(Unofficial Translation)

Notification of the Ministry of Public Health

(No. 431) B.E. 2565 (2022)

Issued by virtue of the Food Act B.E. 2522 (1979)

RE: Foods Derived from Genetically Modified Organisms

At present, there are the plants, animals, microorganisms resulting from the genetically modified organisms are used as the foods or foods ingredient. Therefore, it is appropriate to impose the measure to regulate them to protect the safety of consumers.

By the virtue of the provisions in the first paragraph of Section 5 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 Genetically Modified Organisms" mean

(1) plants, animals, microorganisms 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 ingredient or produced from (1).

(3) the products from (1) which are used as food ingredient or food additive or nutrient.

"Genetically modified organism" means any living organism whose genetic materials are modified through 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 physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection; or

(2) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

"Stacked event" means genetically modified plant which is obtained from traditional breeding of parental lines which are genetically modified plants.

Clause 2 Foods derived from genetically modified organisms are prohibited to be produced, imported, or sold, unless

(1) Food is derived from genetically modified organisms listed in Annex 1 attached to this Notification.

(2) Food is derived from genetically modified organisms that passed food safety assessment.

Clause 3 Foods derived from genetically modified organisms shall have qualities or standards as follows:

(1) Do not contain toxin, hazard substances or hazard component more than that found in its conventional counterpart.

(2) Contain nutritional value or intended quality or specification not less than that of its conventional counterpart.

(3) The qualities or standards of such food product shall comply with the relevant Notifications of the Ministry of Public Health, as the case may be.

(4) Having other qualities or standards (if any) according to the biosafety assessment report, document, or evidence under Clause 5, as the case may be.

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 biosafety assessment report, document or evidence under Clause 5, as the case may be.

Clause 5 Foods derived from genetically modified organisms to be produced, imported or sold shall pass the food safety assessment from the National Center for Genetic Engineering and Biotechnology (BIOTEC) of the National Science and Technology Development Agency (NSTDA) or the food safety assessment agency which are recognized by Thailand Food and Drug Administration. The report of food safety assessment shall be submitted together with data or evidence dossier to the Thailand Food and Drug Administration for approval, according to the submission requirements, as the case may be, as follows:

(1) Foods derived from genetically modified plant; required data and information as specified in Annex 2 attached to this Notification.

(2) Foods derived from genetically modified microorganism; required data and information as specified in Annex 3 attached to this Notification.

(3) Foods derived from genetically modified animals; required data and information as specified in Annex 4 attached to this Notification.

In case of foods derived from genetically modified organism that passed food safety assessment by the joint FAO/WHO scientific advisory bodies or WHO Expert Advisory Panels and Committees, and enzyme used in food production that complies with the Notification of the Ministry of Public Health, Re: Enzyme used in Foods Production, are exempt to submit the report of biosafety assessment for food and the data or information as mentioned in the first paragraph of this clause.

Clause 6 Foods derived from genetically modified organisms to be produced, imported or sold shall obtain detectability confirmation document or letter from the Department of Medical Sciences (DMSC) or other laboratory recognized by Thai Food and Drug Administration.

Clause 7 If new scientific data or information relevant to the safety become available for foods derived from genetically modified organisms that already passed or approved for food safety assessment in accordance with this Notification. The applicant must notify Thai Food and Drug Administration and submit such new data or information without delay to the National Center for Genetic Engineering and Biotechnology (BIOTEC) of the National Science and Technology Development Agency (NSTDA) or other agency assigned by Thailand Food and Drug Administration to review the biosafety assessment for food.

Clause 8 The Analytical methods for foods derived from genetically modified organisms shall comply with the principle as prescribed in Annex 5 attached to this Notification.

Clause 9 Foods derived from genetically modified soybean or genetically modified corn listed in Annex 6 attached to this Notification are granted a waiver to be produced, imported or sold during the biosafety assessment for not exceeding five years from the date this Notification comes into force.

In case that it does not pass the biosafety assessment for food, such food derived from that genetically modified organism shall be prohibited to be produced, imported or sold.

The annex 6 attached to this Notification shall be repealed at the end of five-year of grace period mentioned in the first paragraph of this clause.

Clause 10 This Notification shall come into force after 180 days from the date of its publication in the Government Gazette.

Notified on 1st April B.E. 2565 (2022)

(Mr.Sathit Pitutecha)

Deputy Minister of Public Health

Acting on behalf of the Minister of Public Health

(*Published in the Government Gazette Vol.139, Special Part 127 (Ngor), dated 7th June 2022*)

Note

This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the

Annex 1

Attachment to the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022)

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RE: Foods Derived from Genetically Modified Organisms

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1. List of genetically modified plants that passed biosafety assessment for food

1.1 Corn/ Maize

Traits/Events	Unique Identifier
(1) LY038	REN-ØØØ38-3
(2) MON89034	MON-89Ø34-3
(3) MON89034 × NK603	MON-89Ø34-3 × MON-ØØ6Ø3-6
(4) MON863	MON-ØØ863-5
(5) MON88017	MON-88Ø17-3
(6) GA21	MON-ØØØ21-9
(7) Bt11	SYN-BTØ11-1
(8) Bt11 × GA21	SYN-BTØ11-1 × MON-ØØØ21-9
(9) MON87460	MON 8746Ø-4
(10) MIR604	SYN-IR6Ø4-5
(11) NK603	MON-ØØ6Ø3-6
(12) MIR604 × GA21	SYN-IR6Ø4-5 × MON-ØØØ21-9
(13) Bt11 × MIR604	SYN-BTØ11-1 × SYN-IR6Ø4-5
(14) Bt11 × MIR604 × GA21	SYN-BTØ11-1 × SYN-IR6Ø4-5 × MON-ØØØ21-9
(15) MIR162	SYN-IR162-4

Traits/Events	Unique Identifier
(16) Bt11 × MIR162 × GA21	SYN-BTØ11-1 × SYN-IR162-4 × MON-ØØØ21-9
(17) MON810	MON-ØØ81Ø-6
(18) 5307	SYN-Ø53Ø7-1
(19) T25	ACS-ZMØØ3-2
(20) 3272	SYN-E3272-5
(21) MZHG0JG	SYN-ØØØJG-2
(22) MON87460 × MON89034 × NK603	MON-8746Ø-4 × MON-89Ø34-3 × MON-ØØ6Ø3-6
(23) MZIR098	SYN-ØØØ98-3
(24) Bt11 × MIR162	SYN-BTØ11-1 × SYN-IR162-4
(25) Bt11 × MIR162 × MIR604 × GA21	SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-ØØØ21-9
(26) MON 87427	MON-87427-7
(27) MON87460 × MON89034 × MON88017	MON 8746Ø-4 × MON-89Ø34-3 × MON-88Ø17-3
(28) GA21 × T25	MON-ØØØ21-9 × ACS-ZMØØ3-2
(29) Bt11 × MIR162 × MIR604 × MON89034 × 5307 × GA21	SYN-BTØ11-1 × SYN-IR162-4 × SYN-IR6Ø4-5 × MON-89Ø34-3 × SYN-Ø53Ø7-1 × 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 × MON89788	MON-877Ø1-2 × MON-89788-1
(12) MON87708 × MON87988 × A5547-127	MON-877Ø8-9 × MON-89788-1 × ACS-GMØØ6-4
(13) DAS44406-6	DAS-444Ø6-6
(14) DAS-81419-2	DAS-81419-2
(15) DAS-81419-2 × DAS-44406-6	DAS-81419-2 × DAS-444Ø6-6

2. List of genetically modified microorganisms that passed biosafety assessment for food

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

Annex 2

Attachment to the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022)

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Minimal requirement for food safety assessment of genetically modified plants, as the case may be, as follows:

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

Items	Data Requirements
1	**Description of genetically modified plant:** 1.1 Type of genetically modified plants; 1.2 Description of genetic modification (GM trait, event); 1.3 Characterization of genetic modification; 1.4 Objective of genetic modification.
2	**Description of host plant:** 2.1 Common name and scientific name; 2.2 Taxonomic classification; 2.3 History of use, cultivation and development through breeding; in particular identifying traits that may adversely impact on human health; 2.4 Information on the host plant's genotype and phenotype relevant to its safety, cover other plant related species to the host plant; 2.4.1 Information on any known toxicity; 2.4.2 Information on any known allergenicity; 2.4.3 History of safe use for consumption as food; 2.5 Information for consumption as food or used in food production safely; 2.5.1 Cultivation of the plant; 2.5.2 Transportation and storage; 2.5.3 Special processing required to make the plant safe to eat; 2.5.4 Information on part of plant used as a food source: (a) Part of plant that used as food source; (b) Importance of using as food for consumption in particular subgroups of the population; (c) Macronutrient, micronutrient, and anti-nutrient it contributes to the diet.

Items	Data Requirements
3	**Description of donor organism or source of genetic material:** 3.1 In case of the donor organism(s) provide genetic materials, specify: 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 pathogenicity and relationship to known pathogens if donor organism is microorganisms; 3.1.6 Information on the past and present use, if any, in the food supply and possibility of 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.
4	**Description of the genetic modification:** 4.1 Genetic modification or transformation process: 4.1.1 Method of genetic transformation; 4.1.2 Information on the DNA used to modify the plant: (a) Characteristics of DNA used in transformation process and expected function in the plant; (b) Source of the DNA (e.g. plant, microorganism, virus, synthetic) by specifying details; 4.1.3 Information on intermediate host including the organisms (e.g. microorganism) used to produce or process DNA for transformation of the host organism; 4.2 Information of the introduced DNA: 4.2.1 Characterization of the genetic components to be introduced: (a) Target gene; (b) Marker gene; (c) Promoter; (d) Terminator; (e) Other elements affecting the function of the gene; (f) 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 the introduced DNA.

Items	Data Requirements
5	**Characterization of the genetic modification:** 5.1 Information on the DNA insertion into the plant genome: 5.1.1 Characterization and description of the inserted genetic materials; 5.1.2 Number of insertion sites; 5.1.3 Organization of the inserted genetic material and copy number at each insertion site; 5.1.4 Sequence analysis of the 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 contagious plant genomic DNA to indicate potential of creating fusion protein(s); 5.2 Information on any expressed substance(s) in the genetically modified plant: 5.2.1 Gene product(s) (e.g. protein or untranslated RNA); 5.2.2 Function of the gene product(s); 5.2.3 Phenotypic description of the new trait(s); 5.2.4 Level and site of expression in the plant of the expressed gene product(s), and the levels of its metabolites in the plant, particularly in the edible portions; 5.2.5 Amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein – if possible; 5.3 Other information that shall be included: 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; 5.3.2 Information on whether intended modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affect sites critical for structure or function of the expressed protein; 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; 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; 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; 5.3.6 Information on whether there is any evidence to suggest that one or several genes in the host plant has been affected by the transformation process (either positive or negative impact); 5.3.7 Information to confirm the identity and expression pattern of any new fusion protein(s).

Items	Data Requirements
6	**Compositional analyses of key nutritional components:** 6.1 Information on the analysis of key components of the genetically modified plant, especially those typical of the food, compared with an equivalent analysis of a conventional counterpart grown and harvested under the same conditions. The compositional analysis for each plant species should be selected in accordance with the principles of Codex Alimentarius or OECD: 6.1.1 Key nutrients (macronutrients: carbohydrates, proteins, fats; micronutrient: minerals, vitamins); 6.1.2 Key anti-nutrients; 6.1.3 Key toxicants known to be inherently present in the plant; The statistical analysis method used must be generally accepted at international level. 6.2 Information on 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 and harvested for use as food; 6.3 Information on the number of generations in trials; 6.4 Information on the number of replicas of each trial site to reduce any effect from varied environmental impact and naturally occurring genotypic variation within a crop variety; 6.5 Information on the number of samples (adequate number of plants should be sampled) and the methods of analysis according to international standards.
7	**Evaluation of metabolites:** 7.1 Information on accumulation of metabolites in the food that would adversely impact human health; 7.2 Information on residue and metabolite levels in the food; 7.3 Information on assessment of any alterations in nutrient profile.
8	**Food Processing:** Information describing on the potential effects that may occur due to processing conditions used in the production of the foods derived from genetically modified plant.
9	**Assessment of possible toxicity:** 9.1 The genetic modification of the plant can result in synthesis of new substance(s). The new substance(s) 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 substance(s) might also include new metabolite(s) resulting from the activity of enzyme(s) generated by the expression of the introduced DNA. Safety assessment of the new substance(s) should be conducted:

Items	Data Requirements
	9.1.1 Chemical characterization and function of the newly expressed substance(s); 9.1.2 Analytical data on the concentration of the new substance(s) in the edible parts for human consumption of the genetically modified plant, including variations and mean values; 9.1.3 Dietary exposure assessment; only in the case of having indication of possible health impact or the case of genetic modification for the purpose of altering nutritional properties or experts consider assessment is necessary; In case of altering nutritional properties, divided into 2 cases as follows: (a) If the genetically modified plant is staple food of Thai population, the dietary exposure shall be calculated in all cases; (b) If the genetically modified plant is not staple food of Thai population, the dietary exposure will be calculated on case-by-case basis according to the expert's discretion; 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; 9.1.5 Bioinformatic analysis of amino acid sequence of the newly expressed protein(s) comparing with known protein toxins or anti-nutrients using updated databases within 3 years prior to submission. The applicant should provide up-to-date information for assessment of possible toxicity and must be reported if there is any change of data or information that may lead to significant impact on human health; 9.1.6 Stability of new protein(s): (a) Heat stability at conventional temperature that are used in food processing and reason of conducting test at such temperature; (b) Digestibility in simulated gastric fluid (SGF) and simulated intestinal fluid (SIF); Test must be conducted in Good Laboratory Practice (GLP) accredited laboratory. In case of using citations, references must be published in Peer-reviewed Journals/ Peer-reviewed published articles; 9.2 If history of safe use as food of the new protein(s) is not available and the new protein(s) is not similar with any proteins that have history of safe use as food, acute oral toxicity test of new protein(s) in addition to 9.1, although function in plant of the new protein(s) is known, must be conducted as follows: 9.2.1 Acute toxicity test; 9.2.2 Sub-chronic toxicity test in the case of history of safe use of the new protein(s) is not available or abnormality is found in acute toxicity test;

Items	Data Requirements
	9.2.3 Chronic toxicity test if data from sub-chronic toxicity is not sufficient for assessment; Oral toxicity test must be conducted in accordance with international standards; 9.3 In case of the newly expressed substance(s) is not protein and its history of safe use is not available, potential toxicity of non-protein substance(s) should be assessed on a case-by-case basis depending on the identity and function in the plant of the substance(s) and dietary exposure. Additional information is required for consideration such as studies on metabolism, toxicokinetic, chronic toxicity, sub-chronic toxicity, carcinogenicity, reproductive and development toxicity of the new substance.
10	**Assessment of possible allergenicity:** 10.1 Source of the new protein(s); 10.2 Bioinformatic analysis of amino acid sequence of newly expressed protein(s) comparing with known allergens using updated databases within 3 years prior to submission date. However, the applicant must provide an up-to-date available on allergen safety information. In case of change that significantly impact health, the information of the change must also be submitted. In case of 80 or more amino acids of the newly expressed protein has sequence homology with more than 35% of known allergens in the database (>35% identity in a segment of 80 or more amino acids), additional test such as IgE testing with serum from patients or another appropriate test is necessary; 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; 10.4 Information on possible allergenicity if the newly expressed protein(s) has origin from another organism that cause allergy; 10.5 Information as described in 9.1.1, 9.1.2, 9.1.6 and 11.6.
11	**Nutritional modification:** 11.1 Information on dietary exposure and metabolic requirements of population, especially infants, children, pregnant and lactating women, the elderly, and those with chronic diseases (Detail as in 9.1.3); 11.2 Information on pattern of use, consumption and storage of the plant or food derived from it for additional nutritional assessment if necessary; 11.3 Information on change of nutritional components or profile as a result of genetic modification; 11.4 Information on animal feeding studies, if changes in the bioavailability of nutrients are expected or if the nutritional component is different from conventional counterpart,

Items	Data Requirements
	are evaluated on a case-by-case basis. The criteria for assessment are as follows: 11.4.1 If the genetically modified plant is staple food of Thai population, assessment of must be conducted; 11.4.2 If the genetically modified plant is not staple food of Thai population, assessment is on case-by-case basis if experts considered necessary; 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; 11.6 If information for safety assessment is insufficient, additional properly designed animal studies could be requested on the whole foods.
12	**Other considerations:** Information on potential for accumulation of some substances if the genetic modification may indirectly result in the potential for accumulation of pesticide residues or alteration of pesticide metabolites that may be given to the potential impacts on human health.
13	**Assessment report or other related documents (if any);** 13.1 Safety assessment reports or opinions of food safety assessment agency in other countries; 13.2 Other relevant documents such as license or information on permission from government authority of other countries.
14	**Other additional information:** Experts may request additional information from the above on a case-by-case basis, provided that the expert specifies the required information along with clear indicate rationale for requesting that information.

***Note*:** Conventional counterpart in food safety assessment of genetically modified plants means related plant variety, its components and/or products for which there is experience of establishing safety based on common use as food.

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, as the case may be, as the following:

Case 1 Genetically modified plant with stacked genes that derived from traditional 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 line that did not pass food safety assessment (*not listed in Annex 1 or not complied with Clause 5 of this Notification*), food safety assessment must be subjected to full scale assessment as any new (single) genetically modified plant. Data of paternal and maternal lines can be used to support assessment on case-by-case basis.

Case 2 Genetically modified plant with stacked genes that derived from traditional 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 (*listed in Annex 1 or complied with Clause 5 of this Notification*), food safety assessment of the genetically modified plant with stacked gene is as follows:

Items	Data Requirements
1	**Qualitative confirmation of traits in stacks:** Information for assessment can use information in 1.1 and/or 1.2 as appropriate as follows: 1.1 Protein expression: information on stability, expression level of the target genes, size of the 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.
2	**Compositional Analysis:** 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

Items	Data Requirements
	Codex Alimentarius or OECD.
	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/or 2 reveals difference pattern between the genetically modified plant with stacked genes and the counterpart, further assessment as mentioned in 3 – 5 must be conducted.
3	**Molecular characterization:** Additional information is necessary if proteins expression of the target genes in the genetically modified plant with stacked genes differs from that of the parental lines, such as: ○ ELISA or mRNA analysis to study the level of expression in different tissues at each stage of development of the plant; ○ Enzyme assay to study the activity level of expressed proteins of the target genes; ○ Metabolic analysis to study metabolic pathway changes in case the target genes is an enzyme-related gene, or the target genes cause unusual change of metabolic pathway, or related to the interaction of genes derived from the parental lines; If information indicates unintended effect of the insertion of the target genes, additional information from accepted scientific techniques such as open reading frame (ORF), flanking sequence, Western blot analysis, Northern blot analysis, quantitative PCR analysis, ELISA, protein function analysis and enzyme analysis of the genetically modified plant with stacked genes must be considered as appropriate on case-by-case basis.
4	**Toxicology:** Toxicity study of the new protein(s) or the modified protein(s) resulted from the expression of the target genes, by using sample for analysis from the genetically modified plant with stacked genes, as follows: 4.1 Chemical characterization and function of the newly expressed substance(s); 4.2 Analytical data on the concentration of the new substance(s) in the edible parts for human consumption of the genetically modified plant with stacked genes, including variations and mean values; 4.3 Bioinformatic analysis of amino acid sequence of newly expressed protein(s) comparing with known protein toxins or anti-nutrients using updated databases within 3 years prior to submission. The applicant should provide up-to-date information for assessment of possible toxicity and must be reported if there is any change of data or information that may lead to significant impact on human health; 4.4 Stability of new protein(s):

Items	Data Requirements
	4.4.1 Heat stability at conventional temperature that are used in food processing and reason of conducting test at such temperature; 4.4.2 Digestibility in simulated gastric fluid (SGF) and simulated intestinal fluid (SIF); Test must be conducted in Good Laboratory Practice (GLP) accredited laboratory. In case of using citations, references must be published in Peer-reviewed Journals/ Peer-reviewed published articles; 4.5 Oral toxicity test of the new protein(s) 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(s) 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 Test must be conducted in accordance with international standards.
5	**Assessment of possible allergenicity** Allergenicity information of the new protein(s) or the modified protein(s) resulted from the expression of the target genes, by using sample for analysis from the genetically modified plant with stacked genes, as follows: 5.1 Bioinformatic analysis of amino acid sequence of newly expressed protein(s) comparing with known allergens using updated databases within 3 years prior to submission date. However, the applicant must provide an up-to-date available on allergen safety information. In case of change that significantly impact health, the information of the change must also be submitted. In case of 80 or more amino acids of the newly expressed protein has sequence homology with more than 35% of known allergens in the database (>35% identity in a segment of 80 or more amino acids), additional test such as IgE testing with serum from patients or another appropriate test is necessary; 5.2 Information as described in 4.1, 4.2, and 4.4; 5.3 Glycosylation or post-translational modifications of the newly expressed protein(s).
In case of the genetically modified plant with stacked genes that derived from traditional breeding contains target genes that involve with metabolic pathway or gene interaction, additional food safety assessment must be conducted on case-by-case basis.	
6	**Assessment report or other related documents (if any):** 6.1 Safety assessment reports or opinions of food safety assessment agency in other countries;

Items	Data Requirements
	6.2 Other relevant documents such as license or information on permission from government authority of other countries.
7	**Other additional information:** Experts may request additional information from the above on a case-by-case basis, provided that the expert specifies the required information along with clear indicate rationale for requesting that information.

***Note*:** Conventional counterpart in food safety assessment of genetically modified plant with stacked genes means the comparator used for safety assessment: transgenic parental line, or non-transgenic parental line, or conventional hybrid of non-transgenic parental line.

Annex 3

Attachment to the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022)

Issued by virtue of the Food Act B.E. 2522 (1979)

RE: Foods Derived from Genetically Modified Organisms

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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 or starter culture use 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, acetic acid or vitamins.

2. Summary of data or information requirement for biosafety assessment of food derived from genetically modified microorganisms.

Data/ information Requirements	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. Information relating to the production process and product preparation process including techniques for microorganism removal from food products and examination of remained genetically modified microorganisms or parts of genetic material parts in foods	✓	✓	✓	✓
7. Description of the product and it specification	✓	✓	✓	✓
8. Toxicity Study	✓	✓	✓	✓
9. Compositional analysis	✓	✓	✓(*)	
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	✓			
14. Antibiotic resistance and gene transfer	✓			
15. Other related data or information (if any)	✓	✓	✓	✓
16. Additional information (may be requested on case-by-case basis and it must be indicated the rationale for requested)	✓	✓	✓	✓

(*) Only substance with nutritional or health purposes.

Data or information requirement for biosafety assessment of food derived from genetically modified microorganisms as follows:

Items	Data Requirements
1	**Description of genetically modified microorganism:** 1.1 Description 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 Safety of genetically modified microorganisms with 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: 2.5.1 Production of toxins; 2.5.2 Production of antibiotics; 2.5.3 Antimicrobial activity; 2.5.4 Pathogenicity; 2.5.5 Immunological effect; 2.5.6 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 microbiological culture, transportation, storage, quality assurance measures, strain identity verification, description of production and specifications of microorganisms and food produced by such microorganism, and information on the microbial viability in food.
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;

Items	Data Requirements
	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) Production of toxins; (b) Production of Antibiotics; (c) Antimicrobial activity; (d) Pathogenicity; (e) Immunological effect; 3.1.6 Information in the past and present use (if any) including history of use in the food production, or unintended presence (e.g. as a contaminant) in food; 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.
4	**Description of genetic modification:** 4.1 Description of transformation protocol; 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, or synthesis) 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.

Items	Data Requirements
5	**Characterization of genetic modification:** 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 contagious 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 according to reports; 5.2 Information on any expressed substance in genetically modified microorganisms: 5.2.1 Gene product (protein or untranslated RNA); 5.2.2 Function of the gene product; 5.2.3 Phenotypic description of the new trait; 5.2.4 Level and site of expression in the plant of the expressed gene product and metabolites of the gene product; (a) In case of Gram-negative bacteria, the gene product is produced intracellular or in periplasmic; (b) In case of eukaryotic microorganisms, the gene product is in organelles or secreted. 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; 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; 5.3 Other information that shall be included: 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;

Items	Data Requirements
	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; 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; 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; 5.3.5 Information on whether the transformation process has either positive or negative impact in the host plant; 5.3.6 Information on the identity and expression pattern of any new fusion proteins.
6	**Description of production or processing:** It including techniques for microorganism removal from the products and examination of remained genetically modified microorganisms or parts of genetic material parts in foods on case-by-case basis: 6.1 Production process chart with details of controls used in the process including controlled factors such as temperature, gas quantity, chemical used and eliminated; 6.2 Techniques, measures, or process used to reduce, destroy, or eliminate the genetically modified microorganisms and genetic material from desired product; 6.3 Analysis of existence of the genetically modified microorganisms or examination of ability to multiply of the genetically modified microorganisms; 6.4 Analysis of remaining genetic materials or potential for gene transfer of the genetically modified microorganisms; 6.5 Techniques and methods used for detecting stressed cells by resuscitation culture if the cells of the genetically modified microorganisms can produce spores Examination of cells that may grow of those spores is also necessary.
7	**Characteristics of the products:** 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 described in 7.2.3; 7.2 In case of products other than food additive: 7.2.1 Description and product characterization; 7.2.1.1 Product composition or formulation;

Items	Data Requirements
	7.2.1.2 Chemical name, common name, brand name, synonymous name, and abbreviations; 7.2.1.3 International code (if any) e.g., CAS number; 7.2.1.4 Chemical formula, molecular mass, or subunit structure or amino acid sequence, as the case may be; 7.2.1.5 Information on impurity or contaminants that might occur during the processing (with analytical report) and prevent measure; 7.2.1.6 Physical characteristics of the products 7.2.2 Intended use and mode of action of the products, technology justification, reaction and by product, optimal condition of use and storage; 7.2.3 Characteristics of products derived from genetic modification compared with that of products from conventional counterpart.
8	**Toxicology:** 8.1 In case of food additive which used as a starter culture or new food additive, Information on toxicology of products must be submitted according to Notification of Ministry of Public Health Re: Food Additives; 8.2 In case of the product other than food additive: 8.2.1 Concentration of new substance for human consumption; 8.2.2 In case of new protein or new substance (a novel food), toxicology study in experimental animals according to international standards is necessary; (a) Acute toxicity test; (b) Sub-chronic toxicity test; (c) Chronic toxicity test if data from sub-chronic toxicity test is not sufficient; 8.2.3 Information on metabolic pathway and other toxicity study e.g., metabolism, toxicokinetic, 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); 8.2.4 Data 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; 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;

Items	Data Requirements
	8.2.6 Stability of new protein: (a) Heat stability at cooking temperature and reason of conducting test at such temperature; (b) Digestibility in simulated gastric fluid (SGF) and simulated intestinal fluid (SIF); Test must be conducted in Good Laboratory Practice (GLP) accredited laboratory. References must be published in peer reviewed journal; 8.2.7 Health based guideline value on a case-by-case basis; (a) No observed adverse effect level (NOAEL); (b) ADI or UL which calculate from toxicology study with safety factor ; (c) Toxicological versus physiological responses; 8.2.8 Estimated dietary exposure: (a) In case of food additives, conduct assessment according to Notification of Ministry of Public Health, Re: Food additives; (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.
9	**Compositional analyses of key nutritional components:** 9.1 Analysis of key components of the food produced by 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: 9.1.1 Key nutrients (macronutrients: carbohydrates, proteins, fats; micronutrient: minerals, vitamins); 9.1.2 Key anti-nutrients; 9.1.3 Key toxins naturally occurred in microorganisms; The statistical analysis method used must be generally accepted at international level. 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: 9.2.1 Pattern of use and food and derivatives consumption for estimation of intaking of food derived from genetically modified microorganism; 9.2.2 Information on food intaking for evaluation of nutritional impact of changed nutrient profile; 9.2.3 Evaluation of nutritional condition of different consumer groups.

Items	Data Requirements
10	**Evaluation of metabolites:** 10.1 Possible accumulation of altered metabolite in food that may impact health; 10.2 Analysis of level of altered metabolite in food; 10.3 Impact of the genetic modified microorganism to other microorganisms in food production process that use many strains of microorganisms.
11	**Effects of food processing:** Information on possible impact from condition or food processing to the products produced from the genetic modified microorganism.
12	**Assessment of possible allergenicity:** 12.1 Source of the new protein(s); 12.2 Bioinformatic analysis of amino acid sequence of newly expressed protein(s) comparing with known allergens using updated databases within 3 years prior to submission date. However, the applicant must provide an up-to-date available on allergen safety information. In case of change that significantly impact health, the information of the change must also be submitted. In case of 80 or more amino acids of the newly expressed protein has sequence homology with more than 35% of known allergens in the database (>35% identity in a segment of 80 or more amino acids), additional test such as IgE testing with serum from patients or another appropriate test is necessary; 12.3 Information on possible allergenicity if the newly expressed protein(s) has origin from other organism that cause allergy; 12.4 Information as described in 7.1, 8.1, 8.2, and 8.3
13	**Assessment of viability and residence of microorganisms in the human gastrointestinal tract:** In case of the genetically modified microorganisms remains in food. Information on intended and unintended effect from genetic modification compared with counterpart microorganism is necessary.
14	**Antibiotic resistance and gene transfer:** 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; 14.2 Potential of gene transfer from the genetically modified microorganism and food derived the genetically modified microorganisms to microflora in digestive tract.

Items	Data Requirements
15	**Assessment report or other related documents (if any):** 15.1 Safety assessment reports or opinions of food safety assessment agency in other countries; 15.2 Other relevant documents such as license or information on permission from government authority of other countries or patent document(s).
16	**Other additional information:** Experts may request additional information from the above on a case-by-case basis, provided that the expert specifies the required information along with clear indicate rationale for requesting that information.

Note:

(1) Conventional counterpart for biosafety assessment of food produced from 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) The product 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

Attachment to the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022)

Issued by virtue of the Food Act B.E. 2522 (1979)

RE: Foods Derived from Genetically Modified Organisms

Minimal requirement for food safety assessment of genetically modified animals

Items	Data Requirements
1	**Description of genetically modified animal:** 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.
2	**Description of host/recipient animal:** 2.1 Common name and scientific name; 2.2 Taxonomic classification; 2.3 History of development through breeding, in particular identifying traits that may adversely impact on human health; 2.4 Information on the host/recipient animal's genotype and phenotype relevant to its safety, covering related lines or other animals that are close in their genetic background to the host/recipient animal: 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; 2.5 Information on feed and the effect of feed, rearing, and growth environment on food products; 2.6 History of safe use as food or for food production: 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 of the animal used as a source of nutrients: ○ Importance of use as food in particular subgroups of the population; ○ Macronutrient, micronutrient, and anti-nutrient.
3	**Description of donor organism or source of genetic material:** 3.1 In case of the donor organism(s) provide genetic materials, specify: 3.1.1 Common name and scientific name; 3.1.2 Taxonomic classification; 3.1.3 History of safe use for consumption as food;

Items	Data Requirements
	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 supply and possibility of presence as contaminants; 3.1.6 Information on pathogenicity and relationship to known pathogens in human and animal if donor is microorganism; 3.1.7 Information on the source material (e.g. cell culture) that has been used, and its origins if the donor is animal; 3.1.8 Information on the source material (e.g. cell culture) that has been used, and its origins if the donor is virus; 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.
4	**Description of the genetic modification:** 4.1 Genetic modification or transformation process; 4.1.1 Method of genetic transformation; 4.1.2 Information on the DNA used to modify the animal: (a) Characteristics of DNA used in transformation process and expected function in the animal; (b) Source of the DNA (e.g. animal, plant, microorganism, virus, synthetic) by specifying details; (c) 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 have been used; 4.1.3 Information on intermediate host including the organisms (e.g. microorganism) used to produce or process DNA for transformation of the host organism or the recipient animal; 4.2 Information of the introduced DNA: 4.2.1 Characterization of the genetic components to be introduced: (a) Target gene; (b) Marker gene; (c) Promoter; (d) Terminator; (e) Other elements affecting the function of the gene; (f) Other genetic components; 4.2.2 Size, identity, location and orientation of the DNA sequence in the final

Items	Data Requirements
	vector/ construct; 4.2.3 Function of the introduced DNA.
5	**Description of genetic modified animal development:** 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: 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; 5.2 Descriptions of the methods used to demonstrate heritability; 5.3 Information on how the initial genetically modified animal leads to the production of the genetically modified animal ultimately used as food or for food production, include information on the breeding partners, or surrogate dams including genotype and phenotype, husbandry, and conditions under which they are raised or harvested; 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 on how the animals breed, rear, its food products are obtained and the conditions under which those food products are made available to consumers (e.g., storage, transport, processing).
6	**Characterization of the genetic modification:** 6.1 Information on the DNA insertion into the animal genome: 6.1.1 Characterization and description of the inserted genetic materials including analysis of the potential for mobilization or recombination of any construct material used; 6.1.2 Number of insertion sites; 6.1.3 Organization of the inserted genetic materials and copy number at each insertion site; 6.1.4 Sequence analysis of the 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; 6.1.5 Analysis of open reading frame within the inserted DNA or created by the insertion with contagious animal genomic DNA to indicate potential of creating fusion protein(s); 6.2 Information on any expressed substance(s) in the genetically modified animal: 6.2.1 Gene product(s) (e.g. protein or untranslated RNA); 6.2.2 Function of the gene product(s); 6.2.3 Phenotypic description of the new trait(s);

Items	Data Requirements
	6.2.4 Level and site of expression in the animal of the expressed gene product(s) and the levels of its metabolites in the animal, particularly in the edible portions; 6.2.5 Amount of the target gene product(s) if the function of the expressed sequence(s)/gene(s) is to alter the accumulation of a specific endogenous mRNA or protein – if possible; 6.3 Other information that shall be included: 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; 6.3.2 Information on whether intended modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affect sites critical for structure or function of the expressed protein; 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; 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; 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; 6.3.6 Information on whether there is any evidence to suggest that one or several genes in the host/recipient animal has been affected by the transformation process (either positive or negative impact); 6.3.7 Information to confirm the identity and expression pattern of any new fusion protein(s).
7	**Health status of the genetically modified animal:** 7.1 General health and performance indicators, including behavior, growth and development, general anatomy, and reproductive function; 7.2 Physiological measures including clinical and analytical parameters; 7.3 Other species-specific considerations, where appropriate.
8	**Compositional analyses of key nutritional components:** Information on the analysis of key components of the genetically modified animal,

Items	Data Requirements
	especially those typical of the food, compared with an equivalent analysis of a conventional counterpart grown and bred under the same husbandry conditions. The compositional analysis for each animal species should be selected in accordance with the principles of Codex Allimentarius or OECD: 8.1 Key nutrients (macronutrients: carbohydrates, proteins, fats; micronutrient: minerals, vitamins); 8.2 Key anti-nutrients; 8.3 Key toxicants known to be inherently present in the animal; The statistical analysis method used must be generally accepted at international level.
9	**Food storage and processing:** 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; 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.
10	**Assessment of possible toxicity:** 10.1 The genetic modification of the animal can result in synthesis of new substance(s). The new substance(s) 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 substance(s) might also include new metabolite(s) resulting from the activity of enzyme(s) generated by the expression of the introduced DNA. Safety assessment of the new substance(s) should be conducted: 10.1.1 Chemical characterization and function of the newly expressed substance(s); 10.1.2 Analytical data on the concentration of the new substance(s) in the edible parts for human consumption and other derived food products of the genetically modified animal, including variations and mean values; 10.1.3 Dietary exposure assessment; only in the case of having indication of possible health impact or the case of genetic modification for the purpose of altering nutritional properties or experts consider assessment is necessary; 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 animal that do not normally express those toxic or anti-nutritious characteristics; 10.1.5 Bioinformatic analysis of amino acid sequence of the newly expressed

Items	Data Requirements
	protein(s) comparing with known protein toxins or anti-nutrients using updated databases within 3 years prior to submission. The applicant should provide up-to-date information for assessment of possible toxicity and must be reported if there is any change of data or information that may lead to significant impact on human health; 10.1.6 Stability of new protein(s): (a) Heat stability at conventional temperature that are used in food processing and reason of conducting test at such temperature; (b) Digestibility in simulated gastric fluid (SGF) and simulated intestinal fluid (SIF); Test must be conducted in Good Laboratory Practice (GLP) accredited laboratory. In case of using citations, references must be published in Peer-reviewed Journals/ Peer-reviewed published articles; 10.2 If history of safe use as food of the new protein(s) is not available and the new protein(s) is not similar with any proteins that have history of safe use as food, acute oral toxicity test of new protein(s) in addition to 10.1, , although function in animal of the new protein(s) is known, must be conducted as follows: 10.2.1 Acute toxicity test; 10.2.2 Sub-chronic toxicity test in the case of history of safe use of the new protein(s) is not available or abnormality is found in acute toxicity test; 10.2.3 Chronic toxicity test if data from sub-chronic toxicity is not sufficient for assessment; Oral toxicity test must be conducted in accordance with international standards; 10.3 In case of the newly expressed substance(s) is not protein and its history of safe use is not available, potential toxicity of non-protein substance(s) should be assessed on a case-by-case basis depending on the identity and function in the animal of the substance(s) and dietary exposure. Additional information is required for consideration such as studies on metabolism, toxicokinetic, chronic toxicity, sub-chronic toxicity, carcinogenicity, reproductive and development toxicity of the new substance.
11	**Assessment of possible allergenicity:** 11.1 Source of the new protein(s); 11.2 Bioinformatic analysis of amino acid sequence of newly expressed protein(s) comparing with known allergens using updated databases within 3 years prior to submission date. However, the applicant must provide an up-to-date available on allergen safety

Items	Data Requirements
	information. In case of change that significantly impact health, the information of the change must also be submitted. In case of 80 or more amino acids of the newly expressed protein has sequence homology with more than 35% of known allergens in the database (>35% identity in a segment of 80 or more amino acids), additional test such as IgE testing with serum from patients or another appropriate test is necessary; 11.3 Information on possible allergenicity if the newly expressed protein(s) has origin from other organism that cause allergy; 11.4 Information as described in 10.1.1, 10.1.2, 10.1.6 and 12.6.; However, if the newly expressed protein(s) is derived from an allergenic organism, additional tests, such as a skin prick test, may be considered as appropriate.
12	**Nutritional modification:** 12.1 Information on dietary exposure and metabolic requirements of population, especially infants, children, pregnant and lactating women, the elderly, and those with chronic diseases (Detail as in 10.1.3); 12.2 Information on pattern of use, consumption and storage of the animal or food derived from it for additional nutritional assessment if necessary; 12.3 Information on change of nutritional components or profile as a result of genetic modification; 12.4 Information on animal feeding studies, if changes in the bioavailability of nutrients are expected or if the nutritional component is different from conventional counterpart, are evaluated on a case-by-case basis; 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; 12.6 If information for safety assessment is insufficient, additional properly designed animal studies could be requested on the whole foods.
13	**Other considerations:** Information on the potential for accumulation of some substances or microorganisms if the genetic modification may indirectly result in the potential for 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 may be given to the potential impacts on human health.
14	**Assessment report or other related documents (if any):**

Items	Data Requirements
	14.1 Safety assessment reports or opinions of food safety assessment agency in other countries; 14.2 Other relevant documents such as license or information on permission from government authority of other countries;
15	**Other additional information:** Experts may request additional information from the above on a case-by-case basis, provided that the expert specifies the required information along with clear indicate rationale for requesting that information.

***Note*:** Conventional counterpart in food safety assessment of genetically modified animal means an animal breed with a known history of safe use as food from which the recombinant-DNA animal line was derived, as well as the breeding partners used in generating the animals ultimately used as food, and/or food derived from such animals.

Annex 5

Attachment to the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022)

Issued by virtue of the Food Act B.E. 2522 (1979)

RE: Foods Derived from Genetically Modified Organisms

Analytical methods for food derived from genetically modified organisms

Shall be one of the following:

1. Analytical methods issued by National Organizations or International Standards Organizations, or published in the manuals or publications which are internationally recognized.

2. Performance characteristics of pesticide residue analytical methods must be accurate and reliable. Method validation is performed by a collaborative study or single laboratory based on international guidelines. The result shall be in document comply with the latest version of ISO/IEC 17025.

The methods of analysis as stated under items 1 and 2 shall provide the reliable outcome of food derived from genetically modified organisms.

Annex 6

Attachment to the Notification of the Ministry of Public Health (No. 431) B.E. 2565 (2022)
Issued by virtue of the Food Act B.E. 2522 (1979)
RE: Foods Derived from Genetically Modified Organisms

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

1. Corn/ Maize

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

Traits/ Event	OECD Unique Identifier
(12) Bt11 × MIR604 × TC1507 × 5307 × GA21	SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × SYN-Ø53Ø7-1 × MON-ØØØ21-9
(13) Bt11 × TC1507 × GA21	SYN-BTØ11-1 × DAS-Ø15Ø7-1 × MON-ØØØ21-9
(14) DAS-40278-9	DAS-4Ø278-9
(15) DAS-59122-7	DAS-59122-7
(16) DAS-59122-7 × NK603	DAS-59122-7 × MON-ØØ6Ø3-6
(17) NK603 × MON810	MON-ØØ6Ø3-6 × MON-ØØ81Ø-6
(18) MON87427 × MON89034 × MIR162 × NK603	MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-ØØ6Ø3-6
(19) MON87427 × MON89034 × NK603	MON-87427-7 × MON-89Ø34-3 × MON-ØØ6Ø3-6
(20) MON87427 × MON89034 × TC1507 × MON88017 × DAS-59122-7	MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7
(21) MON87427 × MON89034 × TC1507 × MON87411 × DAS-59122-7	MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-87411-9 × DAS-59122-7
(22) MON87411	MON-87411-9
(23) MON87460 × NK603	MON-8746Ø-4 × MON-ØØ6Ø3-6
(24) MON89034 × MON88017	MON-89Ø34-3 × MON-88Ø17-3
(25) MON89034 × TC1507 × MON88017 × DAS-59122-7	MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7
(26) MON89034 × TC1507 × MON88017 × DAS-59122-7 × DAS-40278-9	MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7 × DAS-4Ø278-9
(27) MON89034 × TC1507 × NK603	MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6

Traits/ Event	OECD Unique Identifier
(28) MON89034 × TC1507 × MIR162 × NK603	MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × SYN-IR162-4
(29) MON89034 × TC1507× NK603 × MIR162 × DAS-40278-9	MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × SYN-IR162-4 × DAS-4Ø278-9
(30) MON87427 × MON89034 × MIR162 × MON87411	MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-87411-9
(31) MON89034 × TC1507 × NK603 × DAS-40278-9	MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6 × DAS-4Ø278-9
(32) NK603 × DAS-40278-9	MON-ØØ6Ø3-6 × DAS-4Ø278-9
(33) NK603 × T25	MON-ØØ6Ø3-6 × ACS-ZMØØ3-2
(34) TC1507	DAS-Ø15Ø7-1
(35) TC1507 × DAS-59122-7	DAS-Ø15Ø7-1 × DAS-59122-7
(36) TC1507 × DAS-59122-7 × MON810 × MIR604 × NK603	DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 × SYN-IR6Ø4-5 × MON-ØØ6Ø3-6
(37) TC1507 × DAS-59122-7 × MON810 × NK603	DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6
(38) TC1507 × DAS-59122-7 × NK603	DAS-Ø15Ø7-1 × DAS-59122-7 × MON-ØØ6Ø3-6
(39) TC1507 × MIR604 × NK603	DAS-Ø15Ø7-1 × SYN-IR6Ø4-5 × MON-ØØ6Ø3-6
(40) TC1507 × MON810 × MIR162 × NK603	DAS-Ø15Ø7-1 × MON-ØØ81Ø-6 × SYN-IR162-4 × MON-ØØ6Ø3-6
(41) TC1507 × MON810 × NK603	DAS-Ø15Ø7-1 × MON-ØØ81Ø-6 × MON-ØØ6Ø3-6
(42) TC1507 × NK603	DAS-Ø15Ø7-1 × MON-ØØ6Ø3-6

2. Soybean

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