NISHIMURA & ASAHI

西村あさひ法律事務所

General Food Safety Regulations in Thailand (Vol. 2)

Asia / Agri-Food Newsletter

January 27, 2023

Author:
E-mail Jirapong Sriwat
E-mail Apinya Sarntikasem
E-mail Pruk Chaweekulrath
E-mail Tanapol Lomtong

1. Introduction

Under the Food Act B.E. 2522 (the "**Food Act**"), the Ministry of Public Health (the "**MOPH**") and the Food and Drug Administration (the "**FDA**") are authorized to issue a wide range of regulations regarding food safety to uphold food safety standards and the safety of the general consumers. This article will explore some of these notifications, ranging from the regulations regarding food derived from genetically modified organism, food production processes, food containers, food labeling, food advertisement, nutrition labeling, and health and nutrition claims to provide a general overview of certain aspects of food safety regulation in Thailand.

2. Genome Editing and Genetic Modification

Up until now, there were no overarching regulatory regimes on food derived from genetic modification in Thailand. However, starting from 4 December 2022, food or food components which are produced from genetically modified organism are to be generally governed under the Notification of the MOPH (No. 431) B.E. 2565 (2022) Issued under the Food Act Re: Food Produced From Genetically Modified Organism (the "**GMF Notification**").[1]

Under Clause 1 of the GMF Notification, several key definitions are provided as follows:

- "Food produced from genetically modified organism" ("**GMF**") means:
  (1) plant, animal, or microbe of which its genetics have been edited, modified, transformed, engineered, or combined with new genetic materials by using modern biotechnology, and consumed as food;
  (2) food product which uses (1) as food ingredient, or which is produced from (1); and
  (3) fruits of (1) which are used as food ingredient, additive, or nutrient;
- "Genetically Modified Organism; GMO" means organism of which its genetic materials have been modified through the use of modern biotechnology;

As a general rule, GMF is prohibited from being produced, imported, or distributed according to Clause 2 of the GMF Notification. However, there are 2 major exceptions to this prohibition, which are:

- GMF listed under Annex 1 of the GMF Notification, i.e. certain species of corn, soybean, and microbes; and
- GMF which passes the assessment on biological food safety.

[1] This notification was published in the Government Gazette on 7 June 2022 and will come into effect 180 days after its publication (i.e. 4 December 2022).

In other words, GMF not listed under Annex 1 of the GMF Notification must first go through the assessment on biological food safety before being allowed to be produced, imported, or distributed in Thailand.

The biological food safety assessment must be conducted either by the National Center for Genetic Engineering and Biotechnology, the National Science and Technology Development Agency, or other institutes as prescribed by the FDA. Thereafter, the assessment report must be submitted for approval with the FDA along with the other required documents and evidence, pursuant to Clause 5 of the GMF Notification.[2]

It may be worth noting that the evidence required for approval of GMF vary depending on whether the GMF is derived from plant, animal or microbes, as prescribed under Annex 2, 3, and 4 of the GMF Notification.

Moreover, in the case where there is new scientific data related to the GMF which has already passed the biological food safety assessment, the applicant must notify the FDA and submit such new scientific data to the prescribed institutes for the reassessment of the biological food safety of such GMF, as stipulated by Clause 7 of the GMF Notification.

Additionally, GMF also must meet the following requirements under Clause 3 of the GMF Notification:

(1) having toxic substance, object, or component which incurs risk to health of not more than those of its conventional counterpart;
(2) having nutritional value or qualifications of not less than those of its conventional counterpart;
(3) having quality or standard as prescribed by the MOPH for such type of food (if any);
(4) having quality or other standard (if any) as prescribed under the biological food safety assessment report, documents or evidences under Clause 5, as the case may be;

On the usage of GMF as food ingredient, the GMF Notification only provides under Clause 4 that such usage shall be in accordance with the MOPH notification on food additives or other relevant MOPH notifications. In the absence of any relevant MOPH notification, such usage shall be in accordance with the biological food safety assessment report, documents or evidence under Clause 5 of the GMF Notification.

3. Food Manufacturing Process and Packaging

Food manufacturing processes are generally regulated under the Notification of the MOPH (No. 420) B.E. 2563 (2020) issued under the Food Act Re: Food Manufacturing Process, Manufacturing Equipment/Utensils, and Storage Practices (the "**Food Manufacturing Notification**").[3] It may be worth noting that this regulation is based on the Good Manufacturing Practice (GMP) of the Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme for the purpose of elevating consumer protection to international standards.[4]

---

[2] However, the following GMF do not require submission of an assessment report to the FDA:

(1) GMF which have passed the biological food safety assessment conducted by the Joint FAO/WHO scientific advisory bodies or the WHO Expert Advisory Panels and Committees, and

(2) enzymes used for the production of such food in accordance with the MOPH Notification regarding enzymes for use as food ingredients.

[3] However, please note that places arranged for preparation of food for sale to buyers for immediate consumption (e.g. restaurant) are subject instead to the Ministerial Regulation on Sanitation of Food Distribution Places B.E. 2561 (2018).

[4] According to the Announcement of the FDA Re: Clarifications to the Food Manufacture Notification.

Under Clause 3 of the Food Manufacturing Notification, the food manufacturing process, manufacturing equipment/utensils, and the storage of food shall be in accordance with the Annex of the Food Manufacturing Notification, which may be summarized below.

- Chapter 1: General Provision
  The provisions under this chapter are applicable to all types of food manufacturing places, with the main purpose being to require the manufacturer to provide measures to prevent, reduce, or eliminate dangers either from the environment, the place of manufacturing, machines, tools, containers, or workers in every step of the food manufacturing process. This part is further sub-divided into 5 parts as follows:
  - ✓ Part 1: Premise, Manufacturing Building, Cleaning, and Maintenance, e.g. the premise must be far from contamination sources, with a proper drainage system;
  - ✓ Part 2: Equipment, Machines, Utensils, Production tools, Cleaning and Maintenance, e.g. tools, machines, and equipment which contact food must be hygienically designed and made of materials that are non-toxic, non-rust, corrosion resistant and not have reactions with foods, and they must be regularly cleaned and protected against contamination;
  - ✓ Part 3: Food Manufacturing Process Control: this part covers the process from raw material selection to ingredient mixing, food packaging, record taking, and internal quality audit;
  - ✓ Part 4: Sanitation, e.g. only clean water shall be used and waste must be properly managed; and
  - ✓ Part 5: Personal Hygiene, e.g. workers and personnel in the production area shall keep their body clean and wear appropriate garments.
- Chapter 2: Specific Provision
  These are additional provisions for specific types of food manufacturers, such as those of bottled drinking water, mineral water, and edible ice which incur high risks if not properly controlled.

In addition, certain food manufacturers must arrange for a food manufacturing process controller who passed the training approved by the FDA, pursuant to Clause 4 of the Food Manufacturing Notification.

Importers of food for distribution also are required to provide certification of the standard equivalent to, or not less than, the standard prescribed in the Annex of the Food Manufacturing Notification, according to Clause 6 of the Food Manufacturing Notification.

In respect of food containers, the Notification of the MOPH No. 92 (B.E. 2528) (1985) Re: Prescription of Quality or Standard for Food Containers, Use of Food Containers, and Prohibition of Things to be Used as Food Containers (the "**Food Containers Notification**") prescribed under Clause 4 that food containers shall have or conform to the following qualities and standards:

- being clean;
- not having been used for packing or filing of food or any other substances before unless it is glass, ceramic, enameled metal or plastic;
- not giving out any heavy metal or other substances to contaminate the food in a volume likely to be harmful to health;
- not containing any germs;
- not giving out any color to contaminate the food;
- not having been previously used to pack or wrap a fertilizer, poisonous substance, or substance likely to be harmful to health; and
- not being made for packing other things which are not food, or which bear a design or any statement that may cause misconception with respect to the material parts of the food contained therein.

Containers which are made of ceramic vessels, or enameled metal vessels also must have or conform to the quality and standards detailed under the Annex of the Food Containers Regulation. However, for containers made of plastic, their qualities and standards are specifically provided under the Notification of the MOPH (No. 435) B.E. 2565 (2022) Issued under the Food Act Re: Prescribing Qualities or Standards of Containers Made of Plastic (the "**Plastic Containers Notification**"), which prescribes that food containers made of plastic shall have or conform to the following qualities and standards:[5]

- being clean;
- not having any germs which may cause sickness;
- not giving out any dangerous substances in the amount affecting health, except for substances prescribed under Annex 1 of the Plastic Containers Notification;
- when containing food, not imparting substances to such food with the effect of the characteristic component thereof becoming altered to an unacceptable level or deteriorated in sensory terms;
- in case of colored containers, using food contact grade color and not contaminating the food;
- in case of markings or texts being imprinted on containers, the imprints must not fall off into the food; and
- having or conforming to the additional qualities or standards prescribed under the Annex of the Plastic Containers Notification.

4. Food Labeling

The general rules relating to food labeling are provided under the Notification of the MOPH (No. 367) B.E. 2557 (2014) Re: Labeling of Prepackaged Foods (the "**Food Label Notification**"). The objectives of this notification are to designate types of food which are required to be labeled, as well as the contents, conditions, and the display of such label, for the interest of all related parties.[6]

Under Clause 3 of the Food Label Notification, all prepackaged food must be labeled,[7] except the following:

- food which producers can provide consumer information related to such food at the time of sale, such as that sold by food hawkers or at food stalls;
- food which has not passed through any process or fresh food which is peeled, eviscerated, trimmed, or has gone through any other means to reduce its size, and packed in containers in which the condition of the food in the containers may be seen, but excluding processed food in containers ready to be distributed under the notification of the MOPH regarding manufacturing process, manufacturing equipment, and storage of processed foods in containers for distribution;[8]
- prepackaged food which is produced, sold, and to be served in food shops, restaurants, hotels, schools, academic institutes, hospitals or any other places of the same kind, including food delivery services.

In addition, certain prepackaged food also may be required to comply with additional label requirements as specifically prescribed by the MOPH, e.g. food additives and GMF.

---

5 Clause 4 and 5 of the Plastic Containers Notification

6 Announcement of the FDA Re: Clarifications to the Food Label Notification

7 Under Clause 2 of the Food Label Notification, "prepackaged food" means food packed in container for sale and according to Section 4 of the Food Act, "label" includes any figure, invented design or text shown on the food, food container or package.

8 At the time of this article, this refers to the Food Manufacturing Notification.

Under Clause 4 of the Food Label Notification, it is mandatory that the labels of prepackaged food, whether manufactured for distribution, imported for distribution, or distributed, must contain text in the Thai language, and at least the following items:

(1) name of the food;
(2) food serial number;
(3) name and address of manufacturer, packager or importer or their head offices, as the case maybe;
(4) volume of the food in the metric system;
(5) percentage by weight of the main ingredients in descending orders;
(6) the following texts: “Information for food allergy: contain...” in case such ingredients is used in the food or “Information for food allergy: may contain…” in case there is contamination in the manufacturing process, as the case maybe;
(7) functional class titles of food additives together with specific names or with International Numbering System: INS for Food Additives, if any;
(8) the following text: “natural imitation odor added”, “artificial flavor added”, “natural flavor added” or “natural imitation flavor added” if any;
(9) date, month, and year where shelf life of such food is not longer than 90 days, or date, month, and year, or month and year where shelf life of such food is longer than 90 days, together with the text “should be consumed before”;
(10) warning statement (if any);
(11) storage instruction (if any);
(12) cooking instruction (if any);
(13) instruction for use and essential text for food intended for use in infant or new-born baby or for particular individuals;
(14) additional texts as specified in the Annex; and
(15) particular texts as specified in specific notifications of the MOPH.

When labeling food not sold directly to consumers, re-packers or food preparers or vendors, the label must contain at least the particulars in Clause 4(1), (2), (3), (4) and (9) and texts on label may be made in English instead of the Thai language, provided that the particulars under Clause 4 are clearly and legibly displayed in the Thai language within the sale documents at all times together with the text “raw materials for food processing only” or any other similar text on the food label.

In the case of food manufactured for export, the label can be made in any language but must at least display the manufacturing country and food serial number, number of food manufacturer establishment, or name and address of manufacturing establishments under Clause 5 of the Food Label Notification.

Label of controlled food or other food prescribed by the MOPH must be submitted to the FDA for prior approval before usage, according to Clause 6 of the Food Label Notification.

In addition, the text on the label must be prominent and readable, and the size of the label and containers or packets must also be proportionate. The label also must not be misleading, either directly or indirectly, between the food and the texts, pictures, pictorials, invented designs, marks or trademarks suggesting other products, according to Clause 8 and 9 of the Food Label Notification. Furthermore, the label must not contain certain prohibited texts prescribed under Clauses 10 and 11 of the Food Label Notification, such as false food information, false advertisement, or indication that prohibited ingredients are used in the food.

The sanctions of incompliance with the Food Label Notification are prescribed in the Food Act. Pursuant to Section 51 of the Food Act, whoever violates the Food Label Notification shall be liable for a fine not exceeding Baht 30,000. Moreover, violation of the Food Label Notification can result in suspensions of the license for producing or importing food for distribution for not more than 120 days each time by virtue of Section 46 of the Food Act.

5. Food Advertisement

Under Section 40 and 41 of the Food Act, false or deceptive advertising of the quality, usefulness, or indication of food is prohibited, and advertisement of food quality, usefulness, or indication of food through media for business purpose must be submitted for prior approval with the FDA before the commencement of such advertisement.

In addition to the above, the FDA has issued the Notification of the FDA Re: Regulations on Food Advertisement B.E. 2564 (2021) (the "**Food Advertisement Notification**") to further address the rules on food advertisement in detail. Key rules on food advertisement are summarized below.

- Certain texts which are unfair to consumers or cause damage to society, or that are false or deceptive, are prohibited, for example:[9]
  - ✓ texts indicating food ingredients where there are none or not in the amount as advertised;
  - ✓ texts which may cause misconception or misunderstanding on the characteristics or consuming methods of the food;
  - ✓ texts comparing or demeaning products of others;
  - ✓ false or overstatement; and
  - ✓ advertisement referencing academic report or statistics which have not been assessed by the FDA.
- Certain kinds of advertisement which may be done without prior approval:[10]
  - ✓ provision of academic information without business purpose and not in a way which may be understood to be advertisement of food quality, usefulness, or indication of food;
  - ✓ presenting corporate image; and
  - ✓ giving facts relating to the food, provided that they are in compliance with the texts and conditions as prescribed in the Annex 2 of the Food Advertisement Notification.
- Certain kinds of advertisement of food quality, usefulness, or indication of food which must be submitted for prior approval, among others:[11]
  - ✓ advertisement of nutrition claims, which are in accordance with the Nutrition Labelling Notification (as defined below); and
  - ✓ health claims other than nutrition claims, which are approved by the FDA.

The Food Advertisement Notification also prescribes the manner in which food advertisement may be conducted. For example, the advertised food must comply with food law and regulations, and the advertisement must indicate the food name and warning texts in the prescribed manners depending on the media used, and must contain the contents as prescribed in the Annex 4 of the Food Advertisement Notification.

---

9 Clause 3 and 4 of the Food Advertisement Notification

10 Clause 5 of the Food Advertisement Notification

11 Clause 6 of the Food Advertisement Notification

Moreover, certain types of food such as baby food, milk, jelly, medical food, convenience food (e.g. flavored noodles and porridge), dietary supplements, etc., must comply with additional advertisement rules depending on the food types.

6. Nutrition Labelling

Aside from the general labelling requirement as discussed in Paragraph 4, certain food is also required to comply with the nutrition labelling requirements prescribed under the Notification of the MOPH (No. 182) B.E. 2541 (1998) Re: Nutrition Labelling (the "**Nutrition Labelling Notification**").

Under Clause 1 of the Nutrition Labelling Notification, the following foods are required to have nutrition labelling:

- foods with nutritional claims;
- foods which utilize food value in sale promotion;
- foods which define consumer groups in sale promotion; and
- other foods to be notified by the FDA.

However, it may be worth noting that this notification is not applicable to (1) certain specific foods where there are specific MOPH notifications on nutrition labelling, (2) foods which are not distributed directly to consumers or which are not manufactured or imported for distribution in Thailand, and (3) foods which are partially packed from bulk batch intended to be distributed in whole.

For the foods subject to this Nutrition Labelling Notification, nutrition label must be shown in Thai, but may include foreign language, and must comply with the rules and conditions as prescribed in the Annexes of the Nutrition Labelling Notification.

Generally, the nutrients required to be displayed in the nutrient label includes calories, saturated fat, cholesterol, protein, carbohydrate, dietary fiber, sugar, sodium, and Thai daily recommended intakes. However, additional nutrients may be displayed either as part of or outside the nutrient label, depending on the type of nutrients.

In addition to the above requirement under the Nutrition Labelling Notification, in view of the MOPH's policy to reduce the consumption of foods with sweet, oily, and salty flavor to prevent overnutrition issues and non-communicable diseases (e.g. obesity, diabetes, and hypertension),[12] the Notification of the MOPH No. 394 (B.E. 2561) (2018) Issued under the Food Act Re: Food Required to Display Nutrition Label and Energy, Sugar, Fat, and Sodium Amount under the Guideline Daily Amounts; GDA Labelling (the "**GDA Labelling Notification**") has been issued to prescribe additional specific foods which must display a nutrition label.

Under Clause 3 and 5 of the GDA Labelling Notification, a total of 13 types of foods in containers ready to be distributed to consumers, e.g. snack, chocolate, convenience food, or certain types of bottled beverage must display:

- the nutrition label under the Nutrition Labelling Notification;
- the energy, sugar, fat, and sodium amount under the Guideline Daily Amounts in the form and conditions as prescribed in the Annex of the GDA Labelling Notification; and
- the following text: "consume in small amount and exercise for healthy condition".

[12] Announcement of the FDA Re: Clarifications to the GDA Labelling Notification

In the case that manufacturers or importers of foods other than the 13 types of foods prescribed above intends to display the energy, sugar, fat, and sodium amount under the Guideline Daily Amounts in their foods label, such display shall be in conformity with this GDA Labelling Notification.

However, this Labelling Notification is not applicable to (1) foods which the preparer distributes directly to consumers or (2) certain specific foods where there are specific MOPH notifications on nutrition labelling, pursuant to Clause 10 of the GDA Labelling Notification.

7. Health Claims and Nutrition Claims

As of the date of this article, there is no direct or general regulation on health and nutrition claims in Thailand. Nevertheless, the rules on making nutrition and health claims may be found in the Annex 4 of the Nutrition Labelling Notification re criteria for nutrition claims on food labelling (the "**Annex 4**"), and the Food Advertisement Notification.

Under the Annex 4, "nutrition claim" means the display of messages or information relating to the nutrition of a food, e.g. display the amount of energy, protein, fat, carbohydrate, vitamin, and various minerals, which may be categorized into 3 categories as described below.

- Nutrient content claim, i.e. claiming the level of nutrition or energy in a food:
  - ✓ claiming the absence of or the low[13] quantity of a nutrient is prohibited if such food type naturally fits under such description without the use of special manufacturing process or specific alteration process or alteration of formula.
- Comparative health claim, i.e. comparison of the quantity of nutrition or energy between at least 2 foods:
  - ✓ comparison may only be made to (1) the manufacturer's own product using the normal formula, or (2) a product of the same type generally representing the food type which is distributed in Thailand;
  - ✓ comparison may only be made between products of the same or similar types;
  - ✓ comparison referencing food which already has "low" or "very low" quantity of nutrient or energy is prohibited.
- Nutrient function claims, i.e. description of the function of a nutrient to the body:
  - ✓ the nutrient described must be the nutrient within Annex 3 of the Nutrition Labelling Notification;
  - ✓ the product must have the claimed nutrient at the level of "good source" per a reference amount and a serving size displayed on the label;
  - ✓ the claim must be approved by the FDA;
  - ✓ etc.

In relation to this, the Notification of the FDA Re: Nutrient Function Claim (the "**Nutrient Function Claim Notification**") prescribes the following conditions of nutrient function claims which are deemed as approved by the FDA, among others:

- the claimed nutrient is in conformity with the Annex 4;
- the claim must be in accordance with the Annex of the Nutrient Function Claim Notification;[14]
- claims other than those provided in the Annex must be submitted for approval with the FDA.

---

13 The use of quantitative words such as "free", "without", "low", "reduced", "increased" must satisfy the conditions under Schedule 1 or 2 of the Annex 4, by virtue of Clause 2 of the Annex 4.

14 The claims prescribed in the Annex of the Nutrient Function Claim Notification are categorized based on 29 nutrient types, each of which contains approximately 1 to 14 claims which may be made.

Additionally, health claim other than the nutrition claim covered under the Nutrition Labelling Notification first must be approved by the FDA for food advertisement as prescribed under Clause 6 of the Food Advertisement Notification. The criteria and conditions for obtaining such approval for health claims are further detailed in the Guideline for Assessment of Health Claim issued by the FDA.

8. Labelling of Novel Food

Under Clause 6 of the Notification of the MOPH (No. 376) B.E. 2559 Re: Novel Food, the labelling of novel food must be in accordance with the Food Label Notification. However, the manufacturing and expiration dates shall be displayed with the words "manufacture", "expire", or "consume before", as the case may be.

Additionally, the following information must be displayed on its label:

- name of material ingredients (if any);
- usage instruction or condition, such as type or category of food and maximum permitted level of use.

9. Labelling of GMF

Under Clause 4 of the Notification of the MOPH (No. 432) B.E. 2565 (2022) Issued under the Food Act Re: Labelling of GMF (the "**GMF Label Notification**"),[15] GMF must have a label which is:

- in compliance with the notification of the MOPH on the respective food; and
- in compliance with the Food Labelling Notification, provided that additional texts must be displayed as prescribed, among others:
  - ✓ for genetically modified plant or animal, which is a component of at least 5 percent of each food ingredient, and genetic materials or protein resulting from genetic modification is detected:
    - the following text: "genetically modified" must be displayed, either with the name of the food (in the case where there are only a single main ingredient) or with the name of the ingredients derived from the genetically modified plant or animal;
    - the following text: [name of the food/product] produced from genetically modified [name of the plant/animal] in the case of product derived from genetically modified plant or animal;
  - ✓ for genetically modified microbe:
    - the following text: "genetically modified" must be displayed, either with the name of the food (in the case where there is only a single main ingredient) or with the name of the ingredient derived from the genetically modified microbe; and
    - the following text: [name of the food/product] produced from genetically modified [name of the microbe] in the case of product derived from genetically modified microbe.

Nevertheless, under Clause 8 of the GMF Label Notification, this GMF Label Notification is not applicable in the following cases:

- Manufacturer or importer having traceable evidence which indicates that no GMF is used as ingredient in the food manufacturing process;
- minor manufacturer distributing directly to consumer;[16]

---

15 This notification was published in the Government Gazette on 7 June 2022 to replace the former Notification of the MOPH (No. 251) B.E. 2545 (2022) and will come into effect 180 days after its publication (i.e. 4 December 2022).

16 "Minor manufacturer" means small-size manufacturer distributing directly to consumers who is able to provide information to consumer directly, according to Clause 2 of the GMF Label Notification.

- person who cooks and distributes food to consumer directly;
- GMF where there remains no genetic materials or protein originating from genetic modification in the final product; and
- protein originating from genetic modification which is used to assist the manufacturing process.

Public Relations Section, Nishimura & Asahi E-mail