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**Report Highlights:**

The Thai Cabinet has approved the draft Biodiversity Law in principle. The draft is in the legislative process and currently with the Council of State for review and approval on text. The Thai Food and Drug Administration finally published its two new genetically engineered (GE) food regulations regarding GE food imports, production, and labeling. Both regulations will be effective on December 4, 2022.

## **Executive Summary:**

The Ministry of Natural Resources and Environment (MONRE) sent the draft Biodiversity Act to the Cabinet for approval in 2021. On February 22, 2022, the Cabinet approved the draft bill on principle, and the Council of State is reviewing the text of the draft. The Council of State approved bill will then head to the National Legislative Assembly (NLA) for approval. The legislative process to finalize the draft bill may take up to two years. The Ministry of Agriculture and Cooperatives (MOAC) is drafting a new act to regulate GE plant cultivation in parallel with the ongoing legislative process of the Biodiversity Act.

The Thai Food and Drug Administration (TFDA) published two notifications regarding genetically engineered (GE) food and labeling in April 2022 that will be effective in December 2022. There remains concern that the implementation of the regulation and the development of the Positive List and the Temporary Approval List will affect trade of processed food containing genetically modified material.

Update on TFDA’s new “GMO” food labeling is also available in Food and Agricultural Import Regulations and Standards Country Report in Section II. Labeling Requirements: 2.5 GM Labeling, published on July 14, 2022.

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## **CHAPTER 1: PLANT BIOTECHNOLOGY**

### **PART A: PRODUCTION AND TRADE**

- a. **RESEARCH AND PRODUCT DEVELOPMENT:** Although there were field trials for several transgenic plant varieties in the 1990s, the Thai government issued a blanket ban in 2003 on

further field trials after public opposition. The Cabinet, however, gave permission for GE crop field trials in Thailand under certain restrictions in 2007. Despite the change in regulations, there have been no GE crop field trials in Thailand since the 2003 ban. Monsanto Thailand planned to partner with Naresuan University to conduct a field trial for NK603 herbicide-resistant corn in 2013, but Naresuan University changed course and declined to host the project. In addition, Syngenta Thailand and Pioneer Thailand have also discontinued their projects to conduct greenhouse trials of GE corn seeds.

- 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 for cooking oil production, which the government does not treat as GE. Cooking oil export markets are mainly in neighboring countries and not the United States.
- 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 2021 came from GE plants. According to the Thai Customs Department, Thailand imported \$2.26 billion of soybean and \$321 million of cotton from all sources in 2021. DDGS, cotton, and soybean imports from the United States totaled \$840 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 given rice for disaster relief in neighboring countries.
- f. **TRADE BARRIERS:** There are no additional biotechnology-related trade barriers beyond the two new genetically modified (GM)<sup>1</sup> food regulations. There is concern that, if enforced, the regulations will delay or disrupt trade flow of all processed foods containing GM organisms and microorganisms into Thailand. The TFDA is requiring 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).

## **PART B: POLICY**

- a. **REGULATORY FRAMEWORK:** The four main government agencies involved in the regulation of agricultural biotechnology are the: 1) the Department of Agriculture (DOA), Ministry of Agriculture and Cooperatives (MOAC), responsible for regulating imported GE seed for planting, conducting GE research and development, and conducting risk assessment; 2) the National Center for Genetic Engineering and Biotechnology (BIOTEC), Ministry of Higher Education, Science, Research and Innovation (MHESI), responsible for conducting GE crop research and

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<sup>1</sup> Specifically denoted in the Thai notifications as “GM” when referring to GE (genetically engineered)

development including DNA technology laboratory development and providing technical advice and research funding; 3) Ministry of Natural Resources and Environment (MONRE), responsible for drafting the National Biodiversity Act Law and being the national focal point for the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety (CPB); and 4) TFDA, Ministry of Public Health (MOPH), responsible for regulating and monitoring the use of GE food including labeling and regulating 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), Ministry of Science and Technology, was established in 1993 to serve as a 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 conducted GE research and development projects. IBC is mainly 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. 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) in 2010. The MOU divides every 5-year increment into phases. The MOU is currently in its the 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 the following:

- 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 IBC.

<b>Legal Term (in official language)</b>	<b>Legal Term (in English)</b>	<b>Laws and Regulations Where Term is Used</b>	<b>Legal Definition (in English)</b>
สิ่งมีชีวิตดัดแปรพันธุกรรม	Living Modified Organism (LMO)	Draft Biodiversity Act	Any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology
สิ่งมีชีวิตดัดแปรพันธุกรรม	Genetically Modified Organism (GMO)	MOPH Ministerial Notification No. 431 Re: Food derived from	The organism whose genetic materials are modified and obtained

		Modern Biotechnology	from 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 the biological unit that sterile, viruses and viroid
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 natural reproduction and that are not techniques used in conventional breeding and variety selection; or (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 from 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 have been modified or altered genetic materials or combined new genetic materials by using of modern biotechnology and for consumption as food.  (2) Food Products that use (1) as a food ingredient or produce from (1). (3) Products from (1) used as a food ingredient or used as food additives or used as nutrient.

MONRE sent its draft Biodiversity Act, which covers research, field trial, and commercialization for genetically modified plant, animal, and microorganisms, to the Cabinet for approval in 2021. The Cabinet approved the bill by principle on February 22, 2022. The Office of Council of State is reviewing the draft bill and the NLA will then need to approve the text. The King of Thailand will make the final approval before it becomes law. The draft Biodiversity Act represents a more than 10-year process to develop a law governing biodiversity. The recent push to finalize biodiversity legislation is 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). BCG will be a vehicle to modernize Thailand's agricultural sector deploying the following strategies:

- Strategy 1: Promoting sustainability of biological resources through balancing conservation and utilization.
- Strategy 2: Strengthening 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: Upgrading and promoting sustainable competitiveness of Thai BCG industries with knowledge, technology, and innovation focusing on green manufacturing.
- Strategy 4: Building resilience to global changes.

The 2015 Biosafety Act received Cabinet approval in November 2015 only for the NLA to reject it a month later due to heavy criticism from anti-biotech non-governmental organizations (NGO) claiming that the law legalized GE. On November 1, 2016, the chairman of the NLA's Science, Telecommunication, and Public Communication Committee created a new subcommittee to draft a new Biosafety Act. The subcommittee completed its draft on December 27, 2016. NLA assigned MONRE with the task of approving their draft legislation and preparing it for a Cabinet review. MONRE chose to include the draft NLA biosafety legislation as a part of its draft Biodiversity Act. The draft legislation's definition of biosafety covers environmental safety, human health safety, and sustainable biodiversity. There is concern that this is too broad of a definition and the complicated organizational process might impede future GE field trials and GE commercialization.

MONRE held public hearings on the revised draft of the Biodiversity Act from March 16 to May 4, 2020. The draft Biodiversity Act's definition of biosafety covers access to biological resources, the fair and equitable sharing of benefits arising from utilization, 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 same criticism that anti-biotech NGOs had with 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 the following activities: importation, exportation, transportation, packaging, classification, usage in controlled environment and in field (a biosafety assessment is required before an 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.

The TFDA finalized the following two new GE food regulations: 1) MOPH Ministerial Notification No. 431 Re: Food Derived from Genetically Modified Organisms (GMOs) also known as Mandatory Safety Assessment Regulation; and 2) MOPH Notification No. 432 Re:

Labeling of Food Derived from GM Organisms. The TFDA published the two regulations in the Royal Gazette in June 2022. Both drafts will come into force 180 days after their publication date or December 4, 2022.

The main contents of MOPH Ministerial Notification No. 431 are the following:

- i. The notification covers all products of food derived from genetically modified organisms and contains the following definitions.
  - (1) Food derived from genetically modified organisms:
    - a) Plants, animals, microorganisms that have been modified or altered genetic materials or combined new genetic materials by using of modern biotechnology and for consumption as food.
    - b) Food Products that use (a) as a food ingredient or produce from (a).
    - c) Products from (a) used as a food ingredient or used as food additives or used as nutrient.
  - (2) Genetically modified organism (GMO): any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.
  - (3) Organism: the biological unit that can be transferred or transcript or multiplied by their own and including the biological unit that sterile, viruses and viroid.
  - (4) Modern Biotechnology:
    - a) Process using nucleic acid in a test tube (in vitro) or in the laboratory including genetic engineering or the use of recombinant deoxyribonucleic acid (DNA) or inserting a nucleic acid into a part of the genetic material of an organism which beyond the scope of breeding naturally. And do not use techniques of propagation or traditional (natural) breeding and selection or.
    - b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barrier and that are not techniques used in traditional breeding and selection.
- ii. The import and/or production and commercialization of food derived from “GM organisms” would be allowed for the following:
  - (1) Food derived from “GM organisms/events” that are on a list of approved organisms (a positive list). The current positive list provided in Annex I of the notification covers “GM plant organisms” for 29 events of corn, 15 events of soybean and 7 events of GMM.
  - (2) TFDA will grant a grace period of 5 years from the effective date of the regulation for food derived from GM organisms that have not been approved in the Positive List but are on the Temporary Approval List as specified in Appendix 6 of the MOPH Regulation No.431. The TFDA will allow importation of GM organisms listed in either the Positive List or the Temporary Approval List (TAL) to ensure uninterrupted trade and supply for food and food processing.
  - (3) Developers of GM plant organisms and GM microorganisms are required to present food safety approval from at least 5 OECD countries to successfully list the particular event in the TAL. The TFDA advises the developers to submit dossiers of events listed in the TAL within the first 3 years of implementation so that the Technical Biotechnology Committee at BIOTEC can perform the risk assessment for the particular event. The average timeline for risk assessment takes 4 months with the maximum taking 12 months. Additionally, the reference material, method of analysis, or other related information needs to be sent to the Department of Medical Science

(DMsC) after the developer received safety assessment report from BIOTEC. Both the safety assessment report and confirmation document from DMsC must be submitted to TFDA to ensure the events receive approval and are listed in the positive list before the 5 years grace period ends. From the 6th year onwards, the importation of GM food will be permitted only for those being itemized in the Positive list.

- (4) TFDA requires each shipment of imported GM grain/products with approved events listed in positive list or TAL to be accompanied with one of following documents:
- analytical report from 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 certification specified event trait or OECD unique identifier of GM plants;
  - health certification specified event trait or OECD unique identifier or specified the absence of any unauthorized GM;
  - identify preservation;
  - invoice or packing list specified event trait or event contained if food derived from GM organisms; and
  - self-verified document issued by 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 same meaning including to contact information of party related to such imported food product.

Details of MOPH Ministerial Notification No. 431 Re: Foods Derived from the Genetically Modified Organisms in unofficial translation in English is attached after the last part of this report. There are altogether 10 clauses in the notification and 6 annexes.

Annex 1: Positive List of GM corn, GM soybean, and GM microorganism

Annex 2: Data minimal requirements for single and stacked gene GM plants

Annex 3: Data minimal requirements for GM microorganism

Annex 4: Data minimal requirements for GM animal

Annex 5: Reference material and detection method

Annex 6: Temporary Approval List (TAL) of GM corn, GM soybean

The main components of MOPH Ministerial Notification No. 452 are the following:

- i. Food containing or consisting of “GM plants, GM animals, and 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.
- ii. 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.”
- iii. 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.
- iv. For produces obtained from “GM plants, GM animals and GMMs” used as ingredient or food additive, labels should display the text "Food/product name" is produced from “type of GM plant/ animal/ microorganism”.



- v. TFDA will exempt food products from labeling if:
  - a. 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;
  - b. produced by small scaled producers;
  - c. prepared and sold by restaurants or vending machines;
  - d. do not contain any detectable genetic material or protein resulting from genetic modification used as processing aid in food manufacturing.
- vi. The TFDA will not allow the terms “Free from GMF” or “Non-GM Food” or any other similar text or symbols.
- vii. Displaying the GE symbol is voluntary.
- viii. Labeling of “GMFs” will no longer be allowed but shall have a 2-year grace period from the enactment date.

Details of MOPH Ministerial Notification No. 432 Re: Labeling of Food Derived from GM Organisms in Thai is available at [https://food.fda.moph.go.th/law/data/announ\\_moph/P432.PDF](https://food.fda.moph.go.th/law/data/announ_moph/P432.PDF).

- g. APPROVALS/AUTHORIZATIONS: No GE crops have been approved for cultivation. The Department of Agriculture, MOAC is preparing biosafety regulations to enforce imported GE seed cultivation for lab testing and field trial to commercialization including conducting risk assessments to be in line with draft the Biodiversity Act. However, there is the BIOTEC’s Biosafety Guideline for GE crops in contained use and confined use for R&D purposes which requires approval from IBC. The guideline also includes genome editing technology and synthetic biology in the definition of modern biotechnology. Document in Thai is available at the following link:

<https://www.biotec.or.th/biosafety/images/document/G01-Biosafety%20Guideline.pdf>

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 the below URL (in Thai):

[https://food.fda.moph.go.th/law/data/announ\\_moph/P431.PDF](https://food.fda.moph.go.th/law/data/announ_moph/P431.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 CODEX principles of substantial equivalence and conventional counterpart with four key considerations of molecular biology, nutrition, toxicology, and allergenicity. The guideline in Thai is available at the following link:

<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.”

- h. **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 exert 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 is available in Thai at the below link:

<https://www.biotec.or.th/biosafety/images/document/guideline/stackedforweb.pdf>

- i. **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.
- j. **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. According to the source, the TFDA plans to publish the food safety assessment for food derived from gene editing technology under the statutory of MOPH Ministerial Notification No 431. 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” - Molecular biology - Product specification	--	Case-by-case assessment with consideration on product characteristics	yes

- Nutrition			
- Toxicology			
- Allergenicity			

**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 editing techniques that used non-homologous end joining (NHEJ) and homology directed repair (HDR) to insert large DNA at target nucleotides sequence.

- k. **COEXISTENCE:** Thailand has not established any framework or guidelines regarding coexistence with non-GE crops.
- l. **LABELING AND TRACEABILITY:** The TFDA currently enforces MOPH Ministerial Notification No. 251 Re: Labeling for Processed Foods Containing GE Plant Materials. This notification is going to be repealed once MOPH Ministerial Notification No.432: Labeling of Food Derived from GMO goes into effect on December 4, 2022. There are 22 food products that are subject to labeling requirements when their contents exceed the five percent threshold under MOPH Ministerial Notification No.251. The labeling requirements are the following:
  - i. 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;” and
  - ii. 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 top three main ingredients of the food product such as “genetically modified corn starch.”

However, the regulation does not apply to small producers who produce and directly sell to consumers. The products that must adhere to the labeling requirements are the following:

- i. soybeans
- ii. cooked soybeans
- iii. roasted soybeans
- iv. bottled or canned soybeans or soybeans contained in retort pouch
- v. natto
- vi. miso
- vii. tofu or tofu fried in oil
- viii. frozen tofu, soybean gluten from tofu or its products
- ix. soybean milk
- x. soybean flour
- xi. food containing product(s) from 1 to 10 as the main ingredient
- xii. food containing soybean protein as main ingredient
- xiii. food containing green soybean as main ingredient
- xiv. food containing soybean sprout as main ingredient

- xv. corn
  - xvi. popcorn
  - xvii. frozen or chilled corn
  - xviii. bottled or canned corn or corn contained in heat-treated pouch
  - xix. corn flour or cornstarch
  - xx. snack foods deriving from corn as main ingredient
  - xxi. food containing product(s) from 15 to 20 as the main ingredient
  - xxii. food containing corn grits as main ingredient
- m. **MONITORING AND TESTING:** Although Thailand has laboratory facilities to test GE products, conducting lab tests in order to detect genetically modified material particularly in processed food products is costly and complicated. This is a key challenge for government officials to ensure compliance of biotech food labeling requirements.
- n. **LOW LEVEL PRESENCE (LLP) POLICY:** Thailand has not established any framework or guidelines regarding low level presence.
- o. **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 research and development (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 GM Prohibited Items List under the Plant Quarantine Act due to their importance in food and feed processing.
- p. **INTELLECTUAL PROPERTY RIGHTS (IPR):** Seed developers believe that the current Thai 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.
- q. **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. In March 2015, the Thai Cabinet approved the Master Plan for Integrated Biodiversity Management B.E. 2558-

2564 (2015-2021). The master plan has been implemented under National Biodiversity Targets, which are divided into three phases (i.e., by 2016, by 2020, and by 2021). Details of the master plan and national biodiversity targets can be found at <http://faolex.fao.org/docs/pdf/tha169773.pdf>.

- r. **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 positions on issues relating to GE crops and related products.
- s. **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:** There are studies on Thais' perception and attitude towards agricultural biotechnology in Thailand. The research conducted in 2005 shows a low understanding of biotechnology. 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. In 2012, the study showed 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 was also influenced. There was also a boarder survey in 2021 that focused on how Thai society's view on "GMOs" has 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 either directly (such as soybean oil) or indirectly (through the garments and processed foods industries that use biotech inputs). 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 rules. This has led to public misinformation about the amount of biotech products that 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 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 the following link:  
<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 the following link: <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 “GMFs.”
- e. **ADDITIONAL REGULATORY REQUIREMENTS:** The Department of Fisheries launched MOAC Ministerial Notification B.E.2564 (2021) to prohibit GE fish for culturing in Thailand unless the Director General (DG) or a competent authority assigned by DG, 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 believes that the majority of the Thai population is not aware of developments in animal biotechnology, including both GE and cloned animals. If any, most private opinions would be negative due to prevailing campaigns by anti-biotech NGOs regularly delivering misinformation to the public.
- 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 is no report 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. Thailand exports/imports alcoholic beverages, dairy products, and processed products from other countries, which may contain microbial biotech-derived food ingredients.
- c. IMPORTS: In 2021, Thailand imported \$798 million worth 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**

- a. REGULATORY FRAMEWORK: The TFDA will enforce the import, manufacturing, and commercialization including labeling of GE food in accordance to Ministerial Notification No. 431 and 432 derived from "GM Microorganisms (GMMs): effective December 4, 2022. Please refer to more information on TFDA's regulation in Chapter 1: Plant Biotechnology, Sub-part b) Policy.

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.

There is no grace period or waiver for cases of food derived from GMMs. 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 does regulate enzymes produced using microbial biotechnology through Notification No. 409 Re: Enzyme used for food production.

Thailand does recognize the importance of microorganisms. 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 on following link:  
[https://www.biotec.or.th/biosafety/images/document/guideline/minimum4GMM\\_forweb.pdf](https://www.biotec.or.th/biosafety/images/document/guideline/minimum4GMM_forweb.pdf).

The Guideline classifies food derived from R-DNA microorganisms into the following four categories:

**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 unrepresented 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 Thai on page 4 of the below URL: [https://food.fda.moph.go.th/law/data/announ\\_moph/P431.PDF](https://food.fda.moph.go.th/law/data/announ_moph/P431.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 list of permitted food additives in Thailand is available in English at [http://food.fda.moph.go.th/law/data/announ\\_moph/V.English/P418\\_E.pdf](http://food.fda.moph.go.th/law/data/announ_moph/V.English/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.409 B.E.2562 Re: Enzymes Used for Food Production (linked here in Thai): [http://www.ratchakittha.soc.go.th/DATA/PDF/2562/E/203/T\\_0017.PDF](http://www.ratchakittha.soc.go.th/DATA/PDF/2562/E/203/T_0017.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 synthetic bioeconomy especially in food ingredients industry. On November 11, 2021, the Office of National Higher Education Science Research and Innovation Policy Council (NXPO) established Synthetic Biology Consortium and signed a mutual of understanding with sixteen organizations from SMEs, startups, large enterprises, research institutes, and universities to drive research, innovation, and application of synthetic biology in Thailand. 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 research, development, 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 (digestive enhanced soybean and silage starter cultures);
- pentosanase for feed applications (digestive enhancer);
- acceleration 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 production of bioactive molecules to serve the need of industrial sectors.

The TBRC strongly promotes bioresource utilization for research and development, as well as providing technical services, to support knowledge sharing among the public and the scientific communities. The group develops effective technology and process 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 comprises of the following two key research teams: 1) Microbial Diversity and Utilization Research Team (IMUT) and 2) Microbial Systems and Computational Biology Research Team

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 are more than 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 to access for research and commercial use.

IMUT focuses on research and development of bioinformatics and data science for genome research and microbial genomics. The exploration of microbiome and microbial interactions in various environments are emphasized along with the construction of genome and microbiome databases with research networking to promote microbial utilization and innovation for effective usage in academics and industries. The Microbial Systems and Computational Biology Research Team also serves the need of Thailand Bioresource Research Center's service, such as 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 believes that Thai consumers have started to learn about the functionality, usage, and advantage of microbial biotechnology. Due to the rise of flexitarians and a larger market acceptance of plant-based food, the number of plant-based meat producers, from big companies to start-ups, is increasing. However, the new food technology is still at its early stage and is trying to develop its ecosystem to engage with more consumers and thrive globally. BIOTEC has successfully produced mycoprotein from edible microbes found domestically. The selected strains can produce a significant number of proteins and do not contain toxins that are harmful to consumers. BIOTEC aims to team up with business partners to launch vegan ground meat and ready-to-eat food products with affordable, quality proteins to compete in the market.

### **Attachments:**

**Unofficial Translation**  
**Notification of the Ministry of Public Health**  
**(No. 431) B.E. 2565 (2022)**  
**Issued under the Food Act B.E. 2522 (1979)**  
**RE: Foods Derived from the Genetically Modified Organisms**

At present, as the plants, animals, microorganism resulting from the Genetically Modified Organism are used as the foods or foods constituent, therefore, it is appropriate to impose the measure to regulate them to protect the safety of consumers.

By virtue of the provisions of Section 5 in the first paragraph and Section 6 (2), (3), (4), (5), (8) and (9) of the Food Act B.E. 2522 (1979), the Minister of Public Health hereby issues the notification as follows:

Clause 1. In this Notification

“Foods derived from the Genetically Modified Organism (GMO)” means

- (1) plant, animal, microorganism whose genetic materials are modified or recombined with new genetic materials by applying modern biotechnology and used as foods for consumption.
- (2) the food products which use (1) as food constituent or produced from (1).
- (3) the products from (1) which are used as food constituent or used as the food additive or nutrient.

“Genetically modified organism” means the organism whose genetic materials are modified and obtained from the use of modern biotechnology.

“Living organism” means any biological entity capable of transferring or replicating generic material, including sterile organisms, viruses and viroids.

“Modern biotechnology” means the application of

- (1) *in vitro* nucleic acid techniques including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, that overcome natural reproduction and that are not techniques used in conventional breeding and variety selection; or
- (2) Fusion of cells beyond the taxonomic family, that overcome natural reproduction and that are not techniques used in conventional breeding and variety selection.

“Stacked plant event” means genetically modified plant which is obtained from conventional breeding of parental lines which are genetically modified plants.

Clause 2. Foods derived from genetically modified organism (GMO) are prohibited to produce, import, or commercialize, unless

- (1) Food is derived from genetically modified organism listed in Annex 1 of this Notification.
- (2) Food is derived from genetically modified organism that passed food safety assessment.

Clause 3. Foods derived from genetically modified organism shall have the quality or standard as follows

- (1) Containing toxin, material or component that pose health risk not more than that of conventional counterpart.
- (2) Having nutritional value or quality not less than that of conventional counterpart.
- (3) The quality or standard of such food shall comply with the relevant Notifications of the Ministry of Public Health, on a case-by-case basis (if any).
- (4) Having other quality or standard (if any) according to the food safety assessment report, document, or evidence under Clause 5., on a case-by-case basis.

Clause 4. Use of foods derived from genetically modified organism as the food ingredient shall be complied with name, type, category or characteristics of food under the Notification of the Ministry of Public Health, RE: Food Additive or the relevant Notifications of the Ministry of Public Health.

Use of foods derived from genetically modified organism as the food ingredient other than mentioned in the first paragraph shall be complied with food safety assessment report, document, or evidence under Clause 5., as the case may be.

Clause 5. Foods derived from genetically modified organism which are produced, imported, or commercialized shall pass the food safety assessment by National Center for Genetic Engineering and Biotechnology (BIOTEC) of National Science and Technology Development Agency or the safety assessment agency which are announced and determined by Thailand Food and Drug Administration (TH FDA). The report of food safety assessment shall be submitted together with

data or evidence dossier to the Thailand Food and Drug Administration according to the submission requirements as follows:

(1) Foods derived from genetically modified plant; submission requirements are they are determined in Annex 2 of this Notification

(2) Foods derived from genetically modified microorganism; submission requirements are they are determined in Annex 3 of this Notification

(3) Foods derived from genetically modified animals; submission requirements are they are determined in Annex 4 of this Notification

In case that foods derived from genetically modified organism passed food safety assessment by the joint FAO/WHO scientific advisory bodies or WHO Expert Advisory Panels and Committees, and enzyme used for food production complies with the Notification of the Ministry of Public Health, RE: Enzyme for Foods Production, the food safety assessment and the dossier mentioned in the first paragraph (of this clause) are not required.

Clause 6. Foods derived from genetically modified organism which are produced, imported or commercialized must obtain detectability confirmation from Department of Medical Sciences or other agency or laboratory assigned by Thailand Food and Drug Administration for using in consideration for approval.

Clause 7. If new scientific information becomes available for foods derived from genetically modified organism that already passed or approved for food safety assessment. The submitter or applicant must inform Thailand Food and Drug Administration and submit the new information for food safety assessment without delay to National Center for Genetic Engineering and Biotechnology, National Science and Technology Development Agency or other agency assigned by Thailand Food and Drug Administration.

Clause 8. Analysis and detection method of food derived from genetically modified organism shall comply with Annex 5 of this Notification.

Clause 9. Food derived from genetically modified soybean or genetically modified corn listed in Annex 6 of this Notification are graced for production, importation, or commercialization during food safety assessment for not exceeding five years from the date this Notification comes into force.

In case that a food derived from genetically modified organism did not pass food safety assessment; production, importation, or commercialization of that food is prohibited. Annex 6 of this Notification shall be repealed at the end of five-year grace period mentioned in the first paragraph of this clause.

Clause 10. This Notification shall come into force after one hundred and eighty days from the date of its publication in the Government Gazette.

Notified on 1st April 2022

Sathit Pitutecha  
Deputy Minister of Public Health for the Minister of Public Health

**Annex 1**  
**of the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022)**  
**Issued under the Food Act B.E. 2522 (1979)**

**1. List of genetically modified plants that passed food safety assessment**

**1.1. Corn**

<b>Traits/Events</b>	<b>Unique Identifier</b>
(1) LY038	REN-ØØØ38-3
(2) MON89034	MON-89Ø34-3
(3) MON89034 x NK603	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6
(4) MON863	MON-ØØ863-5
(5) MON88017	MON-88Ø17-3
(6) GA21	MON-ØØØ21-9
(7) Bt11	SYN-BT Ø11-1
(8) Bt11 x GA21	SYN-BTØ11-1 x MON-ØØØ21-9
(9) MON87460	MON 8746Ø-4
(10) MIR604	SYN-IR6Ø4-5
(11) NK603	MON-ØØ6Ø3-6
(12) MIR604 x GA21	SYN-IR6Ø4-5 x MON-ØØØ21-9
(13) Bt11 x MIR604	SYN-BTØ11-1 x SYN-IR6Ø4-5
(14) Bt11 x MIR604 x GA21	SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9
(15) MIR162	SYN-IR162-4
(16) Bt11 x MIR162 x GA21	SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9
(17) MON810	MON-ØØ81Ø-6
(18) 5307	SYN-Ø53Ø7-1
(19) T25	ACS-ZMØØ3-2
(20) 3272	SYN-E3272-5
(21) MZHGØJG	SYN-ØØØJG-2
(22) MON87460 x MON89034 x NK603	MON-8746Ø-4 x MON-89Ø34-3 x MON-ØØ6Ø3-6
(23) MZIR098	SYN-ØØØ98-3
(24) Bt11 x MIR162	SYN-BTØ11-1 x SYN-IR162-4
(25) Bt11 x MIR162 x MIR604 x GA21	SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-ØØØ21-9
(22) MON 87427	MON-87427-7
(27) MON87460 x MON89034 x MON88017	MON 8746Ø-4 x MON-89Ø34-3 x MON-88Ø17-3
(28) GA21 x T25	MON-ØØØ21-9 x ACS-ZMØØ3-2
(29) Bt11 x MIR162 x MIR604 x MON89034 x 5307 x GA21	SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-89Ø34-3 x SYN-Ø53Ø7-1 x MON-ØØØ21-9

## 1.2. Soybean

Event/Traits	Unique Identifier
(1) MON89788	MON-89788-1
(2) A2704-12	ACS-GMØØ5-3
(3) MON87701	MON-877Ø1-2
(4) 40-3-2	MON-Ø4Ø32-6
(5) MON87705	MON-877Ø5-6
(6) MON87769	MON-87769-7
(7) SYHTOH2	SYN-ØØØH2-5
(8) A5547-127	ACS-GMØØ6-4
(9) FG72	MST-FGØ72-2
(10) MON87708	MON-877Ø8-9
(11) MON87701 x MON 89788	MON-877Ø1-2 x MON-89788-1
(12) MON 87708 x MON 87988 x A5547-127	MON-877Ø8-9 x MON-89788-1 x ACS-GMØØ6-4
(13) DAS44406-6	DAS-444Ø6-6

## 2. List of genetically modified microorganisms that passed food safety assessment

Traits	Usage/Function
(1) <i>Saccharomyces cerevisiae</i> CENPK338	Ice Structuring Protein type IIIHPLC 12 or ISP Type III HPLC 12)
(2) <i>Escherichia coli</i> BL21 (DE3) #1540	Production of 2'-Fucosyllactose (2'-FL)
(3) <i>Escherichia coli</i> K-12 (DH1) SCR6	
(4) <i>Escherichia coli</i> LU21051	
(5) <i>Escherichia coli</i> K-12 (DH1) MDO MAP1001d	
(6) <i>Corynebacterium glutamicum</i> APC199	
(7) <i>Pichia pastolis Bg11</i>	Soy Leghemoglobin preparation (Soy LegH Prep)



**Annex 2**  
**of the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022)**  
**Issued under the Food Act B.E. 2522 (1979)**

**1. Minimal requirement for food safety assessment of genetically modified plants (Single)**

<b>Items</b>	<b>Data Requirements</b>
1	<p><b>Description of genetically modified plant</b></p> <p>1.1 Type of genetically modified plants</p> <p>1.2 Description of genetic modification</p> <p>1.3 Characterization of genetic modification</p> <p>1.4 Objective of genetic modification.</p>
2	<p><b>Description of host plant</b></p> <p>2.1 Common name and scientific name</p> <p>2.2 Taxonomic classification</p> <p>2.3 History of cultivation and development through breeding, in particular identifying traits that may adversely impact on human health</p> <p>2.4 Information on the host plant's genotype and phenotype relevant to its safety</p> <p style="padding-left: 20px;">2.4.1 Information on any known toxicity</p> <p style="padding-left: 20px;">2.4.2 Information on any known allergenicity</p> <p style="padding-left: 20px;">2.4.3 History of safe use for consumption as food</p> <p>2.5 History of safe use as food</p> <p style="padding-left: 20px;">2.5.1 Cultivation of the plant</p> <p style="padding-left: 20px;">2.5.2 Transportation and storage</p> <p style="padding-left: 20px;">2.5.3 Special processing required to make the plant safe to eat</p> <p style="padding-left: 20px;">2.5.4 Information on part of plant used as a food source</p> <p>2 Part of plant that used as food source</p> <p>3 Importance of consumption of the part of plant in particular subgroups of the population</p> <p>4 Macronutrient, micronutrient, and anti-nutrient in the plant.</p>
3	<p><b>Description of donor organism</b></p> <p>3.1 In case of having donor of genetic materials</p> <p style="padding-left: 20px;">3.1.1 Common name and scientific name</p> <p style="padding-left: 20px;">3.1.2 Taxonomic classification</p> <p style="padding-left: 20px;">3.1.3 History of safe use for consumption as food</p> <p style="padding-left: 20px;">3.1.4 Information on naturally occurring toxins, anti-nutrients, and allergens</p> <p style="padding-left: 20px;">3.1.5 Information on pathogenicity and relationship to known pathogens if donor organism is microorganisms</p> <p style="padding-left: 20px;">3.1.6 Information on the past and present use, if any, in the food and possibility of presence as contaminants</p> <p>3.2 In case of synthesized DNA that is not originated from genetic material existing in nature</p> <p style="padding-left: 20px;">3.2.1 Role and function of the synthesized DNA</p> <p style="padding-left: 20px;">3.2.2 Nucleotide sequence of the synthesized DNA.</p>

4	<b>Description of genetic modification</b>
	<p>4.1 Description of transformation process</p> <p>4.1.1 Method of transformation</p> <p>4.1.2 Information on the DNA used to modify the plant</p> <p>(a) Characteristics of DNA used in transformation process and expected function in the plant</p> <p>(b) Source of the DNA (plant, microorganism, virus, synthetic)</p> <p>4.1.3 Information on intermediate host including the organisms (e.g., bacteria) used to produce or process DNA for transformation of the host organism</p> <p>4.2 Information of introduced DNA</p> <p>4.2.1 Characterization of genetic components</p> <p>(a) Target gene</p> <p>(b) Marker gene</p> <p>(c) Promoter</p> <p>(d) Terminator</p> <p>(e) Other elements affecting the function of the DNA</p> <p>(f) Other genetic components</p> <p>4.2.2 Size, identity, location, and orientation of the DNA sequence in the final vector/ construct</p> <p>4.2.3 Function of introduced DNA.</p>

5	<p><b>Characterization of genetic modification</b></p> <p>5.1 Information on inserted DNA in plant genome</p> <p>5.1.1 Characterization and description of the inserted DNA</p> <p>5.1.2 Number of insertion sites</p> <p>5.1.3 Organization of the inserted DNA and copy number of the inserted DNA at each insertion site</p> <p>5.1.4 Analysis of inserted DNA and of the surrounding region at 5' and 3' ends of the inserted DNA that sufficient to identify any substance expressed as a consequence of the inserted DNA</p> <p>5.1.5 Analysis of open reading frame within the inserted DNA or created by the insertion with contagious plant genomic DNA to indicate potential of creating fusion protein</p> <p>5.2 Information on any expressed substance in genetically modified plant</p> <p>5.2.1 Gene product (protein or untranslated RNA)</p> <p>5.2.2 Function of the gene product</p> <p>5.2.3 Phenotypic description of the new trait</p> <p>5.2.4 Level and site of expression in the plant of the expressed gene product and metabolites of the gene product, particularly in the edible portions</p> <p>5.2.5 Amount of the target gene product if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein – if possible</p> <p>5.3 Other information that shall be included</p> <p>5.3.1 Information on whether the arrangement of the genetic material used for insertion has been conserved or whether significant rearrangements have occurred upon integration</p> <p>5.3.2 Information on whether intended modifications made to the amino acid sequence of the expressed protein result in post-translational modification or affect sites critical for structure or function of the expressed protein</p> <p>5.3.3 Information on whether the intended effect of the modification has been achieved and that all expressed traits are expressed and inherited in a manner that is stable through several generations consistent with laws of inheritance</p> <p>5.3.4 Examination of the inheritance of the DNA insert itself or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly from phenotypic characteristics</p> <p>5.3.5 Information on whether the newly expressed trait(s) are expressed as expected in the appropriate tissues in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene</p> <p>5.3.6 Information on whether the transformation process has either positive or negative impact in the host plant</p> <p>5.3.7 Information on the identity and expression pattern of any new fusion proteins.</p>

6	<p><b>Compositional analyses of key components</b></p> <p>6.1 Analysis of key components of the genetically modified plant compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions according with principles of Codex Alimentarius or OECD</p> <p>6.1.1 Key nutrients (macronutrients: carbohydrates, protein, fat; micronutrient: minerals, vitamins)</p> <p>6.1.2 Key anti-nutrients</p> <p>6.1.3 Natural toxicant known to be inherently in the plant</p> <p>Statistical data analysis method used must be generally accepted at international level</p> <p>6.2 The number of trial sites should be sufficient to allow accurate assessment of compositional characteristics over this range. Location of trial sites should be representative of the range of environmental conditions under which the plant varieties would be expected to be grown</p> <p>6.3 Number of generations in trials</p> <p>6.4 Number of replica of each trial site to reduce any effect from varied environmental impact and naturally occurring genotypic variation within a crop variety</p> <p>6.5 Number of sufficient sampling and the methods of analysis according to international standards.</p>
7	<p><b>Evaluation of metabolites</b></p> <p>7.1 Information on accumulation of metabolites in the food that would adversely impact human health</p> <p>7.2 Information on residue and metabolite levels in the food</p> <p>7.3 Information on assessment of any alterations in nutrient profile</p>
8	<p><b>Food Processing</b></p> <p>Information on processing conditions used in the production of the foods derived from genetically modified plant</p>
9	<p><b>Toxicity assessment</b></p> <p>9.1 The genetic modification of the plants can result in synthesis of new substances. The new substances can be conventional components of foods from plant such as proteins, fats, carbohydrates, vitamins which are novel in the context of that genetically modified plant. The new substances might also include new metabolites resulting from the activity of enzymes generated by the expression of the introduced DNA. Safety assessment of the new substances should be conducted.</p> <p>9.1.1 Chemical characterization and function of the newly expressed substance</p>

	<p>9.1.2 Concentration of the substance in the edible parts for human consumption of the genetically modified plant, including variations and mean values</p> <p>9.1.3 Dietary exposure and possible effects of the case of having indication of possible health impact or the case of nutritional modification or experts consider assessment is necessary</p> <p>In case of nutritional modification</p> <p>(a) If the plant is staple food of Thai population, dietary exposure must be calculated</p> <p>(b) If the plant is not staple food of Thai population, dietary exposure will be calculated on case-by-case basis if the experts considered necessary</p> <p>9.1.4 Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to the genetically modified plants that do not normally express those toxic or anti-nutritious characteristics</p> <p>9.1.5 Bioinformatic analysis of amino acid sequence of newly expressed protein comparing with known toxins or anti-nutrient using updated databases within 3 years prior to submission. Submitted information for assessment of possible toxicity must be up-to-date information. Change of data or information that may lead to significant impact on human health impact must be reported.</p> <p>9.1.6 Stability of new protein</p> <p>(a) Heat stability at cooking temperature and reason of conducting test at such temperature</p> <p>(b) Digestibility in simulated gastric fluid: (SGF) and simulated intestinal fluid: (SIF)</p> <p>Test must be conducted in Good Laboratory Practice (GLP) accredited laboratory.</p> <p>References must be published in peer reviewed journals</p> <p>9.2 If history of safe use as food of the new protein is not available and the new protein is not similar with any proteins that have history of safe use as food, acute oral toxicity test of new protein in addition to 9.1, although function of the new protein is known, must be conducted as follows.</p> <p>9.2.1 Acute toxicity test</p> <p>9.2.2 Sub-chronic toxicity test in the case of history of safe use of the new protein is not available or abnormality is found in acute toxicity test</p> <p>9.2.3 Chronic toxicity test if data from sub-chronic toxicity is not sufficient for assessment</p> <p>Test must be conducted in accordance with international standards</p> <p>9.3 In case of the newly expressed product is not protein and its history of safe use is not available, information on metabolism assessment, toxicokinetics, chronic toxicity, sub-chronic toxicity, carcinogenicity, reproductive and development toxicity of the new protein based on its nature and function in the plant and intake quantity in consumption may be additionally considered on case-by-case basis.</p>
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10	<p><b>Assessment of possible allergenicity</b></p> <p>10.1 Source of the new protein</p> <p>10.2 Bioinformatic analysis of amino acid sequence of newly expressed protein comparing with known allergens using updated databases within 3 years prior to submission date. In case of change that significantly impact health, the information of the change must also be submitted. In case of more than 80 amino acids has sequence homology with more than 35% of known allergens in the database, additional test such as IgE reaction with serum from patients or another appropriate test is necessary</p>
	<p>10.3 Information on possible role in the elicitation of gluten-sensitive enteropathy, if the introduced genetic material is obtained from wheat, rye, barley, oats, or related cereal grains</p> <p>10.4 Information on possible allergenicity if the newly expressed protein has origin from allergy organism</p> <p>10.5 Information as described in 9.1.1, 9.1.2, 9.1.6 and 11.6.</p>
11	<p><b>Nutrition modification</b></p> <p>11.1 Dietary exposure and metabolic requirements of population groups especially infants, children, pregnant and lactating women, the elderly, and those with chronic diseases. (Detail as in 9.1.3)</p> <p>11.2 Information on use, consumption and storage of the plant or food derived from it for additional nutritional assessment if necessary</p> <p>11.3 Information on change of nutritional components or profile as a result of genetic modification</p> <p>11.4 Study in animal if bioavailability or nutritional component is different from conventional counterpart. Criteria for assessment is as follows</p> <p style="padding-left: 40px;">11.4.1 If the plant is staple food of Thai population, assessment of must be conducted</p> <p style="padding-left: 40px;">11.4.2 If the plant is not staple food of Thai population, assessment is on case- by-case basis if experts considered necessary</p> <p>11.5 In case that the genetically modified plant designed for health benefits, it is necessary to conduct study on nutrition, toxicology, or other appropriate studies</p> <p>11.6 If information for assessment is insufficient, additional properly designed animal studies could be requested on the whole foods.</p>
12	<p><b>Other considerations</b></p> <p>12.1 Information on potential for accumulation of some substances if the genetic modification may lead to accumulation of pesticide residues or alteration of pesticide metabolites that may be harmful to health.</p>
13	<p><b>Other assessment study</b></p> <p>13.1 Assessment report or opinion of food safety assessment agency in other countries.</p> <p>13.2 Other documents such as license or information on permission from government authority of other countries.</p>
14	<p><b>Additional information</b></p> <p>Additional information may be requested on case-by-case basis. The expert who requests the additional information must indicate rationale and clarify detail of the request.</p>

**Note:** Conventional counterpart in food safety assessment of genetically modified plants means variety, parts, and/or product of the plant that has history of safe use as foods.

## 2. Minimal requirement for food safety assessment of genetically modified plant with stacked genes

Minimal requirement for food safety assessment of genetically modified plant with stacked genes in each case is as follows:

**Case 1** Genetically modified plant with stacked genes that derived from conventional breeding of paternal or maternal line which is not listed in Annex 1 or not complied with Clause 5 of this Notification

In case of genetically modified plant with stacked gene is derived from paternal or maternal lines can be used to support assessment on case-by-case basis.

**Case 2** Genetically modified plant with stacked genes that derived from conventional breeding of paternal or maternal line which is listed in Annex 1 or complied with Clause 5 of this Notification

In case of genetically modified plant with stacked gene is derived from paternal or maternal line that passed food safety assessment, food safety assessment of the genetically modified plant with stacked gene is as follows Items

1.	<p><b>Data Requirements</b>  <b>Qualitative confirmation of traits in stacks</b>  Information for assessment can use information in 1.1 and/or 1.2  1.1 Protein expression: information on level of target genes expression, size of expressed proteins comparing with appropriate counterpart using Western blot analysis or other accepted scientific techniques. The plant sample for gene expression analysis should be from the part of the plant that intended to use as food and collected at harvesting stage or at stage when the plant or part of the plant intended to use as food.  1.2 Phenotypic Efficacy: information on morphology and other phenotypic characteristics resulted from expression of the target genes in the plant comparing with appropriate counterpart to confirm efficiency of gene expression. The information must be a comparison of planting in different locations and seasons using appropriate statistical method.</p>
2	<p><b>Compositional Analysis</b>  Information must demonstrate comparison between genetically modified plant with stacked genes and conventional counterpart which are planted and harvested under the same condition. Compositional analysis of the plant must also be according with principles of Codex Alimentarius or OECD guide.</p>
<p>If assessment in 1 and/or 2 reveal similarity between the genetically modified plant with stacked genes and the counterpart, further assessment is exempted. If assessment in 1 and 2 reveals difference pattern between the genetically modified plant with stacked genes and the</p>	

counterpart, further assessment as mentioned in 3 – 5 must be conducted.	
3	<p><b>Molecular characterization</b>  Additional information is necessary if gene expression of target genes in the genetically modified plant with stacked genes differs from that of the parental lines.  - ELISA or mRNA analysis on level of expression in different tissues at each stage of development of the plant.</p>
4	<p><b>Toxicity assessment</b>  Toxicity information of the new protein or the modified protein resulted from the expression of the target genes as follows.  Test must be conducted in Good Laboratory Practice (GLP) accredited laboratory. References must be published in peer reviewed journals  Test must be conducted in accordance with international standards.</p> <p>4.1 Chemical characterization and function of the newly expressed substance  4.2 Concentration of the substance in the edible parts for human consumption of the genetically modified plant, including variations and mean values  4.3 Bioinformatic analysis of amino acid sequence of newly expressed protein comparing with known toxins or anti-nutrient using updated databases within 3 years prior to submission. Submitted information for assessment of possible toxicity must be up-to-date information. Change of data or information that may lead to significant impact on human health impact must be reported  4.4 Stability of new protein  4.4.1 Heat stability at cooking temperature and reason of conducting test at such temperature  4.4.2 Digestibility in simulated gastric fluid: (SGF) and simulated intestinal fluid: (SIF)  4.5 Oral toxicity test of the new protein of the genetically modified plant with stacked genes as follows.  4.5.1 Acute toxicity test.  4.5.2 Sub-chronic toxicity test in the case of history of safe use of the new protein is not available or abnormality is found in acute toxicity test.  4.5.3 Chronic toxicity test if data from sub-chronic toxicity is not sufficient for assessment.</p>
5	<p><b>Assessment of possible allergenicity</b>  Allergenicity information of the new protein or the modified protein resulted from the expression of the target genes as follows.</p>
6.	<p><b>Other Assessment Studies</b>  6.1 Assessment report or opinion of food safety assessment agency in other countries.  6.2 Other documents such as license or information on permission from government authority of other countries</p>
7.	Additional information



	Additional information may be requested on case-by-case basis. The expert who requests the additional information must indicate rationale and clarify detail of the request.
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**Note:** Conventional counterpart in food safety assessment of genetically modified plant with stacked genes means transgenic parental line, or non-transgenic parental line, or conventional hybrid of non-transgenic parental line.

**Annex 3**  
**of the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022)**  
**Issued under the Food Act B.E. 2522 (1979)**

**1. Food derived from genetically modified microorganisms are in 4 categories as follows.**

**Category 1** Foods that contain genetically modified microorganisms that can multiply or transfer genetic materials. Examples are probiotics, or live starter culture in fermentation process e.g., yogurts.

**Category 2** Foods that contain genetically modified microorganisms that cannot multiply and cannot transfer genetic materials. Examples are heat inactivated starter culture in fermentation processing of vinegar or alcohol, or the genetically modified microorganisms are removed but its gene might remain in the foods.

**Category 3** Foods that are complex product that do not have the genetically modified microorganisms or newly introduced gene remained in the foods. Examples are cell extracts, food additives, and processing aid which are complex products e.g., enzymes and food fiber.

**Category 4** Foods that are chemically purified compounds and substances derived of those compounds from which the genetically modified microorganisms or newly introduced gene are removed. Examples are amino acids, vitamins, food additives, chemically purified processing aid e.g., acetic acid, and nutrients e.g., amino acids.

## **2. Minimal requirement for food safety assessment of genetically modified microorganisms**

	Food Category			
	Category 1	Category 2	Category 3	Category 4
1. Description of genetically modified microorganisms	✓	✓	✓	✓
2. Description of the recipient microorganisms	✓	✓	✓	✓
3. Description of the donor organisms	✓	✓	✓	✓
4. Description of the genetic modification	✓	✓	✓	✓
5. Characterization of the genetic modification	✓	✓	✓	✓
6. Food processing including techniques for microorganism removal from food products and examination of remained genetically modified microorganisms or parts of genetic material parts in foods	✓	✓	✓	✓
7. Specific characteristics of the products from genetic modification	✓	✓	✓	✓
8. Toxicity assessment	✓	✓	✓	✓
9. Compositional analysis	✓	✓	1 (*)	
10. Evaluation of metabolites	✓	✓		
11. Effects of food processing	✓	✓		
12. Allergenicity assessment	✓	✓	✓	
13. Assessment of viability and residence of microorganisms in the human gastrointestinal tract	✓			

(\*) Only substance with nutritional or health purposes.

Data requirements for food safety assessment of genetically modified microorganisms as follows

Items	Data Requirements
1.	1.1 Type of genetically modified microorganisms (bacteria, yeasts, or fungi) 1.2 Strains of genetically modified microorganisms 1.3 Description of genetic modification 1.4 Characterization of genetic modification 1.5 Objective of genetic modification 1.6 Risk level of genetically modified microorganisms and credible references.
2.	Description of recipient microorganism  2.1 Common name and scientific name  2.2 Taxonomic classification  2.3 Accession numbers or other information from a recognized culture repository  2.4 History of use and cultivation, strain development, and traits that may adversely impact human health  2.5 Genotype and phenotype relevant to safety, including related microorganism species and any extra-chromosomal genetic elements that contribute to the functions of the recipient strain. 11.6.1 Toxin 11.6.2 Antibiotics 11.6.3 Pathogenicity 11.6.4 Antibiotic resistance factors 11.6.5 Immunological impact 11.6.6 Genetic stability of the microorganism including mobile DNA elements on case-by-case basis e.g., insertion sequences, transposon, plasmids or prophages.  2.6 History of safe use as food or in food production  2.7 Information on the relevant production parameters used to culture the recipient microorganism  2.8 History of use may include information on microorganism culturing, transportation, storage, quality assurance measures, strain identity verification, production specifications for microorganisms and foods, and whether the microorganisms remain viable in the processed food or are removed or rendered non-viable as a consequence of processing.
3.	Description of donor organism or source of genetic materials 3.1 In case of having donor of genetic materials 3.1.1 Common name and scientific name 3.1.2 Taxonomic classification 3.1.3 Accession numbers or other information from a recognized culture repository 3.1.4 History of safe use for consumption as food of the donor organism or related species of the donor organism 3.1.5 Genotype and phenotype relevant to safety (a) Toxin (b) Antibiotics

	<p>(c) Pathogenicity  (d) Antibiotic resistance factors  (e) Immunological impact</p> <p>3.1.6 Information on the past and present use (if any) including presence in the food supply, or possible presence as contaminants  3.2 In case of synthesized DNA that is not originated from genetic material existing in nature, specify  3.2.1 Role and function of the synthesized DNA  3.2.2 Nucleotide sequence of the synthesized DNA.</p>
4.	<p>Description of genetic modification  4.1 Description of transformation process  4.1.1 Method of transformation  4.1.2 Information on the DNA used  (a) Characteristics of DNA used in transformation process and expected function  (b) Source of the DNA (plant, microorganism, virus, synthetics) in detail  4.1.3 Information on intermediate host including the organisms (e.g., bacteria) used to produce or process DNA for transformation of the host organism  4.2 Information of introduced DNA  4.2.1 Characterization of genetic components  (g) Target gene  (h) Marker gene  (i) Promoter  (j) Terminator  (k) Other elements affecting the function of the DNA  (l) Other genetic components  4.2.2 Size, identity, location and orientation of the DNA sequence in the final vector/ construct  4.2.3 Function of introduced DNA.</p>
5.	<p>Characterization of genetic modification</p> <p>5.1 Information on inserted DNA in genetically modified microorganism  5.1.1 Characterization and description of the inserted, deleted, or modified DNA including plasmid or other carrier DNA used to transfer desired DNA and analysis of the potential for mobilization of any plasmids or other genetic elements used in the genetic modification  5.1.2 Number of insertion sites  5.1.3 Organization of the inserted DNA and copy number of the inserted DNA at each insertion site  5.1.4 Analysis of inserted DNA and of the surrounding region at 5' and 3' ends of the inserted DNA that sufficient to identify any substance expressed as a consequence of the inserted DNA  5.1.5 Analysis of open reading frame within the inserted DNA or created by the insertion with contiguous in the chromosome or in a plasmid, to indicate potential of creating fusion protein.  5.1.6 Potentially harmful functions of nucleotide sequence or amino acid</p>

	<p>according to reports.</p> <p>5.2 Information on any expressed substance in genetically modified microorganisms</p> <p>5.2.1 Gene product (protein or untranslated RNA)</p> <p>5.2.2 Function of the gene product</p> <p>5.2.3 Phenotypic description of the new trait</p> <p>5.2.4 Level and site of expression in the plant of the expressed gene product and metabolites of the gene product</p> <p>(a) In case of Gram-negative bacteria, the gene product is produced intracellular or in periplasmic.</p> <p>(b) In case of eukaryotic microorganisms, the gene product is in organelles or secreted.</p> <p>5.2.5 Amount of the target gene product if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein – if possible</p> <p>5.2.6 Absence of a gene product, or alterations in metabolites related to gene products, if applicable to the intended function of the genetic modification.</p> <p>5.3 Other information that shall be included</p> <p>5.3.1 Information on whether the arrangement of the genetic material used for insertion has been conserved or whether significant rearrangements have occurred upon integration</p> <p>5.3.2 Information on whether intended modifications made to the amino acid sequence of the expressed protein result in post-translational modification or affect sites critical for structure or function of the expressed protein</p> <p>5.3.3 Information on whether the intended effect of the modification has been achieved and that all expressed traits are expressed and inherited in a manner that is stable through several generations consistent with laws of inheritance</p> <p>5.3.4 Information on whether the newly expressed traits are expressed in cell and at location as expected and in consistent with the associated regulatory sequences driving the expression of the corresponding gene</p> <p>5.3.5 Information on whether the transformation process has either positive or negative impact in the host plant</p> <p>5.3.6 Information</p>
6.	<p>Food processing</p> <p>Food processing including techniques for microorganism removal from food products and examination of remained genetically modified microorganisms or parts of genetic material parts in foods on case-by-case basis.</p> <p>6.1 Production process chart with details of controls used in the process including</p>

	<p>controlled factors such as temperature, gas quantity, chemical used and eliminated</p> <p>6.2 Techniques, measures, or process used to reduce, destroy, or eliminate the genetically modified microorganisms and genetic material from desired product</p> <p>6.3 Analysis of existence of the genetically modified microorganisms or examination of ability to multiply of the genetically modified microorganisms</p> <p>6.4 Analysis of remaining genetic materials or potential for gene transfer of the genetically modified microorganisms</p> <p>6.5 Techniques and methods used for detecting stressed cells by resuscitation culture if the cells of the genetically modified microorganisms can produce spores</p> <p>Examination of cells that may grow of those spores is also necessary.</p>
7.	<p>Specific characteristics of the products from genetic modification</p> <p>7.1 In case of food additive, information on identity and specific characteristics of products according to Notification of Ministry of Public Health Re: Food Additives and data requirement described in 7.2.3</p> <p>7.2 In case of other foods</p> <p>7.2.1 Specific characteristics of products</p> <p>7.2.1.1 Product formulation</p> <p>7.2.1.2 Chemical name, common name, brand name, synonymous name, and abbreviations</p> <p>7.2.1.3 International code (if any) e.g., CAS number.</p> <p>7.2.1.4 Chemical formula, molecular mass, or subunit structure or amino acid sequence as the case may be</p> <p>7.2.1.5 Impurity that might occur in food processing (attach analysis report). Identify contaminants, metals, fungal toxins that might occur during the food processing and methods used to prevent or eliminate the impurities and accredited analysis method of the impurities</p> <p>7.2.1.6 Physical characteristics of the products</p> <p>7.2.2 Technological characteristics of the products, objectives of use in foods, reaction and resulting products, optimal condition for use and storage, undesirable by products, and internationally accepted analysis method</p> <p>7.2.3 Characteristics of products derived from genetic modification</p>
8.	<p>Toxicity assessment</p> <p>8.1 In case of food additive which is starter culture that does not have counterpart and new protein or new substance that does not have history of use as food additive. In formation on toxicity of products must be submitted according to Notification of Ministry of Public Health Re: Food Additives.</p>



	<p>8.2 In case of other foods</p> <p>8.2.1 Concentration of new substance for human consumption.</p> <p>8.2.2 In case of the genetically modified microorganisms that does not have counterpart or new substance that does not have history of use as food additive. Toxicology study in experimental animals according to international standards is necessary.</p> <p>(a) Acute toxicity test</p> <p>(b) Sub-chronic toxicity test</p> <p>(c) Chronic toxicity test if data from sub-chronic toxicity test is not sufficient</p> <p>8.2.3 Metabolic mechanism assessment and other toxicity study e.g., metabolism assessment, toxicokinetics, chronic toxicity, sub-chronic toxicity, carcinogenicity, reproductive and development toxicity. (When it is an indication of any of the mentioned toxicity, additional study on case-by-case basis is necessary according to structure, function, metabolite, and consumption quantity of the product.)</p> <p>8.2.4 Examination to confirm that toxin or anti-nutrient genes present in donor organism are not transferred to host microorganism which do not express such toxin or anti-nutrient by its nature</p> <p>8.2.5 Bioinformatic analysis of amino acid sequence of newly expressed protein comparing with known toxins or anti-nutrient using updated databases within 3 years prior to submission. Submitted information for assessment of possible toxicity must be up-to-date information. Change of data or information that may lead to significant impact on human health impact must be reported</p> <p>8.2.6 Stability of new protein</p> <p>(a) Heat stability at cooking temperature and reason of conducting test at such temperature</p> <p>(b) Digestibility in simulated gastric fluid: (SGF) and simulated intestinal fluid: (SIF)</p> <p>Test must be conducted in Good Laboratory Practice (GLP) accredited laboratory. References must be published in peer reviewed journal</p> <p>8.2.7 Determination of safety references on case-by-case basis by referring to not less than the following information</p> <p>(a) No observed adverse effect level (NOAEL)</p> <p>(b) Using safety factor in calculation.</p> <p>(c) Toxicological versus physiological responses</p> <p>8.2.8 Dietary exposure assessment</p> <p>(a) In case of food additives, conduct assessment according to Notification of Ministry of Public Health, Re: Food additives.</p>
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	<p>(b) In case of other foods, conduct dietary exposure assessment if it is an indication of possible adverse effect to health or the experts consider the assessment is necessary according to Environmental Health Criteria 240: Dietary exposure assessment of chemicals in food.</p>
9.	<p>Compositional analysis</p> <p>9.1 Analysis of key components of the food derived from genetically modified microorganisms compared with that of food derived from near isogenic parental strain that are produced under the same condition. Components to be analyzed according to Codex Alimentarius or OECD include:</p> <p>9.1.1 Key nutrients (Major nutrients: carbohydrate, protein, fat. Minor nutrients: minerals, vitamins)</p> <p>9.1.2 Key anti-nutrients</p> <p>9.1.3 Key toxins naturally occurred in microorganisms</p> <p>Statistical analysis must be according to internationally accepted methods.</p> <p>9.2 In case of food derived from genetically modified microorganism with intended traits of quality nutrition modification or nutritional function modification, the following additional assessments must be conducted</p> <p>9.2.1 Pattern of use and food and derivatives consumption for estimation of intaking of food derived from genetically modified microorganism</p> <p>9.2.2 Information on food intaking for evaluation of nutritional impact of changed nutrient profile</p> <p>9.2.3 Evaluation of nutritional condition of different consumer groups.</p>
10.	<p>Evaluation of metabolites</p> <p>10.1 Possible accumulation of altered metabolite in food that may impact health</p> <p>10.2 Analysis of level of altered metabolite in food</p> <p>10.3 Impact of the genetic modified microorganism to other microorganisms in food production process that use many strains of microorganisms.</p>
11.	<p>Effects of food processing</p> <p>Information on possible impact from condition or processing process used in food production using the genetic modified microorganism.</p>
12.	<p>Assessment of possible allergenicity</p> <p>12.1 Source of the new protein</p> <p>12.2 Bioinformatic analysis of amino acid sequence of newly expressed protein comparing with known allergens using updated databases within 3 years prior to submission date. In case of change that significantly impact health, the information of the change must also be submitted. In case of more than 80 amino acids has sequence</p>

	<p>homology with more than 35% of known allergens in the database, additional test such as IgE reaction with serum from patients or another appropriate test is necessary.</p> <p>12.3 Examination on potential allergenicity if the newly expressed protein has origin from allergy organism.</p> <p>12.4 Information as described in 7.1, 8.1, 8.2, and 8.2</p>
13.	<p>Antibiotic resistance and gene transfer</p> <p>14.1 In case of the genetically modified microorganism will remain in ready to eat food. Using microorganism containing transmissible antibiotic resistant genes in genetic modification is prohibited.</p> <p>14.2 Potential of gene transfer from the genetically modified microorganism and food derived the genetically modified microorganisms to microflora in digestive tract.</p>
14.	<p>Other assessment study</p> <p>15.1 Assessment report or opinion of food safety assessment agency in other countries</p> <p>15.2 Other documents such as license or information on permission from government authority of other countries.</p>
15.	<p>Additional information</p> <p>Additional information may be requested on case-by-case basis. The expert who requests the additional information must indicate rationale and clarify detail of the request.</p>

**Note:**

- (1) Conventional counterpart in food safety assessment of the genetically modified microorganism is;
  - (1.1) Microorganism or strain of microorganism that has history of safe use in food production or food processing and relates with the genetically modified microorganism.
  - (1.2) Food produced by conventional microorganism that has history of safe use in general food production.
- (2) New protein/novel protein means protein that is not naturally expressed, resulted from genetic modification and contains different amino acid sequence from conventional protein.

**Annex 4**  
**of the Notification of the Ministry of Public Health (No. 431)**  
**B.E. 2565 (2022) Issued under the Food Act B.E. 2522 (1979)**

**Minimal requirement for food safety assessment of genetically modified animal**

	<p><b>Description of genetically modified animal</b></p> <p>1.1 Type of genetically modified animal  1.2 Variety of genetically modified animal  1.3 Characterization of genetic modification  1.4 Objective of genetic modification</p>
	<p><b>Description of host animal</b></p> <p>2.1 Common name and scientific name  2.2 Taxonomic classification  2.3 History of development, in particular identifying traits that may adversely impact on human health  2.4 Information on the host animal’s genotype and phenotype relevant to its safety</p> <p style="padding-left: 40px;">2.4.1 Information on any known toxicity  2.4.2 Information on any known allergenicity  2.4.3 Symbiosis with toxin-producing organisms  2.4.4 Potential for colonization by human pathogens</p> <p>2.5 Information on the effect of feed, rearing, and growth environment on food products.  2.6 History of safe use as food</p> <p style="padding-left: 40px;">2.6.1 Breeding and rearing of the animal  2.6.2 Method to produce food from the animal e.g., harvesting, slaughtering, milking  2.6.3 Transportation and storage  2.6.4 Information on animal used as a food source</p> <p style="padding-left: 80px;">- Importance of consumption in particular subgroups of the population  - Macronutrient, micronutrient, and anti-nutrient</p>
	<p><b>Description of donor organism</b></p> <p>3.1 In case of having donor of genetic materials</p> <p style="padding-left: 40px;">3.1.1 Common name and scientific name  3.1.2 Taxonomic classification  3.1.3 History of safe use for consumption as food  3.1.4 Information on naturally occurring toxins, anti-nutrients, and allergens  3.1.5 Information on the past and present use, if any, in the food and possibility of presence as contaminants  3.1.6 Information on pathogenicity and relationship to known pathogens in human and animal if donor organism is microorganism</p>

	<p>3.1.7 Information on the source material (e.g., cell culture) that has been used, and its origins if the donor organism is animal</p> <p>3.1.8 Information on the source material (e.g., cell culture) that has been used, and its origins if the donor organism is virus</p> <p>3.2 In case of synthesized DNA that is not originated from genetic material existing in nature</p> <p>3.2.1 Role and function of the synthesized DNA</p> <p>3.2.2 Nucleotide sequence of the synthesized DNA.</p>
	<p><b>Description of genetic modification</b></p> <p>4.1 Description of transformation process</p> <p>4.1.1 Method of transformation</p> <p>4.1.2 Information on the DNA used to modify the animal</p> <p>(a) Characteristics of DNA used in transformation process and expected function</p> <p>(b) Source of the DNA (plant, microorganism, virus, synthetic)</p> <p>4.1.3 Information on natural hosts, target organs, transmission mode, pathogenicity, and potential for recombination with endogenous or exogenous pathogens if viral vectors or known zoonotic organisms used</p> <p>4.1.4 Information on intermediate host including the organisms (e.g., bacteria) used to produce or process DNA for transformation of the host organism</p> <p>4.2 Information of introduced DNA</p> <p>4.2.1 Characterization of genetic components</p> <p>(a) Target gene</p> <p>(b) Marker gene</p> <p>(c) Promoter</p> <p>(d) Terminator</p> <p>(e) Other elements affecting the function of the DNA</p> <p>(f) Other genetic components</p> <p>4.2.2 Size, identity, location and orientation of the DNA sequence in the final vector/ construct</p> <p>4.2.3 Function of introduced DNA.</p>
	<p><b>Description of genetic modified animal development</b></p> <p>Description of the methods used to produce initial genetically modified animal and the processes to produce the genetically modified animal ultimately used as food or for food production.</p> <p>5.1 Techniques and processes that are used to introduce the recombinant DNA to obtain the initial genetically modified animal e.g., transformation of gametes, microinjection of early embryos, and nuclear transfer of transgenic cells</p>

	<p>5.2 Descriptions of heritability</p> <p>5.3 Methods used to generate the genetically modified animal for use as food or in food production including breeding partners, or surrogate dams including genotype and phenotype, husbandry, and conditions under which they are raised or harvested</p> <p>5.4 History of use of the animals involved in the genetic modification (e.g., breeding partners, surrogate dams) in food production. Information may include breeding, rearing, harvesting, and conditions under which those food products are made available to consumers (e.g., storage, transport, processing).</p>
	<p><b>Characterization of genetic modification</b></p> <p>6.1 Information on inserted DNA in animal genome</p> <p>6.1.1 Characterization and description of the inserted DNA including analysis of the potential for mobilization or recombination of any construct material used</p> <p>6.1.2 Number of insertion sites</p> <p>6.1.3 Organization of the inserted DNA and copy number of the inserted DNA at each insertion site</p> <p>6.1.4 Analysis of inserted DNA and of the surrounding region at 5' and 3' ends of the inserted DNA that sufficient to identify any substance expressed as a consequence of the inserted DNA</p> <p>6.1.5 Analysis of open reading frame within the inserted DNA or created by the insertion with contiguous animal genomic DNA to indicate potential of creating fusion protein.</p> <p>6.2 Information on any expressed substance in genetically modified animal</p> <p>6.2.1 Gene product (protein or untranslated RNA)</p> <p>6.2.2 Function of the gene product</p> <p>6.2.3 Phenotypic description of the new trait</p> <p>6.2.4 Level and site of expression in the plant of the expressed gene product and metabolites of the gene product, particularly in the edible portions</p> <p>6.2.5 Amount of the target gene product if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein – if possible</p> <p>6.3 Other information that shall be included</p> <p>6.3.1 Information on whether the arrangement of the genetic material used for insertion has been conserved or whether significant rearrangements have occurred upon integration</p> <p>6.3.2 Information on whether intended modifications made to the amino acid sequence of the expressed protein result in post-translational modification or affect sites critical for structure or function of the expressed protein</p>

	<p>6.3.3 Information on whether the intended effect of the modification has been achieved and that all expressed traits are expressed and inherited in a manner that is stable through several generations consistent with laws of inheritance</p> <p>6.3.4 Examination of the inheritance of the DNA insert itself or the expression of the corresponding RNA if the phenotypic characteristics cannot be measured directly from phenotypic characteristics</p> <p>6.3.5 Information on whether the newly expressed trait(s) are expressed as  expected in the appropriate tissues in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene</p> <p>6.3.6 Information on whether the transformation process has either positive or negative impact in the host plant</p> <p>6.3.7 Information on the identity and expression pattern of any new fusion proteins.</p>
	<p><b>Health status of the genetically modified animal</b></p> <p>7.1 General health and performance indicators, including behavior, growth and development, general anatomy, and reproductive function</p> <p>7.2 Physiological measures including clinical and analytical parameters</p> <p>7.3 Other species-specific considerations as appropriate.</p>
	<p><b>Compositional analyses of key components</b></p> <p>Analysis of key components of the genetically modified animal compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions according with principles of Codex Alimentarius or OECD</p> <p>8.1 Key nutrients (macronutrients: carbohydrates, protein, fat; micronutrient: minerals, vitamins)</p> <p>8.2 Key anti-nutrients</p> <p>8.3 Natural toxicant known to be inherently in the animal</p> <p>Statistical data analysis method used must be generally accepted at international level.</p>

	<p><b>Food storage and processing</b></p> <p>9.1 Information on potential effects of food processing or processing conditions used in the production of a food ingredient from the genetically modified animals</p> <p>9.2 If the modification is intended to change storage or shelf-life, the impact of the modification on food safety and/or nutritional quality should be evaluated.</p>
	<p><b>Toxicity assessment</b></p> <p>10.1 The genetic modification of the plants can result in synthesis of new substances. The new substances can be conventional components of foods from animals such as proteins, fats, carbohydrates, vitamins which are novel in the context of that genetically modified animal. The new substances might also include new metabolites resulting from the activity of enzymes generated by the expression of the introduced DNA. Safety assessment of the new substances should be conducted.</p> <p>10.1.1 Chemical characterization and function of the newly expressed substance</p> <p>10.1.2 Concentration of the substance in the edible parts for human consumption of the genetically modified plant, including variations and mean values</p> <p>10.1.3 Dietary exposure and possible effects of the case of having indication of possible health impact or the case of nutritional modification or experts consider assessment is necessary</p> <p>10.1.4 Information should be provided to ensure that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to the genetically modified plants that do not normally express those toxic or anti-nutritious characteristics</p> <p>10.1.5 Bioinformatic analysis of amino acid sequence of newly expressed protein comparing with known toxins or anti-nutrient using updated databases within 3 years prior to submission. Submitted information for assessment of possible toxicity must be up-to-date information. Change of data or information that may lead to significant impact on human health impact must be reported</p> <p>10.1.6 Stability of new protein</p> <p>(a) Heat stability at cooking temperature and reason of conducting test at such temperature</p> <p>(b) Digestibility in simulated gastric fluid: (SGF) and simulated intestinal fluid: (SIF)</p> <p>Test must be conducted in Good Laboratory Practice (GLP) accredited laboratory. References must be published in peer reviewed journals</p>



	<p>10.2 If history of safe use as food of the new protein is not available and the new protein is not similar with any proteins that have history of safe use as food, acute oral toxicity test of new protein in addition to 10.1, although function of the new protein is known, must be conducted as follows.</p> <p style="padding-left: 40px;">10.2.1 Acute toxicity test</p> <p style="padding-left: 40px;">10.2.2 Sub-chronic toxicity test in the case of history of safe use of the new protein is not available or abnormality is found in acute toxicity test</p> <p style="padding-left: 40px;">10.2.3 Chronic toxicity test if data from sub-chronic toxicity is not sufficient for assessment</p> <p style="padding-left: 80px;">Test must be conducted in accordance with international standards</p> <p>10.3 In case of the newly expressed product is not protein and its history of safe use is not available, information on metabolism assessment, toxicokinetics, chronic toxicity, sub-chronic toxicity, carcinogenicity, reproductive and development toxicity of the new protein based on its nature and function in the animal and intake quantity in consumption may be additionally considered on case-by-case basis.</p>
	<p><b>Assessment of possible allergenicity</b></p> <p>11.1 Source of the new protein</p> <p>11.2 Bioinformatic analysis of amino acid sequence of newly expressed protein comparing with known allergens using updated databases within 3 years prior to submission date. In case of change that significantly impact health, the information of the change must also be submitted. In case of more than 80 amino acids has sequence homology with more than 35% of known allergens in the database, additional test such as IgE reaction with serum from patients or another appropriate test is necessary</p> <p>11.3 Information on possible allergenicity if the newly expressed protein has origin from allergy organism</p> <p>11.4 Information as described in 10.1.1, 10.1.2, 10.1.6 and 12.6.</p>
	<p><b>Nutrition modification</b></p> <p>12.1 Dietary exposure and metabolic requirements of population groups especially infants, children, pregnant and lactating women, the elderly, and those with chronic diseases. (Detail as in 10.1.3)</p> <p>12.2 Information on use, consumption and storage of the plant or food derived from it for additional nutritional assessment if necessary</p> <p>12.3 Information on change of nutritional components or profile as a result of genetic modification</p> <p>12.4 Study in animal if bioavailability or nutritional component is different from conventional counterpart. Assessment will be on case-by-case basis</p>

	<p>12.5 In case that the genetically modified animal designed for health benefits, it is necessary to conduct study on nutrition, toxicology, or other appropriate studies</p> <p>12.6 If information for assessment is insufficient, additional properly designed animal studies could be requested on the whole foods.</p>
	<p><b>Other considerations</b>  Information on the potential for altered accumulation or distribution of xenobiotics (e.g. veterinary drug residues, metals) and the potential for altered colonization by and shedding of human pathogens or new symbiosis with toxin-producing organisms in the genetically modified animal that could have an effect on food safety.</p>
	<p><b>Other assessment study</b>  14.1 Assessment report or opinion of food safety assessment agency in other countries.  14.2 Other documents such as license or information on permission from government authority of other countries.</p>
	<p><b>Additional information</b>  Additional information may be requested on case-by-case basis. The expert who requests the additional information must indicate rationale and clarify detail of the request.</p>

Note: Conventional counterpart in food safety assessment of genetically modified animal means animal variety which is known for its history of safe use as food and derived from parental lines of the same variety as the genetically modified animal.

## **Annex 5**

### **of the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022) Issued under the Food Act B.E. 2522 (1979)**

#### **Detection method of food derived from genetically modified organisms**

Must be one of the following methods.

1. Method announced by national or international standards organization or published in internationally accepted publications
2. Methods that established with performance characteristics and has validation of test result by collaborative study of several laboratories according to international guidelines or by a single laboratory validation according to international guidelines and the method validation shall be according to latest version of ISO/IEC17025

Methods in 1 or 2 must correctly detect the determined foods derived from genetically modified organisms

## Annex 6

### of the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022) Issued under the Food Act B.E. 2522 (1979)

#### List of genetically modified plants temporarily permitted to produce, import, or commercialize

##### 1. Corn

Traits/ Event	OECD Unique Identifier
(1) DP4114	DP-ØØ4114-3
(2) TC1507 X MON810	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6
(3) TC1507 X MON810 X MIR162	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x SYN-IR162-4
(4) TC1507 X MON810 X MIR604 X NK603	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6 x SYN-IR6Ø4-5
(5) 3272 X Bt11 X MIR604 X GA21	SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9
(6) DP4114 X MON810 X MIR604 X NK603	MON-00603-6 x MON-00810-6 x DP004114-3 x SYN-IR604-4
(7) 3272 X Bt11 X MIR604 X TC1507 X 5307 X GA21	SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
(8) Bt11 X DAS-59122-7 X MIR604 X TC1507 X GA21	SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
(9) Bt11 X MIR162 X MON89034 X GA21	SYN-BTØ11-1 x SYN-IR162-4 x MON-89Ø34-3 x MON-ØØØ21-9
(10) Bt11 X MIR162 X MIR604 X TC1507 X 5307 X GA21	SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9
(11) Bt11 X MIR162 X TC1507 X GA21	SYN-BTØ11-1 x SYN-IR162-4 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
(12) Bt11 X MIR604 X TC1507 X 5307 X GA21	SYN-Ø53Ø7-1 x SYN-IR6Ø4-5 x SYN-BTØ11-1 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
(13) Bt11 X TC1507 X GA21	SYN-BTØ11-1 x DAS-Ø15Ø7-1 x MON-ØØØ21-9
(14) DAS-40278-9	DAS-4Ø278-9
(15) DAS-59122-7	DAS-59122-7

(16) DAS-59122-7 X NK603	DAS-59122-7 x MON-ØØ6Ø3-6
(17) MON 810 X NK603	MON-ØØ6Ø3-6 x MON-ØØ81Ø-6
(18) MON 87427 X MON 89034 X MIR 162 X NK 603	MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-ØØ6Ø3-6
(19) MON 87427 X MON 89034 X NK603	MON-87427-7 x MON-89Ø34-3 x MON-ØØ6Ø3-6
(20) MON 87427 X MON 89034 X TC1507 X MON 88017 X DAS-59122-7	MON-87427-7 x MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7
(21) MON 87427 X MON 89034 X TC1507 X MON 87411 X DAS-59122-7	MON-87427-7 x MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-87411-9 x DAS-59122-7
(22) MON 87411	MON-87411-9
(23) MON 87460 X NK603	MON-8746Ø-4 x MON-ØØ6Ø3-6
(24) MON 89034 X MON 88017	MON-89Ø34-3 x MON-88Ø17-3
(25) MON89034 X TC1507 X MON 88017 X DAS-59122-7	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7
(26) MON 89034 X TC1507 X MON 88017 X DAS-59122-7 X DAS-40278-9	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7 x DAS-4Ø278-9
(27) MON 89034 X TC1507 X NK603	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6
(28) MON 89034 X TC1507 X MIR162 X NK603	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x SYN-IR162-4
(29) MON 89034 X TC1507 X MIR162 X NK603 X DAS-40278-9	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x SYN-IR162-4 x DAS-4Ø278-9
(30) MON 87427 x MON 89034 x MIR162 x MON 87411	MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-87411-9
(31) MON 89034 X TC1507 X NK603 X DAS-40278-9	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x DAS-4Ø278-9
(32) NK603 X DAS-40278-9	DAS40278 x NK603
(33) NK603 X T25	MON-ØØ6Ø3-6 x ACS-ZMØØ3-2
(34) TC1507	DAS-Ø15Ø7-1
(35) TC1507 X DAS-59122-7	DAS-Ø15Ø7-1 x DAS-59122-7
(36) TC1507 X DAS-59122-7 X MON810 X MIR604 X NK603	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ81Ø-6 x SYN-IR6Ø4-5 x MON-ØØ6Ø3-6
(37) TC1507 X DAS-59122-7 X MON810 X NK603	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6

(38) TC1507 X DAS-59122-7 X NK603	DAS-Ø15Ø7-1 x DAS-59122-7 x MON-ØØ6Ø3-6
(39) TC1507 X MIR604 X NK603	DAS-Ø15Ø7-1 x SYN-IR6Ø4-5 x MON-ØØ6Ø3-6
(40) TC1507 X MON810 X MIR162 X NK603	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x SYN-IR162-4 x MON-ØØ6Ø3-6
(41) TC1507 X MON810 X NK603	DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x MON-ØØ6Ø3-6
(42) TC1507 X NK603	DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6

## 2. Soybean

(1) DAS-44406-6	DAS-444Ø6-6
(2) FG72 X A5547-127	MST-FGØ72-3 x ACS-GMØØ6-4
(3) DP-305423-1 (HOS)	DP-3Ø5423-1
(4) DP-305423-1 (HOS) X GTS 40-3-2	DP-3Ø5423-1 x MON-Ø4Ø32-6
(5) MON 87708 X MON 89788	MON-877Ø8-9 x MON-89788-1
(6) MON 87751	MON-87751-7
(7) MON87751 X MON87701 X MON87708 X MON89788	MON-87751-7 x MON-877Ø1-2 x MON87708 x MON89788

End of Report.

### Attachments:

No Attachments