems (e.g., insect-resistance, herbicide-tolerance, virus-resistance).
**Category 2**: Transgene modifies the host metabolic systems (e.g., high oleic acid producing soybean).
**Category 3**: Plant metabolites are used by transgene products and new metabolites that are not found in the host are produced.

The Guideline in Thai is at
https://www.biotec.or.th/biosafety/images/document/guideline/stackedforweb.pdf

d. FIELD TESTING: All field trials must be located on government properties, hold public hearings prior to implementation, and obtain approval from the Ministerial Cabinet according to the 2007 Cabinet's criteria.

e. INNOVATIVE BIOTECHNOLOGIES: Some academic and research institutes are unofficially conducting gene editing for a few crops (e.g., tomato, cucumber, sugarcane, and orchid), but research is limited to laboratory experiments. The TFDA has published the Public Manual to publish the food safety assessment for food derived from gene editing technology. BIOTEC has decided to develop the guidelines on the risk assessment of genome editing for food safety assessment and environmental safety assessment of plants derived from gene editing technology. BIOTEC has finalized the food safety assessment of organisms derived from gene editing technology as follows:

| Assessment | Category I SDN1 | Category II SDN2 | Category III SDN3 |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 1. Data on the changed nucleotide sequence before and after genome editing | yes | yes | yes |
| 2. Product data due to genome editing | yes | yes | yes |
| 3. Spurious DNA Insertions outside of potentially affected locus/loci (PAL) | -- | yes | yes |
| 4. Referring to minimal requirements for safety assessment of food derived from "GMOs"<br>- Molecular biology<br>- Product specification<br>- Nutrition<br>- Toxicology<br>- Allergenicity | -- | Case-by-case assessment with consideration on product characteristics | yes |

**Category 1**: Food derived from organisms developed by site-directed nuclease (SDN1) or other genome editing techniques that resulted in site-specific random mutations that include substations, insertions, and deletions at target DNA and do not contain any foreign gene in final products.
**Category 2**: Food derived from organisms developed by site-directed nuclease 2 (SDN2) or other genome editing techniques that used DNA template to modify target nucleotide sequence for expected result by homology directed repair (HDR).
**Category 3**: Food derived from organisms developed by site-directed nuclease 3 (SDN3) or other genome eating techniques that used non-homologous end joining (NHEJ) and homology directed repair (HDR) to insert large DNA at target nucleotides sequence.

The Public Manual of food safety assessment for food derived from gene editing technology in Thai is at:
https://food.fda.moph.go.th/media.php?id=4708568205677117 44&name=9.6.pdf

f. COEXISTENCE: Thailand has not established any framework or guidelines regarding coexistence with non-GE crops.

g. LABELING AND TRACEABILITY: Since December 4, 2022, the TFDA enforces MOPH Notification No. 432 Re: Labeling of Food Derived from GM Organisms with these provisions:

i. Food intentionally containing or consisting of "GM plants, GM animals" less than 5 percent of each ingredient of total weight containing GM organisms at limit of detection of 0.1 percent must be labeled.[2]
ii. Genetically Modified Microorganisms (GMMs) equal to or greater than 5 percent for each ingredient of total weight containing GM organisms at limit of detection of 0.1% must be labeled.
iii. Food containing only one main ingredient should include a statement of "genetically modified" in conjunction with, or in close proximity to, the name of foods such as "genetically modified corn," or "tofu produced from genetically modified soybean."
iv. For multi-ingredient foods, labels should include a statement of "genetically modified" in conjunction with, or in close proximity to, or under the names of such GM ingredients.
v. For products derived from "GM plants, GM animals and GMMs" as ingredient or food additive, the label must display the text "[ Food/product name ] is produced from... [ type of GM plant/ animal/ microorganism]."
vi. TFDA will exempt food products from labeling if:
    i. the food manufacturer can prove that the food is "non-GM organism" by traceability certification. The TFDA requires that manufacturers or importers have a traceability system in place and be able to present evidence of whether GE food ingredients are used, the quantity used, and the percentage by weight of each food ingredient if they want to avoid having to perform a lab analysis of the final product. The lab test result or certificate of analysis (COA) issued by ISO 17025 laboratory with certified accredited body needs to be kept for the duration of the product's shelf life to present to the TFDA if required;
    ii. produced by small scale producers;
    iii. prepared and sold by restaurants or vending machines;
    iv. do not contain any detectable genetic material or protein resulting from genetic modification used as processing aid in food manufacturing.
vii. The TFDA will not allow the terms "Free from GMF" or "Non-GM Food" or any other similar text or symbols.
viii. Displaying the GE symbol is voluntary.
ix. Labeling of genetically modified foods that adhere to the prior MOPH Regulation No.231 requirements will no longer be allowed after a 2-year grace period from December 4, 2022.

Details of MOPH Ministerial Notification No. 432 Re: Labeling of Food Derived from GM Organisms is available at the below link or in the attachment of this report:

https://food.fda.moph.go.th/media.php?id=509441595192516608&name=P432_E.pdf

h. MONITORING AND TESTING: Although Thailand has laboratory facilities to test GE products, conducting lab tests in order to detect genetically modified material particularly in

[2] According to the TFDA, if an importer cannot provide the specification of the raw materials in the product, then TFDA requires packaged food products with detectable GMOs and recombinant protein at the level of detection of 0.1 percent to be labeled only if the product's ingredients consists of GMOs over 5 percent of total weight even if it is unintentional.

processed food products is costly and complicated. This is a key challenge for government officials to ensure compliance with biotech food labeling requirements.

i. LOW LEVEL PRESENCE (LLP) POLICY: Thailand has not established any framework or guidelines regarding low level presence.

j. ADDITIONAL REGULATORY REQUIREMENTS: DOA has the following existing biosafety related regulations:

- Plant Quarantine Act B.E. 2507 (1964) amended by (No.2) B.E. 2542 (1999); amended by (No.3) B.E. 2551 (2008): to prohibit the importation of 33 species, 51 genus, and 1 family into the Kingdom except for R&D.
- Plant Act B.E.2518 (1975) amended by (No.2) B.E. 2535 (1992) and (No.3) B.E. 2550 (2007): to prescribe quality examinations of controlled seed and overseeing reserved plants and conserved plants including the determination of qualifications for the licensee for collection, sale, importation, or exportation of controlled seed for trade.
- Plant Variety Protection Act B.E. 2542 (1999): to register and assess for potential risk of living modified plants.

**Remark**: The National Economic and Social Development Committee delisted corn and soybeans from the GM Prohibited Items List under the Plant Quarantine Act due to their importance in food and feed processing.

k. INTELLECTUAL PROPERTY RIGHTS (IPR): Seed developers believe that Thailand's existing Plant Variety Protection Act (PVP) does not protect patents for new plant varieties derived from genetic engineering. In particular, the PVP that regulates the use of foreign plant varieties to develop new breed seeds in Thailand, including GE crop seeds, is subject to a benefit sharing requirement for local communities. The Thai Seed Trade Association (THASTA) and other stakeholders have worked with MOAC over the past couple years to revise these provisions in accordance with the International Union for the Protection of New Variety of Plants' (UPOV) guidelines. Copyright protection for GE crops is covered under the Trademark Act (No.2) B.E. 2543 (2000), which is regulated by the Ministry of Commerce's Department of Intellectual Property.

l. CARTAGENA PROTOCOL RATIFICATION: Thailand signed the Convention on Biological Diversity (CBD) in 1992. Thailand signed the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety in March 2012.

m. INTERNATIONAL TREATIES and FORUMS: Thailand regularly participates in international organization conventions such as the International Plant Protection Convention (IPPC) and Codex Alimentarius (Codex). However, Thailand has not taken any clear position on issues related to GE crops and related products.

n. RELATED ISSUES: The Thai government, especially the MOAC, promotes organic production and self-sufficient agricultural production. Most Thais perceive organic crops as being safer than

GE crops and view farmers who adopt self-sufficiency in agricultural production as being less dependent on expensive agricultural practices.

## PART C: MARKETING

a. PUBLIC/PRIVATE OPINIONS: In 2010, 66 percent of the 340 surveyed respondents said they would not purchase GE foods. Forty percent of respondents believed that consumption of GE foods could create an allergic reaction, and fifty-six percent believed that consumption could lead to antibiotic resistant diseases. Sixty percent of the respondents felt that GE foods could enhance food traits, while fifty-four percent believed that GE foods should cost less. Sixty-eight percent of the respondents believed that GE crops could cause an unbalanced ecosystem, and seventy-five percent agreed that the GE crops could contaminate traditional crops during production. A 2012 study found that the majority of consumers preferred to avoid GE food and would expect GE food to be cheaper than non-GE food as GE food could pose negative health impacts.

b. MARKET ACCEPTANCE/STUDIES: A 2022 survey on "Consumer Acceptance, Trust and Perceived Risk Regarding Genetically Modified (GM) Food" showed that 72% of respondents accepted the use of genetically engineered food and 90% of respondents were willing to accept "GM products" after reading and hearing of positive information on "GM foods." In addition, household size from 1 to 5 members, labeling, and knowledge of science and technology also influenced consumer acceptance. There was also a boarder survey in 2021 that focused on how Thai society's view on "GMOs" changed from 1994 to 2021. The survey showed that Thai people are still generally scared of consuming GE products. One of the major hurdles of public acceptance is the lack of government policy on GE crop cultivation.

Thai producers, retailers, and consumers remain misinformed about the safety and use of transgenic plants or related foods. Contrary to public perception, Thailand consumes large amounts of biotech crops directly and indirectly. Although mandatory labeling is required for food products with more than five percent GE content, unpackaged products or products packaged in bulk are exempt from the labeling requirement. The Thai public likely substantially underestimates the amount of biotech products they consume.

# CHAPTER 2: ANIMAL BIOTECHNOLOGY

## PART D: PRODUCTION AND TRADE

a. RESEARCH AND PRODUCT DEVELOPMENT: Thailand does not engage in the development or production of genetically engineered animals. Some universities have conducted cloning research in cattle, buffalo, goats, and pet animals, such as Chulalongkorn University, Kasetsart University, and Suranaree University of Technology, but FAS/Bangkok is unaware of initiatives to develop this technology for commercial purposes.

b. COMMERCIAL PRODUCTION: None.

c. EXPORTS: None.

d. IMPORTS: None.

e. TRADE BARRIERS: Trade of GE animals is subject to a de facto import/export ban.

**PART E: POLICY**

a. REGULATORY FRAMEWORK: The TBC, an ad hoc technical advisor of BIOTEC, has the responsibility for the review of biosafety issues for GE animals.

b. APPROVALS/AUTHORIZATIONS: The importation, manufacturing, and commercialization of GE food derived from GE animal organisms must have a GE food safety assessment as promulgated in MOPH Ministerial Regulation No. 431 (see Appendix 4). BIOTEC published the Guideline for Food Safety Assessment of Food Derived from Recombinant-DNA Animals based on CODEX principle of substantial equivalence and conventional counterpart with four key considerations of molecular biology, nutrition, toxicology, and allergenicity. The guideline in Thai is available at https://www.biotec.or.th/biosafety/images/document/guideline/animalminimum60.pdf.

c. INNOVATIVE BIOTECHNOLOGIES: There has been no research on gene editing in Thailand. BIOTEC has developed the biosafety guideline for GE animals in laboratory testing for R&D, which requires approval from IBC. The guideline also includes genome editing technology and synthetic biology in the definition of modern biotechnology. The document in Thai is available at https://www.biotec.or.th/biosafety/images/document/G01-Biosafety%20Guideline.pdf.

d. LABELING AND TRACEABILITY: The TFDA enforces labeling and traceability requirements according to MOPH Ministerial Notification No. 452 Labeling of "GM Foods."

e. ADDITIONAL REGULATORY REQUIREMENTS: The Department of Fisheries launched MOAC Ministerial Notification B.E.2564 (2021) to prohibit the production of GE fish in Thailand unless the Director General (DG) or a competent authority assigned by DG, of the Department of Fisheries approves a license.

- Existing biosafety related laws – Fisheries Act B.E. 2490 (1947); amend (No. 2) B.E. 2496 (1953) and (No.3) B.E. 2558 (2015)

f. INTERNATIONAL PROPERTY RIGHTS (IPR): None.

g. INTELLECTUAL TREATIES and FORUMs: None.

h. RELATED ISSUES: None.

**PART F: MARKETING**

a. PUBLIC/PRIVATE OPINIONS: There has been no survey on public or private opinions. However, FAS/Bangkok understands that the majority of Thais are not aware of developments in animal biotechnology, including both GE and cloned animals. If any, most private opinions would be negative due to frequent anti-biotech campaigns by certain NGOs.

b. MARKET ACCEPTANCE/STUDIES: FAS/Bangkok believes that market acceptance for the sale and use of livestock clones and GE animals in Thailand is very low and probably nonexistent.

## CHAPTER 3: MICROBIAL BIOTECHNOLOGY

### PART G: PRODUCTION AND TRADE

a. COMMERCIAL PRODUCTION: There are neither official report nor statistics of Thailand's production of food ingredients derived from microbial biotechnology.

b. EXPORTS: Exports of products containing microbial biotech-derived food ingredients may include those traditionally used in the production of alcoholic beverages, dairy products, and processed products. The Thai Customs Department's trade statistics indicates Thailand's exports of products likely containing microbial biotech-derived food ingredients [3] reached approximately $4.18 billion in 2022, up 7.7 percent from $3.88 billion in 2021.

c. IMPORTS: In 2022, Thailand imported $951 million, a 19 percent increase over 2021, of food additives and enzymes. However, there are no trade figures specifically for microbial biotechnology-derived food ingredients since there is no specific tariff classification for them.

d. TRADE BARRIERS: TFDA will allow importation of "GMMs" that are listed in the Positive List in Appendix I of the MOPH Ministerial Notification No. 431.

### PART H: POLICY

[3] 0406: Cheese and Curd
190110: Food Preparations for Infant Use, Put Up for Retail Sale, Nesoi
1904: Prepared Foods from Swelling or Roasting Cereals Or Products; Cereals (Exc. Corn), In Grain Form Flakes Or Worked Grain Prepared N.E.S.O.I
1905: Bread, Pastry, Cakes, Biscuits and Other Bakers' Wares; Communion Wafers, Empty Capsules for Medicine Etc., Sealing Wafers, Rice Paper Etc.
2009: Fruit Juices Not Fortified W Vit or Minls (Incl Grape Must) & Vegetable Juices, Unfermented & Not Containing Add Spirit, Wheat or Not Containing Added Sweetening
2103: Sauces and Preparations Therefor; Mixed Condiments and Mixed Seasonings; Mustard Flour and Meal And Prepared Mustard
2106: Food Preparations Nesoi
2203: Beer Made from Malt
2204: Wine of Fresh Grapes, Including Fortified Wines; Grape Must (Having an Alcoholic Strength By Volume Exceeding 0.5% Vol.) Nesoi
3507: Enzymes; Prepared Enzymes Nesoi

a. REGULATORY FRAMEWORK: The TFDA enforces the import, manufacturing, and commercialization including labeling of GE food in accordance to Ministerial Notifications No. 431 and 432 (see Chapter 1: Plant Biotechnology for details) since December 4, 2022.

According to the MOPH Ministerial Notification No. 431, the definition of food derived from GMM are categorized into the following three types:

i. Food produced from GMMs that have had GMMs and newly introduced genes used in genetic modification removed or foods that still contain GMMs, but their GMMs and newly introduced genes used in genetic modification cannot increase in number (multiplication) and cannot transfer genetic material (transferring gene).
ii. Complex products that have no remaining GMMs and newly introduced genes used in the modification in the product.
iii. Foods that are chemically purified compounds and the compounds obtained from a mixture of those compounds in which their GMMs and newly introduced genes used in genetic modification have been removed.

Importers/processors must present evidence for a safety assessment on biotechnology-derived food products where "GMM(s) is(are) approved" as stated in Appendix 3 of the MOPH Ministerial Notification No. 431.

The MOPH regulates enzymes produced using microbial biotechnology through Notification No. 443 Re: Enzyme used for food production.
https://food.fda.moph.go.th/media.php?id=534563427285344256&name=P443.pdf

BIOTEC published guidelines in 2011 titled "Biosafety Guidelines for Contained Use of Genetically Modified Microorganisms at Pilot and Industrial Scales," and updates the guidelines every two year. The guidelines provide basic information to serve operators who are interested in topics such as containment measures, biosafety levels, risk assessment and management, basis for the classification of biohazardous agents by risk group, certified host-vector systems, and good laboratory and industrial large-scale practices including the possession, transport, import, and export of GE microbes. In 2015, GE microbe waste management guidelines were added, the list of microorganisms/agents was updated to conform to the lists of national and international organizations, and an English version was prepared for foreign organizations/institutions working with GE microbes at pilot and industrial scales in Thailand.

The guideline is available in Thai at https://www.biotec.or.th/biosafety/index.php/guideline.

b. APPROVALS/AUTHORIZATIONS: BIOTEC has published the Guideline for Food Safety Assessment of Food Derived from Recombinant-DNA Microorganisms based on ACFS Guidelines for safety assessment of food produced using DNA-editing microorganisms, CODEX principles, and European Food Safety Authority guidance. The Guideline in Thai is available at https://www.biotec.or.th/biosafety/images/document/guideline/minimum4GMM_forweb.pdf.

The Guideline classifies food derived from R-DNA microorganisms into:

**Category 1**: Products consisting of or containing GMMs capable of multiplication or of transferring genes (e.g., live starter cultures for fermented food and feed).
**Category 2**: Products derived from GMMs that are capable of multiplication or unpresented of transferring genes; however, newly introduced genes are still present.
**Category 3**: Complex products in which both GMMs and newly introduced genes are no longer present (e.g., cell extracts, enzyme preparations).
**Category 4**: Chemically defined purified compounds and their mixtures in which GMMs and newly introduced genes have been removed (e.g., amino acids, vitamins).

The importation, manufacturing and commercialization of "GM Food" derived from "GMMs" must pass a "GM food safety assessment" as promulgated in MOPH regulation No. 431 (see Appendix 3). The approved list of GMMs is available in on page 4 of the below URL: https://food.fda.moph.go.th/media.php?id=5094413101014794 24&name=P431_E.pdf

The TFDA provides an exemption from in-country food safety assessment if the Joint WHO/FAO Scientific Advice Bodies or WHO Expert Advisory Panels and Committees have approved the "GM food" derived from "GMM organisms."

The TFDA provides an approved list of food additives under MOPH Ministerial Notification no. 418 B.E.2563 Re: Prescribing the Principle, Conditions, Methods and Proportion of Food Additives (No.2). The English list of permitted food additives in Thailand is available at https://food.fda.moph.go.th/media.php?id=50942995 2660250624&name=P418_E.pdf

The list includes all approved food additives and does not specify microbial biotechnology-derived products. If the food additive is derived from GE microbes and is not listed, a safety assessment is required by BIOTEC for product registration with TFDA. The TFDA also accepts food additives that are identified by CODEX (GSFA).

The list of TFDA permissible enzyme for product registration is in accordance with Appendix 1 of the MOPH Ministerial Notification no.443 B.E.2566 Re: Enzymes Used for Food Production (linked here in Thai):
https://food.fda.moph.go.th/media.php?id=534563427285344256&name=P443.pdf
or JECFA Combined Compendium of Food Additive Specifications (linked here in English): http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en from the FAO.

c. LABELING AND TRACEABILITY: The TFDA requires food additives and enzymes derived from GE microbes to comply with labeling requirements according to MOPH Ministerial Notification No. 372 B.E. 2558 Re: Food Additives (No.3). Food additives and enzymes that are not sold directly to consumers are exempted from declaring ingredients on the label. The name of the food additives or enzymes together with the type of GE microbes they are derived from can be presented in the product manual instead.

d. MONITORING AND TESTING: Although Thailand has laboratory facilities to test GE products, sources indicate that officials do not closely test or monitor manufacturers' compliance of the biotech food labeling requirements.

e. ADDITIONAL REGULATORY REQUIREMENTS: None.

f. INTELLECTUAL PROPERTY RIGHTS (IPR): The Department of Intellectual Property can grant a patent for a new method of GMM production or the GMM itself if the new function or trait can be regulated by the Patent Act B.E. 2522 (1979).

g. RELATED ISSUES: Thailand aims to develop a synthetic bioeconomy, especially in the food ingredients industry. On November 11, 2021, the Office of National Higher Education Science Research and Innovation Policy Council (NXPO) established a Synthetic Biology Consortium and signed a memorandum of understanding with sixteen organizations to drive research, innovation, and application of synthetic biology in Thailand. The organizations included small and medium enterprises, startups, large enterprises, research institutes, and universities. The NXPO synthetic biology ecosystem development roadmap has three phases. Phase I will take one to three years to build capacity with collaboration platforms and demonstrate business opportunities. Phase II will take three to five years to raise the potential of industry and establish industry standards. Phase III will take five years to create deep tech startups and enterprises to support new industries. The following four anchor programs will be established: 1) SynBio Academy, 2) investment & strategic funding program, 3) R&D infrastructure program, and 4) ecosystem and regulatory framework program.

Under BIOTEC's management, the Functional Ingredients and Food Innovation Research Group participates in R&D, and engineering activities involving microbial and enzymatic technology for food and feed as follows:

- development of starter culture for food applications, such as fermented pork sausage, vinegar cider, and pickled mustard green;
- development of starter culture for feeds (e.g., digestive enhanced soybean and silage starter cultures);
- pentosanes for feed applications (digestive enhancer);
- acceleration of the production process for fish sauce production;
- improvement of soy sauce production and quality;
- lactic acid bacterial screening and production; and
- histamine reduction in foods using bacteria.

Additionally, BIOTEC established Thailand Bioresource Research Center (TBRC), which focuses its research on microbial biotechnology to tackle scientific and technological questions in order to support sustainable bioindustry. TBRC is a member of ASIAN Consortium for Conservation and Sustainable Uses of Microbial Biotechnology. TBRC focuses on the following areas of research:

(a) the evolution of microbes at genetic and genomic levels;

(b) development of new techniques for long-term preservation of microbial biomolecules and cells with a high survival rate and a high safety level;
(c) management of microbial database and bioinformatics;
(d) exploration of microbiome or microbial community and its relationship with other living organisms in various environments and ecology; and
(e) high-throughput screening for microorganisms with high potential for the production of bioactive molecules to serve the needs of the industrial sector.

The TBRC strongly promotes bioresource utilization for R&D and provides technical services to support knowledge sharing among the public and the scientific community. The group develops effective technology and processes to facilitate and ensure fair access, transfer, and benefit sharing of biological resources available at TBRC in compliance with national and international regulation and standardization. TBRC consists of the Microbial Diversity and Utilization Research Team (IMUT) and the Microbial Systems and Computational Biology Research Team (IMST).

The primary mission of IMUT is to collect and maintain microorganisms along with relevant information and to serve internal and external researchers. The number of bacteria, yeast, and filamentous fungi exceed 80,000 strains. These microbes are a bio-resource for biotechnology research to find valuable products such as enzymes, biological control, and bioactive compounds. These microorganisms are available for research and commercial use.

IMST focuses on research and development of bioinformatics and data science for genome research and microbial genomics. The team emphasizes the exploration of microbiome and microbial interactions in various environments along with the construction of genome and microbiome databases with research networking to promote microbial utilization and innovation for effective usage in academia and industry. IMST also serves the need of the Thailand Bioresource Research Center by applying MALDI-TOF mass spectrometry to identify microorganisms and enumerate microorganisms from mixed cultures.

**PART I: MARKETING**

a. PUBLIC/PRIVATE OPINIONS: There number of flexitarians in Thailand is growing quickly as the younger generation is more concerned with climate change and animal welfare and is more receptive to new technology to address sustainability and food security. A food industry study showed that the number of vegetarians was 7 million or only 12 percent of the population in 2017, while flexitarians are up to 17 to 18 million people or 25 percent of the population in 2021. Plant-based food has become more popular as an alternative protein with a current market value of approximately $630 million and a forecasted annual growth rate of 15-20% for the next two years.

b. MARKET ACCEPTANCE/STUDIES: FAS Bangkok understands that Thai consumers have started to learn about the functionality, usage, and advantages of microbial biotechnology. Still, the new food technologies are in the early stages. BIOTEC reports R&D advances have contributed approximately $1.76 billion for the private sector in the sector by generating generate

additional income and reducing costs for business partners. Some of these advances include the development of highly concentrated protein beverages, the study of the physical and chemical properties of egg whites, production of vinegar fermented from organic mangosteen and pineapple, peptides from egg white lysozyme, starter of microorganism for the fermentation of naem (Thai sausage), production of a pro-biotic in a pilot plant, low-cyanite tapioca flour, and gluten-free pizza.

**Attachments:** Attachment.docx