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Population growth, rising incomes, changing diets and an increased desire for premium imported food and beverage products across Asia Pacific presents significant opportunities for the food and agribusiness sector across the region.

As tariffs, quotas and other traditional barriers to trade gradually decline with the growth in free trade agreements, the focus on entering the Asia Pacific market has increased significantly. However, the regulatory regimes in many Asia Pacific jurisdictions are complex and sometimes unpredictable. This in itself creates a barrier to trade.

The purpose of this searchable and comparative publication is to summarise food law regulation in 11 jurisdictions across Asia Pacific and to help food businesses navigate the complex regulatory area. Topics covered in the guide include local language and basic labeling requirements, country of origin labeling, mandatory warnings, product registration, import permit and clearance requirements. Changes to the local laws and regulations in some of these areas occur frequently. While we endeavor to keep the site updated, we invite you to seek specific and current advice as needed from appropriate Baker McKenzie contacts.



FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL REGIME

Overview

The regulation of food quality and integrity in Australia is governed primarily by the Australia New Zealand Food Standards Code ("**the Food Code**"). The Food Code is given the force of law in each of the Australian states and territories through local Food Acts (e.g., the Food Act 2003 ("**NSW**"). Compliance with the Food Code is mandatory for all food products imported, manufactured, supplied and sold in Australia. Responsibility for enforcing the Food Code rests with local food authorities in the states and territories. Responsibility for drafting the standards that make up the Food Code rests with Food Standards Australia & New Zealand ("**FSANZ**").

The term "food" is not defined in the Food Code. Local Food Acts in each state and territory define food very broadly as including any substance or thing of a kind used, or represented as being for use, for human consumption, or as an ingredient, additive or other substance used in the preparation of such a substance or thing, but does not include a therapeutic good within the meaning of the Therapeutic Goods Act 1989 (Cth). The distinction between a food (regulated under the Food Code) and a therapeutic good (regulated under the Therapeutic Goods Act) is sometimes difficult to make out, particularly as food businesses focus more on "functional foods" and foods that have health benefits. Generally speaking, a product's principal use will be of primary consideration when determining whether it is a food or a medicine.

The Food Code is very prescriptive as to what can/cannot be added to foods, and in what amounts. Additives, processing aids, vitamins, minerals, novel food substances and nutritive substances must not be added to foods unless expressly permitted under the Food Code. Where permitted, such

substances may only be used in accordance with the limits expressly set by the Food Code.

In addition to the Food Code, some foods are subject to additional regulation. For example, wines and wine products are also subject to the Australian Grape and Wine Authority Act 2013 (Cth).

Food businesses may seek an amendment to the Food Code by applying to FSANZ. Amendments must comply with FSANZ's "Application Handbook" and typically involve a period of public consultation with relevant stakeholders before final approval can be given. Applications to amend the Food Code can be extremely time-consuming, ranging from three months to 12 months depending on the complexity of the proposed amendment.

Basic labeling requirements

Food identification

The Food Code requires that, unless expressly exempt, all food must include on the label:

- the prescribed name of the food (where the name of the food is declared under the Food Code to be a prescribed name) or, in any other case, a name or description sufficient to indicate the true nature of the food;
- the lot identification; and
- the name and business address of the supplier in Australia or New Zealand. The "supplier" includes the packer, manufacturer or importer.

In addition, the Commerce (Trade Descriptions) Regulation 2016 (Cth) prohibits the importation of food unless it bears a trade description that complies with the requirements of the Regulation. There are limited exceptions to this requirement.

In the case of imported pre-packed foods, the trade description must be in English and must include in prominent and legible characters:

- a) a statement of the country of origin of the food determined in accordance with the Country of Origin Food Labeling Information Standard 2016, or if the food is from more than one country, a statement that indicates that the food is of multiple origin or that it is comprised of imported ingredients. In both cases, the country of origin statement must appear in a clearly defined text box; and
- b) a true description of the goods.

Labeling of ingredients

The Food Code requires that all packaged foods must, unless expressly exempt, include a statement of ingredients using either the common name of the ingredient, or a name that describes the true nature of the ingredient or, where applicable, a generic name. Ingredients should be listed in descending order of ingoing weight, except where a concentrated or dehydrated ingredient is reconstituted during the preparation of the product or is intended to be reconstituted according to instructions on the product. In that case, only the weight of the reconstituted ingredient must be taken into account.

Where additives are permitted to be used, they must be listed in the ingredients list on the food label by using the additive's appropriate class name (e.g., sweetener) followed by its prescribed name or code number.

Where a processing aid is permitted to be added to a food, it is not required to be listed in the ingredients list.

Where vitamins and minerals are permitted to be added to a food, they should be declared in the same way as food additives using the class name "vitamin" or "mineral."



Nutritional information panel

Nutritional information panel

The Food Code requires that, unless expressly exempt, the label on a food package must include a nutritional information panel ("NIP") which must include, in prescribed table format, details of, among other things:

- the number of servings of food in the package;
- the average quantity of food in a serving expressed in grams (solid foods) or millilitres (liquid food);
- the average energy content of a serving and per 100 g/100 mL expressed in kilojoules or both kilojoules and calories;
- the average quantity of protein, fat, saturated fat, carbohydrate and sugars in a serving and per 100 g/100 mL;
- the average quantity of sodium in a serving and per 100 g/100 mL; and
- the name and average quantity of any other nutrient or biologically active substance in respect of which a nutrition content claim or health claim is made (refer below for further details regarding nutrition content and health claims).

A NIP may also include information relating to the percentage daily intake of nutrients. If percentage daily intake information is included in a NIP, the NIP must include:

- the percentage daily intake per serving of the following nutrients: energy, protein, fat, saturated fatty acids, carbohydrates, sodium, sugars and dietary fibre (if declared); and
- either of the following statements:
 - ▲ "based on an average adult diet of 8,700 kJ" or
 - ▲ "percentage daily intakes are based on an average adult diet of 8,700 kJ."

The percentage of the recommended daily intake (RDI) for a vitamin or mineral must be included in the NIP if a nutrition content claim or health claim is made about, or based on, a vitamin or mineral in a food, and that vitamin or mineral has an RDI.

Language and legibility requirements

Each word, statement, expression or design prescribed under the Food Code to be set out in a label must be set out legibly and prominently so as to afford a distinct contrast to the background and must be in English. Where a language other than English is used in addition to the English language on a label or in association with the display of food, the information in that other language must not negate or contradict the information on the label in the English language.

Any warning statement must be set out:

- a) in a font size of not less than 3 mm; or
- b) in the case of a small package (i.e., with a surface area of less than 100 cm²), in a font size of not less than 1.5 mm.

Country of origin labeling

On 1 July 2016, the new Country of Origin Food Labeling Information Standard 2016 ("COO Standard") came into force, subject to a two-year transition period. From 1 July 2018, all food businesses must comply with the COO Standard. Under the COO Standard, most packaged food is required to bear a label with a statement of the country of origin, or a statement that identifies where the food was packaged and indicates that the food is of multiple origins or comprised of imported ingredients for foods packaged using food from more than one country. Depending on the type of food, the

label must also comprise a prescribed mark that includes a bar chart which states the proportion of Australian ingredients by ingoing weight. A kangaroo logo is also required if the food was grown, produced or made in Australia. The COO Standard contains specific definitions for the terms "grown," "produced" and "made" in Australia. There is a COO Labeling tool available online to assist businesses available [here](#).

For non-priority foods (such as confectionery, tea and coffee, and alcoholic beverages), the use of a prescribed mark with a bar chart is voluntary.

There are additional requirements for unpackaged foods, imported foods and foods that are exported and re-imported. It is currently mandatory under the Commerce (Trade Descriptions) Regulation 2016 to include a country of origin statement on all imported food labels. Such a statement must be in the English language and include in prominent and legible characters a statement of the country of origin of the food determined in accordance with the COO Standard, or if the food is from more than one country, a statement that indicates that the food is of multiple origins or that it is comprised of imported ingredients. In both cases, the country of origin statement must appear in a clearly defined text box.

Genetically modified foods

All genetically modified foods and ingredients intended for sale must be subjected to a safety evaluation by Food Standards Australia New Zealand ("FSANZ"). This process generally takes at least 12 months.

The label on a package of genetically modified food must include the statement "genetically modified" in conjunction with the name of the food or ingredient or processing aid. Claims such as "GM Free" are entirely voluntary but must not be misleading or deceptive.



Nutrition content claims and health claims

Nutrition content claims

Claims about the presence or absence of specific nutritional properties (including, for example, energy, dietary fibre, fat, carbohydrate and protein) are regulated under the Food Code as "nutrition content claims." Common examples include, for example, "no added sugar" and "low fat." In order to make nutrition content claims, food businesses must satisfy the specific conditions set out in the Food Code. In addition, there are special conditions applicable to claims that compare the nutrition content of one food/brand of food with the nutrition content of a "reference food" where reference food is defined in the Food Code as a food that is (a) of the same type as the food for which the claim is made and has not been further processed, formulated, reformulated or modified to increase or decrease the energy value or the amount of the nutrient for which the claim is made; or (b) a dietary substitute for the food in the same food group as the food for which the claim is made. The Food Code specifically requires that a comparative claim about a food must include together with the claim:

- the identity of the reference food; and
- the difference between the amount of the property of food in the claimed food and the reference food.

Health claims

Claims that state, suggest or imply that a food or property of food has or may have an effect on the human body are regulated under the Food Code as "health claims." The Food Code distinguishes between general level health claims (e.g., "calcium is necessary for normal teeth and bone structure") and high-level health claims (e.g., "helps reduce the risk of coronary heart disease"). Currently, there are very limited high-level health claims that are permitted under the Food Code.

Health claims must not be made unless the food or food property satisfies the relevant conditions set out in the Food Code. The food or food property must also meet the "nutrient profiling scoring criterion." The method for calculating the nutrient profiling score of a food is prescribed under the Food Code.

Unless a specific exception applies, all health claims must be accompanied by a dietary context statement and a statement of the form of the food to which the health claim relates.

Food businesses must not make health claims that are not expressly permitted under the Food Code. There is a limited exception for general level health claims that can be "self-substantiated." Such general level health claims need to be notified to FSANZ and self-substantiated by way of a systematic review in accordance with Schedule 6 of the Food Code. Schedule 6 imposes very specific requirements with respect to the conduct of a systematic review, including, for example, a description of the search strategy used to identify the scientific evidence, an assessment of the quality of each study and an assessment of the results of the studies as a group.

Mandatory warnings and advisory statements

The Food Code requires mandatory warning statements to be displayed on all labels for foods that contain royal jelly. In addition, a mandatory declaration is required where a food contains one or more of the following: sulphites in concentrations of 10 mg/kg or more, cereals containing gluten and their products (other than where present in beer and spirits), crustacean and their products, egg/egg products, fish/fish products, milk/milk products, peanuts/peanut products, sesame seeds/sesame seed products, soybeans/soybean products and tree nuts/tree nut products. The Food Code was amended in May 2017 to include lupin as an allergen

requiring declaration. Food businesses have until 26 May 2018 to update their product labels to ensure compliance with the new declaration requirements.

The Food Code also prescribes specific advisory statements that must be displayed on labels for a number of different foods including: bee pollen, cereal-based beverages, evaporated or dried cereal products, evaporated or dried milk products, foods containing aspartame/quinine/guarana/phytosterols, phytosterols or their esters, cola beverages with added caffeine, unpasteurized egg products and unpasteurized milk products.

Some food labels use "may contain" or "may be present" statements about certain allergens, such as "may contain nuts." These are voluntary statements made by food manufacturers and are not regulated by the Food Code.

Trade measurement markings

Pursuant to the National Measurement Regulations 2009 (Cth), all pre-packed goods must be labeled with a measurement marking shown in metric units, in clear English and shown on the principal display panel of the packaging. If the food is liquid, the marking should be by reference to volume (mL or L). 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).

Specific requirements apply to the height of characters and positioning of measurement markings, depending on a variety of factors. It is, therefore, important to check the Regulations in each case.



Product recalls

Pursuant to the Food Code, manufacturers, wholesalers, distributors and importers of food must have in place a written product recall plan. In the event of a voluntary product recall, notification must be given to FSANZ, the home State/Territory coordinator, the ACCC and the Commonwealth Minister responsible for Consumer Affairs and Fair Trading.

Under the Australian Consumer Law, the ACCC has powers to issue recall notices in cases where:

- it appears that goods will or may cause injury to any person; or
- it appears that reasonably foreseeable use (including a misuse) of such goods will or may cause injury to any person; or
- a safety standard for such goods is in force and the goods do not comply with it; or
- an interim or permanent ban on such goods is in force; or
- it appears that one or more suppliers of such goods have not taken satisfactory action to prevent those goods causing injury to any person.

If a recall notice is issued by the ACCC, suppliers are required to take satisfactory action to prevent the recalled goods causing injury.

Where a food business decides to conduct a voluntary product recall because, for example, it appears that the food may cause injury to a person, it must notify the ACCC of the recall within two business days.

Food safety

Mandatory reporting

The Australian Consumer Law imposes a duty to report on food suppliers who become aware of the death or serious injury or illness of any person and consider that the death or serious injury or illness was caused, or may have been caused, by the use or foreseeable misuse of the relevant food; or become aware that a person (other than the supplier) considers that the death or serious injury or illness was caused or may have been caused by the use or foreseeable misuse of the food. The notice must be given to the ACCC within two days of becoming aware. As a general rule, if a consumer has sought medical advice from a doctor or other medical practitioner, the incident is likely to be reportable.

Legislation was previously proposed to limit such reporting to circumstances where the death or serious injury or illness was a result of food packaging and not food itself given that the requirement was seen to be duplicative and burdensome on industry. However, the future of this legislation remains unclear and mandatory reporting continues to apply to food.

Advertising claims (general)

Australian state and territory food legislation contains provisions which, in general terms, make it an offense to pack, label or advertise a food in a manner that is false, misleading or deceptive (e.g., sections 15 and 18 of the Food Act 2003 NSW). In addition, the Australian Consumer Law (ACL) contains a number of provisions that regulate advertising claims for foods, most notably:

- s18 prohibits a person, including a corporation, from engaging in misleading or deceptive conduct, or conduct that is likely to mislead or deceive, in trade or commerce;

- s29 prohibits a person, including a corporation, from making certain false or misleading representations in connection with the supply or possible supply of goods or services or in connection with the promotion by any means of the supply or use of goods or services; and
- s33 prohibits a person, including a corporation, from engaging in conduct that is liable to mislead the public as to the nature, manufacturing process, the characteristics, the suitability for their purpose or the quantity of any goods.

Examples of misleading conduct or representations in relation to food includes:

- stating that a food has been made in one country or place when in fact it has been made elsewhere;
- stating that a food has a particular certification or endorsement when it does not; and
- representing (whether through names or images) that a food contains certain ingredients when it does not.

Credence claims, e.g., organic, natural

Organic claims

There is no mandated regulatory system for organic products or organic food claims. Nor is there a uniform statutory definition of the term "organic." When making generic organic claims (e.g., 100% organic) or certified organic claims (e.g., "certified organic"), food businesses must not mislead or deceive or make false or misleading representations regarding the standard, quality, value, composition or characteristics of the food. In determining whether an organic claim is misleading or false, the ACCC may have regard to the non-mandatory AS6000-2009, Australian Standard for Organic and Biodynamic Products and the National Standard for Organic Biodynamic Produce.



Natural claims

There is no legal definition of "natural" in Australia. The question is, therefore, whether a "natural" claim in respect of a food is misleading or deceptive or likely to mislead or deceive bearing in mind the impression the reasonable consumer is likely to take away when they see such a claim on a food label. Generally speaking, ingredients of foods that are not derived from nature or that are submitted to processes that have significantly altered their original physical, chemical or biological state should not be described as "natural." In the case of multi-ingredient, processed foods, the level of processing permitted before a "natural" claim becomes misleading is the subject of debate.

Health rating schemes

There is a voluntary front-of-pack labeling system in Australia known as the Health Star Rating ("**HSR**") that rates the overall nutritional profile of packaged foods and assigns a rating between 0.5 (least healthy) and 5 stars (most healthy). The rating is determined in accordance with the HSR Calculator and FSANZ's Nutrition Profiling Scoring Criterion. The HSR considers the energy, saturated fat, sodium and total sugars content of a food along with other factors such as fruit and vegetable content, and in some instances, dietary fibre and protein content. Whether the HSR scheme will become mandatory for food manufacturers and retailers in the future is subject to debate. The Health Star Rating Style Guide is available [here](#).

The inclusion of foreign health ratings or logos on front-of-pack is not prohibited per se and will ultimately depend on the overall impression conveyed to the reasonable consumer and the criteria against which the foreign rating is determined.

Other

Not applicable.

LICENSING AND APPROVALS REQUIREMENTS TO IMPORT/EXPORT FOOD

SUMMARY OF LEGAL REGIME

Customs registration

To be an importer or exporter of record of any goods into Australia, a business needs to register as a client in the Integrated Cargo System ("ICS") maintained by the Australian Border Force ("**Customs**").

Non-resident entities can apply for registration with ICS and there is no need to have an Australian Business Number ("**ABN**").

Import permit

Whether or not an Import Permit is required depends on the identity of the food being imported. To the extent that any imported foods are regulated by the Department of Agriculture and Water Resources (which can be checked using the Department's online "biosecurity import conditions system"/BICON database), an import permit will be required in the name of the importer.

Commercial importers of fresh fruit and vegetables or foods containing milk, egg, meat or other animal products will certainly need to obtain an import permit prior to importing the food.

A non-resident may be the importer of record for a food import permit. Import permits typically take up to 20 working days to process.

Inspection of imported foods

Food entering Australia is subject to the Imported Food Control Act 1992 (Cth), which provides for the inspection and control of imported food using a risk-based border inspection program called the Imported Food Inspection Scheme ("**IFIS**"). FSANZ advises the Department of Agriculture and Water Resources of any foods that pose a medium-to-high risk to human health and safety. Such foods are categorized by the department as "risk foods" requiring a higher level of inspection and testing under the IFIS than low risk "surveillance foods."

Food importers that want to avoid costs and delays associated with inspection and testing under the IFIS may

enter into a food import compliance agreement ("**FICA**") with the Department of Agriculture and Water Resources under the Imported Food Control Act 1992. Under a FICA the importer's food management system for sourcing and importing foods is recognized, offering an alternative to the routine inspection and testing of food products under the IFIS. The importer's food management system is regularly audited by the Department of Agriculture and Water Resources. The audit frequency is determined by the type of food imported under the FICA and previous audit performance.

Under the Imported Food Control Act 1992, surveillance foods imported from New Zealand are exempt from the IFIS as these come under the Trans Tasman Mutual Recognition Arrangement ("**TTMRA**"). The only New Zealand foods that are subject to the IFIS at the border are those classified as "risk foods." Equivalence determination of food safety systems covering dairy products was reached in 2007 and seafood, uncooked pig meat, chicken meat, coconut, pepper, paprika, peanuts and pistachios were aligned in 2011. Accordingly, these foods form part of the TTMRA and there is no need for border inspection or testing of these products when being imported from New Zealand.



The Department of Agriculture and Water Resources has recently proposed a number of imported food reforms for public consultation. The measures are designed to increase importer accountability, increase importers sourcing safe food, improve the management of emerging risks and improve incident response. The reforms are also expected to align the Imported Food Control Act 1992 (Cth) with state and territory food legislation. The Imported Food Control Amendment Bill 2017 ("**Bill**") was put before the Australian parliament in June 2017. It is expected that the new Bill will become law at some time during the course of 2018, but food importers are expected to have 12 months to adjust their business practices to comply with any new supply chain assurance and traceability requirements.

Export permits/clearances

Export requirements differ depending on the product and destination country. The Department of Agriculture and Water Resources uses an online system for export permits (including for meat and dairy products) called EXDOC. The rules for this system state that "Only Australian companies and registered businesses are eligible to register as an EXDOC Exporter."

While the EXDOC registration process is uniform, the export rules differ between goods and destination, and are subject to change from time to time.

Other notifications/approvals/licenses

Importers and exporters of food and food ingredients may also be required to notify the local food authority in the state/territory in which their business is based of their activities. In NSW, for example, a food importer must notify the NSW Food Authority of its activities. The purpose of the notification regime is to enable the NSW Food Authority to maintain a relationship with all food businesses operating

in NSW. Once a food business has notified the NSW Food Authority of its activities by completing the relevant form, there is no requirement to wait for any approval before conducting a food business.

Certain food businesses in Australia are considered high risk and are, therefore, subject to additional licensing requirements under the applicable state/territory food legislation and regulations. In NSW, for example, it is not permissible to conduct a "food business" without a license from the NSW Food Authority. A "food business" for licensing purposes is defined very broadly in the Food Act 2003 ("**NSW**") and the Food Regulation 2015 ("**NSW**") and includes a dairy business, meat business, plant products business, seafood business, egg business and a vulnerable persons food business.

ENFORCEMENT

Enforcement authorities and key responsibilities

There are four main bodies/agencies responsible for enforcement of food-related laws in Australia:

1. Australian Competition and Consumer Commission ("**ACCC**")

The ACCC is an independent Commonwealth statutory authority. One of its key responsibilities is to ensure that businesses comply with the Australian Consumer Law ("**ACL**"). Achieving appropriate remedies for misleading and deceptive conduct is one of the compliance priorities of the ACCC. In particular, the ACCC has identified country of origin claims as one of its key priorities.

The ACCC has a broad range of enforcement powers. These include the power to issue substantiation notices requiring a person who has made a claim promoting the supply of goods

to provide information and/or produce documents that are capable of substantiating the claim made. Substantiation notices may be issued in relation to claims made in advertisements for any food or on the packages or labels of the products themselves. Substantiation notices must be complied with within 21 days of receipt.

2. National Measurements Institute ("**NMI**")

As of 1 July 2010, the NMI (created under the National Measurement Act 1960 (Cth)) has assumed responsibility for Australia's trade measurement system. The NMI acts as a national watchdog whose responsibilities include monitoring the accuracy of measurements and labeling on packaged foods.

3. Australian Border Force

Australian Customs Officers are in charge of examining cargo imported into, and exported from, Australia and to determine whether the goods comply with, among other things, the relevant provisions of the Imported Food Control Act 1992 (Cth), the Biosecurity Act 2015 (Cth) and the Commerce (Trade Descriptions) Regulations 2016 (Cth).

4. Local Food Authorities

Local food authorities in each state and territory are responsible for enforcing its local Food Act. Each state/territory's Food Act gives the national Food Code the force of law in that state/territory and prescribes both civil and criminal penalties for contraventions of the Food Code.

Generally speaking, the local food authorities are most concerned with contraventions of the Food Code that pose a risk to human health and/or safety.



Penalties for non-compliance

Pecuniary penalties for contraventions of the Australian Consumer Law are currently under review and can be expected to significantly increase during the course of 2018.

Section 18: misleading and deceptive conduct

- Action for damages may be taken by any person who suffers economic loss as a result of the conduct.

Sections 29 and 151: false or misleading representations

- Pecuniary penalty up to AUD 1.1 million for a corporation. Also, action for damages may be taken by any person who suffers economic loss as a result of the conduct.
- Criminal offense subject to a fine of up to AUD 1.1 million for a corporation

Sections 33 and 155: misleading conduct as to the nature of goods, etc.

- Pecuniary penalty up to AUD 1.1 million for a corporation. Also, action for damages may be taken by any person who suffers economic loss as a result of the conduct.
- Criminal offense subject to a fine of up to AUD 1.1 million for a corporation

Section 127: failure to comply with a recall order

- Pecuniary penalty up to AUD 1.1 million for a corporation

Section 202: failure to report consumer goods associated with the death or serious injury or illness of a person

- Criminal offense subject to a fine of up to AUD 16,650 for a corporation

Section 205: failure to comply with a substantiation notice

- Criminal offense subject to a fine of up to AUD 16,650 for a corporation

Section 206: providing false or misleading information in response to a substantiation notice

- Criminal offense subject to a fine of up to AUD 27,500 for a corporation

National Measurement Act 1960 (Cth)

Subdivision 2A, Division 2, Part VI: Failure to provide required package information

- Penalty: AUD 4,200 (strict liability offense) or AUD 21,000 (offense requiring intention)

Subdivision 2A, Division 2: Using prohibited expressions

- Penalty: AUD 8,400 (strict liability offense) or AUD 42,000 (offense requiring intention)

Imported Food Control Act 1992 (Cth)

Sections 8 and 8A: importation and labeling offenses

- Max penalty: imprisonment for up to 10 years

Commerce (Trade Descriptions) Act 1905 (Cth)

Section 9: importation of falsely marked goods

- Penalty: AUD 21,000

Section 12: intentionally exporting goods with a false trade description

- Criminal offense
- Penalty: conviction by fine not exceeding AUD 21,000

Local Food Acts and Regulations

Please see below for a summary of relevant penalties for contravention of the NSW Food Act 2003. Different penalties may apply in other states/territories.

Section 15: false description of food (if it is known that a consumer will or is likely to suffer physical harm)

- Maximum penalty: AUD 550,000 for a corporation

Section 18: misleading conduct relating to the sale of food

- Maximum penalty: AUD 275,000 for a corporation

Section 21: non-compliance with Food Code

- Maximum penalty: AUD 275,000 for a corporation



FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL REGIME

Overview

In China, food quality and integrity is governed by the *PRC Food Safety Law* (2015) and its implementing regulations. The *PRC Food Safety Law* sets out comprehensive statutory requirements governing the production, circulation, recall and import/export of food products in China.

Additional regulatory requirements apply to different stages of food safety.

- Food production is governed by the *Administrative Measures for Food Product Permits* (2017), issued by the China Food and Drug Administration (CFDA)*.
- *Due to a recent structural change, CFDA is now part of the State Administration for Market Regulation ("SAMR").
- Food trading is governed by the *Administrative Measures for Food Trading Permits* (2017), issued by the CFDA. The general measures apply to online food trading. In addition, the CFDA has further elaborated on certain aspects of internet-based food-related conducts in its *Measures of the Investigation and Punishment of Illegal Conducts Concerning Online Food Safety* (2016).
- Food import/export is governed by the *Administrative Measures for Food Safety in Importation and Exportation* (2011), issued by the PRC General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ).

Food products, including imported food products, must also comply with compulsory national standards on food safety. There are currently more than 200 compulsory standards

covering a variety of subject matters concerning food safety, such as additives, hygiene, labeling, examination, packaging, etc. For example, the use of additives and processing aids is governed by the compulsory national standards on food additives (**GB 2760-2014**). The use of vitamins, minerals and other nutritive substances is governed by the compulsory national standards on food nutritional additives (**GB 14880-2012**). These standards provide comprehensive requirements on food additives and nutritional additives allowed in China, including the type, maximum amount and source of the additives allowed in various food products.

Novel foods are additionally subject to the Administrative Measures for the Safety Review of New Food Materials (2013, revised in 2017), issued by the PRC National Health and Family Planning Commission (NHFPC)¹. New food materials are defined as materials that are not traditionally consumed in China, including (i) animals, plants and microorganisms; (ii) extracts from animals, plants and microorganisms; (iii) food materials obtained by changing the structure of food materials; and (iv) other newly developed food materials. New food materials must be approved by the NHFPC before they can be used in food products in China. If an imported food product contains food materials that are new in China, the materials must be approved as new food materials before the food product can be imported. Similar requirements also apply to the use of novel food additives and are set out in the Administrative Measures for New Food Additives (2010, revised in 2017).

In China, food products are regulated separately from drugs and biological products. As mentioned above, the statutory basis for food regulation is the *PRC Food Safety Law* (2015). In comparison, the statutory basis for drug and biological product regulation is the *PRC Drug Administration Law* (2015). Although both product types are administered by the same

agency, i.e., the China Food and Drug Administration (**CFDA**), food products are regulated by different CFDA departments from drugs and biological products.

The *PRC Food Safety Law* generally applies to different categories of food products. Additional regulations can apply depending on the specific food type:

- The revised *PRC Food Safety Law* (2015) provides additional requirements for special food products including health food, formula food for special medical use and infant formula. For example, the product formula of infant formula dairy products should be registered with the CFDA. Pursuant to this requirement, the CFDA has enacted the *Administrative Measures for Formula Registration of Infant Formula Dairy Products* (2016).
- Detailed implementing regulations may apply. For example, dairy products are governed by the *Regulations on the Supervision and Administration of Quality and Safety of Dairy Products* (2008). Imported dairy products are additionally governed by the *Administrative Measures on the Supervision of Inspection and Quarantine of Imported and Exported Dairy Products* (2013), issued by the AQSIQ. Food products should also comply with product-specific compulsory national safety standards, for example, GB 7101-2015 is applicable to all types of beverages.
- Food products should also comply with product-specific compulsory national safety standards, for example, GB 7101-2015 is applicable to all types of beverages.

Basic labeling requirements

In China, food labeling is governed by the *Administrative Measures of Food Labeling*. Pre-packaged food must also

¹ NHFPC has now become the National Health Commission of China pursuant to recent structural change.



meet the compulsory national standards on pre-packaged food labeling (**GB 7718-2011**) and pre-packaged food nutrition labeling (**GB 28050-2011**).

In summary, food labels should include the name of the food, the name, address and contact information of the manufacturer, the production date and the expiration date and the ingredient list. Specifically:

- (a) product name - the name must identify the true nature of the food product and comply with the prescribed naming convention;
- (b) the name and contact information of the manufacturer (which must be an entity able to take up full legal responsibility for the product); and
- (c) ingredients identified in descending order by volume/ amount, except for ingredients comprising less than 2% of all the ingredients. Food additives are further regulated by the compulsory national standards on food additives (**GB 2760-2011**) and need to be identified on labels by their commonly used names as indicated in GB 2760-2011, or by their functions with names or INS codes. If the product labels emphasize the addition or lack of a particular food additive, the amount of this food additive should be stated in the ingredient list.

For pre-packaged food products, the following requirements also apply:

- production date and expiration date;
- applicable food standards for producing the product;
- specification, net value of the food (e.g., if the food package contains multiple pre-packaged food products, the food product labels on the external package should state the specification of the smaller units, including the net value of each pre-packaged unit and the number of units);

- storage conditions;
- production license number; and
- other mandatory labeling contents required by laws, regulations or food safety standards.

All information on product labels should comply with the general requirement of being true and not misleading.

Nutritional information panel

Nutrition labeling for pre-packaged food should generally comply with the national standard for pre-packaged food nutritional labeling (**GB 28050-2011**). The nutrition labels should adopt one of the six types of box charts provided under GB 28050-2011 and indicate at least the amount of energy and key nutrients (protein, fat, carbohydrate and sodium), as well as the nutrition reference value (NRV). Below is a bilingual example provided by GB 28050-2011:

营养成分表 nutrition information		
项目/Items	每 100 克 (g) 或 100 毫升 (mL) 或每份 per 100 g/100 mL or per serving	营养素参考值 %/NRV %
能量/energy	千焦 (kJ)	%
蛋白质/protein	克 (g)	%
脂肪/fat	克 (g)	%
碳水化合物/carbohydrate	克 (g)	%
钠/sodium	毫克 (mg)	%

Pre-packaged food products for specific groups of consumers, such as babies and people with medical needs, are subject to separate nutrition labeling requirements under the national standard for pre-packaged food products for specific use labeling (**GB 13432-2013**). In addition to energy and key nutrients, the nutrition labels for these food products should also indicate the amount of required nutritive ingredients as set out in the respective product-specific national standard.

Language and legibility requirements

Food labels should be prominent and clear, with contrast colors in the background to facilitate identification.

When the food package has a surface area larger than 20 square centimeters, compulsory labeling contents should be at least 1.8 millimeters in height.

Simplified Chinese characters should be used on product labels. Foreign languages are allowed on food labels, provided that the contents in a foreign language match the Chinese contents and are not larger in font size than the corresponding Chinese contents. The above requirements do not apply to registered foreign language trademarks.

Country of origin labeling

Food labels should state the country of origin.

Genetically modified (GM) foods

Safety of GM food

Genetically modified food products are regulated by the Ministry of Agriculture (**MOA**). A "Safety Certificate for Genetically Modified Agricultural Organisms" is required when importing food products that are genetically modified.

A foreign manufacturer must apply to the relevant agricultural department, meet the following requirements, and pass a safety evaluation, in order to obtain a Safety Certificate:

- the country of origin has allowed the genetically modified materials for the same use in the market;



- the genetically modified materials have been demonstrated in the country of origin as not harmful to humans, animals and plants, microorganisms, or the ecological environment;
- the genetically modified materials have been tested in China by institutions entrusted by the MOA and it has been verified that no harm will result; and
- there are suitable safety regulations and control measures in place.
- When importing the food products, the foreign manufacturer or its import agent must declare the food products as genetically modified, provide the safety certificate to the local Quality and Technical Supervision Bureau (**QTS**, the local department of PRC General Administration of Quality Supervision, Inspection and Quarantine), and pass the compliance test conducted by the local QTS.

Labeling of GM food

Genetically modified foods should be clearly labeled if the products fall under the MOA's *Catalog of Agricultural Genetically Modified Organisms Subject to Labeling Requirements*:

- If a food product is genetically modified or contains genetically modified materials, the food label should state "Produced/processed from Genetically Modified (animal, plant, microorganism)" in Chinese.
- If a food product is processed from genetically modified materials but contains no genetically modified materials in the final product, it should state "Produced from Genetically Modified (animal, plant, microorganism), but the product no longer contains genetically modified ingredients" in Chinese.

Nutrition content claims and health claims

Claims about nutritional content for pre-packaged food products are regulated by compulsory national standard GB 28050-2011. This standard sets forth the content limits for claiming the presence, richness or absence of particular nutritional contents. For example, the reference value for protein is 60 g; a food product must contain at least 12 g protein/100 g in order to claim that the food product is "high/rich in protein."

In China, health foods are regulated separately from regular food products. Health food products must be registered or recorded with the CFDA or provincial-level FDA before entering the market. Whether registration or recordal is needed depends primarily on the ingredients and functional claims of the health food products, and for imported health food products, whether the products are first-time import.

Regular food products are not allowed to make health claims other than the claims allowed under GB 28050-2011. GB 28050-2011 provides an exclusive list of general health claims that are allowed for regular food products, for example "Calcium helps to make bones and teeth stronger."

Specific types of food products, e.g., food products for infants, may be subject to additional limitations on permitted claims.

Mandatory warnings and advisory statements

Food labels should contain cautionary statements in Chinese if the food products are known to be harmful to specific groups of consumers. For example, pre-packaged food products must identify the following ingredients in the ingredient list:

- wheat products containing gluten;
- shellfish and products containing it;

- fish products;
- egg products;
- peanut products;
- soy bean and products containing it;
- dairy products (including lactose); and
- nuts and products containing them.

If the production process may introduce the above ingredients into food products, it is preferable that the cautionary statement is included in close vicinity to the ingredient list.

Trade measurement markings

Food product labels must state the net value of the food products. If the food package contains multiple pre-packaged food products, the food product labels on the external package should state the specification of the smaller units, including the net value of each pre-packaged unit and the number of units.

In addition, pre-packaged food products must comply with the trade measurement requirements, which are compulsory national standards, set out in GB 7718-2011. For example, the net values of food products in liquid form should be expressed by volume in "L; mL" or by quality in "g; kg."

Product recalls

In China, food product recalls are governed by the relevant provisions of the *PRC Food Safety Law* and the *Administrative Measures for Food Recall* (2015), issued by the CFDA. Food recalls can be conducted voluntarily by the food manufacturer or ordered by the local FDA.



Upon learning that its food products have potential safety risks, food manufacturers should carry out a safety investigation and assessment. If the food products are confirmed to be unsafe, food manufacturers shall immediately cease production, recall food products already on the market, notify relevant business associates and consumers, and keep records of the recall and notifications. Manufacturers must handle the recalled food products appropriately to remove the harm (e.g., through destruction or remedial treatment) and report the recall and subsequent handling of the recalled food products to the local FDA. The recall process and subsequent effects are subject to ongoing monitoring and examination by the local FDA. A food manufacturer's failure to comply with the foregoing can result in reprimand or suspension of business.

Upon discovering instances of non-compliance with the food safety standards, food distributors and providers, including online traders, must immediately cease providing the food products, notify the relevant manufacturer, other business associates and consumers, and keep records of cessation of supply and notifications.

Food safety

To ensure the safety of food products, the *PRC Food Safety Law* imposes the following obligations on food businesses:

- to ensure that the production, processing, packaging and storage facilities are clean and suitable for the type and amount of food products;
- to have food safety specialists, administrative staff members and internal rules in place to ensure food safety. Food manufacturers are obliged to verify that the raw materials, additives and related products used in food production meet relevant food standards. Food manufacturers must keep records of the examination of raw materials, additives and food-related products. In

addition, food manufacturers must also establish product quality measures by testing and verifying the safety of food products sold. Food distributors are obliged to require and keep records of documents showing that the food manufacturers from whom they purchase the food products have a proper production license and that the food products meet relevant national standards;

- to avoid cross-contamination between food products and raw materials;
- to ensure the hygiene of food containers and packages;
- to ensure that the water used in food production meets the hygienic standards of drinking water; and
- to ensure the personal hygiene of production and circulation staff. In addition, employees in the food business must pass an annual physical examination.

Business operators in the food industry, including distributors, retailers or catering service providers, should establish and execute a recall system for problematic food products. When a food operator discovers that a food product fails to meet the relevant standards, it should immediately cease providing the product, seal the problematic products, inform the relevant trade partners and its consumers, keep records of the cessation of supply and any notification, and report the incident to the local administrative agency.

For online sales, providers of third-party platforms for online food trading shall examine the permits of food traders as required by relevant laws and report illegal activities to local authorities. Detailed food safety responsibilities for online food trading are set out in the CFDA's *Measures of the Investigation and Punishment of Illegal Conducts Concerning Online Food Safety* (2016).

Manufacturers of specific types of food products, e.g., baby formula, may be subject to additional food safety responsibilities.

Advertising claims (general)

In China, advertisements (including food advertising) are generally governed by the *PRC Advertising Law*. Under the *PRC Advertising Law*, advertisements cannot contain false information or deceive or mislead consumers. Advertisements cannot use superior or absolute descriptors, such as "the best," "No. 1," etc.

Specific types of food products, e.g., food products for infants, alcohol, etc. may be subject to additional prohibitions on advertising claims.

Food advertising is also governed by the *PRC Food Safety Law*. Food advertising cannot contain false or exaggerated claims. Nor can food advertising refer to the preventative or therapeutic effects of food products. Health food is regulated separately from regular food products and permitted claims are explicitly provided for under applicable regulations. Health foods are subject to product registration/recordal with the CFDA or local FDA, and health food advertising must be approved by local FDAs.

Food administrative agencies (including local FDAs) and food industry associations are prohibited from recommending any food products to consumers. Consumer associations are prohibited from recommending any food products for profit. If an individual (such as a celebrity), social group or any other organization recommends any food product to consumers in a false advertisement, the individual, social group or organization will be held jointly liable for damages suffered by consumers. Endorsement is prohibited for health food and drugs.

Credence claims, e.g., organic

Organic claims are governed by the *Administrative Measures for Organic Product Certification* (2015) issued by the PRC General Administration of Quality Supervision, Inspection and



Quarantine (**AQSIQ**). Under the measures, a food product cannot bear the word “ORGANIC,” its Chinese translation “You Ji in Chinese,” or any other words or logos that may mislead the public into believing that the food products are organic, *unless* an organic product certificate has been obtained. This requirement also applies to imported food products and the certificate must be obtained prior to the import.

An organic product certificate can be obtained by submitting an application and supporting materials to a certification institution approved by the PRC Certification and Accreditation Administration. A basic requirement is that the amount of organic ingredients in the food product should be no less than 95%.

China has another certification called “Green Food,” which certifies that the ecological environment, production and processing of the food products meet relevant requirements. The Green Food certification is a certification trademark, and its issuance is governed by the *Administrative Measures for Green Food Labeling* (2012) issued by the MOA.

Health rating schemes

China does not have a voluntary or mandatory labeling scheme with respect to health ratings. Claims about nutritional contents of pre-packaged food products are regulated by compulsory national standard (**GB 28050-2011**), which sets forth the content limits for claiming the presence, richness or absence of particular nutritional contents, and provides an exclusive list of permissible health claims.

While there is no explicit statutory prohibition against including foreign health rating scheme logos on products imported into China, this labeling may be risky in practice due

to potential misleading effects, as consumers may believe that these products are more beneficial to health compared to local products without such logos.

LICENSING AND APPROVALS REQUIREMENTS TO IMPORT/EXPORT FOOD

SUMMARY OF LEGAL REGIME

Customs registration

Food import and export is generally governed by the *PRC Food Safety Law*, its implementing regulations, and relevant PRC General Administration of Quality Supervision, Inspection and Quarantine (**AQSIQ**)² regulations. Foreign food manufacturers that import food products into China must be registered with the AQSIQ. In comparison, domestic food manufacturers that export food products from China only need to be recorded with the AQSIQ.

Besides foreign food manufacturers, import agents must be recorded with the AQSIQ. In other words, foreign food manufacturers should select recorded agents when importing food products into China.

For certain products, such as meat, seafood and dairy products, additional requirements may be applicable for import.

Import permit

An import permit is generally not required for food products, with the following exceptions:

- For food products that are within the *Merchandise Directory of Automatic Import Permit*, an automatic import permit is required before the food product can be imported into China. The Merchandise Directory is issued jointly by the Ministry of Commerce (**MOFCOM**) and the General Administration of Customs, and is updated annually. In 2017, food products for which automatic import permits are required include, for example, (i) beef, pork, lamb, chicken and related meat products; (ii) milk and milk powder products; (iii) soy bean and bean products; and (iv) canola seed products. Additional permits are required for importing state-operated food products, e.g., vegetable oil, sugar and grains.
- An import permit is required if no existing national standards apply to the food products to be imported. In order to obtain such a permit, the importer should apply to the national food standard technical examination institution and submit materials demonstrating the safety of the food product in question.

Inspection of imported foods

Imported food products are subject to compulsory inspection by local Entry-Exit Inspection and Quarantine Bureau (**CIQ**) at the port of entry. If the imported goods are qualified, the CIQ will issue a Certificate of Inspection for Goods Inward upon which Customs will release the imported foods.

If the food products are being imported into China for the first time, the importer should also provide relevant materials for label examination to ensure that the product labels comply with labeling standards in China.

² AQSIQ is currently being restructured, with its divisions for domestic quality supervision being incorporated into the newly established State Market Supervision Administration and its divisions for cross-border quality supervision being merged into the General Administration for Customs.



Export permits/clearances

An export permit is generally not required for food products, with the following exception:

- For food products that are within the **Merchandise Directory of Export Permit**, an export permit is required before the food products can be exported from China. The Merchandise Directory is issued jointly by the Ministry of Commerce (**MOFCOM**) and the General Administration of Customs, and is updated annually. In 2017, food products for which export permits are required include, for example, (i) corn and corn powder; (ii) wheat and wheat powder; (iii) rice and rice powder; and (iv) livestock (live or frozen meat products).

Other notifications/approvals/licenses

License is required for the production, trading and catering of food products, except for the sale of edible agricultural products. Online traders of food products should be recorded with the local FDA.

ENFORCEMENT

Enforcement authorities and key responsibilities

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

1. State Market Supervision Administration and its local bureaus

Responsible for monitoring and enforcing food safety at all levels across the supply chain in the domestic market, including food advertising.

2. General Administration of Customs and its local bureaus

Responsible for enforcing food-related laws and regulations at ports.

3. National Health Commission (NHFPC)

Responsible for evaluating food safety risks at the national level and issuing food safety standards.

Penalties for non-compliance

PRC Food Safety Law (2015)

Article 122: engage in food production/sale or food additive production activities without proper license.

Penalty:

- confiscate the tools, equipment and raw materials used in production;
- forfeit illegal profits; and
- fine of up to 20 times the value of the products.

Provide a party with a producing or selling facility or other facilitating conditions with the knowledge that the party is engaged in the above prohibited activities.

Penalty:

- forfeit illegal profits;

- fine of up to RMB 100,000; and
- hold jointly liable for damages caused to consumers.

Article 123: use materials or additives not approved in food products and sale of such food products; produce and sell food products for specific groups, the nutritional contents of which fail to meet the relevant food standards; produce or sell meat products that are not examined or which fail the examination; or produce and sell food products containing medicines.

Penalty:

- confiscate the tools, equipment and raw materials used in the production;
- forfeit illegal profits;
- fine of up to 30 times the value of the products;
- revoke food license; and
- detain the personnel and supervisor directly responsible for up to 15 days.

Provide a party with a production or selling facility or other facilitating conditions with the knowledge that the party is engaged in the above prohibited activities.

Penalty:

- forfeit illegal profits;
- fine of up to RMB 200,000; and
- hold jointly liable for damages caused to consumers.

Articles 124 and 129: refuse to recall food products after being ordered to do so; sell expired or unhygienic food products; produce food products that contain excessive ingredients harmful to human health, non-food materials,



excessive food additives or chemical ingredients other than food additives; produce or sell unregistered health food and food products for specific groups; use expired raw materials and food additives in production and sale of such food products; import food products, food additives and food-related products that fail to meet the relevant food standards in China; or export food products inconsistent with relevant regulations.

Penalty:

- confiscate the tools, equipment and raw materials used in the production;
- forfeit illegal profits;
- fine of up to 20 times the value of the products; and
- revoke food license.

Article 125: produce and sell food products and food additives contaminated by the package, the container or in transportation; produce and sell pre-packaged food products without proper labels; produce and sell genetically modified food products without proper labeling; or purchase and use raw food materials and food additives that fail to meet food safety standards.

Penalty:

- confiscate the tools, equipment and raw materials used in the production;
- forfeit illegal profits;
- fine of up to 10 times the value of the products;
- suspend operation; and
- revoke food license.

Articles 126 and 129: fail to examine raw materials and food additives purchased from third parties; fail to establish

and comply with food safety management systems; fail to establish and comply with record-keeping systems; fail to verify permits and relevant documents when purchasing from third parties; fail to establish a food incident response strategy; arrange for staff members with diseases or conditions that may contaminate food products to be in direct contact with food products; or fail to meet recordal requirements for health food and food products for specific groups.

Penalty:

- rectification and warning;
- forfeit illegal profits;
- fine of up to RMB 50,000;
- suspend operation; and
- revoke food license.

Article 128: fail to report and properly handle food safety incidents.

Penalty:

- rectification and warning;
- fine of up to RMB 500,000;
- suspend operation; and
- revoke food license.

Articles 130 and 131: providers of third-party platforms for offline and online food trading fail to comply with relevant requirements.

Penalty:

- rectification and warning;
- forfeit of illegal profits;

- fine of up to RMB 200,000;
- suspend operation; and
- revoke license.

Providers of third-party platforms for online food trading shall be jointly liable for damages caused to consumers.

PRC Advertising Law (2015)

Article 55: use false information in advertisements and deceive or mislead consumers.

Penalty:

- mandate corrective advertisements; and
- fine of up to five times the advertising expense.

Article 58: include a health claim in an advertisement for general food products or fail to comply with relevant requirements for health food advertisements.

Penalty:

- order suspension of illegal advertisements;
- mandate corrective advertisements;
- fine of up to five times the advertising expense; and
- revoke business license.



FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL REGIME

Overview

The basic food law in Hong Kong is set out in Part V of the Public Health and Municipal Services Ordinance (Cap. 132 of Laws of Hong Kong) ("**PHMSO**"). The main provisions cover general protection for food purchasers, offenses in connection with the sale of unfit food and adulterated food, composition and labeling of food, food hygiene, and seizure and destruction of unfit food. In particular, the PHMSO provides the general principle that any food sold or offered for sale should be fit for human consumption. It is also required that the food as offered or sold must also be of the nature, substance and quality demanded by the purchaser. All descriptions on food should be true and non-misleading as to nature, substance or quality.

In addition, the Food Safety Ordinance (Cap. 612) ("**FSO**") provides food safety control measures, including a registration scheme for food importers and food distributors, and a requirement for food traders to maintain proper records of the movement of food to enhance food traceability. It also empowers the authorities to make regulations for tightening import control on specific food types and orders to prohibit the import and supply of problematic foods, as well as to order the recall of such foods. Under the FSO, the Director of Food and Environmental Hygiene ("**DFEH**") has the power to make a food safety order prohibiting the import/supply of any food, or directing that any food be recalled, impounded, isolated, destroyed or otherwise disposed of. Under the FSO, food traders need to maintain proper records of food movement to enhance food traceability.

Specific regulations

Various secondary regulations under the PHMSO apply to specific categories of food products, such as:

- Colouring Matter in Food Regulations (Cap. 132H);
- Dried Milk Regulations (Cap. 132R);
- Sweeteners in Food Regulations (Cap. 132U);
- Food Adulteration (Metallic Contamination) Regulations (Cap. 132V);
- Food and Drugs (Composition and Labelling) Regulations (Cap. 132W);
- Frozen Confections Regulation (Cap. 132AC);
- Harmful Substances in Food Regulations (Cap. 132AF);
- Imported Game, Meat, Poultry and Eggs Regulations (Cap. 132AK);
- Milk Regulation (Cap. 132AQ);
- Mineral Oil in Food Regulations (Cap. 132AR); and
- Preservatives in Food Regulation (Cap. 132BD).

Pharmaceutical products

Pharmaceutical products are regulated separately. Depending on the composition and usage claims of a product, it may be classified as a "pharmaceutical product" (as opposed to a general food product) such that pharmaceutical registration is required under the Pharmacy and Poisons Ordinance (Cap. 138) ("**PPO**").

As a general remark, no medicinal claims (i.e., claims referring to the diagnosis or treatment of a specific disease or symptom) should be made in relation to food products, to avoid pharmaceutical classification.

Pursuant to the Guidance Notes on Classification of Products as "Pharmaceutical Products" under the Pharmacy and Poisons Ordinance (Cap. 138) ("**Guidance Notes**"), a product which the average consumer would regard as something to be eaten, drunk or chewed as part of his/her diet, for example, because of its taste, flavor or nutritional value, is unlikely to be classified as a pharmaceutical product unless it contains one or more ingredients generally regarded as a medicinal substance and indicative of a medical use. Whether a particular product falls within the definition of a "pharmaceutical product" is determined on a case-by-case basis, and product information including the product's composition, presentation, purpose and promotional material will be assessed.

It should be noted that, according to the Guidance Notes, vitamin products (except in injection form) are generally not considered pharmaceutical products unless they belong to certain categories in oral dose form, e.g., Vitamin A with a daily dose of not less than 10,000 I.U. Minerals (e.g., calcium, copper, iodine, iron, magnesium and zinc), except in injection form, are generally not regarded as "medicinal" and use of such substances in itself should not affect the classification of the product.

Basic labeling requirements

All pre-packaged food for sale in Hong Kong must comply with the requirements under the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) ("**FDR**"), which set out requirements on general labeling, nutrition labeling/claims, as well as on the composition of different categories of milk (e.g., skimmed milk, milk beverage, etc.).

The following information is required to be provided on the labels of pre-packaged food:

- name of the food;



- list of ingredients (in descending order of weight or volume determined as at the time of their use when the food was packaged)
 - o The presence of any of the eight listed substances known to cause allergies should be declared. These include cereals containing gluten; crustacea and crustacean products; eggs and egg products; fish and fish products; peanuts, soybeans and their products; milk and milk products (lactose included); tree nuts and nut products; and sulphite in concentrations of 10 parts per million or more.
 - o Any additives should be listed by both the functional class and the specific name or the identification number under the International Numbering System for Food Additives adopted by the Codex Alimentarius Commission.
- indication of "use by" or "best before" date (durability indication) in both Chinese and English, in the prescribed format;
- statement of special conditions for storage or instructions for use;
- name and address of manufacturer or packer (or otherwise in accordance with the requirements as stipulated in the FDR); and
- count, weight or volume of food.

Language and legibility requirements

Schedule 3 of the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) provides that:

- food labels can be in either English only, Chinese only, or both English and Chinese;

- durability indication must be in both English and Chinese; and
- the name of the food and list of ingredients must also be in both English and Chinese if both languages are used on the label.

In general, pre-packaged food must be "legibly marked or labeled" with the requisite information. If any brand name is used which would be likely to mislead a purchaser in any respect as to the nature of the food, such name or mark shall be immediately followed by the word "Brand" (牌子) or the letters "TM" (商標), as appropriate, printed in legible letters or characters of not less than 3 mm in height.

Specific requirements on the display of information apply for milk and cream products, frozen confections, tenderized meat and irradiated foods.

Country of origin labeling

Except for the requirement regarding the name and address of the manufacturer or packer, there is no general requirement for indicating the country of origin.

Genetically modified (GM) foods

Genetically modified foods are permitted in Hong Kong.

- The Guidelines on Voluntary Labeling of Genetically Modified (GM) Food ("**Guidelines**") issued by the Center for Food Safety ("**CFS**") of the Hong Kong Government set out the principles underlying the recommended approaches for GM food, and provide reference for the trader to make truthful and informative labels in a consumer-friendly manner.

The Guidelines are advisory in nature and not legally binding. The Guidelines state the following:

- Any food items with 5% or more GM materials in their respective food ingredient(s) should be labeled as "genetically modified" in parenthesis following the name of the food/food ingredient in the list of ingredients. Alternatively, the words "genetically modified" may appear in a prominent footnote to the list of ingredients, whereas the ingredient concerned would be marked with an asterisk "*". However, the font size of the footnote should be at least the same size as the list of ingredients.
- For any GM food with significant modifications that have taken place under the following conditions, the label should provide additional words in conjunction with the name of the food or food ingredients to inform consumers of the changed characteristics:
 - o the composition or nutritional value is significantly different from that of its conventional counterpart;
 - o the level of anti-nutritional factors or natural toxicants is significantly different from that in its conventional counterpart;
 - o the presence of an allergen that is not found in its conventional counterpart;
 - o the intended use of the food is significantly different from that of its conventional counterpart; or
 - o an animal gene has been introduced into food of plant origin.
- If any GM foods and their products of plant origin contain animal genes, additional information regarding the origin of the animal gene following the name of the food ingredient is recommended.



- "GM-free" and similar labels (e.g., GMO-free, free from GM ingredients, etc.) will give consumers the impression that the food products thus labeled are completely free of GM content. Since there is the possibility of unintentional mixing of GM and non-GM crops, a truly "GM free" status is very difficult to attain. Such absolute terms may, therefore, be misleading to consumers and are not recommended to be used.

Nutrition content claims and health claims

Nutrition content claims are subject to the conditions laid out in Schedule 5 of the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) ("FDR") and the Technical Guidance Notes on Nutrition Labeling and Nutrition Claims issued by the Center for Food Safety ("CFS") of the Food and Environmental Hygiene Department ("FEHD").

There are no specific regulations in relation to claims about the health benefits of foods. However, traders must ensure that, in addition to Part V of the Public Health and Municipal Services Ordinance (Cap. 132) ("PHMSO"), they comply with the Trade Descriptions Ordinance (Cap. 362), which prohibits false trade descriptions, false, misleading or incomplete information, false marks and misstatements in respect of goods and services. Therefore, any claims on the health benefits of foods must be capable of being substantiated.

Care must also be taken to ensure that health claims do not amount to medicinal claims that can lead to a pharmaceutical product classification, or are otherwise prohibited or restricted under the Undesirable Medical Advertisements Ordinance ("UMAO") (Cap. 231).

Mandatory warnings and advisory statements

Schedule 3 of the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) ("FDR") states that the list of

ingredients must declare whether any of the eight specified substances are present, which are known to cause allergies, namely cereals containing gluten; crustaceans and crustacean products; eggs and egg products; fish and fish products; peanuts, soybeans and their products; milk and milk products (lactose included); tree nuts and nut products; and sulphite in concentrations of 10 parts per million or more.

In addition, a statement of special conditions for storage or instructions for use should also be provided where necessary.

Trade measurement markings

There are no specific regulations governing trade measurement markings on foods.

However, Schedule 3 of the Food and Drugs (Composition and Labelling) Regulations (Cap. 132W) ("FDR") states that the net weight/net volume of pre-packaged food shall, as far as is practicable, be indicated in accordance with the Weights and Measures Ordinance (Cap. 68) or with the International System of Units set out in the First Schedule to the Metrication Ordinance (Cap. 214).

Product recalls

Any public officer authorized in writing by the Director of Food and Environmental Hygiene ("DFEH") has the power to examine/seize any food which he/she considers unfit for human consumption (Section 59 of Part V of the Public Health and Municipal Services Ordinance (Cap. 132) ("PHMSO")). Further, the DFEH may make a food safety order prohibiting the import/supply of food, or directing that a recall shall be made (Section 30 of the Food Safety Ordinance (Cap. 612) ("FSO")).

In most cases, food recalls are made on a voluntary basis by traders. The Center for Food Safety has issued Food Recall Guidelines, which provide that traders should complete a "Voluntary Food Recall Notification Form" with the DFEH

when making a product recall, and also inform the public of the recall. Traders should periodically report on the progress of the recall, and the Food and Environmental Hygiene Department ("FEHD") will assess the adequacy of the actions taken by the trader. After the recall is complete, traders shall submit a final report.

Food safety

The main obligations applicable to food businesses in order to ensure the safety of their food products are as follows:

- Section 50 of Part V of the Public Health and Municipal Services Ordinance (Cap. 132) ("PHMSO") – it is an offense for traders to:
 - o add any substance to food, use any substance as an ingredient in the preparation of food, abstract any constituent from food, or subject food to any other process or treatment, so as (in any such case) to render the food injurious to health, with the intention of selling the food for human consumption in that state; and
 - o sell food for human consumption that is rendered injurious to health by any operation described above.
- Section 54 of Part V of the PHMSO – it is an offense for traders to sell food intended for, but unfit for, human consumption, or any drug intended for use by humans but unfit for that purpose.

Hong Kong does not have a mandatory reporting regime for the reporting of illness or injury caused by the use or foreseeable misuse of foods.

The provisions of the Food Safety Ordinance (Cap. 612) ("FSO") are also relevant for ensuring food safety.



Advertising claims (general)

In Hong Kong, no single piece of legislation regulates advertising. Instead, there are various pieces of legislation related to advertising.

Under Part V of the Public Health and Municipal Services Ordinance (Cap. 132) ("**PHMSO**"), it is an offense to publish an advertisement that falsely describes food or is likely to mislead as to the nature, substance or quality of food. The Trade Descriptions Ordinance (Cap. 362) generally provides that descriptions/statements made with respect to a product being distributed and sold in Hong Kong must be true and not misleading and sets out particular offenses triggered by false trade descriptions or unacceptable trade practices.

There are also legally non-binding advertising standards that may apply, namely the Generic Code of Practice on Television Advertising Standards and the Radio Code of Practice on Advertising Standards. Both advertising standards contain rules that pertain to advertisements including claims relating to nutrition or dietary effects, as follows:

- claims of effects or treatment for conditions of health for which qualified medical attention or advice should reasonably be sought are not acceptable;
- specific claims for the nutritional value of food must be supported by sound scientific evidence and must not give a misleading impression of the nutritional or health benefits of the food as a whole;
- advertisements for dietary supplements, including vitamins or minerals, must not state or imply that they are necessary as additions to a balanced diet in order to avoid dietary deficiency or that they are the only means to enhance normal good health;
- no advertisements should encourage patterns of behavior which are prejudicial to health;

- advertisements making nutritional and dietary claims are required to comply with rules governing professional advice and support;
- the licensee must ensure that the advertisements which make claims relating to nutrition or dietary effects comply with all relevant legislation; and
- no advertisements for products, services and establishments which offer or provide treatment aimed at the achievement of weight loss or reduction of body fat are acceptable unless these advertisements state that their services/products are adjunct to having a balanced/healthy diet to achieve such effect.

Credence claims, e.g., organic, natural, fresh

There are no specific laws, regulations or standards applicable to natural claims or fresh claims. The general requirements under the Trade Descriptions Ordinance (Cap. 362) and Part V of the Public Health and Municipal Services Ordinance (Cap. 132) apply.

Hong Kong does not have a specific piece of legislation for organic certification. However, there are two independent organic certification bodies in Hong Kong: the Hong Kong Organic Resource Center and the Hong Kong Organic Certification Center.

Health rating schemes

Hong Kong currently does not have a health rating scheme.

The Center for Food Safety ("**CFS**") currently permits, as a matter of practice, foreign health rating scheme logos to be used on food products imported into Hong Kong in accordance with ratings received overseas.

The CFS generally only tests food products to confirm that they are fit for human consumption and to ensure that any

content claims (e.g., the amount of sugar present) are not false. The CFS does not currently have a policy of testing or verifying foreign health rating scheme logos used on imported food products.

Other

The Center for Food Safety ("**CFS**") intends to propose a regulatory framework to enhance the regulation of nutrition and health claims on formula products and infants and young children ("**IYC**") foods. The rationale is to better protect the health of IYC under the age of 36 months and to facilitate effective regulatory control over nutrition and health claims on formula products and IYC foods. This regulatory framework is currently in the consultation process.

In addition, there have been legislative proposals on the regulation of edible fats and oils and recycling of waste cooking oils. The Hong Kong Government intends to establish a statutory safety standard for edible fats and oils and to strengthen the regulation of edible fats and oils, which are manufactured locally and imported into and exported from Hong Kong, as well as strengthening the regulation of the recycling of waste cooking oils. A consultation document on this proposal was published in July 2015.

Further, the CFS proposes enhancing and updating the Food Adulteration (Metallic Contamination) Regulations (Cap. 132V), with a view to better protecting public health, facilitating effective regulation and promoting harmonization between local and international standards. The public consultation for this proposal was completed in September 2017, and the result of the public consultation was published in January 2018. A series of meetings have been arranged by the CFS since February 2018 to discuss with traders and other interested stakeholders technical issues related to the proposed amendments.



LICENSING AND APPROVALS REQUIREMENTS TO IMPORT/EXPORT FOOD

SUMMARY OF LEGAL REGIME

Customs registration

The Food Safety Ordinance (Cap. 612) ("**FSO**") requires any person who carries on a food importation or food distribution business to register with the Director of Food and Environmental Hygiene. An application for registration must identify the main food categories and food classifications of all food to be imported by the business or supplied wholesale by the business.

Import permit

There are specific legal requirements or administrative arrangements for the import of the following selected food items due to their perishable or high-risk nature:

- (a) game, meat and poultry;
- (b) milk and milk beverages;
- (c) frozen confections; and
- (d) marine products.

Other categories of food items are not subject to import permits and, generally, there is no food testing during Customs clearance.

Import of Mainland China chilled chickens into Hong Kong

- Importers who wish to import chilled chickens from Mainland China are required to obtain prior import permission from the Food and Environmental Hygiene Department ("**FEHD**").
- The chilled chickens must come from mainland processing plants approved by the FEHD.
- Chilled chickens must be transported by a vehicle which has been approved by the Director of Food and Environmental Hygiene ("**DFEH**").
- The FEHD can collect food samples at points of entry to the territory for various food safety analyses, including microbiological and chemical tests.
- The FEHD pledges to process applications for import of chilled chickens within five working days if all required details are available.

Import of milk and milk beverages

- The Milk Regulation (Cap. 132AQ) requires any milk or milk beverage to be imported into Hong Kong from a source of manufacture that has been approved by the DFEH.
- Before importing these food products into Hong Kong, importers need to apply to the Assistant Director (Food Surveillance and Control) of the FEHD in writing and provide the following information:
 - o the full name and address of the milk or milk beverage processing plant;
 - o the law of the country of origin governing the production of milk or milk beverages;
 - o empty containers of the milk or milk beverage with labels;

- o information on the heat treatment method of the milk or milk beverage and facilities, including production equipment and water supply, in the processing plant;
- o a certificate from an appropriate authority in the country of origin for the purpose of:
 - ▲ certifying the effectiveness and efficiency of the heat treatment method in pasteurizing or sterilizing the milk or milk beverage and that the products have been handled, processed and packed under hygienic conditions; and
 - ▲ showing the chemical and bacteriological quality of the products; and
- o a statement from the manufacturer confirming the approximate shelf life of the products.
- The FEHD is empowered to use special procedures for examining imported food. At present, when a milk or milk beverage consignment arrives and before its release, the products will be inspected and, if necessary, sampled by the FEHD. Upon the FEHD's satisfaction, a "release letter" will be issued to the importer.
- The FEHD pledges to process applications for approval of a source of manufacture within 12 working days, and issue "release letters" within 14 working days upon receipt of notification of arrival or actual arrival of consignments, whichever is later.

Import of frozen confections

- The Frozen Confections Regulation (Cap. 132AC) requires any frozen confection to be imported into Hong Kong from a source of manufacture that has been approved by the DFEH



- Before importing these food products into Hong Kong, importers need to apply to the Assistant Director (Food Surveillance and Control) of the FEHD in writing and provide the following information:
 - o the full name and address of the frozen confection processing plant;
 - o the law of the country of origin governing the production of frozen confections;
 - o empty containers or wrappers of the frozen confection with labels;
 - o information on the heat treatment method of the frozen confection and facilities, including production equipment and water supply, in the processing plant;
 - o a certificate from an appropriate authority in the country of origin for the purposes of:
 - ▲ certifying the effectiveness and efficiency of the heat treatment method in sterilizing the frozen confection and that the products have been handled, processed and packed under hygienic conditions; and
 - ▲ showing the chemical and bacteriological quality of the products; and
 - o details of ingredients, including coloring matters, stabilizers and sweetening agents, etc., and the amounts thereof in the frozen confection.
- The FEHD is empowered to use special procedures for examining imported food. At present, when a frozen confection consignment arrives and before its release, the products will be inspected and, if necessary, sampled by the FEHD. Upon the satisfaction of the FEHD, a "release letter" will be issued to the importer.

- The FEHD pledges to process applications for approval of a source of manufacture within 12 working days, and issue "release letters" within 21 working days upon receipt of notification of arrival or actual arrival of consignments, whichever is later.

Import of game, meat, poultry and eggs

- Under the Import and Export Ordinance (Cap. 60), import of frozen or chilled beef, mutton, pork and poultry is subject to import licensing control.
- The FEHD is responsible for issuing import licenses for these foods.
- The Imported Game, Meat, Poultry and Eggs Regulations (Cap. 132AK) ("**IGMPER**") require meat, poultry or eggs to be imported with a health certificate issued by an issuing entity recognized by the DFEH.
- If importers wish to import meat, poultry or eggs from a country where the issuing entity for issuing health certificates is yet to be recognized as an issuing entity, they should ask the relevant issuing entity or government to apply to the FEHD in writing.
- The import of meat, poultry or eggs accompanied by a health certificate issued by an issuing entity does not require prior approval of the FEHD.
- The FEHD requires all game, meat, poultry and eggs to be entered through Man Kam To checkpoint if the import is via land, or the International Airport of Hong Kong if the import is via air. At these checkpoints, the food concerned may be subject to inspection or sampling by the FEHD. If the import of game, meat or poultry is via sea, the importers may be required, if the circumstances warrant it, to keep the game, meat or poultry at a licensed cold store or a registered cold storage for inspection or sampling. If

the import of eggs is via sea, the importers shall report in writing with the relevant documents to the FEHD at least two working days before arrival of the consignment, and if the situation warrants it, the FEHD may require the importers to store the eggs in an appropriate place or deliver the eggs to the food control checkpoint of Kwai Chung Custom House for inspection or sampling for examination. If the result is satisfactory, the FEHD will issue a "release letter" to the importer.

- The FEHD pledges to process applications for the import of game and prohibited meat and import of transshipped meat, poultry or eggs within five working days.

Import of marine products

- Since marine products, being more prone to bacteriological or chemical contamination in the harvesting zone or handling process, are considered to be high-risk food items, the FEHD strongly encourages importers to obtain health certificates issued by health authorities of countries of origin to accompany their imports certifying that the marine products concerned are fit for human consumption.
- The FEHD is empowered to create special procedures for examining imported food. At present, when a consignment of marine products arrives at entry points in Hong Kong, it may be subject to inspection or sampling by the FEHD. If the importer concerned is not able to present a health certificate during inspection, the FEHD will take samples from the consignment for examination before its release.



Inspection of imported foods

Please refer to the section on "import permit" on foods that can be subject to inspection/testing.

Export permits/clearances

Generally, no export permits or clearances are required, unless the food is categorized as a "pharmaceutical product."

Foods of animal origin

- The Food of Animal Origin Unit under Veterinary Public Health Section is responsible for export certification for foods of animal origin.
- The Center for Food Safety ("CFS") is the competent authority to issue Health Certificates for Foods of Animal Origin for food products being exported to countries that require certificates during importation.

Other notifications/approvals/licenses

Food importers and food distributors must register with the Director of Food and Environmental Hygiene.

Food factories and premises such as restaurants, bakeries, fresh provision shops, frozen confection factories, milk factories and composite food shops are all required to obtain licenses from the Food and Environmental Hygiene Department ("FEHD").

The FEHD also issues permits for the sale of restricted foods, such as non-bottled drinks, frozen confections, milk and milk beverages, live fish, shell fish, etc.

Licenses are only issued to food premises if they conform to prescribed safety and hygiene standards.

ENFORCEMENT

Enforcement authorities and key responsibilities

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

1. Food and Environmental Hygiene Department (FEHD)

In general, the FEHD is responsible for enforcing the food legislation in Hong Kong.

The Center for Food Safety ("CFS") is one of three branches under the FEHD. The CFS monitors the safety of imported and locally produced food to ensure that food available for human consumption is wholesome, unadulterated and properly labeled. The CFS also aims to safeguard public health through testing and control of imported live food animals and to advise the public on risk management measures in relation to food and public health matters.

2. Customs & Excise Department

The objectives of the Customs & Excise Department are broad and include:

- to protect the Hong Kong Special Administrative Region against smuggling;
- to protect and collect revenue on dutiable goods;
- to detect and deter narcotics trafficking and abuse of narcotic drugs;
- to protect intellectual property rights;
- to protect consumer interests;

- to protect and facilitate legitimate trade and industry and to uphold Hong Kong's trading integrity; and
- to fulfil international obligations.

It should be noted that the *Trade Descriptions Ordinance* (Cap. 362) ("TDO") was amended on 19 July 2013 to extend the coverage of the TDO so as to prohibit specified unfair trade practices deployed by traders against consumers, including false trade descriptions of services, misleading omissions, aggressive commercial practices, bait advertising, bait-and-switch and wrongly accepting payment. The amendment of the TDO received widespread media attention. Thus, we believe that enforcement of the TDO is a current priority of the Customs & Excise Department.

Penalties for non-compliance

Part V of the Public Health and Municipal Services Ordinance (Cap. 132) ("PHMSO")

Section 50: offenses in connection with preparation and sale of adulterated food or drugs

- Maximum penalty of HKD 10,000 fine and three months' imprisonment

Section 54: offenses in connection with the sale, etc. of unfit food or drugs

- Maximum penalty of HKD 50,000 fine and six months' imprisonment

Section 61: false labeling and advertising of food or drugs

- Maximum penalty of HKD 50,000 fine and six months' imprisonment



Food and Drugs (Composition and Labeling) Regulations (Cap. 132W) ("FDR")

Regulation 5(1): offenses relating to the composition and labeling of food

- Maximum penalty of HKD 50,000 fine and six months' imprisonment

Food Safety Ordinance (Cap. 612) ("FSO")

Section 4: requirement for food importers to be registered

- Maximum penalty of HKD 50,000 fine and six months' imprisonment

Section 5: requirement for food distributors to be registered

- Maximum penalty of HKD 50,000 fine and six months' imprisonment

Section 21: record of local acquisition of food

- Maximum penalty of HKD 10,000 fine and three months' imprisonment

Section 22: record of acquisition of imported food

- Maximum penalty of HKD 10,000 fine and three months' imprisonment

Section 24: record of wholesale supply of food

- Maximum penalty of HKD 10,000 fine and three months' imprisonment

Section 32: contravention of food safety orders

- Maximum penalty of HKD 100,000 fine and one year's imprisonment

Trade Descriptions Ordinance (Cap. 362) ("TDO")

Offenses in respect of trade descriptions of goods

- On conviction on indictment, a fine of HKD 500,000 and imprisonment for five years
- On summary conviction, a fine of HKD 100,000 and imprisonment for two years



FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL REGIME

Overview

The regulation of food in Indonesia is governed by Law No. 18/2012 on Food ("**Food Law**"). The quality of food is specifically governed by Government Regulation No. 28/2004 on Food Safety, Quality, and Nutrition ("**GR 28**"). It should be noted, however, that bureaucracy in Indonesia has wide-ranging discretion in applying these laws and can change policy from time to time, often without public notice.

The term "food" is defined in the Food Law as anything that comes from biological sources of agricultural products, plantations, forestry, fisheries, farms, or marine or water environments, whether processed or unprocessed, which is used as food or drink for human consumption. This can also include additional ingredients for food, raw materials in food and any other material that is used in the preparation, processing and/or manufacture of food or drink.

GR 28 regulates the sanitation of food, additional ingredients that can be added to food, genetically modified foods, food irradiation, food packaging, food guarantees, laboratory analysis, contaminated food, food quality, food quality certification, food nutrition, importation of food, exportation of food, supervision of food, and public participation in the supervision of food.

Medicines/therapeutic goods are regulated separately to food. Foods are regulated under the Food Law, while medicine/therapeutic goods are regulated under Law No. 36/2009 on Health and its implementing regulations. However, both of these goods are supervised by the same agency, i.e., the Food & Drugs Supervisory Agency ("**BPOM**").

In addition to the Food Law, some foods are subject to additional regulation. For example, alcoholic beverages are regulated under President Regulation No. 74/2013 on the Alcoholic Beverages Control and Supervision.

Businesses that distribute food in Indonesia are also subject to Law No. 8/1999 on Consumer Protection ("**Consumer Protection Law**") and Law No. 7/2014 on Trade ("**Trade Law**"). The Consumer Protection Law generally requires businesses in Indonesia to act truthfully and to follow regulatory standards. The Trade Law may impose mandatory national quality standards on food products and how they are manufactured/produced.

Law No. 33/2014 on Halal Assurance ("**Halal Law**") requires halal certification for consumer products in general, including foods and beverages. Prior to this law, halal certification was optional, not mandatory. At the time this guide was written, the implementing regulations of this Law had not been issued, but if it does become fully implemented, we should see all food and beverage products being required to go through the halal certification process.

Basic labeling requirements

Specific labeling requirements are stipulated under Government Regulation No. 69/1999 on Food Labels and Advertisement ("**GR 69**"). According to GR 69, anybody producing or importing packaged food into Indonesia for trade must label food as part of the food packaging. The label must set out relevant information on the food, and must contain, at least, the following details:

- (a) the name of the product;
- (b) a list of materials used;

- (c) the net weight or net content;
- (d) the name and address of the manufacturing party or importer; and
- (e) the date of expiration.

The details on labels shall be written or printed in using the Indonesian language, using Arabic figures and Latin letters. These letters shall be clear and easy to read.

Labeling of ingredients

Information regarding the ingredients used in the production process must be mentioned on labels in the form of a list, beginning with the ingredient which has the largest proportion. This does not apply to vitamins, minerals, and other nutritional supplements.

Information on nutritional content

Information on the nutritional content of food shall be provided on the food label. Where applicable, this is to be accompanied by a declaration of any vitamins, minerals and/or other kinds of nutritional supplement present in the food. Nutritional content information shall be contained in the following order:

- total volume of energy, with specifications based on amounts of energy derived from fat, protein and carbohydrates; and
- total volume of fat, saturated fat, cholesterol, carbohydrates, fiber, sugar, protein, vitamins and minerals.



Nutrition information panel

Head of BPOM Regulation No. HK.00.06.51.0475 on Guidelines on Inclusion of the Nutrition Information in the Label as amended by Head of BPOM Regulation No. HK.03.1.23.11.11.09605 of 2011 ("**Guidelines on Nutrition Label Regulation**") requires that nutrition value information must be included in accordance with the format set out in Guidelines on Nutrition Label Regulation.

The abovementioned regulation sets out different panel formats for different types of packaging and food and beverage products but, in general, the required panel consists of three parts:

- The first part contains the wording "Nutrition Value Information" and information on the serving size and number of servings per package.
- The second part presents information pertaining to the nutrient content. The size of the units listed for each nutrient is divided into three sub-sections and begins with the sentence "Amount Per Serving." The first sub-section contains information pertaining to energy. The second sub-section contains information pertaining to fat, protein, carbohydrate and sodium. The third sub-section contains information pertaining to other vitamins and minerals.
- The third part is a footnote stating that the percentage calculation of the Nutrition Adequacy Figures (Angka Kecukupan Gizi) is based on 2,000 kilocalories (kcal) of energy and the needs of each person may vary.

Language and legibility requirements

Based on GR 69, the details in labels shall be written or printed in the Indonesian language, using Arabic figures and Latin letters. The letters and figures contained in labels shall be clear and easy to read. The main part of labels, which

contains the name of the product, the net weight or net content, and the name and address of the party producing or importing the food into Indonesia, must be arranged in an orderly, not crowded, manner, and clearly placed in an easily readable position. The use of backgrounds, in the form of pictures, colors and/or other decoration that may obscure the writing in the main part of the label, is prohibited.

GR 69 specifically regulates that the size of font must be equal to or greater than the "o" lowercase on Arial font with the minimum size of 1 mm (Arial 6 point).

Country of origin labeling

If food is imported from outside Indonesia, in addition to the name and address of the foreign manufacturer, the name and address of the importing party shall be declared on the label.

Genetically modified (GM) foods

Genetically modified foods are permitted in Indonesia. Based on GR 69, anyone who uses raw materials, food additives and/or other auxiliary materials resulting from genetic engineering in the production of food shall examine the safety of its food first before distribution. The phrase "Genetically Engineered Food" shall be contained on the labels of food resulting from genetic engineering. Where food produced from genetically engineered products is used as an ingredient in other food products, information on the genetically engineered ingredients shall be enough.

Specifically, genetically modified foods are regulated under BPOM Regulation No. HK.03.1.23.03.12.1563 Year 2012 on the Security Assessment of the Genetically Modified Foods as amended by Head of BPOM Regulation No. 19/2016 ("**Genetically Modified Food Regulation**"). Under the

Genetically Modified Food Regulation, all genetically modified food, both produced in Indonesia or imported to Indonesia, must be assessed by the Commission of Biological Genetically Modified Product Safety and approved by the Head of BPOM before being distributed. Based on the Genetically Modified Food Regulation, the assessment period until the issuance of approval from the Head of BPOM would take approximately three months after the Commission of Biological Genetically Modified Product Safety has received the complete documents. However, in practice it may take longer.

In practice, the licensing of genetically modified foods is still at an early stage. Few products have passed the assessment and the assessment process is not very well established.

Nutrition content claims and health claims

Based on GR 69, all food that contains vitamins, minerals and/or other kinds of nutritional supplements must state the presence of such products on the label of the food. Furthermore, under the Ministry of Health Regulation No. 30/2013 on the Inclusion of Information regarding Sugar, Salt and Fat Contents and Healthy Claims for Processed Foods and Fast Foods, anyone who produces processed food for trade must provide the sugar, salt and/or fat and other health information on the food label. Similarly, everyone who produces fast food must also provide the salt, sugar and/or fat information through media and promotion.

Nutrition content and health claims are regulated under BPOM Regulation No. HK.03.1.23.11.11.09909 on the Supervisory Claim in Processed Food Label and Advertisement as amended by Head of BPOM Regulation No. 13 of 2016, which has been further updated by Head of BPOM Regulation No. 5 of 2017 ("**Nutrition Content and Health Claims Regulation**"). Under the Nutrition Content and Health Claims Regulation,



every nutrition and health claim on food must be in accordance with the criteria set out under the Nutrition Content and Health Claims Regulation.

Permissible nutrition content claims are claims regarding energy, protein, carbohydrates, fat, vitamins and minerals, and their derivatives, as set out in the Nutrition Label Reference. Permissible health claims include nutrition function claims, other function claims, and claims as to the decline of risk of disease.

If a manufacturer or the distributor wishes to make nutrition content and/or health claims that differ from those permitted under the Nutrition Content and Health Claims Regulation, the manufacturer or the distributor must submit them to BPOM for review. The assessment period until the issuance of approval from the Head of BPOM would take approximately six months after the BPOM has received the complete documents. However, in practice it may take longer.

Mandatory warnings and advisory statements

The following are major warning and advisory statements required by Indonesian food laws and regulations:

- The words "Irradiated Food" must be contained on labels of food that is subject to irradiation treatment. In the case of foods not allowed to be irradiated again, the words "Not to be Irradiated" must also be contained.
- The words "Genetically Engineered Food" shall be written on the labels of food resulting from genetic engineering.
- Information on labels for processed food for infants, children below five, pregnant or breast-feeding mothers, people on special diets, the elderly and those who suffer from specific diseases must contain information on the allocation, method of use and/or other necessary instructions including any health impact of the food.

Trade measurement markings

Under GR 69, all food sold must contain the following trade measurement markings:

- measurement of content for liquid food must be in milliliters (ml or mL) or liters (l or L);
- measurement of weight for solid food must be in milligrams (mg), grams (g) or kilograms (kg); and
- measurement of content or weight for semi-solid or thick food can be in milligrams (mg), grams (g), kilograms (kg), milliliters (ml or mL) or liters (l or L).

Product recalls

The Consumer Protection Law requires businesses to recall goods that are not in accordance with mandatory standards.

Recalls may be required at a national level by BPOM as an administrative sanction. On a local level, recalls may be ordered by the Governor, Regent/Mayor or the Head of BPOM. Recalled products are required to be destroyed to ensure that the product is not consumed. Voluntary recall is allowed subject to reporting to the Ministry of Trade and BPOM.

Head of BPOM Regulation No. 22/2017 on Food Recall from Distribution ("Food Recall Regulation") states that food that has been recalled from distribution by the producer, importer and/or distributor must be followed up by the Head of BPOM with these actions (i) removal of the food and/or label, (ii) use for something other than human consumption, (iii) reprocess, (iv) re-labeling, and (v) return to suppliers, especially for imported food.

If the producer, importer and/or distributor cannot comply with the product recall requirement as stated under the Food Recall Regulation, they may be subject to administrative sanctions, i.e., a written warning, temporary

suspension of activities, revocation of distribution license and/or termination of registration or certification services at the latest six months.

Product recalls are also regulated under the Ministry of Industry Regulation No. 75/M-IND/PER/7/2010 on Good Manufacturing Practices for Processed Food ("**MOI Regulation No. 75**").

Under MOI Regulation No. 75, product recalls can be carried out by the company if the products are suspected to be the cause of illness or food poisoning. The company must also withdraw other products from the market that are manufactured in the same conditions as the products that are suspected to cause illness or food poisoning. The public must also be informed of the possibility that foods, which may cause illness or food poisoning, are still being sold on the market.

Food safety

Mandatory reporting

If a person finds that someone has been poisoned as a result of contaminated food, they must report this to the nearest medical service unit. The medical service unit must promptly take action to ensure the safety of the victim. If the medical service unit finds that there is an indication of an extraordinary condition of food toxicity, the medical service unit must promptly take samples of the food allegedly causing the toxicity. The medical service unit must also report the event to the regent/municipal service that is in charge of health affairs, and to BPOM.

There is no specific regulation requiring importers or manufacturers to immediately report incidents of illness to BPOM, but this action is advisable to establish that the company is acting in good faith.



Advertising claims (general)

The Consumer Protection Law provides a general requirement for advertising to be truthful and not misleading. The same is required in relation to advertising for food products pursuant to the Food Law.

Based on GR 69, all advertisements for traded food shall contain true statements, and shall represent all mandatory information on the food label. The regulation also stipulates that every advertisement for food shall not contravene the norms of decency and public order.

Credence claims, e.g., organic, natural, fresh

Organic

Organic food is regulated under BPOM Regulation No. HK.00.06.52.0100 Year 2008 on the Supervision of Organic Process Food as amended by Head of BPOM Regulation No. 1 of 2017 ("**Organic Process Food Regulation**"). Processed food that already meets the requirements of organic processed food as stipulated in the Organic Process Food Regulation can be described as "Organic" and use the organic logo on the label and in advertising.

Fresh

GR 69 stipulates that "fresh" claims can only be used in respect of unprocessed foods unless the processing does not affect the nature and contents of the processed food.

Health rating schemes

There are no officially sanctioned health rating schemes under current food-related regulations. Please note that such ratings could be regarded as a claim and that Head of BPOM Regulation No. 12/2016 on Registration of Processed Food as amended by Head of BPOM Regulation No. 27/2017 ("Processed Food Registration Regulation") prohibits statements on the food label that state that processed food can be healthy.

Other

Halal certification

The Halal Law requires all "products" that are imported, distributed and traded within the Indonesian territory to be halal certified ("Halal Certification Requirement"). The Halal Certification Requirement will only come into effect five years after the Halal Law is enacted (i.e., 17 October 2019). Prior to that date, halal certification will be complied with by business actors on a "voluntary" basis.

The Halal Law also required the Halal Product Assurance Implementing Board (Badan Penyelenggara Jaminan Produk Halal or "BPJPH"), which is under the Ministry of Religious Affairs, to be established within three years of 17 October 2014 (i.e., 17 October 2017). BPJPH has been established. However, BPJPH is not fully ready yet to start its operation in handling halal certification applications. BPJPH will start handling halal certification by the statutory deadline to comply with the halal certification, which is 17 October 2019. Therefore, until 17 October 2019, the halal certification will still be handled by MUI using the "old model" certification process that applied before the issuance of the Halal Law.

The Halal Law provides that the non-halal declaration must be made on products, which utilize non-halal materials. It is still unclear whether the use of the materials, which are obviously non-halal (e.g., pork or alcohol) will require business actors to simply declare the name of the materials on the product's labeling or if another declaration that the product is non-halal must also be made on the labeling of the product.

Risk management programs for food industry

The Head of BPOM has issued Regulation No. 2/2017 on the Implementation of Risk Management Programs for Food Safety Within the Food Industry ("**Risk Management Program Regulation**") in order to improve the internal monitoring of the following food industries:

1. infant formula (i.e., formula for newborns babies of up to six months of age);
2. toddler formula (i.e., formula for babies of between six and 12 months of age);
3. growth formula (i.e., formula for babies of between 12 and 36 months of age); and
4. commercial sterilized food.

The Risk Management Program Regulation redefines guidelines for businesses which are engaged in the production of any of the abovementioned food products ("Producers") as regards their compliance with the mandatory obligation to implement risk management programs (program manajemen risiko – "**PMR**"). Previously, similar guidelines were regulated under Head of BPOM Regulation No. 14 of 2015 on the Implementation of Risk Management Program for the Food Safety of Infant Formula, Toddler Formula and Growth Formula.



In order to prove that they have implemented a PMR, Producers are required to secure PMR certificates from the Head of BPOM. This certificate remains valid for five years and must be extended for as long as Producers are still producing the relevant food products, provided that:

1. all applications for extensions are submitted within one month (maximum) of a certificate's date of expiry; and
2. a PMR certificate is only valid for one production facility if the Producers in question own more than one such facility.

LICENSING AND APPROVALS REQUIREMENTS TO IMPORT/EXPORT FOOD

SUMMARY OF LEGAL REGIME

Customs registration

Certain commodities, e.g., horticultural products, are subject to a specific import registration under MOT Regulation No. 30, as amended.

Special import registrations are also applied, from time to time, on the import of certain commodities, usually staple products such as rice, sugar and milk. The importation of foods is specifically regulated under Head of BPOM Regulation No. 27/2013 on the Supervision of Food and Drugs Importation to Indonesia which was further amended several times by Head of BPOM Regulation No. 12 of 2015 and Head of BPOM Regulation No. 25 of 2016 and recently changed to become Regulation No. 4 of 2017 on the Supervision of Imports of Drugs and Food into Indonesia ("Supervision of Import Food Regulation"). Under this regulation, the only processed food that can be imported into Indonesia is food that already has a Market Authorization Permit. In addition to this, the importer must obtain an approval from the Head of BPOM in the form of an Import Information Letter ("SKI").

Import permit

Registration of imported processed foods

BPOM requires the registration of domestically produced processed foods and imported processed foods. Imported processed foods can specifically be registered by their relevant importers or distributors, provided that they satisfy the following conditions:

1. must be in possession of the relevant food import or distribution licenses;
2. must be in possession of a designation letter (in the form of an agreement), as drawn up by the relevant exporting companies in the countries of origin; and
3. must comply with good distribution practices that meet the requirements of the relevant foods.

It is important to note that, if any disputes arise, the registration process may only be completed after the relevant dispute has been settled in the case of designation letters which are specifically non-exclusive in nature.

The abovementioned dispute provision was not previously addressed under Regulation No. 12/2016 on Registration of Processed Food.

Import permit

Furthermore, all imports of food and drugs into Indonesia are still required to comply with the relevant applicable laws and regulations which relate to imports (e.g., Ministry of Trade Regulation No. 48/M-DAG/PER/7/2015 on General Provisions within the Import Sector), as well as with the following requirements.

In order to import food, a business must hold a SKI from the Head of BPOM. The SKI is obtained through an online

application system set by BPOM. After completing all of the required documents, BPOM will evaluate all of the required documents and decide whether or not to grant the SKI. The SKI will be issued one working day after all of the required documents are completed. All imported food and drugs must satisfy the relevant shelf life (masa simpan) requirements. Under Ministry of Trade Regulation No. 30/M-DAG/PER/5/2012, the Provisions for the Importation of Horticultural Products, as amended by MOT Regulation No. 116/M-DAG/PER/4/2013 ("MOT Regulation No. 30"), all importation of horticultural products can only be carried out by a company that has already obtained recognition as Producers or Importers of Horticultural Products, or has gained appointment as a Specific Importer for Horticultural Products from the Minister. The full list of applicable horticultural products is set out in Attachment 1 of MOT Regulation No. 16 and its amendments.

Circulation licensing

The Processed Food Registration Regulation now provides provisions relating to Circulation Licenses. In principle, companies are first required to secure a circulation license from the head of BPOM prior to engaging in the trade of either domestically produced or imported processed foods.

In addition to its commercial function, possession of a circulation license is also necessary for the following food products:

1. food fortifications;
2. foods which adhere to the mandatory Indonesian National Standards (Standar Nasional Indonesia – "SNI");
3. foods from governmental programs;
4. foods for market testing; and
5. food additives.



The abovementioned provision was not previously regulated.

Furthermore, the BPOM has also added two new categories of food product which are exempted from the circulation license requirement, and thus the complete list of exempted processed foods now reads as follows:

1. processed foods produced by home industries;
2. processed foods which have less than seven days of shelf life;
3. fast food; and
4. foods which have undergone minimum processing, which do not contain any food additives (with the exception of waxing), specifically: 1) Washing, 2) Peeling, 3) Drying, 4) Milling, 5) Cutting, 6) Salting, 7) Freezing, 8) Mixing, and/or 9) Pre-heating (blansir), and so forth.

Numbers (3) and (4) above were not incorporated under the previous framework.

Export/permits clearance

Unlike the importation of food, food exports generally do not require a specific permit. However, in some cases, the export destination country may require the exporter to provide specific documents, such as health certificates or certificates of free sale. Please note that from time to time the tax office may impose a specific tax for exported foods.

It should be noted that, under the Food Law, the government may restrict the export of certain commodities (usually staple foods) to protect domestic supply, e.g., by requiring the payment of an export duty or requiring the exporter to obtain a specific permit.

Other notifications/approvals/licenses

Besides complying with the applicable BPOM Regulations, all imported food in Indonesia must also comply with regular custom regulations. Generally speaking, manufacturers are allowed to import food products as inputs for producing other goods only. Traders are allowed to import food products for resale only.

ENFORCEMENT

Enforcement authorities and key responsibilities

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

1. Food & Drugs Supervisory Agency ("BPOM")

BPOM is an institution in Indonesia that oversees the distribution of medicines and food in Indonesia. BPOM's main responsibilities are to conduct assessments and formulate national policies in the areas of drug and food supervision. BPOM is also tasked with the implementation of specific policies in the field of food and drugs supervision.

BPOM priorities are to have an effective and efficient drug and food control system in order to protect consumer security and health in Indonesia and overseas.

2. Directorate General of Standardization and Consumer Protection – Ministry of Trade ("DJSPK")

The main job of the DJSPK is to formulate and implement policy in the field of standardization and consumer protection, as well as to develop guidelines, norms, standards, procedures and criteria in the field of standardization and consumer protection.

Penalties for non-compliance

GR 28

Article 47: violation in the field of processed food

- Administrative action such as a written warning, a temporary prohibition on distribution, an order to recall the food from the market, food extermination if it is proven that the food endangers health and life, temporary cessation of production, imposition of a fine of maximum IDR 50 million and/or revocation of production licenses, business licenses or production approvals.

Supervision of Import Food Regulation

Article 24: every violation of Supervision of Import Food Regulation

- Administrative sanction, such as a written warning, suspension of importation or distribution, extermination or re-exportation, suspension or revocation of Market Authorization Permit.

Process Food Regulation

Article 39: violation of process food regulations

- Administrative sanction such as written warning, prohibition to distribute, suspension of activities, revocation of Registration License.



The Food Law

Article 144: production of Processed Food without implementing the Food Processing procedure, causing the decline or loss of the food nutrition of raw materials

- Imprisonment for one year or fine of not more than IDR 2 billion.

Article 135: any business that organizes the manufacture, storage, transportation or distribution of foods that do not meet the requirements of food sanitation as set by the Food Law

- Imprisonment for two years or a maximum fine of IDR 4 billion.

Article 136: deliberate addition of food additives that exceed the maximum specified limits, or use of prohibited materials

- Imprisonment for five years or a fine of IDR 10 billion.

Article 137: any business that produces food using Genetically Engineered Ingredients without obtaining any safety approval, or produces Processed Food using raw materials, food additives and/or other materials produced from genetically engineered food without any approval

- Imprisonment for five years or a fine of IDR 10 billion.

Breach of Article 139: use of food packaging that endangers human health

- Imprisonment for two years or a maximum fine of IDR 4 billion.

Article 140: food does not meet the Food Safety standards

- Imprisonment for two years or a fine of IDR 4 billion.

Article 142: does not have a Market Authorization Permit

- Imprisonment for two years or a maximum fine of IDR 4 billion.

Article 143: deletes, removes, covers or replaces the labels and/or changes the date, month, year of food expiration

- Imprisonment for two years or a maximum fine of IDR 4 billion.

Article 144: giving misleading information or statements on food labels

- Imprisonment for three years or a maximum fine of IDR 6 billion.

Article 145: giving misleading information or statements regarding food through advertising

- Imprisonment for three years or a maximum fine of IDR 6 billion.

Consumer Protection Law

Article 62: to produce or sell food that is not in accordance with what is written on the label or failing to declare information regarding the expiration date, or to sell damaged, defective or contaminated food

- Imprisonment for five years or a maximum fine of IDR 2 billion.

Article 62(2): close out sales to deceive/mislead consumers by raising prices before the sales; not fulfilling orders, and not including food risks in advertisements

- Imprisonment for two years or a maximum fine of IDR 500 million.



FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL REGIME

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 sodium). 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 declared as long as they are based on scientific evidence.

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 recall

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

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.



LICENSING AND APPROVALS REQUIREMENTS TO IMPORT/EXPORT FOOD

SUMMARY OF LEGAL REGIME

Customs registration

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

Import permit

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

The main obstacle to obtaining the permit is the food inspection.

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 MHLW as prescribed by ministerial ordinance under the FSA. During document examination by the quarantine station, the food sanitation inspector validates facts such as (i) whether

the imported food, etc. complies with the manufacturing standards regulated under the 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 information such as the country of export, imported items, manufacturer, the place of manufacture, ingredients and materials, methods of manufacture and use of additives.

If, as a result of the document examination, the food sanitation inspector judges that 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 next section) will be carried out in order to confirm whether 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 of 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 air freight.

Inspection 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 the cargo's compliance with the 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 very likely to violate the FSA, the MHLW will issue an inspection order and suspend the import procedure until the food, etc. 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 disclosed to the public every year.
- 2. Monitoring Inspection System:** "Monitoring inspections" are carried out at the Ministry of Health, Labor 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 to 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 the sanitary status of diverse food items that are brought into Japan as well as to promote the smooth distribution of these items. While MHLW food sanitation supervisors carry out sample inspections, the import procedures can progress 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. Additionally, for some first-time imports or regular imports, 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 seven days before the estimated date of the cargo's arrival. Except for the 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 intended to be imported repeatedly, an import plan can be submitted with 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 results of the inspection 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 the 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, and 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 the import notification.

Export permits/clearances

A business wishing to export foods must declare the nature of the goods to the Director General of Customs, 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 (Hozai) area or a specially permitted place for storage. The exporter or his/her 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 (e.g., exportation of strategically sensitive materials under the control of the Ministry of Economy, Trade and Industry).

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 other 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, Labor 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 proven and confirmed, Customs will not permit the cargo to be exported.



Other notifications/approvals/licenses

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 be able to sell certain foods listed in the Ordinance for Enforcement of the FSA and local ordinances, including milk, ice cream, meat, seafood, ice cream and other foods.

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 FSA.

2. Food sanitation inspectors at local health centers

- Monitor and provide guidance to companies.

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 FSA.

4. Secretary General of the CAA

- Order proprietors to comply with food labeling 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 labeling 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 Labeling Act.
- Conduct an on-the-spot inspection of the proprietor to verify compliance with food labeling obligations.

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 three years, or a fine of not more than JPY 3 million.
- In case of firms: a fine of not more than JPY 100 million.

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

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

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 one year, or a fine of not more than JPY 1 million.

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

- A fine of not more than JPY 500,000.

Health Promotion Act

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

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

Food Labeling Act

Violation of a business improvement order

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

Sale of food violating food labeling standards

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



FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL REGIME

Overview

The regulation of food quality and integrity in Malaysia is governed primarily by the Food Act 1983 ("**Act**") and its subsidiary legislation, the most pertinent of which is the Food Regulations 1985 ("**Regulations**"). Compliance with the Act and the Regulations is mandatory, except in relation to any food prepared, produced or packaged for export outside Malaysia.

The term "food" is defined broadly in the Act as including "every article manufactured, sold or represented for use as food or drink for human consumption or which enters into or is used in the composition, preparation or preservation of any food or drink and includes confectionery, chewing substances and any ingredient of such food, drink, confectionery or chewing substances."

The Regulations are very prescriptive as to what can or cannot be added to foods, and in what amounts. Additives, processing aids, vitamins, minerals, novel food substances and nutritive substances must not be added to foods unless expressly permitted under the Regulations. Where permitted, such substances may only be used in accordance with the limits expressly set by the Regulations.

There is a distinction between "foods," which are regulated by the Food Safety and Quality Division of the Ministry of Health Malaysia ("**FSQD**"), and "drugs," which are regulated by the National Pharmaceutical Regulatory Agency of the Ministry of Health Malaysia ("**NPRA**"). However, it may sometimes be difficult to determine whether a product is a "food" or a "drug." These products are termed as "Food-Drug Interface products." Generally, the main criteria in deciding whether

a product is regulated by the FSQD or the NPRA are the ingredients used in the product. Other relevant criteria include the product's intended use and dosage form.

In addition, the Department of Veterinary Services of the Ministry of Agriculture and Agro-Based Industry Malaysia ("**DVS**") is empowered by the Animal Rules 1962 and regulates the importation of live animals or birds and livestock products into Malaysia.

The importation of milk and milk products is regulated by two authorities: the DVS and the Malaysian Quarantine & Inspection Services Section of the Ministry of Agriculture and Agro-Based Industry Malaysia ("**MAQIS**").

In general, the DVS is in charge of ensuring that the products originate from a country which complies with the required standards, whilst the MAQIS has the responsibility of enforcing compliance with the import requirements through the conduct of spot-checks at Customs.

Basic labeling requirements

Food identification

The Regulations require that, unless expressly exempted, every package containing food for sale must include a label containing the appropriate designation of the food or a description of the food containing the common name of its principal ingredients. In some cases, specific statements are further required. For example, in the case of food containing beef or pork, its derivatives, or lard, the label must contain a statement as to the presence of such beef, pork, its derivatives, or lard.

Content

The Regulations require the inclusion of a statement as to the minimum net weight or volume, or the number of the contents of the package on the label. In the case of food packed in liquid, a statement of the minimum drained weight of the food must be included on the label.

Labeling of ingredients

The Regulations require that, where the food consists of two or more ingredients, other than water, food additives or added nutrients, the appropriate designation of each of those ingredients in descending order of proportion by weight and, wherever required by the Regulations, a declaration of the proportion of such ingredients, be included on the label.

Additionally, if the food contains ingredients known to cause hypersensitivity, the ingredients must be declared on the label.

Where the food contains food additives, a statement as to the presence in that food of such food additives must be included on the label.

Where the food contains vitamins and minerals, the label of the food may contain writing stating the amount of said vitamins and minerals in accordance with the criteria expressly laid down in the Regulations.

Supplier details

In the case of locally manufactured or packed foods, the name and business address of the manufacturer or packer, or the owner of the rights of manufacture or packing (or the agent of any of them) must be included on the label.





In the case of imported food, the name and business address of the manufacturer or packer, or the owner of the rights to manufacture or pack (or the agent of any of them), and the name and business address of the importer in Malaysia and the name of the country of origin of the food must be included on the label.

Nutrition information panel

In relation to a package of food, "nutrition labeling" is defined under the Regulations as meaning "a description intended to inform the customer of the nutrient content of a food." Except where expressly provided otherwise under the Regulations, the label of the food must include its nutrient content, including, but not limited to, the following:

- the amount of energy, expressed in kilocalorie (kcal) or kilojoule (kJ) or both per 100 g or 100 ml or per package if the package contains only a single portion and per serving as quantified on the label;
- the amount of protein, available carbohydrate (that is carbohydrate excluding dietary fiber) and fat, expressed in g per 100 g or per 100 ml (or per package if the package contains only a single portion) and per serving as quantified on the label; and
- on a package of ready-to-drink beverage, the amount of total sugars in the prescribed form.

The following list of information, among others, may also be included:

- the amount of vitamins and minerals in accordance with the prescribed criteria;
- the amount of cholesterol and sodium expressed in mg per 100 g or per 100 ml (or per package if the package contains

only a single portion) and per serving as quantified on the label; and

- the amount of dietary fiber expressed in g per 100 g or per 100 ml (or per package if the package contains only a single portion) and per serving as quantified on the label.

Language and legibility requirements

The particulars required to be set out must appear conspicuously and prominently on the label of a food product.

Font size

The size of the letters to be used on labels may be prescribed by the Regulations in respect of certain foods. If not specifically prescribed, the following general rules are applicable:

- the font must be written in no smaller than 10-point lettering; but
- the statement of ingredients must be written in no smaller than 4-point lettering.

Position

If not expressly provided otherwise under the Regulations, the lettering for the particulars that are required to appear on a label must be so prominent in height, visual emphasis and position as to be conspicuous by comparison with any other matter appearing on the label.

Every label required by the Regulations to be borne on a package must be legibly and durably marked either on the material of the package or on material firmly or permanently attached to the package.

However, a label may be firmly placed inside a package if:

- the package is made of clear transparent material; and
- the food contained in the package:
 - (i) is not ready for direct consumption; or
 - (ii) in the case of food ready for direct consumption, is completely enclosed in its natural shell or pod or interior wrapper such that it has no direct contact or is not likely to come into contact with the label.

No label must appear on the extra wrapper of any food, pursuant to the Regulations.

Language

Except as otherwise provided in the Regulations, any word, statement, information or direction that is required by the Regulations to appear on the label of any package of food must:

- in the case of food produced, prepared or packaged in Malaysia, be in Bahasa Malaysia; or
- in the case of imported food, be in Bahasa Malaysia or English.

In either case, the language used may include a translation in any other language.

Country of origin labeling

In the case of imported food, the Regulations require that the name of the country of origin of the food must be included on the label.





Genetically modified (GM) foods

Under the Regulations, no person must import, prepare, sell or advertise for sale any food or food ingredients obtained through modern biotechnology without the prior written approval of the Deputy Director General of Health (Public Health) of the Ministry of Health Malaysia ("**Director**").

Labeling

Generally, these labeling requirements do not apply to food which contains, consists of or is produced from a GMO in a proportion not more than 3% of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable.

Specifically for food or ingredients known to cause hypersensitivity, the origin of food and food ingredients obtained through modern biotechnology must be stated as "gene derived from (origin)."

As for food and food ingredients obtained through modern biotechnology, they must be labeled as follows:

- in the case of food and food ingredients that are composed of or contain genetically modified organisms, the words "genetically modified (name of the ingredient)" must appear on the label;
- in the case of food and food ingredients that are produced from, but do not contain, genetically modified organisms, the words "produced from genetically modified (name of the ingredient)" must appear on the label;
- for the purpose of paragraphs (a) and (b), in the case of single-ingredient foods, the information must appear on the principal display panel close to the name of the food and must be in at least 10-point lettering;

- for the purpose of paragraphs (a) and (b), in the case of multi-ingredient foods, the information must appear in the list of ingredients immediately following the ingredients; and
- for the purpose of paragraph (d), the statement "contains genetically modified ingredient" must be stated on the principal display panel close to the name of the food and must be in at least 10-point lettering.

Nutrition content claims and health claims

Under the Regulations, claims which highlight the absence or non-addition of a particular substance in or to food may be included on the label provided that the claims are able to be substantiated, are not misleading and the substance:

- is not subject to specific requirements in the Regulations;
- is one which consumers would normally expect to find in the food;
- has not been substituted by another substance giving the food equivalent characteristics unless the nature of the substitution is clearly stated with equal prominence; and
- the presence or addition is permitted in the food.

Claims about the physiological role of the nutrient in the growth, development and normal functions of the body are also regulated by the Regulations. These are termed "nutrient function claims," and they must not imply or include any statement to the effect that the nutrient would afford a cure or treatment for or protection from a disease. The Regulations are further prescriptive as to what nutrient function claims may be made, and even then, such claims may only be made in relation to specific prescribed nutrients.

Mandatory warnings and advisory statements

The Regulations provide that if a food contains ingredients known to cause hypersensitivity, the ingredients must be declared on the label. Specific foods or ingredients known to cause hypersensitivity are prescribed in the Regulations and include:

- cereal containing gluten including wheat, rye, barley and oat;
- nut and nut products including peanut and soybean;
- fish and fish products;
- milk and milk products (including lactose); and
- egg and egg products.

Where the food contains beef or pork, or its derivatives, or lard, a statement as to the presence of beef or pork, or its derivatives or lard, in the prescribed form must be included on the label.

Trade measurement markings

Pursuant to the Weights and Measures Act 1972, the only units of measurement which may be used are those prescribed in the National Measurement System Act 2007. Generally, these are units accepted internationally for use with the International System of Units (SI).

Product recalls

Under the Act, where any food is found to have contravened, or is reasonably suspected to have contravened, any provision of the Act or any regulations made under the Act, the Director or any officer authorized by the Director may, by





notice in writing, order that the food be recalled, removed or withdrawn from sale from any food premises within such time as may be specified in the notice.

The Act also imposes a duty on any person who prepares, packages, labels, advertises or sells any food to recall, remove or withdraw from sale any food if such person knows or has reason to believe that any such food imported, manufactured, packed, farmed, prepared or sold by him/her:

- contains substances injurious to health;
- is unfit for human consumption; or
- has been adulterated.

Food safety

There is currently no mandatory reporting regime for the reporting of illness or injury caused by the use or foreseeable misuse of foods. This is an entirely voluntary act and such reporting may be made to the Food Safety and Quality Division of the Ministry of Health Malaysia, State Health Department, or directly to the Ministry of Health itself.

Advertising claims (general)

The Act prohibits any person who, for the purpose of affecting or promoting the sale of any food, publishes or causes to be published, either on his/her own account or as an agent, any advertisement likely to cause any person to believe that it relates to such food, or to any ingredient or constituent thereof, which:

- (a) directly or indirectly qualifies or is inconsistent with or contrary to any particulars required by the regulations made under the Act to be marked on or attached to such food or marked on or attached to any package containing such food;

- (b) is prohibited by any such regulations from being marked on or attached to such food or marked on or attached to any package containing such food;
- (c) omits from the name or description of any food any word or words required by regulations made under the Act to be included in the name or description marked on or attached to such food or marked on or attached to any package containing such food; or
- (d) is likely to deceive a purchaser with regard to the character, nature, value, substance, quality, strength, purity, composition, merit or safety, weight, proportion, origin, age or effects of any food or of any ingredient or constituent thereof.

The Act also prohibits any person from publishing any advertisement which does not contain a statement setting forth the true name of the person by whom or on whose behalf the advertisement is published and the address of his/her place of business or residence.

The Regulations prohibit any claims which highlight the absence or non-addition of a particular substance in or to food, unless the claims are not misleading and the substance:

- (a) is not subject to specific requirements in this Regulation;
- (b) is one which consumers would normally expect to find in the food;
- (c) has not been substituted by another substance giving the food equivalent characteristics unless the nature of the substitutions is clearly stated with equal prominence; and
- (d) the presence or addition is permitted in the food.

Credence claims, e.g., organic, natural, fresh

The Regulations provide that food labels should not include the words "organic," "biological," "ecological," "biodynamic" or any other words of the same significance unless the food conforms to the requirements specified in the Malaysian Standards MS 1529: The Production, Processing, Labeling and Marketing of Plant-Based Organically Produced Foods. This standard contains provisions and requirements in practice for organically produced products and the type of food treatments that can be carried out and be considered organic.

Organic claims

For locally produced organic food, an "Organic Certificate" must first be obtained from the Department of Agriculture of the Ministry of Agriculture and Agro-Based Industry Malaysia for such food to be labeled as "organic." If the food is imported, the Organic Alliance of Malaysia has the mandate to determine whether the food is organically produced.

Natural claims

There is no legislation or guidelines in place that govern natural claims for food. Nevertheless, in practice, the use of such claims is generally not allowed by the FSQD. If a person makes a "natural" claim, he/she must ensure that the food is actually a natural product; failure to do this may result in action being taken by the FSQD for false, misleading or deceptive labeling of the food under the Act.

Health rating schemes

While there are no laws or guidelines, either voluntary or mandatory, which regulate the front of pack labeling scheme with respect to health ratings, please note that Regulation





18(1) provides that no descriptive matter appearing on or attached to or supplied with any package of food shall include any comment on, reference to or explanation of any statement or label required by these Regulations to be borne on any package of food if such comment, reference, or explanation, either directly or by implication, contradicts, qualifies or modifies the statement or the content of that label.

As such, the inclusion of foreign health rating scheme logos on the products imported into Malaysia may contravene Regulation 18 by indirectly qualifying, modifying or contradicting nutrition content on the label, as the foreign health rating scheme may imply that the product has a higher nutrition content than its actual nutrition content stated on the label.

Other

Several amendments were recently introduced to the Regulations. In particular:

1. Food (Amendment) Regulations 2016 ("Amendment No. 1")

The key changes in Amendment No. 1 are as follows:

- The insertion of compounded hard liquor into the Regulations. Compounded hard liquor is defined as any alcoholic beverage, apart from those prescribed in regulations 377 to 384, with a blend of two or more types of spirits containing added ethyl alcohol of agricultural origin or distillates of agricultural origins and equal to or greater than 32.5% volume per volume of alcohol.
- The revision of the general standards for alcoholic beverages. Particularly, alcoholic beverages are to be labeled with the words "MEMINUM ARAK BOLEH MEMBAHAYAKAN KESIHATAN" (Translation: Drinking

alcoholic beverages can endanger your health) and similar notices have to be placed at locations where alcoholic beverages are offered for sale. Furthermore, the age limit of the person to whom alcoholic beverages can legally be sold has been increased from 18 to 21 and sellers are required to conspicuously display a sign on the prohibition of sale of alcoholic beverages to anyone under the age of 21.

Amendment No. 1 came into effect on 1 December 2017.

2. Food (Amendment) (No. 2) Regulations 2016 ("Amendment No. 2")

Amendment No. 2 expands the permitted food additives to include those permitted in the Codex Alimentarius. Prior to Amendment No. 2, only the preservatives permitted under the Sixth Schedule could be added into food. Amendment No. 2 came into force on 1 September 2016.

3. Food (Amendment) (No. 2) Regulations 2017 ("Amendment No. 2 2017")

Amendment No. 2 2017 has amended the Regulations, among others, to broaden the type of incidental constituent, which may be permitted to be found in food, to include those specified in the Codex Alimentarius. This change came into force on 15 April 2017.

4. Food (Amendment) (No. 4) Regulations 2017 ("Amendment No. 4")

Amendment No. 4 came into force on 1 December 2017, and has amended the Regulations to facilitate enforcement as follows:

- an authorized officer now has the additional option of delivering samples to an analyst for microbiological, physical or chemical analysis through registered mail or by courier services, provided that the officer obtains an acknowledgement of receipt for the delivery. Under the

previous provisions, an officer must deliver samples to an analyst for physical and chemical analysis, personally by hand; and

- the general penalty for contravening the Regulations has doubled from RM 5,000 (approx. USD 1,200) to RM 10,000 (approx. USD 2,400).

5. Food (Compounding of Offenses) Regulations 2017

Effective since 1 December 2017, certain offenses under the Regulations may now be compounded if the Public Prosecutor gives his or her written consent in a prescribed form.

LICENSING AND APPROVALS REQUIREMENTS TO IMPORT/EXPORT FOOD

Customs registration

Registration with the Royal Malaysian Customs Department ("**Customs**") must occur when the food arrives at the Malaysian border. Usually, delay and trouble will be minimized by appointing an agent, rather than declaring personally at the border, as the agent will have all the relevant documents and information as well as an agent code, which will speed things up at the border. Naturally, this will incur a cost for the importer.

Import permit

Whether or not an import permit is required depends on the type of food being imported. There is a list of food published by the FSQD which contains special and additional requirements that need to be fulfilled. This list is available on the [FSQD's website](#). Kindly note that the website is





predominantly in Bahasa Malaysia with certain segments of it in English and that currently there is no English translation available.

Non-residents may also be able to obtain import permits. Importation of food must always be registered with the Food Safety Information System of Malaysia ("**FOSIM**"), which is essentially a database for importers.

Import authority

Some types of food are regulated by specific authorities. For example, the DVS and the MAQIS are in charge of regulating the import of food such as raw meat, milk and dairy products. In general, the DVS is in charge of ensuring that the products originate from a country which complies with the required standards. MAQIS, on the other hand, has the responsibility of enforcing compliance with the import requirements through the conduct of spot-checks at the point of importation. In this case, an E-Permit, once issued, will be valid for one consignment and for 30 days. This can be extended to 60 days upon request.

Inspection of imported foods

Imported foods will first be checked by MAQIS officers or another relevant body (depending on the identity of the foods and the body regulating their import/export). Upon the matching of their documents/permits with the imported food, and assuming that there are no further issues, the inspection by the MAQIS officers is concluded.

Another inspection round will then be conducted by Customs. This will be done on a random basis rather than on every imported food. Customs is usually more lenient in terms of inspection of food when the imported food arrives at the Malaysian border. Customs understands that the food, especially fresh food, should not be delayed too long at the border.

The only way to minimize delay at the border is to ensure that the permits and documents are prepared properly and are readily available to avoid giving rise to any doubts and/or suspicion on the part of the officers, which would lead to further investigations and unavoidable delays.

Export permits/clearances

Export requirements differ depending on the product and destination country. For example, food regulated by MAQIS requires an export permit to be applied for by submitting the relevant documents and registering on the online registration system called [DagangNet](#). Export permits are much easier to obtain than import permits.

Other notifications/approvals/licenses

Depending on the type of food, certain foods may require additional licenses or certificates before they can be imported into Malaysia. The list of such foods and any additional requirements is continuously being updated on the [FOSIM's website](#). For example, a health certificate from the importing country will be required for food such as meat and poultry.

In the event such requirements are not complied with, the consignment will be placed under Level 5 of the FOSIM and be subjected to a "Hold, Test and Release" procedure where sampling would be conducted on the consignment.

ENFORCEMENT

Enforcement authorities and key responsibilities

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

1. MAQIS

Responsibility includes enforcement of the Malaysian Quarantine and Inspection Services Act 2011 ("MQISA"). Other legislative responsibilities exist relating to inspection, quarantine and enforcement at entry points, quarantine stations and quarantine premises for plants, animals, carcasses, fish, agricultural products, soil, micro-organisms and Malaysia's imported and exported food which adheres to the requirements of human, animal, plant and fish health and food safety.

Other legislation enforced by MAQIS includes:

1. Plant Quarantine Act 1976;
2. Animals Act 1953;
3. Fisheries Act 1983;
4. Federal Agricultural Marketing Authority Act 1965;
5. Lembaga Kemajuan Ikan Malaysia Act 1971; and
6. Food Act 1985.

2. Customs

Responsibilities include combating all forms of smuggling and fraud so as to ensure that all laws and regulations administered by the department are fully complied with.





Customs carries out the following tasks:

- (a) prevention and seizure;
- (b) investigation;
- (c) prosecution; and
- (d) intelligence.

3. Department of Agriculture

This department is tasked with developing the Agriculture Food and Soil Information Center for planning purposes and implementing development programs for the sector.

4. Ministry of Domestic Trade, Co-operatives and Consumerism ("MDTCC")

The key areas of enforcement by the MDTCC include:

- a) the protection of intellectual property rights;
- b) the eradication of the exploitation of subsidized items;
- c) the protection of consumer rights; and
- d) the monitoring of supplies and prices of goods,

based on the following laws and subsidiary legislations:

- (i) Control of Supplies Act 1961;
- (ii) Hire Purchase Act 1967;
- (iii) Weights and Measures Act 1972;
- (iv) Copyright Act 1987;
- (v) Consumer Protection Act 1999;
- (vi) Price Control and Anti-profiteering Act 2011;

(vii) Trade Descriptions Act 2011; and

(viii) Anti-Money Laundering and Anti-Terrorism Financing and Proceeds of Unlawful Activities Act 2001.

5. Local food authorities

Local food authorities in each state and territory are responsible for enforcing the relevant food laws in Malaysia.

Penalties for non-compliance

Under MQISA

Section 11: Requirement for permit, license and certificate

- Fine not exceeding RM 100,000 or imprisonment for a term not exceeding six years, or both. For a second or subsequent offense, a fine not exceeding RM 150,000 or imprisonment for a term not exceeding seven years or both.

Section 13: False permit, license and certificate

- Fine not exceeding RM 50,000 or imprisonment for a term not exceeding two years, or both. For a second or subsequent offense: a fine not exceeding RM 75,000 or imprisonment for a term not exceeding five years, or both.

Section 14: Import of plant, animal, carcass, etc. with pests, diseases or contaminants

- Fine not exceeding RM 100,000 or imprisonment for a term not exceeding six years, or both. For a second or subsequent offense: a fine not exceeding RM 150,000 or imprisonment for a term not exceeding seven years, or both.

Section 15: Compliance with import and export conditions

- Fine not exceeding RM 100,000 or imprisonment for a term not exceeding six years, or both. For a second or subsequent offense: a fine not exceeding RM 150,000 or imprisonment for a term not exceeding seven years, or both.

Under Customs Act 1967

Section 133: Making incorrect declarations and falsifying documents

- Fine not exceeding RM 500,000 or imprisonment for a term not exceeding five years, or both.

Section 134: Refusing to answer questions or giving false information

- Fine not exceeding RM 1,000 or imprisonment for a term not exceeding six months, or both.

Section 136: Assaulting or obstructing Customs officers and rescuing goods

- For a first conviction: fine not exceeding RM 10,000 or imprisonment for a term not exceeding three years, or both. For second or subsequent conviction: a fine not exceeding RM 20,000 or imprisonment for a term not exceeding five years, or both.

Under the regulations

Section 397: Matter forbidden on any label

- Fine not exceeding RM 5,000 or imprisonment for a term not exceeding two years.





Under the Consumer Protection Act 1999

Section 9: Misleading conduct

- For body corporates, fine not exceeding RM 250,000. For a second or subsequent offense: a fine not exceeding RM 500,000. In the case of a continuing offense, fine not exceeding RM 100,000 for each day or part of a day during which the offense continues after conviction.

Section 10: False or misleading representation

- For body corporates, fine not exceeding RM 250,000. For a second or subsequent offense: a fine not exceeding RM 500,000. In the case of a continuing offense, fine not exceeding RM 100,000 for each day or part of a day during which the offense continues after conviction.

Section 16: Demanding or accepting payment without intending to supply

- For body corporates, fine not exceeding RM 250,000. For a second or subsequent offense: a fine not exceeding RM 500,000. In the case of a continuing offense, fine not exceeding RM 100,000 for each day or part of a day during which the offense continues after conviction.

Under the Act

Section 13: Food containing substances injurious to health

- Fine not exceeding RM 100,000 or imprisonment for a term not exceeding 10 years, or both.

Section 13A: Food unfit for human consumption

- Fine not exceeding RM 30,000 or imprisonment for a term not exceeding five years, or both.

Section 13B: Adulterated food

- Fine not exceeding RM 20,000 or imprisonment for a term not exceeding five years, or both.

Section 15: Labeling, etc., not complying with standard of food

- Fine or imprisonment for a term not exceeding three years, or both.

Section 16: False labeling, etc.

- Fine or imprisonment for a term not exceeding three years, or both.

Section 17: False advertisement

- Fine or imprisonment for a term not exceeding three years, or both.





FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL RESUME

Overview

Consumer product quality and standards are primarily governed by the Consumer Act ("**Consumer Act**"), which is a general law on consumer products. In addition, the Food and Drug Administration Act of 2009 (Republic Act No. 9711), which amends the Foods, Drugs and Devices and Cosmetics Act (Republic Act No. 3720) ("**FDA Law**"), specifically regulates "health products," which include food and other consumer products that may have an effect on health.

"Food" is defined as any substance, whether processed, semi-processed or raw, intended for human consumption. This includes chewing gum, drinks and beverages, and any substance which has been used as an ingredient or a component in the manufacture, preparation or treatment of food. "Food/dietary supplements" are processed food products intended to supplement the diet. These supplements generally contain one or more of the following dietary ingredients: a vitamin, mineral, amino acid, herb, or other dietary substance of botanical, animal, artificial or natural origin. Their purpose is to increase the total daily intake in an amount conforming to the latest Philippine recommended energy and nutrient intakes or internationally agreed minimum daily requirements. It is usually in the form of capsules, tablets, liquids, gels, powders or pills and is not represented for use as a conventional food or as the sole item of a meal or diet or a replacement for drugs and medicines.

The Food and Drug Administration ("**FDA**") is the regulatory authority under the Philippine Department of Health ("**DOH**")

that implements the FDA Law. The FDA Center for Food Regulation and Research ("**CFRR**") is tasked with regulating the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of and/or, where appropriate, the use and testing of food products and food/dietary supplements. The CFRR is also mandated to conduct research on the safety, efficacy and quality of food, and to institute standards relating to food safety and quality.

The Department of Trade and Industry ("**DTI**") is primarily tasked with implementing the Consumer Act. The DTI Bureau of Product Standards ("**BPS**") formulates Philippine National Standards for consumer products, including food.

Standards for food are prepared by the technical committees and sub-committees of the BPS and the FDA. Food standards are published as Philippine National Standards.

To ensure that product quality standards are complied with, among others, the FDA requires entities that manufacture, import, export, sell and distribute food products to obtain a License to Operate ("**LTO**") from the FDA for their intended activities. These entities also require a Certificate of Product Registration ("**CPR**") for each food product that they manufacture, import, export and market in the Philippines. An LTO covering a particular food establishment shall be prima facie evidence of the licensee's authority to engage in the activity/ies specified in the LTO. A CPR covering a food product shall be prima facie evidence of the registrant's marketing authority for the said health product in connection with the activity/ies permitted pursuant to the LTO. Only establishments with a valid LTO from the FDA may apply for a CPR.

In addition, certain food products are subject to special laws and regulations, for example, milk (Executive Order No. 51,

National Code of Marketing of Breast milk Substitutes and Other Related Products, also known as the "**Milk Code**").

Basic labeling requirements

The following labeling requirements set out by the **DOH** in Administrative Order No. 30-2014 ("Revised Rules and Regulations Governing the Labeling of Pre-packaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984") ("**Food Labeling Rules**")¹ apply to food products, including food supplements, whether imported or locally produced and distributed in the Philippines:

Food identification

The following information on pre-packaged food products must be placed on the label:²

- product name/name of the food;
- use of brand name and/or trademark;
- complete list of ingredients;
- net contents and drained weight;
- name and address of manufacturer, repacker, packer, importer, trader and distributor;
- lot identification;
- storage condition;
- expiry or expiration date/use-by date/consume-before date (recommended last consumption date);
- food allergen information; and
- nutrition facts/nutrition information/nutritive value.

¹ The Food Labeling Rules took effect on 15 September 2014

² Sec. IV(A), DOH Administrative Order No. 30-2014 dated 8 September 2014 ("Revised Rules and Regulations Governing the Labeling of Pre-packaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984").



Labeling of ingredients

The Food Labeling Rules provide for specific information which must be stated on food labels for each of the items above. With respect to the list of ingredients, generally, the following rules apply:

- a. except for a single ingredient food, a complete list of ingredients shall be declared on the label;
- b. the list of ingredients shall be headed or preceded by an appropriate title which consists of or includes the term "ingredients;"
- c. the complete list shall be declared in descending order of proportion on either the principal display panel or information panel;
- d. added water shall be declared in the list of ingredients, except when the water forms part of an ingredient, such as brine, syrup or broth used in the compound food and declared as such in the list of ingredients. Water or other volatile ingredients that evaporate in the course of manufacture need not be declared;
- e. where an ingredient is itself the product of two or more ingredients, the compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by a list, in brackets, of its ingredients in descending order of proportion;
- f. where a compound ingredient constitutes less than 5% of the food, the ingredients, other than food additives which serve a technological function in the finished product, need not be declared;
- g. a specific name, not a collective (generic) name shall be used for an ingredient unless a general class name would

be more informative and not in conflict with existing regulations/standards;

- h. flavors and flavoring substances shall be declared;
 - i. any pyroligneous acid or other artificial smoke flavors used shall be declared as artificial flavor or artificial smoke flavor;
 - j. coloring substances shall be declared by their common name or as "food color(s)" or "color(s)" for those derived from or identical with substances derived from plant materials, and as "artificial colors" for coal-tar dyes or other synthetic chemical compounds; and
- k. food additives shall be declared by their common name and their functional categories.

Other regulations and policies of the FDA may also apply. For example, under FDA Circular No. 2, series of 1999, the labels of all food supplements shall indicate the phrase "No approved therapeutic claim" to inform the consumers that food/dietary supplements have no approved curative effects.

Declaration of food additives

As mentioned above, food additives must be declared in the list of ingredients by their common name or their class name, which indicates their functional categories. Under the Food Labeling Rules, the provisions of the Guidelines of Codex Standard for Food Additives Labeling (General Standard for Food Labeling of Food Additives when sold as such, CODEX STAN 107-1981) are adopted.

Processing aids and food additives carried over into food (from another food that was used as an ingredient) at levels less than those required to achieve a technological function, need not be declared in the list of ingredients.

Open-date marking

The expiration/expiry date shall be printed clearly, conspicuously and legibly on all product labels (except alcoholic beverages) in the following order: Day, Month, Year.

The declaration of day and year are numerical while the declaration of month must be in words to avoid confusion (e.g., Expiry date: 01 January 2012 or 01 Jan. 12).

Consumer complaint desk address

Under Department Administrative Order No. 01, series of 2008, issued by the DTI, all manufacturers and importers of consumer products sold in the Philippines, including food, must specify their consumer complaint desk address on the label.

For milk and milk substitutes, special guidelines on labeling are provided in DOH Department Circular No. 2007-0276.

Exemptions from labeling requirements

The following are exempted from the labeling requirements under the Food Labeling Rules:

- Food materials to be served in restaurants or to be served in airline catering, which are not labeled, and are pre-packaged and made available to the consumer (e.g., schools, cafeterias, trains, airplanes and retail stores) for immediate consumption.
- Bulk food materials (including raw materials, ingredients and processed food products) for further processing or repacking or for catering or food service use and not intended for retail sale, on the condition that these are properly identified as may be appropriate and product specifications are provided in supporting documents.



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- Foods in primary packages with available label space of less than 10 cm² (e.g., pack of gum, individually wrapped candies), provided that the secondary packaging contains all the required labeling information.
- Exemptions from any specific provision/s of the Food Labeling Rules may be granted under justifiable circumstances as may be determined by the FDA Director General. Petitions for such exemptions should be submitted to the FDA for appropriate action.

Nutrition information panel

Under the Food Labeling Rules, the nutrition facts shall be presented in tabulated form (as illustrated below) through the declaration of protein, carbohydrates (including dietary fiber and sugar), fat (including saturated fat, trans fat and cholesterol), sodium, energy value or calories.

All nutrient quantities shall be declared in relation to the average or usual serving in terms of slices, pieces or a specified weight or volume. The declaration of nutrients can also be expressed either in units per serving or % Recommended Energy and Nutrient Intake (“**RENI**”) or in both, provided that all locally manufactured food products intended for local consumption shall also indicate the corresponding RENI valued in an actual percentage, expressed in whole numbers.

- a. Carbohydrates, protein, fats (cholesterol expressed in milligrams (mg)), sugar and dietary fiber shall be expressed in the nearest gram (g). Energy values shall be expressed in calories (kcal). Sodium shall be declared in mg.

- b. Vitamins and minerals shall be expressed in mg or micrograms (mcg or <µg). International units (I.U.) shall be used for Vitamins A, D & E.

Below is a sample of the Nutrition Facts Declaration:

Nutrition Facts	
Serving Size:	
No. of Servings per Container/Pack:	
Amount per Serving _____	% RENI*
Calories (kcal) _____	Calories from Fat _____
Total Fat (g)	
Saturated Fat** (g) _____	
Trans Fat** (g) _____	
Cholesterol (mg) _____	
Sodium (mg)	
Total Carbohydrates (g) _____	
Dietary Fiber (g) _____	
Sugar (g) _____	
Total Protein (g) _____	
* Percent RENI values are based on FNRI reference adult requirements for a 19-29 year old. However, if a product is specifically intended for a different age group, percent RENI values are based on the appropriate FNRI reference requirement.	
** For coconut products, Medium Chain Triglycerides (MCTs) are predominant.	

Language and legibility requirements

Under the Food Labeling Rules, the language used for all information on the label of food products must be either English or Filipino or a combination thereof. For food products intended for export, the language acceptable to the importing country shall be used.



In the case of imported food products, labels where the information appears in a foreign language shall always carry the corresponding English translation.

In the case of a change of labels, and where it is permitted by the FDA to use up the existing labels, the use of a provisional sticker label for the English or Filipino translation shall only be allowed for a maximum period of six months. All information should be accurate, legible and must be contained in a single sticker. The sticker must be durable, i.e., cannot be easily removed from the label or packaging.

Where the label of a food package is so small that it prevents the use of letters of the prescribed size or where it concerns secondary or optional information, letters of proportionately reduced size may be used, provided the prescribed particulars are visible and legibly shown and the designated label space is proportional to the size of the package. For other small packages that will not be able to accommodate label information, only the brand name and product name may be indicated. However, these shall not be sold separately and shall not be for retail sale.

Country of origin labeling

Under the Philippine Customs Modernization and Tariff Act ("Customs Act"), every article of foreign origin imported into the Philippines shall be marked in any official language of the Philippines, being either Filipino or English. The country of origin shall be marked in a conspicuous place as legibly, indelibly and permanently as the nature of the article (or container) will permit.

Furthermore, under the Food Labeling Rules, the name and address of the manufacturer, repacker, packer, importer, trader or distributor of the food shall be declared on the label of locally manufactured products.

For imported products, the complete name and address of the importer, as well as the country of origin shall also be declared.

If a manufacturer has a plant in many cities and/or towns, the corporate head office address would suffice provided every food package has a code/mark to identify the processing plant where it was produced. In the case of products carrying foreign brands or manufactured under license by a foreign company, the name and/or address of the foreign company, if declared, shall be in letters of type size not bigger than those used for the local company.

When food undergoes processing in a second country which changes its nature, the second country in which the processing is performed shall be considered to be the country of origin for the purposes of labeling.

Genetically modified (GM) foods

The existing regulations on genetically modified organisms in the Philippines are Executive Order No. 430 series of 1990, which created the National Committee on Biosafety of the Philippines, and Joint Circular No. 1 Series of 2016 of the Department of Science and Technology, Department of Agriculture ("**DA**"), Department of Environment and Natural Resources, the DOH, and Department of Interior and Local Government ("**DILG**") ("**GM Circular**").

Under the GM Circular, no genetically modified plant or its products ("**GM Plant**") may be tested, commercially propagated and directly used without first obtaining the applicable Biosafety Permit. In case of commercial propagation of GM Plants, aside from obtaining the Biosafety Permit, it must be shown that: (i) based on field trials conducted in the Philippines, the GM Plant does not pose greater risks to biodiversity, human and animal health than its conventional counterpart; (ii) food and feed safety studies

show that the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart, consistent with CODEX Alimentarius Guidelines on the Food Safety Assessment of Foods Derived from the Recombinant-DNA Plants and protocols of the DOH and BAI on feeding trials; and (iii) if the GM Plant is a pest-protected plant, its transformation event that serves as the plant-incorporated protectant has been duly registered with the Fertilizer and Pesticide Authority of the Philippines. Under current policies and practices, and in the absence of unforeseen complications, the Biosafety Permit will be issued by the Bureau of Plant Industry within four months from complete submission of documentary requirements.

Furthermore, if a GM Plant is used for food and feed, or for processing, aside from obtaining the Biosafety Permit for Direct Use, the GM Circular also requires: (i) that in the case of an imported GM Plant, the GM Plant has been authorized for commercial distribution as food and feed in the country of origin; and (ii) regardless of the intended use, the regulated article does not pose greater risks to biodiversity, human and animal health than its conventional counterpart.

All importation of GM Plants, for whatever use, must be covered by a Sanitary and Phytosanitary Import Clearance ("**SPSIC**") issued by the Bureau of Plant Industry. No shipment of any GM Plant shall be allowed without a SPSIC.

Similarly, under the current policies of the FDA, food products derived from biotechnology are not prohibited. However, such products must pass the food safety assessment based on international standards (The UN FAO/WHO CODEX Alimentarius Risk Analysis of Food Derived From Modern Biotechnology (CAC/GL 44-2003) and Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL45-2003)).



The FDA has yet to issue its guidelines on labeling of pre-packaged foods derived from or containing ingredients derived from modern biotechnology including genetically modified foods.

Nutrition content claims and health claims

The use of nutrition claims or health claims in food shall be covered by the Food Labeling Rules, and the Codex Guidelines for use of Nutrition and Health Claims under CAC/GL 23-1997 ("**Codex Guidelines**"), including the latest amendments, as applicable. However, when any portion of the amendments to the Codex Guidelines are contrary to existing Philippine laws and their rules and regulations, in consideration of national policies and interest, the Food Labeling Rules shall apply as supplementary.

Pursuant to the Codex Guidelines, the following general claims can be made relating to health products:

- Nutrition Claim – this refers to any representation which states, suggests or implies that a food has particular nutritional properties, including, but not limited to, the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals. Nutrition claims may be permitted only if they relate to energy, protein, carbohydrates and fat, and the components thereof, fiber, sodium and vitamins and minerals for which Nutrient Reference Values have been defined in the Codex Guidelines for Nutrition Labeling.
- Health Claim – this refers to any representation that states, suggests or implies that a relationship exists between a food or a constituent of that food and health. Health claims include: (i) a nutrition claim that describes the physiological role of the nutrient in growth, development and normal functions of the body; and (ii) claims concerning specific beneficial effects of the consumption of foods or their constituents, in the context of the total diet on normal functions or biological activities

of the body. Such claims relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health.

Furthermore, the following information should appear on the label of the food bearing a Health Claim:

- a statement of the quantity of any nutrient or other constituent of the food that is the subject of the claim;
- the target group, if appropriate;
- how to use the food to obtain the claimed benefit and other lifestyle factors or other dietary sources, where appropriate;
- if appropriate, advice to vulnerable groups on how to use the food, and to groups, if any, who need to avoid the food;
- maximum safe intake of the food or constituent where necessary;
- how the food or food constituent fits into the context of the total diet; and
- a statement on the importance of maintaining a healthy diet.
- Reduction of disease risk claims – this refers to representations that link the consumption of a food or food constituent, in the context of the total diet, to the reduced risk of developing a disease or health-related condition. The presentation of risk reduction claims must ensure that consumers do not interpret them as prevention claims.

The Food Labeling Rules provide that, in addition to the provisions stipulated in the Codex Guidelines on the Use of Nutrition and Health Claims and the Codex General Guidelines on Claims, any of the following representations or suggestions, whether directly or indirectly stated, shall

constitute misleading, deceptive and untruthful declarations, and are prohibited:

- that the food because of the presence or absence of certain dietary properties is adequate or effective in the prevention, cure, mitigation or treatment of any disease or symptom of an illness;
- that a balanced diet of ordinary foods cannot supply an adequate amount of nutrients;
- that the food has dietary properties when such properties are of no significant value or need in human nutrition;
- that a synthetic vitamin in a food is superior to a natural vitamin;
- claims which could give rise to doubt about the safety of similar food or which could cause or exploit fear in the consumer;
- claims which highlight the absence or addition of any food additive or nutrient supplement, if the addition of such food additive or nutrient supplement is not permitted or prohibited;
- claims on the absence of beef or pork or its derivatives or lard or added alcohol are prohibited if the food does contain such ingredient;
- claims on the presence of any substance when the food does not contain such ingredient;
- claims that a product is superior to any other existing product of the same kind that cannot be substantiated;
- claims stating that any given food will provide an adequate source of all essential nutrients, except in the case of well-defined products for which a Codex standard regulates such claims as admissible claims or where the FDA has accepted, through an issuance, that the product is an adequate



source of all essential nutrients. (Codex General Guidelines on Claims CAC/GL 1-1979, Amended 2009, Section 3.1 on Prohibited Claims);

- claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition unless they are:
 - in accordance with the provisions of the Codex standards or guidelines for foods as developed by the Committee on Nutrition and Foods for Special Dietary Uses and follow the principles set forth in these guidelines; or
 - in the absence of an applicable Codex standard or guideline, permitted by the FDA.
- meaningless claims including incomplete comparatives and superlatives; and
- claims as to good hygienic practice, such as "wholesome," "healthful" or "sound."

Mandatory warnings and advisory statements

Pictures of food preparations or dishes may appear on the labels of products like sauce mixes or other similar food products that are used as ingredient(s) for the preparation of such food/dishes shown in the pictures, provided the statement "Serving Suggestion" or any other statement of similar meaning appears with the picture.

Food allergen information on the label of products containing the following ingredients, but not limited to those listed below, shall be indicated clearly, conspicuously and indelibly, located directly below the List of Ingredients (e.g., "Contains food allergen: egg;" or "Allergen Information: may contain ____"/"Manufactured using equipment that processes ____;" or a similar expression).

The following ingredients known to cause hypersensitivity shall always be declared:

- cereal containing gluten, i.e., wheat, rye, barley, oat, spelt or their hybridized strain and products of these;
- crustaceans and products of these;
- eggs and egg products;
- fish and fish products;
- peanuts, soybeans and products of these;
- milk and milk products (lactose included);
- tree nut and nut products;
- sulphite in concentrations of 10 mg/kg or more; and
- any other ingredient that may be included by the FDA through appropriate issuance.

The labels of all food supplements shall indicate the phrase "No approved therapeutic claim" to ensure that such products are not commercially sold or advertised with therapeutic claims. The font size for the phrase is 14, type face Arial, and must be printed in bold capital letters on the primary display panel of all labeling materials used for the food supplements. If the label is too small, the phrase shall be printed as 1/2 the size of the largest text in the primary display panel, while maintaining the other specifications.

In addition, under current FDA policies, warning labels are required for products that may cause a "reaction to [a] certain ingredient."

Trade measurement markings

Under the Food Labeling Rules, the net content of food products shall be declared using the metric system of measurement or the SI (International Systems of units) on

either the principal display panel or the information panel and in line generally parallel to the base of the package. The declaration shall be made in the following manner:

- for liquids, by volume;
- for solid foods, by weight, except that when such foods are sold by number, a declaration of count may be made; and
- for semi-solid or viscous foods, either by weight or volume.

Foods packed in a liquid medium normally discarded before consumption shall carry a declaration of drained weight. For the purposes of this requirement, liquid medium means water, aqueous solutions of sugar and salt, fruit and vegetable juices, in canned fruits and vegetables only, or vinegar, either singly or in combination.

For multi-unit retail packages, a statement of the quantity of contents on the outside package shall include the number of individual units, the net content of each individual unit, and, in parenthesis, the total quantity of contents of the multi-unit package.

A multi-unit retail package may thus be properly labeled:

- "20 x 10 g sachets (net wt. 200 g)"; or
- "6 x 300 ml bottles (1.8 L or 1000 ml)".

Product recalls

FDA Circular 2016-012 dated 25 July 2016 ("**Recall Guidelines**") contains the latest Guidelines for Product Recall of health products. The Recall Guidelines state that the Market Authorization Holder ("**MAH**") shall be the party primarily responsible for the recall.

The Recall Guidelines contain a non-exclusive list of events which may trigger a recall. These events are:



- health product quality/complaints processing;
- adverse events monitoring and events-based surveillance response reports;
- sampling, testing and verifying of health products;
- post-licensing inspection, monitoring and investigations;
- post-evaluation of acknowledgement notifications;
- advertisements and promotional materials monitoring;
- coordination with other regulatory agencies and international partners; and
- findings of other MAHs as a result of their post-marketing surveillance activities.

Once a trigger event has occurred, the Product Recall Committee ("**PRC**") shall review and evaluate the health hazards. The following factors shall be considered in making a decision to recall a particular health product:

- disease, injury, illness or poisoning has already occurred from the use of the health product;
- any existing condition(s) that may lead to exposure of the population;
- hazard to various segments of the population who are expected to be exposed to such health product;
- severity of the hazard to which the population at risk may be exposed;
- likelihood of the occurrence of the risk of exposure to which the population may be exposed;
- short- and long-term consequence of the health effects;
- risk of gross deception to the general public;
- non-compliance with FDA standards;

- misdeclaration of hazardous substance content;
- materials that contaminated the product, whether accidental or intentional; and
- other factors that an attending circumstance may warrant.

Once the PRC decides to move forward with the recall, it shall then determine the classifications of the product recalls as follows:

Class I Recall – product defects/conditions that are potentially life threatening or could result in severe health risk, health impairment or effects such as permanent damage to health or death.

Class II Recall – product defects/conditions that could cause poisoning or temporary/medically reversible adverse health problems or mistreatment.

Class III Recall – product defects/conditions that may not pose a significant hazard to health, but withdrawal may have been initiated for some other reason.

Food safety

The Food Safety Act of 2013 ("**Food Safety Act**") requires food business operators to ensure that food satisfies the requirements of food law relevant to their activities in the food supply chain and that control systems are in place to prevent, eliminate or reduce risks to consumers.

It identifies the responsibilities of Food Safety Regulatory Agencies ("**FSRAs**") and other government agencies, as well as the food establishment operators.

The FSRAs are composed of the DA and its associated agencies (the Bureau of Animal Industry, the National Meat Inspection Service, the Bureau of Fisheries and Aquatic Resources, the

Bureau of Plant Industry, the Fertilizer and Pesticide Authority, the Philippine Coconut Authority, the Sugar Regulatory Administration and the National Food Authority) as well as the DOH and its associated agencies (the FDA-CFRR and the Bureau of Quarantine). The Food Safety Act also created a Food Safety Regulation Coordinating Board. The board will, among other things, monitor and coordinate the performance and implementation of the mandates of the DA, the DOH, the DILG and the local government units in food safety regulation, and establish a rapid alert system for the notification of a direct or indirect risk to human health due to food.

Under the Food Safety Act, appropriate authorizations shall be developed and issued in the form of a permit, license and certificate of registration or compliance that would cover establishments, facilities engaged in production, post-harvest handling, processing, packing, holding or producing food for consumption in accordance with the mandated issuances of regulatory agencies issuing such authorizations. Special derogations shall be provided due to geographical location and after an assessment of risks, especially for micro, small and medium-sized food business operators and health products.

Also, foods imported, produced, processed and distributed for domestic and export markets shall comply with the following requirements:

- Food to be imported into the country must come from countries with an equivalent food safety regulatory system and shall comply with international agreements to which the Philippines is a party.
- Imported foods shall undergo cargo inspection and clearance procedures by the DA and the DOH at the first port of entry to determine compliance with national regulations. This inspection by the DA and the DOH shall always take place prior to assessment for tariff and other charges by the Bureau of Customs ("**BOC**"). The BOC and the Association



of International Shipping Lines shall provide the DA and the DOH documents such as the Inward Foreign Manifest of Arriving Vessels to enable the DA and the DOH to identify shipments requiring food safety inspection. Shipments not complying with national regulations shall be disposed of according to policies established by the DA and the DOH.

- Exported foods shall comply at all times with national regulations as well as the regulations of the importing country. Returned shipments shall undergo border inspection clearance.

A food establishment has the following responsibilities under the Food Safety Act:

- it should be knowledgeable of the specific requirements of food law relevant to their activities;
- if it has reason to believe that a food which it produced, processed, distributed or imported is not safe or not in compliance with food safety requirements, it shall immediately initiate procedures to withdraw the food from the market and inform the relevant regulatory authority;
- it shall allow inspections of their business and collaborate with regulatory authorities to avoid risks posed by food products which they have supplied; and
- where an unsafe or non-compliant food product may have reached the consumer, it shall effectively and accurately inform the consumers of the reason for withdrawal and, if necessary, recall the product from the market.

The following are prohibited acts under the Food Safety Act:

- to produce, handle or manufacture for sale, offer for sale, distribute in commerce, or import into the Philippines any food or food product which is not in conformity with an applicable food quality or safety standard promulgated in accordance with the law;

- to produce, handle or manufacture for sale, offer for sale, distribute in commerce, or import into the Philippines any food or food product which has been declared as a banned food product by a rule promulgated in accordance with the law;
- to refuse access to pertinent records or entry of inspection officers of the FSRA;
- to fail to comply with an order relating to the recall of unsafe products;
- to adulterate, misbrand, mislabel, or falsely advertise any food product which misleads consumers, and carry out any other acts contrary to good manufacturing practices;
- to operate a food business without the appropriate authorization;
- to connive with food business operators or food inspectors, which will result in food safety risks to consumers; and
- to violate the implementing rules and regulations of the Food Safety Act.

The implementing rules and regulations of the Food Safety Act, which elaborate the provisions of the Food Safety Act, were passed on 20 February 2015 and took effect on 23 March 2015.

Advertising claims (general)

Advertising for consumer products is governed in general by the provisions of the Consumer Act, and the Code of Ethics of the Ad Standards Council ("**ASC**") (which the Consumer Act requires all advertising materials to comply with).

Under the Implementing Rules and Regulations of the FDA Law ("**FDA IRR**"), the following are the general rules on advertisements, promotions, sponsorship and other marketing activities of any health product, including food:

- no health product that has not been registered or authorized shall be advertised, promoted or subjected to any marketing activities;
- no claim in the advertisement, promotion and sponsorship and other marketing activities shall be made other than those contained in the approved label or packaging of the health product, or as duly approved by the FDA;
- no claims, therapeutic, scientific or otherwise, shall be made that have not been duly approved by the FDA; and
- all health products that are permitted to be promoted must specifically state the authority or reference number that approved the promotional, sponsorship or marketing activities.

The Consumer Act also contains certain provisions that regulate advertisements of consumer products, including food. Under the Consumer Act, it is prohibited to advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety. The Consumer Act also prohibits the use of any reference to any laboratory report or analysis required to be furnished to the FDA unless such laboratory report is duly approved by the FDA. Furthermore, the Consumer Act requires all advertising materials to conform to the Code of Ethics of the ASC. Please note that in the Philippines, the advertising industry is self-regulating and is not specifically regulated by any government agency.

The ASC Code of Ethics does not specifically provide for guidelines regarding advertisements for food. Under the general guidelines of the ASC, any advertisement should respect the country and the law, and should not contain messages that deride or otherwise discredit the law and its enforcement. Furthermore, advertisements must endeavor to promote the improvement of the quality of life of Filipinos, positive Filipino family values, customs and traditions. Furthermore,



presentations and acts of profanity, obscenity, vulgarity or those that are offensive or indecent, as well as those which exploit or tend to promote physical, verbal or psychological violence or the use of deadly weapons, are prohibited.

The ASC Code of Ethics contains specific guidelines for advertisements involving food supplements, health supplements, alcoholic beverages and products covered by the Milk Code.

Credence claims, e.g., organic, natural, fresh

The Consumer Act requires food product labels to state whether ingredients used are natural or synthetic.

Furthermore, under the Food Labeling Rules, flavors and flavoring substances, whether in any of the categories below, shall also be declared as part of the list of ingredients. Flavor as classified shall be declared as "Natural Flavor(s)," "Nature - identical flavor(s)" or "Artificial Flavor(s)," respectively. In the case of combination of Natural Flavors and Nature - identical flavor(s) where there are identical flavors, – it shall be declared as such or simply as "Flavors."

- Natural flavors – flavoring substance derived through appropriate physical processes from spices, herbs, fruits or fruit juices, vegetable or vegetable juices, edible yeast, bark, bud, root, leaf of plant materials, meat, fish, poultry, eggs, dairy products or fermentation products thereof.
- Nature - identical flavoring substance – substances chemically derived from aromatic materials or obtained synthetically, which are chemically identical to substances present in natural products intended for human consumption.
- Artificial flavoring substances – substances that impart flavor but which have not been identified in natural products or natural sources of flavorings.

Health rating schemes

Currently, the Philippines does not have regulations that are specific to health ratings.

Nonetheless, the Philippine government promotes the fortification of food with certain micronutrients so as to combat malnutrition. Under Philippine laws and regulations, fortification is mandatory for certain staple foods, and voluntary for processed food. Food products, which meet the minimum requirements for fortification, shall use the Diamond Sangkap Pinoy Seal for staple food, and the Sangkap Pinoy Seal for processed food. The intention of these seals is to guide consumers in choosing food that is more nutritious.

Diamond Sangkap Pinoy Seal – Fortified Staple Food

Mandatory fortification is imposed by Republic Act No. 8172, otherwise known as the Asin (Salt) Law, and Republic Act 8976, otherwise known as the Food Fortification Law of 2000 (collectively, the "**Food Fortification Laws**"). Under these laws, the following food staples must be fortified:

Food	Micronutrient
Salt	Iodine
Rice	Iron
Flour	Vitamin A and Iron
Sugar	Vitamin A
Cooking oil	Vitamin A

Under DOH Administrative Order 82 Series of 2003, food that meets the minimum standards imposed in the Food Fortification Laws shall have the Diamond Sangkap Pinoy Seal on their labels. The standards for mandatory fortification are as follows:

Prescribed level of Iodine in Salt under the Asin Law:

	Type of Container/Package	
Sampling Point	Bulk (>2 kg)	Retail (≤2 kg)
Production Site	70-150 mg/kg	60-100 mg/kg
Port of Entry	70-150 mg/kg	60-100 mg/kg
Retail Site	≥ 50 mg/kg	≥ 40 mg/kg

Prescribed level of micronutrients for other staple food under the Food Fortification Law of 2000:

Food	Fortificant	Minimum	Maximum
Rice	Iron Ferrous Sulfate	60 mg Fe/ kg raw rice	90 mg Fe/ kg raw rice
Flour	Vitamin A Retinol palmitate/ acetate	3.0 mg/kg retinol	6.5 mg/kg retinol
Salt	Iron Elemental Iron	70 mg Fe/kg	105 mg Fe/ kg
	Iron Ferrous Sulfate or Ferrous Fumarate	50 mg Fe/kg	75 mg Fe/kg
Sugar	Vitamin A Retinol palmitate	5 mg/kg	30 mg/kg
Cooking oil	Vitamin A Retinol palmitate	12 mg RE/L	23 mg RE/L



Sangkap Pinoy Seal – Fortified Processed Food

Bureau of Food and Drugs (now known as the FDA) Administrative Order 4-A Series of 1995 ("**Fortification AO**") contains the Guidelines on Micronutrient Fortification of Processed Food, which encourages manufacturers of processed food to fortify the same. Fortification of processed food is voluntary. Below are the relevant guidelines for voluntary fortification under the Fortification AO:

1. For essential nutrients that are deficient in the Filipino diet, the added nutrients shall supply at least 1/3 of the Recommended Dietary Allowances ("RDA") of the target consumer, except that vitamin C shall be supplied at not less than 100% of the RDA in fortified juices/flavored drinks. These levels shall be uniformly distributed in the total number of services likely to be consumed in a day.
2. For nutrients that are essential but have not been established to be deficient in the Filipino diet, the added nutrients shall supply at least 1/5 (or 20%) of the RDA of the target consumer.
3. For nutrients that are essential but have no established RDA, the added nutrients shall supply at least 20% of the estimated safe and adequate levels for daily intake as recommended by the Food and Nutrition Board of the US National Research Council.
4. For processed foods to be fortified with nutrient(s) with known toxicity (e.g., vitamins A, D, E, K, Zn, Se), the level of such nutrient(s) in the food shall not exceed 150% of the RDA for the target consumer per prescribed serving(s) likely to be consumed per day.
5. For essential amino acids, fortification levels shall be in accordance with the recommendations of the Joint FAO/

WHO/UNU Expert Consultation on Energy and Protein Requirements (WHO TRS 724, 1985). Food manufacturers who wish to fortify their products with amino acids are required to consult a qualified professional with expertise in human nutrition and shall submit a certificate of such consultation.

6. For nutrients that have not been established as essential for humans, fortification with such nutrients shall be at a significant level above the natural state as determined by the precision of the analytical method at its lowest detection limit.

Processed food products, which comply with the standards set forth in the Fortification AO, shall include the Sangkap Pinoy Seal on their labels.

Other

None.

LICENSING AND APPROVALS REQUIREMENTS TO IMPORT/EXPORT FOOD

Customs registration

Regular importers, including food importers, are required to secure accreditation from the BOC. As part of the accreditation process with the BOC, the importer is also required to be registered with the Client Profile Registration System.

The accreditation must be obtained preferably prior to the arrival of the goods, and must not be obtained later than 30 days from arrival of the goods. Otherwise, the importer will

not be allowed to file an import entry, and will risk forfeiture of the goods. Under customs law, the non-filing of the import entry within 30 days from arrival of the cargo will result in the deemed abandonment of the goods and forfeiture thereof in favor of the government.

In addition, manufacturers, importers, traders, distributors and exporters of food must obtain an LTO from the FDA, as well as a CPR for each product.

Import permit

Under FDA Circular No. 2013-32, no import clearance is required from the FDA for the importation of finished food products. The importer, however, must be able to present a valid LTO and CPR. In particular:

- only the LTO shall be presented or submitted to the BOC for raw materials to be used in food, including ingredients and additives, that are imported by licensed food establishments for their own use; and
- both the LTO and the CPR must be presented or submitted to the BOC for raw materials to be used in food, including ingredients and additives, when intended for distribution or for sale by licensed food establishments.

Food products that are not covered by CPRs, but are intended to be imported for use as exhibition, in trade promotions or for clinical trial purposes, among others, must be covered by the FDA import clearance or certification.³

In addition, under the GM Circular, all importation of GM Plants, for whatever use, must be covered by a SPSIC issued by the Bureau of Plant Industry. No shipment of any GM

³ FDA Memorandum Circular 2013-032, 28 August 2013.



Plant shall be allowed without a SPSIC. Furthermore, only GM Plants which are included in the Registry of Approved Regulated Articles, which is updated by the Bureau of Plant Industry, may be imported into the Philippines.

Inspection of imported foods

Under the Food Safety Act, imported foods shall undergo cargo inspection and clearance procedures by the DA and the DOH at the first port of entry to determine compliance with national regulations. This inspection by the DA and the DOH shall take place prior to the assessment for tariff and other charges by the BOC.

The Customs Code also provides for the conduct of examination of imported goods. The customs officer tasked with examining, classifying and appraising imported articles shall determine whether the packages designated for examination and their contents are in accordance with the declaration in the entry, invoice and other pertinent documents. The officer will also indicate whether the articles have been truly and correctly declared at entry with regard to their quantity, measurement, weight and tariff classification and are not imported contrary to law. He shall submit samples to the laboratory for analysis when feasible to do so and when such analysis is necessary for the proper classification, appraisal and/or admission into the Philippines of the imported articles.

Export permits/clearances

All exporters in general, including exporters of food, are required to secure accreditation, depending on whether they are investment or export-oriented.⁴

The accrediting agencies for investment promotion-oriented exporters are the Bureau of Investments, Philippine Economic Zone Authority, Freeport Zone Authorities (i.e., Clark Development Corporation, Subic Bay Metropolitan Authority, Authority of Freeport Area of Bataan, Cagayan Economic Zone Authority) and Zamboanga City Special Economic Zone Authority.

The accrediting agency for export promotion-oriented exporters, as well as coffee exporters operating under the Export Development Act and the International Coffee Organization Certifying Agency is the Bureau of Export Trade Promotion-Department of Trade and Industry.

The accrediting authority for exporters not falling within any of the above, except Customs Bonded Warehouse operators, shall be the Philippine Exporters Confederation, Inc.

Once accreditation with the relevant government agency is obtained, the Exporter may proceed with its registration with the Client Profile Registration System. Please note that this is separate and distinct from the CPRS registration as importer.

Furthermore, under the FDA Law, importers, traders, distributors and exporters of food must obtain an LTO as an establishment from the FDA, and a CPR for each product.

Under the Food Safety Act, exported foods shall comply at all times with the national regulations of the importing country. Returned shipments shall undergo border inspection clearance as imported products.

Under the FDA Law, food intended for export shall not be deemed to be adulterated or misbranded if: (i) it conforms with the specification of the foreign purchaser; (ii) it is not in violation of the laws of the country to which it is intended for export; and (iii) it is labeled on the outside of the shipping package that it is intended for export. However, if such article is sold or offered for sale in the Philippines, it must comply

with the applicable laws and regulations for products that are distributed locally.

In addition, the Bureau of Plant Industry has export certification procedures and a phytosanitary certification system for the export of regulated articles, which are implemented by its Plant Quarantine Service.

Other notifications/approvals/licenses

Before obtaining the industry-specific licenses and registrations from the FDA, there are basic registration requirements for entities that intend to do business in the Philippines.

A person or corporation that intends to do business in the Philippines, including manufacturers, importers, traders, distributors and exporters of food, must obtain the appropriate registration or license from the SEC (for domestic and foreign corporations) or the DTI (for sole proprietorship).

In addition to the registration or license from the SEC or the DTI, the entity must obtain certain basic registrations and licenses, as follows:

- business/mayor's permit with the local government unit where it is located;
- BIR, as a taxpayer;
- Philippine employment agencies, as an employer (Social Security System, Philippine Health Insurance Corporation, Home Development Mutual Fund and Department of Labor and Employment); and
- if an importer, with the BOC.

Also, Presidential Decree No. 856, otherwise known as the Code of Sanitation of the Philippines, states under Section 14

⁴ Customs Memorandum Order No. 007-12, 4 May 2012.



that "No person or entity shall operate a food establishment for public patronage without securing a permit from the local health office." Moreover, under Section 15, it states that "No person shall be employed in any food establishment without a Health Certificate issued by the local health authority."

Under Section 37 of the Food Safety Act, it is unlawful for any person to fail to comply with an order relating to notifications to recall unsafe products.

ENFORCEMENT

Enforcement authorities and key responsibilities

The main bodies/agencies that are responsible for enforcement of food-related laws in the Philippines are outlined below:

1. FDA

The FDA is primarily responsible for administering the implementation of the FDA Law and the FDA IRR.

Its powers include the following:

- issue cease and desist orders;
- after due process, order the ban, recall, withdrawal and/or destruction of any health product found to have caused the death of, or serious illness or serious injury to a consumer or patient, or is found to be imminently injurious, unsafe, dangerous or grossly deceptive; and
- impose administrative penalties/sanctions in accordance with the FDA Law.

2. DOH and DA

The DOH and the DA are the FRSAs under the Food Safety Act. The DOH shall be responsible for the safety of processed and pre-packaged foods, foods locally produced or imported under this category and the conduct of monitoring and epidemiological studies on food-borne illnesses.

The DA shall be responsible for food safety in the primary production and post harvest stages of food supply chain and foods locally produced or imported in this category.

3. Bureau of Plant Industry

Under the Consumer Act, the Bureau of Plant Industry functions to ensure the safe supply of fresh agricultural crops and to improve the quality of local fresh agricultural crops and promote its export.

Penalties for non-compliance

- Penalties under the FDA Law and the FDA IRR:

▲ *Violations:*

- the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertising or sponsorship of any health product that is adulterated, unregistered or misbranded;
- the adulteration or misbranding of any health product;
- the refusal to permit entry or inspection as authorized by the FDA or to allow samples to be collected;

- forging, counterfeiting, simulating or falsely representing or, without proper authority, using any mark, stamp, tag label, or other identification device authorized or required by regulations promulgated under the provisions of the FDA Law;
- the alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of health products or committing any other act with respect to health products if such act is carried out while such article is held for sale (whether or not the first sale) and results in such article being adulterated or misbranded, provided that a retailer may sell in smaller quantities subject to guidelines issued by the FDA;
- the manufacture, importation, exportation, sale, offering for sale, distribution, transfer, non-consumer use, promotion, advertisement or sponsorship of any health product which, although requiring registration, is not registered with the FDA pursuant to the FDA Law;
- the manufacture, importation, exportation, transfer or distribution of any food substance without the license to operate from the FDA required under the FDA Law; and
- the sale, offering for sale, importation, exportation, distribution or transfer of any health product beyond its expiration or expiry date, if applicable.

▲ *Imposable penalties:*

- payment of fines and imprisonment of officers from the liable entity;



- suspension of the validity or cancelation of the LTO, CPR or other appropriate authorizations for a period which shall not exceed one year;
- revocation of LTO, CPR or appropriate authorization; and
- destruction and/or appropriate disposition of the health product at issue.

• Penalties under the Food Safety Act:

▲ *Violation:*

- the production, handling or manufacture for sale, offering for sale, distribution in commerce or importation into the Philippines of any food or food product which is not in conformity with an applicable food quality or safety standard promulgated in accordance with the Food Safety Act;
- the production, handling or manufacture for sale, offering for sale, distribution in commerce or importation into the Philippines of any food or food product which has been declared as a banned food product by a rule promulgated in accordance with the Food Safety Act;

- refusing access to pertinent records or entry of inspection officers of the FDA;
- failure to comply with an order relating to notification to recall unsafe products;
- adulteration, misbranding, mislabeling, falsely advertising any food product which misleads the consumers and carrying out any other acts contrary to good manufacturing practices;
- operating a food business without the appropriate authorization;
- conniving with food business operators or food inspectors, which will result in food safety risks to the consumers; and
- violating the implementing rules and regulations of this Food Safety Act.

▲ *Imposable penalties:*

- payment of fines and imprisonment of officers from the liable entity; and
- suspension of authorizations granted under the Food Safety Act.



FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL REGIME

Overview

The Sale of Food Act (Cap 283) ("**SFA**") and the Sale of Food Act (**Food Regulations**) (collectively "**Food Regulations**") govern food quality and integrity. These apply to primary produce (e.g., meat, fish, fruits and vegetables), processed food and food appliances. The Food Regulations also set out permissible limits of food additives, minerals and nutrient supplements, and also specify particular requirements with which various foods must comply. Non-compliance with any of the provisions in the Food Regulations is an offense and the person shall be liable on conviction to pay a fine of up to SGD 5,000, and in the case of a second/subsequent conviction, a fine of up to SGD 10,000, or imprisonment for up to three months, or both.

Foods that are high in nutrient content, e.g., vitamin drinks, may be considered health supplements, which are defined in the Health Supplements Guidelines from the Health Sciences Authority of Singapore ("**HSA**") as products that are used to supplement a diet, with benefits beyond those of normal nutrients, and/or to support or maintain the healthy functions of the human body. Health supplements may contain a combination of vitamins, minerals, amino acids, or substances derived from natural sources, and may be administered in small unit doses, e.g., liquids/syrups/capsules.

While food/supplements of a food nature are regulated by the Agri-Food & Veterinary Authority of Singapore ("**AVA**"), medicinal products/health supplements are regulated by the HSA. If it is not clear whether the product in question is food or a health supplement, the product should be submitted to the HSA for classification. The classification process will take approximately three to six weeks.

Basic labeling requirements

Basic labeling requirements for pre-packed food products are set out in:

- the Food Regulations;
- the AVA's Guide to Food Labeling and Advertisements ("**AVA Guide**"); and
- the Singapore Health Promotion Board's Handbook on Nutrition Labeling ("**Nutrition Handbook**").

The label shall be in legibly and durably printed letters attached to the package of food, and shall state the following information in English:

- (a) name/description of the food – terms used for the common names or descriptions to comply with the requirements under Part IV of the Food Regulations;
- (b) a statement of ingredients;
- (c) declaration of allergenic ingredients;
- (d) net content;
- (e) name and address of the local manufacturer or importer; and
- (f) country of origin of the food.

Basic labeling requirements do not apply under the following circumstances:

- food weighed, counted or measured in the presence of the purchaser;
- food that is loosely packed at the retailer's premises; or
- intoxicating liquors are not required to carry a statement of ingredients on their labels.

In addition to the basic labeling requirements, specific pre-packed food products have to meet the following labeling requirements:

- (a) date marking the expiry date for products with a limited shelf life (e.g., perishable products, products whose quality may deteriorate over time or products that are susceptible to contamination, etc.);
- (b) advisory statements for food containing certain sweetening agents (e.g., acesulfame-K, saccharin, etc.);
- (c) labeling of special purpose foods for specific groups of consumers (e.g., sugar-free foods, low-calorie foods, diabetic foods, etc.);
- (d) nutrition labeling with the information declared in a panel;
- (e) specific labeling for certain food categories (e.g., irradiated food, wholegrain, milk, fruit wine, etc.); and
- (f) advisory statements for certain ingredients (e.g., royal jelly, aspartame) need to be labeled with the relevant advisory statement or any other statements to the same effect.

It should be noted that under the Food (Amendment No. 2) Regulations 2017, the generic names or descriptions of ingredients and additives that are not listed in the Food Regulations can be used on labels, provided that these ingredients and food additives are permitted under the Food Regulations. Also, infant formulae for infants aged 0-6 months are not required to carry the notice that infants more than six months old need complementary feeding.



Nutrition information panel

A nutrition claim must be supported by a nutrition information panel. A nutrition claim is a representation that suggests or implies that a food has a nutritive property, whether general or specific, and it can be stated affirmatively or negatively, and includes reference to:

- energy;
- salt, sodium or potassium;
- amino acids, carbohydrates, cholesterol, fats, fatty acids, fiber, protein, starch or sugars;
- vitamins or minerals; or
- any other nutrients.

The nutrition information panel must specify the energy value, the amounts of protein, carbohydrate and fat, and the amount of any other nutrients which are the subject of the nutrition claim. A nutrition information panel is not required if the pre-packed food in question has a total surface area of less than 100 cm² and has included in its label statements information about the quantity of each nutrient or the energy yield of the food in support of the specific nutrition claim. If the label includes a nutrition claim with reference to salt, sodium or potassium or any two or all of them, but does not include any other nutrition claim, reference to energy or nutrients other than sodium and potassium may be omitted from the panel.

The Nutrition Handbook provides that a nutrition information panel should include the following basic requirements:

- (a) the core list of nutrients;
- (b) the energy and nutrient values stated in per 100 g/100 ml and per serving of the food;

- (c) the number of servings per package and the serving size;
- (d) for powdered beverages and liquid concentrates, an additional column of per 100 ml; and
- (e) the variance between the declared value and analyzed value has to be within 20%.

The Twelfth Schedule of the Food Regulations sets out a prescribed form for the nutrition information panel, and further guidelines are provided in the Nutrition Handbook.

Language and legibility requirements

The text of the label should be provided in English. The name/description of the food, statement of ingredients, declaration of allergenic ingredients and net content of the food should be in printed letters not less than 1.5 mm in height. However, if the food for sale is so small as to prevent the use of wording of the prescribed size, a reduced size may be used as long as it is clearly legible.

Certain specified pre-packed foods must bear a date-marking to indicate the expiry of the food, such as (amongst others) cream, cultured milk, pasteurized milk, yogurt, pasteurized fruit/vegetable juice, tofu, cut fruits and vegetables, vitaminized fruit/vegetable juice, and infants' food. For date-markings, the date must be permanently marked or embossed on the package, and printed in letters not less than 3 mm in height.

Country of origin labeling

Regulation 5(4)(e) of the Food Regulations prescribes that the name of the country of origin (and not the name of a city/town/province) should be stated on the labels of imported foods.

Genetically modified (GM) foods

Genetically modified ("**GM**") foods and ingredients found in processed foods are generally permitted in Singapore. However, GM plants, whether imported for consumption or for agriculture-related activities, must undergo an approval process before they can be imported. The Singapore Guidelines on the Release of Agriculture-Related GM Organisms published by the Genetic Modification Advisory Committee of Singapore ("**GMAC**") provide the framework for the safe import, release and use in Singapore of GM foods. The importer will have to submit a proposal to the GMAC for safety evaluation and endorsement. The AVA will then take the GMAC's recommendations into account and conduct further safety evaluations before granting approval for the import of the GM plants.

There are currently no guidelines or legislation for labeling requirements that apply specifically to GM foods. The GMAC has set up a subcommittee to monitor international developments and to consider a labeling regime for the labeling of GM foods. The AVA and GMAC have also been working with the international body, the Codex Committee on Food Labeling, to develop guidelines on the labeling of GM foods.

Nutrition content claims and health claims

Nutrition content claims

The Food Regulations and the AVA Guide prescribe the conditions for nutrition claims, i.e., claims which suggest/ imply that the food has a general/specific nutritive property. The Nutrition Handbook and the new AVA Guidelines on Use of Signs with Implied Claims on Food Labels and Advertisements provide advisory guidelines on the use of signs on food labels and advertisements with nutrition



content claims and health claims. This nutritive property claim can be stated positively/negatively, and may refer to energy, salt, amino acids, carbohydrates, vitamins or minerals, etc. Generally, claims cannot be false or misleading. A nutrition claim must also be supported by a nutrition information panel as mentioned above. These claims are allowed so long as the food in question complies with the criteria for specific foods as set out in the Food Regulations.

Health claims

Under the Codex Guidelines for Use of Nutrition and Health Claims, a health claim means any representation that states, suggests or implies that a relationship exists between a food, or a constituent of that food, and health. Health claims include nutrient function claims, other function claims and reduction of disease risk claims.

Apart from the health claims specifically permitted under the AVA Guide, local manufacturers and importers may also apply to the AVA for approval to use new health claims. Information required to support an application includes evidence that the claim has been assessed and approved for use by other national regulatory authorities, and studies to substantiate the proposed claims, among others.

Under the Food (Amendment) Regulations 2017, in the case of prepacked food that contains barley beta-glucan and meets certain criteria, the following claim may be made on a label: "Barley beta-glucans have been shown to lower/reduce blood cholesterol. High blood cholesterol is a risk factor in the development of coronary heart disease."

Mandatory warnings and advisory statements

It is compulsory to declare food allergens in a product (e.g., gluten, eggs, peanuts, milk) as part of the basic labeling

requirements. The following food products are also required to carry a precautionary warning on their labels:

- food products containing royal jelly: "WARNING – THIS PRODUCT MAY NOT BE SUITABLE FOR ASTHMA AND ALLERGY SUFFERERS;"
- food products containing aspartame: "PHENYLKETONURICS: CONTAINS PHENYLALANINE;"
- natural mineral water containing more than 1 ppm of fluoride: "CONTAINS FLUORIDE;" and
- natural mineral water containing more than 1.5 ppm of fluoride: "CONTAINS FLUORIDE. THE PRODUCT IS NOT SUITABLE FOR INFANTS AND CHILDREN UNDER THE AGE OF SEVEN YEARS."

The Food Regulations also mandate that food products containing sweetening agents shall carry advisory statements regarding consumption by children in the prescribed form. An example of such an advisory statement would be: "Children aged nine years and under should not consume more than one serving a day, based on a serving size of 140 g."

Trade measurement markings

Under the Food Regulations, the net quantity of the food in the package must be expressed on the label in the following terms:

- for liquid foods, by volume (mL or L);
- for solid foods, by weight (grams or kg);
- for semi-solid/viscous foods, either by weight or volume; and
- for food packed in a liquid medium, by the net weight of the food together with the liquid medium, as well as by drained weight of the food.

Product recalls

There are no specific laws or regulations governing food product recalls. It is advisable for companies to have their own food recall plans, and provide a copy of them with emergency contact details to the AVA for record purposes. Food product recalls can be carried out either by the company or by the AVA.

Under the standard recall procedure proposed by the AVA, in the event of a product recall, the company should cooperate with the AVA to obtain and consolidate all necessary information about the food product, stop the distribution and sale of the affected product as soon as possible, notify other relevant parties of the product recall, remove the affected product from the market, and report on the recall to the AVA.

Food safety

Food businesses should ensure that their workers observe good manufacturing and food handling practices. In this regard, there are several informal guidelines that companies can adopt, such as the Food Handler's Handbook published by the National Environment Agency ("NEA") and the Singapore Standard SS583:2013 for Guidelines on Food Safety Management for Food Service Establishments published by the NEA and SPRING Singapore.

Singapore does not have a mandatory reporting regime for food poisoning incidents. Generally, any person may make a health-related complaint to the Ministry of Health or a hygiene-related complaint to the NEA, which will work with the AVA to investigate the relevant food establishment.



Advertising claims (general)

The Food Regulations specifically regulate food advertising in Singapore. While advertising claims do not require prior approval from the AVA, the Food Regulations prescribe that such advertisements should not contain false or misleading statements. The AVA Guide provides guidelines on the permitted and prohibited claims for use in advertisements.

General consumer protection laws and guidelines may also apply. These include the Consumer Protection (Fair Trading) Act (Cap 52A) ("**CPFTA**"), the Consumer Protection (Trade Descriptions and Safety Requirements) Act (Cap 53) ("**CPTDA**"), and the Singapore Code of Advertising Practice ("**SCAP**"). For the avoidance of doubt, only the SCAP is not legally binding.

The CPFTA and the CPTDA prohibit unfair practices and false trade descriptions respectively, whereas certain provisions of the SCAP are relevant to food advertising, for example:

- (a) paragraph 5 of the "General Principles" section, which states that advertisements should not mislead by inaccuracy, ambiguity, exaggeration, omission or otherwise;
- (b) appendix F, section 6.24.1, which states that advertisements for food products (or food supplements) containing polyunsaturated fats should not contain any claim that the consumption of such food offers any specific health benefit; and
- (c) appendix F, section 6.30, which prohibits certain claims for products containing vitamins, pro-vitamins or minerals.

Credence claims, e.g., organic, natural

Generally, there are no prescriptive laws, regulations or standards applicable to natural claims.

Regulation 9(B)(5) of the Food Regulations provides that a label with the word "organic" or similar words shall only be used when the food has been certified as organic under an inspection and certification system:

- that complies with section 6.3 of the Codex Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods, GL 32-1999; or
- that substantially complies with the guidelines mentioned above and is acceptable to the Director-General as being a suitable system for the certification of organic food.

The Nutrition Handbook stipulates that organic claims cannot be verbally and visually associated with the Board's Healthier Choice Symbol.

Additionally, regulation 9(B)(4) of the Food Regulations provides that the word "pure" or similar words shall only be used on food that is free from other added substances, or food that is of the same standard (i.e., composition, strength and quality) as what is prescribed in the Food Regulations.

Health rating schemes

The Health Promotion Board administers a voluntary front-of-pack labeling scheme known as the Healthier Choice Symbol ("**HCS**"). The HCS logo carries nutritional taglines including, but not limited to, "higher in whole grains," "higher in calcium," "no added sugar," "lower in sugar," "no added sodium," "lower in saturated fats," "trans fat free," etc. The food product will be eligible for the HCS if it satisfies the nutrition guidelines specified for each food category as set out in the Healthier

Choice Symbol Nutrient Guidelines ("**HCS Guidelines**"). The HCS Guidelines also prescribe the mandatory primary taglines that are pre-allocated for each sub-food category. The HCS guidelines currently cover more than 60 food categories.

Under Regulation 9(1) of the Food Regulations, "[no] written, pictorial, or other descriptive matter appearing on (...) food is to include any claim or suggestion, whether in the form of a (...) mark purporting to indicate the nature, stability, quantity, strength, purity (...) of food or its ingredients, that is false, misleading or deceptive, or is likely to create an erroneous impression regarding the value, merit or safety of the food."

The inclusion of foreign health rating scheme logos on the packaging (e.g., the Australian Health Star Rating logo) may create the erroneous impression that such products bearing the logo are healthier than other products which do not bear the logo, which may not necessarily be the case. Such products should be accompanied with suitable disclaimers providing more information about the foreign health rating scheme, and clarifying that the product bearing the logo may not necessarily be healthier than other products which do not bear the logo as they have not been rated under the scheme.

Other

The Food (Amendment) Regulations 2017 came into effect on 1 April 2017.

The key changes are as follows:

- Permitting the use of new food additives and ingredients (e.g., Spirulina extract, cyanobacterial-phycoerythrin and beet red);
- Permitting the extension of use of existing food additives to additional food categories (e.g., Quillaia extracts (Type I, II or both) may be used, up to maximum levels of 40 ppm



for alcoholic beverages and 50 ppm for soft drinks, whereas polyglycerol polyricinoleate may be used as a permitted emulsifier/stabilizer in food, under good manufacturing practice);

- Permitting the use of a new health claim relating to barley beta-glucan;
- Introducing maximum limits for incidental constituents in food; and
- Deleting the maximum residue limits for pesticides.

The Food (Amendment No. 2) Regulations 2017 came into effect on 15 June 2017.

The key changes arising from the second set of amendments are as follows:

- Permitting the use of generic names or descriptions of ingredients and additives that are not listed in the Food Regulations provided that these ingredients and food additives are permitted under the Food Regulations; and
- Clarifying that infant formulae for infants aged 0-6 months are not required to carry the notice that infants more than six months old need complementary feeding.

LICENSING AND APPROVALS REQUIREMENTS TO IMPORT/EXPORT FOOD

Customs registration

The business must first register with the Accounting and Corporate Regulatory Authority to obtain a Unique Entity Number ("UEN"). With the UEN, it can register an account with Singapore Customs. It must also open and maintain

a GIRO account with the AVA to pay fees and permits. Thereafter, the business can apply for a license/register with the AVA to import food.

If the food to be imported is meat and fish products, fresh fruits or vegetables, the business will require a license from the AVA. The license will generally take 1-5 working days to be processed by the AVA depending on the type of food. Otherwise, if the food to be imported is processed food (excluding the above types of food) or food appliances, only registration with the AVA is necessary.

Foreign companies will be required to appoint a local agent or open a branch office to apply for the relevant license on their behalf.

All food and food products being exported to Singapore must originate from sources approved by the AVA. Overseas food establishments that export food and food products (i.e., meat and meat products, processed/fresh table eggs, live poultry, processed food and food appliances, fish and fish products) to Singapore must meet the relevant accreditation requirements and procedures from the AVA. No AVA accreditation will be needed for processed food products and food appliances, fresh fruits and vegetables, and these products must be obtained only from establishments regulated by overseas competent authorities.

Import permit

The relevant import license/registration with the AVA and an import permit are required before a business may import food into Singapore. The import license is valid for one year, and an import permit is required per consignment. However, where the business is a foreign entity, it may appoint a local agent or branch office to apply for the permit on its behalf.

If the import of the food product is specifically regulated by the AVA, additional documentary proof, such as laboratory test reports or health certificates, is required when applying for the import permit. Approval of the import permit will take around one working day.

Inspection of imported foods

All imported food products and food appliances are subject to inspection at ports of entry and samples may be taken for laboratory analysis. Sampling is compulsory for meat products. Some consignments may be placed on "hold and test," i.e., the consignment cannot be sold or distributed until the laboratory results indicate that the sample is compliant with Singapore food laws.

It is advisable to book an appointment for inspection using the online AVA Inspection & Laboratory e-Services system. All importers of fresh eggs coming through Changi Airfreight Center are required to make an online booking for inspections at least one day before inspection.

Although it is not compulsory for the importer to send the food for testing prior to importing it, it may be good practice to have laboratory analyses done to show evidence of quality control and compliance with the Sale of Food Act (Cap 283) and associated regulations.

Consignments that fail the inspection are not permitted to be sold or distributed in Singapore. Importers of such consignments will have to return or dispose of the consignments. Depending on the severity of the non-compliance, the source and/or exporter may be suspended from exporting to Singapore. The importers may also be suspended from importing from these sources and/or exporters.



Export permits/clearances

An export permit as well as the same license/registration required with the AVA is needed to export meat, fish and processed eggs out of Singapore. However, the export of fresh eggs, fresh fruits and vegetables, processed food and food appliances is not regulated by the AVA. Such exporters will only require an export permit from Singapore Customs.

Food and food products to be exported from Singapore will have to meet the destination country's import requirements, which may include obtaining export certification. The following types of export certification may be applied from the AVA:

- Free Sale Certificate (Food);
- Export Health Certification for Meat, Fish and Dairy Products; and
- Export Certification for Processed Food.

Other notifications/approvals/licenses

A license is required to operate a food retail establishment ("**Food Shop License**") where food and drink are sold wholly by retail (Environmental Public Health Act (Cap 95)). This is obtained from the National Environment Agency.

However, if the food establishment is for manufacturing, processing or packing food (excluding meat and fish), a license to operate such a food factory ("**Food Processing Establishments License**") should be obtained from the AVA pursuant to section 21 of the Sale of Food Act (Cap 283).

If the food establishment is for processing meat/fish or for use as a cold store, yet another license is required under section 12(1) of the Wholesome Meat and Fish Act (Cap 349A) ("**Meat or Fish Processing Establishment or Cold Store License**"). This should also be obtained from the AVA.

All food storage warehouses are required to apply with the AVA for the "Registration to Operate a Food Storage Warehouse." A food storage warehouse refers to any building, facility, structure or premises, where food is stored for the sale or distribution to other processors, wholesalers or any other business selling or distributing to the ultimate consumer. For meat and fish storage, a coldstore license from the AVA is required instead of registration.

ENFORCEMENT

Enforcement authorities and key responsibilities

There are five main authorities responsible for the enforcement of food-related laws and regulations.

1. AVA

The AVA oversees food safety, animal health and agriculture/fish farming. In relation to food, the AVA is responsible for ensuring food safety/quality and regulating food establishments. The AVA has wide powers to investigate and prevent the sale of food which may be dangerous for public consumption. An authorized officer has the power to do any of the following:

- (a) enter any premises to inspect, seize and destroy any food intended for sale which is deleterious to health;
- (b) require, or may reasonably require, any person to furnish information that is relevant to enforcement; and
- (c) demand, select and take/obtain samples for examination.

Based on recent amendments to the SFA in 2017, the AVA may also institute a mandatory product recall.

The AVA generally monitors the safety of food imports from countries such as Japan and Foot-and-Mouth Disease-affected countries, and initiates various product recalls for contaminated food.

2. NEA

The NEA deals with food hygiene and retail food establishments. Pursuant to the Environmental Public Health Act, the NEA is responsible for issuing licenses for retail food establishments. Licensees will also have to abide by the Environmental Public Health (Food Hygiene) Regulations ("**EPHFHR**"), which set out (amongst others) practices such as time-stamping of catered food, storage of raw food, and restrictions on sale of expired food.

3. Singapore Customs

The Singapore Customs facilitates trade, promotes trade security, and enforces taxes on the goods where necessary. It administers the TradeNet portal through which the relevant import permit applications are made to Competent Authorities, such as the AVA.

4. Ministry of Trade and Industry

The Ministry of Trade and Industry administers the CPFTA and the CPTDA. In relation to consumer complaints under the CPFTA, the Consumers Association of Singapore is a non-profit non-governmental consumer watchdog that facilitates the resolution of such complaints.



5. Advertising Standards Authority of Singapore ("ASAS")

The ASAS enforces the Singapore Code of Advertising Practice with the endorsement of the AVA and various other organizations and government agencies.

Penalties for non-compliance

SFA

Sections 16 and 49: selling food which is not labeled in accordance with the SFA and the Food Regulations

- a fine of up to SGD 5,000. In the case of a second/subsequent conviction, a fine of up to SGD 10,000 and/or imprisonment for up to three months applies.

Sections 17 and 49: selling food which is labeled or advertised in a false/misleading manner

- a fine of up to SGD 5,000. In the case of a second/subsequent conviction, a fine of up to SGD 10,000 and/or imprisonment for up to three months applies.

Food Regulations

Regulation 261: non-compliance with any of the Food Regulations

- a fine of up to SGD 1,000. In the case of a second/subsequent conviction, a fine of up to SGD 2,000 applies.

Environmental Public Health (Food Hygiene) Regulations ("EPHFHR")

Regulation 33: non-compliance with any provision of the EPHFHR

- a fine of up to SGD 2,000. In the case of a continuing offense, a further fine of up to SGD 100 for every day or part thereof during which the offense continues after conviction.

Regulation of Imports and Exports Regulations

Regulation 45: failure to obtain the relevant import/export permits

- the greater of a fine of up to SGD 100,000 or three times the value of the goods in respect of which the offense was committed, and/or imprisonment for up to two years. For a second/subsequent conviction, the greater of a fine of up to SGD 200,000 or four times the value of the goods in respect of which the offense was committed and/or imprisonment for up to three years.

CPFTA

Section 6: consumer's right to sue for unfair practice

- a civil claim for up to SGD 30,000

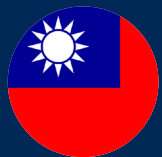
CPTDA

Section 4 and section 15: falsely applying a trade description or selling goods that bear a false trade description

- a fine of up to SGD 10,000 and/or imprisonment for up to two years

SCAP

- no criminal or civil consequences. However, the ASAS can withdraw advertising space or time from offending advertisers in breach of the SCAP. The outcome of investigations by the ASAS can also be published, subjecting advertisers to possible negative publicity.



FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL REGIME

Overview

1. General food products

In Taiwan, food is defined by the **Act Governing Food Safety and Sanitation ("Act")**, last amended on 24 January 2018, as "goods provided to people for eating, drinking or chewing, and the raw materials of such goods." Food products, including food materials, 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 supplementary regulations and notices periodically promulgated by the Taiwan Food and Drug Administration ("**TFDA**"). Novel foods are not allowed to be manufactured, processed, exported, 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 labeled with specific healthcare effects are classed as "health foods" and are governed by the **Health Food Control Act** (last amended on 24 January 2018).

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

The term "healthcare 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 "healthcare effects" are prescribed by the **TFDA**. As of 26 March 2018, the **TFDA** has designated 13 healthcare effects which can be claimed for a food product with health food registration if the healthcare effect to be claimed can be substantiated by test results, among others. These 13 healthcare effects 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 iron absorption.

In addition, the **TFDA** has also allowed fish oil and monascus with health food registration to claim "to lower blood triglyceride" and "to lower the total blood cholesterol," respectively, if the ingredients of fish oil or monascus meet the specifications prescribed by the **TFDA**. Testing results to support either healthcare effect are not required for fish oil and monascus to be registered.

3. Medicines or therapeutic goods are not food

A clear line is drawn 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** (last amended on 31 January 2018).

4. Alcoholic beverages

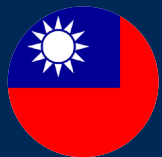
Alcoholic beverages are separately regulated by the **Tobacco and Alcohol Administration Act** (last amended on

27 December 2017) along with tobacco-related products. "Alcoholic beverages" referred to in the Tobacco and Alcohol Administration **Act** include beverages having an alcohol content by volume of more than 0.5%, as well as undenatured 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 classified as a medicine by the **TFDA**, it is exempt from the Tobacco and Alcohol Administration **Act**.

Basic labeling requirements

According to the **Act**, the container or external packaging of food has to conspicuously indicate the following matters in Chinese and common symbols:

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, for domestic certified agricultural products, the tracing sources of these products as well as the production systems prescribed by the central agricultural competent authority in a public announcement;
6. country of origin (see "Country of origin labeling" for further details);
7. expiry date;



8. nutrition label;
9. genetically modified raw materials for food; and
10. any other matters designated by the central competent authority in a public announcement.

Nutrition information panel

The Regulation on Nutrition Labeling for Packaged Food sets out detailed requirements for the nutrition labeling of a packaged food on the market. This requires the following information to be conspicuously displayed:

- (1) items of labeling: (a) the title "Nutrition label;" (b) energy contents; (c) amount of protein, fat, saturated fat, trans fat, carbohydrate, sugar and sodium contained; (d) contents of other nutrients referred to in any nutrition claim; and (e) contents of other nutrients labeled by the manufacturer voluntarily (note that dietary fiber can be listed under carbohydrates and that cholesterol can be listed under fat and after trans fat);
- (2) with respect to the amount of energy and nutrients, the labeling value should be expressed (i) in units of 100 grams and grams per serving for solid (semi-solid) food, and in units of 100 milliliters and milliliters per serving for liquid food (drinks), or (ii) in units of grams for solid (semi-solid) food (or milliliters 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; and
- (3) labeling unit for the contents of energy, nutrients and trans fat.

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.

Country of origin labeling

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 Import Goods*.

Primarily, a food product's country of origin is determined by:

1. the location where such food product is wholly produced; or
2. the location where such food product underwent 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 product is different from those of the food product's raw materials; or (b) if the Customs Import Tariff code remains unchanged, the major process has been completed or the value-added rate is more than 35%.

Genetically modified (GM) foods

Genetically modified raw materials for food may not be used in foods until they have passed a regulatory health risk assessment and are registered with the **TFDA**. In practice, the assessment and registration will take at least one year and should not exceed 540 days. 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 food raw materials.

Nutrition content claims and health claims

Claims about the presence or absence of nutritional properties are governed by the *Regulations on Nutrition Claims for Packaged Foods*, which set out the specific form and wording to be followed for such claims. For example, where food is listed as sugar-free, the amount of sugar in such food may not be more than 0.5 g per 100 g of solid (semi-solid) food or per 100 ml of liquid food.

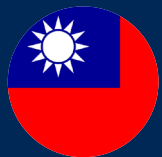
Foods claiming specific healthcare effects are regulated under the Health Food Control **Act**. Pursuant to the Health Food Control **Act**, no foods may be labeled or advertised as a health food or claim any of the approved 13 healthcare effects before passing a health food evaluation and being registered with the **TFDA** as a health food.

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

Mandatory warnings and advisory statements

The Rule Governing Labeling of Allergens in Food Products, which was announced by the **TFDA** on 7 March 2014 and came into force on 1 July 2015, 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 **TFDA** 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.



Trade measurement markings

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

Product recalls

Food businesses may recall food products voluntarily. If a food business finds that its 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 **TFDA** may require a food business to recall specified products or products from specified areas on the basis of a risk assessment made by the **TFDA** or any epidemiological survey results; and
- (2) the Department of Health of each municipal government ("**Local DOH**") may order, at its discretion, a food business to recall food products if there is found to be a violation of the **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 counterfeited;
 - C. the food products are determined as causes of food poisoning; or

- D. the food business fails to comply with labeling requirements set forth in the **Act**, to the extent that the violation is serious.

Food safety

Since a series of food safety scandals in Taiwan from 2009, the **TFDA** has intensified its control on food safety. In general, food safety control in Taiwan partly relies on the control of the **TFDA** and Local DOHs as well as partly on self-management by food businesses.

To ensure food sanitation and safety, the **TFDA** and Local DOHs 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**. 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. Food businesses designated by the **TFDA** are required to formulate a food safety monitoring plan (including the implementation of compulsory self-inspection) to ensure food safety. If a food business finds that its 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 an incident to the Local DOH.

The **TFDA**'s and Local DOHs' 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 the **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.

Advertising claims (general)

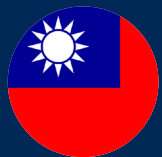
The advertisement of food products is primarily supervised by the **TFDA** and the Local DOH pursuant to the **Act**. The Health Food Control **Act** may apply when claims pertaining to healthcare effects are involved.

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 NTD 4 million (about USD 136,340) 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 USD 170,430) and the Local DOH can immediately confiscate and destroy the products in question.

In order to implement 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"), last amended on 13 March 2017. 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;



- claims that incorporate exaggerated or misleading statements (e.g., about physiological functions) are not allowed;
- examples of allowable descriptions for foods include "nourish and tone up the body," "build up physical strength," "maintain vigorous vitality," etc.; and
- certain claims that refer to the physiological functions of dietary fiber, vitamins and minerals are allowed (e.g., it is permissible to claim that Vitamin C promotes the formation of collagens, assists in healing wounds, maintains a tight arrangement of cells, assists in 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 as, or labeled with the phrase, "health food" or advertised as having any healthcare effects. Breach of this provision is a criminal offense and may incur a criminal fine of up to NTD 1 million (about USD 34,080).

A health food may not make any claim that is false, exaggerated or misleading, or claim a healthcare 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 NTD 2 million (about USD 68,170). If the violation is serious, the violating health food business may be further ordered by the Local DOH to recall the products.

Credence claims, e.g., organic, natural, fresh

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.

1. Organic claims

In Taiwan, organic claims can only be used on certified organic foods under the Agricultural Production and Certification Act ("**Certification Act**"), last amended on 29 January 2007. Under the Certification Act, "organic product" means any agricultural product that is cultivated, processed and packaged in accordance with relevant regulations and is certified under the Certification Act. Chemical pesticides, chemical fertilizers, animal drugs or any other chemicals, except for those permitted by the authority, cannot 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 NTD 1 million (about USD 34,080) may be imposed on the manufacturer or importer/seller.

2. Other credence claims

Pursuant to Art. 28 of the Act, 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 Local DOH 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 NTD 4 million (about USD 136,340).

Health rating schemes

There are several food quality marks, which can be labeled on food packaging in Taiwan. Those food quality marks may be granted by governmental organizations (e.g., Health Food Mark granted by the TFDA) or by independent food associations (e.g., Taiwan Quality Food (TQF) Mark granted by the Taiwan Quality Food Association), provided that certain criteria set by those parties are fulfilled.

The inclusion of foreign health ratings or logos on the packaging of the food products to be imported to Taiwan is not prohibited, as long as those foreign health ratings or logos are true and non-misleading. Nevertheless, the substantiations to support those foreign health ratings or logos may be required at the request of the health authorities during food inspections.

Other

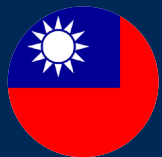
Not applicable.

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 carried out with the Bureau of Foreign Trade ("**BOFT**") instead of with Customs.

A Taiwanese entity (including a 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.



Import permit

1. Registration with the 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 foods into Taiwan. A special business license 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 Ministry of Finance before the import/export registration.

2. Product registration with the 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 tablets or capsules (Tablet or Capsule Foods), health foods, special dietary foods and vacuum-packed soy instant foods. 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 must 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 dietary foods, about 16-22 months for health foods, about two months for food additives, and at least 12 months for genetically modified foods.

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 foods to be imported. To the extent that the imported foods fall under the "Consolidated List of Commodities Subject to Import Restriction and Commodities Assisted by Customs for Import Examination" (please refer to the BOFT's online "Classification of Commodities and Regulations" database available at <https://fbfh.trade.gov.tw/rich/text/indexfhE.asp> 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 two to three working days to obtain.

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

Inspection of imported foods

Food entering Taiwan is subject to the Act and Regulations of *Inspection of Imported Foods and Related Products* ("**Inspection Regulations**"), last amended on 24 June 2015,

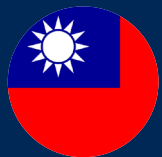
which provide statutory requirements and procedures for the inspection and control of imported foods at the border.

Some imported foods (e.g., genetically modified raw materials for food and food additives) are subject to special inspections by the TFDA (please refer to the Bureau of Foreign Trade's online "Classification Commodities and Regulations" database available at <https://fbfh.trade.gov.tw/rich/text/indexfhE.asp> 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 the ingredients and contents of imported foods.

Furthermore, the TFDA may implement preferential measures for food importers with excellent performance records regarding the import inspection stipulated in the Inspection Regulations. This may reduce costs for importers and may minimize the delays associated with inspection and testing under the Act and the Inspection Regulations.

Export permits/clearances

Basically, as long as a business is registered with the BOFT as an importer/exporter, it can export foods from Taiwan. However, an export permit may be required depending on the type of foods to be exported. Where the exported foods are regulated by the BOFT's "Consolidated List of Commodities Subject to Export Restriction and Commodities Assisted by Customs for Export Examination" (please refer to the BOFT's online "Classification of Commodities and Regulations" database available at <https://fbfh.trade.gov.tw/rich/text/indexfhE.asp> for details), an export permit will be required in the name of the exporter.



Other notifications/approvals/license

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 26 March 2018, this registration requirement is applicable to certain importers, dealers and manufacturers of food products as well as restaurants/food and beverage businesses.

ENFORCEMENT

Enforcement authorities and key responsibilities

Local DOH/TFDA

The Local DOHs are the primary enforcers of the Act. The TFDA may also act as an enforcer when necessary; however, this is not common in practice.

Penalties for non-compliance

Basis

Violation of the requirements set out in the Act

Penalties:

1. fines ranging from NTD 60,000-NTD 3 million (USD 1,875-USD 93,750) in principle, or NTD 200 million (USD 6,250,000) in an extreme case;
2. suspension or termination of its business; and
3. revocation of all or part of the business registration or factory registration.

Otherwise, food products involved may be confiscated and destroyed or ordered to be recalled.

Basis

Manufacturing, processing, selling, etc. food products or food additives that are adulterated or counterfeit or contain food additives not approved by the TFDA

Penalties:

- maximum penalty: seven years of imprisonment in principle or life imprisonment in an extreme case



FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL REGIME

Overview

In Thailand, the general law governing food quality and integrity is the Food Act BE 2522 (AD 1979) ("**Food Act**"). The Food Act is applicable to the manufacture and importation of food for sale in Thailand. Manufacturers and importers are required to obtain licenses prior to manufacturing and/or importing food into Thailand.

The use of, among others, additives, processing aids, vitamins, minerals, novel foods, nutritive substances and other substances are subject to the Food Act. Such substances may be used in accordance with the limits set out by the Food Act.

According to the Food Act, the definition of "food" means edible materials or materials required for the sustenance of life which include:

- a) all kinds of substances eaten, drunk, held in the mouth or taken into the body by human beings, irrespective of the means or manner in which they are consumed, excluding medicines, psychotropic substances or narcotics which may be governed by other laws; or
- b) substances aimed to be used, or used as, ingredients in the manufacture of foods, including food additives, colors and flavorings.

Accordingly, medicines and therapeutic goods are not regulated by the Food Act as they are subject to the Drug Act BE 2510 (AD 1967).

In addition to the Food Act, certain foods are subject to separate laws and/or regulations, i.e., among others, alcoholic beverages and liquor are subject to the Excise Act BE 2560 (AD 2017).

Basic labeling requirements

The Notification of the Ministry of Public Health (No. 367) BE 2557 (AD 2014) Re Display of Food Labels on Containers ("Notification No. 367") and the Notification of the Ministry of Public Health (No. 383) BE 2560 (AD 2017) Re Display of Food Labels on Containers (No. 2) ("Notification No. 383") enacted under the Food Act provides the following minimum pieces of information to be shown on the labels of food in a container which is manufactured for sale, imported for sale, or sold:

1. name of food;
2. food serial number;
3. name and address of manufacturer, packer or importer (for imported food, the country of manufacture should be specified);
4. quantity of food using metric units;
5. essential ingredients in approximate percentage of the weight, in order of greater to lesser quantity;
6. "information for food allergies: contains ..." or "information for food allergies: may contain ..." (if any);
7. name and number of additives pursuant to the international numbering system: INS for food additives;
8. natural odor added/artificial natural odor added/synthetic odor added/natural flavor added/artificial natural flavor added (if any);
9. date/month/year of manufacture, or date/month/year of expiry, or date/month/year by which the food should be consumed with the statement "best before;"
10. warning (if any);
11. advice on storage of food (if any);
12. method of cooking (if any);

13. method of usage statement, necessary for food intended to be used with infants or children or any group of persons specifically;
14. any additional statement prescribed in Notifications Nos. 367 and 383; and
15. any other statement prescribed by a Notification of the Ministry of Public Health.

Nutrition information panel

In addition to the labels of food mentioned in the basic labeling requirements, certain foods, i.e., food with nutritional claims, food using nutrition characteristics for sales promotion, food for specific groups of consumers for sales promotion, and other foods prescribed by the Food and Drug Administration ("**FDA**") with the approval of the Food Board, are also subject to nutrition labels according to the Notification of the Ministry of Public Health (No. 182) BE 2541 (AD 1998) Re: Nutrition Label ("**Notification No. 182**"), and the Notification of the Ministry of Public Health (No. 219) BE 2544 (AD 2001) Re: Nutrition Label (No. 2) ("**Notification No. 219**"). Notifications Nos. 182 and 219 provide that the nutrition information panel shall be provided in the prescribed table format detailing, among others, the following in the Thai language:

1. number of servings of food in the package;
2. nutritional value per one serving;
3. percentage of daily recommended quantity;
4. percentage of daily recommended intake; and
5. information on the daily energy needs of one person.

Further to the nutrition information panel, the FDA has issued the Notification of the Ministry of Public Health (No. 374)



BE 2559 (AD 2016) Re Foods Required to Display Nutrition Label and Energy, Sugar, Fat and Sodium Values in GDA Form ("**Notification No. 374**") for certain foods, i.e., snacks, chocolate and similar products, baked goods, semi-processed foods and chilled and frozen ready-to-eat meals. Notification No. 374 provides that such foods shall display the following information in the Thai language in the prescribed format:

1. nutritional value per one serving;
2. number of servings of food in the package;
3. amount of energy value in kilocalories and percentage calculated as a percentage of maximum daily intake;
4. amount of sugar value in grams and percentage calculated as a percentage of maximum daily intake;
5. amount of fat value in grams and percentage calculated as a percentage of maximum daily intake; and
6. amount of sodium value in milligrams and percentage calculated as a percentage of maximum daily intake.

Language and legibility requirements

The display of information on the labels of food in a container which is manufactured for sale, imported for sale, or sold, as prescribed under Notifications Nos. 367 and 383, shall be in the Thai language. The statements on the label must be set out legibly and prominently so as to afford a distinct contrast to the background, and the size of characters must be relative to the size of label area. The size of characters depends on the type of statement displayed on the label.

Country of origin labeling

Notifications Nos. 367 and 383 provide that the label shall include the country of manufacture of imported food.

Genetically modified (GM) foods

Genetically modified foods ("**GM Foods**") are not prohibited from manufacture, importation or sale in Thailand. GM Foods are governed by the Food Act.

Please note that the Notification of the Ministry of Public Health (No. 251) BE 2545 (AD 2002) Re Display of Label of Foods Obtained from Genetic Modification or Genetic Engineering Techniques provides specific labeling requirements for GM Foods, i.e., among others, soybean and products of soybean, corn and products of corn, in addition to the requirements under Notifications Nos. 367 and 383 as follows:

1. "genetically modified" shall be displayed incorporating the name of GM Foods, for example, among others, "genetically modified corn;"
2. the display of statements such as "free of genetically modified food," "not genetically modified food," "containing no genetically modified ingredients," "genetically modified ingredients sorted or separated," or other similar statements, is prohibited for GM Foods; and
3. the display of the above statements shall be in clearly legible characters of a size relating to the size of the label area.

Nutrition content claims and health claims

Nutrition claims

Notification No. 182 divides nutritional claims into three categories, namely: nutrient content claim, comparative claim and nutrient function claim.

1. Nutrient content claims are claims made about the level of nutrients or energy in the food, i.e., "source of calcium," "high in fiber and low in fat," etc.

2. Comparative claims are a comparison of nutrient content or energy in the food from two items or more, i.e., "less than," "more than," "reduced," "light," etc. However, the compared product must only be of the same category or a similar product. The display of a comparative claim must state the type of referenced food and compare the levels of nutrients of two items as a percentage or fraction per serving.
3. Nutrient function claims are claims that refer to the function of nutrients in the body. The product under this claim must have the said nutrient content to a level that can be considered as a "source of" as provided in Notification No. 182. In addition, the said claim must be supported by reliable scientific proof and must not contain any statement or meaning which would lead consumers to the understanding that the consumption of said nutrient can prevent or cure any diseases.

Health claims

Further to Notification No. 182, relating the function of nutrients to the body is considered a nutrient function claim, which is subject to the Notice of Food and Drug Administration Re Display of Nutrient Function Claims ("**Notice Re Nutrient Function Claims**"). Examples of health claims under the Notice Re Nutrient Function Claims include, among others, "Vitamin A helps promote good vision," "Copper plays a role in the creation of hemoglobin," "Zinc helps body growth," etc.

Mandatory warnings and advisory statements

Notification No. 367 provides that if the ingredients of the food cause certain types of allergies, i.e., nuts, eggs, fish, dairy, oats, etc., the statement "information for food allergies: contains ..." or "information for food allergies: may contain ..." must be displayed on the label.



Trade measurement markings

Notifications Nos. 367, 383, 182 and 219 provide that the quantity of food must be indicated in metric units.

Product recalls

The Food Act does not provide a specific provision regarding product recall. However, the Food Act does provide that, to safeguard the benefits and safety of consumers, the competent authority shall have the following powers to order:

1. the manufacturer, importer, seller or advertiser of foods to cease advertising if he/she is in violation of the Food Act; or
2. the manufacturer, importer, seller or advertiser of foods to cease manufacturing, importing, selling and/or advertising foods that the authority finds do not have the benefits, qualities or properties advertised.

Advertising claims (general)

The Food Act prohibits advertising the benefits, qualities or efficacies of foods which are false or misleading. The advertising of benefits, qualities or efficacies of foods through radio broadcasting, television, motion picture, newspaper, printed media or by any other means for trading purposes must be submitted to the Food and Drug Administration for approval prior to advertising. Accordingly, the Notice of Food and Drug Administration Re Bases on Food Advertisement BE 2551 (AD 2008) ("**Notice Re Food Advertisement**"), the Notice of Food and Drug Administration Re Bases on Food Advertisement (No. 2) BE 2555 (AD 2012) and the Notice of Food and Drug Administration Re: Bases on Food Advertisement (No. 3) BE 2559 (AD 2016) enacted under the Food Act provide procedures and guidelines for advertising of food.

Samples of advertising claims under the Notice Re Food Advertisement include, among others:

1. "new" can be used for products which are put on sale for not more than one year;
2. "safe" can be used when there is a picture or statement displayed concerning the manufacturing process and there is evidence of HACCP certification by a certified body with standards according to ISO/IEC Guide 65 or standards governing product certification; and
3. advertisements that represent that the food is sold worldwide must be supported by evidence showing that such food has been sold in not less than 15 countries on three continents.

Please note that the Notice Re Food Advertisement prohibits the use of a statement that is a comparison to, or a defamation of, another person's product. Words such as "excellent," "superb," "exceptional," "absolute," "sacred," "miraculous," "extremely," or other words with similar meanings, are also not permitted to be used in advertising the benefits, qualities or efficacies of foods.

Credence claims, e.g., organic, natural, fresh

Organic claims

The Notice Re Food Advertisement provides that agricultural products, which use the words "organic agricultural product," "organic product" or "organic" in the advertisement by the manufacturer, seller or importer, must be certified. This certification must meet the requirements of the International Federation of Organic Agriculture Movement ("IFOAM"), Codex, or other foreign organic agricultural standards (if such foreign country has enforced regulations concerning

production of organic agricultural products). It may also be issued by an inspection agency whose certification system has been certified pursuant to the criteria of IFOAM, ISO/IEC Guide 65 System, or has been registered by an agency of a country with regulations on organic agriculture.

Natural claims

The Notice Re Food Advertisement provides that the word "natural" can be used for food products that occur naturally, such as vegetables, fruit, meat, etc., and which have been passed through a primary process, conversion or manufacturing process, with no addition of food additives, colors, odors, vitamins and minerals.

Fresh claims

The Notice Re Food Advertisement provides that the word "fresh" can be used in relation to a natural food which is not yet converted, or can be used with food that specifies that the period of sale is not more than three days from the date of manufacture, such as bread, etc.

Health rating schemes

The FDA has introduced a voluntary front-of-pack logo program that identifies healthier food options in Thailand pursuant to the Notification of the Ministry of Public Health (No. 373) BE 2559 (AD 2016) Re: Display of Nutrition Logo on Label ("**Notification No. 373**"). If the food has been examined and certified by the specified organization, it is permitted to display the Healthier Choice logo on the front of the label. To grant the said logo, the FDA uses a scoring system in considering the energy, fat, sugar and sodium content of food.



THAILAND



In addition, the inclusion of foreign health rating scheme logos on products imported into Thailand is not prohibited. However, the food business operator should ensure that the evidence of all references mentioned in the label, including foreign health rating scheme logos, are readily available for submission to the FDA upon their request.

Other

Not applicable.

LICENSING AND APPROVALS REQUIREMENTS TO IMPORT/EXPORT FOOD

Customs registration

To import or export any goods, including foods, into or from Thailand, an importer or exporter is required to register with the Thai Customs Department according to the Customs Act BE 2560 (AD 2017) (the "Customs Act").

Import permit

To import foods for sale into Thailand, the importer is required to obtain either an import license from the FDA under the Food Act, or an import license from the Ministry of Commerce ("**MOC**") under the Export and Import of Goods Act BE 2522 (AD 1979), depending on the types of products.

To obtain an import license from the FDA, it takes approximately seven working days to process from the date of submitting the complete set of required documents. For an

import license from the MOC, the timeframe would depend on the types of products being imported.

A non-resident is not permitted to apply for an import license with the FDA or MOC. It is advisable to have a local body apply for an import license as the language used in processing the license is Thai.

Inspection of imported foods

Foods imported for sale into Thailand are subject to inspection at the border by the FDA and/or Customs under the Notice of Food and Drug Administration Re Inspection of Foods Imported into the Kingdom. If the results and analysis of the inspection show that the imported foods fail to meet the standards, the relevant authority is entitled to notify the importer to take the problematic foods in question back and/or consider taking legal action against the importer.

For a subsequent importation of the same kind of foods that were previously imported into Thailand, if the results and analysis of the inspection show that the recent imported foods fail to meet applicable standards, the said foods shall be attached at the place of importation with samples taken for analysis. If the results of the analysis show that the food meets the standards, the attachment will be lifted.

On the other hand, if the results of the analysis show that the foods continue to fail to meet applicable standards, the relevant authority is entitled to take legal action against the importer and/or to implement monitoring measures for subsequent imports of the same kind of food.

If the importer has duly improved the foods to meet applicable standards as per the relevant authority's order, the FDA may consider lifting the monitoring measures.

Export permits/clearances

Export requirements differ depending on the product and destination country. The export rules differ between goods and destination and are subject to change from time to time.

Other notifications/approvals/licenses

The Food Act provides that setting up a factory to manufacture foods for sale, or the importation of foods for sale into Thailand are subject to license requirements. However, the distribution and/or sale of foods do not require a license under the Food Act.

ENFORCEMENT

Enforcement authorities and key responsibilities

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

1. Food and Drug Administration ("FDA")

The key responsibility of the FDA is to ensure that businesses comply with Thai food laws and regulations. This includes the granting of manufacturing licenses or import licenses, quality control, advertising licenses, etc.



For the purpose of food control, and so as to ensure that food is hygienic and free from harm for consumers, the FDA is entitled to, among other things:

1. issue orders in writing for permit holders who produce or import food to modify or remedy the production premises or the premises for storing food;
2. order that the manufacture or import of food without a permit, or of food that has been approved, should be stopped; and
3. announce to the public the results of food tests where it is apparent that the results of the tests suggest that the food is impure, fake, substandard, or may be harmful to the health of the public, or that a container may be harmful when used to contain food.

So as to perform the duties under the Food Act, the relevant authority also has the power to, among others:

1. enter premises used for the manufacture, storage or sale of food, or the business premises of a manufacturer, safe keeper, seller, or importer. This must occur during business or daylight hours for the purposes of inspection and control in accordance with the Food Act.
2. in the case of reasonable grounds to suspect that an offense has been committed under the Food Act, enter upon any premises or conveyances for food inspection and seize or attach food and the tools and instruments involved in the commission of the offense, as well as food containers and packages and all documents concerning the food;
3. take food in a reasonable amount as a sample for the purpose of an inspection or testing;
4. seize or attach food or containers suspected of being able to cause harm to the health of, or be unhealthy for, the public; and

5. seize or attach impure, fake or substandard food or containers that are suspected of being able to cause harm to the health of the public or of having a description that is incorrect according to the quality or standard the Minister announced.

2. Royal Thai Police

The police are the general enforcement authority in Thailand. The FDA works and coordinates with the police to enforce compliance with the Food Act.

3. Customs Department

Thai Customs Officials are responsible for examining goods imported into and exported from Thailand and to determine whether the goods comply with, among others, the Customs Act and the relevant provisions of importation and exportation of goods into and from Thailand.

Penalties for non-compliance

Food Act BE 2522 (AD 1979)

Section 6: quality and standard of foods and container of foods.

- Sections 47-51: maximum penalty of up to 2 years' imprisonment and/or a fine up to THB 30,000 (approx. USD 1,000).

Section 13: compliance with the authority order.

- Section 52: imprisonment not exceeding 1 month and/or a fine not exceeding THB 1,000 (approx. USD 33).

Sections 14-15: manufacture and import license.

- Section 53: imprisonment not exceeding 3 years and/or a fine not exceeding THB 30,000 (approx. USD 1,000).

Section 25: the manufacturing, importation for sale and sale of impure, bogus or substandard food.

- Sections 53-61: maximum penalty of up to 10 years' imprisonment and/or a fine up to THB 100,000 (approx. USD 3,333).

Section 30: failure to comply with the FDA order to cease manufacturing or importing the food without a permit.

- Section 63: a fine not exceeding THB 50,000 (approx. USD 1,666) and a daily fine of THB 500 (approx. USD 16) throughout the time of failing to comply with the order.

Section 40: falsely advertising the benefits, quality or properties of food or advertising to deceive and create an unreasonable belief.

- Section 70: imprisonment not exceeding 3 years and/or a fine not exceeding THB 30,000 (approx. USD 1,000).

Section 41: advertising the benefits, quality or properties of food without the FDA's approval.

- Section 71: a fine not exceeding THB 5,000 (approx. USD 166).



FOOD PRODUCT AND SAFETY REGULATION

SUMMARY OF LEGAL REGIME

Overview

The Vietnamese National Assembly adopted Law No. 55/2010/QH12 on Food Safety on 17 June 2010 ("Food Safety Law"). The Food Safety Law stipulates the rights and obligations of food products manufacturers in relation to food safety, manufacturing conditions to ensure food safety, food business operations, importing and exporting food, food advertising, food labeling, and preventing breakdowns in food safety and properly handling breakdowns if they do occur.

In addition to the Food Safety Law, food products are regulated by:

- Decree No. 15/2018/ND-CP dated 2 February 2018 of the Government on Providing Detailed Regulations Regarding Some Provisions of Food Safety Law ("**Decree No. 15**")

Regarding the use/addition of additives and processing aids in/to food products, the Food Safety Law generally states that manufacturers and traders are not allowed to use materials whose shelf life is passed, or are not listed as permitted to be used, or that exceed the allowable dosage.¹

The term "**food additives**" is defined in the Food Safety Law as a substance with or without nutritional value, which is intentionally added to food in the process of production in order to retain or improve particular characteristics of the food.² The Vietnamese jurisdiction recognizes specific regulations regarding the use/addition of food additives in Circular No. 27/2012/TT-BYT of the Ministry of Health, dated 30 November 2012, on Guidance on the Management of Food Additives. This Circular, as amended by Circular No. 08/2015/

TT-BYT, dated 11 May 2015, provides a list of permissible food additives in the production, processing and trade of foods, and the maximum limits on the amount of food additives in food products.

The term "**processing aids**" is defined in the Food Safety Law as a substance which is intentionally used in the processing of food materials or food ingredients in order to achieve a technological purpose and can be removed from or remains in the food. The regulations on the use as well as the allowable dosage of processing aids are detailed in Decision No. 46/2007/QĐ-BYT, dated 19 December 2007, and Circular No. 24/2013/TT-BYT of the Ministry of Health on "Regulation of maximum Level of Biological and Chemical Pollution in Food," dated 14 August 2013.

With respect to "**functional foods**," the Ministry of Health promulgated Circular No. 43/2014/TT-BYT ("**Circular No. 43**") providing the definition of functional foods. Accordingly, functional foods consist of food supplements, health supplements and medical foods, including foods for special diets.

Vietnamese food legislation provides certain guidelines for the use/addition of **vitamins, minerals and nutritive substances** in/to food, or the maximum amount of those allowed for foods. In particular, the national technical regulations set forth certain requirements with regards to the amount of vitamins, minerals and nutritive substances, such as folic acid, Fe and zinc, which can be added to food. For functional food, health supplements and medical food, Circular No. 43 also sets out Recommended Nutrient Intakes ("**RNI**"), which govern the maximum amount that manufacturers may add to such foods.

In addition to the Food Safety Law, depending on product characteristics, some foods are subject to additional regulations. For example, wine and wine products are subject

to the separate regulations under Decree No. 105/2017/ND-CP, dated 14 September 2017, of the Government on Trading of Wine.

Basic labeling requirements

The labeling regulations of Vietnam require the below information to be clearly stated on the label for food products:³

- name of the food;
- name and address of the organization or individual responsible for the food;
- origin of the food;
- quantity;
- date of manufacture and expiry date;
- ingredients or ingredient quantities;
- information about warnings (if any); and
- instructions for use and preservation.

In addition, depending on each type of packaged food, the label must also satisfy the specific requirements as required by law.

Nutrition information panel

Nutritional value of food or its ingredients on labels of food products. Apart from the information disclosure requirement applied to health claims, manufacturers/importers are not required to provide nutrition information.

¹ Food Safety Law, Article 5.3.

² Food Safety Law, Article 2.13.

³ Decree No. 43/2017/ND-CP, dated 14 April 2017, of the Government on Labeling of Goods, Article 10 and Annex I, Article 5, Joint Circular No. 34/2014/TTLT-BYT-BNNPTNT-BCT, dated 27 October 2014.



Language and legibility requirements

The individual or organization responsible for labeling the goods may determine the size of the label, including the size of the letters and figures expressed on the label, but must ensure the following requirements:⁴

- All the compulsory content under the law must be recorded.
- The size of letters and figures must enable them to be read with the naked eye, and they must also satisfy the following requirements:
 - (a) The size of letters and figures expressing a unit of measurement must comply with the provisions of the law on measurement.
 - (b) If the goods are foodstuffs, food additives or food processing aids, which are pre-packed, then the height of the letters for compulsory contents of the label must not be less than 1.2 mm. If the label is recorded on one side of the packaging (excluding the joining parts or margins), which is less than 80 cm², then the height of the letters must not be less than 0.9 mm.

The organization or individual responsible for the labeling of the goods must ensure that the colors of the letters, signs, numbers, drawings, images, marks, etc., present on the label are clear. In particular, the color in which the compulsory information is expressed must contrast with the background color of the label.⁵

All compulsory information must be expressed in Vietnamese. Vietnamese law does not require the translation of any optional information written in a foreign language.

Vietnamese law allows some contents to be presented in other Latin origin languages, including:⁶

- the international name or scientific name of a medicine for human use when the medicine does not have a corresponding Vietnamese name;
- the international name or scientific name enclosed with a chemical formula or composition formula of a chemical, chemical substance, adjuvant or ingredient of a medicine;
- the international name or scientific name of an ingredient and the quantity of the ingredient when such name cannot be translated into Vietnamese or when the Vietnamese translation is meaningless; and
- names and addresses of foreign enterprises involved in manufacture of the goods.

Country of origin labeling

The Food Safety Law requires that all packaged foods must include a statement on the package that identifies the country in which it was made or produced.

The manufacturer or importer of goods shall itself determine and record on the label the origin of its goods, ensuring truthfulness and accuracy and compliance with the law of Vietnam on origin of goods or in compliance with treaties in which Vietnam is a member or which Vietnam has signed. The method of recording the origin of goods is regulated as follows: record the words "*Manufactured in*" or "*Produced in*" or "*Country of origin*" or "*Origin*" or "*Manufactured by*"

followed by the name of the country or territory where the goods were manufactured. The name of the country or territory where the goods were manufactured may not be abbreviated.⁷

Furthermore, the Law No. 59/2010/QH12 on Protection of Consumers' Rights ("**Protection of Consumers' Rights Law**") adopted by the National Assembly on 17 November 2010 and the Product and Goods Quality Law prohibit traders from making false or misleading representations about the place of origin of goods.

The mandatory requirement for country of origin labeling also applies to all imported food.

Genetically modified (GM) foods

All genetically modified foods and ingredients intended for sale must be subjected to a safety evaluation by the Vietnam Ministry of Agriculture and Rural Development. Such GM foods must be granted a "Certificate of Genetically Modified Organisms Which Are Eligible For Use As Food" before being put in the Vietnamese market. This process generally takes a minimum of 8-10 months.⁸

The law requires that organizations and individuals circulating GM foods or foods containing genetically modified organisms at a rate greater than 5% of each component must, in addition to complying with the provisions of the law on labeling, also declare on the label specific information about the genetically modified organisms, except in the following cases:⁹

- The prepackaged GM food contains GM ingredients without discovery of the modified gene or products of the modified gene in the food.

⁴ Circular No. 43, Article 5.

⁵ Circular No. 43, Article 6.

⁶ Circular No. 43, Article 7.

⁷ Circular No. 43, Article 15.

⁸ Decree No. 69/2010/ND-CP, dated 21 June 2010, of the Government on Biosafety for Genetically Modified Organisms, Genetic Specimens and Products of Genetically Modified Organisms, as amended by Decree No. 108/2011/ND-CP, Article 28.

⁹ Decree No. 15, Article 10.



- Fresh GM foods, unpackaged processed GM foods sold directly to consumers.
- GM foods serving recovery from a natural disaster or epidemic.

It is compulsory for the statement "genetically modified" to appear on the label of GM foods.¹⁰

Nutrition content claims and health claims

Vietnamese law provides certain regulations addressing claims about the presence or absence of nutritional properties of a processed food, a food additive or a food processing aid under Joint Circular No. 34/2014/TTLT-BYT-BNNPTNT-BCT ("**Joint Circular No. 34**"), and for functional foods under Circular No. 43. In general, ingredients and the quantity of ingredients are amongst the compulsory contents which must be stated on the labels of food products.¹¹ Claims about the presence or absence of specific ingredients for the sole purpose of advertising are prohibited if the functionality of such ingredient is similar to that of other ingredients in the same group.¹²

Health Claims must be supported by scientific evidence. The following are regulations relating to nutrition content claims and health claims for certain types of food:

- For food supplements: Nutrition content/health claims must not apply to ingredients of which the content in the food is lower than the 10% RNI thresholds.¹³

- For health supplements: Nutrition content claims must not apply to ingredients of which the content in the food is lower than the 15% RNI thresholds. Health Claims must comply with scientific evidence. If the content of an ingredient is lower than the threshold stated in such scientific evidence, the manufacturers must not provide health claims for such ingredients.
- For medical food: Nutrition content/health claims apply to all nutritional ingredients on the basis of the RNIs on serving sizes.

Mandatory warnings and advisory statements

It is compulsory under Vietnamese law to indicate safety warnings/instructions on the label of food products.¹⁴ Vietnamese law, however, is silent on how such warnings/instructions must be presented. For ingredients or substances in compound ingredients of "goods of special categories" which contain "preservatives" with a prescribed dosage and which are included on the list of those which may cause allergic reactions or be harmful to humans, animals and the environment, the names of such preservatives must be presented on the label. It is unclear which goods fall under the special categories.¹⁵

Trade measurement markings

Measurement markings shall follow international standards.¹⁶ For liquid food, measurement marking refers to the net volume. For solid food, measurement marking refers to the net weight.

Both methods of measurement markings shall apply if the product consists of both characteristics.

Product recalls

The Food Safety Law requires that the following foods must be recalled:¹⁷

- foods which are still marketed after their shelf life;
- foods not conforming with relevant technical regulations;
- foods that are new technological products not yet permitted for circulation;
- foods which degenerate during the process of preservation, transportation or trading; and
- foods containing substances which are banned from use or have contaminants in excess of the allowable limits.

After being recalled, unsafe foods must be handled in one of the following ways:

- correction of products' flaws or labeling errors;
- change of use purposes;
- re-export; or
- destruction.

The traders or producers of unsafe foods may voluntarily recall these foods, or must recall them if directed by a competent state authority. For voluntary recall, traders or producers are responsible for stopping the sale of foods within 24 hours from issuance of the decision on a recall.¹⁸

¹⁰ Food Safety Law, Article 44.2.

¹¹ Decree No. 43, Article 10 and Annex I.

¹² Joint Circular No. 34, Article 11.4.

¹³ The RNI thresholds are regulated under Circular No. 43.

¹⁴ Decree No. 43, Article 10 and Annex I.

¹⁵ Decree No. 43, Article 17.6.

¹⁶ Joint Circular No. 34, Article 8.

¹⁷ Food Safety Law, Article 55.

¹⁸ Circular No. 17/2016/TT-BYT on recalls of unsafe foods under the management of the Ministry of Health, Article 3.



Producers and traders of recalled foods must publish information about the recall and must pay all expenses for recalling and disposing of such recalled foods.

In some emergency cases, state authorities may directly recall and dispose of the unsafe foods and afterward request the traders or producers to reimburse the recall and disposal expenses.

Furthermore, under the Protection of Consumers' Rights Law, upon the detection of defective products, manufacturers/traders must promptly take all necessary measures to stop the supply of such defective products in the market. This includes recall of the defective products and the publication of information regarding the defective products in at least 5 consecutive issues of a daily newspaper or 5 consecutive days on the radio or television of the locality where such products are circulated. Additionally, if the defective products cause serious harm to the life or health of consumers, the traders/manufacturers must pay compensation to the consumers (even when they are not aware of or not at fault for such defects).

Food safety

Under the Protection of Consumers' Rights Law, upon the detection of defective products, including food products, manufacturers/traders must promptly take all necessary measures to stop the supply of such defective products in the market. Information must be published regarding the defective products in at least five consecutive issues of a daily newspaper or five consecutive days on the radio or television of the locality where such products are circulated.¹⁹ The following content must be announced:

- description of the goods to be recalled;

- reasons for the recall and warning of damage possibly caused by defects of such goods;
- time, place and mode of recall;
- time and mode of remedy of defects; and
- necessary measures to protect consumer rights during the recall.

After completing the product recall, a report on the results must be sent to the competent authorities, i.e., Vietnam Competition Authority.

Additionally, if the defective products cause serious harm to the life or health of consumers, even when they are not aware of or not at fault for such defects, the traders/manufacturers must pay compensation to the consumers.²⁰

Advertising claims (general)

Generally, all advertising activities in Vietnam are governed by Law No. 16/2012/QH13 on Advertising adopted by the National Assembly on 2 July 2012 ("**Advertising Law**"). This law also contains provisions on advertising special goods that may have an impact on human health.

Regarding the content of advertising, including advertising claims, the Advertising Law and other food legislation contains provisions which, in general terms, make it an offense to pack, label or advertise food in a manner that is false, misleading or deceptive. The content must be truthful, accurate and clear without causing damage to producers, traders and advertisement recipients.

Furthermore, the following are prohibited:

- advertising which is untruthful or causes confusion regarding:

- the business competence or the ability to provide products, goods and services of organizations and individuals trading in such products, goods and services;
- the quantity, quality, prices, utilities, designs, packages, brand names, origins, types, methods of service, and warranty duration of the products, goods and services as registered or announced;
- advertising using direct comparison of the prices, quality and efficiency of one's products, goods or services against those of another's products, goods or services of the same type; and
- advertising using the words "best," "only," "the best," "number one" or words with a similar meaning but that are not supported with evidentiary documents as stipulated by the Ministry of Culture, Sports and Tourism.

In addition, the Product and Goods Quality Law and the Protection of Consumers' Rights Law contain a number of provisions that regulate advertising for food products, most notably:

- prohibition on traders/manufacturers from engaging in misleading or deceptive conduct, or conduct that is likely to mislead or deceive;
- prohibition on traders/manufacturers from making certain false or misleading representations in connection with the supply or possible supply of goods or services; and
- prohibition on traders/manufacturers from engaging in conduct that is likely to mislead the public as to the nature, manufacturing process, characteristics, suitability for their purpose or the quantity of any goods.

¹⁹ Protection of Consumers' Rights Law, Article 22.

²⁰ Protection of Consumers' Rights Law, Article 22 and Article 23.



Credence claims, e.g., organic, natural, fresh

The Vietnamese legislation on foods does not recognize any mandated regulatory system regarding credence claims.

Health rating schemes

Health rating schemes are not regulated under the food regulation in Vietnam.

Other

Micronutrients are required to be added to certain foods

From 15 March 2017, micronutrients including iodine, iron, zinc and vitamin A must be added to certain foods, particularly as follows:²¹

- from 15 March 2017, iodine must be added to cooking salt; and
- from 15 March 2018:
 - iron and zinc must be added to cooking flour; and
 - vitamin A must be added to vegetable oils, which include soybean oil, palm tree oil, cabbage seed oil or peanut oil (except vegetable oils used in the food industry).

LICENSING AND APPROVALS REQUIREMENTS TO IMPORT/EXPORT FOOD

Customs registration

Before being imported into Vietnam, imported food products must satisfy the following:

- the Announcement On Conformity With Regulation on Food Safety must be registered at a competent state agency; and
- a Certificate of Compliance with the Foods Import Requirements must be issued by a designated inspection agency for each consignment.

These requirements also apply to imported foods that are exempted from an inspection as listed in the "**Inspection of imported foods**" section below.

In addition to the above, functional food, micronutrient-fortified food, genetically modified food and irradiated food must obtain a Certificate of Free Sale or Health Certificate.

Import permit

Once the food product is self-declared or registered, the import permit is not required.

Inspection of imported foods

Food products entering Vietnam are subject to the State inspection for food safety. Imported food products are transported to warehouses for preservation pending customs clearance only when they have registration for food safety

inspection. The customs clearance will only be effected when there is a written certification of satisfaction of import requirements. Under Decree 15/2018, imported and exported food is exempted from inspection in the following cases:²²

- products which have a certificate of registered product declaration;
- foods in the hand luggage of inbound passengers that are sent before or after the passengers arrive to serve the passengers' personal needs, and gifts within duty-free allowances;
- imports serving the personal needs of people eligible for diplomatic immunity;
- products in transit, temporarily imported or in bonded warehouses;
- test samples whose quantities are suitable for the testing purposes and confirmed by the owners;
- products used for display at exhibitions or fairs;
- products and raw materials that are manufactured or imported for production or processing of exports or internal production and are not sold domestically;
- temporarily imported products for sale at duty-free shops; and
- imports serving emergency purposes under orders of the Government or the Prime Minister.

However, if there is a food safety warning for such products, a state inspection is still required.

²¹ Decree No. 09/2016/ND-CP on fortification of micronutrients in food.

²² Decree No. 15/2018/ND-CP, Article 13.



Please note that at least five days before the arrival of the goods at a port or border gate, the importer must register for the hygiene and safety inspection with the competent inspection agency. Inspection agencies are technically specialized agencies possessing sufficient technical conditions and capabilities. They are assigned by the Ministry of Health to perform this specific function (e.g., the Institute of Hygiene and Public Health of certain cities and provinces).

In order to avoid costs and delays associated with inspection and testing under the State inspection, exporting countries may consider the Vietnam Treaty on Mutual Recognition of Food Safety Certification.

When making an assessment for mutual recognition, the competent authorities of the exporting countries will send a registration dossier to the Ministry of Agriculture and Rural Development.

Within 30 working days from the date of receiving the complete registration dossiers listing the trading and manufacturing facilities of the competent authorities of the exporting countries, the competent authorities of the Ministries of Vietnam shall appraise, and inform the competent authorities of the exporting countries of, the results of the appraisal and the inspection plan if inspection of the exporting country is necessary.

Under Vietnamese laws, there are three types of inspection methods: reduced inspection which is a document inspection of up to 5% of the shipments within a year that is randomly chosen by the customs authority; normal inspection which is an inspection of the documents only; or a tightened inspection which is an inspection of both the document and sampling.

Export permits/clearances

Export requirements differ depending on the product and destination country. The competent Vietnamese authority may grant Certificates of Free Sale, Health Certificates, Certificates of Origin or other certificates for exported food, if so requested by the country of importation.

Other notifications/approvals/licenses

In addition to the Announcement On Conformity With Regulation on Food Safety, an importer/trader must obtain a "Certificate of Food Hygiene and Safety for Distribution Center." This certificate is aimed at regulating the hygiene of the food and the safety standards of the related traders' premises, as well as the behavior of their staff. This certificate is not only required for the business entities that are importing and storing food products, but also for those that are selling and distributing the food products in Vietnam (i.e., traders).

The term of the certificate is three years from the date of issuance. If an importer or trader wishes to continue producing or trading the product, they must submit an application for the renewal of the certificate within six months prior to the expiry of the certificate.

ENFORCEMENT

Enforcement authorities and key responsibilities

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

1. Ministry of Health, Vietnam Food Administration under Ministry of Health, Departments of Health

The Vietnam Food Administration, under the Ministry of Health, is the core agency responsible for food safety.

The local food authorities in each city and province are responsible for enforcing regulations on food safety in their cities/provinces. Generally speaking, the local food authorities are most concerned with violations that pose a risk to human health and/or safety.

2. Vietnam Competition Authority under the Ministry of Industry and Trade

The Vietnam Competition Authority ("VCA"), under the Ministry of Industry and Trade, is the authority in charge of competition, consumer protection and trade remedies concerning imported goods into Vietnam. The VCA consists of six boards, including the Antitrust Investigation Board, the Competition Policy Board, the Unfair Competition Investigation Board, the Consumer Protection Board (the Consumers' Interests Protection Associations), the Trade Remedies Board, and the International Cooperation Board. The VCA also includes the Departmental Office, the Center for Competition Information and Data, and the Center for Investigator Training.



The main function of the VCA is assisting the Ministry of Industry and Trade in state administration over competition, consumer protection and trade remedies concerning imported goods into Vietnam. The main obligations of the VCA are as follows:

- promoting a fair competitive environment;
- protecting enterprises and consumer's interests against activities which restrict competition;
- preventing unfair competitive practices;
- protecting the rights and interests of consumers;
- establishing a fair competition environment for domestic industries; and
- supporting domestic industries to prevent foreign anti-dumping, anti-subsidy and safeguard cases.

The VCA has a broad range of enforcement powers in protecting consumer rights. These include the power to settle complaints within its jurisdiction, to carry out or to propose remedies for violations of the Protection of Consumers' Rights Law, and to publicize the lists of organizations and individuals who violate the rights of consumers in the mass media and at the VCA's head office as well as on the VCA website.

3. The Consumers' Interests Protection Association

The Consumers' Interests Protection Association ("CIPA") under the Vietnam Competition Authority was established in accordance with the Protection of Consumers' Rights Law. Pursuant to Article 28, Protection of Consumers' Rights Law, the main obligations of the CIPA are as follows:

- to provide guidance, assistance and counseling of consumers upon request;
- to provide representation for consumers' own lawsuit(s) that foster the public interest;

- to provide state management agencies with information on violations by law institutions and violations by individuals trading goods and services to protect the interests of consumers;
- to conduct independent surveys to protect consumer interests, which include the following responsibilities: testing; announcing survey results; testing the quality of goods and services; checking the validity of information and warnings provided to consumers about goods and services; providing warnings to consumers and suggesting appropriate state agencies which are competent to handle violations of legislation on the protection of consumer interests;
- to participate in formulating laws, guidelines, policies, plans and measures to protect the interests of consumers; and
- to participate in advocacy, legal education and the advancement of knowledge of consumers.

Penalties for non-compliance

Decree No. 178/2013/ND-CP, dated 14 November 2013, of the Government on the Penalties for Administrative Violations of Food Safety

- In principle, the penalties imposed for the failure to comply with regulations on food safety are VND 100 million (USD 4,800) for individuals and VND 200 million for organizations (USD 9,600). However, for certain violations, the penalties may be as high as 7 times the value of the violating foods.

Decree No. 185/2013/ND-CP, dated 15 November 2013, of the Government on Providing the Penalties on Administrative Violations in Commercial Activities, and Production of and Trading in Counterfeit or Banned Goods and Protection of Consumer Rights and Decree 124/2015/ND-CP of the Government provide amendments to some articles of the Decree No. 2185/2013/ND-CP on the Penalties for Administrative

Violations of Commercial Activities, and Production of and Trading in Counterfeit or Banned Goods and Protection of Consumer Rights.

- Depending on the type of violation, the penalty ranges from VND 10 million to VND 30 million (equivalent to USD 500 to USD 1,500). For example, for providing false and misleading information regarding the products, the penalty ranges from VND 10 million to VND 20 million (equivalent to USD 500 to USD 1,000).
- The penalty ranges from VND 10 million to VND 30 million (USD 500 to USD 1,500) for failure to comply with a product recall.

Decree No. 158/2013/ND-CP, dated 12 November 2013, of the Government on Penalties for Administrative Violations Pertaining to Culture, Sports, Tourism and Advertising and Decree No. 28/2017/ND-CP, dated 20 March 2017, of the Government provide amendments to some articles of Decree No. 158/2013/ND-CP, Decree No. 131/2013/ND-CP on Penalties for Administrative Violation against Copyrights and Related Rights and Decree No. 158/2014/ND-CP on Penalties for Administrative Violations against Regulations on Culture, Sports, Tourism and Advertising.

- The penalties imposed for the failure to comply with regulations on advertising of food products range from VND 5 million to VND 30 million (equivalent to USD 250 to USD 1,500).



AUSTRALIA



Elisabeth White
Partner, Sydney
+61 2 8922 5386
elisabeth.white
@bakermckenzie.com



Julie Cox
Special Counsel, Sydney
+61 2 8922 5232
julie.cox
@bakermckenzie.com

CHINA



Andrew Sim
Partner, Beijing
+86 10 6535 3916
andrew.sim
@bakermckenzie.com



Yilan Yang
Associate, Beijing
+86 10 6535 3906
yilan.yang
@bakermckenzie.com

HONG KONG



Isabella Liu
Partner, Hong Kong
+852 2846 1689
isabella.liu
@bakermckenzie.com

INDONESIA



Mochamad Fachri
Associate, Partner
+62 21 2960 8547
mochamad.fachri
@bakermckenzie.com



Cahyani Endahayu
Partner, Jakarta
+62 21 2960 8515
cahyani.endahayu
@bakermckenzie.com

JAPAN



Daisuke Tatsuno
Partner, Tokyo
+81 3 6271 9479
daisuke.tatsuno
@bakermckenzie.com



Mihiko Ida
Counsel, Tokyo
+81 3 6271 9508
mihoko.ida
@bakermckenzie.com

MALAYSIA



Kherk Ying Chew
Partner, Kuala Lumpur
+603 2298 7933
kherkying.chew
@wongpartners.com



Melissa Koh
Associate, Kuala Lumpur
+603 2298 7837
melissa.koh
@wongpartners.com

PHILIPPINES



Christina Macasaet-Acaban
Partner, Manila
+63 2 819 4947
christina.macasaet-acaban
@quisumbingtorres.com



Carmina Mangalindan
Junior Associate, Manila
+63 2 819 4906
carmina.mangalindan
@quisumbingtorres.com

SINGAPORE



Ren Jun Lim
Associate, Singapore
+65 6434 2721
ren.jun.lim
@bakermckenzie.com

TAIWAN



Belle Chiou
Partner, Taipei
+886 2 2715 7206
belle.chiou
@bakermckenzie.com



Say Sujintaya
Partner, Bangkok
+66 26662824 4545
say.sujintaya
@bakermckenzie.com

VIETNAM



Lan Phuong Nguyen
Partner, Ho Chi Minh City
+84 28 3520 2643
lanphuong.nguyen
@bakermckenzie.com

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