Food product and safety regulation

Overview

The main law that governs food quality and integrity in Japan is the Food Sanitation Act ("FSA") and the law that comprehensively governs food labelling regulation is the Food Labelling 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
- requiring food business to be licensed.

Under the FSA, additives and foods containing additives must not be sold, or be produced, imported, processed, used, stored, or displayed for marketing purposes unless the Minister of Health, Labour 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"). In addition, it is not permissible to add any processing aids, vitamins, minerals, novel foods or nutritive substances to food unless they have been expressly declared by the MHLW as having no risk to human health.

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 Pharmaceutical Affairs Act. There are no particular foods that are subject to specific or separate regulation.
Basic labelling requirements

In Japan, the Food labelling Act and Cabinet Office Ordinance which prescribes the specific methods for labelling ("Labelling Standards Ordinance", collectively with the Food Labelling Act, "Labelling Regulations") generally control labelling of food for sale. Under the Labelling 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 labelling rules are prescribed for each of these categories. Generally, there are some differences between labelling 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. The labelling requirements for additives are separately prescribed under the Labelling Regulations, but are generally the same as the labelling requirements for foods, other than identifying it as an additive.

The basic labelling 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 natrium/sodium)
- Country of origin (applicable only to 15 specific kinds of food prescribed in the Ordinance)
- 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).

For fresh food:

- Product name
- Place of origin
- 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).
Japan

Language and legibility requirements

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

Country of origin labelling

Under the Labelling Regulations, domestic food must identify that it is 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 as “domestic food”.
Genetically modified foods

Genetically modified foods are permitted in Japan, subject to regulatory pre-approval. 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 April 10, 2014, 290 varieties of foods (mainly crops such as corn, soybeans, etc.) and 17 additives (a-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 labelled 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 labelled “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 labelled “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 labelled “Non-GMO segregated from GMO” or “non-genetically modified” on a voluntary basis.

Notwithstanding the GM labelling obligations above, food which is not sold directly to consumers and separately prescribed processed food may be exempted from GM labelling obligations.
Nutrition content claims and health claims

Nutrition content claims

Certain nutrition components can be labelled in either absolute terms (e.g. high in XYZ, rich in XYZ, etc.) or comparative terms (e.g. 20% more, half calorie, etc.). Absolute labelling is possible when the quantity of a nutrition component per 100 g (100 ml for liquid product) exceeds or falls below the prescribed standard level. Comparative labelling is possible when the difference in a certain nutrition component compared with a food product exceeds or falls below the prescribed standard level (for protein and alimentary fibre, it must be 25% or more or 25% or less compared to other food to show this labelling).

Foods with Nutrient Function Claims (FNFCs) are foods that can supplement nutrients that are not sufficiently absorbed from your everyday diet due to changes in lifestyle or age. On a food labelled “Food with Nutrient Function Claims (XYZ)” the nutrient and its function must also be labelled, so consumers can tell how much of what nutrient it supplies. Consumers are required to be advised that too much of a nutrient can be bad for your health, to read the warnings and recommended daily intake carefully, add FNFCs to your diet skillfully, 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) is required in order to sell a food with "Food for Special Dietary Uses" labelling, i.e. the food must be approved to state on the label that the food is appropriate for uses to maintain health and/or recover 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 can 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.
Japan

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 allergic reactions they cause, i.e. prawn, crab, wheat, buckwheat, eggs, milk, and peanuts. A 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. Labelling 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 labelled at all stages of food distribution.

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

The Labelling Standards Ordinance lists seven foods as materials containing allergic substances. However, other foods including abalone, cuttlefish, salted 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 Minister of Health, Labour and Welfare recommends that labelling of processed foods which contain these foods as raw materials should state that they contain such raw materials as much as possible.
Japan

Trade measurement markings

The Measurement Act requires that all imported products and shipping documents show metric weights and measures. Also, 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).
Japan

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 so reported by companies undertaking a product recall will be published on the Tokyo Metropolitan Government’s website. The Tokyo Metropolitan Government will monitor recalls in order to avoid the recalled products going to market again. Also, Tokyo Metropolitan Government's website is useful in determining the company’s action – you can see various precedents of what other companies are doing.
Food safety

Under the Food Sanitation Act ("FSA"), distribution, processing, manufacturing, importation of the following food additives is 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 that involve many legal violations
- Live stock carrying certain diseases
- Food additives other than those recognized under laws/regulations
- Food/food additives that do not satisfy the standards established by Minister of Health, Labour and Welfare ("MHLW")

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

- Hazardous equipment and containers/packaging
- Equipment and containers/packaging manufactured by a particular country, region or person that involves many legal violations
- Equipment and containers/packaging that do not satisfy the standards established by MHLW
Japan

Advertising claims

The Food Labelling Act prohibits the following claims:

- a claim which misleadingly states that the product is significantly better or beneficial than it actually is;
- a claim which contradicts the labelling standards prescribed in the Labelling 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 from a 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.
Japan

Credence claims

Organic claims

It is mandatory for businesses, including producers and processors of crops or processed foods in Japan, to obtain organic 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.

A business that illegally labels products is subject to penalties in line with the Act for Standardization and Proper Labelling 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 have an inspection from a registered certification body to evaluate their competence, system, and equipment to produce/process organic food.
Japan

Licensing and approvals requirements to import/export food

Customs registration

There is no specific registration requirement before a business can import or export foods to or from Japan.
Japan

Import permit

A business wishing to import foods must declare them to the Director-General of Customs and obtain an import permit after necessary examination of the foods concerned under the Customs Act. The formalities start with the lodging of an import declaration and end with issuance of an import permit after the necessary examination and payment of Customs duty and excise tax. A non-resident can obtain an import permit. The main obstacle to obtaining the permit is the food inspection process.

When foods for import require a permit and approval under laws and regulations other than the Customs Act, a certificate of application for a permit and approval under other laws and regulations must be submitted as well as the Import declaration mentioned above. Especially for food, a business wishing to import a food, food additive, apparatus, or container/package intended for sale or for use in business must notify at each import the quarantine station of the Minister of Health, Labour and Welfare ("MHLW") as prescribed by ministerial ordinance under the Food Sanitation Act. During document examination by the quarantine station, the food sanitation inspector validates items such as (i) whether the imported food complies with the manufacturing standards regulated under the Food Sanitation Act ("FSA"), (ii) whether the use of additives complies with the standards, (iii) whether the import item contains any poisonous or hazardous substance, and (iv) whether the manufacturer or the place of manufacturing has a record of sanitation issues in the past, based on the information reported in the Notification Form. The document examination focuses on such information as the country of export, imported items, manufacturer, the place of manufacture, ingredients and materials, methods of manufacturing and use of additives.

If, as a result of the document examination, the food sanitation inspector judges the cargo should be inspected (cargo with a history of non-compliance, imported swellfish, etc.), an inspection order (inspection order system), a public inspection (other inspection systems) and other inspections (see the section on "Inspection of Imported Foods") will be carried out in order to confirm that the cargo complies with applicable laws.

If, as a result of the document examination and cargo inspection, the food sanitation inspector finds that the cargo complies with applicable laws (cargo which has "passed" the inspection), a "Certificate of Notification" will be returned to the importer from the MHLW quarantine station where the notification was first submitted. The import procedures will then proceed to the next step. On the other hand, cargo that is judged not to comply with applicable laws (cargo that "did not pass" the inspection) cannot be imported into Japan. The MHLW quarantine station will notify the importer how the cargo violates the FSA, leaving the importer to take the necessary steps in accordance with the station's instructions.

Import permits typically take around 60 hours for shipping and 15 hours for airfreight.
Japan

Inspection and testing of imported foods

As mentioned above, if following a document examination it is judged that the cargo needs to be inspected, the following inspections will be carried out in order to confirm compliance of the cargo with applicable laws.

1. **Inspection Order System**: If examination of the import documents and information on the sanitary situation of the exporting country, the nature of the food and related items, or record of non-compliance of similar items in the past suggests that the food concerned is highly likely to violate the Food Sanitation Act ("FSA"), the Minister of Health, Labour and Welfare will issue an inspection order and suspend the import procedure until the food concerned is proven to comply. This system is called the "Inspection Order System" and the importer is responsible for the cost of the inspection. The items that are subject to this system are designated by cabinet order, and details of each item are published every year.

2. **Monitoring Inspection System**: "Monitoring inspections" are carried out at the Ministry of Health, Labour and Welfare Quarantine Station for food and related items that are unlikely to be non-compliant with the Food Sanitation Law. Every year, the monitoring inspection system designates the items subject for the monitoring inspections based on the annual import amount and record of past non-compliance for each item. The purpose of the monitoring inspection system is to collect information and data on sanitary status of diverse food items that are brought into Japan as well as to promote the smooth distribution of these items. While Minister of Health, Labour and Welfare ("MHLW") food sanitation supervisors carry out sample inspections, the import procedures can be progressed without waiting for the inspection results.

3. **Other Inspection Systems**: In addition to monitoring inspections, MHLW food sanitation inspectors conduct other kinds of inspections, such as inspections of food and related items that are imported for the first time into Japan, inspections to examine items that do not comply with the FSA, and inspections to examine food and related items that have experienced an accident during transportation. Also, on some occasions of a first-time import or regular import, the MHLW quarantine station requires the importer to conduct an inspection of the cargo in relation to some necessary items, based on the idea that importers also have an obligation to secure food sanitation and safety.

In order to simplify and expedite import procedures, simplified systems of import notification are also available.

1. **Advance Notification System**: For all food and related products, the import notification form can be submitted starting 7 days before the estimated date of the cargo's arrival. Except for cargo that needs an inspection, a copy of the certificate of notification is issued immediately, either before the arrival of the cargo or after the cargo is unloaded to the bonded area.

2. **Planned Import system**: If a certain food or related item is planned to be imported repeatedly, an import plan can be submitted at the time of the first import. If the plan is found satisfactory, the submission of import notifications is exempted for a certain period.

3. **Inspection Results by Official Inspection Organizations in Other Countries**: If the cargo is inspected by an official inspection organization in the exporting country prior to export, and a report of the inspection results is attached to the cargo, the cargo may be exempted from inspection at the quarantine station. Inspection items whose results are subject to change during transportation (bacteria, mycotoxin, etc.) are excluded.

4. **Continuous Import of Same Items**: If certain foods and related products are imported repeatedly and inspection results are attached to the import notification form at the initial import, if document examination reveals no problem, inspection can be exempted in relation to future occasions of import for a certain period.
5. **Advance Approval of Imported Foods and related Products:** If the imported foods, etc. are confirmed to comply with the FSA, the items and the manufacturers may be registered. Inspection in relation to future imports is exempted for these items for a certain period of time and the certificate of notification is issued immediately after submission of import notification.
Japan

Export permits/clearances

A business wishing to export foods must declare to the Director-General of Customs the nature of the goods as well as the quantity, price, and any other prescribed particulars. An export permit must also be obtained after the prescribed physical examination.

Goods for export must be brought into the Customs (Hozei) area or a specially permitted place for storage. The exporter or his proxy (known as a Customs broker) prepares an export declaration describing the nature, quantity, and value, of the goods to be exported. This declaration is accompanied by invoices and other supporting documents and, if required by Japanese laws and regulations other than the Customs Act ("other laws and regulations"), by other documents, such as permits, approvals, or licenses.

The submitted export declaration is checked against invoices and other supporting documents at Customs.

Document checking is conducted when a statistical classification is correctly made according to the Export Statistical Schedule, when the required permission or approval is secured with respect to pertinent goods, and when a correct application for approved excise tax exemption accompanies the goods which are to be exempted. In checking the submitted documents, Customs decides whether the goods have to be physically examined to ascertain the correctness of the classification of goods and to see whether the examinations required by other laws and regulations have been completed.

In principle, Customs examinations of goods are conducted at a Customs examination zone in the Customs house or where the goods are stored in cases where the goods cannot be brought to the Customs examination zone.

At the time of export declaration, the exporter is requested to submit two copies of the export report. One is for statistics and the other is kept at Customs for needs such as export certification.

The Customs Act is the fundamental law concerning exports. In addition, depending on the type of cargo, there are cases which require a permit or prior approval for export of the cargo before export declaration. These must be issued by other authorities, such as the Ministry of Economy, Trade and Industry, and the Ministry of Health, Labour and Welfare, in accordance with the requirements of other laws and regulations.

Under other laws and regulations, exporters of cargo who are required to obtain permits or approvals or pass examinations, must prove to Customs that these requirements have been met during the Customs clearance procedure, which then needs to be confirmed. Unless these requirements are proved and confirmed, Customs will not permit the cargo to be exported.
Japan

Other notifications/approvals/licences

In terms of import or export of foods, there are no other required notifications/approvals.

Permits issued by the prefectural governor will be required to sell certain foods listed in the Ordinance for Enforcement of the Food Sanitation Act ("FSA") and local ordinances, including milk, cream, meat, seafood, ice and other foods.
Japan

Enforcement

Enforcement authorities and key responsibilities

The main bodies/agencies responsible for enforcement of food related laws in Japan are outlined below:

1. Prefectural governor

   - Prohibit distribution of certain foods, food additives, equipment or containers that do not conform to the required standards.
   - Order disposal of food or take any other necessary measures (including recall) to eliminate food sanitation hazards.
   - Prohibit carrying on of business in whole or in part, or suspend the business for a specified period.
   - Publish the names of companies which have violated the Food Sanitation Act.

2. Food sanitation inspectors at local health centers

   - Monitor and provide guidance to food business.

3. Minister of Health, Labor and Welfare

   - Order disposal of food or take any other necessary measures (including recall) to eliminate food sanitation hazards.
   - Prohibit carrying on of business in whole or in part, or suspend the business for a specified period.
   - Publish the names of companies which have violated the Food Sanitation Act.

4. Secretary General of the CAA

   - Order proprietors to comply with food labelling obligations or to dispose of food or take any other necessary measures (including recall) to eliminate food sanitation hazards arising from non-compliance with food labelling obligations.
   - Prohibit carrying on of business in whole or in part, or suspend the business for a specified period.
   - Publish the names of companies which have violated the Food Labelling Act.
   - Conduct an on-the-spot inspection of the proprietor to verify compliance with food labelling obligations.
Japan

Penalties for non-compliance

Food Sanitation Act

Sale of hazardous food, use of unspecified additives, violation of order to dispose, violation of order to suspend business

- Imprisonment of not more than 3 years, or a fine of not more than 3 million JPY
- In case of a corporation: a fine of not more than 100 million JPY

Sale of food violating specifications and standards; sale of food violating labelling standards (applicable violation of specifications and standards and labelling standards)

- Imprisonment of not more than 2 years, or a fine of not more than 2 million JPY. In case of a corporation: a fine of not more 100 million JPY

Violation of facilities standards; violation of a business improvement order; violation by doctor of provisions for reporting food poisoning cases

- Imprisonment of not more than 1 year, or a fine of not more than 1 million JPY

Refusal to submit to a spot inspection; false reporting, etc.

- A fine of not more than 500 thousand JPY

Health Promotion Act

Punishments of the registration organizations (e.g. violation of confidentiality obligations by the staff of relevant organizations)

- Imprisonment of not more than 1 year, or a fine of not more than 1 million JPY

Food Labelling Act

Violation of a business improvement order

- Imprisonment of not more than 3 years, or a fine of not more than 3 million JPY. In case of a corporation: a fine of not more 300 million JPY.

Sale of food violating food labelling standards

- Imprisonment of not more than 2 years, or a fine of not more than 2 million JPY. In case of a corporation: a fine of not more 100 million JPY.