Asia Pacific Food Law Guide - Philippines

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# Food product and safety regulation

## 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.

**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 prepackaged 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.

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 factsServing SizeNo. of Serving per container/pack       Amount per servingCalories (kcal) \_\_\_\_\_\_\_\_\_\_\_\_ Calories from Fat \_\_\_\_\_\_\_Total Fat (g)               Saturated fat \*\* (g) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_               Trans fact\*\* (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 requirement of 19-29 years old. However, if a product is specifically intended for a different age bracket group, percent RENI values are based on the appropriate FNRI reference requirement.\*\*For coconut products, Medium Chain Triglycerides (MCTs) is predominant.  | % RENI\* |

## 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 provisionary 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 prepackaged 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** | **Micronutrients**  |
|  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 ARetinol palmitate/acetate | 3.0 mg/kg as retinol | 6.5 mg/kg as retinol |
| IronElemental Iron | 70 mg Fe/kg | 105 mg Fe/kg |
| IronFerrous Sulfate or Ferrous Fumarate | 50 mg Fe/kg | 75 mg Fe/kg |
| Sugar | Vitamin ARetinol palmitate | 5 mg/kg | 30 mg/kg |
| Cooking oil | Vitamin ARetinol 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.

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 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 and testing 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.

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 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.

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