

CFRR Electronic Registration User Manual for the Modified E-Reg Portal Version 2

Center for Food Regulation and Research

FOREWORD

Since the launch of the Electronic Registration portal in 2016, a lot has been changed in the processing of License to Operate and Certificate of Product Registration Applications. Just like any other platform or system during its initial phase, there could be changes to further improve it and provide a more seamless experience to users, in this case, the stakeholders.

The adaption to the Ease of Doing Business Law has also further pushed the modification of the platform to adjust according to the flow of processing as prescribed by the law. The pre-assessment stage, albeit not part of the processing timeline, proves to help companies to correct deficiencies in terms of documentary requirement completeness in the early stage of processing of applications through preliminary assessment.

Just like the previous Electronic Registration Portal, this system aims to simplify the filing of applications by using the current technology, most especially in this time of pandemic where the movement of people is extremely limited. In order to provide clients/stakeholders of a guide to navigate this Electronic portal, this Electronic Registration User Manual provides step-by-step procedure on how to file different types of applications. Processes have been simplified for the user to easily navigate the system by just using this manual as their guide. It also contains references and well-defined terminologies to properly guide the user of the encountered terms in the context of food product regulations. With its publication, I hope that this electronic registration user manual will bridge the gap between the stakeholders and the FDA-CFRR.

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INTRODUCTION, USES AND APPLICATION

Terminology

Blister pack label means a label affixed to or printed on the strip or blister pack. The strip/blister pack needs to be repacked in another container or accompanied with a catch cover where label can display information.

Complementary Food means any food except milk substitutes, whether manufactured or locally prepared, suitable as a complement to breastmilk to satisfy the nutritional requirements of infants.

Food for Special Medical Purposes refers to a category of foods for special dietary uses which are specially processed or formulated and presented for the dietary management of patients and may be used under medical supervision (adopted from Codex Stan 180-1991).

Food/Dietary Supplement means a processed food product intended to supplement the diet that contains one or more of the following dietary ingredients: vitamin, mineral, amino acid, herb, or other dietary substance of botanical, animal, artificial or natural origin to increase the total daily intake in amounts 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, liquid, gels, powders or pills and 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.

Formulated Complementary Foods for Older Infants and Young Children refers to foods that are suitable for use during the complementary feeding period. These foods are specifically formulated with appropriate nutritional quality to provide additional energy and nutrients to complement the family foods derived from the local diet by providing those nutrients which are either lacking or are present in insufficient quantities.

High Risk Food Products means foods that contain pathogenic microorganisms and will support the formation of toxins or the growth of pathogenic microorganisms; and foods that may contain harmful chemicals.

Infant Formula means one of the breastmilk substitutes formulated industrially in accordance with applicable Codex Alimentarius Commission (CAC) standards (Adopted from A.O. 2006-0012).

Terminology

Low Risk Food Products means foods that are unlikely to contain pathogenic microorganisms and will not normally support their growth because of food characteristics; and foods that are unlikely to contain harmful chemicals.

Medium Risk Food Products means foods that may contain pathogenic microorganisms but will not normally support their growth because of food characteristics; or food that is unlikely to contain pathogenic microorganisms because of food type or processing, but may support the formulation of toxins or the growth of pathogenic microorganisms.

Milk Supplement product name shall be used in place of “follow-up” formula. It means a food intended for use as a liquid part of the complementary food for the infant from the 6th month on and for young children; (adopted from Codex Stan 156-1987 stated that designated name is allowed in accordance with national usage).

Processed Cereal-Based Foods are prepared primarily from one or more milled cereals, which should constitute at least 25% of the final mixture on a dry weight basis. The four categories distinguished are: (1) Products consisting of cereals which are or have to be prepared for consumption with milk or other appropriate nutritious liquids; (2) Cereals with an added high protein food; (3) Pasta and (4) Rusks and Biscuits.

Stability Studies refers to the real time and accelerated studies/testing undertaken on primary batches according to a prescribed stability protocol to establish or confirm the re-test period of a substance or shelf-life of a finished product.

Accelerated Stability Studies Studies designed to increase the rate of chemical degradation or physical change of a finished product by using exaggerated storage conditions as part of the formal stability studies. (Data from these studies, in addition to long term stability studies, can be used to assess longer term chemical effects at non-accelerated condition and to evaluate the effect of short-term excursions outside the label storage conditions such as might occur during shipping.

Real Time Stability Studies Stability studies under the recommended storage condition for the re-test period or shelf life proposed (or approved) for labelling.

General Guidelines in the Registration of Food Products

1. Requirements for registration are based on the requirements indicated in Administrative Order 2014-0029 and FDA Circular 2020-013:

A. Proof of payment or fees as prescribed by current FDA regulations;

B. Clear and complete loose labels or artworks, as applicable, of all packaging size, or equivalents as defined by FDA regulations except of bulk raw materials, ingredients and food additives intended for further processing or for distribution to establishments/manufacturers for further processing;

C. Pictures of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered, as applicable;

D. For food supplement, a sample in actual commercial presentation shall be submitted.

E. For food products with label claims: as applicable, documents to substantiate claims, such as technical, nutritional or health studies or reports, market research studies, Certificate of Analysis, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal on Sangkap Pinoy, halal, Organic, or Kosher food and in compliance with current labelling regulations.

F. Additional requirements for food supplement are the following: *Certificate of Analysis for physico-chemical and microbiological parameters *Shelf life study with stability data containing relevant information on the critical parameters of the finished product, period conducted, conclusion, and signed/verified by competent technical staff to support shelf life declaration. *Safety data (Acute Oral Toxicity Test (LD-50 Test, Heavy Metals Test, other cytotoxicity tests, safe history of use or other tests to assess potential toxicity as applicable)

2. All food additives must conform with the Updated List of Food Additives and/or latest General Standard for Food Additives based on Bureau Circular 2006-016 and Administrative Order 2014-0029. Food flavours must be listed in Flavors and Extracts Manufacturers Association (FEMA) or International Organization of the Flavor Industry (IOFI) Generally Recognized As Safe Lists based on B.C. 2006-016 or latest FDA Regulation on Food Additives.

3. Based on FDA Circular 2016-007, additional requirements for imported products include ANY of the following scanned copy of the original documents: (1) Foreign Agency Agreement or (2) Certificate of Distributorship or (3) Appointment letter or (4) Proforma Invoice or (5) Memorandum of Agreement from the supplier. and ANY of the following documents issued by the Regulatory/ Health Authority/Internationally Recognized Certifying Body: (1) Certificate of Registration with GMP Compliance or its equivalent or (2) Valid Sanitary Phyto-Sanitary Certificate or (3) Health Certificate or (4) ISO 22000 Certificate or (5) FSSC Certificate or (6) HACCP Certificate or (7) Certificate of Free Sale issued to the Manufacturer. In case, the Certificate of

Free Sale is issued by the Chamber of Commerce or trade association, this should be duly authenticated by the Philippine Consulate from the country of origin.

4. Food products with standards of identity should conform with the specification in the corresponding standards thru submission of Certificate of Analysis. Refer to Annex A for the List of Philippine National Standards. For the analysis required (both AO) see Annex B. Summary of Current Food Standards.

5. Medium and high-risk food products should conform with the microbiological parameters as indicated in Annex c (Revised Guidelines for the Assessment of Microbiological Quality of Processed Foods).

6. Processed food products containing food additives with restricted levels (e.g. nitrite in meat products) should not exceed the maximum levels allowed in the Updated List of Food Additives (B. C. 2006-016) or FDA latest Regulation on Food Additives. A Certificate of Analysis on the level of such restricted food additive in the finished product must be submitted.

7. Thermally processed food products packed in hermetically sealed containers (e.g. can, bottle) should submit Tests Results for Commercial Sterility.

8. Labels of food products applying for registration should conform to the current labelling guidelines based on Administrative Order 2014-0030. Refer to Annex D (Rules and Regulations Governing the Labeling of Prepackaged Food Products).

The mandatory labelling requirements are:

- Brand name
- Product name
- List of ingredients including common name and function of food additives
- Net weight
- Complete name and address of manufacturer, packer, distributor, trader or importer. For imported products, country of origin should be declared.
- Nutrition labelling (nutrition facts)
- Expiration date/use by date/consume before date
- Lot identification code
- Allergen information as applicable
- Storage instruction/Instruction for use as applicable.

- % alcohol for alcoholic beverages only
- Country of origin (for imported products only)
- English translation if Foreign language is used
- Additional labelling requirements for food supplements: Mandatory declaration of “Food Supplement” and NO APPROVED THERAPEUTIC CLAIMS based on Bureau Circular 2 s. 1999 (bold, Arial, font size 14 and all capital letters). Food products for export should conform with the labelling requirements of the importing country.
- Additional labelling requirements apply to specific products with standards of identity or Philippine National Standards.
- Additional precaution/caution statements are declared on the label. Refer to Annex E.

If labels of processed food products bear any health and nutrition claims, these should comply with the Guidelines for Health and Nutrition Claims based on the Codex Guidelines on Health and Nutrition Claims for Use in Food as adopted thru Bureau Circular 2007-002 (Annex F). 9. For food products requiring the use of salt as an ingredient, it is mandatory to use iodized salt for local food products intended for local distribution based on Republic Act 8172 (ASIN Law)

9. For food products requiring the use of salt as an ingredient, it is mandatory to use iodized salt for local food products intended for local distribution based on Republic Act 8172 (ASIN Law).

10. The following staple food products should be fortified with Vitamin A and/or iron -based on Republic Act 8976 and must submit the Certificate of Analysis and compliant label as additional requirements in the registration:

*Cooking Oil-Vitamin A

*Wheat Flour-Iron and Vitamin A

*Sugar-Vitamin A

*Rice-Vitamin A

11. Voluntary fortification of processed food products must conform with AO 04 s. 1995.

12. The following high risk food products should conform with the corresponding Codex Standards:

- Infant Formula: Codex Standard for Formula for Special Medical Purposes Intended for Infants and Infant Formula (Codex STAN 72-1981 Rev. 2006)
- Follow up Formula or Milk Supplement: Codex Standard for Follow
- Up Formula (Codex STAN 156-1987)
- Cereal-based Foods for Older Infants and Young Children: Codex Standard for Processed Cereal-based Foods for Older Infants and Young Children (Codex STAN 074-1981 Revised 2006)

- Formulated Complementary Foods for Infants and Young Children (Codex GL -9-1991 Revised 2013)
 - Canned Baby Foods: Codex Standard for Canned Baby Foods (Codex STAN 73-1981)
 - Foods for Special Medical Purposes: Codex Guidelines for the Labeling and Claims of Foods for Special Medical Purposes (Codex STAN 180-1991)
 - Foods for Special Dietary Uses: Codex Standard for the Labeling of Prepackaged Foods for Special Dietary Uses (Codex STAN 146-1985)
 - Formula Foods for Weight Control Diets: Codex Standard for Formula Foods for Weight Control Diets)
- The complete documentary and labeling requirements for the above high-risk foods are presented in Annexes G and H.

Risk Classification of Food Products

LOW RISK FOOD PRODUCTS

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. FATS, OILS AND FAT EMULSIONS Definition: Includes all fat-based products that are derived from vegetable, animal or marine sources, or their mixtures.	1. Butter oil, Anhydrous Milk Fat, Ghee	<p>The milk fat products anhydrous milk fat, anhydrous butter oil and butter oil are products derived exclusively from milk and/or products obtained from milk by a process that almost completely removes water and non-fat solids.</p> <p>Ghee is a product obtained exclusively from milk, cream or butter by a process that almost completely removes water and non-fat solids; it has a specially developed flavour and physical structure.</p>	
	2. Vegetable oils and Fats Fats & Oils Coconut, Palm, Soybean and Corn Oil—covered by: Republic Act 8976 on Food Fortification	<p>Edible fats and oils obtained from edible plant sources. Products may be from a single plant source or marketed and used as blended oils that are generally designated as edible, cooking, frying, table or salad oils. Virgin oils are obtained by mechanical means (e.g. pressing or expelling), with application of heat only so as not to alter the natural composition of the oil. Virgin oils are suitable for consumption in the natural state. Cold pressed oils are obtained by mechanical means without application of heat.</p>	Virgin olive oil, cottonseed oil, peanut oil, and vanaspati

	<p>3. Animal fats (lard, tallow, fish oil and other animal fats)</p> <p>Lard AO No. 231 s. 1974</p>	<p>All animal fats and oils should be derived from animals in good health at the time of slaughter and intended for human consumption.</p> <p>Lard is fat rendered from the fatty tissue of swine. Edible beef fat is obtained from fresh bovine fatty tissue covering the abdominal cavity and surrounding the kidney and heart, and from other compact, undamaged fat tissues. Such fresh fat obtained at the time of slaughter is the “killing fat.” Prime beef fat (premiere jus or oleo stock) is obtained by low-heat rendering (50-55°C) of killing fat and selected fat trimmings (cutting fat). Secunda beef fat is a product with typical beef fat odour and taste obtained by rendering (60-65°C) and purifying beef fat. Rendered pork fat is fat obtained from the tissue and bones of swine.</p> <p>Edible tallow (dripping) is produced by the rendering of fatty tissue (excluding trimmings and cutting fat), attached muscles and bones of bovine animals or sheep.</p> <p>Fish oils are derived from suitable sources such as herring, sardines, sprat, and anchovies.</p>	<p>Tallow and partially defatted beef or pork fatty tissue</p>
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
<p>A. FATS, OILS AND FAT EMULSIONS (continued) Definition: Includes all fat-based products that are derived from vegetable, animal or marine sources, or their mixtures.</p>	<p>4. Fat emulsions mainly of type oil-in-water, including mixed and/or flavored products based on fat emulsion</p>	<p>Includes fat-based counterparts of dairy-based foods excluding dessert products. The fat portions of these products are derived from sources other than milkfat (e.g. vegetable fats and oils).</p>	<p>Imitation milk (a fat-substituted milk produced from non-fat milk solids by addition of vegetable fats (coconut, safflower or corn oil)); non-dairy whipped cream; non-dairy toppings; and vegetable cream</p>

	<p>5. Fat emulsions mainly of type water-in-oil (butter, fat spreads, margarine dairy fat spreads and blended spreads)</p> <p>Margarine</p> <p>AO No. 232 s. 1974</p>	<p>Include all emulsified products excluding fat-based counterparts of dairy products and dairy desserts.</p> <p>Butter is a fatty product consisting of a primarily water-in-oil emulsion derived exclusively from milk and/or products obtained from milk.</p> <p>Includes fat spreads (emulsions principally of the type water and edible fats and oils), dairy fat spreads (emulsions principally of the type water-in-milkfat), and blended spreads (fat spreads blended with higher amounts of milkfat) Examples include margarine (a spreadable or fluid water-in-oil emulsion produced mainly from edible fats and oils); products derived from butter (e.g. “butterine,” a spreadable butter blend with vegetable oils) blends of butter and margarine; and minarine (a spreadable water-in-oil emulsion produced principally from water and edible fats and oils that are not solely derived from milk). Also includes reduced fat-based products derived from milkfat or from animal or vegetable fats, including reduced-fat counterparts of butter, margarine, and their mixtures (e.g. three-quarter fat butter, three-quarter fat margarine, or three-quarter fat butter-margarine blends).</p>	<p>Margarine (a spreadable or fluid water-in-oil emulsion produced mainly from edible fats and oils)</p> <p>Products derived from butter: “butterine,” a spreadable butter blend with vegetable oils</p> <p>Blends of butter and margarine; and minarine (a spreadable water-in-oil emulsion produced principally from water and edible fats and oils that are not solely derived from milk).</p> <p>Three-quarter fat butter, three-quarter fat margarine, or three-quarter fat butter-margarine blends.</p>
	<p>6. Fat-based desserts excluding dairy-based desserts</p>	<p>Includes fat-based counterparts of dairy-based desserts. Includes ready-to-eat products and their mixes. Also includes non-dairy fillings for desserts. An example is an ice cream-like product made with vegetable fats.</p>	<p>Ice cream-like product made with vegetable fats</p>

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. FATS, OILS AND FAT EMULSIONS Definition: Includes all fat-based products that are derived from vegetable, animal or marine sources, or their mixtures.	1. Butter oil, Anhydrous Milk Fat, Ghee	The milk fat products anhydrous milk fat, anhydrous butter oil and butter oil are products derived exclusively from milk and/or products obtained from milk by a process that almost completely removes water and non-fat solids. Ghee is a product obtained exclusively from milk, cream or butter by a process that almost completely removes water and non-fat solids; it has a specially developed flavour and physical structure.	
	2. Vegetable oils and Fats Fats & Oils Coconut, Palm, Soybean and Corn Oil—covered by: Republic Act 8976 on Food Fortification	Edible fats and oils obtained from edible plant sources. Products may be from a single plant source or marketed and used as blended oils that are generally designated as edible, cooking, frying, table or salad oils. Virgin oils are obtained by mechanical means (e.g. pressing or expelling), with application of heat only so as not to alter the natural composition of the oil. Virgin oils are suitable for consumption in the natural state. Cold pressed oils are obtained by mechanical means without application of heat.	Virgin olive oil, cottonseed oil, peanut oil, and vanaspati
	3. Animal fats (lard, tallow, fish oil and other animal fats) Lard AO No. 231 s. 1974	All animal fats and oils should be derived from animals in good health at the time of slaughter and intended for human consumption. Lard is fat rendered from the fatty tissue of swine. Edible beef fat is obtained from fresh bovine fatty tissue covering the abdominal cavity and surrounding the kidney and heart, and from other compact, undamaged fat tissues. Such fresh fat obtained at the time of slaughter is the “killing fat.” Prime beef fat (premiere jus or oleo stock) is obtained by low-heat rendering (50-55°C) of killing fat and selected fat trimmings (cutting fat). Secunda beef fat is a product with typical beef fat odour and taste obtained by rendering (60-65°C) and purifying beef fat. Rendered pork fat is fat obtained from the tissue and bones of swine. Edible tallow (dripping) is produced by the rendering of fatty tissue (excluding trimmings and cutting fat), attached muscles and bones of bovine animals or sheep. Fish oils are derived from suitable sources such as herring, sardines, sprat, and anchovies.	Tallow and partially defatted beef or pork fatty tissue

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. FATS, OILS AND FAT EMULSIONS (continued) Definition: Includes all fat-based products that are derived from vegetable, animal or marine sources, or their mixtures.	4. Fat emulsions mainly of type oil-in-water, including mixed and/or flavored products based on fat emulsion	Includes fat-based counterparts of dairy-based foods excluding dessert products. The fat portions of these products are derived from sources other than milkfat (e.g. vegetable fats and oils).	Imitation milk (a fat-substituted milk produced from non-fat milk solids by addition of vegetable fats (coconut, safflower or corn oil)); non-dairy whipped cream; non-dairy toppings; and vegetable cream
	5. Fat emulsions mainly of type water-in-oil (butter, fat spreads, margarine dairy fat spreads and blended spreads) Margarine AO No. 232 s. 1974	<p>Include all emulsified products excluding fat-based counterparts of dairy products and dairy desserts.</p> <p>Butter is a fatty product consisting of a primarily water-in-oil emulsion derived exclusively from milk and/or products obtained from milk.</p> <p>Includes fat spreads (emulsions principally of the type water and edible fats and oils), dairy fat spreads (emulsions principally of the type water-in-milkfat), and blended spreads (fat spreads blended with higher amounts of milkfat) Examples include margarine (a spreadable or fluid water-in-oil emulsion produced mainly from edible fats and oils); products derived from butter (e.g. “butterine,” a spreadable butter blend with vegetable oils) blends of butter and margarine; and minarine (a spreadable water-in-oil emulsion produced principally from water and edible fats and oils that are not solely derived from milk). Also includes reduced fat-based products derived from milkfat or from animal or vegetable fats, including reduced-fat counterparts of butter, margarine, and their mixtures (e.g. three-quarter fat butter, three-quarter fat margarine, or three-quarter fat butter-margarine blends).</p>	<p>Margarine (a spreadable or fluid water-in-oil emulsion produced mainly from edible fats and oils)</p> <p>Products derived from butter: “butterine,” a spreadable butter blend with vegetable oils</p> <p>Blends of butter and margarine; and minarine (a spreadable water-in-oil emulsion produced principally from water and edible fats and oils that are not solely derived from milk).</p> <p>Three-quarter fat butter, three-quarter fat margarine, or three-quarter fat butter-margarine blends.</p>

	6. Fat-based desserts excluding dairy-based desserts	Includes fat-based counterparts of dairy-based desserts. Includes ready-to-eat products and their mixes. Also includes non-dairy fillings for desserts. An example is an ice cream-like product made with vegetable fats.	Ice cream-like product made with vegetable fats
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
B. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) SEAWEEDS, AND NUTS AND SEEDS	6. Fruit preparations, including pulp, purees, fruit toppings and coconut milk	Fruit pulp is not usually intended for direct consumption. It is a slurry of lightly steamed and strained fresh fruit, with or without added preservatives.	
		Fruit puree (e.g. <u>mango puree, prune puree</u>) is produced in the same way, but has a smoother, finer texture, and may be used as fillings for pastries, but is not limited to this use.	Mango puree, prune puree
		Fruit sauce (e.g. <u>pineapple sauce or strawberry sauce</u>) is made from boiled fruit pulp with or without added sweeteners and may contain fruit pieces. Fruit sauce may be used as toppings for fine bakery wares and ice cream sundaes.	Pineapple sauce or strawberry sauce
		Fruit syrup (e.g. <u>blueberry syrup</u>) is a more liquid form of fruit sauce that may be used as a topping e.g. for pancakes.	Blueberry syrup

		<p>Coconut milk and coconut cream are products prepared using a significant amount of separated, whole, disintegrated macerated or comminuted fresh endosperm (kernel) of coconut palm and expelled, where most filterable fibers and residues are excluded, with or without coconut water, and/or with additional water. Coconut milk and coconut cream are treated by heat pasteurization, sterilization or ultrahigh temperature (UHT) processes. Coconut milk and coconut cream may also be produced in concentrated or skim (or “light”) forms. Examples of traditional foods in this sub-category are: tamarind concentrate (clean extract of tamarind fruit with not less than 65% total soluble solids), tamarind powder (tamarind paste mixed with tapioca starch), tamarind toffee (mixture of tamarind pulp, sugar, milk solids, antioxidants, flavours, stabilizers and preservatives), and fruit bars (a mixture of fruit (mango, pineapple, or guava) pulp mixed with sugar, flavours and preservatives, dried into a sheet).</p>	
	<p>7. Cooked fruits Banana Chips PNS/BFAD 13:2007</p>	<p>Fruit that is steamed, boiled, baked, or fried, with or without a coating, for presentation to the consumer.</p>	<p>Baked apples, fried apple rings, and peach dumplings (baked peaches with a sweet dough covering)</p>
	<p>8. Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds</p>	<p>Fresh vegetables are generally free of additives. However, fresh vegetables that are coated or cut or peeled for presentation to the consumer may contain additives</p>	<p>Quick-frozen corn, quick-frozen French-fried potatoes, quick frozen peas, and quick frozen whole processed tomatoes</p>

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
<p>B. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera)</p>	<p>6. Fruit preparations, including pulp, purees, fruit toppings and coconut milk</p>	<p>Fruit pulp is not usually intended for direct consumption. It is a slurry of lightly steamed and strained fresh fruit, with or without added preservatives.</p>	
		<p>Fruit puree (e.g. <u>mango puree</u>, <u>prune puree</u>) is produced in the same way, but has a smoother, finer texture, and may be used as fillings for pastries, but is not limited to this use.</p>	<p>Mango puree, prune puree</p>

vera) SEAWEEEDS, AND NUTS AND SEEDS		Fruit sauce (e.g. <u>pineapple sauce</u> or <u>strawberry sauce</u>) is made from boiled fruit pulp with or without added sweeteners and may contain fruit pieces. Fruit sauce may be used as toppings for fine bakery wares and ice cream sundaes.	Pineapple sauce or strawberry sauce
		Fruit syrup (e.g. <u>blueberry syrup</u>) is a more liquid form of fruit sauce that may be used as a topping e.g. for pancakes.	Blueberry syrup
		Coconut milk and coconut cream are products prepared using a significant amount of separated, whole, disintegrated macerated or comminuted fresh endosperm (kernel) of coconut palm and expelled, where most filterable fibers and residues are excluded, with or without coconut water, and/or with additional water. Coconut milk and coconut cream are treated by heat pasteurization, sterilization or ultrahigh temperature (UHT) processes. Coconut milk and coconut cream may also be produced in concentrated or skim (or “light”) forms. Examples of traditional foods in this sub-category are: tamarind concentrate (clean extract of tamarind fruit with not less than 65% total soluble solids), tamarind powder (tamarind paste mixed with tapioca starch), tamarind toffee (mixture of tamarind pulp, sugar, milk solids, antioxidants, flavours, stabilizers and preservatives), and fruit bars (a mixture of fruit (mango, pineapple, or guava) pulp mixed with sugar, flavours and preservatives, dried into a sheet).	
	7. Cooked fruits Banana Chips PNS/BFAD 13:2007	Fruit that is steamed, boiled, baked, or fried, with or without a coating, for presentation to the consumer.	Baked apples, fried apple rings, and peach dumplings (baked peaches with a sweet dough covering)
	8. Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds	Fresh vegetables are generally free of additives. However, fresh vegetables that are coated or cut or peeled for presentation to the consumer may contain additives	Quick-frozen corn, quick-frozen French-fried potatoes, quick frozen peas, and quick frozen whole processed tomatoes

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
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C. CONFECTIONERY	3. Decorations (e.g. for fine bakery wares, sugar flowers), toppings (non-fruit), and sweet sauces	<p>Includes ready-to-eat icings and frostings for cakes, cookies, pies and bread and flour confectionery, as well as mixes for these products.</p> <p>Also includes sugar- and chocolate-based coatings for baked goods.</p> <p>Sweet sauces and toppings include butterscotch sauce for use, e.g. on ice cream.</p>	
D. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares in Letter F below. Definition: Includes unprocessed and various processed forms of cereal and cereal-based products.	1. Flours, starches (including soybean powder) and flour mixes Wheat Flour Republic Act 8976 PNS-BAFPS 75:2010 Coconut Flour	<p>The basic milled products of cereal grains, roots, tubers, pulses, pith or softy core of palm tree or legumes sold as such or used as ingredients (e.g. in baked goods).</p> <p>b.1. Flour is produced from the milling of grain, cereals and tubers (e.g. cassava) and pith or soft core of palm tree. Includes flour pastes for bread and flour confectionery, flour for bread, pastries, noodles and pasta, and flour mixes <u>Examples include: durum wheat flour, self-rising flour, enriched flour, instantized flour, corn flour, corn meal, bran, farina, roasted soybean flour (kinako), konjac flour (devil's tongue jelly powder, konnayaku-ko), and maida (refined wheat flour) and sago flour.</u></p> <p>b.2. Starch is a glucose polymer occurring in granular form in certain plant species, notably seeds (e.g. cereals, pulses, corn, wheat, rice, beans, peas) and tubers (e.g. tapioca, potato). The polymer consists of linked anhydro-alpha-D-glucose units. Native starch is separated by processes that are specific for each raw material.</p>	<p><u>durum wheat flour, self-rising flour, enriched flour, instantized flour, corn flour, corn meal, bran, farina, roasted soybean flour (kinako), konjac flour (devil's tongue jelly powder, konnayaku-ko), and maida (refined wheat flour) and sago flour.</u></p> <p><u>Coconut Flour</u></p>
	2. Breakfast cereals including rolled oats	<p>Includes all ready-to-eat, instant, and regular hot breakfast cereal products. <u>Examples include: granola-type breakfast cereals, instant oatmeal, farina, corn flakes, puffed wheat or rice, multi-grain (e.g. rice, wheat and corn) breakfast cereals, breakfast cereals made from soy or bran, and extruded-type breakfast cereals made from grain flour or powder.</u></p>	<p><u>Includes granola-type breakfast cereals, instant oatmeal, farina, corn flakes, puffed wheat or rice, multi-grain (e.g. rice, wheat and corn) breakfast cereals, breakfast cereals made from soy or bran, and extruded-type breakfast cereals made from grain flour or powder.</u></p>

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
C. CONFECTIONERY	3. Decorations (e.g. for fine bakery wares, sugar flowers), toppings (non-fruit), and sweet sauces	Includes ready-to-eat icings and frostings for cakes, cookies, pies and bread and flour confectionery, as well as mixes for these products. Also includes sugar- and chocolate-based coatings for baked goods. Sweet sauces and toppings include butterscotch sauce for use, e.g. on ice cream.	
D. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares in Letter F below. Definition: Includes unprocessed and various processed forms of cereal and cereal-based products.	1. Flours, starches (including soybean powder) and flour mixes Wheat Flour Republic Act 8976 PNS-BAFPS 75:2010 Coconut Flour	The basic milled products of cereal grains, roots, tubers, pulses, pith or softy core of palm tree or legumes sold as such or used as ingredients (e.g. in baked goods). b.1. Flour is produced from the milling of grain, cereals and tubers (e.g. cassava) and pith or soft core of palm tree. Includes flour pastes for bread and flour confectionery, flour for bread, pastries, noodles and pasta, and flour mixes <u>Examples include: durum wheat flour, self-rising flour, enriched flour, instantized flour, corn flour, corn meal, bran, farina, roasted soybean flour (kinako), konjac flour (devil's tongue jelly powder, konnayaku-ko), and maida (refined wheat flour) and sago flour.</u> b.2. Starch is a glucose polymer occurring in granular form in certain plant species, notably seeds (e.g. cereals, pulses, corn, wheat, rice, beans, peas) and tubers (e.g. tapioca, potato). The polymer consists of linked anhydro-alpha-D-glucose units. Native starch is separated by processes that are specific for each raw material.	<u>durum wheat flour, self-rising flour, enriched flour, instantized flour, corn flour, corn meal, bran, farina, roasted soybean flour (kinako), konjac flour (devil's tongue jelly powder, konnayaku-ko), and maida (refined wheat flour) and sago flour.</u> <u>Coconut Flour</u>
	2. Breakfast cereals including rolled oats	Includes all ready-to-eat, instant, and regular hot breakfast cereal products. <u>Examples include: granola-type breakfast cereals, instant oatmeal, farina, corn flakes, puffed wheat or rice, multi-grain (e.g. rice, wheat and corn) breakfast cereals, breakfast cereals made from soy or bran, and extruded-type breakfast cereals made from grain flour or powder.</u>	<u>Includes granola-type breakfast cereals, instant oatmeal, farina, corn flakes, puffed wheat or rice, multi-grain (e.g. rice, wheat and corn) breakfast cereals, breakfast cereals made from soy or bran, and extruded-type breakfast cereals made from grain flour or powder.</u>

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
<p>D. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares in Letter F below.</p> <p>Definition: Includes unprocessed and various processed forms of cereal and cereal-based products.</p>	<p>7. Soybean products (excluding soybean-based seasonings and condiments under LR Letter I (seasonings, condiments and sauces))</p>	<p>Includes dried, cooked, fried or fermented soybean products, and soybean curd products.</p> <p>Soybean-based beverages - Products prepared from dried soybeans that are soaked in water, pureed, boiled and strained, or prepared from soybean flour, soybean concentrate, or soybean isolate. In a number of countries this category includes products referred to as soybean milk. Soybean-based beverages may be consumed as is, or used to prepare other soybean products. Also includes soybean products, such as soybean-based beverage powder, which is sold as is, for reconstitution, or as a mix containing a coagulant that can be reconstituted by the consumer for preparation of home-made soft tofu.</p> <p>Soybean-based film - Film formed on the surface of boiling soybean-based beverage that is dried. It may be deep-fried or softened in water prior to use in soups or poached food. Also known as <i>fuzhu</i> or <i>yuba</i>.</p> <p>Soybean curd (tofu) - Soybean curd is prepared from dried soybeans that are soaked in water, pureed, and strained to produce soybean-based beverage, which is then made into a curd with a coagulant, and placed in a mould. Soybean curds may be of a variety of textures (e.g. soft, semi-firm, firm).</p> <p>Semi-dehydrated soybean curd - Soybean curd that has been pressed while being moulded into blocks so that some moisture has been removed, but so that it is not completely dried. Semi-dehydrated soybean curd typically contains 62% water, and has a chewy texture.</p> <p>Thick gravy-stewed semi- dehydrated soybean curd – Partially dehydrated soybean curd that is cooked (stewed) with a thick sauce (e.g. miso sauce). The partially dehydrated soybean curd typically absorbs the sauce, and so regains its original texture.</p> <p>Deep fried semi-dehydrated soybean curd - Partially dehydrated soybean curd that is deep-fried. It may be consumed as such, or cooked (e.g. stewed in sauce) after frying</p>	<p>Dried, cooked, fried or fermented soybean products, and soybean curd products</p> <p>Soybean-based beverage powder</p>

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
<p>D. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree, excluding bakery wares in Letter F below.</p> <p>Definition: Includes unprocessed and various processed forms of cereal and cereal-based products.</p>	<p>7. Soybean products (excluding soybean-based seasonings and condiments under LR Letter I (seasonings, condiments and sauces))</p>	<p>Includes dried, cooked, fried or fermented soybean products, and soybean curd products.</p> <p>Soybean-based beverages - Products prepared from dried soybeans that are soaked in water, pureed, boiled and strained, or prepared from soybean flour, soybean concentrate, or soybean isolate. In a number of countries this category includes products referred to as soybean milk. Soybean-based beverages may be consumed as is, or used to prepare other soybean products. Also includes soybean products, such as soybean-based beverage powder, which is sold as is, for reconstitution, or as a mix containing a coagulant that can be reconstituted by the consumer for preparation of home-made soft tofu.</p> <p>Soybean-based film - Film formed on the surface of boiling soybean-based beverage that is dried. It may be deep-fried or softened in water prior to use in soups or poached food. Also known as <i>fuzhu</i> or <i>yuba</i>.</p> <p>Soybean curd (tofu) - Soybean curd is prepared from dried soybeans that are soaked in water, pureed, and strained to produce soybean-based beverage, which is then made into a curd with a coagulant, and placed in a mould. Soybean curds may be of a variety of textures (e.g. soft, semi-firm, firm).</p> <p>Semi-dehydrated soybean curd - Soybean curd that has been pressed while being moulded into blocks so that some moisture has been removed, but so that it is not completely dried. Semi-dehydrated soybean curd typically contains 62% water, and has a chewy texture.</p> <p>Thick gravy-stewed semi- dehydrated soybean curd – Partially dehydrated soybean curd that is cooked (stewed) with a thick sauce (e.g. miso sauce). The partially dehydrated soybean curd typically absorbs the sauce, and so regains its original texture.</p> <p>Deep fried semi-dehydrated soybean curd - Partially dehydrated soybean curd that is deep-fried. It may be consumed as such, or cooked (e.g. stewed in sauce) after frying</p>	<p>Dried, cooked, fried or fermented soybean products, and soybean curd products</p> <p>Soybean-based beverage powder</p>

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
F. BAKERY WARES AND BAKERY RELATED PRODUCTS	1. Bread and ordinary bakery wares and mixes	Steamed bread and buns - Oriental-style leavened wheat or rice products that are cooked in a steamer. Products may be made with or without filling. In China, products without filling are called steamed bread (<i>mantou</i>), and those with filling are called steamed buns (<i>baozi</i> or <i>bao</i>). Twisted rolls of various shapes (<i>huajuan</i>) may also be prepared.	Includes filled dumplings and steamed bun with meat, jam or other filling (<i>manjyu</i>).
		Mixes for bread and ordinary bakery wares - Includes all the mixes containing the dry ingredients to which wet ingredients (e.g. water, milk, oil, butter, eggs) are added to prepare a dough for baked goods.	Includes French bread mix, tin bread mix, panettone mix, ciabatta mix, among others.
	2. Fine bakery wares (sweet, salty or savory) and mixes	Includes sub-categories for ready-to-eat products as well as mixes for preparing fine baked goods. a. Mixes for fine bakery wares (e.g. cakes, pancakes) - Mixes containing the dry ingredients to which wet ingredients (e.g. water, milk, oil, butter, eggs) are added to prepare a dough for fine baked goods.	Includes cake mix, flour confectionery mix, pancake mix, pie mix, and waffle mix.

<p>G. SWEETENERS, INCLUDING HONEY</p> <p>Definition: Includes all standardized sugars, non-standardized products and natural sweeteners.</p>	<p>1. Refined and raw sugars</p> <p>Refined Sugars Republic Act 8976</p>	<p>Nutritive sweeteners, such as fully or partially purified sucrose (derived from sugar beet and sugar cane), glucose (derived from starch), or fructose.</p> <p>White sugar, dextrose anhydrous, dextrose monohydrate, fructose - White sugar is purified and crystallized sucrose with a polarisation of not less than 99.7oZ. Dextrose anhydrous is purified and crystallized D-glucose without water of crystallization. Dextrose monohydrate is purified and crystallized D-glucose with one molecule of water of crystallization. Fructose is purified and crystallized D-fructose.</p> <p>Powdered sugar, powdered dextrose - Powdered sugar (icing sugar) is finely pulverized white sugar with or without added anticaking agents. Powdered dextrose (icing dextrose) is finely pulverized dextrose anhydrous or dextrose monohydrate, or a mixture of the two, with or without added anticaking agents.</p>	<p>(e.g. hard or soft candies).</p>
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
<p>F. BAKERY WARES AND BAKERY RELATED PRODUCTS</p>	<p>1. Bread and ordinary bakery wares and mixes</p>	<p>Steamed bread and buns - Oriental-style leavened wheat or rice products that are cooked in a steamer. Products may be made with or without filling. In China, products without filling are called steamed bread (<i>mantou</i>), and those with filling are called steamed buns (<i>baozi</i> or <i>bao</i>). Twisted rolls of various shapes (<i>huajuan</i>) may also be prepared.</p> <p>Mixes for bread and ordinary bakery wares - Includes all the mixes containing the dry ingredients to which wet ingredients (e.g. water, milk, oil, butter, eggs) are added to prepare a dough for baked goods.</p>	<p>Includes filled dumplings and steamed bun with meat, jam or other filling (<i>manjyu</i>).</p> <p>Includes French bread mix, tin bread mix, panettone mix, ciabatta mix, among others.</p>

	2. Fine bakery wares (sweet, salty or savory) and mixes a. Mixes for fine bakery wares (e.g. cakes, pancakes) - Mixes containing the dry ingredients to which wet ingredients (e.g. water, milk, oil, butter, eggs) are added to prepare a dough for fine baked goods.	Includes sub-categories for ready-to-eat products as well as mixes for preparing fine baked goods.	Includes cake mix, flour confectionery mix, pancake mix, pie mix, and waffle mix.
G. SWEETENERS, INCLUDING HONEY Definition: Includes all standardized sugars, non-standardized products and natural sweeteners.	1. Refined and raw sugars Refined Sugars Republic Act 8976	Nutritive sweeteners, such as fully or partially purified sucrose (derived from sugar beet and sugar cane), glucose (derived from starch), or fructose. White sugar, dextrose anhydrous, dextrose monohydrate, fructose - White sugar is purified and crystallized sucrose with a polarisation of not less than 99.7oZ. Dextrose anhydrous is purified and crystallized D-glucose without water of crystallization. Dextrose monohydrate is purified and crystallized D-glucose with one molecule of water of crystallization. Fructose is purified and crystallized D-fructose. Powdered sugar, powdered dextrose - Powdered sugar (icing sugar) is finely pulverized white sugar with or without added anticaking agents. Powdered dextrose (icing dextrose) is finely pulverized dextrose anhydrous or dextrose monohydrate, or a mixture of the two, with or without added anticaking agents.	(e.g. hard or soft candies).

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
G. SWEETENERS, INCLUDING HONEY Definition: Includes all standardized sugars, non-	5. Honey	Honey is the natural sweet substance produced by honeybees from the nectar of blossoms or secretions of plants. The honeybees collect the nectar or secretions, transform it by combination with specific substances of the bees' own, and store it in a honeycomb to ripen and mature.	Includes wildflower Honey and clover honey.

standardized products and natural sweeteners.	6. Table-top sweeteners, including those containing high-intensity sweeteners	Includes products that are preparations of high-intensity sweeteners and/or of polyols which may contain other additives and/or nutritive ingredients, such as carbohydrates. These products, which are sold to the final consumer, may be in powder, solid (e.g. tablets or cubes), or liquid form.	Acesulfame potassium, sorbitol
1. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS	1. Salt and salt substitutes Iodized Salt Republic Act 8172	Includes salt and salt substitutes used as seasoning for food. Salt - Primarily food-grade sodium chloride. Includes table salt, iodized and fluoride iodized salt, and dendritic salt. Salt substitute - Salt substitutes are seasonings with reduced sodium content intended to be used on food in place of salt.	
	2. Herbs, spices, seasonings and condiments (e.g. seasoning for instant noodles)	This category describes items whose use is intended to enhance the aroma and taste of food.	
		Herbs and spices are usually derived from botanical sources, and may be dehydrated, and either ground or whole.	Includes basil, oregano and thyme.
		Spices may also be found as blends in powder or paste form. Examples of spice blends include chilli seasoning, chilli paste, curry paste, curry roux, and dry cures or rubs that are applied to external surfaces of meat or fish.	Includes cumin and caraway seeds.
		Condiments include seasonings such as meat tenderizers, onion salt, garlic salt, Oriental seasoning mix (dashi), topping to sprinkle on rice (furikake, containing, e.g. dried seaweed flakes, sesame seeds and seasoning), and seasoning for noodles. The term “condiments” as used in the Food Category System does not include condiment sauces (e.g. ketchup, mayonnaise, mustard) or relishes.	Includes seasonings such as meat tenderizers, onion salt, garlic salt, Oriental seasoning mix (dashi), topping to sprinkle on rice, seasoning for noodles

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
G. SWEETENERS, INCLUDING HONEY Definition: Includes all standardized sugars, non-standardized products and natural sweeteners.	5. Honey	Honey is the natural sweet substance produced by honeybees from the nectar of blossoms or secretions of plants. The honeybees collect the nectar or secretions, transform it by combination with specific substances of the bees' own, and store it in a honeycomb to ripen and mature.	Includes wildflower Honey and clover honey.
	6. Table-top sweeteners, including those containing high-intensity sweeteners	Includes products that are preparations of high-intensity sweeteners and/or of polyols which may contain other additives and/or nutritive ingredients, such as carbohydrates. These products, which are sold to the final consumer, may be in powder, solid (e.g. tablets or cubes), or liquid form.	Acesulfame potassium, sorbitol
I. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS	1. Salt and salt substitutes Iodized Salt Republic Act 8172	Includes salt and salt substitutes used as seasoning for food. Salt - Primarily food-grade sodium chloride. Includes table salt, iodized and fluoride iodized salt, and dendritic salt. Salt substitute - Salt substitutes are seasonings with reduced sodium content intended to be used on food in place of salt.	
	2. Herbs, spices, seasonings and condiments (e.g. seasoning for instant noodles)	This category describes items whose use is intended to enhance the aroma and taste of food.	
		Herbs and spices are usually derived from botanical sources, and may be dehydrated, and either ground or whole. Spices may also be found as blends in powder or paste form. Examples of spice blends include chilli seasoning, chilli paste, curry paste, curry roux, and dry cures or rubs that are applied to external surfaces of meat or fish.	Includes basil, oregano and thyme. Includes cumin and caraway seeds.

		<p>Condiments include seasonings such as meat tenderizers, onion salt, garlic salt, Oriental seasoning mix (dashi), topping to sprinkle on rice (furikake, containing, e.g. dried seaweed flakes, sesame seeds and seasoning), and seasoning for noodles. The term “condiments” as used in the Food Category System does not include condiment sauces (e.g. ketchup, mayonnaise, mustard) or relishes.</p>	<p>Includes seasonings such as meat tenderizers, onion salt, garlic salt, Oriental seasoning mix (dashi), topping to sprinkle on rice, seasoning for noodles</p>
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
I. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS	8. Soybean-based seasonings and condiments Soy Sauce FDA Memorandum No. 2011-028	<p>Includes products that are derived from soybeans and other ingredients intended for use as seasonings and condiments.</p> <p>a. Fermented soybean paste (e.g. miso) - The product is made of soybeans, salt, water and other ingredients, using the process of fermentation. <u>The product includes dou jiang (China), doenjang (Republic of Korea), or miso (Japan), which may be used in the preparation of soups or dressings, or as a seasoning.</u></p> <p>b. Soybean sauce - A liquid seasoning obtained by fermentation of soybeans, non-fermentation (e.g. hydrolysis) of soybeans, or by hydrolysis of vegetable protein.</p> <p>Fermented soybean sauce - A clear, non-emulsified sauce made of soybeans, cereal, salt and water by the fermentation process.</p> <p>Non-fermented soybean sauce - which is also known as non-brewed soybean sauce, may be produced from vegetable proteins, such as defatted soybeans that are acid-hydrolyzed (e.g. with hydrochloric acid), neutralized (e.g. with sodium carbonate), and filtered.</p> <p>Other soybean sauce - Non-emulsified sauce made from fermented soybean sauce and/or non-fermented soybean sauce, with or without sugar, with or without caramelization process.</p>	<p>Fermented soybean paste and soybean sauces</p> <p><u>includes dou jiang (China), doenjang (Republic of Korea), or miso (Japan)</u></p>
	9. Protein products other than from soybeans, marinades	Includes, for example, milk protein, cereal protein and vegetable protein analogues or substitutes for standard products, such as meat, fish or milk.	Includes vegetable protein analogues, fu (a mixture of gluten (vegetable protein) and flour that is sold dried (baked) or raw, and is used as an ingredient, e.g. in miso soup) and proteinaceous meat and fish substitutes.

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
I. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS	8. Soybean-based seasonings and condiments Soy Sauce FDA Memorandum No. 2011-028	<p>Includes products that are derived from soybeans and other ingredients intended for use as seasonings and condiments.</p> <p>a. Fermented soybean paste (e.g. miso) - The product is made of soybeans, salt, water and other ingredients, using the process of fermentation. <u>The product includes dou jiang (China), doenjang (Republic of Korea), or miso (Japan), which maybe used in the preparation of soups or dressings, or as a seasoning.</u></p> <p>b. Soybean sauce - A liquid seasoning obtained by fermentation of soybeans, non-fermentation (e.g. hydrolysis) of soybeans, or by hydrolysis of vegetable protein.</p> <p>Fermented soybean sauce - A clear, non-emulsified sauce made of soybeans, cereal, salt and water by the fermentation process.</p> <p>Non-fermented soybean sauce - which is also known as non-brewed soybean sauce, may be produced from vegetable proteins, such as defatted soybeans that are acid-hydrolyzed (e.g. with hydrochloric acid), neutralized (e.g. with sodium carbonate), and filtered.</p> <p>Other soybean sauce - Non-emulsified sauce made from fermented soybean sauce and/or non-fermented soybean sauce, with or without sugar, with or without caramelization process.</p>	<p>Fermented soybean paste and soybean sauces</p> <p><u>includes dou jiang (China), doenjang (Republic of Korea), or miso (Japan)</u></p>

	9. Protein products other than from soybeans, marinades	Includes, for example, milk protein, cereal protein and vegetable protein analogues or substitutes for standard products, such as meat, fish or milk.	Includes vegetable protein analogues, fu (a mixture of gluten (vegetable protein) and flour that is sold dried (baked) or raw, and is used as an ingredient, e.g. in miso soup) and proteinaceous meat and fish substitutes.
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
J. BEVERAGES, excluding dairy products	2. Alcoholic beverages, including alcohol-free and low-alcoholic counterparts Basi PNS/BFAD 20:2009	Fortified grape wine, grape liquor wine, and sweet grape wine - Grape wines produced either by: (i) the fermentation of grape must (juice) of high sugar concentration; or (ii) by the blending of concentrated grape juice with wine; or (iii) the mixture of fermented must with alcohol.	Includes grape dessert wine
	Tropical Fruit Wines PNS/FDA 30:2010	d. Wines (other than grape) - Includes wines made from fruit other than grapes, apples and pears and from other agricultural products, including grain (e.g. rice). These wines may be still or sparkling.	Rice wine (sake), and sparkling and still fruit wines
	Coconut Lambanog PNS/BAFPS 47:2011	e. Mead - Alcoholic liquor made from fermented honey, malt and spices, or just of honey.	Honey wine

		<p>f. Distilled spirituous beverages containing more than 15% alcohol - Includes all distilled spirituous beverages derived from grain (e.g. corn, barley, rye, wheat), tubers (e.g. potato), fruit (e.g. grapes, berries) or sugar cane that contain greater than 15% alcohol.</p>	<p>Includes aperitifs, brandy (distilled wine), cordials, liqueurs (including emulsified liqueurs), bagaceira belha (grappa from Portugal; bagaceira is a drink distilled from bagaço (pressed skins, seeds and stalks of the grapes)), eau de vie (a brandy), gin, grappa (Italian brandy distilled from the residues of pressed wine), marc (brandy distilled from grape or apple residue), korn (grain spirit (schnapps) of Germany, usually derived from rye (Roggen), sometimes from wheat (Weizen) or both (Getreide); also labelled as Kornbrannt or Kornbranntwein), mistela (also mistelle (France) and jeropico (South Africa); unfermented grape juice fortified with grape alcohol), ouzo (Greek spirit drink flavoured with aniseed), rum, tsikoudia (grape marc spirit from Crete), tsipouro (grape marc spirit from certain regions in Greece), wienbrand (style of grape brandy devised by Hugo Asbach, Rudesheim, Germany; literally, “burnt wine”), cachaça (Brazilian liquor made from fermented distilled sugar cane juice), tequila, whiskey, and vodka</p>
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
J. BEVERAGES, excluding dairy products	2. Alcoholic beverages, including alcohol-free and low-alcoholic counterparts	<p>Fortified grape wine, grape liquor wine, and sweet grape wine - Grape wines produced either by: (i) the fermentation of grape must (juice) of high sugar concentration; or (ii) by the blending of concentrated grape juice with wine; or (iii) the mixture of fermented must with alcohol.</p>	Includes grape dessert wine

	Basi PNS/BFAD 20:2009	d. Wines (other than grape) - Includes wines made from fruit other than grapes, apples and pears and from other agricultural products, including grain (e.g. rice). These wines may be still or sparkling.	Rice wine (sake), and sparkling and still fruit wines
	Tropical Fruit Wines PNS/FDA 30:2010	e. Mead - Alcoholic liquor made from fermented honey, malt and spices, or just of honey.	Honey wine
	Coconut Lambanog PNS/BAFPS 47:2011	f. Distilled spirituous beverages containing more than 15% alcohol - Includes all distilled spirituous beverages derived from grain (e.g. corn, barley, rye, wheat), tubers (e.g. potato), fruit (e.g. grapes, berries) or sugar cane that contain greater than 15% alcohol.	Includes aperitifs, brandy (distilled wine), cordials, liqueurs (including emulsified liqueurs), bagaceira belha (grappa from Portugal; bagaceira is a drink distilled from bagaço (pressed skins, seeds and stalks of the grapes)), eau de vie (a brandy), gin, grappa (Italian brandy distilled from the residues of pressed wine), marc (brandy distilled from grape or apple residue), korn (grain spirit (schnapps) of Germany, usually derived from rye (Roggen), sometimes from wheat (Weizen) or both (Getreide); also labelled as Kornbrantt or Kornbrantwein), mistela (also mistelle (France) and jeropico (South Africa); unfermented grape juice fortified with grape alcohol), ouzo (Greek spirit drink flavoured with aniseed), rum, tsikoudia (grape marc spirit from Crete), tsipouro (grape marc spirit from certain regions in Greece), wienbrand (style of grape brandy devised by Hugo Asbach, Rudesheim, Germany; literally, "burnt wine"), cachaça (Brazilian liquor made from fermented distilled sugar cane juice), tequila, whiskey, and vodka

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES

K. READY-TO-EAT SAVOURIES	1. Snacks – potato-, cereal- or starch-based (from roots and tubers, pulses and legumes), including chips and crunchies Fried Corn Snacks (Chichacorn) PNS/BFAD 22:2010	Includes all savoury snacks, with or without added flavourings, but excludes unsweetened crackers.	Potato chips, popcorn, pretzels, rice crackers (senbei), flavoured crackers (e.g. cheese-flavoured crackers), bhujia (namkeen; snack made of a mixture of flours, maize, potatoes, salt, dried fruit, peanuts, spices, colours, flavours, and antioxidants), and papads (prepared from soaked rice flour or from black gram or cow pea flour, mixed with salt and spices, and formed into balls or flat cakes).
	2. Chicharon		
	3. Snacks – fish-based	This describes savoury crackers with fish, fish products or fish flavouring.	

Medium Risk Food Products

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
B. FROZEN DESSERTS	1. Non-Dairy based (e.g. sherbet, sorbet) 2. Edible ices – popsicles		Includes water-based frozen desserts, confections and novelties, such as fruit sorbet, “Italian”-style ice, and flavoured ice.
C. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) SEaweeds, AND NUTS AND SEEDS Definition: Includes all forms of processing other than peeling, cutting and surface treating fresh fruits and vegetables.	1. Tomato products Tomato Catsup AO No. 233 s. 1974 Spaghetti Sauce and Spaghetti Sauce variants PNS 247:1993		Includes tomato catsup, tomato puree, tomato sauce, tomato paste, canned tomatoes and spaghetti sauce.
	2. Frozen fruits	Fruit that may or may not be blanched prior to freezing. The product may be frozen in a juice or sugar syrup.	Includes frozen fruit salad and frozen strawberries
	3. Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine	Fully preserved product in which fresh fruit is cleaned and placed in cans or jars with natural juice or sugar syrup (including artificially sweetened syrup) and heat-sterilized or pasteurized.	Includes canned fruit salad, and applesauce in jars
	4. Fruit-based desserts, gelatin (including water-based fruit flavored desserts, i.e. gels)	Includes the ready-to-eat products and mixes. This category does not include fine bakery wares containing fruit (MR Letter J.a), fruit-flavoured edible ices (MR Letter B.2), or fruit-containing frozen dairy desserts (HR Letter A.5).	Includes fruit-flavoured gelatine, rote gruze, frutgroed, fruit compote, nata de coco, and mitsumame (gelatine-like dessert of agar jelly, fruit pieces and syrup).
	5. Fermented fruit products	Type of pickled product produced by preservation in salt by lactic acid fermentation.	Includes fermented plums

	6. Fruit fillings for pastry	Includes the ready-to-eat products and mixes. Includes all type of fillings excluding purees (LR Letter B.6). These fillings usually include whole fruit or fruit pieces.	Includes cherry pie filling and raisin filling for oatmeal cookies.
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
B. FROZEN DESSERTS	1. Non-Dairy based (e.g. sherbet, sorbet) 2. Edible ices – popsicles		Includes water-based frozen desserts, confections and novelties, such as fruit sorbet, “Italian”-style ice, and flavoured ice.
C. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) SEAWEEDS, AND NUTS AND SEEDS Definition: Includes all forms of processing other than peeling, cutting and surface treating fresh fruits and vegetables.	1. Tomato products Tomato Catsup AO No. 233 s. 1974 Spaghetti Sauce and Spaghetti Sauce variants PNS 247:1993		Includes tomato catsup, tomato puree, tomato sauce, tomato paste, canned tomatoes and spaghetti sauce.
	2. Frozen fruits	Fruit that may or may not be blanched prior to freezing. The product may be frozen in a juice or sugar syrup.	Includes frozen fruit salad and frozen strawberries
	3. Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine	Fully preserved product in which fresh fruit is cleaned and placed in cans or jars with natural juice or sugar syrup (including artificially sweetened syrup) and heat-sterilized or pasteurized.	Includes canned fruit salad, and applesauce in jars
	4. Fruit-based desserts, gelatin (including water-based fruit flavored desserts, i.e. gels)	Includes the ready-to-eat products and mixes. This category does not include fine bakery wares containing fruit (MR Letter J.a), fruit-flavoured edible ices (MR Letter B.2), or fruit-containing frozen dairy desserts (HR Letter A.5).	Includes fruit-flavoured gelatine, rote gruze, frutgrod, fruit compote, nata de coco, and mitsumame (gelatine-like dessert of agar jelly, fruit pieces and syrup).

	5. Fermented fruit products	Type of pickled product produced by preservation in salt by lactic acid fermentation.	Includes fermented plums
	6. Fruit fillings for pastry	Includes the ready-to-eat products and mixes. Includes all type of fillings excluding purees (LR Letter B.6). These fillings usually include whole fruit or fruit pieces.	Includes cherry pie filling and raisin filling for oatmeal cookies.

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
B. FROZEN DESSERTS	1. Non-Dairy based (e.g. sherbet, sorbet) 2. Edible ices – popsicles		Includes water-based frozen desserts, confections and novelties, such as fruit sorbet, “Italian”-style ice, and flavoured ice.
C. PROCESSED FRUITS, VEGETABLE AND EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera)	1. Tomato products Tomato Catsup AO No. 233 s. 1974 Spaghetti Sauce and Spaghetti Sauce variants PNS 247:1993		Includes tomato catsup, tomato puree, tomato sauce, tomato paste, canned tomatoes and spaghetti sauce.
SEAWEEDS, AND NUTS AND SEEDS	2. Frozen fruits	Fruit that may or may not be blanched prior to freezing. The product may be frozen in a juice or sugar syrup.	Includes frozen fruit salad and frozen strawberries
Definition: Includes all forms of processing other than peeling, cutting and surface treating fresh fruits and vegetables.	3. Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine	Fully preserved product in which fresh fruit is cleaned and placed in cans or jars with natural juice or sugar syrup (including artificially sweetened syrup) and heat-sterilized or pasteurized.	Includes canned fruit salad, and applesauce in jars

	4. Fruit-based desserts, gelatin (including water-based fruit flavored desserts, i.e. gels)	Includes the ready-to-eat products and mixes. This category does not include fine bakery wares containing fruit (MR Letter J.a), fruit-flavoured edible ices (MR Letter B.2), or fruit-containing frozen dairy desserts (HR Letter A.5).	Includes fruit-flavoured gelatine, rote gruze, frutgrod, fruit compote, nata de coco, and mitsumame (gelatine-like dessert of agar jelly, fruit pieces and syrup).
	5. Fermented fruit products	Type of pickled product produced by preservation in salt by lactic acid fermentation.	Includes fermented plums
	6. Fruit fillings for pastry	Includes the ready-to-eat products and mixes. Includes all type of fillings excluding purees (LR Letter B.6). These fillings usually include whole fruit or fruit pieces.	Includes cherry pie filling and raisin filling for oatmeal cookies.

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
D. CONFECTIONERY Definition: Includes all cocoa and chocolate products	d. Cocoa and chocolate products, including “tablea”; and imitation chocolate, chocolate substitute products Ethnic Milk-Based Confectioneries PNS/FDA 34:2011	Chocolate is produced from cocoa nibs, mass, press cake, powder, or liquor with or without addition of sugar, cocoa butter, aroma or flavouring substances, and optional ingredients (e.g. nuts).	Includes bonbons, cocoa butter confectionery (composed of cocoa butter, milk solids and sugar), white chocolate, chocolate chips (e.g. for baking), milk chocolate, cream chocolate, sweet chocolate, bitter chocolate, enrobing chocolate, chocolate covered in a sugar-based “shell” or with coloured decorations, filled chocolate (chocolate with a texturally distinct center and external coating, excluding flour confectionery and pastry products of category MR Letter J.a and chocolate with added edible ingredients, yema, pastillas
E. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree – Soybean products	1. Fermented soybeans (e.g. natto, tempe) 2. Fermented Soybean curd	The product is prepared from soybeans that have been steamed and fermented with certain fungi or bacteria (starter). The product is prepared by forming soybean curd into a loaf during the fermentation process.	Includes products such as dou chi (China), natto (Japan), and tempe (Indonesia).
F. PROCESSED	1. Processed meat, poultry and game products in whole or cuts		

MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME	1.a. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled)	This category describes several treatment methods (e.g. curing, salting, drying, pickling) that preserve and extend the shelf life of meats.	
	1.a.1. Cured (including salted) non-heat treated processed meat, poultry and game products	Salted products are treated with sodium chloride. Dry cured (dry pickled) products are prepared by rubbing salt directly on the meat surface. Wet pickle cured products are prepared by submerging the meat in a brine solution. Pump cured products are prepared by injecting brine into the meat. Curing may also be achieved by addition of additives. Smoked products are also included here.	Includes bacon (cured, dry-cured, immersion-cured, pump-cured); side bacon; corned beef; marinated beef; and different types of Oriental pickled products: miso-pickled meat (miso-zuke), koji-pickled meat (koji-zuke), and soy sauce-pickled meat (shoyu-zuke).

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
D. CONFECTIONERY Definition: Includes all cocoa and chocolate products	d. Cocoa and chocolate products, including “tablea”; and imitation chocolate, chocolate substitute products Ethnic Milk-Based Confectioneries PNS/FDA 34:2011	Chocolate is produced from cocoa nibs, mass, press cake, powder, or liquor with or without addition of sugar, cocoa butter, aroma or flavouring substances, and optional ingredients (e.g. nuts).	Includes bonbons, cocoa butter confectionery (composed of cocoa butter, milk solids and sugar), white chocolate, chocolate chips (e.g. for baking), milk chocolate, cream chocolate, sweet chocolate, bitter chocolate, enrobing chocolate, chocolate covered in a sugar-based “shell” or with coloured decorations, filled chocolate (chocolate with a texturally distinct center and external coating, excluding flour confectionery and pastry products of category MR Letter J.a and chocolate with added edible ingredients, yema, pastillas)

E. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree – Soybean products	1. Fermented soybeans (e.g. natto, tempe)	The product is prepared from soybeans that have been steamed and fermented with certain fungi or bacteria (starter).	Includes products such as dou chi (China), natto (Japan), and tempe (Indonesia).
	2. Fermented Soybean curd	The product is prepared by forming soybean curd into a loaf during the fermentation process.	
F. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME	1. Processed meat, poultry and game products in whole or cuts		
	1.a. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled)	This category describes several treatment methods (e.g. curing, salting, drying, pickling) that preserve and extend the shelf life of meats.	
	1.a.1. Cured (including salted) non-heat treated processed meat, poultry and game products	Salted products are treated with sodium chloride. Dry cured (dry pickled) products are prepared by rubbing salt directly on the meat surface. Wet pickle cured products are prepared by submerging the meat in a brine solution. Pump cured products are prepared by injecting brine into the meat. Curing may also be achieved by addition of additives. Smoked products are also included here.	Includes bacon (cured, dry-cured, immersion-cured, pump-cured); side bacon; corned beef; marinated beef; and different types of Oriental pickled products: miso-pickled meat (miso-zuke), koji-pickled meat (koji-zuke), and soy sauce-pickled meat (shoyu-zuke).

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
D. CONFECTIONERY Definition: Includes all cocoa and chocolate products	d. Cocoa and chocolate products, including “tablea”; and imitation chocolate, chocolate substitute products Ethnic Milk-Based Confectioneries PNS/FDA 34:2011	Chocolate is produced from cocoa nibs, mass, press cake, powder, or liquor with or without addition of sugar, cocoa butter, aroma or flavouring substances, and optional ingredients (e.g. nuts).	Includes bonbons, cocoa butter confectionery (composed of cocoa butter, milk solids and sugar), white chocolate, chocolate chips (e.g. for baking), milk chocolate, cream chocolate, sweet chocolate, bitter chocolate, enrobing chocolate, chocolate covered in a sugar-based “shell” or with coloured decorations, filled chocolate (chocolate with a texturally distinct center and external coating, excluding flour confectionery and pastry products of category MR Letter J.a and chocolate with added edible ingredients, yema, pastillas

E. CEREAL-BASED PRODUCTS, derived from cereal grains, from roots and tubers, pulses, legumes and pith or soft core of palm tree – Soybean products	1. Fermented soybeans (e.g. natto, tempe)	The product is prepared from soybeans that have been steamed and fermented with certain fungi or bacteria (starter).	Includes products such as dou chi (China), natto (Japan), and tempe (Indonesia).
	2. Fermented Soybean curd	The product is prepared by forming soybean curd into a loaf during the fermentation process.	
F. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME	1. Processed meat, poultry and game products in whole or cuts		
	1.a. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled)	This category describes several treatment methods (e.g. curing, salting, drying, pickling) that preserve and extend the shelf life of meats.	
	1.a.1. Cured (including salted) non-heat-treated processed meat, poultry and game products	Salted products are treated with sodium chloride. Dry cured (dry pickled) products are prepared by rubbing salt directly on the meat surface. Wet pickle cured products are prepared by submerging the meat in a brine solution. Pump cured products are prepared by injecting brine into the meat. Curing may also be achieved by addition of additives. Smoked products are also included here.	Includes bacon (cured, dry-cured, immersion-cured, pump-cured); side bacon; corned beef; marinated beef; and different types of Oriental pickled products: miso-pickled meat (miso-zuke), koji-pickled meat (koji-zuke), and soy sauce-pickled meat (shoyu-zuke).

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
G. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS	2.d. Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms (e.g. fish paste), excluding products under MR Letter H.2.a to c above		Includes fish or crustacean pates and traditional Oriental fish paste.

H. EGG AND EGG PRODUCTS	1. Preserved eggs, including alkaline, salted and canned eggs (salted eggs, century eggs)		Includes traditional Oriental preserved products, such as salt-cured duck eggs (Hueidan), and alkaline treated “thousand-year-old-eggs” (pidan).
	2. Egg-based desserts (e.g. custard)	Includes ready-to-eat products and products to be prepared from a dry mix.	Includes custard fillings for fine bakery wares (e.g. pies).
I. BAKERY WARES AND BAKERY RELATED PRODUCTS	1. Fine bakery wares (sweet, salty or savory) and mixes		
	1.a. Cakes, cookies, pies, pastries, doughnuts, sweet rolls, scones, muffins, waffles – plain/without filling	Cakes, cookies and pies (e.g. fruit-filled or custard types): The term “sweet cracker” or “sweet biscuit” used in this category refers to a cookie-like product that may be eaten as a dessert.	Includes butter cake, cheesecake, fruit-filled cereal bars, pound cake (including kasutera), moist cake (type of starchy dessert (namagashi)), western cakes, moon cakes, sponge cake, fruitfilled pies (e.g. apple pie), oatmeal cookies, sugar cookies and British “biscuits” (cookies or sweet crackers).
		Other fine bakery products (e.g. doughnuts, sweet rolls, scones, and muffins): Includes products that may be eaten as a dessert or as breakfast.	Includes pancakes, waffles, filled sweet buns (anpan), Danish pastry, wafers or cones for ice cream, flour confectionery, and trifles.
	1.b. Frozen dough		

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
G. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS	2.d. Semi-preserved fish and fish products, including molluscs, crustaceans and echinoderms (e.g. fish paste), excluding products under MR Letter H.2.a to c above		Includes fish or crustacean pates and traditional Oriental fish paste.
H. EGG AND EGG PRODUCTS	1. Preserved eggs, including alkaline, salted and canned eggs (salted eggs, century eggs)		Includes traditional Oriental preserved products, such as salt-cured duck eggs (Hueidan), and alkaline treated “thousand-year-old-eggs” (pidan).
	2. Egg-based desserts (e.g. custard)	Includes ready-to-eat products and products to be prepared from a dry mix.	Includes custard fillings for fine bakery wares (e.g. pies).
I. BAKERY WARES AND BAKERY RELATED PRODUCTS	1. Fine bakery wares (sweet, salty or savory) and mixes		
	1.a. Cakes, cookies, pies, pastries, doughnuts, sweet rolls, scones, muffins, waffles – plain/without filling	Cakes, cookies and pies (e.g. fruit-filled or custard types): The term “sweet cracker” or “sweet biscuit” used in this category refers to a cookie-like product that may be eaten as a dessert.	Includes butter cake, cheesecake, fruit-filled cereal bars, pound cake (including kasutera), moist cake (type of starchy dessert (namagashi)), western cakes, moon cakes, sponge cake, fruitfilled pies (e.g. apple pie), oatmeal cookies, sugar cookies and British “biscuits” (cookies or sweet crackers).
		Other fine bakery products (e.g. doughnuts, sweet rolls, scones, and muffins): Includes products that may be eaten as a dessert or as breakfast.	Includes pancakes, waffles, filled sweet buns (anpan), Danish pastry, wafers or cones for ice cream, flour confectionery, and trifles.
	1.b. Frozen dough		

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
K. BEVERAGES, excluding dairy products	1. Non-alcoholic (“soft”) beverages		
	1.a. Fruit and vegetable juices - (fruit juice, vegetable juice, concentrates for fruit juice, concentrates for vegetable juice) Mango Beverage PNS/BFAD 09:2007	Fruit juice: Fruit juice is the unfermented but fermentable liquid obtained from the edible part of sound, appropriately mature and fresh fruit or of fruit maintained in sound condition by suitable means.	Includes orange juice, apple juice, black currant juice, lemon juice, orange-mango juice and coconut water.
		Vegetable juice is the liquid unfermented but fermentable product intended for direct consumption obtained by mechanical expression, crushing, grinding, and/or sieving of one or more sound fresh vegetables or vegetables preserved exclusively by physical means.	Includes products that may be based on a single vegetable (e.g. carrot) or blends of vegetables (e.g. carrots, celery)
		Citrus Beverage PNS/BFAD 11:2007	Concentrates for vegetable juice: Prepared by the physical removal of water from vegetable juice. Sold in liquid, syrup and frozen forms for the preparation of a ready-to-drink juice by addition of water.
	1.b. Fruit and vegetable nectars (fruit nectar, vegetable nectar, concentrates for fruit nectar, concentrates for vegetable nectar) Mango Beverage PNS/BFAD 09:2007	Fruit and vegetable nectars are beverages produced from purees, juices, or concentrates of either, blended with water and sugar, honey, syrups, and/or sweeteners.	
		Fruit nectar is the unfermented but fermentable product obtained by adding water with or without the addition of sugar, honey, syrups, and/or sweeteners to fruit juice, concentrated fruit juice, fruit purees or concentrated fruit purees, or a mixture of those products.	Includes pear nectar and peach nectar.
		Vegetable nectar: Product obtained by adding water with or without the addition of sugar, honey, syrups, and/or sweeteners to vegetable juice or concentrated vegetable juice, or a mixture of those products.	
		Concentrates for fruit nectar: Prepared by the physical removal of water from fruit nectar or its starting materials. Sold in liquid, syrup and frozen forms for the preparation of a ready-to-drink nectar by addition of water.	Includes pear nectar concentrate and peach nectar concentrate.
		Concentrates for vegetable nectar: Prepared by the physical removal of water from vegetable nectar. Sold in liquid, syrup and frozen forms for the preparation of ready-to-drink nectars by addition of water.	

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
K. BEVERAGES, excluding dairy products	1. Non-alcoholic (“soft”) beverages		
	1.a. Fruit and vegetable juices - (fruit juice, vegetable juice, concentrates for fruit juice, concentrates for vegetable juice) Mango Beverage PNS/BFAD 09:2007 Citrus Beverage PNS/BFAD 11:2007	Fruit juice: Fruit juice is the unfermented but fermentable liquid obtained from the edible part of sound, appropriately mature and fresh fruit or of fruit maintained in sound condition by suitable means.	Includes orange juice, apple juice, black currant juice, lemon juice, orange-mango juice and coconut water.
		Vegetable juice is the liquid unfermented but fermentable product intended for direct consumption obtained by mechanical expression, crushing, grinding, and/or sieving of one or more sound fresh vegetables or vegetables preserved exclusively by physical means.	Includes products that may be based on a single vegetable (e.g. carrot) or blends of vegetables (e.g. carrots, celery)
		Concentrates for vegetable juice: Prepared by the physical removal of water from vegetable juice. Sold in liquid, syrup and frozen forms for the preparation of a ready-to-drink juice by addition of water.	Includes carrot juice concentrate.
	1.b. Fruit and vegetable nectars (fruit nectar, vegetable nectar, concentrates for fruit nectar, concentrates for vegetable nectar) Mango Beverage PNS/BFAD 09:2007	Fruit and vegetable nectars are beverages produced from purees, juices, or concentrates of either, blended with water and sugar, honey, syrups, and/or sweeteners.	
		Fruit nectar is the unfermented but fermentable product obtained by adding water with or without the addition of sugar, honey, syrups, and/or sweeteners to fruit juice, concentrated fruit juice, fruit purees or concentrated fruit purees, or a mixture of those products.	Includes pear nectar and peach nectar.
		Vegetable nectar: Product obtained by adding water with or without the addition of sugar, honey, syrups, and/or sweeteners to vegetable juice or concentrated vegetable juice, or a mixture of those products.	
		Concentrates for fruit nectar: Prepared by the physical removal of water from fruit nectar or its starting materials. Sold in liquid, syrup and frozen forms for the preparation of a ready-to-drink nectar by addition of water.	Includes pear nectar concentrate and peach nectar concentrate.

		Concentrates for vegetable nectar: Prepared by the physical removal of water from vegetable nectar. Sold in liquid, syrup and frozen forms for the preparation of ready-to-drink nectars by addition of water.	
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
K. BEVERAGES, excluding dairy products	1.c. Water-based flavored drinks, including “sport,” “energy,” or “electrolyte” drinks and particulated drinks		Includes all carbonated and non-carbonated varieties and concentrates; products based on fruit and vegetable juices; and coffee-, tea- and herbal-based drinks.
	1.c.1. Carbonated water-based flavored drinks Citrus Beverage PNS/BFAD 11:2007	Includes water-based flavoured drinks with added carbon dioxide with nutritive, non-nutritive and/or intense sweeteners and other permitted food additives.	Includes gaseosa (water-based drinks with added carbon dioxide, sweetener, and flavour), and sodas such as colas, pepper-types, root beer, lemon-lime, and citrus types, both diet/light and regular types. Also, includes so-called “energy” drinks that are carbonated and contain high levels of nutrients and other ingredients (e.g. caffeine, taurine, carnitine).

	<p>1.c.2. Non-carbonated water-based flavored drinks, including punches and ades</p>		<p>Include water-based flavoured drinks without added carbon dioxide, fruit and vegetable juice-based drinks (e.g. almond, aniseed, coconut-based drinks, and ginseng drink), fruit flavoured ades (e.g. lemonade, orangeade), squashes (citrus-based soft drinks), capile groselha, lactic acid beverage, ready-to-drink coffee and tea drinks with or without milk or milk solids, and herbal-based drinks (e.g. iced tea, fruit-flavoured iced tea, chilled canned cappuccino drinks) and “sports” drinks containing electrolytes. Also, includes so-called “energy” drinks that are non-carbonated and contain high levels of nutrients and other ingredients (e.g. caffeine, taurine, carnitine).</p>
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High Risk Food Products

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions Definition: Includes all types of dairy products that are derived from the milk of any milking animal (e.g. cow, sheep, goat, buffalo). In this category, a “plain” product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients, unless permitted by relevant standards. Analogues are products in which milk fat has been partially or wholly replaced by vegetable fats or oils.	1. Milk and dairy-based drinks		
	1.a. Milk (plain) and buttermilk (plain) (A.O. No. 132 s. 1970)	Includes plain fluid products only. Includes reconstituted plain milk that contains only dairy ingredients.	
		Milk (plain): Fluid milk obtained from milking animals (e.g. cows, sheep, goats, buffalo).	
		Buttermilk (plain): Buttermilk is the nearly milkfat-free fluid remaining from the butter-making process (i.e. the churning fermented or non-fermented milk and cream).	
	1.b. Dairy-based drinks, actuale and/or fermented (e.g. chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks) PNS/BFAD 08:2007 (Fermented Milks)	Includes all ready-to-drink flavoured and aromatized milk-based fluid beverages and their mixes, excluding mixes for cocoa (cocoa-sugar mixtures, MR Letter D.a.)	Includes hot chocolate, chocolate malt drinks, strawberry-flavoured yoghurt drink, lactic acid bacteria drinks, and lassi (liquid obtained by whipping curd from the lactic acid fermentation of milk, and mixing with sugar or synthetic sweetener).
	2. Fermented and renneted milk products (plain), excluding dairy-based drinks in HR Letter A.1.b Codex Stan 243-2003 (Codex Standards for Fermented Milks)	Includes all plain products based on skim, part-skim, low-fat and whole milk.	
	2.a. Fermented milks (plain) PNS/BFAD 08:2007 (Fermented Milks)	Includes all plain products, including fluid fermented milk, acidified milk and cultured milk.	
	2.a.1) Fermented milk (plain), not heat-treated after fermentation PNS/BFAD 08:2007 (Fermented Milks)	Includes fluid and non-fluid plain products	Includes yoghurt.

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions Definition: Includes all types of dairy products that are derived from the milk of any milking animal (e.g. cow, sheep, goat, buffalo). In this category, a “plain” product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients, unless permitted by relevant standards. Analogues are products in which milk fat has been partially or wholly replaced by vegetable fats or oils.	1. Milk and dairy-based drinks		
	1.a. Milk (plain) and buttermilk (plain) (A.O. No. 132 s. 1970)	Includes plain fluid products only. Includes reconstituted plain milk that contains only dairy ingredients.	
		Milk (plain): Fluid milk obtained from milking animals (e.g. cows, sheep, goats, buffalo).	
		Buttermilk (plain): Buttermilk is the nearly milkfat-free fluid remaining from the butter-making process (i.e. the churning fermented or non-fermented milk and cream).	
	1.b. Dairy-based drinks, lacteale and/or fermented (e.g. chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks) PNS/BFAD 08:2007 (Fermented Milks)	Includes all ready-to-drink flavoured and aromatized milk-based fluid beverages and their mixes, excluding mixes for cocoa (cocoa-sugar mixtures, MR Letter D.a.)	Includes hot chocolate, chocolate malt drinks, strawberry-flavoured yoghurt drink, lactic acid bacteria drinks, and lassi (liquid obtained by whipping curd from the lactic acid fermentation of milk, and mixing with sugar or synthetic sweetener).
	2. Fermented and renneted milk products (plain), excluding dairy-based drinks in HR Letter A.1.b Codex Stan 243-2003 (Codex Standards for Fermented Milks)	Includes all plain products based on skim, part-skim, low-fat and whole milk.	
	2.a. Fermented milks (plain) PNS/BFAD 08:2007 (Fermented Milks)	Includes all plain products, including fluid fermented milk, acidified milk and cultured milk.	
	2.a.1) Fermented milk (plain), not heat-treated after fermentation PNS/BFAD 08:2007 (Fermented Milks)	Includes fluid and non-fluid plain products	Includes yoghurt.

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions Definition: Includes all types of dairy products that are derived from the milk of any milking animal (e.g. cow, sheep, goat, buffalo). In this category, a “plain” product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients, unless permitted by relevant standards. Analogues are products in which milk fat has been partially or wholly replaced by vegetable fats or oils.	2.a.2) Fermented milks (plain), heat-treated after fermentation PNS/BFAD 08:2007 (Fermented Milks)	Products similar to that in HR Letter A.2.a.2), except that they have been heat-treated (e.g. sterilized or pasteurized) after fermentation.	
	2.b. Renneted milk (plain)	Plain, coagulated milk produced by the action of milk coagulating enzymes.	Includes curdled milk.
	3. Cream (plain) and the likes (cream analogs) (A.O. No. 132 s. 1970)	Cream is a fluid dairy product, relatively high in fat content in comparison to milk.	Includes all plain fluid, semi-fluid and semi-solid cream and cream analogue products.
	3.a. Pasteurized cream (plain)	Cream subjected to pasteurization by appropriate heat treatment or made from pasteurized milk.	Includes milk cream and “half-and-half.”
	3.b. Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain) (A.O. No. 132 s. 1970)	Includes every cream, regardless of fat content, which has undergone a higher heat-treatment than pasteurization. Also includes pasteurized creams with a reduced fat content, as well as every cream intended for whipping or being whipped.	Includes whipping cream, heavy cream, whipped pasteurized cream, and whipped cream-type dairy toppings and fillings.
	3.c. Clotted cream (plain)	Thickened, viscous cream formed from the action of milk coagulating enzymes.	Includes sour cream (cream subjected to lactic acid fermentation achieved as described for buttermilk (HR Letter A.1.a).
	3.d. Cream analogues	Cream substitute consisting of a vegetable fat-water emulsion in liquid or powdered form for use other than as a beverage whitener (MR Letter A.1.b)	Includes instant whipped cream toppings and sour cream substitutes.
	4. Cheese and analogs (A.O. No. 200-A s. 1973)	Cheese and cheese analogues are products that have water and fat included within a coagulated milk protein structure.	

	4.a. Unripened cheese	Unripened cheese, including fresh cheese, is ready for consumption soon after manufacture.	Includes cottage cheese (a soft, unripened, coagulated curd cheese), creamed cottage cheese (cottage cheese covered with a creaming mixture),
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions Definition: Includes all types of dairy products that are derived from the milk of any milking animal (e.g. cow, sheep, goat, buffalo). In this category, a “plain” product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients, unless permitted by relevant standards. Analogues are products in which milk fat has been partially or wholly replaced by vegetable fats or oils.	2.a.2) Fermented milks (plain), heat-treated after fermentation PNS/BFAD 08:2007 (Fermented Milks)	Products similar to that in HR Letter A.2.a.2), except that they have been heat-treated (e.g. sterilized or pasteurized) after fermentation.	
	2.b. Renneted milk (plain)	Plain, coagulated milk produced by the action of milk coagulating enzymes.	Includes curdled milk.
	3. Cream (plain) and the likes (cream analogs) (A.O. No. 132 s. 1970)	Cream is a fluid dairy product, relatively high in fat content in comparison to milk.	Includes all plain fluid, semi-fluid and semi-solid cream and cream analogue products.
	3.a. Pasteurized cream (plain)	Cream subjected to pasteurization by appropriate heat treatment or made from pasteurized milk.	Includes milk cream and “half-and-half.”
	3.b. Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain) (A.O. No. 132 s. 1970)	Includes every cream, regardless of fat content, which has undergone a higher heat-treatment than pasteurization. Also includes pasteurized creams with a reduced fat content, as well as every cream intended for whipping or being whipped.	Includes whipping cream, heavy cream, whipped pasteurized cream, and whipped cream-type dairy toppings and fillings.
	3.c. Clotted cream (plain)	Thickened, viscous cream formed from the action of milk coagulating enzymes.	Includes sour cream (cream subjected to lactic acid fermentation achieved as described for buttermilk (HR Letter A.1.a).
	3.d. Cream analogues	Cream substitute consisting of a vegetable fat-water emulsion in liquid or powdered form for use other than as a beverage whitener (MR Letter A.1.b)	Includes instant whipped cream toppings and sour cream substitutes.

	4. Cheese and analogs (A.O. No. 200-A s. 1973)	Cheese and cheese analogues are products that have water and fat included within a coagulated milk protein structure.	
	4.a. Unripened cheese	Unripened cheese, including fresh cheese, is ready for consumption soon after manufacture.	Includes cottage cheese (a soft, unripened, coagulated curd cheese), creamed cottage cheese (cottage cheese covered with a creaming mixture),

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions Definition: Includes all types of dairy products that are derived from the milk of any milking animal (e.g. cow, sheep, goat, buffalo). In this category, a “plain” product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients, unless permitted by relevant standards. Analogues are products in which	4.a. Unripened cheese	Unripened cheese, including fresh cheese, is ready for consumption soon after manufacture.	cream cheese (rahmfrischkase, an uncured, soft spreadable cheese) mozzarella and scamorza cheeses and paneer (milk protein coagulated by the addition of citric acid from lemon or lime juice or of lactic acid from whey, that is strained into a solid mass, and is used in vegetarian versions of, e.g. hamburgers). Includes the whole unripened cheese and unripened cheese rind (for those unripened cheeses with a “skin” such as mozzarella). Most products are plain, however, some, such as cottage cheese and cream cheese, may be flavoured or contain ingredients such as fruit, vegetables or meat.
	4.b. Ripened cheese	Ripened cheese is not ready for consumption soon after manufacture, but is held under such time and temperature conditions so as to allow the necessary biochemical and physical changes that characterize the specific cheese. Includes cheese in brine, which is a ripened semi-hard to soft cheese, white to yellowish in colour with a compact texture, and without actual rind that has been preserved in brine until presented to the consumer.	Includes ripened cheese that may be soft (e.g. camembert), firm (e.g. edam, gouda), hard (e.g. cheddar), or extra-hard.

milk fat has been partially or wholly replaced by vegetable fats or oils.	4.b.1) Ripened cheese, includes rind	Refers to ripened (including mould-ripened) cheese, including rind, or any part thereof, such as cut, shredded, grated or sliced cheese.	Includes blue cheese, brie, gouda, acteal, hard grating cheese, and Swiss cheese.
	4.b.2) Rind of ripened cheese	The rind of the cheese is the exterior portion of the cheese mass that initially has the same composition as the interior portion of the cheese, but which may dry after brining and ripening.	
	4.b.3) Cheese powder (for reconstitution; e.g. for cheese sauces)	Dehydrated product prepared from a variety or processed cheese.	Includes spray-dried cheese.

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions Definition: Includes all types of dairy products that are derived from the milk of any milking animal (e.g. cow, sheep, goat, buffalo). In this category, a “plain” product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients, unless	4.c. Whey cheese	A solid or semi-solid product obtained by concentration of whey with or without the addition of milk, cream or other materials of milk origin, and moulding of the concentrated product.	Includes the whole cheese and the rind of the cheese.
	4.d. Processed cheese	Product with a very long shelf life obtained by melting and emulsifying cheese. Includes products manufactured by heating and emulsifying mixtures of cheese, milkfat, milk protein, milk powder, and water in different amounts. Products may contain other added ingredients, such as aromas, seasonings and fruit, vegetables and/or meat. Product may be spreadable or cut into slices and pieces. The term “processed” does not mean cutting, grating, shredding, etc. of cheese.	
	4.d.1) Plain processed cheese	Processed cheese product that does not contain added flavours, seasonings, fruit, vegetables and/or meat.	Includes American cheese, requeson.
	4.d.2) Flavored processed cheese, including those containing fruits, vegetables, meat, etc	Processed cheese product that contains added flavours, seasonings, fruit, vegetables and/or meat.	Includes actealed cheese spread with vegetables, pepper jack cheese, cheddar cheese spread with wine, and cheese balls (formed processed cheese coated in nuts, herbs or spices).

permitted by relevant standards. Analogues are products in which milk fat has been partially or wholly replaced by vegetable fats or oils.	4.e. Cheese analogues	Products that look like cheese, but in which milkfat has been partly or completely replaced by other fats.	Includes imitation cheese, imitation cheese mixes, and imitation cheese powders.
	4.f. Whey protein cheese	Product containing the protein extracted from the whey component of milk. These products are principally made by coagulation of whey proteins.	Includes ricotta cheese.
	5. Dairy-based desserts (e.g. pudding, fruit or acteale yoghurt)	Includes ready-to-eat flavoured dairy dessert products and dessert mixes. Includes frozen dairy confections and novelties, and dairy-based fillings.	Includes flavoured yoghurt (a milk product obtained by fermentation of milk and milk products to which flavours and ingredients (e.g. fruit, cocoa, coffee) have been added) that may or may not be heat-treated after fermentation.

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions Definition: Includes all types of dairy products that are derived from the milk of any milking animal (e.g. cow, sheep, goat, buffalo). In this category, a “plain” product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients, unless permitted by relevant standards. Analogues are products in which milk fat has been partially or wholly replaced by vegetable fats or oils.	5. Dairy-based desserts (e.g. pudding, fruit or acteale yoghurt)		Also includes ice cream (frozen dessert that may contain whole milk, skim milk products, cream or butter, sugar, vegetable oil, egg products, and fruit, cocoa, or coffee), ice milk (product similar to ice cream with reduced whole or skim milk content, or made with nonfat milk), jellied milk, frozen flavoured yoghurt, junket (sweet custard-like dessert made from flavoured milk set with rennet), dulce de leche (cooked milk with sugar and added ingredients such as coconut or chocolate), butterscotch pudding and chocolate mousse. Includes traditional milk-based sweets prepared from milk concentrated partially, from khoa (cow or buffalo milk concentrated by boiling), or chhena (cow or buffalo milk, heat coagulated aided by acids like citric acid, lactic acid, malic acid, etc), sugar or synthetic sweetener, and other ingredients (e.g. maida (refined wheat flour), flavours and colours (e.g. peda, burfee, milk cake, gulab jamun, rasgulla, rasmalai, basundi).
	6. Whey and whey products, excluding whey cheeses	Includes a variety of whey-based products in liquid and powdered forms.	
	6.a. Liquid whey and whey product	Whey is the fluid separated from the curd after coagulation of milk, cream, skimmed milk or buttermilk with milk coagulating enzymes during the manufacture of cheese, casein or similar products. Acid whey is obtained after the coagulation of milk, cream, skimmed milk or buttermilk, mainly with acids of the type used for the manufacture of fresh cheese.	

	6.b. Dried whey and whey products	Whey powders are prepared by spray- or roller-drying whey or acid whey from which the major portion of the milkfat has been removed.	
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions Definition: Includes all types of dairy products that are derived from the milk of any milking animal (e.g. cow, sheep, goat, buffalo). In this category, a “plain” product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients, unless permitted by relevant standards. Analogues are products in which milk fat has been partially or wholly replaced by vegetable fats or oils.	5. Dairy-based desserts (e.g. pudding, fruit or acteale yoghurt)		Also includes ice cream (frozen dessert that may contain whole milk, skim milk products, cream or butter, sugar, vegetable oil, egg products, and fruit, cocoa, or coffee), ice milk (product similar to ice cream with reduced whole or skim milk content, or made with nonfat milk), jellied milk, frozen flavoured yoghurt, junket (sweet custard-like dessert made from flavoured milk set with rennet), dulce de leche (cooked milk with sugar and added ingredients such as coconut or chocolate), butterscotch pudding and chocolate mousse. Includes traditional milk-based sweets prepared from milk concentrated partially, from khoa (cow or buffalo milk concentrated by boiling), or chhena (cow or buffalo milk, heat coagulated aided by acids like citric acid, lactic acid, malic acid, etc), sugar or synthetic sweetener, and other ingredients (e.g. maida (refined wheat flour), flavours and colours (e.g. peda, burfee, milk cake, gulab jamun, rasgulla, rasmalai, basundi).
	6. Whey and whey products, excluding whey cheeses	Includes a variety of whey-based products in liquid and powdered forms.	

	6.a. Liquid whey and whey product	Whey is the fluid separated from the curd after coagulation of milk, cream, skimmed milk or buttermilk with milk coagulating enzymes during the manufacture of cheese, casein or similar products. Acid whey is obtained after the coagulation of milk, cream, skimmed milk or buttermilk, mainly with acids of the type used for the manufacture of fresh cheese.	
	6.b. Dried whey and whey products	Whey powders are prepared by spray- or roller-drying whey or acid whey from which the major portion of the milkfat has been removed.	

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
C. CONFECTIONERY	Chocolate with nuts		Masareal (Sugar, nuts, milk)
D. BAKERY WARES AND BAKERY RELATED PRODUCTS	1. Fine bakery products with fillings: meat, milk, poultry, cream, other perishable foods; icings; and coatings		
	2. Cookies with nuts		
E. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME	1. Processed meat, poultry and game products in whole or cuts		
A.O. No. 154 s. 1971 (Meat and Meat Products)	1.a. Heat-treated processed meat, poultry and game products (canned)	Includes cooked (including cured and cooked, and dried and cooked), heat-treated (including sterilized) and canned meat cuts.	Includes cured, cooked ham; cured, cooked pork shoulder; canned chicken meat; and meat pieces boiled in soy sauce (tsukudani).
	1.b. Frozen processed meat, poultry and game products (marinated pork/ beef/ chicken cuts)	Includes raw and cooked meat cuts that have been frozen.	Includes whole chickens, frozen chicken parts, and frozen beef steaks.
	2. Processed comminuted meat, poultry and game products		

PNS 891:1993 UDC (Shelf-stable, Chilled and Frozen Corned Beef)	2.a. Heat-treated processed meat, poultry and game products (canned)	Includes cooked (including cured and cooked, and dried and cooked), heat-treated (including sterilized) and canned comminuted products.	Includes pre-grilled beef patties; foie gras and pates; brawn and head cheese; cooked, cured chopped meat; chopped meat boiled in soy sauce (tsukudani); canned corned beef; luncheon meats; meat pastes; cooked meat patties; cooked salami-type products; cooked meatballs; saucises de acteaed; breakfast sausages; brown-and-serve sausages; and terrines (a cooked chopped meat mixture).
	2.b. Frozen processed meat, poultry and game products (nuggets, patties, dumplings, salami, meat loaf, hotdog)	Includes raw, partially cooked and fully cooked comminuted or mechanically deboned meat products that have been frozen.	Includes frozen hamburger patties; frozen breaded or battered chicken fingers.

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
C. CONFECTIONERY	Chocolate with nuts		Masareal (Sugar, nuts, milk)
D. BAKERY WARES AND BAKERY RELATED PRODUCTS	1. Fine bakery products with fillings: meat, milk, poultry, cream, other perishable foods; icings; and coatings		
	2. Cookies with nuts		
E. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME	1. Processed meat, poultry and game products in whole or cuts		
	1.a. Heat-treated processed meat, poultry and game products (canned)	Includes cooked (including cured and cooked, and dried and cooked), heat-treated (including sterilized) and canned meat cuts.	Includes cured, cooked ham; cured, cooked pork shoulder; canned chicken meat; and meat pieces boiled in soy sauce (tsukudani).

A.O. No. 154 s. 1971 (Meat and Meat Products) PNS 891:1993 UDC (Shelf-stable, Chilled and Frozen Corned Beef)	1.b. Frozen processed meat, poultry and game products (marinated pork/beef/ chicken cuts)	Includes raw and cooked meat cuts that have been frozen.	Includes whole chickens, frozen chicken parts, and frozen beef steaks.
	2. Processed comminuted meat, poultry and game products		
	2.a. Heat-treated processed meat, poultry and game products (canned)	Includes cooked (including cured and cooked, and dried and cooked), heat-treated (including sterilized) and canned comminuted products.	Includes pre-grilled beef patties; foie gras and pates; brawn and head cheese; cooked, cured chopped meat; chopped meat boiled in soy sauce (tsukudani); canned corned beef; luncheon meats; meat pastes; cooked meat patties; cooked salami-type products; cooked meatballs; sausages de acteaed; breakfast sausages; brown-and-serve sausages; and terrines (a cooked chopped meat mixture).
	2.b. Frozen processed meat, poultry and game products (nuggets, patties, dumplings, salami, meat loaf, hotdog)	Includes raw, partially cooked and fully cooked comminuted or mechanically deboned meat products that have been frozen.	Includes frozen hamburger patties; frozen breaded or battered chicken fingers.

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
F. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS	1. Processed fish and fish products, including molluscs, crustaceans and echinoderms		
	1.d.2) Cooked molluscs, crustaceans and echinoderms	Cooked products include steamed, boiled or any other cooking method except frying see HR Letter F.1.d.3).	Includes cooked crangon crangon and crangon vulgaris (brown shrimp; cooked shrimp, clams and crabs.
	1.d.3) Fried fish and fish products, including molluscs, crustaceans and echinoderms	Ready-to-eat products prepared from fish or fish portions, with or without further dressing in eggs and bread crumbs or batter, that are fried, baked, roasted or barbecued, and then packaged or canned with or without sauce or oil.	Includes ready-to-eat fried surimi, fried calamari, and fried soft-shell crabs.

	2. Fully preserved, including canned or fermented fish and fish products, including molluscs, crustaceans and echinoderms PNS/BFAD 06:2006 ICS 67.120.30 (Thermally Processed Fish Products) PNS/FDA 36:2014 (Salt Fermented Fish and Shrimps [Bagoong])	Products with extended shelf life, manufactured by pasteurizing or steam retorting and packaging in vacuum-sealed air-tight containers to ensure sterility. Products may be packed in their own juice or in added oil or sauce.	Includes canned tuna, clams, crab, fish roe and sardines; gefilte fish balls; and surimi (heat-pasteurized).
G. EGG AND EGG PRODUCTS	a. Liquid egg products	The purified whole egg, egg yolk or egg white is pasteurized and chemically preserved (e.g. by addition of salt).	
	b. Frozen egg products	The purified whole egg, egg yolk or egg white is pasteurized and frozen.	Includes frozen eggs, frozen egg whites, frozen egg yolks
	c. Dried and/or heat coagulated egg products	Sugars are removed from the purified whole egg, egg yolk or egg white, which is then pasteurized and dried.	Includes dried eggs, dried egg whites, dried egg yolks

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
F. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS	1. Processed fish and fish products, including molluscs, crustaceans and echinoderms		
	1.d.2) Cooked molluscs, crustaceans and echinoderms	Cooked products include steamed, boiled or any other cooking method except frying see HR Letter F.1.d.3).	Includes cooked crangon crangon and crangon vulgaris (brown shrimp; cooked shrimp, clams and crabs.

	1.d.3) Fried fish and fish products, including molluscs, crustaceans and echinoderms	Ready-to-eat products prepared from fish or fish portions, with or without further dressing in eggs and bread crumbs or batter, that are fried, baked, roasted or barbecued, and then packaged or canned with or without sauce or oil.	Includes ready-to-eat fried surimi, fried calamari, and fried soft-shell crabs.
	2. Fully preserved, including canned or fermented fish and fish products, including molluscs, crustaceans and echinoderms PNS/BFAD 06:2006 ICS 67.120.30 (Thermally Processed Fish Products) PNS/FDA 36:2014 (Salt Fermented Fish and Shrimps [Bagoong])	Products with extended shelf life, manufactured by pasteurizing or steam retorting and packaging in vacuum-sealed air-tight containers to ensure sterility. Products may be packed in their own juice or in added oil or sauce.	Includes canned tuna, clams, crab, fish roe and sardines; gefilte fish balls; and surimi (heat-pasteurized).
G. EGG AND EGG PRODUCTS	a. Liquid egg products	The purified whole egg, egg yolk or egg white is pasteurized and chemically preserved (e.g. by addition of salt).	
	b. Frozen egg products	The purified whole egg, egg yolk or egg white is pasteurized and frozen.	Includes frozen eggs, frozen egg whites, frozen egg yolks
	c. Dried and/or heat coagulated egg products	Sugars are removed from the purified whole egg, egg yolk or egg white, which is then pasteurized and dried.	Includes dried eggs, dried egg whites, dried egg yolks

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
H. FOODSTUFFS INTENDED FOR PARTICULAR NUTRITIONAL USES	Codex Stan 72-1981 (Standard for Infant Formulas for Special Medical Purposes Intended for Infants)	Formulae for special medical purposes intended for infants: Foods for special dietary use that are specially processed or formulated and presented for the dietary management of infants and may be used only under medical supervision. They are intended for the exclusive or partial feeding of infants with limited or impaired capacity to take, digest, absorb or metabolize ordinary infant formulae or certain nutrients contained therein, or who have other special medically determined nutrient requirement, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.	
	2. Complementary foods for infants and young children Codex Stan 73-1981 (Codex Standard for Canned Baby Foods) Codex Stan 074-1981, Rev. 1-2006 (Codex Standard for Processed Cereal-Based Foods for Infants and Young Children) CAC/GL 8-1991 (Guidelines on Formulated Complementary Foods for Older Infants and Young Children)	Foods that are intended for infants 6 months of age and older, and for progressive adaptation of infants and children to ordinary food. Products may be ready-to-eat or in powder form to be reconstituted with water, milk, or other suitable liquid.	Includes cereal-, fruit, vegetable-, and meatbased “baby foods” for infants, “toddler foods,” and “junior foods”; acetal flour, biscuits and rusks for children.
	3. Dietetic foods intended for special medical purposes (excluding products under HR Letter H.1) Codex Stan 180-1991 (Codex Standard for Labelling of and Claims for Foods	Foods for special dietary use that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foods or certain nutrients contained therein, or who have other special medically-determined nutrient requirement, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a	

	Special Medical Purposes)	combination of the two.	
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CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
H. FOODSTUFFS INTENDED FOR PARTICULAR NUTRITIONAL USES	Codex Stan 72-1981 (Standard for Infant Formulas for Special Medical Purposes Intended for Infants)	Formulae for special medical purposes intended for infants: Foods for special dietary use that are specially processed or formulated and presented for the dietary management of infants and may be used only under medical supervision. They are intended for the exclusive or partial feeding of infants with limited or impaired capacity to take, digest, absorb or metabolize ordinary infant formulae or certain nutrients contained therein, or who have other special medically determined nutrient requirement, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.	
	2. Complementary foods for infants and young children Codex Stan 73-1981 (Codex Standard for Canned Baby Foods) Codex Stan 074-1981, Rev. 1-2006 (Codex Standard for Processed Cereal-Based Foods for Infants and Young Children) CAC/GL 8-1991 (Guidelines on Formulated Complementary Foods for Older Infants and Young Children)	Foods that are intended for infants 6 months of age and older, and for progressive adaptation of infants and children to ordinary food. Products may be ready-to-eat or in powder form to be reconstituted with water, milk, or other suitable liquid.	Includes cereal-, fruit, vegetable-, and meatbased “baby foods” for infants, “toddler foods,” and “junior foods”; acteal flour, biscuits and rusks for children.

	<p>3.Dietetic foods intended for special medical purposes (excluding products under HR Letter H.1)</p> <p>Codex Stan 180-1991 (Codex Standard for Labelling of and Claims for Foods Special Medical Purposes)</p>	<p>Foods for special dietary use that are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary foods or certain nutrients contained therein, or who have other special medically-determined nutrient requirement, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for special dietary uses, or by a combination of the two.</p>	
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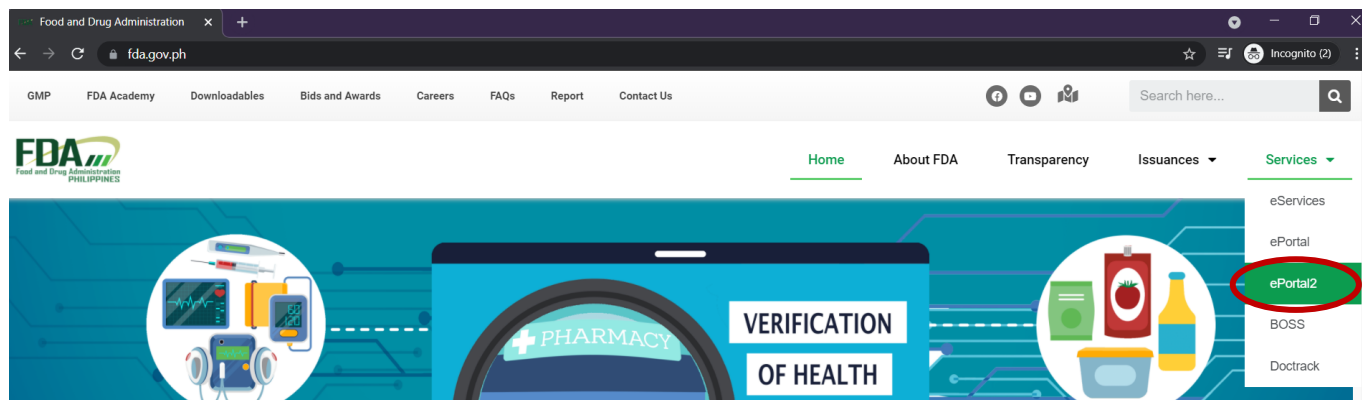
CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
<p>J. FOOD SUPPLEMENT/ HERBAL FOOD/ HERBAL DIETARY SUPPLEMENTS</p> <p>The Adopted Negative List of Active Ingredients (Animal or Plant) for Traditional Medicines</p> <p>ASEAN GL Minimising Risk of Transmission TSE TMHS V1.0 (1Oct14)</p> <p>ASEAN GP for the Use of Additives & Excipients in TMHS V2.0(1Oct14)</p> <p>ANNEX III ASEAN GL on Limits of Contaminations TMHS V1.0(13Nov14) (1)</p> <p>B.C. No. 02 s. 1999 (Additional Labelling Requirement for Food Supplements)</p> <p>B.C. No. 16 s. 2004 (Guidelines on Probiotics)</p> <p>B.C. No. 17 s. 2004 (Taheebo/Pau d'arco/Lapacho)</p> <p>Pharm'l Excipient 6^a</p> <p>PNS/BAFPS 22:2004 (Virgin Coconut Oil 2015 Philippine Dietary Reference Intake</p>			

CATEGORY	FOOD STUFF	DESCRIPTORS/DEFINITION	EXAMPLES
<p>J. FOOD SUPPLEMENT/ HERBAL FOOD/ HERBAL DIETARY SUPPLEMENTS</p> <p>The Adopted Negative List of Active Ingredients (Animal or Plant) for Traditional Medicines</p> <p>ASEAN GL Minimising Risk of Transmission TSE TMHS V1.0 (1Oct14)</p> <p>ASEAN GP for the Use of Additives & Excipients in TMHS V2.0(1Oct14)</p> <p>ANNEX III ASEAN GL on Limits of Contaminations TMHS V1.0(13Nov14) (1)</p> <p>B.C. No. 02 s. 1999 (Additional Labelling Requirement for Food Supplements)</p> <p>B.C. No. 16 s. 2004 (Guidelines on Probiotics)</p> <p>B.C. No. 17 s. 2004 (Taheebo/Pau d'arco/Lapacho)</p> <p>Pharm'l Excipient 6ⁿ</p> <p>PNS/BAFPS 22:2004 (Virgin Coconut Oil)</p> <p>2015 Philippine Dietary Reference Intake</p>			

Electronic Registration Guidelines and Procedure

STEP-BY-STEP PROCEDURE IN THE INITIAL APPLICATION OF PRODUCT REGISTRATION

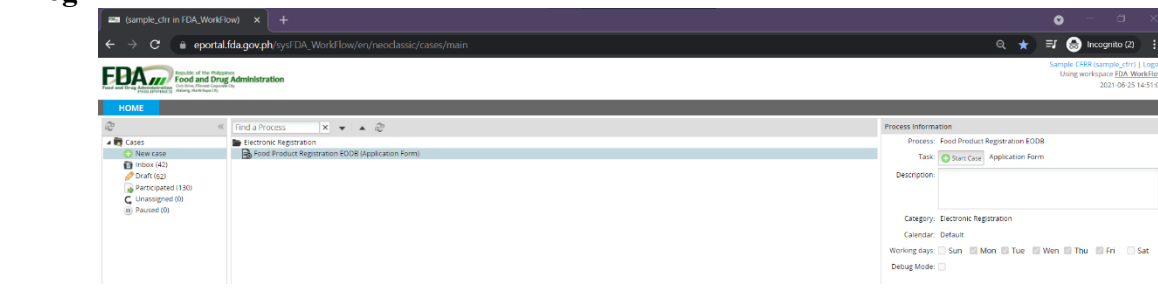
I. GUIDELINES ON THE INITIAL APPLICATION OF CERTIFICATE OF PRODUCT REGISTRATION USING THE E-PORTAL V.2



Step 1. Access the online portal version 2 (E-registration system) thru <https://eportal2.fda.gov.ph/syseportal/en/neoclassic/login/login> or go to the FDA website (<https://www.fda.gov.ph/>) and click the “Services” and choose “**ePortal2**” as shown in the image above.



STEP 2. Enter the MAH’s Electronic Registration account Username and Password then click “Login”



STEP 3. Click “New Case” and choose “Food Product Registration EODB (Application Form)” under the Electronic Registration folder. Select “Start Case” to begin a new application.

Note: Please read and understand the declaration. This declaration conveys binding agreement of the applicant with the FDA to provide accurate information, affirm full responsibility for the safety of the product being registered, and comply with all applicable rules and regulations.

STEP 4. Click “Yes, I agree” then “Continue” to proceed to the initial application form. Declining the declaration shall mean forfeiture of the opportunity to proceed with E-registration application.

The screenshot shows a web form titled "DECLARATION" with a "Next Step" link in the top right corner. The form contains several paragraphs of text, each preceded by "I undertake to..." or "I declare...". The text covers topics such as responding to FDA requests, providing technical and safety information, notifying the authority of adverse events, acting on food safety concerns, and agreeing to indemnify the FDA. At the bottom of the form, there is a red asterisk followed by a dropdown menu with "Yes, I Agree" selected, and a "Continue" button. Below the button, a red asterisk is followed by the text "Required Field".

DECLARATION

I undertake to respond to and cooperate fully with Food and Drug Administration (hereafter referred to as "THE AUTHORITY") with regard to any subsequent post-marketing activity initiated by the authority.

I undertake to ensure that the product's technical and safety information are made readily available to the authority concerned and to keep records of the distribution of the products for product recall purposes, and other purposes as provided in existing laws, rules and regulations.

I undertake to notify the Authority of any adverse event, fatal or life threatening serious adverse event as soon as possible by telephone, facsimile transmission, email or in writing, and in any case, no later than 48 hours after first knowledge.

I undertake to act immediately on potential food safety concerns should my product source or origin declare/announce/notify a product recall order or any actions taken involving safety issues, and I am responsible to stop distribution or remove product from the outlets or take appropriate actions and inform the Authority on risk management actions undertaken and/or to be undertaken.

I declare that the particulars given in this product registration are true, all data, and information of relevance in relation to the registration have been supplied and that the documents enclosed are authentic or true copies.

I understand that I shall be responsible for ensuring that each consignment of my product continues to meet all the legal requirements, and conforms to all the standards and specifications of the product that I have declared to the Authority.

I understand that I cannot place reliance on the acceptance of my product registration by the authority in any legal proceedings concerning my product, in the event that my product has failed to conform to any of the standards or specifications that I had previously declared to the Authority.

I understand that I will need to comply with all the labeling requirements as stipulated by Administrative Order No. 2014-0030 and other pertinent laws and regulations associated with labeling.

I undertake to declare truthful product information and shall not cause the dissemination of any false, deceptive or misleading advertisement 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 the product.

I understand that any change or variation in the formulation of registered product will require new registration to the Authority and the subject shall be treated as new product.

I hereby agree and affirm full responsibility for the safety of my product/s and agree to indemnify and/or hold FDA free and harmless against any issues that may arise in the manufacture, import, export, distribute, transfer, promote, advertise, sponsor, sell, offer for sale, and where appropriate the use and testing, and marketing of my food product/s

I hereby understand that the registration of the product herein granted shall not be interpreted or construed as an endorsement or representation by FDA that I have the right or privilege to the use of the name or brand so registered. I hereby agree and affirm to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or intellectual property rights from the registration of the product listed on the first page thereof.

* Yes, I Agree

Continue

* Required Field

STEP 5. Choose “Initial” and click “Next”

Previous Step

Next Step

General Information

* Application Type Initial

Next

* Required Field

STEP 6. Fill out the Initial Application Form

IMPORTANT GUIDELINES:

- All information filled out by the applicant during the process will be reflected exactly in the final output, either Certificate of product Registration (CPR) or Letter of Denial (LOD). Thus, it is imperative for the client to be strictly cautious and diligent in filling out all required information.
- Fill out all necessary information in CAPITAL LETTERS, except for trademark, Corporate De Facto (e.g. GmbH) and e-mail address. Please read all the noted indicated after the data entries.
- All data entries with **red** asterisk (*) are mandatory fields. The application will not proceed to the next step upon clicking “**Continue**” if not all mandatory fields are filled out.

Food Product Application Form

Fill out all necessary information in ALL CAPS, except for Trademark, Corporate De Facto (e.g. GmbH) and email address

* Type of Food Product

* Food Categorization

Name appropriated by the manufacturer, repacker, distributors, trader, or importer to distinguish its product in the market as per AO No. 2005-0016. Strictly for Raw Materials without brand name, please indicate a dash (-) symbol

* Brand Name

Must be specific and not generic, shall indicate the true nature of the product, and must be consistent with the declaration on the label (eg. -Barbecue Flavored Corn Snack, Coarse Ground Black Pepper, Grapeseed Extract with Vitamin E Plus Minerals Food Supplement Capsule). For Raw Material using code as product name (e.g. TPX001), declare true nature of the product being registered (e.g. TPX001 MALTODEXTRIN)

* Product Name

* Company Name (As listed in LTO)

* Address (As listed in LTO)

* Region

* LTO No.

* LTO Validity

* Number of Years applied for Product Registration

Contact Information. Please provide at least two (2) contact information. Must be in the form of:

- Telephone
- Mobile

New		
Type	* Detail	
1 <input type="text" value="Mobile"/>	<input type="text" value="0123456789"/>	Delete

[Next](#)

* Required Field

Vitamins and Minerals and Amino Acids are under Medium Risk Food Product and categorized as: MRM1. Vitamins and minerals as Food Supplement and MRM2. Amino Acids as Food Supplement.

Food Supplement Products with herbs and botanicals and product with other nutritional substances (plant or animal origin) and/or combination are under High Risk Food Product and categorized as HRK1.

* Brand Name

Must be specific and not generic, shall indicate the true nature of the product, and must be consistent with the declaration on the label (eg. -Barbecue Flavored Corn Snack, Coarse Ground Black Pepper, Grapeseed Extract with Vitamin E Plus Minerals Food Supplement Capsule). For Raw Material using code as product name (e.g. TPX001), declare true nature of the product being registered (e.g. TPX001 MALTODEXTRIN)

* Product Name

Indicate the true nature or a more appropriate product description such as:

Product Name: Swiss Choco Hazelnut Flavored Ice Cream
(Chocolate Ice Cream Infused with Hazelnut
Flavor and Milk –Choco Coated Biscuits,
Glazed with Chocolate Ripple
Brand Name: SWISSE ICE CREAM ®

Products such as Foods for Special Medical Purpose shall be declared as:

Product Name: Low Lactose Formula for Special Medical Purpose Intended
for Infants from 0-12 Months (For Lactose Intolerance)
Brand Name: ALTA VITA ®

Product Name: Meal Replacement Shake Powder - Vanilla Flavor
Brand Name: VITA E-LITE®

For Products that are exclusive for **Export** or for **Institutional Use**, declare it after the product name in the data entry.

Example:

- MENTHOL CANDY (FOR EXPORT MARKET ONLY)
- SOY SAUCE (FOR INSTITUTIONAL USE ONLY)
- INFANT FORMULA (FOR EXPORT TO MALAYSIA)

Products for **Institutional Use** are classified according to their risk categorization.

Example:

Product: MAYONNAISE (FOR INSTITUTIONAL USE ONLY)
Type of Food Product: Medium Risk Food Product
Food Categorization: MRK2a. Emulsified sauces and dips

The declaration of the Brand Name and Product Name should be consistent with the submitted label. Product name shall indicate the true nature of the food and shall normally be specific; not generic.

Example of wrong data entry:

Declaration on the label:	Declaration on the application:
Brand Name: ABC	Brand Name: ABC
Product Name: Menthol Candy	Product Name: MENTHOL

For products formulated for an intended age group, special medical purpose, or special dietary use, include the target population in the product name:

Example:

- INFANT FORMULA (0 TO 6 MONTHS)
- FORMULA FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS 0-6 MONTHS – FOR THE DIETARY MANAGEMENT OF LOW BIRTHWEIGHT INFANTS
- MILK SUPPLEMENT (FROM 6-12 MONTHS)
- CEREAL FOR INFANTS – BROWN RICE WITH BANANA (6+ MONTHS)
- BISCUIT AND CEREAL IN ONE – FORMULATED COMPLEMENTARY FOOD FOR OLDER INFANTS AND YOUNG CHILDREN

Brand Name should not be misleading, confusing and likely create erroneous impression regarding its character or nature in any respect. For those Brand Name with a registered Trade Mark or with an IPO certificate, the symbol TM or ® must be declared and a Trade Mark or IPO Certificate must be submitted.

Product Name should indicate the true nature of the product (e.g. Vitamin A, B1 & C plus Minerals) and shall be specific and not generic. Also, the word “Food/Dietary Supplement” and its product form (e.g. tablet, capsule, syrup, granules, liquid, gummies, powder) must be part of the product name.

* Company Name (As listed in LTO)

* Address (As listed in LTO)

* Region

* LTO No.

* LTO Validity

The declaration of the company name and address should be **consistent** with the declaration in the

valid LTO.

Example of Wrong Data Entry:

Declaration on the valid LTO:

Company Name: **COOKIES CORP.**

Company Address: **BLK 15, LOT 3, SALCEDO VILLAGE,
MAKATI CITY**

Declaration on the Application:

Company Name: **COOKIES CORPORATION**

Company Address: **B 15, L 3, SALCEDO VILL. MAKATI**

STEP 7. Click “**Next**” once all information on the Food Product Application Form has been filled out completely and correctly.

IMPORTANT GUIDELINES:

A. For Companies with LTO activity as IMPORTER/DISTRIBUTOR

If the product is imported and not directly sourced from the manufacturer, click “**No**” in the field of “**Directly Sourced?**”, upload Documentary Requirements and indicate the complete name and address of the supplier as well as the complete name and address of the manufacturer.

Establishment Information

* Please select the corresponding company activity/activities


* Type of Source

* Country of Origin

Country in which the final processing is performed (eg. An alcoholic beverage is distilled in France but bottled in Ireland, the Country of Origin is Ireland)

* Directly Sourced?

No file chosen

 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

For products sourced from supplier, upload ANY of the following scanned copy of the original documents:

- Foreign Agency Agreement, or
- Certificate of Distributorship, or
- Appointment Letter, or
- Proforma Invoice, or
- Memorandum of Agreement from each supplier

AND ANY of the following documents issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin:

- Certificate of Registration with GMP Compliance or its equivalent,
- Valid Sanitary Phyto-Sanitary Certificate, or
- Health Certificate, or
- ISO 22000 Certificate, or
- FSSC 22000, or
- HACCP Certificate
- Certificate of Free Sale

* Complete Name of Supplier

* Complete Address of Supplier

* Complete Name of Manufacturer

* Complete Address of Manufacturer

Step 7.A.1. Choose the option “**Importer Wholesaler Distributor**” as the company activity, consistent with the License to Operate (LTO) number declared in the data entry under Food Product Application Form.

Establishment Information

* Please select the corresponding company activity/activities

* Type of Source

Step 7.A.2 Select the option “**Imported**” in the Type of Source.

* Type of Source

Step 7.A.3. Determine the correct “**Country of Origin**” of the product being imported. Refer to the guide statement regarding the definition of the country of origin.

* Country of Origin

Country in which the final processing is performed (eg. An alcoholic beverage is distilled in France but bottled in Ireland, the Country of Origin is Ireland)

Step 7.A.4. Choose “**Yes**” if the product is directly sourced and “**No**” if otherwise. If the product is directly sourced, it was imported directly from the manufacturer in the country of origin of the product. If not, the product was imported through a “middle-man” or the supplier.

Example:

Directly Sourced:

Manufacturer: USA —> Importer: Philippines


* Directly Sourced?

Not Directly Sourced:

Manufacturer: USA —> Supplier: China —> Importer: Philippines

* Directly Sourced?

Step 7.A.5. Click the “**Choose File**” to attach ANY of the following scanned copy of the original documents issued by the regulatory or health authority of the country of origin or of source: Valid Manufacturer’s Certificate of Registration with GMP compliance or its equivalent, Valid Sanitary Phyto-sanitary Certificate or Health certificate, Valid ISO 22000 Certification, Valid HACCP Certificate, or Certificate of Free Sale.

No file chosen
 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

For products sourced from the manufacturer, upload ANY of the following scanned copy of the original documents:

- Foreign Agency Agreement, or
- Certificate of Distributorship, or
- Appointment Letter, or
- Proforma Invoice, or
- Memorandum of Agreement from the manufacturer

AND ANY of the following documents issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate from the country of origin:

- Certificate of Registration with GMP Compliance or its equivalent,
- Valid Sanitary Phyto-Sanitary Certificate, or
- Health Certificate, or
- ISO 22000 Certificate, or
- FSSC 22000, or
- HACCP Certificate, or

Step 7.A.6. For Directly sourced products, declare the complete name and address of the Manufacturer.

* Complete Name of Manufacturer
 * Complete Address of Manufacturer

For products NOT directly sourced, declare the complete name and address of the supplier and the manufacturer.

* Complete Name of Supplier
 * Complete Address of Supplier
 * Complete Name of Manufacturer
 * Complete Address of Manufacturer

Step 7.A.7. Click “**Next**” to continue.

B. For Companies with LTO activity as DISTRIBUTOR/WHOLESALE

Step 7.B.1. Choose the option “**Distributor Wholesaler**” as the company activity, consistent

with the License to Operate (LTO) number declared in the data entry under Food Product Application Form.

[Previous Step](#)

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Establishment Information


* Please select the corresponding company activity/activities

* Directly Sourced?

Step 7.B.2. Choose if the product is Directly Sourced or not.

Step 7.B.3. Click the “**Choose File**” to attach ANY of the following scanned copy of the original documents issued to the applicant by the establishment from which it sources the products it sells: Valid notarized distributorship agreement, or Letter of appointment between the applicant and the FDA-licensed source

No file chosen

 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

For products sourced from supplier/manufacturer, upload ANY of the following scanned copy of the original documents:

- Valid notarized distributorship agreement, or
- Letter of appointment between applicant and FDA-licensed source

Step 7.B.4. If the product is not directly sourced, declare the complete name and address of the supplier and manufacturer.

* Complete Name of Supplier

* Complete Address of Supplier

* Complete Name of Manufacturer

* Complete Address of Manufacturer

Step 7.B.5. If the product is directly sourced, declare the complete name and address of the manufacturer.

* Complete Name of Manufacturer

* Complete Address of Manufacturer

C. For Companies with LTO activity as TRADER

Step 7.C.1. Choose the option “**Trader**” as the company activity, consistent with the License to Operate (LTO) number declared in the data entry under Food Product Application Form.

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Establishment Information


* Please select the corresponding company activity/activities

* Directly Sourced?

Step 7.C.2. Choose if the product is Directly Sourced or not.

Step 7.C.3. Click the “**Choose File**” to attach ANY of the following scanned copy of the original documents. For products sourced from supplier/manufacturer, upload the scanned copy of the Valid and notarized toll manufacturing and/or repacking agreement with FDA-licensed toll manufacturer and/or repacker.

No file chosen

 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

For products sourced from toll manufacturer, upload the scanned copy of the Valid and notarized Toll Manufacturing and/or repacking agreement with FDA-licensed toll manufacturer and/or repacker

Step 7.C.4. If the product is not directly sourced, declare the complete name and address of the supplier and manufacturer.

* Complete Name of Supplier

* Complete Address of Supplier

* Complete Name of Manufacturer

* Complete Address of Manufacturer

Step 7.C.5. If the product is directly sourced, declare the complete name and address of the manufacturer.

* Complete Name of Manufacturer

* Complete Address of Manufacturer

Next

Step 7.C.6. Click “**Next**” to continue.

For Applications with Multiple Suppliers

Declare the complete name and address of the suppliers separated by semicolon (;).

* Complete Name of Supplier

* Complete Address of Supplier

D. For Companies with LTO activity as MANUFACTURER/ REPACKER/ TOLL MANUFACTURER

Step 7.D.1. Choose the option “**Manufacturer**” as the company activity, consistent with the License to Operate (LTO) number declared in the data entry under Food Product Application Form.

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Establishment Information

* Please select the corresponding company activity/activities

Next

* Required Field

Step 7.D.2. Click “**Next**” to continue.

For products with appointed Wholesaler, please upload a valid distributorship agreement as part of the documentary requirements.

STEP 8. Fill out the complete list of ingredients in descending order and click “Continue” to proceed to the next step.

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Complete List of Ingredients

In descending order of proportion. Product formulation must be consistent with the Ingredient List on the label. Declaration of Food additives should specify its common name not the functional name only and indicate levels eg. LECITHIN (EMULSIFIER) 0.1%.

- For multi-component ingredients declaration:
NON DAIRY CREAMER (as follows)
(GLUCOSE SYRUP)
(HYDROGENATED VEGETABLE FAT)
- For food supplement, ingredients declaration should be in the following format:
Specific Name of Ingredient Amount per Serving
Example: Zeaxanthin 1 mg
- For Vitamins and minerals as Food Supplement, ingredients declaration should be in the following format:
Specific Name (Form/ Chemical nature of Vitamin or Mineral) Amount per Serving
Example: Vitamin A (Beta-carotene) 300 µgRE
- For Amino acids as Food Supplement, ingredients declaration should be in the following format:
Specific Name Amount per Serving
Example: Leucine 50 mg
- For Herbs and Botanicals as Food Supplement, ingredients declaration should be in the following format:
Specific Name (Scientific name) Plant Part Used Amount per Serving
Example: Guyabano (Annona muricata) Fruit 100 mg
- For Products with Nutritional Substances (plant or animal origin) as Food Supplement, ingredients declaration should be in the following format:
Specific name Plant or animal source Amount per Serving
Examples: Collagen from Fish 500mg
Allicin from Garlic 100mg

Please indicate one ingredient per data entry. Click New to add more entry.

[New](#)

* Name of Ingredient

1 [Delete](#)

2 [Delete](#)

3 [Delete](#)

IMPORTANT GUIDELINES:

For Wine products, declare the grape variety/ies used.

Flavors – declare the classification as, “Natural”, “Artificial”, “Nature identical” and “Flavors (Combination of Natural and Nature Identical)”.

Coloring substances – declare common name or as “Food Color(s)” or “Colors” for those derived from or identical with substances derived from plant materials, and the common name of the “Artificial Color(s)” for coal-tar dyes or other synthetic chemical compounds

In case of reformulation, apply for an initial registration for the reformulated product. Reformulation includes the increase or decrease in the amount of existing ingredients of a product, or addition of new ingredient/s or deletion of existing ingredients of the product.

Please refer to CODEX Advisory list of nutrient compounds for use in Infant Formula and Formula for Special Medical Purposes Intended for Infants and Milk Supplements.

Please refer to Bureau Circular 2006-016, Administrative Order 88a. S. 1984 and GSFA for List of Approved Food Additives and its functional category.

The complete list of ingredients and amount per serving (e.g. capsule, tablet, ml, sachet, stick, gummies, softgel, mg, g) must be declared. It should be stated as:


- Form/Chemical Nature for Vitamins and Minerals
- Common Name (Scientific name) and Plant Part used for Herbs and Botanicals
- Common name (Scientific name) of Plant/Animal source and part used for Product with other nutritional substances (plant or animal origin).

STEP 9. Fill out the Product Specifications for the Physical, Chemical and Microbiological Categories. Declare the correct product description. Then click “Next”






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Product Specifications

Ensure the completeness and accuracy of the details for the parameters and specifications in coherence with FDA Standards (eg, Philippine National Standards, Administrative Orders, and other relevant Issuances)

* Product Description 

Physical

I. Color	<input type="text" value="COLOR"/>	 
II. Odor	<input type="text" value="ODOR"/>	 
III. Taste	<input type="text" value="TASTE"/>	 
IV. Texture	<input type="text" value="TEXTURE"/>	 
V. Form	<input type="text" value="FORM"/>	 

e.g. powder, liquid, gel, etc.

Chemical (e.g. Moisture Content, Water Activity, pH, etc)

 New

* Parameter

* Specification

1

[Delete](#)

Microbiological (e.g. Coliforms)

 New

* Parameter

* Specification

1

[Delete](#)

[Next](#)

IMPORTANT GUIDELINES:

- Declare the appropriate product description of the food including type of packing medium, form or style, and the condition or type of treatment it has undergone (e.g. Canned Spanish Style Tuna Chunks, Pickled Cucumber in Brine, Dried Fish, Frozen Corn Kernel, Milk Powder, etc.)
- Ensure the **completeness and accuracy** of the details for the parameters and specifications (Physical, Chemical and Microbiological) in coherence with the Local and International Standards (e.g. Philippine National Standards, Administrative Orders, and other relevant issuances).

Examples of Chemical Parameters:

Moisture content, Water activity, pH, Heavy metals such as lead, mercury, arsenic, cadmium.

Examples of declaration of Chemical Specifications:

Not more than 10%, Minimum of 10 ppm, etc.

Examples of Microbiological Parameters:

Coliforms, Total Plate Count, Salmonella *spp.*, Yeast & Molds, *E. Coli.*; Commercial Sterility, *S. Aureus*

Examples of Microbiological Specifications:

Maximum 10 cfu/g, <100 cfu/mL, etc.

MAL 10,000 cfu/ml ;

Bottled Drinking Water: Please refer to A.O. 18-A s. 1993 for the parameters and standard of bottled drinking water.

Food for Special Dietary Uses and food for Special Medical Purposes: Please refer to applicable CODEX Standards.

STEP 10. Fill out the Shelf Life and Other Information completely and correctly. Click “Next” once all information has been declared on the data entry.

Shelf Life and Other Information

* Shelf Life Declaration (in Months)

For Alcoholic Beverages without Shelf Life, Indicate 0 (Zero)

* Type

* Packaging Material Type/Name

eg. Glass Bottle; Polyethylene Terephthalate (PET); Polyethylene; Polypropylene; Cellophane; Paper (such as Glassine, Vegetable Parchment); Can coated with Oleoresinous, Phenolic, Epoxy or Vinyl; Polyamide; Aluminum; Blister Pack; etc

Description of Product in Commercial Presentation

eg. Individually Wrapped in Pillow Packs Inside Laminated Plastic Pack, in Bottle, in Box, in 90g (2sachets x 45g) carton box

Storage Condition Requirements

e.g. Product should be stored in a cool and dry place with air humidity of 70% maximum, cool storage is recommended

Function of the Food material

Function of the Food Material applies to Food Additives and Ingredients only. (e.g. preservative, nutrient, emulsifier, bakery ingredient)

Source of Allergen (if any)

eg. Cereal containing gluten; Crustaceans and products of these; Eggs and egg products; Peanuts, soybeans, and products of these; Milk and Milk products (lactose included); Tree nut and nut products; Sulphite in concentrations of 10 mg/kg or more

Lot Code and Interpretation

e.g. 230115A where 23- day, 01- month, 15- year, and A- 1st batch

Open Date Marking/ Expiry Date

* Required Field

For products with different and/or multiple packaging material and shelf life, please use “semi-colon” to separate/delineate declaration in the data entry.

Example:

Shelf Life Declaration (in Months): 6; 12

Packaging Material Type/Name: PLASTIC PACK; ALUMINUM FOIL PACK

The declared packaging material in the data entry should be specific and consistent with the submitted pictures of the product.

STEP 11. Upload all necessary document consistent with the product being applied. Click “Next” once all documents needed has been uploaded.

Documentary Requirements

Please upload the necessary documents

Upload the Image of the product label (PNG or PDF File Format)

Choose File No file chosen

(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Please upload the Picture of the Product In Commercial Presentation in all angles and in different packaging sizes and from at least two different perspectives

Choose File No file chosen

(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Is your product for Export

No

Upload any of the following, Purchase Order, Request for Quotation, or valid notarized agreement signed by Importing and Exporting parties of the Importing Company

Choose File No file chosen

(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Do you have Nutrient Content Claim/ Nutrient Function Claim/ Other Function Claims/ Health Claim/ Comparative Claim/ Non-addition claim/ Reduction of disease risk claim/ Other claims?

No

Upload documents to substantiate claims, such as technical, nutritional, or health studies or reports, market-research studies, Certificate of Analysis, quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification in compliance with current labelling regulations

Choose File No file chosen

(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Do you have any IPO/ Trademark, or logo/ seal (e.g. Sangkap Pinoy, Organic, Halal) on your label?

If Yes, For products with Halal or Organic claims on the label, kindly Indicate Certificate Number and Certifying Body. Click New to add more entry.

Yes

New

Certification Number

Certifying Body

1 Halal Certificate Number XXXX

Name of Certifying Body

Delete

2 Organic certificate Number XXXXX

Name of Certifying Body

Delete

Upload the document to substantiate use of logo/seal/ certification?

Choose File Halal Certificate.pdf

(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

COOKING OIL (i.e. Coconut, Palm, Soybean, Corn).

Certificate of Analysis for Vitamin A based on Republic Act 8976.

Choose File No file chosen

(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

NOTE:

- For the list of standards or issuances (e.g. PNS, Codex standards, FDA issuances, local or international standards) please refer to the CFRR Electronic Registration User Manual.

- In case you need to upload additional documents to substantiate your application or double check your submitted requirements, please click Next to view the list of submitted documents

- For all food products with Halal or Organic claims on the label, kindly indicate Certificate Number and Certifying Body. Click New to add more entry.

Next

IMPORTANT GUIDELINES:

- Upload **clear and complete loose labels or artworks**, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations. The product label **shall be named** following the format:

“Label_(Case Number)”

Example: “Label_36252.pdf” or “Label_36252.png”

For products with **multiple labels**, the product label **shall be named** following the format:

“Label1_(Case Number)” and “Label2_(Case Number)”.

Also, submit **pictures of the product** in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered.

Note: When scanning documents for upload, preferably use the **150 x 150 dpi setting**. Check **clarity** of the label information before uploading the labels and pictures of the product. Please be reminded that you may only upload documents in **.PNG** and **.PDF** format.

If there is IPO, Trademark and other logo/seal, Certification must be submitted.

The **Certificate of Analysis** should be **recent** (issued six months from the date of application).

*See Annex D of FDA Circular 2020-033 for the list of critical documents and reference standards for Medium and High Risk Food Products (i.e. Infant Formula, Milk Supplement/Follow-Up Formula, Foods for Special Medical Purposes, Foods for Special Dietary Uses, Cereal-based Foods for Infants & Young Children, Canned Baby Foods, Formula Foods for Weight Control Diets).

You may only upload a **single document** in this step per Documentary requirement. If you need to upload more documents, click **“Continue”** to proceed to the next step where you may **review** and **upload** additional documents.

The submitted Stability Data should indicate:

1. Conclusion Parameters Used
2. Methodology (This should declare the following: product name, batch number, production date, dates of analysis, tabulated data results in terms of physical and chemical properties, and name and signature of the QA Analyst and QA Manager. (Accelerated Shelf Life Study until

6 mos. can be accepted for Initial Application and Real Time Shelf Life Study for Renewal Applications.)

Upload Certificate of Analysis reflecting the Physical, Chemical, and Microbiological properties of the finished product with Nutrient Analysis and Heavy Metals as applicable.

Upload LD-50 Toxicity Test to justify the safety of the product, as applicable) e.g. food supplements)

[Previous Step](#)

[Next Step](#)

Documentary Requirements/ Substantiation of Claims/ Product Label
Input Document

Max of 2MB per attachment (.PNG or .PDF Format) or a total of 25MB for all attached files per application. Please upload documents to determine conformance to the standard/s of product identity. For food supplement (if applicable), please upload safety data (e.g. LD50 toxicity tests). For the list of standards or issuances (e.g. PNS, Codex standards, FDA Issuances, local or international standards) please refer to the CFRR Product Registration Manual of Procedure/ Handbook

[Attach](#)

Title	Version	Creator	Comment	Created Date
No records found				

[Next Step](#)

- Click “**Attach**” to upload: Other Documentary Requirements, Substantiation of Claims and Product Label (Labeling Artwork, Box, Blister Pack, Sachet, Stick).

For Food Supplements: The word “**FOOD SUPPLEMENT**” and “**NO APPROVED THERAPEUTIC CLAIMS**” must be declared on the principal display panel. The precaution: “For Adult Use only. Not recommended for children, pregnant and lactating women” should be declared if the product is not intended for children nor pregnant women. The uploaded label should not contain therapeutic claims and unnecessary images/photographs that is not part of the ingredients and will likely create erroneous impression regarding its character or nature in any respect. The phrase Nutrition Facts should be used instead of Supplement Facts.

Please be reminded that only **25MB** is allotted per product application. This includes all the documents uploaded during **initial** application, **amendment** application and **reapplication**. Uploaded documents can also be deleted by the applicant company if there are unnecessary or wrong documents included before proceeding to the pre-assessment stage.

STEP 12. Click “**Continue**” to proceed with the pre-assessment stage.

Previous Step

Assign Task

Next Task: Pre-Assessment

Empl PRE-ASSESSOR 2

Continue

A pre-assessed food product application for registration could be approved only if it conforms to all of following requirements:

- A. Correct e-portal account consistent with the applicant company
- B. Valid License to Operate (LTO). A valid LTO and approved product line is a pre-requisite to food product registration. For locally manufactured products, the product being applied should be included in the list of products and/or product line in the LTO. If there is an existing application for LTO variation to include product line, the applicant company should wait for its approval before proceeding to submit application for pre-assessment. Otherwise, this will be a ground for denial of the application.
- C. Clear, valid and readable uploaded documents with integrity
- D. Correct and complete data entry declaration consistent with uploaded documents
- E. Compliance of the product being applied with requirements as stipulated in the Citizen's Charter based on existing rules and regulation (Please see annex: AO 2014-0029 (specify link), FDA Circular 2013-010 (specify link), AO 2014-0030 (specify link), standards of identity based on FDA regulations, (specify link), and all other applicable existing regulations. Refer to Annex D of FDA Circular 2020-033 to determine if a particular documentary requirement conforms to the regulations.

A pre-assessed application with complete requirements shall receive a notification thru the registered email address and may settle the corresponding fees through BancNet online payment gateway or Link.Biz portal payment channel following the procedure per FDA Circular No. 2017-010 (specify link), FDA Advisory2021-046 (specify link) or any applicable payment system prescribed by the FDA.

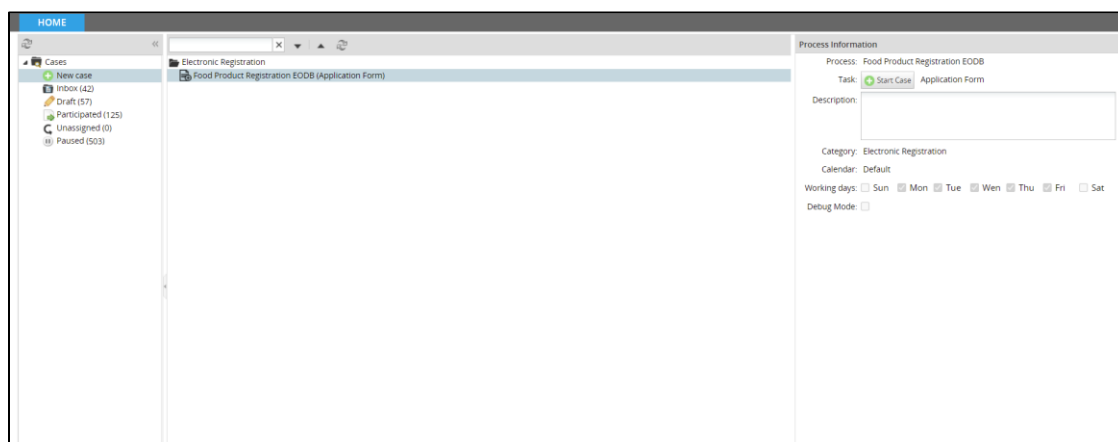
AMENDMENT

Guidelines on Amendment

- For Amendment application from previously approved CPR under the E-Registration V.1 the Certificate of Product Registration number and Old Case Number must be declared to capture all the Initial uploaded documents. This application is termed as “AMENDMENT DATA CAPTURE” and will only be used for product applications previously filed from E-Registration V.1.
- For Automatic Amendment application, the previously approved case number (approved through E-portal v.2) shall be used in applying for Amendment application.

AMENDMENT DATA CAPTURE

Step 1: Click “**New case**” on the upper left corner and then click the “**Food and Product Registration EODB (Application Form)**”.



Step 2: Read and understand the Declaration and choose “**Amendment**” as type of action.

[Previous Step](#)
[Next Step](#)

General Information

* Application Type
Amendment

* Certificate of Product Registration (CPR)

Please provide your OLD Certificate of Product Registration (CPR). It is in the following format, e.g. FR-999999

* Old Case Number

* Date Issued

* CPR Validity

Next

* Required Field

Step 3: Fill-out all the data entry. Please be careful in declaring the Old case number, it should be correct to capture all the uploaded documents in the E-registration v.1.

[Previous Step](#)
[Next Step](#)

General Information

* Application Type
Amendment

* Certificate of Product Registration (CPR)
500000123456

Please provide your OLD Certificate of Product Registration (CPR). It is in the following format, e.g. FR-999999

* Old Case Number
12345

* Date Issued
2021-06-10

* CPR Validity
2021-08-13

Next

* Required Field

Step 4: Fill-out all necessary information. In declaring information it should be consistent with the approved data entry in E-Registration V.1.

AMENDMENT FORM

[Previous Step](#)

Amendment Form

☐ Change in Brand Name

☐ Change in Product Name / Additional Product Description

☐ Change in Business / Company Name

☐ Change in / Additional Supplier

☐ Change in / Additional Packaging Type or Material

☐ Change in / Additional Commercial Presentation

☐ Change or Extension in Shelf Life

☐ Change in/ Additional Packaging Design

☐ Transfer of Ownership of a Registered Product

☐ Change in Importer/Distributor/ Trader

☐ Change in Company Address/Business Address

☐ Updating in LTO Number and/or LTO Validity

☐ Change in Product Specification

☐ Any type of amendments (other than stated in this list) given that there is no changes that is an indication for initial product registration

☐ Exportation of Previously Registered Product Initially for Local Distribution/ Additional Design of the Product Intended for Local Distribution Initially Registered for Exportation

* LETTER OF INTENT stating the specific change/s made from the previously approved product and the proposed change/s.

No file chosen

(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Next

* Required Field

Step 5: Choose the type of amendment you are applying for.

Step 6: Click the “Next” button to proceed.

[Previous Step](#)
[Next Step](#)

Documentary Requirements/ Substantiation of Claims/ Product Label

Input Document

Max of 2MB per attachment (.PNG or .PDF Format) or a total of 25MB for all attached files per application. Please upload documents to determine conformance to the standard/s of product identity. For food supplement (if applicable), please upload safety data (e.g. LD50 toxicity tests). For the list of standards or issuances (e.g. PNS, Codex standards, FDA Issuances, local or international standards) please refer to the CFRR Product Registration Manual of Procedure/ Handbook

[Attach](#)

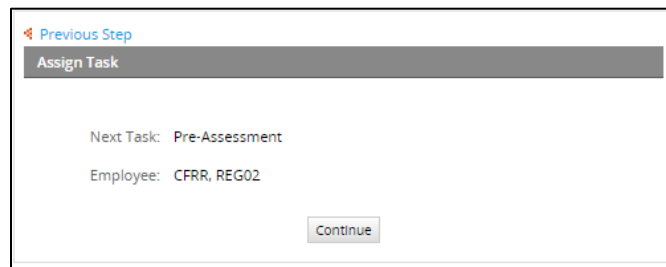
Title	Version	Creator	Comment	Created Date	
Apple juice label.PNG	1	Sample CFRR		2021-07-01	<input type="button" value="Download"/>
Foreign Agency Agreement and Certificate of Registration with GMP Compliance or its equivalent..pdf	1	Sample CFRR		2021-06-11	<input type="button" value="Download"/>
LOI.PNG	1	Sample CFRR		2021-07-01	<input type="button" value="Download"/>
LOI.PNG	1	Sample CFRR		2021-07-01	<input type="button" value="Download"/>

Rows 1-4/4

Page 1/1

Next Step

Step 7: Double check all the submitted documents through the “Documentary Requirements” step then click “**Next Step**”.



Previous Step

Assign Task

Next Task: Pre-Assessment

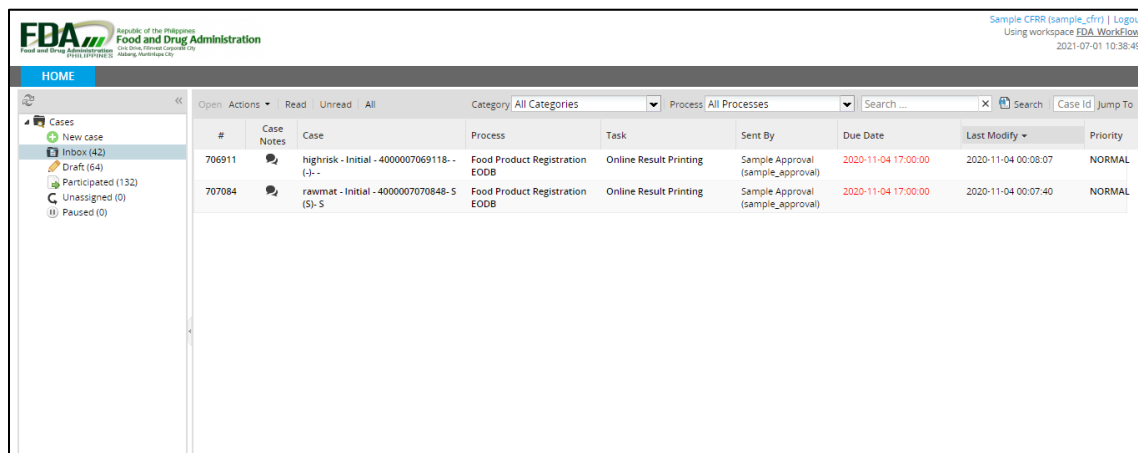
Employee: CFRR, REG02

Continue

Step 8: Select the “**Continue**” button to forward your application to the Pre-Assessment Task.

AUTO AMENDMENT

Step 1: Choose the approved application that you want to Amend in your Inbox.



#	Case Notes	Case	Process	Task	Sent By	Due Date	Last Modify	Priority
706911		highrisk - Initial - 4000007069118 -	Food Product Registration EODB	Online Result Printing	Sample Approval (sample_approval)	2020-11-04 17:00:00	2020-11-04 00:08:07	NORMAL
707084		rawmat - Initial - 4000007070848 - S	Food Product Registration EODB	Online Result Printing	Sample Approval (sample_approval)	2020-11-04 17:00:00	2020-11-04 00:07:40	NORMAL

Step 2: Read and understand the Declaration and choose “**Amendment**” as type of action

Step 3: Proceed to Amendment Form and Choose the type of amendment you are applying for.

[Previous Step](#)

Amendment Form

☐ Change in Brand Name

☐ Change in Product Name / Additional Product Description

☐ Change in Business / Company Name

☐ Change in / Additional Supplier

☐ Change in / Additional Packaging Type or Material

☐ Change in / Additional Commercial Presentation

☐ Change or Extension in Shelf Life

☐ Change in/ Additional Packaging Design

☐ Transfer of Ownership of a Registered Product

☐ Change in Importer/Distributor/ Trader

☐ Change in Company Address/Business Address

☐ Updating in LTO Number and/or LTO Validity

☐ Change in Product Specification

☐ Any type of amendments (other than stated in this list) given that there is no changes that is an indication for initial product registration

☐ Exportation of Previously Registered Product Initially for Local Distribution/ Additional Design of the Product Intended for Local Distribution Initially Registered for Exportation

* LETTER OF INTENT stating the specific change/s made from the previously approved product and the proposed change/s.

No file chosen

(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

* Required Field

Step 4: Click the “Next” button to proceed.

[Previous Step](#)
[Next Step](#)

Documentary Requirements/ Substantiation of Claims/ Product Label

Input Document

Max of 2MB per attachment (.PNG or .PDF Format) or a total of 25MB for all attached files per application. Please upload documents to determine conformance to the standard/s of product identity. For food supplement (if applicable), please upload safety data (e.g. LD50 toxicity tests). For the list of standards or issuances (e.g. PNS, Codex standards, FDA Issuances, local or international standards) please refer to the CFRR Product Registration Manual of Procedure/ Handbook

[Attach](#)

Title	Version	Creator	Comment	Created Date	
Apple juice label.PNG	1	Sample CFRR		2021-07-01	<input type="button" value="Download"/>
Foreign Agency Agreement and Certificate of Registration with GMP Compliance or its equivalent..pdf	1	Sample CFRR		2021-06-11	<input type="button" value="Download"/>
LOI.PNG	1	Sample CFRR		2021-07-01	<input type="button" value="Download"/>
LOI.PNG	1	Sample CFRR		2021-07-01	<input type="button" value="Download"/>

Rows 1-4/4

Page 1/1

Step 5: Double check all the submitted documents through the “Documentary Requirements” step then click “**Next Step**”.

[Previous Step](#)

Assign Task

Next Task: Pre-Assessment

Employee: CFRR, REG02

Continue

Step 6: Select the “**Continue**” button to forward your application to the Pre-Assessment Task.

You can monitor your application by logging in your account. Look for the “**Participated**”.

HOME

Cases

New Case

Inbox (85)

Draft (537)

Participated (817)

Unassigned (8)

Paused (8)

Open

Started by Me

Completed by Me

All

Category: All Categories

Process: All Processes

Status: All Status

Search

Case ID

Jump To

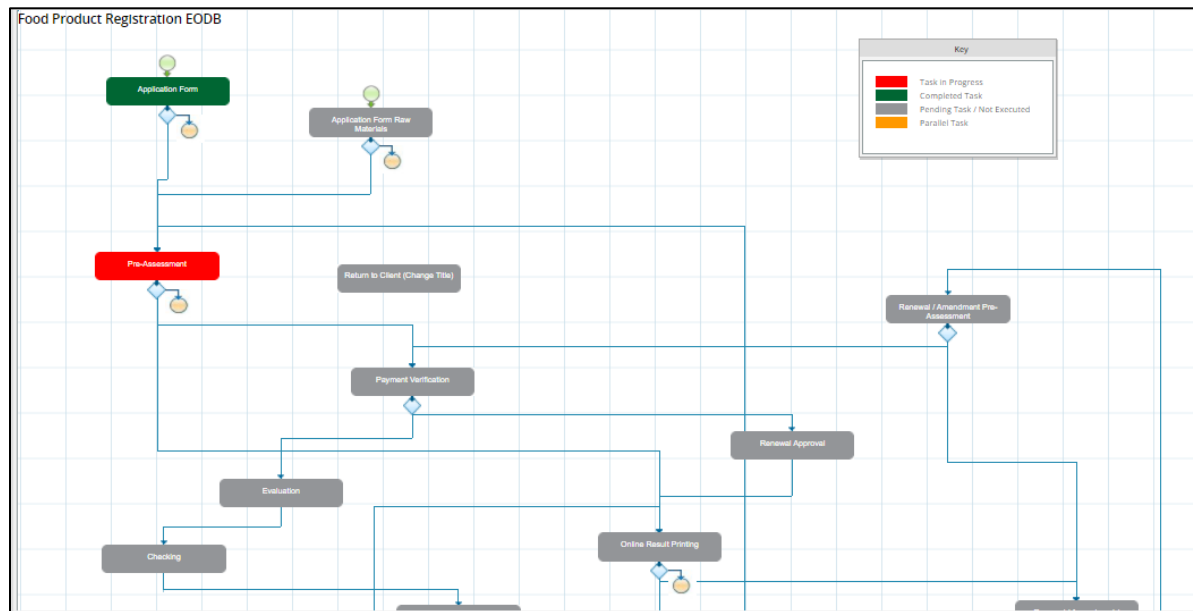
#	Summary	Case Notes	Case	Process	Task	Current User	Last Modify	Status
859			4000000008590 - n	Raw Material and Low Risk Food Product Registration	Initial Application Form	FDA_User1 (FDA/User1)	2016-05-27 14:57:12	Draft
858			3000000008586 - nryk (Not Application)	License To Operate v2.0	Payment	[UNASSIGNED]	2016-05-26 14:44:50	To do
857			4000000008574 - n	Raw Material and Low Risk Food Product Registration	Initial Application Form	FDA_User1 (FDA/User1)	2016-05-27 07:33:29	do
856			4000000008561 - n	Raw Material and Low Risk Food Product Registration	Initial Application Form	FDA_User1 (FDA/User1)	2016-05-23 14:49:39	Draft

Double click the “**Case Number**”.

The screenshot shows the FDA User Interface. On the left, a sidebar menu is open with the 'Cases' option selected. The main content area displays the 'Case Properties' for a specific case. The case title is '4000000008990 - (p)'. The case number is '859'. The case status is 'Draft'. The case is associated with the 'Raw Material and Low Risk Food Product Registration' process.

- Click the “**Information**” button located in the upper most part of the application.
-

To monitor your application, click “**Process Map**”.



Guidelines on Amendment

You can click multiple options depending on the changes applicable to your application. Payment is based on the number of amendments to be applied.

SINGLE APPLICATION

[Previous Step](#)

Amendment Form

Change in Brand Name ☒

From Brand Name JUNE10

* To Brand Name

Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations

Apple juice label.PNG
(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

IPO registration, if available No file chosen
(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Authority from the source or the owner of the brand No file chosen
(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

EXAMPLE: CHANGE IN BRAND NAME

- Click “**Change in Brand Name**”
- Enter the new Brand Name.
- Click the “**Choose file**” button to upload the requirements as per FDA Circular 2020-033 (Letter of Intent, New product label reflecting the change, Authority from the Source or the owner of the brand, if imported, IPO registration, if available).
- Click the “**Next**” button to proceed.

MULTIPLE AMENDMENT

The screenshot displays the 'Amendment Form' interface. At the top left, there is a 'Previous Step' link. The form is titled 'Amendment Form' in a grey header bar. Below this, the 'Change in Brand Name' section is active, indicated by a checked checkbox. It includes fields for 'From Brand Name' (JUNE 10) and 'To Brand Name' (JUNE 11). Below these fields, there are three file upload sections, each with a 'Choose File' button and a note: '(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]'. The first file upload section has 'Apple juice label.PNG' selected. The second and third sections show 'No file chosen'. Below the 'Change in Brand Name' section, the 'Change in Product Name / Additional Product Description' section is also active, with a checked checkbox. It includes fields for 'From Product Name' (APPLE JUICE) and 'To Product Name' (APPLE JUICE DRINK). Below these fields, there is a file upload section with a 'Choose File' button and the same 2 MB limit note, showing 'No file chosen'. At the bottom of the form, there are two unchecked checkboxes: 'Change in Business / Company Name' and 'Change in / Additional Supplier'.

As shown in the picture above, the type of amendment applications applied were “Change in Brand Name, Change in Product Name and Change in/Additional Packaging Design”.

- Provide the data entry with all the changes to be made.
- Click the “**Choose file**” button to upload the requirements as per FDA Circular 2020-033 (Letter of Intent, New product label reflecting the change, Authority from the Source or the owner of the brand, if imported, IPO registration, if available).

Click the “**Next**” button to proceed.

[Previous Step](#)
[Next Step](#)

Documentary Requirements/ Substantiation of Claims/ Product Label

Input Document

Max of 2MB per attachment (.PNG or .PDF Format) or a total of 25MB for all attached files per application. Please upload documents to determine conformance to the standard/s of product identity. For food supplement (if applicable), please upload safety data (e.g. LD50 toxicity tests). For the list of standards or issuances (e.g. PNS, Codex standards, FDA Issuances, local or international standards) please refer to the CFRR Product Registration Manual of Procedure/ Handbook

[Attach](#)

Title	Version	Creator	Comment	Created Date	
Apple juice label.PNG	1	Sample CFRR		2021-07-01	Download
Foreign Agency Agreement and Certificate of Registration with GMP Compliance or its equivalent..pdf	1	Sample CFRR		2021-06-11	Download
LOI.PNG	1	Sample CFRR		2021-07-01	Download
LOI.PNG	1	Sample CFRR		2021-07-01	Download

Rows 1-4/4
Page 1/1

[Next Step](#)

Double check all the submitted documents through the “Documentary Requirements” step then click “Next Step”.

[Previous Step](#)

Assign Task

Next Task: Pre-Assessment

Employee: CFRR, REG02

[Continue](#)

Select the “**Continue**” button to forward your application to the Pre-Assessment.

OTHER TYPES OF AMENDMENT

1. CHANGE IN BRAND NAME

[Previous Step](#)

Amendment Form

Change in Brand Name ☒

From Brand Name JUNE10

* To Brand Name

Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations Apple juice label.PNG
(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

IPO registration, if available No file chosen
(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Authority from the source or the owner of the brand No file chosen
(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Click **“Change in Brand Name”**.

Provide the data entry with all the changes to be made.

Click the **“Choose file”** button to upload the requirements as per FDA Circular 2020-033 (Letter of Intent and New product label reflecting the change)

Click the **“Next”** Step button to proceed.

[Previous Step](#) [Next Step](#)

Documentary Requirements/ Substantiation of Claims/ Product Label
Input Document

Max of 2MB per attachment (.PNG or .PDF Format) or a total of 25MB for all attached files per application. Please upload documents to determine conformance to the standard/s of product identity. For food supplement (if applicable), please upload safety data (e.g. LD50 toxicity tests). For the list of standards or issuances (e.g. PNS, Codex standards, FDA Issuances, local or international standards) please refer to the CFRR Product Registration Manual of Procedure/ Handbook

[Attach](#)

Title	Version	Creator	Comment	Created Date	
Apple juice label.PNG	1	Sample CFRR		2021-07-01	<input type="button" value="Download"/>
Foreign Agency Agreement and Certificate of Registration with GMP Compliance or its equivalent..pdf	1	Sample CFRR		2021-06-11	<input type="button" value="Download"/>
LOI.PNG	1	Sample CFRR		2021-07-01	<input type="button" value="Download"/>
LOI.PNG	1	Sample CFRR		2021-07-01	<input type="button" value="Download"/>

Rows 1-4/4 Page 1/1

Double check all the submitted documents through the **“Documentary Requirements”** step then click **“Next Step”**.

◀ Previous Step ▶ Next Step

Documentary Requirements/ Substantiation of Claims/ Product Label
Input Document

Max of 2MB per attachment (.PNG or .PDF Format) or a total of 25MB for all attached files per application. Please upload documents to determine conformance to the standard/s of product identity. For food supplement (if applicable), please upload safety data (e.g. LD50 toxicity tests). For the list of standards or issuances (e.g. PNS, Codex standards, FDA Issuances, local or international standards) please refer to the CFRR Product Registration Manual of Procedure/ Handbook

▶ Attach

Title	Version	Creator	Comment	Created Date	
Apple juice label.PNG	1	Sample CFRR		2021-07-01	Download
Foreign Agency Agreement and Certificate of Registration with GMP Compliance or its equivalent.pdf	1	Sample CFRR		2021-06-11	Download
LOI.PNG	1	Sample CFRR		2021-07-01	Download
LOI.PNG	1	Sample CFRR		2021-07-01	Download

Rows 1-4/4 Page 1/1

[Next Step](#)

Double check all the submitted documents through the “Documentary Requirements” step then click “**Next Step**”.

2. CHANGE IN PRODUCT NAME / ADDITIONAL PRODUCT DESCRIPTION

Click “**Change in Product Name / Additional Product Description**”.

Provide the data entry with all the changes to be made.

Click the “**Choose file**” button to upload the requirements as per FDA Circular 2020-033 (Letter of Intent and New product label reflecting the change)


Click the “**Next**” Step button to proceed.

Change in Product Name / Additional Product Description ☒

From Product Name: APPLE JUICE

To Product Name:

[Choose File](#) Apple juice label.PNG

Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations  (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

3. CHANGE IN BUSINESS NAME

The screenshot shows the 'Amendment Form' with the following fields and options:

- Change in Brand Name**: ☐
- Change in Product Name / Additional Product Description**: ☐
- Change in Business / Company Name**: ☒
- From Company Name (As listed in LTO)**: LOVEMEORHATEME INC.
- * To Company Name (As listed in LTO)**: **Choose File** NEW LTO.PNG
- Proof of change in business name (Valid License to Operate reflecting the new business name)**: **Choose File** Apple juice label.PNG

Click **“Change in Business/ Company Name”**.

Provide the data entry with all the changes to be made.

Click the **“Choose file”** button to upload the requirements as per FDA Circular 2020-033 (Letter of Intent, New product label reflecting the change and Scanned copy of LTO).

Click the **“Next”** Step button to proceed.

4. CHANGE IN / ADDITIONAL SUPPLIER

The screenshot shows the 'Change in / Additional Supplier' form with the following fields and options:

- Change in / Additional Supplier**: ☒
- From Complete Name of Supplier**: Not Applicable
- From Complete Address of Supplier**: Not Applicable
- To Complete Name of Supplier**: **Choose File** Agreement.PNG
- To Complete Address of Supplier**: **Choose File** Agreement.PNG
- Any of the following scanned copy of the original documents: Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement from the new supplier.**:

Click **“Change in / Additional Supplier”**.

Provide the data entry with all the changes to be made.

Click the **“Choose file”** button to upload the requirements as per FDA Circular 2020-033 (Letter of Intent and Source documents from the supplier)

Click the **“Next”** Step button to proceed.

Note: This type of amendment is only applicable provided that the manufacturer is the same. If the amendment is to add new supplier, re-type the existing information and use semi-colon (;) in the data entry to delineate the new one.

5. CHANGE IN/ADDITIONAL PACKAGING MATERIAL


Change in / Additional Packaging Type or Material ☒

eg. Glass Bottle; Polyethylene Terephthalate (PET); Polyethylene; Polypropylene; Cellophane; Paper (such as Glassine, Vegetable Parchment); Can coated with Oleoresinous, Phenolic, Epoxy or Vinyl; Polyamide; Aluminum; etc


From Packaging Material Type/Name TETRA PACK

To Packaging Material Type/Name


Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations

Apple juice label.PNG
 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Pictures of the product in all angles and in different packaging sizes, and from at least two different perspectives allowing visual recognition of a product as the same with the one being registered.

Apple juice label.PNG
 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

Proof of suitability of packaging material for food, including stability of the product in the new packaging.

Proof of Suit...le juice.PNG
 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

- Click “**Change in Packaging Material and/or Additional Packaging Type**”.
- Provide the data entry with all the changes to be made.
- If applicable, click “**Change in Packaging in Commercial Presentation**” given that there will be changes in size, presentation or description.
- Enter the new Packaging in Commercial Presentation.
- If applicable, click “**Change or Extension of Shelf Life**” if the new packaging material would affect the Shelf Life of the product.
- Click the “**Choose file**” button to upload the requirements as per FDA Circular 2020-033 (Letter of Intent, Picture of the product in all angles and Proof of suitability).
- Click the “**Next**” Step button to proceed.

NOTE: If the amendment is to add packaging material, commercial presentation or shelf-life declaration, re-type the existing information and use semi-colon (;) in the data entry to delineate the new one.

Example:

TETRA PACK; TETRA BRICK or 350 ML; 500 ML TETRA PACK or 12 MONTHS; 16 MONTHS

6.CHANGE IN PACKAGING PRESENTATION

Change in / Additional Commercial Presentation ☒

eg. Individually Wrapped in Pillow Packs inside Laminated Plastic Pack, In Bottle, In Box, In 90g (2sachets x 45g) carton box


From Product Commercial Presentation 250ml and 500ml TETRA PACK

To Product Commercial Presentation 350ml and 500ml

Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations

Choose File

Apple juice label.PNG

 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

- Click “**Change of Packaging in Commercial Presentation**”.
- Provide the data entry with all the changes to be made.
- Click the “**Choose file**” button to upload the requirements as per FDA Circular 2020-033 (Letter of Intent and New product label reflecting the change)
- Click the “**Next**” Step button to proceed.

Note: If the amendment is to add commercial presentation, re-type the existing information and use semi-colon (;) in the data entry to delineate the new one.

7. CHANGE OR EXTENSION IN SHELF LIFE

Change or Extension in Shelf Life ☒

For Alcoholic Beverages without Shelf Life, indicate 0 (Zero)


From Shelf Life Declaration (in Months) 7

To Shelf Life Declaration (in Months) 10

Stability study results with conclusion to support extension or change in shelf-life

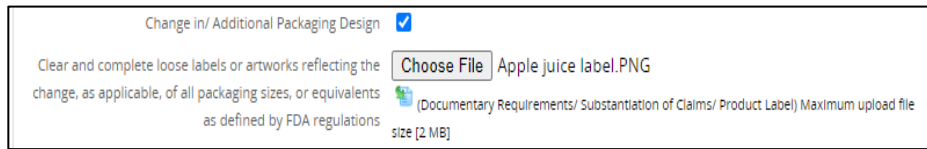
Choose File

Stability Study.PNG

 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

- Click “**Change or Extension in Shelf Life**”.
- Provide the data entry with all the changes to be made.
- Click the “**Choose file**” button to upload the requirements as per FDA Circular 2020-033 (Letter of Intent and Stability study)
- Click the “**Next**” Step button to proceed.

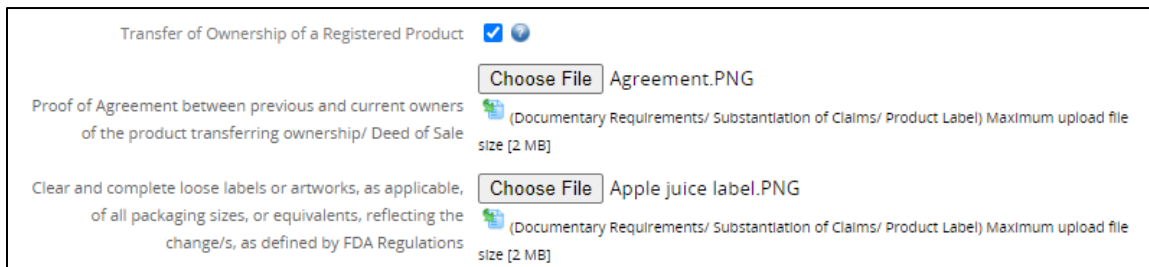
8. CHANGE OR ADDITIONAL DESIGN



- Click **“Change in/Additional Packaging Design”**.
- Click the **“Choose file”** button to upload the requirements as per FDA Circular 2020-033 (Letter of Intent and New product label reflecting the change)
- Click the **“Next”** Step button to proceed.

Note: The amendment “Exportation of previously registered product initially for local distribution” will be under Change or Additional Design.

9. TRANSFER OF OWNERSHIP OF A REGISTERED PRODUCT



- Click **"Transfer of Ownership of a Registered Product"**
- Click the **“Choose file”** button to upload the requirements as per FDA Circular 2020-033 (Letter of intent and new product label reflecting the change, termination agreement/deed of assignment, Agreement of new manufacturer/ importer/distributor or Appointment letter).
- Click the **“Next”** Step button to proceed.

Note: This type of Application should be coursed through the E-portal account of the new owner using new case number.

10. CHANGE IN IMPORTER/DISTRIBUTOR/TRADER

Change in Importer/Distributor/ Trader <input checked="" type="checkbox"/>	
Termination of agreement/Deed of assignment	<input type="button" value="Choose File"/> Agreement.PNG (Amendment Documents) Maximum upload file size [2 MB]
Agreement of new importer/distributor or Appointment letter	<input type="button" value="Choose File"/> Agreement.PNG (Amendment Documents) Maximum upload file size [2 MB]
Clear and complete loose labels or artworks, as applicable, of all packaging sizes, or equivalents, reflecting the change/s, as defined by FDA Regulations	<input type="button" value="Choose File"/> Apple juice label.PNG (Amendment Documents) Maximum upload file size [2 MB]
Proof of cancellation of the previously issued FR No. under the E-portal account of previous owner.	<input type="button" value="Choose File"/> No file chosen (Amendment Documents) Maximum upload file size [2 MB]

- Click "**Change in Importer/Distributor/Trader**"
- Click the "**Choose file**" button to upload the requirements as per FDA Circular 2020-033 (Letter of intent, new product label reflecting the change, termination agreement/deed of assignment, Agreement of new manufacturer/ importer/distributor or Appointment letter and Proof of cancellation of the previously issued FR no. under the E-portal account of previous owner).
- Click the "**Next**" Step button to proceed.

11. CHANGE IN COMPANY ADDRESS/ BUSINESS ADDRESS

Change in Company Address/Business Address <input checked="" type="checkbox"/>	
Old company Address	CIVIC DRIVE, MUNTINLUPA CITY
To:	
New company address	PALACIO DRIVE, KATBUNTON CITY
Proof of change in business address (Valid License to Operate reflecting the new business address)	<input type="button" value="Choose File"/> NEW LTO.PNG (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]
Clear and complete loose labels or artworks reflecting the change, as applicable, of all packaging sizes, or equivalents as defined by FDA regulations	<input type="button" value="Choose File"/> Apple juice label.PNG (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

- Click "**Change in Company Address/ Business Address**".
- Provide the data entry with all the changes to be made.
- Click the “**Choose file**” button to upload the requirements as per FDA Circular 2020-033 (Letter of intent, new product label reflecting the change and scanned copy of new LTO).
- Click the “**Next**” Step button to proceed.

12. UPDATING IN LTO NUMBER AND/OR LTO VALIDITY

Updating in LTO Number and/or LTO Validity ☒

Old LTO No.

Old LTO Validity

To:

New LTO No.

New LTO Validity

NEW LTO.PNG

Copy of updated License to Operate (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

- Click "**Updating in LTO Number and/or LTO Validity**"
- Provide the data entry with all the changes to be made.
- Click the “**Choose file**” button to upload the requirements as per FDA Circular 2020-033 (Letter of intent and new product label reflecting the change, scanned copy of new LTO).
- Click the “**Next**” Step button to proceed.

13.CHANGE IN PRODUCT SPECIFICATIONS

Change in Product Specification ☒

Copy of updated Product Specification Sheet Product specs.PNG


(Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

- Click "**Change in Product Specification**"
- Click the “**Choose file**” button to upload the requirements as per FDA Circular 2020-033 (Letter of intent and scanned copy of new product specification)
- Click the “**Next**” Step button to proceed.

14. CHANGE IN MANUFACTURERS' NAME

Any type of amendments (other than stated in this list) given that there is no changes that is an indication for initial product registration ☒

Documents to substantiate the intended change No file chosen

 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]


- Click "Any type of amendments (other than stated in this list)"
- Click the "Choose file" button to upload the requirements as per FDA Circular 2020-033 (Letter of intent, new product label reflecting the change and Source documents from the manufacturer).
- Click the "Next" Step button to proceed.

Note: Change in Manufacturer's Address is automatically an INITIAL APPLICATION.

15. EXPORTATION OF PREVIOUSLY REGISTERED PRODUCT INITIALLY FOR LOCAL DISTRIBUTION/ ADDITIONAL DESIGN OF THE PRODUCT INTENDED FOR LOCAL DISTRIBUTION INITIALLY REGISTERED FOR EXPORTATION

Exportation of Previously Registered Product Initially for Local Distribution/ Additional Design of the Product Intended for Local Distribution Initially Registered for Exportation ☒

Clear and complete loose labels or artworks as applicable, of all packaging sizes, or equivalents as defined by FDA regulations Apple juice label.PNG

 (Documentary Requirements/ Substantiation of Claims/ Product Label) Maximum upload file size [2 MB]

- Click "Exportation of Previously Registered Product Initially for Local Distribution/ Additional Design of the Product Intended for Local Distribution Initially Registered for Exportation"
- Click the "Choose file" button to upload the requirements as per FDA Circular 2020-033 (Letter of intent and new product label reflecting the change).
- Click the "Next" Step button to proceed.

RENEWAL

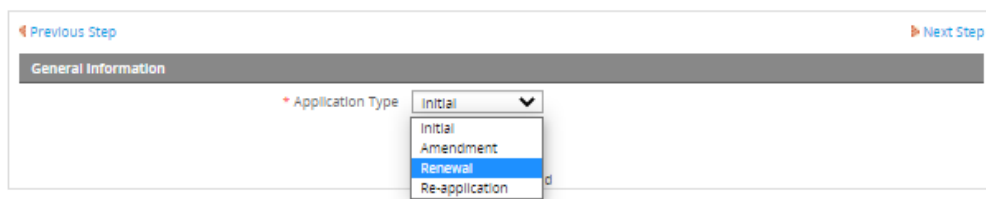
Renewal in E-registration is the action of extending the period of validity of the existing Certificate of Product Registration (CPR) with the following conditions:

- a. No change/s in the product formulation; and
- b. No change/s in manufacturer or re-packer.

- **Renewal application should be filed THREE (3) months prior to expiration date.**
- A surcharge of 50% of renewal fee is collected if renewal registration is submitted within three (3) months after the expiration of the CPR. Application for renewal filed beyond the third month after expiration of CPR shall be considered as initial application. Corresponding surcharges shall be made accordingly.

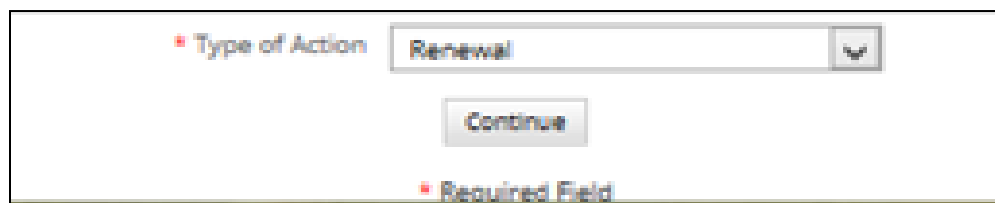
PROCEDURE FOR E-REG “RENEWAL”

1. Double click the Case Number due for “**RENEWAL**”
2. Look for “**Type of Action**” button and select “**RENEWAL**” from the drop down box.



The screenshot shows a web form titled "General Information". At the top, there are links for "Previous Step" and "Next Step". Below the title bar, there is a field for "Application Type" with a dropdown menu. The dropdown menu is open, showing four options: "Initial", "Amendment", "Renewal", and "Re-application". The "Renewal" option is currently selected and highlighted in blue.

3. Once “**Renewal**” is selected, click the “**Continue**” button.



The screenshot shows a web form with a field labeled "Type of Action" containing the text "Renewal". Below this field is a "Continue" button. At the bottom of the form, there is a red asterisk followed by the text "Required Field".

Filing of renewal data capture is similar to the procedures when filing an initial application. Please refer to the step-by-step procedure in filing of initial application which includes uploading of documents and declaring data entry information.

Important reminder is to declare correctly the previously approved case number in the data entry under “Old Case”. The last digit shall be excluded and the “400000” as well, i.e. FR-40000012345, declare only 1234. All the uploaded documents from the previously approved case number in the Version 1 of the E-portal shall be automatically captured. Old documents will not be captured if declaration is incorrect and this shall be a ground for disapproval in the pre-assessment stage.

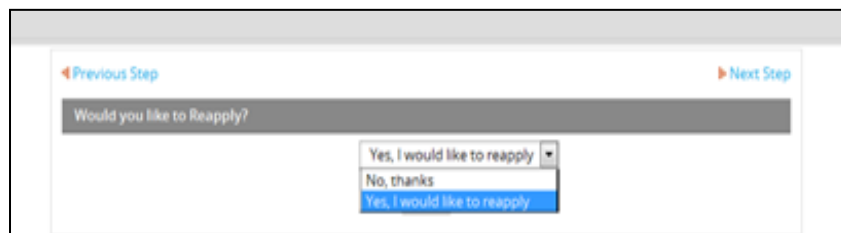
Note: Renewal data capture is only applicable to applications approved in the Version 1 of the E-portal. If the application is approved in the Version 2, just use the same case number when filing renewal.

Applications will proceed to Pre-assessment. Once approved the company will be notified thru email the order of payment

REAPPLICATION

Filing of Reapplication is when a previous application which underwent evaluation, checking and director’s final decision has been disapproved due to deficiencies.

1. Select the type of application from the drop-down menu after the “Declaration”.

A screenshot of a web application interface. At the top, there are two navigation links: "Previous Step" with a left-pointing arrow and "Next Step" with a right-pointing arrow. Below these is a grey rectangular box containing the text "Would you like to Reapply?". Underneath this box is a dropdown menu. The dropdown menu is open, showing three options: "Yes, I would like to reapply" (the top option, which is currently selected), "No, thanks", and "Yes, I would like to reapply" (the bottom option, which is highlighted in blue).

2. Choose “**Yes, I would like to reapply**”.

Reminder: Reapplication can be done within six (6) months from the date of receipt of the Letter of Denial.

If Reapplication was not filed after six months or was DENIED, application will be turned Initial.

3. Click “**Attach**” to upload each document to comply to specific deficiency stated in the Letter of Denial (Example: Certificate of Analysis of 3MCPD for soy sauce, Vitamin A for cooking oil, Food Supplement label with phrase “NO APPROVED THERAPEUTIC CLAIMS”).

Note: A previously denied application in the pre-assessment stage shall be filed as initial application or the type of application originally filed (e.g. amendment, renewal). A new case number must be created instead of using the previous case number which was disapproved in the pre-assessment stage.

Reminder: Submit a clear and readable copy of your compliance in ".PNG" or ".PDF" format not exceeding 2MB in size per file.

CANCELLATION OF CPR IN ELECTRONIC REGISTRATION

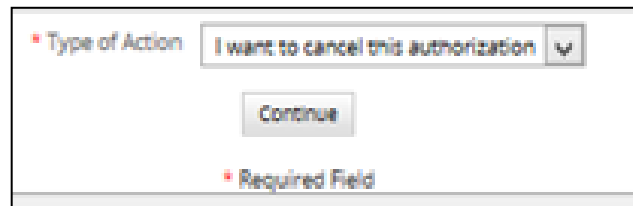
Cancellation or “**I want to cancel this authorization**” in E-registration is the invalidation (null and void) of the existing Certificate of Registration (CPR) due to reasons below:

- A. Product has become non-existent;
- B. Product is no longer manufactured by/distributed/traded/imported.

PROCEDURE:

1. Double click the Case Number due for “**CANCELLATION**”
2. Drop down “**Type of Action**” button and select “**I want to cancel this authorization**”.

3. Once “**I want to cancel this authorization**” is selected, click and select the “**Continue**” button.



A screenshot of a web form. At the top, there is a label "Type of Action" followed by a dropdown menu. The dropdown menu is open, showing the selected option "I want to cancel this authorization". Below the dropdown menu is a button labeled "Continue". At the bottom of the form, there is a red error message that says "Required Field".

4. Task is done once “**Finish**” button is clicked

Post-CPR Approval Duties and Responsibilities of Food Establishments

Ensure that the food product, along the food chain, is not and will not be adulterated, contaminated, misbranded and misleading.

Example:

Self-initiated testing of contaminants of products, assessment and verification of capability of sources to produce quality and safe raw materials or finished goods, vigilance along the food chain on where hazards may occur and acting on to mitigate, eliminate the hazard (e.g. observance of the optimal temperature in delivery of frozen goods, manner of stacking of deliverymen that prevents denting of canned acidic products, etc.).

Ensure the traceability of the food products through proper documentation and observance, at the minimum, of the “one-step-backward and one-step-forward” approach.

Example:

Maintenance of records (Invoices, Certificate of Free Sale) from where the raw materials/imported products came from and where the finished food products will be distributed or delivered.

In cases that the company detects non-compliances of their own products to food safety standards of the Food and Drug Administration (e.g. level of contaminants, quality standards, etc.), the company must immediately report to FDA the appropriate action to address the potential food safety issue.

Example:

The company must notify FDA Center for Food Regulation and Research through submission of letter explaining the nature of the risk or non-compliance and the initial steps conducted to contain the hazard or potential risk to consumers. In cases where the unsafe or non-compliant food product may have reached the consumer, the company must be proactive in withdrawing the product and informing the consumer of the reason for such withdrawal.

ANNEX

ANNEX A. REVISED GUIDELINES FOR THE ASSESSMENT OF MICROBIOLOGICAL QUALITY OF PROCESSED FOODS



REPUBLIC OF THE PHILIPPINES
DEPARTMENT OF HEALTH
FOOD AND DRUG ADMINISTRATION
Filinvest Corporate City
Alabang, Muntinlupa City



FDA CIRCULAR
NO. **2013-010**

27 February 2013

TO: ALL CONCERNED

SUBJECT: **REVISED GUIDELINES FOR THE ASSESSMENT OF
MICROBIOLOGICAL QUALITY OF PROCESSED FOODS**

As part of the mandate of the Food and Drug Administration to protect the public health and pursuant to the provisions of Republic Act No. 9711 otherwise known as the "Food and Drug Administration Act of 2009", the Bureau Circular No. 01-A s. 2004 *Guidelines for the Assessment of Microbiological Quality of Processed Food* is hereby revised with the following considerations: 1. Addition of new food category/products, 2. The need to update old references, 3. Adoption of approved CODEX Alimentarius Commission Guidelines.

This FDA Circular is hereby issued to serve as guidelines for the assessment of microbiological quality of certain processed foods; and help ensure that food manufacturers comply with Good Manufacturing Practices (GMP).

The reference criteria are prescribed in Tables 1-14. The tables contain a description of the food to which a criterion applies, the required test(s) or the microorganisms considered to be acceptable, marginally acceptable or critical, and the number of samples which should conform to the limits.

The methods used for the enumeration or detection of specified microorganisms shall be those that have been internationally established. Such methods, as well as the cited specifications were obtained from the following internationally recognized references:

1. FDA Bacteriological Analytical Manual published by the AOAC
2. Compendium of Analytical Methods of the Canadian Health Protection Branch
3. Compendium of Methods for the Microbiological Examination of Foods compiled by the American Public Health Association (APHA)
4. Specifications and Standards for Foods, Food Additives, etc., Japan External Trade Organization
5. Microorganisms in Foods by the International Commission on Microbiological Specifications for Foods (ICMSF)
6. Codex Alimentarius Commission Guidelines
7. International Standards Organization (ISO) Microbiological Methods
8. Australia New Zealand Food Authority (ANZFA)

This FDA Circular shall take effect immediately and supersede other regulations or guidelines inconsistent herewith.


KENNETH Y. HARTIGAN-GO, MD
Acting Director IV

TABLE 1. MILK AND DAIRY PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Milk Powders (e.g. whole, nonfat or filled milk, buttermilk, whey & whey protein concentrate) (intended for children more than 36 months of age and adults)	<i>Salmonella</i> /25g, normal routine for high risk population SPC/APC, cfu/g Enterobacteriaceae cfu/g	10 30 5 5	0 0 2 1	0 0 5x10 ³ 10	5x10 ⁴ 10 ²
Sweetened Condensed Milk	¹ Coliforms, cfu/g Yeast and Molds Count, cfu/g SPC/APC, cfu/g	5 5 5	1 1 1	10 10 10 ³	10 ² 10 ² 10 ⁴
Liquid Milk (evaporated or ready to drink) & Cream (UHT/sterilized)	Commercial Sterility	6	0	Commercially sterile	
Pasteurized Milk	² Coliforms, cfu/mL	5	1	10 ²	10 ³
	<i>Salmonella</i> /25mL	5	0	0	
	<i>Listeria monocytogenes</i> /25 mL	5	0	0	
	Psychrotrophic bacteria, cfu/mL	5	1	10	10 ²
	SPC/APC, cfu/mL	5	1	5x10 ⁴	10 ⁵
	➤ for flavored milk	5	2	5x10 ⁴	10 ⁶
Pasteurized Cream	¹ Coliforms, cfu/g	5	1	10 ²	10 ³
	<i>Salmonella</i> /25g	5	0	0	
	<i>Listeria monocytogenes</i> /25g	5	0	0	
	Psychrotrophic bacteria, cfu/g	5	1	10	10 ²
	SPC/APC, cfu/g	5	1	5x10 ⁴	10 ⁵
Yogurt and other fermented milk	<i>S. aureus</i> (coagulase +), cfu/mL	5	2	10	10 ²
	¹ Coliforms, cfu/mL	5	2	10	10 ²
	<i>Salmonella</i> /25mL	5	0	0	
	Lactic Acid, cfu/mL				
	(required minimum level: ≥10 ⁶)	-	-	-	-

¹ Coliforms must be negative for *E. coli*

Legend: n – number of sample units selected from a lot of food to be examined

m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

TABLE 1. MILK AND DAIRY PRODUCTS cont.

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Cheese and Cheese Products; e.g. Cottage Cheese; Soft and Semi-soft cheese (moisture $\geq 39\%$, pH > 5)	<i>S. aureus</i> (coagulase +), cfu/g	5	2	10^2	10^3
	<i>E. coli</i> , MPN/g	5	1	11	110
	Coliforms, MPN/g	5	1	11	10^3
	Psychrotrophic bacteria, cfu/g	5	2	10^2	10^3
	<i>Salmonella</i> /25g	5	0	0	
	<i>Listeria monocytogenes</i> /25g	5	0	0	
Processed Cheese Spread	Coliforms, cfu/g	5	1	10	10^2
	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10	10^2
	SPC/APC, cfu/g	5	2	10^4	5×10^4
All Raw Milk Cheese; Raw Milk Un-ripened cheese w/moisture > 50%, pH > 5.0	<i>Campylobacter</i> /25g	5	0	0	
	<i>Salmonella</i> /25g	5	0	0	
	<i>Listeria monocytogenes</i> /25g	5	0	0	
	<i>S. aureus</i> (coagulase +), cfu/g	5	2	10^2	10^3

¹ Coliforms must be negative for *E. coli*

TABLE 2. FATS, OILS AND FAT EMULSIONS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Butter (whipped, pasteurized)	Enterococci, cfu/g	5	1	10	10^2
	YMC, cfu/g	5	1	20	10^2
	Proteolytic bacteria, cfu/g	5	1	10^2	10^3
	Coliforms, cfu/g	5	1	10	10^2
	<i>S. aureus</i> (coagulase +), cfu/g	5	0	10^2	
	Psychrotrophic bacteria, cfu/g	5	1	10	10^2
	SPC/APC, cfu/mL	5	1	5×10^4	10^5
Butter made from unpasteurized milk or milk products	Coliforms, cfu/g	5	1	10	10^2
	<i>E. coli</i> , MPN/g	5	1	3	11
	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10	10^2
	<i>Salmonella</i> /25g	5	0	0	
	<i>Listeria monocytogenes</i> /25g	5	0	0	
	SPC/APC, cfu/g	5	1	5×10^4	10^5
Margarine	<i>S. aureus</i> (coagulase +), cfu/g	5	0	10	
	Faecal Coliform, MPN/g	5	2	50	5×10^2
	<i>Listeria monocytogenes</i> /25g	5	0	0	
	<i>Salmonella</i> /25g	5	0	0	
	SPC/APC, cfu/g	5	2	2.5×10^4	2.5×10^5
	YMC, cfu/g	5	2	50	5×10^2

Legend: n – number of sample units selected from a lot of food to be examined

m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

TABLE 3. EDIBLE ICES, INCLUDING SHERBET AND SORBET

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Ice Cream & Sherbet (plain and flavored)	¹ Coliforms, cfu/g	5	1	10	10 ³
	<i>Listeria monocytogenes</i> /25g	5	0	0	
	<i>Salmonella</i> /25g	5	0	0	
	SPC/APC, cfu/g	5	2	10 ⁴	5x10 ⁴
	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10	10 ²
Ice Cream with added ingredients (nuts, fruits, cocoa etc.)	¹ Coliforms, cfu/g	5	2	10	10 ³
	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10	10 ²
	<i>Salmonella</i> /25g	5	0	0	
	SPC/APC, cfu/g	5	2	5x10 ⁴	2x10 ⁵
	<i>Listeria monocytogenes</i> /25g	5	0	0	
Flavored Ice (e.g. Ice candy)	SPC/APC, cfu/g	5	2	10 ²	10 ⁴
	Coliforms, MPN/g	5	0	3.0	
	YMC, cfu/g	5	0	10 ²	
	<i>Salmonella</i> /25g	5	0	0	

¹ Coliforms must be negative for *E. coli*

TABLE 4. CONFECTIONERIES

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Cocoa Powder	Molds, cfu/g	5	2	10 ²	10 ⁴
	<i>Salmonella</i> / 25g	5	0	0	
	Coliforms, MPN/g	5	2	1.8	10
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁶
Chocolate Products	Molds, cfu/g	5	2	10 ²	10 ⁴
	<i>Salmonella</i> / 25g	10	0	0	
	Coliforms, MPN/g	5	2	1.8	10 ²
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁶
Chocolate Confectionaries (chocolate bars, blocks, bonbons)	Molds, cfu/g	5	2	10 ²	10 ³
	<i>Salmonella</i> / 25g	5	0	0	
	Coliforms, MPN/g	5	2	1.8	10 ²
	SPC/APC, cfu/g	5	2	10 ³	10 ⁶
Sugar Confectionaries (Hard and soft candies, toffees, caramel, fondants, creams, nougats and pastes)	Molds, cfu/g	5	2	10	10 ²
	<i>Salmonella</i> / 25g	5	0	0	
	Coliforms, MPN/g	5	2	1.8	10 ²
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁶

Legend: n – number of sample units selected from a lot of food to be examined

m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

TABLE 5. FRUITS AND VEGETABLES, NUTS AND SEEDS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Frozen Vegetables & Fruits (pH >4.5)	<i>E.coli</i> , MPN/g	5	2	110	10 ³
Fermented Vegetables, Ready to Eat (e.g. Kimchi)	YMC, cfu/g	5	2	10 ²	10 ⁴
	Coliforms, MPN/g	5	0	3	
	<i>E.coli</i> , MPN/g	5	0	3	
	<i>Salmonella</i> /25g	5	0	0	
	<i>Staphylococcus aureus</i> , cfu/g	5	0	10	
Fruits & Vegetable products in Hermetically sealed containers (thermally processed)	Commercial sterility	6	0	Commercially sterile	
Dried Vegetables	<i>E. coli</i> , MPN/g	5	2	110	10 ³
Coconut (desiccated)	Refer to PNS/BAFPS 25:2007				
Peanut Butter & other Nut Butters ➤ consumed without heating or other treatment to destroy microbes ➤ used as ingredient in high moisture food	<i>Salmonella</i> / 25g	10	0	0	
	<i>Salmonella</i> / 25g	20	0	0	
Sun Dried Fruits	Molds, cfu/g	5	2	10 ²	10 ⁴
	Osmophilic Yeasts, cfu/g	5	2	10	10 ³
	<i>E.coli</i> , MPN/g	5	2	3	11

¹Coliforms must be negative for *E.coli*

TABLE 6. EGG AND EGG PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Pasteurized Egg Products (liquid, frozen or dried)	Coliforms, cfu/g	5	2	10	10 ³
	<i>Salmonella</i> /25g	10	0	0	
	YMC, cfu/g (for dried products)	5	0	10	10 ⁵
	SPC/APC, cfu/g	5	0	2.5x10 ⁴	

Legend: n – number of sample units selected from a lot of food to be examined

m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

TABLE 7. CEREALS AND CEREAL PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Breakfast Cereals	Molds, cfu/g	5	2	10	10 ³
	Yeast & Yeastlike fungi, cfu/g	5	2	10	10 ²
	Coliform, cfu/g	5	2	10	10 ²
	SPC/APC, cfu/g	5	2	10 ³	10 ⁴
Cereals/Cereal Grains	YMC, cfu/g	5	2	10 ²	10 ⁴
	SPC/APC, cfu/g	5	2	10 ²	10 ⁶
	Coliform, cfu/g	5	2	10 ²	10 ⁴
	<i>E.coli</i> , MPN/g	5	2	10 ²	10 ⁴
Cultured seeds and grains (e.g. bean sprouts, alfalfa etc.)	<i>E. coli</i> , MPN/g	5	2	10	10 ²
	Coliforms, cfu/g	5	2	10 ²	10 ⁴
	<i>Salmonella</i> /25g	5	0	0	
Soya Flours, Concentrates and Isolates	Molds, cfu/g	5	2	10 ³	10 ⁵
	<i>Salmonella</i> /25g	5	0	0	
Flour, Corn meal, Corn grits, Semolina	Molds, cfu/g	5	2	10 ²	10 ⁴
	Yeast & Yeastlike fungi, cfu/g	5	2	10	10 ²
	Coliform, cfu/g	5	2	10	10 ²
	<i>Bacillus subtilis</i> , cfu/g	5	2	10	10 ²
	"rope spores"	5	2	10	10 ²
Frozen entrees containing Rice or Corn Flour as main ingredient	<i>B. cereus</i> , cfu/g	5	1	10 ²	10 ⁴
Soy Protein	Coliforms, cfu/g	5	2	10 ²	10 ³
	<i>E. coli</i> , MPN/g	5	1	10	10 ²
	Psychrotrophic bacteria, cfu/g	5	2	10 ²	10 ⁴
	<i>Clostridium perfringens</i> , cfu/g	5	2	10	10 ²
	YMC, cfu/g	5	2	10	10 ²
	<i>Salmonella</i> / 25g	5	0	0	
	SPC/APC, cfu/g	5	2	10 ²	10 ⁵
Tofu	<i>B. cereus</i> , cfu/g	5	2	10 ²	10 ³
	<i>E. coli</i> , MPN/g	5	0	1.8	
	<i>S. aureus</i> (coagulase +), cfu/g	5	2	10 ²	10 ³
Pasta Products and Noodles Uncooked (wet & dry)	Coliforms, cfu/g	5	2	10	10 ³
	YMC, cfu/g	5	2	10 ²	10 ⁵
	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10 ²	10 ⁴
	<i>Salmonella</i> / 25g	5	0	0	
	SPC/APC, cfu/g	5	2	10 ³	10 ⁵
Starch	Coliforms, cfu/g	5	2	10	10 ²
	YMC, cfu/g	5	2	10 ²	10 ³
	<i>Salmonella</i> /25g	5	0	0	
	SPC/APC, cfu/g	5	2	10 ³	5x10 ⁴

Legend: n – number of sample units selected from a lot of food to be examined

m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

TABLE 8. BAKERY PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Frozen Bakery products (ready to eat) with low- acid or high a_w fillings or toppings	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10 ²	10 ⁴
	<i>Salmonella</i> / 25g	5	0	0	
Frozen Bakery Products (to be cooked) with low- acid or high a_w fillings or toppings (e.g. meat pies, pizzas)	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10 ²	10 ⁴
	<i>Salmonella</i> / 25g	5	0	0	
Frozen and Refrigerated Doughs (Chemically leavened)	Molds, cfu/g	5	2	10 ²	10 ⁴
	Yeasts & Yeastlike Fungi, cfu/g	5	2	10 ⁵	10 ⁶
	Coliforms, cfu/g	5	2	10	10 ²
	Psychrotrophic bacteria, cfu/g	5	2	10	10 ³
	SPC/APC, cfu/g	5	2	10 ²	10 ⁷
	<i>Salmonella</i> / 25g	5	0	0	
	<i>S. aureus</i> (coagulase +) , cfu/g	5	2	10 ²	10 ⁴
	<i>E. coli</i> , MPN/g	5	0	3.0	
Frozen & Refrigerated Doughs	Molds, cfu/g	5	2	10 ²	10 ⁴
	Yeasts & Yeastlike Fungi, cfu/g	5	2	10 ⁵	10 ⁶
	Coliforms, cfu/g	5	2	10	10 ²
	Psychrotrophic bacteria, cfu/g	5	2	10	10 ³
	SPC/APC, cfu/g	5	2	10 ³	10 ⁶
Baked Goods (microbiologically sensitive types e.g containing eggs & dairy products)	<i>S. aureus</i> (coagulase +), cfu/g	5	2	10 ²	10 ⁴
	MYC, cfu/g	5	2	10 ²	10 ⁴
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁶
	Coliforms, cfu/g	5	2	50	10 ³
Coated or Filled, Dried Shelf-Stable Biscuits	¹ Coliforms, MPN/g	5	2	3	20
	<i>Salmonella</i> /25g	10	0	0	

¹Coliforms must be negative for *E.coli*

TABLE 9. READY TO EAT SAVOURIES

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Snack Foods	Molds, cfu/g	5	2	10	10 ³
	Yeast & Yeastlike fungi, cfu/g	5	2	10	10 ²
	Coliform, cfu/g	5	2	10	10 ²
	SPC/APC, cfu/g	5	2	10 ³	10 ⁴

Legend: n – number of sample units selected from a lot of food to be examined

m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

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TABLE 10. MEAT AND MEAT PRODUCTS**

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Dried Animal Products	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10 ²	10 ⁴
	<i>Clostridium perfringens</i> , cfu/g	5	1	10 ²	10 ⁴
	<i>Salmonella</i> /25g	10	0	0	
Meat Paste & Paté (heat treated)	<i>Salmonella</i> /25g	5	0	0	
	<i>Clostridium perfringens</i> , cfu/g	5	2	10 ²	10 ³
	<i>S. aureus</i> (coagulase +), cfu/g	5	2	10 ²	10 ³
	¹ Coliforms, cfu/g	5	2	10	10 ²
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁵
Cold Cuts, Frozen & Chilled Hot Dogs, Corned Beef, Luncheon Meat	<i>E. coli</i> , MPN/g	5	0	1.8	
	<i>Salmonella</i> /25g	10	0	0	
	<i>S. aureus</i> (coagulase +), cfu/g	5	2	10 ²	10 ³
	SPC/APC, cfu/g	5	2	10 ⁵	10 ⁶
Packaged cooked cured/salted meat (ham, bacon)	<i>S. aureus</i> (coagulase +), cfu/g	5	2	10 ²	10 ³
	<i>Salmonella</i> /25g	5	0	0	
	<i>Listeria monocytogenes</i> /25g	5	0	0	
Fermented, comminuted meat, not cooked (dry & semi-dry fermented sausages)	<i>E. coli</i> , MPN/g	5	0	1.8	
	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10 ³	10 ⁴
	<i>Salmonella</i> /25g	5	0	0	
Cooked Poultry Meat, Frozen to be reheated before eating (e.g. prepared frozen meals)	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10 ³	10 ⁴
	<i>Salmonella</i> /25g	5	0	0	
Cured/Smoked Poultry Meat	<i>S. aureus</i> (coagulase +), cfu/g	10	1	10 ³	10 ⁴
	<i>Salmonella</i> /25g	10	0	0	
Dehydrated Poultry Products	<i>Salmonella</i> / 25g	10	0	0	
Fresh/Frozen Raw Chicken (during processing)	SPC/APC, cfu/g (at 20°C)	5	3	5x10 ⁵	10 ⁷
Meat Products in hermetically sealed containers	Commercial sterility	6	0	Commercially sterile	

¹Coliforms must be negative for *E. coli*

** Effective 16 February 2010, all meat and meat products are being handled and regulated by the National Meat Inspection Service (NMIS) of the Department of Agriculture as mandated by RA 9296 "Meat Inspection Code of the Philippines and DA-DOH joint Administrative Order No.1 s 2009". Any guidelines set by the NMIS shall supersede the specifications herein stated once it is made available.

Legend: n – number of sample units selected from a lot of food to be examined

m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

TABLE 11. FISH AND FISH PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Fresh Frozen Fish^a and Cold-Smoked^b	<i>E. coli</i> , MPN/g	5	3	11	500
	<i>S. aureus</i> (coagulase +), cfu/g	5	2	10 ³	10 ⁴
	<i>V. parahaemolyticus</i> , cfu/g	5	2	10 ²	10 ³
	<i>Salmonella</i> /25g	5	0	0	
	SPC/APC, cfu/g	5	3	5x10 ⁵	10 ⁷
Pre-Cooked Breaded Fish	<i>E. coli</i> , MPN/g	5	2	11	500
	<i>S. aureus</i> (coagulase +), cfu/g	5	1	10 ³	10 ⁴
	SPC/APC, cfu/g	5	2	5x10 ⁵	10 ⁷
Frozen Raw Crustaceans^c	<i>E. coli</i> , MPN/g	5	3	11	500
	<i>S. aureus</i> (coagulase +), cfu/g	5	2	10 ³	10 ⁴
	<i>Salmonella</i> /25g	5	0	0	
	<i>V. parahaemolyticus</i> , cfu/g	5	1	10 ²	10 ³
	SPC/APC, cfu/g	5	3	10 ⁶	10 ⁷
Frozen Cooked Crustaceans	<i>E. coli</i> , MPN/g	5	2	11	500
	<i>S. aureus</i> (coagulase +), cfu/g	5	0	10 ²	
	<i>Salmonella</i> /25g	20	0	0	
	<i>V. parahaemolyticus</i> , cfu/g	10	1	10 ²	10 ³
	SPC/APC, cfu/g	5	2	5x10 ⁵	5x10 ⁶
Cooked, Chilled & Frozen Crabmeat^d	<i>E. coli</i> , MPN/g	5	1	11	500
	<i>S. aureus</i> (coagulase +), cfu/g	5	0	10 ³	
	<i>V. parahaemolyticus</i> , cfu/g	10	1	10 ²	10 ³
	SPC/APC, cfu/g	5	2	10 ⁵	10 ⁶
Fresh & Frozen Bivalve Molluscs^e	<i>E. coli</i> , MPN/g	5	0	16	
	<i>Salmonella</i> /25g	20	0	0	
	<i>V. parahaemolyticus</i> , cfu/g	10	1	10 ²	10 ³
	SPC/APC, cfu/g	5	0	5x10 ⁵	
Fish & Shellfish products in hermetically sealed containers (thermally processed)	Commercial Sterility	6	0	Commercially sterile	

^a For fish derived from inshore/inland waters of doubtful bacteriological quality, particularly warm areas or harvested during summer. Tests for *Salmonella* and *V. parahaemolyticus* recommended if fish is to be eaten raw.

^b Test for *S. aureus* recommended for smoked fish.

^c Test for *S. aureus* recommended for breaded products. *Salmonella* and *V. parahaemolyticus* applied to products from waters or harvested during summer.

^d SPC/APC for frozen products only

^e Criteria to be used only for molluscs from approved harvesting areas where waters are free from enteric bacteria or virus contamination and no significant contamination by toxic metals or chemicals may be accumulated by animals. Tests for *Salmonella* and *V. parahaemolyticus* recommended for molluscs from endemic areas or harvested from warm waters during summer.

Legend: n – number of sample units selected from a lot of food to be examined

m – acceptable level of microorganism determined by a specified method; the values are generally based on levels that are achievable under GMP

M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

TABLE 12. SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Dry Mixes for Soup and Sauces	<i>Clostridium perfringens</i> , cfu/g	5	2	10 ²	10 ³
	YMC, cfu/g	5	3	10 ²	10 ⁴
	Coliforms, cfu/g	5	3	10	10 ³
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁶
	<i>Salmonella</i> /25g	5	0	0	
Yeast	<i>Salmonella</i> /25g	20	0	0	
Spices	<i>Molds</i> , cfu/g	5	2	10 ²	10 ⁴
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁶
Spices (ready to eat)	¹ Coliforms, cfu/g	5	2	10 ²	10 ³
	<i>S. aureus</i> (coagulase +), cfu/g	5	2	10 ²	10 ⁴
	<i>Salmonella</i> /25g	5	0	0	
	<i>Molds</i> , cfu/g	5	2	10 ²	10 ⁴
	SPC/APC, cfu/g	5	2	10 ⁴	10 ⁶
Salad Dressing, pH ≤ 4.6 (e.g. Mayonnaise, Thousand Island, Ranch, French)	SPC/APC, cfu/g	5	2	10	10 ²
	YMC, cfu/g	5	2	10	10 ²
	<i>Salmonella</i> /25g	5	0	0	
	<i>Listeria monocytogenes</i> /25g	5	0	0	

¹Coliforms must be negative for *E.coli*

TABLE 13. BEVERAGES

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Non Alcoholic Beverages (e.g. Ready to drink, softdrinks, iced tea, energy drinks)	YMC, cfu/mL	5	0	1	
	Coliforms, cfu/mL	5	0	1	
	SPC/APC, cfu/mL	5	1	10	10 ²
Frozen Juice Concentrate	SPC/APC, cfu/mL	5	2	10 ²	10 ⁵
	YMC, cfu/mL	5	1	10	50
Powdered Beverages (e.g. iced tea, powdered juices/mixes)	SPC/APC, cfu/g	5	0	3x10 ³	
	Coliforms, cfu/g	5	0	10	

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M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

TABLE 14. FOOD FOR INFANTS AND YOUNG CHILDREN

FOOD DESCRIPTION	TEST/MICROORGANISM Reference Criteria	n	c	m	M
Powdered Infant Formula with or without added Lactic acid producing cultures (intended for 0 to 6 months old)	Routine analysis:				
	<i>Cronobacter</i> spp. / 10g	30	0	0	
	* <i>Salmonella</i> / 25 g	60	0	0	
	For complaint investigation (additional to routine analysis):				
	¹ Coliforms, MPN/g	5	2	3	11
	<i>E. coli</i> , MPN/g	10	1	1.8	10
Follow-up Formula/Milk Supplement (intended for infants 6 months on and for young children 12-36 months of age)	² Process Hygiene Indicators:				
	SPC/APC, cfu/g	5	2	5x10 ²	5x10 ³
	Enterobacteriaceae/ 10g	10	2	0	³ NA
	Routine analysis:				
Infant Formula - liquid (UHT/sterilized)	* <i>Salmonella</i> / 25 g	60	0	0	
	For complaint investigation (additional to routine analysis):				
	¹ Coliforms, MPN/g	5	2	3	11
	<i>E. coli</i> , MPN/g	10	1	1.8	10
	² Process Hygiene Indicators:				
	SPC/APC, cfu/g	5	2	5x10 ²	5x10 ³
Baby foods in hermetically sealed containers	Enterobacteriaceae/ 10g	10	2	0	³ NA
	Commercial Sterility	6	0	Commercially Sterile	
Dried and Instant products requiring reconstitution	Commercial Sterility	6	0	Commercially Sterile	
Dried products requiring reconstitution and boiling before consumption	¹ Coliforms, MPN/g	5	1	3	20
	SPC/APC, cfu/g	5	2	10 ³	10 ⁴
	* <i>Salmonella</i> /25g	60	0	0	
	<i>Listeria monocytogenes</i> /25g	5	0	0	
Cereal based foods for infants	¹ Coliforms, cfu/g	5	2	10	10 ²
	<i>Salmonella</i> /25g	5	0	0	
	SPC/APC, cfu/g	5	3	10 ⁴	10 ⁵
	<i>Bacillus cereus</i> , cfu/g	10	1	10 ²	10 ⁴
Cereal based foods for infants	<i>Clostridium perfringens</i> , cfu/g	5	1	10	10 ²
	SPC/APC, cfu/g	5	2	10 ³	10 ⁴
	<i>Salmonella</i> /25 g	10	0	0	
	Coliforms, MPN/g	5	2	3	20

¹ Coliforms must be negative for *E. coli**25g sample units may be composited to a quantity not to exceed 400g
n = 60 → 4 x 15 (25g) composite units² Process hygiene criteria to be applied to the finished product (powder form) or at any other previous point that provides the information necessary for the purpose of verification. The criteria is intended to be used by the manufacturer as a means of ongoing assessment of their hygiene programs. (CAC/RCP 66-2008)³ NA = not applicable

Legend: n – number of sample units selected from a lot of food to be examined

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M – level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage

c – maximum allowable number of defective or marginally acceptable units

ANNEX B. RULES AND REGULATIONS GOVERNING THE LABELING OF PREPACKAGED FOOD PRODUCTS



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

SEP 08 2014

ADMINISTRATIVE ORDER
NO. 2014 – 0030

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 Pre-packaged 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 (tetra-pack) 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, freeze-dried, 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.
- l. 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 cm² the same may be exempted from the requirements of lot identification code only when sold together with the primary packaging.

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.

- 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* 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) _____	

*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

*% 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;
- 3) Prepackaged foods in multi-units retail packages such as candies with surface area less than 10 cm² 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 cm² (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;

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 as 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 cm² (e.g. pack of gum, individually wrapped candies), provided that the secondary packaging contains all the required labeling information.

Exemptions from any specific provision/s of 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.

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.

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

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.

Details of the food additive:

- A. 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.
 - 1) 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.
 - 2) 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.
 - 3) 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.
 - 4) The words “For Food Use” or a statement substantially similar thereto shall appear in a prominent position on the label.
 - 5) The words “For Food Use” or a statement substantially similar thereto shall appear in a prominent position on the label.

. 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;
- 3) 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.

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 Sub-sections C.1.a to C.1.f, may be given on the documents relating to the sale.

ANNEX C. CAUTION/ADVISORY STATEMENTS

In case a product contains one of the following ingredients, the corresponding caution statement shall be declared as additional labelling requirements.

INGREDIENTS/ COMPONENTS	CAUTION STATEMENT
Aspartame	Phenylketonurics : Contains Phenylalanine
Bee Pollen and or Propolis	This product contains bee pollen and or propolis and may cause severe allergic reaction including fatal and anaphylactic reaction to susceptible individuals . Asthma and allergic sufferers may be at greater risk .
Caffeinated Beverages (e.g. energy and sports drinks)	Excessive intake of caffeine may cause sleeplessness, palpitation and other similar side effects. Not recommended for children, pregnant and lactating women, people who may have heart problems and/or those sensitive to caffeine”
<i>FSMP – with polydextrose</i> Lactitol, maltitol, maltitol syrup, xylitol, mannitol (alone or in combination) ³ 10 g/100 g Sorbitol, erythritol, isomalt, polydextrose (alone or in combination) ³ 25 g/100 g	Statement to the effect that “excessive consumption of the food containing these substances may have a laxative effect”
Ginkgo Biloba	Ginkgo Biloba : It is advised that Ginkgo Biloba should not be taken for 6 months or longer and it should not be used with warfarin and other thrombolytic agents.
Glucomannan (konjac mannan) 1 g of glucomannan per quantified portion	Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake — advice on taking plenty of water to ensure the substance reaches the stomach. Take 1-2 glasses of water, before meals and in the context of an energy-restricted diet

Guar Gum a daily intake of 10 g of guar gum.	Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake — advice on taking plenty of water to ensure that the substance reaches the stomach
High dose of Vitamin C - Beyond tolerable upper limit	Adverse effects of high intake of Vitamin C may contribute to common complaints such as diarrhea, nausea, abdominal cramps and disturbances due to the osmotic effect of unabsorbed Vitamin C in the gastrointestinal tract and kidney stone formation in patients with pre-existing hyperoxaluria.
Hydroxypropyl methylcellulose (HPMC)- 4 g of HPMC as part of the meal.	Warning of choking to be given for people with swallowing difficulties or when ingesting with inadequate fluid intake — advice on taking plenty of water to ensure that the substance reaches the stomach
<i>Kava</i>	‘Use in moderation.’ ‘May cause drowsiness.’
Royal Jelly	Warning : This product may not be suitable for asthma and allergy sufferers
Taheebo/Pau d’arco/Lapacho	‘This product is not intended to diagnose, treat, cure and prevent disease’, ‘Maximum daily intake up to 3 cups per day only, ‘Should not be taken with aspirin, ticlopidine, ginko biloba, ginseng, warfarin & heparin’, ‘Should not be taken by pregnant or breast-feeding mother’, ‘Should not be taken at least one week before contemplated operation’, ‘Stop intake of this product in the event of nausea, vomiting, diarrhea, skin pallor, bruises and nose bleeding’.

ANNEX D. EVALUATION OF HIGH-RISK FOOD PRODUCTS

	<u>Foods for Special Medical Purposes</u>
Related Reference Standards	Codex Stan 180-1991
	Codex Stan 192-1995
Critical Documents	Scientific studies indicating safety and benefits of the product for intended medical condition
	Certificate of Analysis to Support Nutrition Facts
Labelling Requirements	<p>-Nutrition Labelling: Energy, Vitamins and Minerals per 100 g or per 100 ml of the food as sold or as applicable, per serving as suggested for consumption</p> <p>-Osmolality or osmolarity and/or acid base balance when appropriate</p> <p>-Nature of the animal or plant proteins or protein hydrolysates</p> <p>-Modification of the content or nature of proteins, fats or carbohydrates, other nutrients with rationale for such modification</p> <p>-USE UNDER MEDICAL SUPERVISION shall be declared in bold in an area separated from other written, printed or graphic information</p> <p>-Additional warning statement in bold letters if the product poses a health hazard when it is consumed by individuals who do not have the disease.</p> <p><i>Additional Reqt's:</i></p> <p>-A statement that the product is not to be used for parenteral administration.</p> <p>-A prominent statement indicating whether the product is or is not intended as the sole source of nutrition.</p> <p>-The statement “For the dietary management of ____” with specific disease, disorder or medical condition for w/c the product is intended and for w/c it has been shown to be effective.</p> <p>-Adequate precautions, known side effects, contraindication and product-drug interaction, as applicable.</p> <p>-Rationale for the use of the product and a description of the properties or characteristics that make it useful.</p> <p>-Specific age group if the product is formulated for this age group</p> <p>-Feeding instruction, including method of administration and serving size.</p>

	Infant Formula	Milk Supplement/ Follow Up Formula
Related Reference Standards	Codex Stan 72-1981 Rev. 2007 CAC/GL 10-1979	Codex Stan 156-1987
	CAC/GL 10-1979	CAC/GL 10-1979
	Codex Stan 192-1995	Codex Stan 192-1995
	D.C. 2008-0006	D.C. 2008-0006
Critical Documents	<p>Certificate of Analysis (<i>Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates per 100g, Vitamins and Minerals, Trace Minerals and Other Substances, Lauric/Mystiric/Trans Fatty Acids per 100 kcal, Optional Ingredients – Taurine, DHA, Contaminants, Microbiological Tests, Test Results to Support Nutrition Facts</i>)</p> <p>Vitamins and Minerals should be included in the Codex Advisory List of Nutrient Compounds for Use In Foods for Infants and Young Children (CAC/GL 10-1979)</p> <p>Food additives must conform with Codex Stan 72-1981 Rev. 2007</p>	<p>Certificate of Analysis (<i>Energy, Protein, Total Fat, Linolenic Acid, Total Carbohydrates, Vitamins and Minerals, Trace Minerals and Other Substances, Optional Ingredients – suitable for 6 mos onwards and scientifically proven, Additives, Microbiological Tests, Test Results to Support Nutrition Facts</i>)</p> <p>Vitamins and Minerals should be included in the Codex Advisory List of Nutrient Compounds for Use In Foods for Infants and Young Children (CAC/GL 10-1979)</p> <p>Food additives must conform with Codex Stan 156-1987</p> <p><i>Must not be treated by ionizing radiation</i></p>
Labelling Requirements	<i>See Annex 1 for complete summary of D.C. 2008-0006</i>	<i>See Annex 1 for complete summary of D.C. 2008-0006</i>

	Foods for Special Dietary Uses
Related Reference Standards	Codex Stan 146-1985
	Codex Stan 192-1995
Critical Documents	<ul style="list-style-type: none"> • Scientific studies indicating safety and suitability of the product to specific disease and disorder to which it is intended • Certificate of Analysis to Support Nutrition Facts
Labelling Requirements	<ul style="list-style-type: none"> • Product Name: The designation “Special dietary” or “Special dietetic” or an appropriate equivalent term shall be declared; characterizing essential feature but not the condition shall be stated in appropriate description near the product name. • List of ingredients • Nutrition labeling: Energy, Protein, CHO, Fats, Vitamins and Minerals per 100 g or per 100 ml of the food as sold, or as applicable, per serving as suggested for consumption • Net content • Storage instruction for opened food • Claims should conform with Guidelines on Health and Nutrition Claims • Claims on prevention, alleviation, treatment, or cure of a disease, disorder or particular physiological condition are not allowed. • Advise statement indicating that advice from a qualified medical person is needed. (e.g. USE ONLY UNDER MEDICAL SUPERVISION)

	Cereal-Based Foods for Infants & Young Children
Related Reference Standards	Codex Stan 074-1981, Rev. 1-2006
	CAC/GL 10-1979
	Codex Stan 192-1995
Critical Documents	Certificate of Analysis <i>(Energy, Protein, Carbohydrates, Lipids, Minerals – Critical: Sodium and Calcium, Vitamins – A B1, D, per 100 kcal Microbiological Tests)</i>
Labelling Requirements	<ul style="list-style-type: none"> • Product Name: Dry Cereal for Infants (and/or Young Children), Rusks or Biscuits for Infants (and/or Young Children) • List of ingredients • Nutrition labeling-energy, vitamins and minerals shall be expressed per 100 g or per 100 ml of the food as sold and where appropriate per specified quantity (per serving) as suggested for consumption) • Date marking and Storage Instructions; Date marking (best before) shall be declared by date, month and year in uncoded numerical sequence except for products with shelf life of more than 3 months, the month and year will suffice. • Information for Utilization-Direction for use, storage keeping before and after opening • Other information-age group; statement indicating when precisely to begin complementary feeding should be made in consultation with a health worker. • Additional statement (bold, in the lowermost level of the information display panel): Infants six months onwards should be given fresh, indigenous and natural food in combination with continued breast feeding.

	Canned Baby Foods
Related Reference Standards	Codex Stan 73-1981 amended 1989
	Codex Stan 192-1995
Critical Documents	<ul style="list-style-type: none"> • Certificate of Analysis (to support <i>Nutrition Facts</i>, <i>Sodium Content</i> and , <i>Microbiological Tests</i>) • Food additives must conform with Codex Stan 73-1981 amended 1989 • <i>Must not be treated by ionizing radiation</i>
Labelling Requirements	<ul style="list-style-type: none"> • Product Name: Indicate the major or characterizing ingredient with words suitable to indicate consistency or intended use. • List of ingredients • Nutrition labeling: Energy, Protein, CHO, Fats, Vitamins and Minerals per 100 g, and per serving size as suggested for consumption • Date marking and storage instructions: Date marking (best before) shall be declared by date, month and year in uncoded numerical sequence except for products with shelf life of more than 3 months, the month and year will suffice. • Information for Utilization: Direction for use, storage keeping before and after opening • Net Content

	Formula Foods for Weight Control Diets
Related Reference Standards	Codex Stan 181-1991
	Codex Stan 192-1995
Critical Documents	Certificate of Analysis to Support Nutrition Facts
Labelling Requirements	<ul style="list-style-type: none"> • Product name: Meal Replacement for Weight Control • List of ingredients • Nutrition labeling: Energy, Protein, CHO, Fats, Vitamins and Minerals per 100 g or per 100 ml of the food as sold or as applicable, per serving as suggested for consumption • Date Marking • Storage Instructions for opened and unopened food <p>If direction for use indicate that the food should be combined with other ingredients, the nutritive value of the final combination should be declared.</p> <p>Additional Provisions:</p> <ul style="list-style-type: none"> • The label shall not make reference to the rate or amount of weight loss which result from the use of the food or to reduction in hunger or an increase in the sense of satiety. • Statement on the importance of maintaining an adequate fluid intake when the product is used. • If there is sugar alcohol in excess of 20 g, a statement on the label that the food may have a laxative effect. • Statement that the food maybe useful in weight control only as a part of an energy-controlled diet. • The label shall bear a prominent statement recommending that if the food is used for more than 6 weeks, medical advice should be sought.

Complementary Foods for Older Infants and Young Children	
Related Reference Standard/s	CAC/GL 8-1991
	Codex Stan 192-1995
	CAC/GL 10-1979
Critical Documents	Certificate of Analysis to support Nutrition Facts
Labelling Requirements	Product Name: Indicate that the food is a Formulated Complementary Food for Older Infants and Young Children. The major source of protein and the age from which the product is recommended for use shall appear in close proximity to the name of the food.
	List of Ingredients
	Nutrition labelling: Energy, Protein, CHO, Fats, Vitamins and Minerals per 100g, and per feeding suggested for consumption.
	<ul style="list-style-type: none"> • Directions for use preferably accompanied by graphical representations. • Storage keeping and date markings • Suggested number of feedings per day. • In case that addition of water is needed, the directions for the preparations shall include a precise statement that: (a) where the food contains non-heat-processed basic ingredients, the food must be adequately boiled in a prescribed amount of water (b) where the food contains heat-processed basic ingredients: (i) the food requires boiling or (ii) can be mixed with boiled water that has been cooled. • Other information- age group; statement indicating when precisely to begin complementary feeding should be made in consultation with a health worker • Additional Statement (bold, in the lowermost level of the information display panel):
	Infants six months onwards should be given fresh, indigenous and natural food in combination with continued breast feeding.

	Formula Foods for Weight Control Diets
Related Reference Standards	Codex Stan 181-1991
	Codex Stan 192-1995
Critical Documents	Certificate of Analysis to Support Nutrition Facts
Labelling Requirements	<ul style="list-style-type: none"> • Product name: Meal Replacement for Weight Control • List of ingredients • Nutrition labeling: Energy, Protein, CHO, Fats, Vitamins and Minerals per 100 g or per 100 ml of the food as sold or as applicable, per serving as suggested for consumption • Date Marking • Storage Instructions for opened and unopened food <p>If direction for use indicate that the food should be combined with other ingredients, the nutritive value of the final combination should be declared.</p> <p>Additional Provisions:</p> <ul style="list-style-type: none"> • The label shall not make reference to the rate or amount of weight loss which result from the use of the food or to reduction in hunger or an increase in the sense of satiety. • Statement on the importance of maintaining an adequate fluid intake when the product is used. • If there is sugar alcohol in excess of 20 g, a statement on the label that the food may have a laxative effect. • Statement that the food maybe useful in weight control only as a part of an energy-controlled diet. • The label shall bear a prominent statement recommedning that if the food is used for more than 6 weeks, medical advice should be sought.

**ANNEX E. SUMMARY OF LABELLING GUIDELINES FOR BREASTMILK
SUBSTITUTES, INFANT FORMULA, FOLLOW UP FORMULA/MILK
SUPPLEMENT OTHER MILK PRODUCTS, FOODS AND BEVERAGES, AND OTHER
RELATED PRODUCTS WITHIN THE SCOPE OF E.O. 51 (“MILK CODE”) AS PER
D.C. 2008-0006**

PRINCIPAL DISPLAY PANEL	<p>-Product name shall be “Infant Formula”, “Formula for Special Medical Purposes Intended for Infants” or “Milk Supplement” or Follow-up Formulas in accordance with relevant Codex Standards</p> <p>-Source of Protein</p> <p>-“Infant Formula Based on Cow’s Milk” (<i>if cow’s milk is the only protein source</i>)</p> <p>-“Contains No Milk or Milk Products” or equivalent phrase (<i>if the product does not contain milk or any milk derivative</i>)</p> <p>-It shall be contrary to public policy to use as brand name and/or trade mark or any word or set of words that may be considered as nutritional, healthful, and superlative and other terms of similar import.</p> <p>-Net Content and Drained Weight (SI Unit)</p> <p>-Primary Messages</p> <p style="padding-left: 20px;">a. At the <u>center uppermost level</u>; In bold, all capital letters, font type: Arial, font size: 1/3 of the size of the biggest letter on the label:</p> <p style="padding-left: 20px;"><i>English:</i> “BREASTMILK IS THE BEST FOR BABIES UP TO 2 YEARS OF AGE AND BEYOND”</p> <p style="padding-left: 20px;"><i>Filipino:</i> “ANG GATAS NG INA ANG PINAKAMABUTI PARA SA BATA HANGGANG 2 TAON O HIGIT PA”</p> <p style="padding-left: 20px;">b. At the <u>center lowermost level</u>; In bold, all capital letters, font type: Arial, font size: 1/3 of the size of the biggest letter on the label:</p> <p style="padding-left: 20px;"><i>English:</i> “IMPORTANT NOTICE: THERE IS NO SUBSTITUTE FOR BREASTMILK”</p> <p style="padding-left: 20px;"><i>Filipino:</i> “MAHALAGANG PAALALA: WALANG ANUMANG GATAS ANG PWEDENG IPALIT SA GATAS NG INA”</p>
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INFORMATION PANEL	<ul style="list-style-type: none"> -List of ingredients in descending order of proportion -Declaration of Nutritive Value <ul style="list-style-type: none"> Per 100 grams and per specified quantity of the food as suggested per consumption: <i>Energy in calories (kcal) and/or kilojoules (kJ); Protein, Carbohydrates, and Fat in grams</i> Per 100 grams and per specified quantity of the food as suggested per consumption or per 100 calories (100 kilojoules): <i>Vitamins and Minerals, Choline for infant formula, and any optional ingredients listed in the codex standards of infant formula and milk supplement (follow-up formula)</i>
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INFORMATION PANEL	<ul style="list-style-type: none"> -If shelf – life is < 3 months, declare the expiration date in the sequence day, month, and year. If shelf – life is \geq 3 months, the month and year will do. The month must be declared in word. -Storage instructions shall be declared near the date marking -Directions for appropriate preparation and use of the product including its storage and disposal after preparation -Clear graphic illustration of the method of preparation -Warning about health hazards of inappropriate preparation, storage and use -Other statements: <ul style="list-style-type: none"> <i>On the lowermost level, bold and prominent:</i> “Infants six months onwards should be given fresh, indigenous, and natural foods in combination with continued breastfeeding” <i>At the uppermost level, bold and prominent, font type: Arial, font size: 1/6 of the biggest letter on the label:</i> <i>English:</i> “THIS PRODUCT MAY CONTAIN PATHOGENIC MICROORGANISMS AND MUST BE PREPARED AND USED APPROPRIATELY” <i>Filipino:</i> “ANG PRODUKTONG ITO AY MAAARING MAGKAROON NG MIKROBYO NA NAGDUDULOT NG SAKIT AT DAPAT IHANDA AT GAMITIN NG TAMA” OR <i>English:</i> “THERE IS LIKELIHOOD THAT PATHOGENIC MICROORGANISMS WILL BE IN THIS PRODUCT WHEN IT IS PREPARED AND USED INAPPROPRIATELY” <i>Filipino:</i> “ANG PRODUKTONG ITO AY MAAARING MAGKAROON NG MIKROBYO NA NAGDUDULOT NG SAKIT KAPAG HINDI TAMA ANG PAGHAHANDA AT PAGGAMIT” -Complete name and address of the manufacturer/packer/repacker/distributor/importer/exporter -Country of origin -Lot identification number -Food Registration (F.R.) Number
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INFORMATION PANEL	<p>Secondary Messages</p> <p>At the <u>uppermost level</u>; In bold, all capital letters, font type: Arial, font size: 1/6 of the size of the biggest letter on the label:</p> <p><i>English:</i> “The Use of Infant Formula/Milk Supplements must only be upon the advice of a health professional”</p> <p><i>Filipino:</i> “Ang paggamit ng gatas na ito ay dapat sang-ayon sa payo ng Doctor o health professional”</p> <p><i>English:</i> “The unnecessary and improper use of this product may be dangerous to your child’s health”</p> <p><i>Filipino:</i> “Ang maling paggamit ng gats na ito ay maaaring makasama sa kalusugan ng bata”</p>
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Additional Labelling Information for Milk Supplements/Follow Up Formula:

REFERENCES

PNS Number	Title
PNS/BFAD 01:2005	Ethnic Food Products: Dry Base Mixes for Soups and Sauces
PNS/BFAD 02:2005	Ethnic Food Products: Sweet Preserves
PNS/BFAD 03:2006	Recommended Code of Practice for the Processing and Handling of Sweet Preserves
PNS/BFAD 04:2006	Ethnic Food Products: Dried, Salted Fish
PNS/BFAD 05:2006	Recommended Code of Practice for the Processing and Handling of Dried Fish
PNS/BFAD 06:2006	Thermally Processed Fish Products
PNS/BFAD 08:2007	Standard for Fermented Milks
PNS/BFAD 09:2007	Mango Beverage Standard
PNS/BFAD 10:2007	Recommended code of practice for the processing and handling of mango beverage products
PNS/BFAD 11:2007	Citrus Beverage Standard
PNS/BFAD 12:2007	Recommended code of practice for the Processing and Handling of Citrus Beverage Products
PNS/BFAD 13:2007	Banana chips – Specification
PNS/BFAD 14:2007	Recommended Code of Practice for the Processing and Handling of Banana Chips
PNS/BFAD 15:2007	Dried Mango Products – Specification
PNS/BFAD 16:2007	Dried Tropical Fruits – Specification
PNS/BFAD 17:2007	Recommended Code of Practice for the Processing and Handling of Dried Tropical Products
PNS/BFAD 18:2008	Flour Sticks (Pancit Canton) – Specification
PNS/BFAD 19:2008	Recommended Code of Practice for the Processing and Handling of Flour Sticks (Pancit Canton)
PNS/BFAD 20:2009	Sugar Cane Wine (Basi) – Specifications

PNS/BFAD 21:2009	Recommended Code of Practice for the Processing and Handling of Sugar Cane Wine
PNS/BFAD 22:2010	Fried Corn Snacks (Chichacorn)
PNS/BFAD 23:2010	Recommended Code of Practice for the Processing and Handling of Fried Corn Snacks

PNS Number	Title
PNS/FDA 24:2010	Purple Yam (Ube) Jam (Halaya)
PNS/FDA 25:2010	Recommended code of practice for the processing and handling of purple yam jam
PNS/FDA 26:2010	Smoked Fish – Specifications
PNS/FDA 27:2010	Recommended Code of Practice for the Processing and Handling of Smoked Fish
PNS/FDA 28:2010	Processed Pili Nut Products – Specifications
PNS/FDA 29:2010	Recommended Code of Practice for the Processing and Handling of Processed Pili Nut Products
PNS/FDA 30:2010	Tropical Fruit Wines – Specifications
PNS/FDA 31:2010	Recommended Code of Practice for the Processing and Handling of Tropical Fruit Wines
PNS/FDA 32:2010	Ethnic Flour-based Confectioneries (Pulvoron, Piaya, Barquillos) – Specifications
PNS/FDA 33:2010	Recommended Code of Practice for the Processing and Handling of Ethnic Flour-based Confectioneries (Pulvoron, Piaya, Barquillos)
PNS/FDA 34:2011	Ethnic Milk-based Confectioneries (Yema, Pastillas) – Specifications
PNS/FDA 35:2011	Recommended Code of Practice for the Processing and Handling of Ethnic Milk-based Confectioneries (Yema, Pastillas)
PNS/FDA 36:2014	Salt Fermented Fish and Shrimps (Bagoong) – Specifications
PNS/FDA 37:2014	Recommended Code of Practice for the Processing and Handling of Salt Fermented Fish and Shrimps (Bagoong)
PNS/FDA 38:2015	Fish Sauce (Patis) and Fish Flavoured Sauce – Specifications

PNS/FDA 39:2015	Recommended Code of Practice for the Processing and Handling of Fish Sauce (Patis) and Fish Flavoured Sauce
PNS/FDA 40:2015	Banana Ketchup – Specifications
PNS/FDA 41:2015	Recommended Code of Practice for the Processing and Handling of Banana Ketchup

REFERENCES

2015 Philippine Dietary Reference Intake

A.O. No. 18-A S. 1993	Standards of Quality and Requirements for the Processing, Packaging and Labeling of Bottled Drinking Water
A.O. No. 50 2001	Revised 2001 Schedule of Fees and Charges for the Corresponding Services Rendered by the Bureau of Food and Drugs
A.O. No. 88-A s 1984	Regulatory Guidelines Concerning Food Additives
A.O. No. 123-A s. 1985	Standards of Banana Sauce
A.O. No. 132 s. 1970	Regulation Prescribing the Standards of Identity and Quality of Milk and Milk Products (B-4.12-01) Department of Health
A.O. No. 134 s. 1970	Regulation Prescribing the Standard of Identity and Quality of Vinegar (B-4.9 Condiments, Sauces, Seasonings) Department of Health
A.O. No. 136-A & 136-B s.1985	Standard For Instant Coffee; Standard for Soluble Coffee with Added Carbohydrates Republic of the Philippines Ministry of Health BUREAU OF FOOD AND DRUGS
A.O. No. 154 s. 1971	Regulation B-4 Definition and Standards of Identity for Foods; A.14 Meat and Meat Products. A.14.01 Sausages Department of Health
A.O. No. 200-A s. 1973	Regulation B-4 Definitions & Standards of Identity for Foods, B-4.5 Cheese and Cheese Products
A.O. No. 231 s. 1974	Regulation B-4 Definitions and Standards for Food B-4.15 Fats and Oils B-4.15-02 Lard
A.O. No. 232 s. 1974	Regulation B-4 Definitions and Standards for Food, B-4.18 Margarine
A.O. No. 233 s. 1974	Regulation B-1 Definitions and Standards for Food B-1.6 Condiments, Sauces, Seasoning B-1.9-01 Tomato Catsup (Catsup)
A.O. No. 235 s. 1975	Regulation B-4 Definition and Standards of Identity of Foods: 4.6 Dressings for Food 4.6.01 Mayonnaise (Mayonnaise Dressing and Mayonnaise Salad Dressing)
A.O. No. 239 s. 1975	Regulation B-4 Definition and Standards of Food, B-4.13 Jams (Fruit Preserves), B-4.13-02 Jellies (naming the fruit)
A.O. No. 325 s. 1977	Regulation B-4 Definition and Standard for Foods, 4.9 Condiments, Sauces and Seasonings, 4.9-04 Standard of Identity and Quality for Patis
A.O. No. 357 s. 1978	Standards for Wines

A.O. No. 2014-0029	Rules and Regulations on the Licensing of Food Establishments and Registration of Processed Food, and Other Food Products, and for Other Purposes
A.O. No. 2014-0030	Revised Rules and Regulations Governing the Labeling of Pre-packaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984 or the “Rules and Regulations Governing the Labeling of Pre-packaged Food Products Distributed in the Philippines,” and For Other Purposes

ANNEX III ASEAN GL on Limits of Contaminations TMHS V1.0(13Nov14) (1)

ASEAN GL Minimising Risk of Transmission TSE TMHS V1.0 (1Oct14)

ASEAN GP for the Use of Additives & Excipients in TMHS V2.0(1Oct14)

ASEAN Guidelines on Stability Study and Shelf-Life of Traditional Medicines and Health Supplements.

B.C. No. 02 s. 1999	Additional Labelling Requirement for Food Supplements
B.C. No. 16 s. 2004	Guidelines on Probiotics
B.C. No. 17 s. 2004	Taheebo/Pau d’arco/Lapacho
B.C. No. 2006-016	Updated List of Food Additives
B.C. No. 2007-002	Guidelines in the Use of Nutrition and Health Claims in Food
CAC/GL 10-1979	Advisory Lists of Nutrient Compounds for Use in Foods for Special Dietary Uses intended for Infants and Young Children
CAC/GL 8-1991	Guidelines on Formulated Complementary Foods for Older Infants and Young Children
CAC/GL 23-1997	Guidelines for Use of Nutrition and Health Claims
CODEX STAN 73-1981	CODEX STANDARD FOR CANNED BABY FOODS
CODEX STAN 72-1981, REV. 2007	CODEX STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS
Codex Stan 074-1981, Rev. 1-2006	Codex Standard for Processed Cereal-Based Foods for Infants and Young Children
Codex Stan 146-1995	General Standard for the Labelling of and Claims for Prepackaged Foods for Special Dietary Uses

Codex Stan 156-1987	Codex Standard for Follow-Up Formula
Codex Stan 180-1991	Codex Standard for Labelling of and Claims for Foods Special Medical Purposes
Codex Stan 181-1991	Standard for Formula Foods for Use in Weight Control Diets
Codex Stan 203-1995	Codex Standard for Formula Foods for Use in Very Low Energy Diets for Weight Reduction
Codex Stan 243-2003	Codex Standards for Fermented Milks
D.C. 2008-0006	Amendments to Department Circular No. 2007-0276 dated 07 December 2007, Re: Guidelines for the Labeling of Breastmilk substitutes, infant formula, other related products, foods and beverages, and other related products within the scope of E.O. 51, otherwise known as the “Milk Code”, and to Department Circular No. 2007-272 dated December 2007, Re: Containers and Labels of Milk Products within the Scope of EO 51 otherwise Known as “Milk Code”.
E.O 51	Adopting a National Code of Marketing of Breastmilk Substitutes, Breastmilk Supplements, and Related Products. It will Take Effect 30 Days after Publication in the Official Gazette
FDA Circular No. 2020-033	Procedure for the use of Electronic Registration (E-Registration) System for Prepackaged Processed Food Products
FDA Memorandum No. 2011-028	Safety of Soy Sauce in the Philippines: CODEX Limit on 3 MCPD
A Guide to Food Labelling and Advertisements—A publication of the Agri-Food and Veterinary Authority, Singapore	
MC No. 13 s. 1989	Standards for Alcohols
Office Order No.22 s.1991	Guidelines for the Classification of Vitamins and Minerals as Drug or as Food