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Food Safety Regulations in the Philippines (Vol. 2)

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1. Food Manufacturing and Packaging

Food manufacturing and packaging in the Philippines are primarily regulated under Republic Act No. 10611, otherwise known as the Food Safety Act of 2013 ("**FSA**"),[1] and its implementing rules and regulations, Department of Agriculture-Department of Health Joint Administrative Order No. 2015-0007 ("**FSA IRR**").[2]

Under the FSA, *food* refers to any substance or product whether processed, partially processed or unprocessed that is intended for human consumption. It includes drinks, chewing gum, water, and other substances which are intentionally incorporated into the food during its manufacture, preparation, and treatment.[3]

The Food and Drug Administration ("**FDA**") prescribes the control measures, standards, regulations and requirements for the safety of processed and prepackaged foods, and verify that these, and all requirements of food law related to activities and products, including locally produced and imported processed food products under this category, are met.[4] The FDA is also responsible for the overall regulation of all activities pertaining to processed food (prepackaged or not prepackaged) including, but not limited to, inspection, licensing, registration, post-market monitoring, and laboratory analysis. It regulates the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of all processed and prepackaged food products and food supplements/dietary supplements.[5]

In relation to this, any person who intends to engage in the manufacture and/or packaging of food must first register with and secure market authorization from the FDA.[6] Particularly, the food manufacturer or packager must secure from the FDA a license to operate ("**LTO**") and in addition, a manufacturer must secure a

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1 https://www.officialgazette.gov.ph/2013/08/23/republic-act-no-10611/#:~:text=Food%20Law%20Objectives.,practices%20in%20the%20food%20trade (accessed 11 October 2022).

2 https://www.officialgazette.gov.ph/2015/02/20/implementing-rules-and-regulations-of-republic-act-no-10611/#:~:text=10611%2C%20%E2%80%9CAN%20ACT%20TO%20STRENGTHEN,FOOD%20SAFETY%20ACT%20OF%202013.%E2%80%9D (accessed 11 October 2022).

3 Sec. 4(g), Article II, FSA.

4 Rule 15b.4, Art. V, FSA IRR.

5 Rule 18.a.1, Art. V, FSA IRR.

6 Rule 8a.3, FSA IRR.

Certificate of Product Registration ("**CPR**") for each food product that it manufactures.[7] To secure and maintain an LTO and a CPR, the food manufacturer or packager must, in general, comply with Good Manufacturing Practices[8]/HACCP[9] provisions and their food handlers and stewards must have valid health certificates from the Bureau of Quarantine.

Aside from the FSA and the FSA IRR, establishments that manufacture and package food also are subject to Presidential Decree No. 856, s. 1975, otherwise known as the Code on Sanitation of the Philippines[10] and the Implementing Rules and Regulations of Chapter III ("**Sanitation IRR**").[11] The Sanitation IRR lays down the sanitation requirements for operating a food establishment[12] including the permit requirements, health certificates of their employees, quality and protection standards for all types of food, structural requirements of the premises, and inspection and evaluation of food establishments, among others.

1.1 Good Manufacturing Practice ("GMP") Rules

To align current good manufacturing practice in the Philippines with international standards, the Department of Health ("**DOH**") established DOH Administrative Order No. 153-2004 ("**GMP Rules**")[13] which specifies the regulations covering persons or establishments that manufacture, package, repack, or hold food products to ensure their quality and safety. Compliance by food manufacturers with the GMP Rules is currently the basis for issuance of an LTO by the FDA.

Further, to comply with the ASEAN General Principles of Food Hygiene, the FDA has drafted an Administrative Order entitled "General Standard for Food Hygiene Repealing Administrative Order No. 153-2004 "Revised Guidelines on Current Good Manufacturing Practice in Manufacturing, Packing, Repacking, or Holding Food" which is available on the FDA website. The FDA, however, has yet to approve the Administrative Order and, as such, the GMP Rules are still enforced.[14]

The GMP Rules provide requirements for the organization, qualifications, and required training and responsibilities for personnel in food establishments. It also specifies requirements for the premises of the establishment and required equipment and utensils directly utilized for food manufacturing, as well as the requirements for sanitation and hygiene.

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7 Sec. 28, Art. VIII, FSA IRR; FDA Administrative Order No. 2020-0017. Each importer, exporter, wholesaler, manufacturer, supplier, or repacker/toll manufacturer must secure an LTO from the FDA.

8 Good Manufacturing Practices as defined in the FSA IRR refer to a quality assurance system aimed at ensuring that products are consistently manufactured, packed, repacked, or held to quality standards appropriate for the intended use. It is concerned with both manufacturing and quality control procedures.

9 HACCP refers to Hazard Analyses and Critical Control Points as defined in the FSA IRR, which is a science-based system that identifies, evaluates, and controls hazards significant for food safety at critical points during a given stage in the food supply chain.

10 https://www.officialgazette.gov.ph/1975/12/23/presidential-decree-no-856-s-1975/ (accessed 11 Oct. 2022).

11 https://doh.gov.ph/sites/default/files/publications/Chapter_3_Food_Establishments.pdf (accessed 11 Oct. 2022).

12 A food establishment is defined as an establishment where food or drinks are manufactured, processed, stored, sold or served, including those that are located in vessels (Section 2(h), Sanitation IRR).

13 https://www.fda.gov.ph/wp-content/uploads/2021/08/Administrative-Order-No.-2004-0153.pdf (accessed 11 Oct. 2022).

14 The draft Administrative Order can be accessed at https://www.fda.gov.ph/wp-content/uploads/2020/03/General-Standard-for-Food-Hygiene-Repealing-Administrative-Order-No.-153-s.-2004.pdf

According to the GMP Rules, a quality control system also must be established to ensure that products contain the correct materials of specified quality and quantity and are manufactured under proper conditions following standard procedures to ensure the quality and safely of the product. The quality control involves sampling, inspecting, and testing of starting materials, in process, intermediate, bulk, and finished products. It also includes where applicable, review of batch documentation, sample retention programs, stability studies, product complaints, product recalls, and maintaining correct specifications of materials and products.[15]

2. Food Labeling

2.1 Food Products in General

Republic Act No. 7394 or the Consumer Act of the Philippines (the "**Consumer Act**") provides the general standards for labeling requirements on all consumer products (including food) and prohibits the manufacture, import, export, sale, offer for sale, or distribution of any food that is adulterated or mislabeled.[16] Hence, all food products manufactured and sold in the Philippines must comply with the general requirements of the Consumer Act, subject to additional requirements for specific food types discussed further below.

2.1.1 Mandatory Label Information

Under the Consumer Act, all consumer products domestically sold, whether manufactured locally or imported, by any person (either as a principal or agent), must indicate the following in their respective packaging labels:[17]

(a) correct and registered trade name or brand name;

(b) duly registered trademark;

(c) duly registered business name;

(d) addresses of the manufacturer, importer, and re-packer of the consumer product in the Philippines;

(e) general make or active ingredients;

(f) net quality of contents, in terms of weight, measure or numerical count rounded to at least the nearest tenths in the metric system;

(g) country of manufacture, if imported; and

(h) if a consumer product is manufactured, refilled or repacked under license from a principal, the label shall so state the fact.

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15 Part F, GMP Rules.

16 https://www.officialgazette.gov.ph/1992/04/13/republic-act-no-7394-s-1992/ (accessed 11 Oct. 2022).

17 Art. 77, the Consumer Act.

The following additional labeling requirements shall be imposed by the certain concerned department for food:

(a) expiry or expiration date, where applicable;

(b) whether the consumer product is semi-processed, fully processed, ready-to-cook, ready-to-eat, prepared food or just plain mixture;

(c) nutritive value, if any;

(d) whether the ingredients use are natural or synthetic, as the case may be;

(e) such other labeling requirements as the concerned department may deem necessary and reasonable.

2.1.2 Violations and Sanctions

Any person who mislabels food[18] or otherwise violates the labeling requirements on food under the Consumer Act shall be subject to a fine of PHP500.00 to PHP20,000.00, or imprisonment of three months to two years or both, at the discretion of the court.[19] If the offender is a corporation, the director, officer, or employee of the corporation who authorized, ordered, or performed the offense may be subject to the mentioned penalties.

2.2 Fresh Food

Republic Act No. 9296 or the Meat Inspection Code of the Philippines as amended ("**Meat Inspection Code**") provides the regulations for the safety and quality of meat[20] or meat products.[21] Pursuant to this, the Department of Agriculture ("**DA**") established Administrative Order No. 24, Series of 2010 which lays down the general guidelines on labeling of meat and meat products ("**Meat Labeling Guidelines**").

2.2.1 Mandatory Label Information

The meat establishment[22] operator is responsible for all labels on their product.[23] Under the Meat Labeling Guidelines, the following are mandatory label information:

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18 The instances when food is deemed mislabeled are specified in Art. 85 of the Consumer Act.

19 Art. 95, the Consumer Act.

20 "Meat" is defined in the Meat Inspection Code as fresh, chilled or frozen edible carcass including offal derived from food animals.

21 "Meat Product" is defined in the Meat Inspection Code as any product capable of use as human food which is made wholly or in part from any meat or portion of the carcass of any food animals, excepting products which contain meat or other portions of such carcasses only in a relatively small proportion or historically have not been considered by consumers as products of the meat industry, and which are exempted from definition as a meat product by the Secretary of Agriculture under such conditions as he may prescribe to assure that the meat or other portions of such carcasses contained in such product are not adulterated and that such products are not represented as meat products.

22 This refers to premises such as slaughterhouse, poultry dressing plant, meat processing plant, meat cutting plant, cold storage, warehouse and other facilities in which food animals or meat products are slaughtered, prepared, processed, handled packed or stored (Section 1.23 Meat Labeling Guidelines).

23 Section 8.1, Meat Labeling Guidelines.

(a) name of the product;

(b) net quantity;

(c) list of ingredients;

(d) name and address of the manufacturer, packer/distributor and country of origin if imported;

(e) date of preparation or production;

(f) lot identification code;

(g) safe handling instruction for chilled or frozen meats (e.g. “KEEP REFRIGERATED/FROZEN”);

(h) information for irradiated food;[24]

(i) expiration date;

(j) establishment accreditation number assigned by the National Meat Inspection Service to the slaughterhouse, cutting plant, or processing plant where the meat/meat products are sourced;

(k) claim, symbol, or recognized logo on religious preparation may be used (e.g. halal, kosher); and

(l) nutrition information may be included on the label or in the labeling.[25]

2.2.2 Exemptions from Labeling Requirements

Under the Meat Labeling Guidelines, the following meat and meat products under the following conditions, are exempted from labeling:

(a) meat not in a package or meat/meat products made and packaged on the premises from where it is to be sold to the consumer or which is packaged in the presence of the consumer;

(b) meat products delivered packaged, and ready for consumption, at the express orders of the purchaser.

2.2.3 Violations and Sanctions

Any person who violates the provisions of the Meat Labeling Guidelines may be subject to a fine of PHP500.00 to PHP20,000.00 or imprisonment of three months to two years or both, at the discretion of the court.[26] If the offender is a corporation, the director, officer, or employee of the corporation who authorized, ordered, or performed the offense may be subject to the mentioned penalties.

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24 Section 4, Meat Labeling Guidelines.

25 Section 5, Meat Labeling Guidelines.

26 Section 11.1, Meat Labeling Guidelines.

Meat and meat products sold in market outlets without the prescribed label also may be seized or confiscated in accordance with the Meat Inspection Code.[27]

2.3 Processed Food

Processed food is the product obtained from the processing stage of the food supply chain. The processing stage of the food supply chain is that stage that substantially alters the initial raw materials or product or ingredients including, but not limited to, heating, smoking, curing, maturing, drying, marinating, extraction, extrusion and a combination of those processes intended to produce food.[28]

Philippine regulations do not provide any specific labelling requirements for processed food. Hence, the mandatory label information under the Consumer Act applies. Certain regulations however provide certain rules or guidelines on the labeling requirements of particular processed food as follows:

2.3.1 Registration Rules of Processed Food

FDA Administrative Order No. 2014-0029 or the Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food and Other Food Products ("**Registration Rules of Processed Food**") requires that labels on processed food are clear and bear the complete label information. Further, food supplements must not have curative claims or therapeutic claims. Other claims shall be in accordance to existing and relevant labeling guidelines. Finally, advertising and promotional materials of food establishments and food business operators shall not make curative or therapeutic claims without scientific data or clinical trials to substantiate such claims.[29]

2.3.2 Micronutrient Fortification Guidelines

The DOH also released Administrative Order No. 4-A s. 1995 or the Guidelines on Micronutrient Fortification of Processed Foods ("**Micronutrient Fortification Guidelines**"). These Guidelines contain requirements before a food product can use label declarations "fortified" and other similar terms that imply fortification like "enriched", "added with", or "supplemented with". Descriptive terms like "rich in", "good source of", "excellent source of" are not necessarily considered to imply fortification and shall be used in accordance with the FDA's food labeling regulations.[30]

2.3.3 FDA Circular No. 2012-015

Finally, the FDA also released guidelines on the voluntary declaration of energy or calorie content on the "front-of-pack" labeling of processed food products. FDA Circular No. 2012-015 provides for the format of the energy declaration on the principal display panel, the presentation of information inside a cylindrical format, and an illustration of the exact presentation of the front-of-pack nutrition declaration.[31]

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27 Section 11.2, Meat Labeling Guidelines.

28 Rule 15b.2, FSA IRR.

29 Sec. VI(C), Registration Rules for Processed Food.

30 Sec. VII, Micronutrient Fortification Guidelines.

31 https://www.fda.gov.ph/wp-content/uploads/2021/05/FDA-Circular-No-2012-015-1.pdf (accessed 11 Oct. 2022).

2.3.4 Violations and Sanctions

Any established or processed prepackaged food product found to be in violation of the above regulations shall be a ground for disapproval of application, suspension, revocation, or cancellation of its LTO, CPR, or any authorization pursuant to the FDA IRR.[32] Notwithstanding such actions, the FSA IRR allows for application of penalties and sanctions, which impose a fine of PHP50,000.00 to PHP500,000.00 as well as suspension of appropriate authorizations, payment of hospitalization costs, and/or permanent revocation of authorizations and closure of the establishment, depending on the severity of the case and the track record of the violating entity.[33]

If the offender is a corporation, the director, officer or agent who authorized, ordered, or performed any of the acts or practices constituting in whole or in part the violation, and who had knowledge or notice of noncompliance received by the corporation from the concerned department, shall be subjected to the prescribed penalties.[34]

2.4 Prepackaged Food

The DOH Administrative Order No. 2014-0030 ("**AO No. 2014-0030"**) provides for specific regulations governing the labeling of prepackaged food products distributed in the Philippines. "Prepackaged food" refers to those packaged or made up in advance in a container, ready for sale to the consumer, or for catering purposes.[35]

2.4.1 Mandatory Label Information

The labels of all prepackaged food must bear the following minimum mandatory information:

(a) product name/name of the food;

(b) use of brand name and/or trademark;

(c) complete list of ingredients;

(d) net contents and drained weight;

(e) name and address of manufacturer, re-packer, packer, importer, trader, and distributor;

(f) lot identification;

(g) storage condition;

(h) expiry or expiration date/use-by-date/consume-before date (recommended last consumption date);

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32 Sec. 5(3) and (4), Art. XI, Book III of the FDA IRR.

33 Sec. 38 of the FSA IRR,

34 Sec. 38 of the FSA IRR,

35 Sec. IV(21), AO No. 2014-0030.

(i) food allergen information;

(j) direction/instruction(s) for use; and

(k) nutrition facts/nutrition information/nutritive value.[36]

2.4.2 Other key requirements[37]

For alcoholic beverages, alcohol content in terms of percentage volume or proof units must be indicated on the label.

The language used for all information on the label shall be either in English or Filipino or combination of both. For exported food products, the language acceptable in the importing country must be used. For imported food products, labels where the information is declared in a foreign language must always carry the corresponding English translation.

Additional information mandated in a food standard or any other FDA regulation or as deemed necessary to assure safety of use shall be indicated on the label. Other declarations on the label must be substantiated such as Halal, Kosher, organic, and the like.

Front-of-pack labels that claim that a food product is free of trans-fatty acids shall be prohibited.[38]

2.4.3 Exemptions from Labeling Requirements

Exemptions from labeling requirements may be allowed in the following situations:

(a) Food materials to be served in restaurants or to be served in airline catering, which are not labeled or prepackaged, available to consumers for immediate consumption;

(b) Bulk food materials (including raw materials, ingredients, and processed food products) for further processing or repacking or for catering or for food service use and not intended for retail sale, on condition that these are properly identified as may be appropriate and product specifications are provided in supporting documents;

(c) Foods in primary packages with available label space of less than 10cm^2 (such as a pack of gum) provided that the secondary packaging contains all the required labeling information.

A petition for exemption from any specific mandatory requirement under labeling regulations may be granted under justifiable circumstances as may be determined by the FDA Director General.[39]

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36 Sec. VI(A), AO 2014-0030.

37 Sec. VI(B), AO 2014-0030.

38 DOH Administrative Order No. 2021-0039.

39 Sec. VIII, AO 2014-0030.

2.4.4 Violations and Sanctions

Any violation of the FDA's food labeling regulations under AO 2014-0030 will render the food "misbranded" under Republic Act 9711 (the "**FDA Act**"), and the misbranded food and products along with the responsible person will be subject to action and penalties under the FSA. Violations under the FSA are punished with a fine of PHP50,000.00 to PHP300,000.00 and suspension of the appropriate authorization/permit for one to six months, depending on the number of convictions. If the violation results in slight physical injury of a person, the offender may be subject to a fine of PHP200,000.00 to PHP300,000.00 and suspension of the appropriate authorization/permit for six months. The offender also shall pay the hospitalization and rehabilitation cost of the injured person.

If the violation results in less serious or serious physical injury of a person, the offender may be subject to a fine of PHP200,000.00 to PHP300,000.00 and suspension of the appropriate authorization/permit for one year. The offender also shall pay the hospitalization and rehabilitation cost of the injured person. If the violation results in death of a person, the offender may be subject to imprisonment for six months and one day to six years and one day and a fine of PHP300,000.00 to PHP500,000.00 and permanent revocation of the appropriate authorization/permit to operate a food business.

If the offender is a corporation, the director, officer, or agent of the corporation who authorizes, orders or performs any of the prohibited acts, and who has knowledge or notice of noncompliance received by the corporation from the concerned department, will be subject to the above penalties.

If a violation is committed by, or in the interest of a foreign juridical person duly licensed to engage in business in the Philippines, such license to engage in business in the Philippines immediately shall be revoked.[40]

2.5 Food Additives

Under AO 2014-0030, the FDA adopted the provisions of the Guidelines of Codex Standard for Food Additives Labeling (General Standard for the Labeling of Food Additives when Sold as such — CODEX STAN 107-1981) to govern labeling requirements for food additives.

2.5.1 Mandatory Label Information

Prepackaged food additives sold by retail are required to bear the following information:

(a) details of the food additive:

i) the specific name of each food additive, indicating its true nature;
ii) if two or more food additives are present, their names shall be given in the form of a list in the order of the proportion by weight;
iii) in the case of mixtures of flavourings, the generic expression "flavour" or "flavouring" may be used, together with a true indication of the nature of the flavour;
iv) expiration date; and
v) the words "For Food Use" or a statement substantially similar thereto shall appear in a prominent position on the label.

40 Rule 38.2, FSA IRR.

(b) instructions on storage and use;

(c) net contents declared in either the metric;

(d) name and address of the manufacturer, packer, distributor, importer, exporter of the food additive;

(e) Country of Origin; and

(f) Lot Identification.

2.5.2 Violations and Sanctions

Violation of the above labelling requirements in relation to food additives will constitute a violation of AO 2014-0030 and the discussion under Section 2.4.4 above will apply.

3. Nutritional Information

The Consumer Act requires, in general, for all labels to indicate the nutritive value in the food product.[41] Based on this, the requirement to include the nutritional information on the label of the food product is mandatory for all types of food. The FDA, under AO No. 2014-0030, provides for specific labeling requirements regarding nutrition facts, information, or nutritive values for prepackaged food. Apart from the general labeling requirements of the Consumer Act and the FDA IRR, however, there are no equivalent requirements specific to fresh food and processed food with respect to nutritional information.

Generally, AO No. 2014-0030 requires that the nutrition facts for prepackaged food must be presented in tabulated form through the declaration of protein, carbohydrates (including dietary fiber and sugar), fat (including saturated fat, trans fat and cholesterol), sodium, and energy value or calories. Added Vitamin A, iron and iodine for the products covered by the Food Fortification Program or vitamins and minerals and/or other nutrients like fatty acids and linolenic acids for other products claimed to contain such, also shall be included in the tabulation.

It also requires that all nutrient quantities are 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 unit per serving or as percentage of recommended energy and nutrient intake (RENI) or both.[42]

Violation of the above labelling requirements in relation to nutritional information will constitute a violation of AO 2014-0030 and the discussion under Section 2.4.4 above will apply.

4. Food Advertisements

Advertisements regarding food are regulated under Republic Act No. 9711, otherwise known as the Food and Drug Administration Act of 2009 ("**FDA Act**") and its implementing rules and regulations ("**FDA IRR**").

41 Art. 84, the Consumer Act.

42 For a full list of the labelling requirements, please refer to Sec. VI(A)(11), AO 2014-0030.

As a general rule, food business operators are prevented from misrepresenting labels and falsely advertising the presentation of food, including their shape, appearance, or packaging, the packaging materials used, the manner in which they are arranged, the setting in which they are displayed, and the product description, including the information made available about them through all mediums. Where relevant, the presentation of goods must provide consumers a basis to make informed choices in relation to the food they purchase.[43]

The FDA IRR list the following general rules on advertisements, promotions, sponsorship, and other marketing activities:

(a) No health product that has not been registered or authorized shall be advertised, promoted, or subjected to any marketing activities;

(b) 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;

(c) No claims, therapeutic or scientific otherwise, shall be made that has not been duly approved by the FDA;

(d) All health products that are permitted to be promoted must specifically state the authority or reference number that approved the same promotional, sponsorship, or marketing activities.[44]

Any violation will subject the product to seizure, confiscation, and/or suspension or revocation of the authorization.[45]

The Consumer Act similarly prohibits the dissemination of any false, deceptive or misleading advertisement by Philippine mail or in commerce by print, radio, television, outdoor advertisement or other medium for the purpose of inducing or which is likely to induce directly or indirectly the purchase of consumer products or services. An advertisement shall be false, deceptive or misleading if it is not in conformity with the provisions of the Consumer Act or if it is misleading in a material respect. In determining whether any advertisement is false, deceptive or misleading, there shall be taken into account, among other things, not only representations made or any combination thereof, but also the extent to which the advertisement fails to reveal material facts in the light of such representations, or materials with respect to consequences which may result from the use or application of consumer products or services to which the advertisement relates under the conditions prescribed in said advertisement, or under such conditions as are customary or usual.[46]

As a supplement to the Consumer Act and FDA regulations, the Ad Standards Council prepared a guidebook for specific guidelines on consumer products, which include food/dietary supplements, alcoholic beverages, and products under the Milk Code. The 2019 Ad Standards Council Guidebook may be accessed through this link: http://asc.com.ph/wp-content/uploads/2016/06/ASC_Guidebook.pdf.

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43 Rule 8a.6(b), Article IV, FSA IRR.

44 Sec. 2, Art. V, Book II, FDA IRR.

45 Sec. 3, Art. V, FSA IRR.

46 Art. 110, the Consumer Act.

5. Nutrition or Health Claims

5.1 Codex Guidelines on Nutrition and Health Claims

The FDA adopts the Codex Alimentarius Commission Guidelines for use of Nutrition and Health Claims under CAC/GL 23-1997, Rev. 1-2004) to form part of its labeling regulations ("**Codex on Nutrition and Health Claims**").[47]

Among the rules provided in the Codex, the guidelines provide that the only nutrition claims permitted shall be those relating to energy, protein, carbohydrate, and fat and components thereof, fibre, sodium and vitamins and minerals for which Nutrient Reference Values (NRVs) have been laid down in the Codex Guidelines for Nutrition Labelling.[48] Health claims must be based on current relevant scientific substantiation and the level of proof must be sufficient to substantiate the type of claimed effect and the relationship to health as recognized by generally accepted scientific review of the data and the scientific substantiation should be reviewed as new knowledge becomes available.

The health claim must consist of two parts:

(a) information on the physiological role of the nutrient or on an accepted diet-health relationship; followed by

(b) information on the composition of the product relevant to the physiological role of the nutrient or the accepted diet-health relationship unless the relationship is based on a whole food or foods whereby the research does not link to specific constituents of the food.[49]

5.2 Misleading Declarations/Representations/Prohibited Claims[50]

In addition to the provisions stipulated in the Codex Guidelines which were adopted by the DOH to supplement its food labeling regulations, the following direct or indirect representations or suggestions are prohibited and shall constitute misleading, deceptive, and untruthful declarations in violation of AO 2014-0030:

(a) that the food is adequate or effective in the prevention, cure, mitigation, or treatment of any disease or symptom of an illness because of the presence or absence of certain dietary properties;

(b) that a balanced diet of ordinary foods cannot supply adequate amount of nutrients;

(c) that the food has dietary properties when such properties are of no significant value or need in human nutrition;

(d) that a synthetic vitamin in a food is superior to natural vitamin;

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47 FDA Bureau Circular No. 2007-002. A copy of this Codex may be accessed through https://www.fao.org/ag/humannutrition/32444-09f5545b8abe9a0c3baf01a4502ac36e4.pdf.

48 Sec. 4.1, Codex on Nutrition and Health Claims.

49 Sec. 8.1.1, Codex on Nutrition and Health Claims.

50 Sec. VII, AO 2014-0030.

(e) claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer;

(f) claims which highlight the absence or addition of any food additive or nutrient supplement, if the addition of such additive or supplement is not permitted or prohibited;

(g) claims on the absence of beef or pork or its derivatives or lard or added alcohol are prohibited if the food does not contain such ingredient;

(h) claims on the absence of any substance when the food does not contain such ingredient;

(i) claims that a product is superior to any other existing product of the same kind that cannot be sustained;

(j) 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 FDA has accepted, through an issuance, that the product is an adequate source of all essential nutrients;

(k) claims as to the suitability of a food for use in the prevention, alleviation, treatment, or cure of a disease, disorder, or particular psychological condition unless they are:

i) in accordance with Codex standards or guidelines for food as developed by the Committee on Nutrition and Foods for Special Dietary Uses and follow the principles set forth in these guidelines; or
ii) in the absence of applicable Codex standards or guidelines, permitted by the FDA.

(l) meaningless claims including incomplete comparatives and superlatives;

(m) claims as to good hygiene practice, such as “wholesome,” “healthful,” or “sound;”

(n) use of photographs or graphic representations;

(o) use of names of places; or

(p) other analogous cases as determined by the FDA.

5.3 No approved therapeutic claims

In relation to therapeutic claims, the FDA has provided under FDA Bureau Circular No. 2, s. 1999 specifications with respect to printing the caption “No Approved Therapeutic Claim” on the labels of all food supplements, to ensure that these products are not commercially sold or advertised with therapeutic claims.

Particularly, manufacturers must use font size 14 pts, Arial, in all capital and bold letters. This caption must be printed on the primary display panel of all labeling materials used for food supplements (i.e. immediate label of the container, box, carton, brochures, leaflets, etc.). In case the label is too small to accommodate the above stated printing specifications, the letters of the caption shall be printed as 1/2 size of the largest test in the primary display panel, while still maintaining the other specifications.[51]

[51] FDA Bureau Circular No. 2, s. 1999.

6. Novel Food

There are currently no specific regulations on the labeling of novel food. In this case, the treatment of novel food will follow the same general labeling rules as other food in accordance with FDA and DA regulations as well as the Consumer Act's advertising and labeling requirements.

7. General Regulations on Genetically-Modified Organisms

"Genetically-modified organisms" ("**GMOs**") are defined as "living modified organisms" under the Cartagena Protocol on Biosafety and refer to any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.[52] The FDA currently does not have specific labeling guidelines with respect to food involving modern biotechnology and genetically modified organisms. The Philippines has only adopted the Codex Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL45-2003) and the Codex Risk Analysis of Food Derived from Modern Biotechnology (CAC/GL 44-2003).

To supplement these, the Department of Science and Technology, the DOH, DA, Department of Environment and Natural Resources, and the Department of Interior and Local Government issued a joint circular in 2021 entitled "Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology" (the "**Joint Circular**"). The Joint Circular provides for a general policy on the direct use of regulated articles for food and feed, or for processing, regulations for genetically modified plants and plant products with stacked events, as well as the procedural requirements for securing a biosafety permit.

Under the Joint Circular, the contained use of regulated articles (which refer to genetically modified plants and plant products) shall be governed by the Department of Science and Technology Biosafety Committee in accordance with the Biosafety Guidelines for Contained Use of Genetically Modified Organisms approved by the National Committee on Biosafety of the Philippines.[53] No regulated article shall be released into the environment for field trial unless a Biosafety Permit for Field Trial has been secured in accordance with the Joint Circular.[54]

Furthermore, no regulated article shall be released for commercial propagation unless: (a) a Biosafety Permit for Commercial Propagation has been secured in accordance with this Circular; (b) the field trial conducted in the Philippines shows that the regulated article does not pose greater risks to human health and the environment as compared to its conventional counterpart; (c) food and feed safety studies show that the regulated article does not pose greater risks to human health as compared to its conventional counterpart, consistent with the Codex Alimentarius Commission Guidelines 44-2003: Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and 45-2003: Guideline for the Conduct of Food Safety Assessment of Foods Derived from the Recombinant-DNA Plants; and, (d)

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52 Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology, Joint DOST-DA-DENR-DOH-DILG Department Circular No. 001-21, 2021.

53 Sec. 10, the Joint Circular.

54 Sec. 11, the Joint Circular.

if the regulated article is a pest-protected plant, its transformation event producing the active ingredient that serves as plant-incorporated protectant ("**PIP**") has been duly registered with the Fertilizer and Pesticide Authority.[55]

No regulated article, whether imported or developed domestically, shall be permitted for direct use as food and feed, or for processing, unless: (a) a Biosafety Permit for Direct Use has been issued by the Bureau of Plant Industry ("**BPI**"); (b) in the case of an imported regulated article, the regulated article has been authorized for commercial distribution as food and feed in the country of origin; and (c) regardless of the intended use, the regulated article does not pose greater risks to human health as compared to its conventional counterpart, consistent with the Codex Alimentarius Commission Guidelines 44-2003: Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and 45-2003: Guideline for the Conduct of Food Safety Assessment of Foods Derived from the Recombinant-DNA Plants.[56]

All importations of regulated articles shall be covered by the DA's general guidelines on the importation of plants, planting materials, and plant products, which is being implemented by the BPI-National Plant Quarantine Services Division. Only single events listed in the Approval Registry for Field Trial, Commercial Propagation, or Direct Use and their stack combinations shall be allowed to be imported into the country for the use specified in the particular registry.[57]

The Joint Circular does not provide for specific penalties and sanctions for violations of its provisions. However, the circular made reference to general administrative remedies of concerned departments and agencies that must be made available to all applicants, including the right to appeal, Philippine laws on liability and compensation for damages and injuries arising from any violation of the Joint Circular, as well as the applicability of international legal norms on liability and compensation, including those adopted under the Cartagena Protocol on Biosafety.[58]

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55 Sec. 14, the Joint Circular.

56 Sec. 17, the Joint Circular.

57 Sec. 24, the Joint Circular.

58 Sec. 36, the Joint Circular.