# Philippines

## Food product and safety regulation

## Overview

Consumer product quality and standards are primarily governed by a general law on consumer products, known as the Consumer Act ("**Consumer Act**"). In addition, The Food and Drug Administration ("**FDA**") 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 includes foods and other consumer products that may have an effect on health.

The term "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. 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 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 to regulate 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, ("**PNS**").

To ensure that product quality standards are complied with, the FDA requires entities that manufacture, import, export, sell and distribute "health products" to obtain a License to Operate ("**LTO**") from the FDA for its intended activities. These entities also require a Certificate of Product Registration ("**CPR**") for each food product that it manufactures, imports, exports and markets 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 Breastmilk Substitutes and Other Related Products).

# Philippines

## Basic labelling requirements

The following labelling requirements set out by the Philippine Department of Health ("**DOH**") in DOH Administrative Order No. 30-2014 ("*Revised Rules and Regulations Governing the Labelling of Pre-packaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984*") ("**Food Labelling Rules**") 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:

- Product Name / Name of the Food
- Complete list of ingredients
- Net Contents and Drained Weight
- Name and address of Manufacturer, Repacker, Packer, Importer, Trader or Distributor
- Lot Identification
- Storage Conditions (if any)
- Expiry or Expiration Date/Use-by-date/Consume Before Date (Recommended last consumption date)
- Food Allergen Information
- Nutrition Facts/Nutrition Information/Nutritive Value

**Labelling of ingredients**

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 consist 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, such a compound ingredient may be declared, as such, in the list of ingredients, provided that it is immediately accompanied by the 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 and 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 "natural 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;

k. food additives shall be declared by their common name and their functional categories.

In addition, other rules issued by the Food and Drug Administration ("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.

**Nutrition information panel**

Under the Food Labelling Rules, the nutrition information shall be presented in tabulated form (please see illustration 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 and the declaration of nutrients can also be expressed either in unit per serving or % Recommended Energy and Nutrient Intake ("RENI") or both.

a. Carbohydrates, protein, fats (cholesterol expressed in mg), sugar and dietary fiber, shall be expressed in 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 Milligram (mg) or Microgram (mcg or µg). International units (I.U.) shall be used for Vitamins A, D & E.
c. Carbohydrates, protein, fats (cholesterol expressed in mg), sugar and dietary fiber, shall be expressed in nearest Gram (g). Energy values shall be expressed in Calories (kcal). Sodium shall be declared in mg.
d. Vitamins and minerals shall be expressed in Milligram (mg) or Microgram (mcg or µg). International units (I.U.) shall be used for Vitamins A, D & E.
e. Locally manufactured food products intended for local consumption shall also indicate the corresponding Recommended Energy and Nutrient Intake (RENI) values in actual percentage expressed in whole numbers:

**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 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.

**Declaration of Food Additives**

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 Labelling Rules, the provisions of the Guidelines of Codex Standard for Food Additives Labelling (General Standard for Food

Labelling 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 technological function, need not be declared in the list of ingredients.

**Open-Date Marking**

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 the Department Administrative Order No. 01, series of 2008 ("**AO 01**"); all manufacturers and importers of consumer products sold in the Philippines, including food, are to specify on the label their consumer complaint desk address.

For milk and milk substitutes, special guidelines on labelling are provided in Philippine Department of Health Department Circular No. 2007-0276.

**Exemptions from Labelling Requirements**

The following situations are exempted from the labelling requirements under the Food Labelling Rules:

- Food materials to be served in restaurants or to be served in airline catering, which are not labelled and prepackaged available to the consumer (e.g. schools, cafeterias, trains, airplanes and retail stores) and 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 and not intended for retail sale, provided that they are properly identified 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 labelling information.

Exemptions from any specific provision/s of the Food Labelling 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.

# Philippines

## Language and legibility requirements

Under the DOH Administrative Order No. 30-2014 ("*Revised Rules and Regulations Governing the Labelling of Pre-packaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984*") ("**Food Labelling 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, information declared in a foreign language shall always carry the corresponding English translation.

In cases of exhaustion of existing labels permitted by the FDA, the use of provisionary sticker label for the English or Filipino translation is only allowed for a maximum period of 6 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 for retail sale.

# Philippines

## Country of origin labelling

Under the Philippine Tariff and Customs Code ("**Customs Code**"), every article of foreign origin imported into the Philippines shall be marked in any official language of the Philippines. 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 DOH Administrative Order No. 30-2014 ("*Revised Rules and Regulations Governing the Labelling of Pre-packaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984*") ("**Food Labelling 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.

If a manufacturer has a plant in many cities and/or towns, the corporate head office address will 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 a 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 labelling.

# Philippines

## Genetically modified 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 the Department of Agriculture ("**DA**") No. 8, series of 2002, providing for guidelines for the importation and use of GM crops ("**DA AO 8**"). These are implemented by the Bureau of Plant Industry ("**BPI**") and Bureau of Animal Industry ("**BAI**") under the DA.

Under 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)).

Under DA AO 8, no GM plant may be imported for direct use as food, or feed, or for processing, unless: (i) the importation has been duly authorized by the BPI; (ii) the regulated article has been authorized for commercial distribution as food or feed, as the case may be, in the country of origin, and (iii) regardless of the intended use, the regulated article poses no significant risks to human and animal health.

The importation or release of an article that has been altered or produced through the use of modern biotechnology shall not be allowed (a) if the donor organism, host organism or vector agent belongs to any of the genera or taxa classified by the BPI as meeting the definition of plant pest, or is a medium for introduction of noxious weeds; or (b) if it poses significant risks to human health and the environment based on available scientific information, unless (1) a risk assessment is conducted in accordance with applicable rules and regulations; (2) a biosafety permit ("**Permit**") is obtained by the technology developer from the BPI. The Permit could be for (i) import for contained use; (ii) field testing, (iii) propagation, or (iv) import for direct use as food, feed or processing.

The FDA has released guidelines on labelling of pre-packaged foods derived from or containing ingredients derived from modern biotechnology including genetically modified foods. Such guidelines are not yet effective and are published only for public comment.

# Philippines

## Nutrition content claims and health claims

The DOH Administrative Order No. 30-2014 ("Revised Rules and Regulations Governing the Labelling of Pre-packaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984") ("Food Labelling Rules") provide that rules on any use of nutrition claims or health claims in food shall be covered by such rules, and/or the CODEX Guidelines for use of Nutrition and Health Claims under CAC/GL 23-1997, including the latest amendment as applicable, except when any portion of the amendments are contrary to existing Philippine laws and their rules and regulations, in consideration of national policies and interest, in which case the Food Labelling Rules shall apply as supplementary.

The Food Labelling Rules provide that, in addition to the provisions stipulated in Codex Guidelines on the Use of Nutrition and Health Claims and Codex General Guidelines on Claims, any of the following representations or suggestions whether directly or indirectly stated shall constitute misleading, deceptive, and untruthful declaration, 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 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.
- 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:
  - o in accordance with the provisions of 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
  - o in the absence of an applicable Codex standard or guideline, permitted by the FDA.
- Meaningless claims including incomplete comparatives and superlatives.
- Claims as to good hygienic practice, such as "wholesome," "healthful," or "sound"

# Philippines

## 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 the ingredient(s) for the preparation of such food/dishes provided the statement "Serving Suggestion" or any other statement of similar importance appear 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 in equipment that processes _____"; or 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 eggs 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 10mg/kg or more;
- Such other ingredient as may be included by FDA through appropriate issuance.

The labels of all food supplements must display 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 points, type face Arial, and must be printed in bold capital letters on the primary display panel of all labelling 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.

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

# Philippines

## Trade measurement markings

Under the DOH Administrative Order No. 30-2014 ("*Revised Rules and Regulations Governing the Labelling of Pre-packaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984*") ("**Food Labelling Rules**"), the net contents 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 with 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 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 labelled:

- "20 x 10 g sachets (net wt. 200 g)"; or
- "6 x 300 ml bottles (1.8 L or 1800 ml)"

# Philippines

## Product recalls

FDA Bureau Circular No. 8 Series of 2001 prescribes the procedure for the recall of all products regulated by the FDA (including food) by manufacturers and/or distributors. This may be at their own initiative or in response to a recall order issued by the FDA if the products are likely to or have caused negative health consequences or present a risk of gross deception to the public.

For company initiated or voluntary recalls, if the company believes that the product presents a risk of injury and does not conform to registered specifications, it must notify the FDA immediately of the following:

- identity of the product involved;
- reason for the removal or correction, and the date and circumstances under which the product deficiency or possible deficiency was discovered;
- evaluation of the risk associated with the deficiency or possible deficiency;
- total amount of such products produced and/or time span of production;
- total amount of such products estimated to be in distribution channels;
- distribution information, including the number of distribution outlets and where necessary, the name and addresses of the distribution outlets;
- a copy of the company's recall communication, if any has been issued, or a proposed communication if none has been issued yet;
- proposed strategy for conducting the recall;
- name and number of the official who will act as the Company's contact person during the recall.

For FDA-initiated recalls, the director of the FDA may commence recall procedures upon the recommendation of the FDA Committee for Product Recall when the following determinations have been made:

- a product that has been distributed presents a risk of illness or injury or gross consumer deception;
- the firm has not initiated a recall of the product;
- an agency action is necessary or advisable to protect the public health and welfare.

# Philippines

## Food safety

The Philippine Congress has recently passed the Food Safety Act of 2013 ("**Food Safety Act**"), which 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. [3]

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 Department of Agriculture ("**DA**") and its attached 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 Philippine Department of Health ("**DOH**") and its attached agencies (the Food and Drug Administration Center for Food Regulation and Research and the Bureau of Quarantine). The Food Safety Act also creates 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 LGUs 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 ("**AISL**") 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 according to policies established by the DA and the DOH; and
- Exported foods shall at all times comply with national regulations as well as the regulations of the importing country. Returned shipments shall undergo border inspection clearance.

Food establishments have the following responsibilities under the Food Safety Act:

- they should be knowledgeable of the specific requirements of food law relevant to their activities;
- if it has reason to believe that 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;
- where 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. [4]

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;
- failing to comply with an order relating to the recall of unsafe products;
- 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
- violation of 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, was passed on 20 February 2015 and took effect on 23 March 2015.

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3. Art. V, Sec. 13, R.A. No. 10611, Food Safety Act of 2013

4. Sec. 14, Food Safety Act of 2013.

# Philippines

## Advertising claims

Under the Implementing Rules and Regulations of the Food and Drug Administration Act of 2009 (Republic Act No. 9711) ("**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 Food and Drug Administration ("the **FDA**");
- No claims (therapeutic, scientific or otherwise) shall be made that have not been duly approved by the FDA;
- 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 Ad Standards Council. 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. However, specific guidelines are made for food supplements, health supplements, alcoholic beverages, and products covered by the Milk Code.

# Philippines

## Credence claims

Claims about the quality of a food (e.g., fresh, natural) are subject to the Consumer Act and must not be false, misleading or deceptive.

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

Furthermore, under the DOH Administrative Order No. 30-2014 ("Revised Rules and Regulations Governing the Labelling of Pre-packaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984") ("Food Labelling Rules"), flavors and flavoring substances must be declared as part of the list of ingredients. Flavor 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 — 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.

# Philippines

## Licensing and approvals requirements to import/export food

## Customs registration

Regular importers, including food importers, are required to secure accreditation from the Bureau of Internal Revenue ("**BIR**") and the Bureau of Customs ("**BOC**"). The BIR accreditation constitutes the first phase of the accreditation process. Only importers who are accredited by the BIR will be given a BIR Import Clearance Certificate ("**BIR-ICC**"), which shall then be presented by the importers to the BOC  together with their application for BOC accreditation. As part of the accreditation process with the BOC, the importer is also required to be registered with the Client Profile Registration System ("**BOC-CPRS**").

The accreditation should ideally be obtained prior to the arrival of the goods, but can be obtained up to thirty (30) days from arrival of the goods. Without accreditation, 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 thirty (30) days from arrival of the cargo will result in 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 a License to Operate as an establishment from the FDA, and a Certificate of Product Registration for each product.

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# Philippines

## 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 License to Operate (“**LTO**”) and Certificate of Product Registration ("**CPR**"). In particular, for raw food materials, including ingredients and additives that are either:

> (a) imported by licensed food establishments for their own use, the LTO shall be presented or submitted to the Bureau of Customs ("**BOC**");
> (b) intended for distribution or for sale by licensed food establishments, the LTO and the CPR must be presented/submitted to the BOC.

From 1 September 2014, all food distributors and importers are required to present their LTO and a valid CPR to the BOC for the importation of every raw food material, food ingredient or food additive.

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.[5]

In addition, under DA MC No. 8, s. 2003, no plant or plant product intended for direct use as food, feed, or processing shall be allowed entry into the country unless it has undergone the approval process with the Bureau of Plant Industry. The imported commodity of GM origin must carry a certificate of GMO content issued by an authorized body or accredited laboratory from the country of origin, shipper or importer. Plant or plant products intended for direct use as food, feed, or processing listed in the Approval Registry shall be accompanied by an import permit and/or phytosanitary certificate to be allowed entry into the country.

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

# Philippines

## Inspection and testing of imported foods

Under the Food Safety Act of 2013, imported foods shall undergo cargo inspection and clearance procedures by the Department of Agriculture and the Philippine Department of Health ("DOH") at the first port of entry to determine compliance with national regulations. This inspection by the Department of Agriculture and DOH shall take place prior to the assessment for tariff and other charges by the Bureau of Customs.

The Customs Code also provides for the conduct of examination of imported goods. The customs officer tasked to examine, classify, and appraise 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 in regards 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.

# Philippines

## 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.[6]

The accrediting agencies for investment promotion-oriented exporters are the Bureau of Investments ("**BOI**"), Philippine Economic Zone Authority ("**PEZA**"), 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 ("**BETP**").

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

Once accreditation with the relevant government agency is obtained, the exporter may proceed with its registration with the Client Profile Registration System ("**BOC-CPRS**"). Please note that this is separate and distinct from the CPRS registration as importer.

Furthermore, under the Food and Drug Administration ("**FDA**") Act of 2009 (Republic Act No. 9711) ("**FDA Law**"), importers, traders, distributors and exporters of food must obtain a License to Operate as an establishment from the FDA, and a Certificate of Product Registration for each product.

Under the Food Safety Act of 2013, exported foods shall at all times comply 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 (1) it conforms with the specification of the foreign purchaser, (2) is not in violation of the laws of the country to which it is intended for export and (3) is labelled 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.

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

# Philippines

## Other notifications/approvals/licences

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 Department of Trade and Industry ("**DTI**") (for sole proprietorship).

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

- business/mayor's permit with the local government unit where it is located;
- Bureau of Internal Revenue, 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 Bureau of Customs.

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.”

# Philippines

## Enforcement

## Enforcement authorities and key responsibilities

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

**1. Food and Drug Administration**

The FDA is primarily responsible for administering the implementation of the Food and Drug Administration Act of 2009 (Republic Act No. 9711) ("**FDA Law**") and the Implementing Rules and Regulations of the Food and Drug Administration Act of 2009 (Republic Act No. 9711) ("**IRR**").

Its powers include:

- issue cease and desist orders;
- after due process, to order the ban, recall, withdrawal and/or destruction of any health product found to have caused the death, 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. Philippine Department of Health ("DOH") and Department of Agriculture ("DA")**

The DOH is 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 is 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.

# Philippines

## Penalties for non-compliance

Food and Drug Administration Act of 2009 (Republic Act No. 9711), and the Implementing Rules and Regulations of the Food and Drug Administration Act of 2009 (Republic Act No. 9711) :

*Offence/contravention:*

- The applicant made misrepresentations, false entries, or withheld any relevant data contrary to the provisions of the FDA Law,  or appropriate standards;
- The owner has violated any of the terms and conditions of its license or authorization;
- The label of the health product is false and misleading or does not conform with current labelling requirements;
- The holder or owner of the Certificate of Product Registration ("CPR")/authorization, without legitimate reason, fails to sell the health product or fails to cause it to be marketed during an uninterrupted period of at least three (3) years from date of issuance or renewal of the registration, or the last date of operation or marketing;
- Such other analogous grounds or causes as determined by the FDA.

*Penalties*

- Suspension of the validity of the License to Operate (“LTO”), CPR, or other appropriate authorizations for a period which shall not exceed one (1) year;
- Revocation of LTO, CPR or appropriate authorization.

*Offence/contravention*

- Refusal or failure to conduct an effective product recall: (FDA Bureau Circular No. 8, series of 2001)

*Penalties*

- Seizure and destruction of products and other court action