Asia Pacific Food Law Guide - Japan

Food product and safety regulation

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# Overview

The main law that governs food quality and integrity in Japan is the Food Sanitation Act ("FSA"). The law that comprehensively governs the food labeling regulation is the Food Labeling Act.

The FSA regulates food quality and integrity by:

establishing standards and specifications for food, additives, apparatus, and food containers and packaging;

providing for inspection to see whether the established standards are met;

providing for hygiene management in the manufacture and sale of food; and

licensing food businesses.

Japan does not have specific laws or regulations regarding the use or addition to food of any of the following:

additives;

processing aids;

vitamins;

minerals;

novel foods; or

nutritive substances.

However, under the FSA, additives and preparations and food containing additives must not be sold, or be produced, imported, processed, used, stored, or displayed for marketing purposes,
unless the Minister of Health, Labor and Welfare ("MHLW") has declared them as having no risk to human health after seeking the views of the Pharmaceutical Affairs and Food Sanitation Council ("PAFSC"). As such, additives, processing aids, vitamins, minerals, novel foods and nutritive substances must not be added to food unless they have been expressly declared by the
MHLW as having no risk to human health.

In addition, the MHLW may establish specifications for methods of producing, processing, using, cooking or preserving food or additives to be served to the public for marketing purposes ("Specifications"), or may establish standards for food ingredients or additives to be served to
the public for marketing purposes ("Standards") pursuant to the FSA. Accordingly, where substances are allowed to be added to food, they may only be used within the limits expressly set by the Specifications and Standards.

Japanese laws distinguish between foods and medicines/therapeutic goods, the latter being governed separately by The Law on Security Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical devices.

There are no particular foods that are subject to specific or separate regulation.

# Basic labeling requirements

In Japan, the Food Labeling Act and Cabinet Office Ordinance, which prescribe the specific methods for labeling ("Labeling Standards Ordinance," collectively with the Food Labeling Act, "Labeling Regulations"), generally control labeling of food for sale. Under the Labeling Regulations, food is divided into processed food and fresh food, each of which is again divided into food for general use and food for commercial use, and detailed labeling rules are prescribed for each of these categories. Generally, there are some differences between labeling requirements for processed food and fresh food as briefly described below, but no significant difference exists between food for general use and food for commercial use whether processed food or fresh food, except for regulations on genetically modified food (see the genetically modified food section below). The labeling requirements for additives are separately prescribed under the Labeling Regulations, but are generally the same as those for food other than identifying it as an additive.

The basic labeling requirements for prescribed food and additives, and the basic information which must be displayed on products, are as follows:

For processed food:

product name;

use-by-date/best-before-date;

name and address of manufacturer (importer, if imported foods);

storage instructions;

raw materials;

amount contained;

additives;

nutrient components (calorie, protein, fat, carbohydrate and sodium;

country of origin (only applicable to 15 specific kinds of food prescribed in the Ordinance); and

other items required for specifically categorized food (see also sections on GM foods, nutrition content claims and health claims and mandatory warnings and advisory
statements below).

**For fresh food:**

product name;

place of origin; and

other items required for specifically categorized food (see also sections on GM foods, nutrition content claims and health claims and mandatory warnings and advisory
statements below).

# Nutrition information panel

Nutrition labeling is voluntary in Japan, except for calories, protein, fat, carbohydrates and sodium chloride equivalent (for natrium). However, if a nutrient declaration is made on the label of the food offered for sale, nutrition information must be provided in accordance with the Nutrition Labeling Standards under the Health Promotion Act.

**Required nutrition information**
The following basic information needs to be expressed in kcal per 100 g, 100 ml, serving, package, or other standard size, and must be included in the nutrition information when any nutrient is declared:

energy (calories);

protein;

total fat;

carbohydrates (or available carbohydrates and dietary fiber); and

sodium chloride equivalent.

**Voluntary nutrition information**
For the following nutrients, Dietary Reference Intakes (DRIs) have been established under the Nutrition Labeling Standards:

13 vitamins and 12 minerals (Vitamins: Niacin, Pantothenic acid, Biotin, Vitamin A, Vitamin B1, Vitamin B2, Vitamin B6, Vitamin B12, Vitamin C, Vitamin D, Vitamin E, Vitamin K and
Folic acid. Minerals: Zinc, Potassium, Calcium, Chromium, Selenium, Iron, Copper, Sodium, Magnesium, Manganese, Iodine and Phosphorus);

sugars (monosaccharides and disaccharides);

saturated fats; and

cholesterol.

Nutrients whose DRIs are not established under the Nutrition Labeling Standards, such as collagen galactooligosaccharides and polyphenol, may also be

# Language and legibility requirements

The required information must be displayed in Japanese in a conspicuous place on the container or package in a manner that is easily readable without opening the container or package.

# Country of origin labeling

Under the Labeling Regulations, domestic food must identify that it is a domestic product and imported food must identify the country of origin, but domestic food can also be identified by reference to place of origin, etc. instead of being identified as "domestic food."

# Genetically modified (GM) foods

Genetically modified foods are permitted in Japan, subject to regulatory pre-approval. This pre-approval procedure takes approximately one year. The safety of a food or additive produced by recombinant DNA techniques ("GM food") must be assessed before receiving official approval. The Food Safety Commission established under the Food Safety Basic Act is responsible for evaluating the safety of individual plants, foods and food additives.

As the name suggests, the "Standard for Manufacturing Foods and Food Additives Produced by Use of Recombinant DNA Techniques" provides standards for the manufacture of GM foods. As of 23 February 2018, 318 varieties of foods (mainly crops such as corn, soybeans, etc.) and 31 additives (α-amylase, lipase, etc.) had been approved as GM foods that have undergone safety assessment.

Foods, namely crops produced by recombinant DNA technologies ("GM crops"), and processed food made from such foods, must be labeled as follows:

GM crops, and processed food made from GM crops (including food made from processed food made from GM crops), which are confirmed to have been segregated from non-GMO ingredients, must be labeled "genetically modified."

Food produced, distributed or processed in such a way that GM crops and non-GM crops have not been segregated at any stage of the process, and processed food made from
such food, must be labeled "Not segregated from GMO."

Non-GM crops, and processed food made from such foods (including food made from processed food made from non-GM crops), may be labeled "Non-GMO segregated from
GMO" or "non-genetically modified" on a voluntary basis.

Notwithstanding the GM labeling obligations above, food which is not sold directly to consumers and separately prescribed processed food may be exempted from GM labeling obligations.

# Nutrition content claims and health claims

**Nutrition content claims**
Certain nutrition components can be labeled in either absolute terms (e.g., high in XYZ, rich in XYZ, etc.) or comparative terms (e.g., 20% up, half calorie, etc.). Absolute labeling is possible when the quantity of a nutrition component per 100 g (100 ml for liquid products) exceeds or falls below the prescribed standard level. Comparative labeling is possible when the difference in
a certain nutrition component compared with a food product exceeds or falls below the prescribed standard level.

Food with Nutrient Function Claims (FNFCs) is food that can supplement nutrients that are not sufficiently absorbed from your everyday diet due to changes in lifestyle or age. On a food labeled "Food with Nutrient Function Claims (XYZ)," the nutrient and its function will also be labeled, so consumers can tell how much of what nutrient it supplies. It is required to advise consumers that too much of a nutrient can be bad for their health, to read the warnings and recommended daily
intake carefully, add FNFCs to their diet discerningly, and consume an appropriate amount of the nutrient.

**Health claims**
"Foods for Specified Health Uses" are those that contain dietary ingredients that have beneficial effects on the physiological functions of the human body to maintain and promote health and to improve specific health-related conditions. Approval from the Consumer Affairs Agency ("CAA") will be required in order to sell a food with "Food for Special Dietary Uses" labeling, i.e., the food must be approved so that it is allowed to state on the label that the food is appropriate for maintaining health and/or recovering from diseases, particularly in infants, young children, pregnant and
lactating women, and patients.

**Functional claims**
"Foods with functional claims" are those which state, at the proprietor's risk, that the food would fulfil a specific health purpose based on scientific grounds. Approval from the CAA is not required, but specific information regarding safety and grounds for the function needs to be filed to the Secretary General of the CAA before the food is sold.

# Mandatory warnings and advisory statements

Of those foods that have been identified to have links to food allergies, seven kinds of food have been designated as "specified raw materials" in reference to the incidence and the severity of the allergic reactions they cause, i.e., prawn, crab, wheat, buckwheat, eggs, milk and peanuts. Processed food containing any specified raw material must carry a label stating that it contains the relevant specified raw material. Similarly, foods which contain additives derived from specified raw
materials must carry a label indicating that they contain these additives and that the additives are derived from specified raw materials. Labeling requirements for allergic substances are different from those of GMO foods. These substances, including those used as raw materials in foods not sold directly to consumers, must be labeled at all stages of food distribution.

A label stating that a raw material or additive contains specific raw materials must be labeled with brackets immediately after the raw material or additive or after all raw materials or additives in a group.

The Labeling Standards Ordinance lists seven foods as materials containing allergic substances. However, other foods including abalone, cuttlefish, salmon roe, oranges, kiwi fruit, beef, walnuts, salmon, mackerel, soybeans, chicken, banana, pork, matsutake mushroom, peaches, yams, apples
and gelatin have also been found through experience and scientific studies to contain allergic substances. The MHLW recommends that labeling of processed foods which contain these foods as raw materials should state that they contain such raw materials as much as possible.

# Trade measurement markings

The Measurement Act requires that all imported products and shipping documents show metric weights and measures. In addition, businesses, which import or sell foods specified by Cabinet Order indicating the quantity, must measure the quantity of such foods in statutory measurement units so as not to exceed the measurement error level specified by Cabinet Order. Typical statutory measurement units for foods are as follows: if the food is liquid, the marking should be by reference to volume (ml or L) and if the food is solid, semi-solid, or partly solid and partly liquid and is not ordinarily sold by number, the measurement marking should be by reference to mass (mg/g/kg).

# Product recalls

There are no specific laws or regulations governing the product recall procedure.

However, some local governments impose reporting obligations. For example, the Food Safety Regulations established by the Tokyo Metropolitan Government require companies that undertake a voluntary recall of a food product to submit a business report when commencing the process. The Regulations do not make recall mandatory, but do impose a reporting obligation when undertaking voluntary recall. Any information concerning voluntary recall reported by companies undertaking a product recall will be published on the Tokyo Metropolitan Government's website. The Tokyo Metropolitan Government will monitor recall in order to avoid the recalled products going to market again. Additionally, the Tokyo Metropolitan Government's website is useful for determining
a company's action and observing various precedents of what other companies are doing.

# Food safety

Under the FSA, the distribution, processing, manufacturing and importation of the following food additives are prohibited:

foods/food additives which are not hygienic;

new foods/food additives that may pose a health hazard (not proven);

foods/food additives that are manufactured by a particular country, region or person and involve many legal violations;

livestock contracting certain diseases;

food additives other than those recognized under laws/regulations; and

food/food additives that do not satisfy the standards established by MHLW.

Under the FSA, the distribution, processing, manufacturing and importation of the following equipment and containers/packaging are prohibited:

hazardous equipment and containers/packaging;

equipment and containers/packaging manufactured by a particular country, region or person that involves many legal violations; and

equipment and containers/packaging that do not satisfy the standards established by the MHLW.

Under the FSA, a physician who has diagnosed a person who has been or is suspected to have been poisoned by food, additives, apparatus, or containers and packaging or has examined a corpse must notify the director of the nearest health center to that effect immediately. Please refer to the Product Recall section in relation to reporting obligations.

# Advertising claims (general)

The Food Labeling Act prohibits the following claims:

a claim which misleadingly states that the product is significantly better and more beneficial than it actually is;

a claim which contradicts the labeling standard prescribed in the Labeling Standards Act;

a claim that food made from a crop other than a non-GMO crop which is confirmed to have been segregated from a GMO crop at any stage of the manufacturing and distribution process, is made from non-GMO crop;

a functional claim that a food can treat or prevent an illness, or falsely gives the impression that the food has been approved by the Secretary General of the CAA; and

a false claim that the food has a particular health effect (food for a specific health use, food with a particular function and food with a particular nutritional function) or which implies
that the food serves a particular health purpose.

# Credence claims (e.g., organic, natural, fresh)

**Organic claims**
It is mandatory for businesses, including producers and processors of crops or processed foods in Japan, to obtain organic "Japanese Agricultural Standards" ("JAS") certification from a registered certification body by having their operation inspected in order to claim that their products are "Yuuki" or "Organic" (organic JAS certification is voluntary if JAS marks are not intended to be attached on organic livestock, organic feed and organic food processed mainly from non-crop ingredients). Businesses that are not JAS certified are not allowed to put organic JAS marks on the products and/or claim organic food.

A business that illegally labels products is subject to penalties in line with the Act on Standardization, etc. of Agricultural and Forestry Products ("JAS Act"). National organic standards are set as "Japanese Agricultural Standards ("JAS") for Organic plants," "JAS for Organic Processed Foods," "JAS for Organic Feeds," and "JAS for Organic Livestock" (hereafter called JAS standards). JAS standards lay down production/processing methods of organic food. A producer, a manufacturer (processor), a repacker and an importer have to be inspected by a registered certification body to evaluate their competence, system and equipment to produce/process organic food.

# Health rating schemes

Although there is no health "rating" scheme in Japan, a voluntary labeling scheme in relation to various claims (i.e., nutrition content claims, health claims and functional claims) is available subject to the relevant requirements such as a CAA approval (see the "Nutrition Content Claims and Health Claims" section above).

Inclusion of foreign health rating scheme logos on products imported into Japan is permitted as long as the labeling does not misleadingly claim that the product is significantly better and more beneficial than it actually is.

# Other

Not applicable.

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