Taiwan

Food product and safety regulation

Overview

1. General food products

In Taiwan, food is defined as: "goods provided to people for eating, drinking, or chewing, and the raw materials of such goods" by the Act Governing Food Safety and Sanitation ("Act"). Food products, including food additives and processing aids which are used during food manufacturing, as well as vitamins, minerals and nutritive substances without claiming healthcare or therapeutic effects, are primarily regulated in accordance with the Act as well as any relevant regulations and announcements promulgated by the Taiwan Food and Drug Administration ("TFDA") from time to time. Novel foods are not allowed to be manufactured, processed, prepared, packaged, transported, stored, sold, imported, exported, presented as a gift or publicly displayed before they pass a regulatory safety evaluation.

2. Health foods

Food products that claim, advertise or are labelled with specific health care effects are classed as a "health food" and are governed by the Health Food Control Act (last amended on May 17, 2006).

Under the Health Food Control Act, food products that intend to claim, advertise or label itself with specific health care effects must pass a health food evaluation before being registered as a "health food" with the TFDA. Food products without such registration are banned from claiming any health care effects or from describing themselves as a "health food." They should be treated as general food products as provided under the Act.

The term "health care effect" means an effect that has been scientifically proven to be capable of improving peoples' health, and decreasing the harm and risk of disease. However, it is not a medical treatment aimed at treating or remedying human diseases. These "health care effects" are prescribed by the TFDA. As of July 2015, the TFDA has approved thirteen (13) health care effects which can be claimed by a registered health food. These include: regulation of blood lipids and blood glucose, modulation of allergic constitution, immune-modulatory effects, regulation of body fat formation, anti-fatigue effects, bone health, anti-aging, improvement of gastrointestinal functions, liver care (for chemical damage to the liver), tooth care, regulation of blood pressure, and improvement of ferrous ion absorption.

3. Medicines or therapeutic goods are not food

A clear line is set between food products and medicines or therapeutic goods. Food products (including general foods and health foods) are strictly banned from claiming any therapeutic effect. Medicines or therapeutic goods are primarily governed by the Pharmaceutical Affairs Act.

4. Alcoholic beverages

Alcoholic beverages are separately regulated by the Tobacco and Alcohol Administration Act.
along with tobacco related products. "Alcoholic beverage" referred to in the Tobacco and Alcohol
Administration Act includes beverages having an alcohol content by volume of more than 0.5
percent, as well as un-denatured ethyl alcohol and other ethyl products that can be used for the
production or preparation of the above-mentioned beverages. However, if an alcoholic beverage
has been classed as a medicine by the TFDA, it is exempt from the Tobacco and Alcohol
Administration Act.
Taiwan

Basic labelling requirements

According to the Act Governing Food Safety and Sanitation ("Act"), the container or external packaging of food has to conspicuously indicate in Chinese and common symbols the following matters:

1. Product name
2. List of ingredients. Products containing two or more ingredients need to indicate the respective ingredients in descending order of proportion
3. Net weight, volume or quantity
4. Name of food additives. In the case of a mixture of two or more food additives which are named according to a function, the name of each additive should be indicated separately
5. Name, telephone number and address of the manufacturer or of the responsible domestic company
6. Country of origin (see section "Country of origin labelling" for further detail)
7. Expiry date
8. Nutrition information
9. Genetically modified raw food materials
10. Any other matters designated by the central competent authority in a public announcement.

In addition, the Regulation on Nutrition Labeling for Packaged Food sets out detailed requirements for the nutrition labelling for packaged food. This requires the following information to be conspicuously displayed:

1. Items of labelling: (A) the title "Nutrition labelling"; (B) energy contents; (C) amount of protein, fat, saturated fat, trans fat, carbohydrate, sugar and sodium contained (note that carbohydrate includes dietary fibre); (D) contents of other nutrients referred to in any nutrition claim; and (e) contents of other nutrients labelled by the manufacturer voluntarily.
2. With respect to the amount of energy and nutrients, the labelling value should be expressed (i) in units of 100 grams and grams per serving for solid (semi-solid) food, and in units of 100 millilitres and millilitres per serving for liquid food (drinks), or (ii) in units of grams for solid (semi-solid) food (or millilitres for liquid food) per serving and daily percentage reference value. The number of servings contained in each package of the product should also be specified.
3. Labelling unit for the contents of energy, nutrients and trans fat.
Taiwan

Language and legibility requirements

All food labels must be written and displayed conspicuously in the Chinese language and using common symbols such as ml, g or kg.
Taiwan

Country of origin labelling

Containers or external packaging of food must conspicuously indicate the country of origin in Chinese and common symbols. The country of origin is to be determined in accordance with the Regulations Governing the Determination of Country of Origin of an Import Good.

Primarily, the country of origin of food products is determined by:

1. The location where such food products are wholly produced; or
2. The location where such food products have undergone the last substantial transformation, when the processing or manufacturing processes involved two or more countries or regions. A substantial transformation would be where; (A) the first six digits of the Customs Import Tariff code of such food products are different from those of the food products' raw materials; or (B) though the Customs Import Tariff code remains unchanged, the completed major process or added value rate is more than 35%.
Taiwan

Genetically modified foods

Genetically modified raw food materials may not be used in foods until they have passed a regulatory health risk assessment and are registered with the Taiwan Food and Drug Administration ("TFDA"). Registration is valid for one to five years, subject to the discretion of the TFDA, and can be renewed before expiration.

The registration holder is required to establish a traceability system for tracing the source and tracking the flow of the genetically modified raw food materials.
Taiwan

Nutrition content claims and health claims

The nutrition labelling requirements for packaged food are set out in the Regulation on Nutrition Labelling for Packaged Food (please see section on Basic Labelling Requirements for more detail).

Foods claiming specific health care effects are regulated under the Health Food Control Act as discussed in the section on Basic Labelling Requirements. Pursuant to the Health Food Control Act, no foods may be labelled or advertised as a health food or claim any of the 13 approved health care effects before passing a health food evaluation and being registered with the Taiwan Food and Drug Administration as a health food.

As a general rule, no food product (including general foods and health foods) may claim any therapeutic effect.
Taiwan

Mandatory warnings and advisory statements

The Rule Governing Labelling of Allergens in Food Products requires food products containing shrimp, crab, mango, peanut, milk, egg and products made thereof to add a statement to warn consumers that such products contain an allergen.

In addition to warnings pertaining to allergens, the Taiwan Food and Drug Administration has also published advisory statements for the use of novel foods or materials. For example, food products containing Aloe must state that such product is not suitable for women during pregnancy.
Taiwan

Trade measurement markings

There are no specific laws or regulations governing trade measurement markings on foods in Taiwan. Any measurement markings related to trade is governed generally by the Weights and Measures Act. Taiwan adopts the International System of Units and the acceptable measurements include mL, kg, etc.
Taiwan

Product recalls

Food businesses may recall food products voluntarily. If a food business finds that their food product may have a safety or sanitation concern, it should cease manufacturing, processing and selling such product, and should recall such products circulated on the market.

Food products must be recalled in accordance with a mandatory request of the competent authorities in any of the following circumstances:

1. When a significant or an unexpected food safety incident occurs, the Taiwan Food and Drug Administration ("TFDA") may require a food business to recall specified products or products from specified areas on the basis of the risk assessment made by the TFDA or any epidemiological survey results.
2. The Department of Health of each local government may order, at its discretion, a food business to recall food products if there is found to be a violation of the Act Governing Food Safety and Sanitation ("Act"), for example:
   A. the food product contains an additive that has not been approved by the TFDA;
   B. the food products are adulterated or counterfeit;
   C. the food products are determined as causes of food poisoning;
   D. the food business fails to comply with labelling requirements set forth in the Act, to the extent that the violation is serious.
Taiwan

Food safety

Since a series of food safety scandals exploded in Taiwan from 2009, the Taiwan Food and Drug Administration ("TFDA") has intensified its control on food safety. In general, food safety control in Taiwan partly relies on the control of the TFDA and Department of Health of each local government ("Local DOH") as well as partly on self-management by food businesses.

To ensure food sanitation and safety, the TFDA along with Local DOH are obligated to establish a reporting system to collect and handle the reporting of suspicious food poisoning incidents according to Art. 6 of the Act Governing Food Safety and Sanitation ("Act"). In addition, if a serious violation of the Act is found, the TFDA or the Local DOH may order the violator to recall its product as part of its sanctions.

Food businesses in Taiwan are also expected to actively pursue self-management to ensure food sanitation and safety. If a food business finds that their food products may be harmful to sanitation and safety, it is obligated to cease the manufacturing, processing and sale and to recall the food products concerned. The food business must also report such incident to the Local DOH.

The TFDA's and Local DOH's processes for determining the causes of food safety scandals, food poisoning incidents etc. are usually difficult and time-consuming. In order to trace the cause of a food safety scandal or food poisoning incident more efficiently and to ensure a prompt reaction by the TFDA or Local DOH to such event, certain food businesses (e.g. food additives businesses) designated by TFDA are required to establish their own traceability system for tracing the source and the flow of the raw materials, semi-products and end products according to their respective industry practice.
Taiwan

Advertising claims

Advertisement of food products are primarily supervised by the Taiwan Food and Drug Administration ("TFDA") and the Department of Health of each local government ("Local DOH") pursuant to the Act Governing Food Safety and Sanitation ("Act"). The Health Food Control Act may apply when claims pertaining to health care effects are involved.

As a general rule, a food business is prohibited from making false, exaggerated or misleading statements (Art. 28(1) of the Act) or from claiming any therapeutic effects (Art. 28(2) of the Act) on/in its food labels, advertisements or promotional materials.

If a general food product makes false, exaggerated or misleading statements, the advertiser may incur a fine of up to NTD4 million (about USD134,000) and be ordered to recall the products. If the violation continues, the Local DOH may even confiscate and destroy the products concerned. If a general food product claims any therapeutic effect, the advertiser may incur a fine of up to NTD 5 million (about USD167,000) and the Local DOH can immediately confiscate and destroy the products in question.

In order to enforce such provisions for product advertising, the TFDA has published the ‘Guidelines on Determining False and Exaggerated Wording or Therapeutic Claim Contained in Food Advertisements or Labels’ ("Guidelines"). The Guidelines provide:

1. Claims that mention therapeutic effects (such as preventing, remedying, alleviating, diagnosing, or treating certain diseases or physiological conditions etc.) are not allowed.
2. Claims incorporate exaggerated or misleading statements (eg about physiological functions) are not allowed.
3. Examples of allowable descriptions for foods include "nourish and tone up the body", "build up physical strength", "maintain vigorous vitality" etc.).
4. Certain claims that refer to the physiological functions of dietary fibre, vitamins and minerals are allowed (e.g., it is permissible to claim that Vitamin C promotes the formation of collagens, assists in wound healing, maintains a tight arrangement of cells, and the growth of bones and teeth, promotes the absorption of iron, and has an anti-oxidation effect).

Pursuant to Art. 6 of the Health Food Control Act, prior to obtaining approval from the TFDA to be registered as a health food, a food product must not be advertised or labelled with the phrase "health food" or any health care effects. Breach of this provision is a criminal offence and may incur a criminal fine of up to NTD1 million (about USD33,000).

A health food may not make any claim that is false, exaggerated or misleading or a health care effect outside the scope approved by the TFDA, or that involves any therapeutic effects. Violation of such restriction is punishable by a fine of up to NTD2,000,000 (USD66,000). If such violation is serious, the violating health food business may be further ordered by the Local DOH to recall the products.
Taiwan

Credence claims

Taiwan does not have regulations specifically for the governance of credence claims. However, organic claims can only be used on a certified organic food. Other credence claims, such as natural, fresh etc., are allowed to be used as long as they are not false, exaggerated or misleading.

Organic claims

In Taiwan, organic claims can only be used on certified organic foods under the Agricultural Production and Certification Act (last amended on January 29, 2007) ("Agricultural Act"). Under the Agricultural Act, 'organic product' means any agricultural product that is cultivated, processed and packaged in accordance with relevant regulations and is certified under the Agricultural Act. Chemical pesticides, chemical fertilizers, animal drugs or any other chemicals, except for those permitted by the authority, can not be used in organic products or their processed products. If a food product without any organic certification makes an organic claim, a fine of up to NTD1 million (about USD33,300) may be imposed on the manufacturer or importer/seller.

Other credence claims

Pursuant to Art. 28 of the Act Governing Food Safety and Sanitation, except for claims that are false, exaggerated or misleading or involve any therapeutic effects, other claims are generally allowed to be made for food products. Therefore, credence claims such as natural and fresh are allowed to be used as long as they are genuine. In practice, the Department of Health of each local government occasionally inspects products with such credence claims. If such claims are determined to be false, exaggerated or misleading, the food business will face a fine of up to NTD4 million (about USD134,000).
Taiwan

Licensing and approvals requirements to import/export food

Customs registration

There are registration requirements before a business can import or export foods to/from Taiwan, i.e., import/export registration. However, the registration procedure should be done with the Bureau of Foreign Trade ("BOFT"), instead of with Customs.

A Taiwan entity (including the subsidiary or branch office of a foreign company) engaging in wholesale, retail sale and/or international trade business which involves import/export activities, must apply for importer/exporter registration with the BOFT.
Taiwan

Import permit

1. Registration with the Bureau of Foreign Trade ("BOFT") as an importer/exporter (Import/Export Registration)

Basically, as long as a food business has registered with the BOFT as an importer/exporter, it can import food into Taiwan. A special business licence is normally not required. However, to import alcoholic beverages, the importer will need to obtain a business license for an alcoholic drink importer from the authorities before the import/export registration.

2. Product registration with the Taiwan Food and Drug Administration ("TFDA") for specific categories

Prior product registration with the TFDA is required for the import of certain categories of food products. These include: food additives (single ingredient as raw materials), genetically modified foods, general foods in the form of tablet or capsule ("Tablet or Capsule Foods), health food and special dietary food. For general foods that are not Tablet or Capsule Foods, there is usually no need to apply for such registration.

The applicant and holder of the product registration has to be a local entity.

Such product registration allows the holder to import the registered products.

Normally, it takes about three months from filing to complete the product registration for a tablet or capsule food, at least six months for special nutrition food, about 16-22 months for health foods, about two months for food additives; and about ten (10) months for genetically modified food.

3. Import permit subject to the classification of the BOFT

An import permit issued by the BOFT, the Bureau of Animal and Plant Health Inspection and Quarantine ("BAPHIQ") or the TFDA may be required depending on the type of food to be imported. To the extent that the imported foods fall under the 'Consolidated List of Commodities Subject to Import Restriction' (please refer to the BOFT’s online "Classification of Commodities and Regulations" database for details), relevant import permits stipulated in the "Classification of Commodities and Regulations" database in the name of the importer will be required.

For foods that meet the requirements of Code "MW0", permits from the BOFT are required; for Code "B01", permits from the BAPHIQ are required; and for Code "F01", permits from the TFDA are required.

Subject to the requirements of the relevant authority, different products may have different documentation requirements or processes to obtain the import permit. Depending on whether the required documents or processes have been completed, import permits typically take up to 2-3 working days to obtain.

A non-resident may be the importer on record for a food import permit.
Taiwan

Inspection and testing of imported foods

Food entering Taiwan is subject to the Act Governing Food Safety and Sanitation ("Act") and Regulations of Inspection of Imported Foods and Related Products ("Inspection Regulations") which provide statutory requirements and procedures for the inspection and control of imported food at the border.

Some imported foods (e.g. genetically modified raw food materials and food additives), are subject to special inspections by the Taiwan Food and Drug Administration ("TFDA") (please refer to the Bureau of Foreign Trade’s online “Classification Commodities and Regulations database for details). In those cases, the food importer must apply for inspection and must declare relevant information about the food to the TFDA in accordance with the customs commodity code and classification. The inspection will focus on ingredients and contents of imported food.

Further, the TFDA may impose preferential measures to food importers with excellent performance records regarding the import inspection stipulated in the Inspection Regulations. This may save importers some cost and may minimise the delays associated with inspection and testing under the Act and the Inspection Regulations.
Taiwan

Export permits/clearances

Basically, as long as a business is registered with the Bureau of Foreign Trade ("BOFT") as an importer/exporter, it can export food from Taiwan. However, an export permit may be required depending on the type of food to be exported. Where the exported foods are regulated by the BOFT 'Consolidated List of Commodities Subject to Export Restriction' (please refer to the BOFT's online "Classification of Commodities and Regulations" database for details), an export permit will be required in the name of the exporter.
Taiwan

Other notifications/approvals/licences

Pursuant to the Regulations Governing the Registration of Food Businesses, food importers are required to commence business operations only after applying for registration with the local competent authorities. This can be completed in writing or by way of electronic verification. As of July 31, 2015, this registration requirement is applicable to certain importers, dealers and manufacturers of food products as well as restaurants/food and beverage businesses.
Taiwan

Enforcement

Enforcement authorities and key responsibilities

Department of Health of each local government ("Local DOH")/ Taiwan Food and Drug Administration ("TFDA")

The Local DOHs are the primary enforcers of the Act Governing Food Safety and Sanitation ("Act"). The TFDA may also act as an enforcer when necessary, however, this is not common in practice.
Taiwan

Penalties for non-compliance

Offence/violation

- Violation of the requirements set forth in the Act Governing Food Safety and Sanitation ("Act").

Penalties

1. Fines ranging from NTD60,000-NTD3,000,000 (USD2,000-USD101,300) in principle, or NTD200,000,000 (USD 6,667,000) in an extreme case;
2. Suspension or termination of its business;
3. Revocation of all or part of the business registration or factory registration;
4. Order to recall food products;
5. Confiscation and destruction of food products.

Offence/violation

- Manufacturing, processing, selling, etc. food products or food additives that are adulterated or counterfeit; or contain food additives not approved by the Taiwan Food and Drug Administration.

Penalties

- Maximum penalty: 7 years of imprisonment in principle, or a life imprisonment in an extreme case.