

# Republic of the Philippines Department of Health

# OFFICE OF THE SECRETARY

SEP 0 8 2014

ADMINISTRATIVE ORDER NO. <u>2014 – 00</u>30

SUBJECT: Revised Rules And Regulations Governing The Labeling of Prepackaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984 or the "Rules and Regulations Governing the Labeling of Prepackaged Food Products Distributed in the Philippines," and For Other Purposes

#### I. RATIONALE

Administrative Order No. 88-B series of 1984 was promulgated governing the Rules and Regulations for the Labelling of Pre-packaged Food Products Distributed in the Philippines to establish standards and quality measures for food; to implement the policy of the State to ensure safe and good quality supply of food; and to regulate the production, sale and traffic of the same to protect the health of the people.

With the increasing trade of prepackaged food in the country, its safety must at all times be assured. One effective national food safety and control system is consumer information about the food product through its label.

Product label is the most readily available material to inform the consumer about the product contents, shelf life and traceability, among others. It protects against dishonest or misleading advertising or promotion, and facilitates sound choice to acquire the knowledge necessary to be an informed consumer.

Accordingly, with the aim to provide coherence in the Food and Drug Administration's regulatory system for food establishments and prepackaged food products, this Order is hereby issued amending for this purpose certain provisions of Administrative Order No. 88-B s. 1984 or the "Rules and Regulations Governing the Labeling of Prepackaged Food Products Distributed in the Philippines" and for other purposes.

# II. OBJECTIVES

A. To promulgate rules and regulations on the revised labeling guidelines of prepackaged food products in order to protect the consumer against hazards to health and safety and provide information and education to facilitate sound choice in the proper exercise of their rights



B. To establish provisions on the exemption to the requirements of labeling of prepackaged food products which are, in accordance with the practice of trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed

#### III. SCOPE

This Order covers the labeling of all prepackaged food products, including food supplements, whether locally manufactured or imported into the Philippines.

# IV. DEFINITION OF TERMS

For the purpose of this labeling regulation, the term:

- 1. **Brand Name** refers to the name appropriated by the manufacturer, repacker, distributors, trader or importer to distinguish its product in the market.
- 2. **Bulk Food Materials** refers to raw materials, ingredients, and food additives that are packed in wholesale containers either for food industry use for further processing or institutional use or food service or catering business or generally not intended for commercial distribution.
- 3. **Container** means any form of packaging material which completely or partially enclosed the food and includes wrappers. A container may enclose the food as a single item or several units or types of prepackaged food when such is presented for sale to the consumer.
- 4. Country of Manufacture/Country of Origin means the country in which the processing is performed shall be considered to be the country of origin for the purposes of labeling (CODEX STAN 1-1985, Amended 2010)
- 5. *Directions/Instructions for Use* refers to the relevant information regarding the reconstitution, preparation and consumption of a food product.
- 6. Expiry or Expiration Date/Use-by-date/ Consume Before (Recommended last consumption date) means the date which signifies the end of the estimated period under any stated storage condition, after which the product will not have the quality attributes normally expected by the consumers. After this date the food should not be regarded as marketable.
- 7. **Food** means any processed substance, which is intended for human consumption and includes drinks for human beings, beverages, chewing gum and any substance which have been used as an ingredient in the manufacture, preparation or treatment of food.
- 8. Food Additive means any substance not normally consumed as a food by itself and not normally used as a typical ingredient of the food, whether or not it has nutritive value, the intentional addition of which to food for a technological (including organoleptic) purpose in the manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food results, or may be reasonably expected to result (directly or indirectly), in it or its by-products becoming a component of or



- otherwise affecting the characteristics of such foods. The term does not include contaminants or substances added to food for maintaining or improving nutritional qualities. (Codex GSFA 2013)
- 9. **Food Allergen** is any food or ingredient known to cause hypersensitivity that contains protein, peptide derived from any of, but not limited to, the following: milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.
- 10. Food Authorization Number means the number assigned to a particular registered food product as proof that it is permitted or authorized by the Food and Drug Administration (FDA) to be manufactured, imported, exported, sold, offered for sale, distributed, transferred, promoted, advertised, and/or used in sponsorship activities. This refers to both the license to operate (LTO) and the food registration (FR) numbers.
- 11. Food Standard is a regulatory guideline that defines the identity of a given food product (i.e. its name and the ingredients used for its preparation) and specifies the minimum quality factors and, when necessary, the required fill of container. It may also include specific labeling requirements other than or in addition to the labeling requirements generally applicable to all prepackaged foods.
- 12. Information Panel means that part of the label immediately contiguous to the principal display panel and in the case of rectangular, cylindrical or four-sided (tetrapack) containers, any of the sides adjacent to the principal display panel except the bottom side which serves as the base of package.
- 13. *Ingredient* means any substance, including a food additive, used as a component in the manufacture or preparation of food and present in the final product (in its original or modified form).
- 14. Label means a display of written, printed or graphic matter upon the immediate container of any article and a requirement made by or under authority of existing law that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper of the retail package of such article or is easily legible through the outside container or wrapper.
- 15. *Labeling* means any written, printed or graphic matter (1) upon any article or any of its container or wrappers or (2) accompanying the packaged food.
- 16. Lot refers to quantity of food produced under essentially the same conditions during a particular production schedule.
- 17. Lot identification code refers to a specific code indicating food produced during a period of time and under more or less the same manufacturing condition.
- 18. Medium Chain Triglycerides (MCT) are medium chain fatty acid esters of glycerol, containing 6 to 12 carbon atoms and are constituents of coconut and palm kernel oils.



- MCTs are more easily digested, absorbed, and metabolized than long-chain triglycerides.
- 19. Nutrition facts/ declarations mean a standardized statement or listing of the nutrient content of a food.
- 20. Nutrition Labeling is a description intended to inform the consumer of the nutritional properties of a food.
- 21. **Prepackaged** means packaged or made up in advance in a container, ready for sale to the consumer, or for catering purposes.
- 22. *Primary Food Commodity* means food of plant or animal origin that has not undergone any means of processing.
- 23. *Principal Display Panel* means that part of the label which, either through design or general use, is presented or shown to the consumer under customary conditions of display for retail sale.
- 24. **Processed Food** means the product, resulting from the application of physical, chemical or biological processes to a "primary food commodity" intended for direct sale to the consumer, for direct use as an ingredient in the manufacture of food or for further processing.
- 25. **Processing Aid** means a substance or material not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfill a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.
- 26. **Product Name** refers to the name of the food that indicates the true nature of the food and shall normally be specific and not generic.
- 27. Spices which include dried aromatic plants, refers to natural dried component or mixture used in food for flavoring, seasoning, and imparting aroma. The term applies equally to spices in the whole, broken or ground form.
- 28. Storage Condition refers to the prevailing specified temperature range, humidity and other environmental factors within which optimal stability of the food product is ensured based on laboratory data.

# V. GENERAL RULES AND REGULATIONS

- A. Prepackaged Food shall not be described or presented in any label or labeling in a manner that is false, misleading or deceptive or is likely to create erroneous impression regarding its character in any respect.
- B. Prepackaged Food shall not be described or presented in any label or labeling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product with which such food might be confused, or in such



- a manner as to lead the purchaser or consumer to suppose that the food is connected with such other product.
- C. Food packages shall be labeled with the required information, of which shall be contained in the principal display or information panel.
- D. Every word, figure or statement required to be placed on the label or labeling shall be printed legibly with such conspicuousness and in such terms as to render it likely to be understood under customary condition of purchase and use.
- E. 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 or not for retail sale.
- F. Claims on the label and labeling materials regarding nutrition and health shall follow the Guidelines in the Use of Nutrition and Health Claims in Food (Bureau Circular 2007-002), Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and Codex General Guidelines on Claims (CAC/GL 1-1979 revised in 1991) and their subsequent amendments in so far as it does not conflict with existing laws.
- G. Claims other than health and nutrition not covered under the Guidelines in the Use of Nutrition and Health Claims in Food (Bureau Circular 2007-002), Codex Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997) and Codex General Guidelines on Claims (CAC/GL 1-1979 revised in 1991) and their subsequent amendments shall be evaluated based on submitted substantiation.

# VI. SPECIFIC RULES AND REGULATIONS

## A. Mandatory Label Information

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

#### 1. Product Name/ Name of the Food

The product name shall be specific and not generic and shall indicate the true nature of the food.

- a. Where a product name or names have been established for a particular food in a Food Standard, any one of the names shall be used.
- b. In other cases, a common or usual product name, or in the absence thereof, an appropriate descriptive product name which is not misleading, deceptive, or confusing shall be used.
- c. A "coined" or "fanciful" name may be used provided it is not misleading, deceptive or confusing and it accompanies one of the names specified in (a) and (b).
- d. For the consumer's better understanding of the true nature and condition of the food, there shall appear in the label either in conjunction with, or in close proximity to the product name of the food, such additional words or phrases, as necessary, to state the type of packing medium, form or style,



- and the condition or type of treatment it has undergone (e.g. dried, freezedried, concentrated, smoke, reconstituted, etc.).
- e. The product name/name of the food shall be presented prominently on the principal display panel in bold type letters and shall be in a size reasonably related to the biggest printed matter on such panel, e.g., trade mark or brand name.

# 2. Use of Brand Name and/or Trademark

- a. If an establishment has a registered brand name or trade mark, it shall be mandatory for the holder or owner of the same to indicate such correct brand name or trade mark in the label of its product, but may not be declared if the product will be used for further processing.
- b. Any brand name or trade mark used shall be placed in conjunction with the product name referred in item 1 above and must not be misleading, deceptive, confusing, or is likely to create erroneous impression regarding its character or nature in any respect.
- c. No brand name shall be allowed that is identical to those already registered with the Food and Drug Administration in the same product classification or those that is offensive, obscene, scandalous or otherwise contrary to public morals based on AO No.2005-0016 entitled "General Policies and Guidelines Governing Brand Names of Products for Registration with the Bureau of Food and Drug" which shall remain as basis unless amended by future issuances.
- d. Identical brand name may be allowed provided that it is authorized by the same brand owner.

#### 3. Complete List of Ingredients

- a. Except for 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 'ingredient.'
- c. The complete list of ingredients shall be declared in descending order of proportion on either the principal display panel or information panel.
- d. Added water shall also be declared in the list of ingredients except when the water forms part of an ingredient such as brine, syrup or broth used in a 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 (m/m).
- 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 other existing regulations or standards the class names in attached **Table 1** Annex A may be used.
- h. Flavors and flavoring substances whether in any of the category 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 flavors it shall be declared as such or simply as "Flavors."
  - 1) 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.
  - 2) 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.
  - 3) Artificial flavoring substances substances that impart flavor but which have not been identified in natural products or natural sources of flavorings.
- i. Any pyroligneous acid or other artificial smoke flavors used as an ingredient in a food shall be declared as artificial flavor or artificial smoke flavor. *Provided that, no* representation may be made, either directly or implied, that a food flavored with pyroligneous acid or other artificial smoke flavor has been smoked or has a true smoke flavor, or that a seasoning sauce or similar product containing pyroligneous acid or other artificial smoke flavor and used to season or flavor other food will result in a smoked product or one having a true smoked flavor.
- j. Coloring substances shall be declared by their common name or as "Food Color(s)" or "Color(s)" for those that are derived from or identical with substances derived from plant materials, and as "Artificial Color(s)" for coal-tar dyes or other synthetic chemical compounds.
- k. Food additives shall be declared by their common name and their functional categories as provided under Bureau Circular No. 2006-016 or in the latest amendment by the FDA.
- 1. 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.

# 4. Net Contents and Drained Weight

- a. The net content shall be declared using the metric system of measurement or "SI" (International System of Units) on either the principal display panel or the information panel and in parallel to the base of the package. The Declaration shall be made in the following manner:
  - 1) For liquid foods, by volume;
  - 2) For solid foods, by weight, except that when such foods are sold by number, a declaration of count shall be made;



3) For semi-solid or viscous foods, either by weight or volume.

- b. 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.
- c. 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)"

# 5. Name and address of Manufacturer, Repacker, Packer, Importer, Trader and Distributor

a. 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 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.

- b. If the prepackaged food is not manufactured by the person or company whose name appears on the label, the name must be qualified by "Manufactured for" or "Packed for" or similar expression.
- c. For imported products, the complete name and address of importer and the country of origin shall be declared.
- d. In the case of products carrying foreign brands or manufactured under license by a foreign company, the name and address of the foreign company, shall be in letters of type and size not bigger than those used for the local company.
- e. 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 labeling.

#### 6. Lot Identification

The lot identification code shall be embossed or otherwise permanently marked individually on the immediate packages or containers. For Prepackaged foods in multi-units retail packages such as candies with surface area less than  $10 \text{ cm}^2$  the same may be exempted from the requirements of lot identification code only when sold together with the primary packaging.

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# 7. Storage Condition

For products that need special storage condition other than normal room temperature, the storage condition shall be printed clearly, conspicuously and indelibly on all product label or labeling.

# 8. Expiry or Expiration Date/ Use-by-date/ Consume Before Date (Recommended last consumption date)

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 01Jan12).

# 9. Food Allergen Information

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:

- a. Cereal containing gluten, i.e. wheat, rye, barley, oat, spelt or their hybridized strain and products of these;
- b. Crustaceans and products of these;
- c. Eggs and eggs products;
- d. Fish and fish products;
- e. Peanuts, soybeans and products of these;
- f. Milk and milk products (lactose included);
- g. Tree nut and nut products;
- h. Sulphite in concentrations of 10mg/kg or more
- i. Such other ingredient as may be included by FDA through appropriate issuance
- 10. **Direction/ Instruction(s)** for Use shall also be printed, where applicable or as necessary to ensure correct utilization of the food.

#### 11. Nutrition Facts / Nutrition Information/ Nutritive Value

- a. The nutrition facts shall be presented in tabulated form as shown in Figure 1 through the declaration of protein, carbohydrates (including dietary fiber and sugar), fat (including saturated fat, trans fat and cholesterol), sodium, 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, shall also be included in the tabulation.
- b. 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.
- c. The declaration of nutrients can also be expressed either in unit per serving or % RENI or both.

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- 1) 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
- 2) Vitamins and minerals shall be expressed in Milligram (mg) or Microgram  $(mcg \text{ or } \leq \mu g)$ . International units (I.U.) shall be used for Vitamins A, D & E
- 3) 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)	

<sup>\*</sup>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.

# Figure 1. Sample Format for Nutrition Facts Declaration

- d. For purposes of computing the nutrient content expressed in terms of % RENI the computation shall be based on the Philippine Recommended Energy and Nutrient Intake (RENI) for male adults ages nineteen (19) to twenty nine (29). In cases of food products intended for a specific group, RENI values for the said group shall be made as the basis of RENI declaration and such fact shall be indicated on the label.
- e. Nutrients present in amounts less than 2 percent of the RENI shall be indicated by the statement "contains less (or symbol "<") 2% RENI" or by an asterisk referring to this statement.
- f. The rules on any use of nutrition claims or health claims in food shall be covered by these 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 national laws and their rules and regulations, in consideration of national policies and interest, in which case these rules shall apply as supplementary.



g. Actual nutrient values or content must be consistent with the nutrient label declarations. However, in consideration of the stability of the vitamins and nutrients, the nutrient content of a food shall in no case be lower than 80 percent % of the value for the nutrient declared on the label at any point in time within the expected shelf-life of the product. Further, where a standard has been set by a special law for a particular product, compliance to the standard is mandatory.

The following tolerance limits shall be applied in nutrient label declarations provided that no related nutrition and health claims are made:

Nutrients	Analytical tolerance*
For energy, fat and carbohydrates	Min. 80% of the declared nutrient value on label and max. 120% of the declared nutrient value on label.
For other nutrients: protein, fiber, vitamins and minerals	Min. 80% of the declared nutrient value on the label

<sup>\*%</sup> refers to the ratio between the nutrient level from actual analytical result and the declared level multiplied by 100

The values used in nutrient declaration should be weighted average values derived from data specifically obtained from analyses of products which are representative of the product being labelled.

# h. Nutrition Labeling Exemptions:

- 1) Foods for Special Dietary Uses and Foods for Special Medical Purposes covered by a separate guideline or Codex Standard;
- 2) Bottled drinking water which has its own prescribed labeling guidelines;
- Prepackaged foods in multi-units retail packages such as candies with surface area less than 10 cm<sup>2</sup> may be exempted from the requirements of nutrition labeling when sold together with the primary packaging;
- 4) Foods served or sold in restaurants which are not labeled or prepackaged available to the consumer (e.g. schools, cafeterias, trains, airplanes and retail stores) for immediate consumption;
- 5) Foods that contain insignificant amounts of all nutrients to be listed in nutrition labeling (e.g. coffee and most spices, flavor extract, food color, as determined by FDA);
- 6) Bulk materials for further manufacturing or repacking;
- 7) Foods in packages with available label space of less than 10 cm<sup>2</sup> (e.g. pack of gum) provided that no health and nutrition claim is made;
- 8) Food sold from bulk containers except products covered by R.A. 8976, provided that nutrition information is provided at point of sale;
- 9) Foods for infants and young children such as infant formula, follow-up formula which should follow their own labeling standard;
- 10) Alcoholic beverages;
- 11) Other products that may be identified by the FDA through appropriate issuance;

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# **B.** Other Requirements

## 1. Alcoholic Beverages

In addition to the applicable labeling requirements above, the Alcohol content in terms of percentage (%) volume or proof units shall be indicated on the label of alcoholic beverages.

# 2. Language

The language used for all information on the label shall be either in 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 in the information are 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 shall only be 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.

#### 3. Irradiated Foods

The labeling of all food irradiation and all irradiated foods shall follow the guidelines below, as stated in Section 4-E numbers 2-4 of Policies and Guidelines as contained in Administrative Order No. 152 s. 2004 entitled Prescribing Regulations for Irradiated Food:

- "4-E. Labeling of Irradiated Food
  - 2. The labeling of pre-packaged irradiated food at the retail outlets shall contain the international logo for irradiated food with the statement "treated by irradiation" or its equivalent, in addition to the mandatory labeling information required by BFAD for pre-packaged food.
  - 3. The information required for pre-packaged irradiated food shall be posted and/or conspicuously displayed in the shelves where irradiated food which are not pre-packaged are being displayed for sale to consumers at the retail outlets.
  - 4. Irradiated food for wholesale or distribution to retailers shall be labeled with sufficient information to identify the product and shall be accompanied by documents that will contain the following:
    - a. Irradiation facility where the products were treated and its address
    - b. License number of the facility and its validity period
    - c. Date of irradiation
    - d. Purpose of irradiation"

#### 4. Additional Information

Additional information when 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 shall be substantiated such as Halal, Kosher, organic, etc.

The assigned food authorization number to the food product to be manufactured, imported, exported, and/or distributed may be printed clearly and indelibly, on the principal display panel or information display panel. A sticker may be allowed to reflect the FAN which consists of LTO number and FR number.

## C. Labeling of Food Additives

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) are hereby adopted. See attached *Annex B* for reference.

# VII. MISLEADING DECLARATION/ REPRESENTATION/ PROHIBITED CLAIMS 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:A. 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.

  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.
- 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 food additive or nutrient 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 substantiated.
- 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 have accepted, through an issuance, that the product to be an adequate source of all essential nutrients. (Codex General Guidelines on Claims CAC/GL 1-1979, Amended 2009, Section 3.1 on Prohibited Claims)
- K. 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:

- 1. 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
- 2. In the absence of an applicable Codex standard or guideline, permitted by FDA.
- L. Meaningless claims including incomplete comparatives and superlatives.
- M. Claims as to good hygienic practice, such as "wholesome," "healthful," or "sound"
- N. Use of Photographs and Graphic Representations
  - 1. Photographs of fruits, vegetables, poultry, fish, meat or eggs whether fresh or cooked, whole or sliced shall not appear on the label unless the product contains such materials or substances naturally derived from them. If flavoring substances have been added to boost or reinforce the natural flavor of a given material, the words "Flavor Added" or any statement to that effect shall appear conspicuously and in close proximity to the photograph
  - 2. Graphic representations used to depict the above mentioned materials (fruits, vegetables, etc.) are acceptable provided these do not vividly illustrate the actual appearance of such materials.
  - 3. 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 provided the statement "Serving Suggestion" or any other statement of similar importance appear with the picture.
- O. Use of Names of Places
  - 1. Names of places may be used as part of the name of the product (a) if the product is produced in the place cited or (b) if the product contains the characterizing ingredient(s) and/or prepared in exactly the same manner as the product identified with the said place. However, in the case of (b), if the place cited is in another country, it shall be qualified by the word "style" except when reference to the place is accepted ad a generic term for that product.
  - 2. Use of names of places as Brand Name is acceptable provided the presentation is not misleading, i.e., it does not appear as part of the name of the product.
- P. Such other analogous cases as determined by the FDA.

# VIII. EXEMPTIONS FROM THE LABELING REQUIREMENTS

Exemptions from the labeling requirements shall 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 and prepackaged available to the consumer (e.g. schools, cafeterias, trains, airplanes and retail stores) and for immediate consumption.
- B. 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 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 10 cm<sup>2</sup> (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 this labeling regulation 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.

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#### IX. VIOLATIONS AND SANCTIONS

Any violation of the provisions of this Administrative Order shall render the food product misbranded under RA 9711, and such misbranded food products and the responsible person shall be subject to actions and penalties available to the FDA as provided under Republic Act No. 3720 as amended by Executive Order No. 175 and further amended by Republic Act No. 9711 and its implementing rules and regulations.

#### X. TRANSITORY PROVISIONS

- A. For products with existing valid CPR, a non-extendible period of twelve (12) months for exhaustion of old labels will be allowed.
- B. For products with pending renewal application, a non-extendible period of twelve (12) months for exhaustion of old labels will be allowed; compliant labels must however be submitted.
- C. For new products and products with pending initial application, compliance to these guidelines is mandatory.

After 12 months from the effectivity of this Order, non-compliant products shall thereafter be deemed misbranded and appropriate sanctions against the violating establishment shall be imposed.

#### XI. REPEALING CLAUSE

Provisions of AO No. 88-B s. 1984 and issuances which are inconsistent to those reflected hereon are modified, and/or repealed accordingly.

#### XII. SEPARABILITY CLAUSE

If any part or provision of this Revised AO be declared invalid or unconstitutional, such invalidity or unconstitutionality shall not affect the other provisions which shall remain in full force and effect.

# XIII.EFFECTIVITY

This regulation shall take effect immediately upon approval and publication in two (2) Newspapers of general circulation.

ENRIQUE T. ONA, MD, FPCS, FACS Secretary of Health

# ANNEX A

Table 1. Class Names for Use in Ingredients Listing

NAME OF CLASSES	CLASS NAMES for Use in Ingredients Listing
Refined oils other than olive*	'Oil' together with either the
	term 'vegetable' or 'animal',
	qualified by the term
	'hydrogenated' or 'partially-
	hydrogenated', as appropriate
	'Fat' together with either, the
	term 'vegetable' or 'animal',
Refined fats*	as appropriate provided that
	for animal fat the specific
	animal source must be
	declared (i.e. pork, beef)
Starches, other than chemically modified	
starches	Starch
All species of fish where the fish constitutes	
an ingredient of another food and provided	
that the labeling and presentation of such	Fish
food does not refer to a specific species of	
fish	
All types of poultry meat where such meat	4
constitutes an ingredient of another food and	
provided that the labeling and presentation of	Poultry meat
such a food does not refer to a specific type	
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NAME OF CLASSES	CLASS NAMES for Use in Ingredients Listing
All types of cheese where the cheese or	
mixture of cheeses constitutes an ingredient	
of another food and provided that the	•
labeling and presentation of such food does	Cheese
not refer to a specific type of cheese	
All spices and spice extracts not exceeding	'Spice', 'spices', or
2% by weight either singly or in combination	'mixed spices', as
in the food	appropriate
All herbs or parts of herbs not exceeding 2%	'Herbs' or 'mixed
by weight either singly or in combination in	herbs', as appropriate
the food	
All types of gum preparations used in the	
manufacture of gum base for chewing gum	Gum base
All types of sucrose	Sugar
Anhydrous dextrose and dextrose	
monohydrate	'Dextrose' or 'glucose'
All types of caseinates	Caseinates
Milk products containing a minimum of 50%	Milk Protein
of milk protein (m/m) in dry matter**	
Press, expeller or refined cocoa butter	Cocoa Butter
All crystallized fruit not exceeding 10% of	
the weight of the food	Crystallized Fruit

<sup>\*</sup>Not applicable to list of ingredients declaration of fats and oils products



<sup>\*\*</sup>Calculation of milk protein content: Kjeldahl nitrogen  $\times$  6.38

# ANNEX B

# **Labeling of Food Additives**

The following 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) are hereby adopted:

# 1. Mandatory Labeling of Prepackaged Food Additives Sold by Retail

The labels of all food additives sold by retail shall bear the information required by sub-sections a.1 to a.6 of this section, as applicable to the food additive being labelled.

#### a. Details of the food additive:

- 1) The name of each food additive present shall be printed. The name shall be specific and not generic and shall indicate the true nature of the food additive. Where a name has been established for a food additive in a Codex list of additives, that name shall be used. In other cases the common or usual name shall be listed or, where none exists, an appropriate descriptive name shall be used.
- 2) If two or more food additives are present, their names shall be given in the form of a list. The list shall be in the order of the proportion by weight which each food additive bears to the total contents of the container, the food additive present in the greatest proportion by weight being listed first. Where one or more of the food additives is subject to a quantitative limitation in a food covered by a Codex standard, the quantity or proportion of that additive may be stated. If food ingredients are part of the preparation, they shall be declared in the list of ingredients in descending order of proportion.
- 3) In the case of mixtures of flavourings, the name of each flavouring present in the mixture need not be printed. The generic expression "flavour" or "flavouring" may be used, together with a true indication of the nature of the flavour. The expression "flavour" or "flavouring" may be qualified by the words "natural", "nature-identical", "artificial", or a combination of these words, as appropriate. This provision does not apply to flavour modifiers, but does apply to "herbs" and "spices", wherein generic expressions may be used where appropriate.

- 4) All food additives shall carry an expiration date which shall signify that beyond this date the effectivity of the additive for its intended use is diminished.
- 5) The words "For Food Use" or a statement substantially similar thereto shall appear in a prominent position on the label.

# b. Instructions on storage and use

Adequate information shall be given about the manner in which the food additive is to be kept and is to be used in food.

#### c. Net contents

The net contents shall be declared in either the metric (Système International Units) or avoirdupois or both systems of measurement as required by the country in which the food additive is sold. This declaration shall be made in the following manner:

- 1) for liquid food additives, by volume or weight;
- 2) for solid food additives, other than those sold in tablet form, by weight:
- for semi-solid or viscous food additives, either by weight or volume:
- 4) for food additives sold in tablet form, by weight together with the number of tablets in the package.

#### d. Name and Address

The name and address of the manufacturer, packer, distributor, importer, exporter of the food additive shall be declared.

# e. Country of Origin

- The country of origin of a food additive shall be declared if its omission is likely to mislead or deceive the consumer.
- 2) When a food additive undergoes processing in a second country which changes its chemical or physical nature, the country in which the processing is performed shall be considered to be the country of origin for the purposes of labelling.

#### f. Lot Identification

Each container shall be marked in code or in clear to identify the producing factory and the lot.

# 2. Mandatory Labelling of Prepackaged Food Additives Sold Other than by Retail

The labels of all food additives sold other than by retail shall bear the information required by Sub-sections C.1.a to C.1.f, as applicable to the food additive being labeled; except that, where the food additives in non-retail containers are solely destined for further industrial processing, the required information, other than that described in Subsections C.1.a to C.1.f, may be given on the documents relating to the sale

