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General Food Safety Regulations in Thailand

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1. Introduction

The Food Act B.E. 2522 (1979) (the "**Food Act**") is the primary regulation governing food safety in Thailand, with its key purposes being the control of food quality and to safeguard consumer safety. Primarily, the contents of the Food Act concern the licensing requirements for food producers and importers, food quality control, registration and advertisement of food, and sanctions in the case of violation. The Ministry of Public Health (the "**MOPH**") and the Food and Drug Administration (the "**FDA**") are the key regulators under the Food Act. As such, various regulations covering a wide array of issues concerning food safety are announced by the MOPH and the FDA, such as notifications regarding prohibited food, food quality and standards, food containers, food labeling, food additives, pesticides in food, and novel foods, among others. However, in some aspects, the issue of food safety relates to other laws, such as consumer rights under the Consumer Protection Act B.E. 2522 (1979) and food distribution sanitation measures under the Public Health Act B.E. 2535 (1992).

This newsletter provides an overview of the main regulatory regime regarding food safety in Thailand, with special focus on the Food Act and related secondary legislation.

2. Definitions under the Food Act

Under Section 4 of the Food Act, some key terms are defined as follows:

- "food" means edible items or sustenance, which are:
  - ✓ objects that can be eaten, drank, sucked, or brought into the body either by mouth or by other means, regardless of its form, but not including medicine, psychotropic substance, or narcotics under the relevant laws, as the case may be; and
  - ✓ substances intended for use or to be used as ingredients in the production of food, including food additives, and coloring and flavoring materials;
- "controlled foods" means foods published in the Government Gazette by the MOPH as quality or standard-controlled food;
- "food recipe" means a list of substances which are used as ingredients in the production of food with specified contents;
- "container" means any objects used for containing food whether by being a receptacle for placing, wrapping or by any other methods;
- "label" includes any figure, invented design, sign, or any text shown on food, food containers, or packages of food containers;
- "produce" means to make, mix, or transform, and includes repacking;

- "distribution" includes sale, giveaways or exchange for commercial purposes, as well as possession for distribution purposes;
- "import" means to bring or order into Thailand;
- "export" means to bring or deliver outside Thailand; and
- "factory" means factory under the factory law[1] set up for the production of food.

3. License Requirement for Production and Importation of Food

Under Sections 14 and 15 of the Food Act, a person who wishes to (i) establish a factory to produce food for distribution, or (ii) import food for distribution, must obtain approval from the FDA (a "**License**").
In this regard, a food production establishment may be deemed a "factory" (i.e. under the Food Act) only in the case where it involves the use of machines with a combined total of 50 horsepower (or equivalent) or more, or where 50 workers or more are employed, regardless of whether machines are used, to engage in factory operation (e.g. manufacturing, production, assembly, repair or maintenance), pursuant to Section 4 of the Food Act and Section 5 of the Factory Act.
However, under Section 16 of the Food Act, such License requirement is exempted in the following cases:

- occasional production or importation of food where occasional licenses are obtained from the authority on intermittent occasions; and
- production or exportation of food samples for registration or for consideration before order.

Once the License is granted, it would be valid until 31 December of the third year from the year in which the license is granted and extension of the License must be filed before the License expires, pursuant to Section 18 Paragraph One of the Food Act.
Therefore, in the case where an establishment for production of food uses machines with a combined total of less than 50 horsepower and where there are less than 50 employees working in such establishment, such establishment would not be categorized as a "factory" under the Factory Act. Thereby, the owner of such establishment would not be required to obtain a License for food production under the Food Act.
However, in addition to the License requirement above, under the FDA Regulation: Operations Relating to Food Serial Numbers B.E. 2562, certain food (e.g. controlled food, food with specified quality or standards, or foods which require food labels) is required to have an FDA number (i.e. food serial number). Therefore, producers or importers of such food may have to apply for an FDA number with the authority even in the case where a License under the Food Act is not required.
In any case, it should be noted that any production, importation, or distribution of food is required to conform to the prescribed food quality and other standards under Section 25 of the Food Act, regardless of whether the License requirement is applicable or not.

4. Duty of the Licensee

Under Sections 20 and 21 of the Food Act, a person who has a License (a "**Licensee**") may only produce, import, or store food in the area designated in the License and such area may only be relocated with the approval of the FDA.
Additionally, the Licensee has the duty to affix the License in an open area at the place of production or importation designated in the License as well as affix a sign showing the approved place of production or importation in an open area outside the place of production or importation under Section 23 of the Food Act.
Moreover, for the benefit of exportation or when it is necessary for the Licensee to occasionally produce controlled food for export, the FDA may grant occasional licenses for the Licensee to produce controlled food according to the standards of foreign countries or international standards, regardless of whether the

[1] At present, this refers to the Factory Act B.E. 2535 (1992) (the "Factory Act")

standards are lower or higher than the standard specified by the MOPH, pursuant to Section 24 of the Food Act. More specific duties of the Licensee are also prescribed under Ministerial Regulation No. 1 and Ministerial Regulation No. 2 B.E. 2522 (1979) issued pursuant to the Food Act. For example, a Licensee of a food production License is required, among others, to:

- keep the area of production, filling, and storage of finished products and other areas clean and sanitary;
- provide appropriate equipment and utensils free from contamination;
- provide a sufficient garbage disposal area kept in sanitary condition, including an appropriate method of waste and smog disposal;
- provide workers who mix or process food with clean garments which are appropriate to each type of operation;
- prohibit workers having lesions or diseases which may contaminate the food from operations which contact the food for a particular duration;
- prohibit or prevent all persons from having any objectionable manner or engaging in objectionable activity in relation to the sanitation of the food production area, such as smoking or spitting in the area of production or storage of processed products and materials;
- protect and maintain the areas of production or storage of processed products and raw materials from all kinds of animals.

5. Food Control

Under Sections 25 to 29 of the Food Act, the following categories of food are prohibited from being produced, imported for distribution, or distributed:

- impure foods, which are:
  - ✓ food which contains things likely to be harmful to health;
  - ✓ food in which substances of chemical adulteration have been mixed at a rate that could deteriorate the food quality, unless such admixture is necessary for the production and approved by the competent officer;
  - ✓ food unhygienically produce, packed, or stored;
  - ✓ food produced from animals having a disease which might be communicated to humans; or
  - ✓ food in containers made from materials likely to be harmful to health;
- adulterated foods, which are:
  - ✓ food for which other substances are partly substituted or in which valuable substances are wholly or partly removed and is sold as or under the name of genuine food;
  - ✓ substances or food produced to imitate any food and sold as such genuine food;
  - ✓ food mixed or prepared in any means to conceal defects or inferior quality of such food;
  - ✓ food labelled in order to deceive or try to deceive the purchasers in matters of quality, quantity, usefulness, special nature or place or country of production; or
  - ✓ food which is not up to the quality or standards prescribed by the MOPH and the quality or standards of that food deviates from the upper or lower specified limit by more than 30 percent or its deviation may be harmful to the consumer;
- substandard foods, which are food that is not in accordance with the standards prescribed by the MOPH, but its deviation is not as high as the deviation of item (2)e; and
- other food specified by the MOPH, which includes:
  - ✓ food which is not safe for consumption;
  - ✓ food with unreliable indications; or
  - ✓ food of which its value or nutrition is not appropriate to the human body.

In addition, more specific food control regulations concerning the quality and standards of specific foods or food in general are also prescribed by the MOPH, for example Notification of the MOPH (No. 196) B.E. 2543

(2000) prescribes the quality and standards of tea, while Notification of the MOPH (No. 354) B.E. 2556 (2013) prescribes the quality and standards of ice-cream.
The MOPH may also issue notifications on food safety in a more general sense, such as notifications concerning pesticides in food, novel foods, food labels, food serial numbers, food contaminants, food containers, food production processes, tools, and storage, among others, by virtue of Section 6 of the Food Act.

6. Registration of Controlled Food

Licensees who wish to produce or import food prescribed as “controlled food” must register the recipe of such controlled food with the FDA and may only produce or import such controlled food when a certificate of registration is granted. In this regard, the production or importation of controlled food must be in line with the recipe registered with the FDA, pursuant to Sections 31 and 34 of the Food Act.
Under Section 35 of the Food Act, the information to be registered in the recipe registration must include:

- the food name;
- name and quantity of the components of the food;
- packing size;
- the label;
- name of the producer and production place;
- analysis results of the food by the government sectors or institutions as prescribed; and
- other matters related to the registration of the food.

7. Advertisement of Food

Under Sections 40 and 41 of the Food Act, false or deceptive advertisement of the quality, nutrition or indication of a food is prohibited, and anyone who wishes to advertise the qualities, nutrition or indications of a food for commercial purposes must submit such advertisement to the FDA for review prior to publication of such advertisement.

8. Sanctions

The Food Act prescribes several sanctions either in the form of FDA actions or criminal punishments, for example:

- the FDA may issue an order in writing to the Licensee to modify or correct its place of food production or storage (Section 30 (1) of Food Act);
- the FDA may order the suspension of production or importation of food which is produced without a License or food that the results of analysis show as not fit for consumption (Section 30 (2) of Food Act);
- the FDA may notify the public of the food testing results in which the food is found impure, adulterated, substandard, or potentially hazardous to public health, with the name of the food producer or distributor being fully disclosed (Section 30 (3) of Food Act);
- the FDA may order the cessation of any advertisement in violation of the Food Act (Section 42 (1));
- the FDA may order the cessation of the production, importation, distribution, or advertisement of food which is deemed as not having the nutrition, quality, or usefulness advertised (Food Act, Section 42 (2));
- the FDA may order food proven to be impure, adulterated, or substandard, or food designated by the MOPH, or containers which may be hazardous to the health of the consumer, to be destroyed, provided that there are no pertinent legal proceedings in the court (Section 44 of Food Act);
- violation of the licensing requirements may result in imprisonment of not more than 3 years or a fine not exceeding Baht 30,000 or both (Section 53 of Food Act);

- violation of the food standard as prescribed by the MOPH may result in a fine of not exceeding Baht 50,000 (Section 60 of Food Act);
- distribution of unregistered controlled food may result in a fine of Baht 1,000 to Baht 10,000 (Section 65 of Food Act);
- false advertisement of food may result in imprisonment of not more than 3 years or a fine not exceeding Baht 30,000, or both (Section 70 of Food Act);
- commission of certain offences such as the distribution of prohibited food which is done by retailers to consumers directly may result in imprisonment of not more than 6 months or a fine not exceeding Baht 5,000 or both, while re-commissioning of an offence within 6 months of the previous offence may result in imprisonment of not more than one year or a fine not exceeding Baht 10,000, or both (Section 73 of Food Act); and
- adulteration of food intended for consumption or use where such adulteration is likely to cause injury to health, or distribution, or offering to sell such adulterated food for consumption and use may result in imprisonment of not more than 3 years or a fine not exceeding Baht 60,000, or both (Section 236 of the Criminal Code).

9. Food Additives

The main regulation that governs the use of food additives in Thailand is Notification of the MOPH (No. 281) B.E. 2547 Re: Food Additives (the "**Food Additives Notification**").

Under Clauses 2 and 3 of the Food Additives Notification, food additives, which are prescribed as a controlled food, are substances that are not usually used as food or as essential ingredients of food, whether such substances have nutritional value or not, but are added to the food for the benefits of production technology, coloring, flavor and scent, packaging, storage or transportation, that affect the qualities, standards or characteristics of the food. Food additives also include substances not directly added to the food, but that are found in the container packed together with food for the abovementioned purposes, such as moisture or oxygen absorbents. However, food additives do not include nutrients added to fortify or maintain the nutritive value of the food, such as protein, fat, carbohydrates, vitamins or minerals.

Food additives must remain in accordance with the qualities and standards of any one of the following, pursuant to Clause 4 of the Food Additives Notification:

- the Codex Advisory Specification for the Identity and Purity of Food Additives;
- the notifications of the FDA; or
- the approval of the Subcommittee on Problem Analysis and Academic Diagnostics Concerning Food, provided that the producer or importer submits the required safety analysis results and details, such as the chemical characteristics of the food additives and testing methods to the subcommittee.

The method for analyzing the food additives must be in accordance with the Codex Advisory Specifications for the Identity and Purity of Food Additives or the method prescribed by the FDA.

In addition, the use of food additives must be in accordance with the name of the food additives, food category or type, the function in the production technology, and the maximum quantity as prescribed in Annexes 1 and 2 of the Food Additives Notification pursuant to Clause 6 of the Food Additives Notification and any deviation from such prescribed usage must be approved by the FDA, under Clause 6/1 of the Food Additives Notification.[2]

Regarding the producer or importer of food additives, such producer or importer must comply with the relevant notifications regarding food production processes, tools and food storage, and must disclose

[2] The usage of food additives as explained above may not be applicable to certain controlled food or foods with specific qualities or standards as prescribed by the MOPH where there are notifications in place for the usage of food additives in relation to such specific foods, pursuant to Clause 6/2 of the Food Additives Notification.

information necessary for food producers to comply with the Food Additives Notification, pursuant to Clauses 8 and 8/1 of the Food Additives Notification. Moreover, containers and labels of food additives are required to comply with the relevant notifications on containers and labels under Clauses 9 and 10 of the Food Additives Notification.
In addition, the labels of food additives must contain the information prescribed under Clauses 10, 10/1 and 10/2 of the Food Additives Notification, e.g. including the phrase "food additives" or functional classes in the name of the food and showing the FDA number, name and place of business of the producer, importer, or packer.
It is also worth noting that pursuant to Clause 11 of the Food Additives Notification, this notification is not applicable to flavoring agents, which are subject instead to another MOPH notification on flavoring agents.[3]

10. Pesticides

The regulation that governs the issue of pesticide, with regard to food products, is Notification of the MOPH (No. 387) B.E. 2560 Re: Food Which Has Pesticide Residue (the "**Pesticide Notification**").
Under Clause 3 of the Pesticide Notification, some of the key terms are defined as follows:

- "pesticide residue" means any residue in a food as a result of the use of pesticide, including any derivatives of a pesticide, such as conversion products, metabolites, reaction products and impurities considered to be of toxicological significance;
- "pesticide" means any substance intended to be used to prevent, destroy, attract, repel or control any pests, including unwanted species of plants or animals, whether during cultivation, storage, transportation, distribution or processing of food, or substances which may be administered to animals for the control of ectoparasites. "Pesticide" also includes substances intended for plant growth regulation, defoliant, fruit thinning substance or sprouting inhibitors, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. However, the term pesticide excludes fertilizers, plant and animal nutrients, food additives, feed additives and veterinary drugs;
- "maximum residue limit (MRL)" means the maximum concentration of a pesticide residue in food arising from use of a pesticide, which is expressed in milligrams of pesticide residue per kilogram of the food;
- "extraneous maximum residue limit (EMRL)" means the maximum concentration of a pesticide residue in food arising from environmental residue contamination, including contamination from pesticides which have been banned from usage but, because of their persistent properties, still exist in the environment, which is expressed in milligrams of pesticide residue per kilogram of food;
- "default limit" means the maximum concentration of a pesticide residue in food for which specific MRL have not been set out, which is expressed in milligrams of pesticide residue per kilogram of food.

  Under Clause 4 of the Pesticide Notification, pesticide residue of Type 4 hazardous substances under the Hazardous Substance Act B.E. 2535 (1992) designated in Annex 1 of the Pesticide Notification must not be found in food in any concentration.

  For other types of pesticide residues, their quantities in food are limited as follows:
  - ✓ not exceeding the MRL designated in Annex 2 of the Pesticide Notification;
  - ✓ for other types of pesticide residue not included in Annex 2 of the Pesticide Notification, not exceeding the Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme;

[3] Under the Notification of the MOPH (No. 223) B.E. 2544 Re: Flavoring Agents, flavoring agents mean substances used for modifying the flavor or taste of food, which may be categorized as (1) natural flavoring agent; (2) imitation of natural favoring agent; and (3) synthesized flavoring agent.

- ✓ in cases other than (1) and (2), not exceeding the default limit for plants and animals of 0.01 mg per 1 kg of food, except for the default limit for plants designated in Annex 3 of the Pesticide Notification; and
- ✓ not exceeding the EMRL designated in Annex 4 of the Pesticide Notification.

The maximum limit of pesticide residue may also depend on the type of each agricultural product according to the Annexes of the Pesticide Notification.

11. Novel Food

The main regulation that governs novel food in Thailand is Notification of the MOPH (No. 376) B.E. 2559 Re: Novel Food (the "**Novel Food Notification**").

Under Clause 1 of the Novel Food Notification, "novel food" means:

- any substance used as food or food ingredients which have a history of being used for human consumption for less than 15 years based on academic evidence;
- any substance used as food or food ingredients which is a product of a production process not generally used for such food, in which such process significantly changes the composition, structure or type of the food, which affects its nutritional value, metabolism or level of undesirable substances; or
- any food products containing either (1) or (2) as an ingredient.

However, food additives and food produced through genetic modification techniques are not considered as novel food (the food additives are governed by the Food Additives Notification while food from genetic modification techniques is governed by the Notification of the MOPH (No. 431) B.E. 2565 (2022) Re: Food from Genetically Modified Organism).

Pursuant to Clauses 2 and 3 of the Novel Food Notification, novel food must pass the safety assessment conducted by an entity approved by the FDA and its label must be submitted to the FDA for review prior to its usage. In addition, novel food must have qualities or standards and usage conditions as approved by the FDA under Clause 4 of the Novel Food Notification.

In addition, the labels of novel foods must describe, among others, the name of the principle substance (if any) and the method and conditions for consumption or usage, e.g. the type of food and maximum quantity allowed for usage.

The Novel Food Notification is not applicable to novel food produced for exportation, according to Clause 7 of the Novel Food Notification.

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