Annex A

Definition of Terms

All terms in Republic Act No. 10611 and its IRR and other relevant laws, shall retain their respective meanings in these Rules and Regulations. In addition the terms:

A. Activity refers to either processing, packaging, repackaging, trading, import, wholesale, export, sale, promotion, or offer for sale, of a food product.

B. Advertising refers to the business of conceptualizing, presenting or making available to the public, through any form of mass media, fact, data or information about the attributes, features, quality or availability of food and its related products for the purpose of promoting its sale or distribution and enhancing economic activity.

C. Authorization refers to the permission embodied in a document granted by a regulatory agency to a natural or juridical person who has submitted an application for a food business operation from primary production, post-harvest handling, distribution, processing, manufacture, importation, exportation, sale, and offer for sale, transfer and preparation for human consumption. The authorization can take the form of a permit, license, certificate of registration and certificate of compliance or exemption or any similar document.

D. Bottled Water means water that is placed in a sealed food grade container or package and is offered for sale for human consumption as drinking water as distinguished from those refilled bottles in refilling stations.

E. Certificate of Product Registration (CPR) is an authorization issued by the FDA for specific health products after evaluation and approval of submitted registration requirements.

F. Commissary refers to a food establishment where bulk preparation, packaging and storage of food products, meant to be distributed in the FBO's outlets is being conducted.

G. Consolidator refers to a natural or juridical person who for compensation acts as a middleman to facilitate shipments or cargo consignments of goods for export.

H. Contaminant refers to any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop industry, animal husbandry and veterinary medicine) post-harvest handling, manufacturing, processing, preparation, treatment, packing, packaging, transport or holding of such food as a result of environmental contamination.

I. Control measure refers to any action and activity that can be used to prevent or eliminate food safety hazard or to reduce it to an acceptable level.

J. Distribute means the delivery or sale of any health product for purposes of distribution in commerce, except that such term does not include the manufacture or retail of such product.

K. Distribution means any activity where a food product is stored by an establishment and/or transported to another establishment, with the intention of possible further retail.

L. Distributor/Importer/Exporter refers to any establishment that imports or exports raw material, ingredients and/or finished products for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer. Further, in addition to the existing activities of the distributor, similar or parallel activities in other locations, i.e. importers with branches in the regions and issues invoice, shall be covered by the original authorization and therefore subject to the same responsibilities and corresponding sanctions if violations are committed from the other declared locations.

M. Distributor/Wholesaler refers to any establishment that procures raw materials, active ingredients and/or finished products from a local establishment for local distribution on a wholesale basis.

N. Establishment means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products, including the facilities and installation needed for its activities.

O. Export refers to distribution outside of origin by crossing international borders.

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

Q. Food additive refers to 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.

R. Food-borne illnesses refer to diseases, usually either infectious or toxic in nature, caused by agents that enter the body through the ingestion of food.

S. Food business refers to any undertaking, whether public or private, which carries out any of the activities related to, or any of the stages of the food supply chain.

T. Food Business Operator refers to a person engaged in the food business including one's agents and is responsible for ensuring that the requirements of the Food Safety Act of 2013 are met by the food business under one's control. It can be classified as manufacturer, repacker, distributor, importer, exporter or trader.

U. Food / Dietary Supplement refers to a processed food product intended to supplement the diet that bears or contains one or more of the following dietary ingredients: vitamins, 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, liquids, gels, powders or pills and is not represented for use as a conventional food or as the sole item of a meal or diet or a replacement for drugs and medicines.

V. **Fortification** means the addition of nutrients to processed foods or food products at levels above the natural state.

W. **Good Manufacturing Practice (GMP)** refers to a quality assurance system aimed at ensuring that products are consistently manufactured, packed or held to quality standards appropriate for the intended use. It is thus concerned with both manufacturing and quality control procedures.

X. **Good Distribution Practice (GDP) or Good Storage Practice (GSP)** refers to a part of the quality assurance system where appropriate procedures for sanitary handling of food on storage and distribution are established. Storage and transportation of finished food should be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container. Warehouses are kept free from rodents, insects, birds and other pests.

Y. **Hazard Analysis and Critical Control Points (HACCP)** refers to a science-based system which identifies, evaluates and controls hazards which are significant for food safety at critical points during a given stage in the food supply chain.

Z. **Import** refers to the distribution into a local destination by crossing international borders. In case of imported food products, the manufacturer's representative or, in his absence, the importer shall be deemed the manufacturer taking full accountability to ensure quality and safety of imported food products locally distributed.

AA. **Indentor** refers to a natural or juridical person who for compensation acts as a middleman to facilitate shipment, purchase and sale of goods between a foreign supplier and a local purchaser. An Indentor is in the same class as commercial broker or commission merchant.

BB. **Ingredients** is any substance including food additive, used as a component in the manufacture or preparation of a food and present in the final product in its original or modified form.

CC. **Inspection** refers to the examination of food, food production facilities or establishments, and the management and production systems of food businesses, including the examination of documents, finished product testing and registration, and of the origin and destination of production inputs and outputs to verify compliance with legal requirements by an agency mandated to perform food safety regulatory and /or enforcement functions.

DD. **Label** refers to the display of written, printed or graphic matter upon the immediate container, tag, literature or other suitable material affixed thereto for the purpose of giving information as to identify components, ingredients, attributes, directions for use, specifications and such other information as may be required by law or regulations.

EE. Licensing means the process of approval by the DOH of an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, and transfer.

FF. Local Government Unit (LGU) shall mean the city or municipality, provincial or regional government unit which issues the Sanitary Permit in compliance with the National Sanitation Code of the Philippines and the Mayor's Permit.

GG. Manufacturer means an establishment engaged in any and all operations involved in the production of health products including preparation, processing, compounding, formulating, filling, packaging, repacking, altering, ornamenting, finishing and labeling with the end in view of its storage, sale or distribution. Likewise, it may also manufacture as a commissary for products intended for institutional use and for distribution in its various outlets. It shall be allowed to import raw materials or finished products as ingredients or additives for their own use to manufacture registered products. A trader, on the other hand, shall be categorized as a manufacturer in which its products are manufactured by a licensed manufacturing facility, otherwise termed as toll-manufacturer. In such a case, the trader owns the formulation of the product. A trader may also import its own raw materials which shall be processed by its toll manufacturer.

HH. Monitoring refers to the systematic gathering of data through the sampling of commodities as well as monitoring of food-borne diseases, collation and interpretation of collected data.

II. Packaging refers to an activity where a product is contained and sealed with the intention of storage and/or transport. Packaging may refer to either the primary packaging that is directly attached to the food product (sachet/blister then box) or the secondary packaging containing the wrapped food (aluminum foil then box). Another layer, tertiary packaging (box of 12 to box of 6), i.e. bulk boxing, or shrink wrap (not part of repacking) shall be considered as bundle packing or bundling.

JJ. Packer/repacker means any establishment that repacks a finished product into smaller quantities in a separate container and/or secondary packaging, including but not limited to relabeling, stickering and bundling for promo packs with the end view of storage, distribution, or sale of the product. Repacker is any establishment engaged in the process of packaging or changing of container, wrapper (that may include changing of label) from a bulk material to retail packaging sizes in furtherance of distribution of food. Note that packaging may refer to either the primary packaging that is directly attached to the food product (sachet/blister then box) or the secondary packaging containing the wrapped food (aluminum foil then box). Another layer, tertiary packaging (box of 12 to box of 6), i.e. bulk boxing, or shrink wrap (not part of repacking) shall be considered as bundle packing or bundling. Therefore, if the establishment is importing food products that will be packed/boxed locally, the establishment shall secure an LTO as Repacker/Importer of Raw Materials for Own Use. Food Distributors bundling (no re-labelling, no repacking, with at least 6-month expiration period) of products for promo or donation may be allowed. Stickering for additional information on labels is likewise an allowed activity for the licensed food distributor.

KK. Permit refers to a form of authorization that is issued by the FDA to an establishment that has complied with the application requirements.

LL. Processing refers to any action that substantially alters the initial raw materials or product or ingredients including, but not limited to, heating, smoking, curing, maturing, drying, marinating, extraction, extrusion, freezing, fermentation or a combination of those processes intended to produce/manufacture food.

MM. Product bundling means a kind of sales promotion campaign whereby two or more products are bonded, pasted, tied, put or sold together as a combination at the usual price of the product being promoted or at a price lower than the sum of the bonded products thereby increasing the benefit for their purchase. (IRR 7394)

NN. Raw materials are all substances that are employed in the processing of a finished product, packed in bulk containers and not labelled as a finished product. Raw Materials or ingredients would have product specifications that comply with the client requirements and not necessarily a single component.

OO. Repackaging refers to a manufacturing activity where a food product is taken out of a larger or bulk packaging and again contained with the intention of further storage, transport and distribution.

PP. Retailer means any establishment which sells or offers to sell any health product directly to the consuming general public including online sellers.

QQ. Risk refers to a function of the probability of an adverse health effect and the severity of the effect, consequential to a hazard(s) in food.

RR. Salt Iodization refers to the addition of iodine to salt intended for human consumption in accordance with the specifications as to form, fortificant type, method, manner and composition as may be prescribed by the FDA.

SS. Source refers to any establishment able to supply food products to another establishment through further importation, wholesale or export.

TT. Trader means any establishment which is a registered owner of food and food products and/or procure the raw materials and packing components, quality control standards and procedures, but subcontracts the manufacture of such products to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products. A trader may only subcontract to a licensed manufacturer that is likewise authorized to toll-manufacture the particular product based on an approved LTO variation. and that such an agreement should be binding in writing.

UU. Toll Manufacturer refers to the manufacturer that conducts contract manufacturing where conditions of the contract are defined, agreed and controlled; and all aspects of contracted work are specified to obtain quality product/s conforming to the agreed standards.

VV. Water refilling station business - refers to the selling for profit retail of water placed in refillable water containers or in customer's containers in refilling stations.

WW. Wholesale refers to local distribution of pre-packaged food products in commercial quantities.

ANNEX B

PROCESSED FOOD PRODUCTS CLASSIFICATION ACCORDING TO MICROBIOLOGICAL RISK

The following list, but not limited to, shows food products identified by FDA based from the Food Category Descriptors of Codex Alimentarius General Standard for Food Additives (GSFA) and the UN Food and Agriculture Organization (FAO) Risk Categories:

A. LOW RISK FOODS

Low Risk (LR) Foods – 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.

Table 1. List of Low Risk Food Products

LOW RISK FOOD PRODUCTS
A. FATS, OILS AND FAT EMULSIONS 1. Butter oil, anhydrous milkfat, ghee 2. Vegetable oils and fats 3. Animal fats (lard, tallow, fish oil and other animal fats) 4. Fat emulsions mainly of type oil-in-water, including mixed and/or flavored products based on fat emulsion 5. Fat emulsions mainly of type water-in-oil (butter, fat spreads, margarine dairy fat spreads and blended spreads) 6. Fat-based desserts excluding dairy-based desserts
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 1. Dehydrated fruits or vegetables, including candied fruits (mechanically dried) 2. Jams, jellies, marmalades (pastry, topping, filling, coconut spreads) 3. Dehydrated Vegetable protein products 4. Fruits or vegetables in vinegar, oil or brine 5. Fruit-based spreads (e.g. chutney) excluding jams, jellies and marmalades 6. Fruit preparations, including pulp, purees, fruit toppings and coconut milk 7. Cooked fruits 8. Frozen vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds 9. Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed in pulps and preparations (e.g. vegetable desserts and sauces, candied vegetables) other than food in HR Letter B.2 (Vegetable purees, spreads – peanut butter) 10. Cooked or fried vegetables(including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), and seaweeds
C. CONFECTIONERY 1. Confectionery including hard and soft candy, nougats, marzipans, etc. other than in MR Letter D (cocoa products and chocolate products)

2. Chewing gum
3. Decorations (e.g. for fine bakery wares, sugar flowers), toppings (non-fruit), and sweet sauces

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

1. Flours, starches (including soybean powder) and flour mixes
2. Breakfast cereals including rolled oats
3. Pasta and noodles and like products (e.g. rice paper, rice vermicelli, soybean pastas and noodles)
    a. Fresh pastas and noodles and like products
    b. Dried pastas and noodles and like products
    c. Pre-cooked pastas and noodles and like products
4. Cereal and starch based desserts (e.g. rice pudding, tapioca pudding, native delicacies)
5. Batters (e.g. for breading or batters for fish or poultry)
6. Pre-cooked or processed rice products, including rice cakes (Oriental type only)
7. Soybean products (excluding soybean-based seasonings and condiments under LR Letter H (seasonings, condiments and sauces)
    a. Soybean-based beverages
    b. Soybean-based film
    c. Soybean curd (tofu)
    d. Semi-dehydrated soybean curd
        i. Thick gravy-stewed semi-dehydrated soybean curd
        ii. Deep fried semi-dehydrated soybean curd
        iii. Semi-dehydrated soybean curd, other than in LR Letter D.7. d. i) and 7.d.ii
    e. Dehydrated soybean curd (kori tofu)
    f. Other soybean protein products

E. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME

Edible casings (e.g. sausage casings)

F. BAKERY WARES AND BAKERY RELATED PRODUCTS

1. Bread and ordinary bakery wares and mixes
    a. Breads and rolls – yeast-leavened breads and specialty breads, soda breads
    b. Crackers, excluding sweet crackers
    c. Other ordinary bakery products (e.g. bagels, pita, English muffins)
    d. Bread-type products, including bread stuffing and bread crumbs
    e. Steamed bread and buns
    f. Mixes for bread and ordinary bakery wares
2. Fine bakery wares (sweet, salty or savory) and mixes – Mixes for fine bakery wares (e.g. cakes, pancakes)

G. SWEETENERS, INCLUDING HONEY

1. Refined and raw sugars
    a. White sugar, dextrose anhydrous, dextrose monohydrate, fructose
    b. Powdered sugar, powdered dextrose

c. Soft white sugar, soft brown sugar, glucose syrup, dried glucose syrup, raw cane sugar
    i. Dried glucose syrup used to manufacture sugar confectionery
    ii. Glucose syrup used to manufacture sugar confectionery
d. Lactose
e. Plantation or mill white sugar

2. Brown sugar excluding products under LR Letter G.1.c (soft white sugar, etc.)
3. Sugar solutions and syrups, also (partially) inverted, including treacle and molasses, excluding products under G.1.c(soft white sugar, etc.)
4. Other sugars and syrups (e.g. xylose, maple syrup, sugar toppings), including coconut sugar
5. Honey
6. Table-top sweeteners, including those containing high-intensity sweeteners

H. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS

1. Salt and salt substitutes
2. Herbs, spices, seasonings and condiments (e.g. seasoning for instant noodles)
3. Vinegars
4. Mustards
5. Soups and broths – Mixes for soups and broths
6. Sauces and like products
    a. Mixes for sauces and gravies
    b. Clear sauces (fish sauce)
7. Yeast and like products
8. Soybean-based seasonings and condiments
    a. Fermented soybean paste (e.g. miso)
    b. Soybean sauce
        i. Fermented soybean sauce
        ii. Non-fermented soybean sauce
        iii. Other soybean sauces
9. Protein products other than from soybeans, marinades

I. BEVERAGES, excluding dairy products

1. Non-alcoholic ("soft") beverages
    a. Non-alcoholic ("soft") beverages without herbal ingredients (e.g. Coffee, coffee substitutes, tea, and other hot cereal and grain beverages)
    b. Non- alcoholic ("soft") beverages with herbal ingredients (e.g. Herbal tea or Tea blends)
2. Alcoholic beverages, including alcohol-free and low-alcoholic counterparts
    a. Beer and malt beverages
    b. Cider and perry
    c. Grape wines
        i. Still grape wine
        ii. Sparkling and semi-sparkling grape wines
        iii. Fortified grape wine, grape liquor wine, and sweet grape wine
    d. Wines (other than grapes)
    e. Mead
    f. Distilled spirituous beverages containing more than 15% alcohol
    g. Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)

J. READY-TO-EAT SAVOURIES 1. Snacks – potato-, cereal- or starch-based (from roots and tubers, pulses and legumes), including chips and crunchies 2. Chicharon 3. Snacks – fish-based
K. FOOD ADDITIVES*

B. MEDIUM RISK FOODS

Medium Risk (MR) Foods – 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 micro-organisms because of food type or processing, but may support the formation of toxins or the growth of pathogenic microorganisms.

Table 2. List of Medium Risk Food Products

MEDIUM RISK FOOD PRODUCTS
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions 1. Condensed milk and analogues (plain) (evaporated/reconstituted milk) a. Condensed milk (plain) b. Beverage whiteners 2. Milk powder and cream powder and powder analogues (plain) 3. Milk products for specific age groups or target population (e.g. children above 3 years; pregnant women)
B. FROZEN DESSERTS 1. Non-Dairy based (e.g. sherbet, sorbet) 2. Edible ices – popsicles
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 1. Tomato products 2. Frozen fruits 3. Canned or bottled (pasteurized) or retort pouch fruit and vegetable preserve in juice, syrup, brine 4. Fruit-based desserts, gelatin (including water-based fruit flavored desserts, i.e. gels) 5. Fermented fruit products 6. Fruit fillings for pastry 7. Fermented vegetable products (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) and seaweed products, excluding fermented soybean products MR Letter E.1 and E.2 (fermented soybeans and fermented soybean curd) and LR Letters H.8.b. 1 to 3 (soybean sauces) 8. Vegetable protein products (canned and frozen)
D. CONFECTIONERY/Cocoa products and Chocolate products including imitations and chocolate substitutes 1. Cocoa mixes (powders) and cocoa mass/ cake 2. Cocoa mixes (syrups) 3. Cocoa-based spreads, including fillings 4. Cocoa and chocolate products, including *"tablea"*; and imitation chocolate, chocolate substitute products

5. Chocolate Confectioneries w/out nuts (chocolate coated polvoron chocolate bars, blocks and bonbons)

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

F. PROCESSED MEAT AND MEAT PRODUCTS, INCLUDING POULTRY AND GAME

1. Processed meat, poultry and game products in whole or cuts
    a. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled)
        i. Cured (including salted) non-heat treated processed meat, poultry and game products
        ii. Cured (including salted) and dried non-heat treated processed meat, poultry and game products
        iii. Fermented non-heat treated processed meat, poultry and game products
2. Processed comminuted meat, poultry and game products
    a. Non-heat treated processed meat, poultry and game products (cured, fermented, chilled)
        i. Cured (including salted) non-heat treated processed meat, poultry and game produ
        ii. Cured (including salted) and dried non-heat treated processed meat, poultry and game products (jerky, shredded beef/ pork)
        iii. Fermented non-heat treated processed meat, poultry and game products

G. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS

1. Processed fish and fish products, including mollusks, crustaceans and echinoderms
    a. Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans and echinoderms
2. Semi-preserved fish and fish products, including mollusks, crustaceans and echinoderms
    a. Fish and fish products, including mollusks, crustaceans and echinoderms – marinated and/or in jelly
    b. Fish and fish products, including mollusks, crustaceans and echinoderms – pickled and/or in brine
    c. Salmon substitutes, caviar and other fish roe products
    d. Semi-preserved fish and fish products, including mollusks, crustaceans and echinoderms (e.g. fish paste), excluding products under MR Letter G.2.a to c above

H. EGG AND EGG PRODUCTS

1. Preserved eggs, including alkaline, salted and canned eggs (salted eggs, century eggs)
2. Egg-based desserts (e.g. custard)

I. BAKERY WARES AND BAKERY RELATED PRODUCTS fine bakery wares (sweet, salty or savory) and mixes

1. Cakes, cookies, pies, pastries, doughnuts, sweet rolls, scones, muffins, waffles – plain / without filling
2. Frozen dough

J. SALT, SPICES, SOUPS, SAUCES, SALADS AND PROTEIN PRODUCTS 1. Soups and broths Ready-to-eat soups and broths, including canned, bottled and frozen 2. Sauces and like products a. Emulsified sauces and dips (e.g. mayonnaise, salad dressing, onion dips) b. Non-emulsified sauces (ketchup, cheese sauce, cream sauce, brown gravy) 3. Salads (e.g. macaroni salad, potato salad) and sandwich spreads excluding cocoa- and nut-based, spreads under HR Letter B.2 (peanut butter)and MR D.3 (cocoa-based spreads including fillings)
K. BEVERAGES, excluding dairy products 1. Non-alcoholic ("soft") beverages a. Fruit and vegetable juices - (fruit juice, vegetable juice, concentrates for fruit juice, concentrates for vegetable juice) b. Fruit and vegetable nectars (fruit nectar, vegetable nectar, concentrates for fruit nectar, concentrates for vegetable nectar) c. Water-based flavored drinks, including "sport," "energy," or "electrolyte" drinks and particulated drinks i. Carbonated water-based flavored drinks ii.Non-carbonated water-based flavored drinks, including punches, ades and jelly drinks iii. Concentrates (liquid or solid) for water-based flavored drinks d. Powdered cocoa drink mixes (cocoa)
. L. FOOD SUPPLEMENT/ HERBAL FOOD/ HERBAL DIETARY SUPPLEMENTS 1. Vitamins and minerals 2. Amino acids
M. READY-TO-EAT SAVOURIES Processed nuts, including coated nuts and nut mixtures (with e.g. dried fruits)
N. FROZEN TO BE REHEATED Prepared frozen meals

C. HIGH RISK FOOD

High Risk (HR) Food – foods that may contain pathogenic microorganisms and will support the formation of toxins or the growth of pathogenic microorganisms and foods that may contain harmful chemicals.

Table 3. List of High Risk Food Products

HIGH RISK FOOD PRODUCTS
A. DAIRY PRODUCTS and ANALOGUES, excluding products under Fats, Oils and Fat Emulsions 1. Milk and dairy-based drinks a. Milk (plain) and buttermilk (plain) b. Dairy-based drinks, flavored and/or fermented (e.g. chocolate milk, cocoa, eggnog, drinking yoghurt, whey-based drinks) 2. Fermented and renneted milk products (plain), excluding dairy-based drinks in HR A.1.b a. Fermented milks (plain) i. Fermented milk (plain), not heat-treated after fermentation ii. Fermented milks (plain), heat-treated after fermentation

b. Renneted milk (plain)

3. Cream (plain) and the likes (cream analogs)
    a. Pasteurized cream (plain)
    b. Sterilized and UHT creams, whipping and whipped creams, and reduced fat creams (plain)
    c. Clotted cream (plain)
    d. Cream analogues
4. Cheese and analogs
    a. Unripened cheese
    b. Ripened cheese
        i. Ripened cheese, includes rind
        ii. Rind of ripened cheese
        iii. Cheese powder (for reconstitution; e.g. for cheese sauces)
    c. Whey cheese
    d. Processed cheese
        i. Plain processed cheese
        ii. Flavored processed cheese, including those containing fruits, vegetables, meat, etc
    e. Cheese analogues
    f. Whey protein cheese
5. Dairy-based desserts (e.g. pudding, fruit or flavored yoghurt)
6. Whey and whey products, excluding whey cheeses
    a. Liquid whey and whey products
    b. Dried whey and whey products
7. Dairy-based frozen desserts (e.g. ice cream)

B. PROCESSED FRUITS, VEGETABLES and EDIBLE FUNGI (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds

1. Dried Fruits and vegetable – plain/ sun-dried (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera) seaweeds, and nuts and seeds
2. Vegetable (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweed, and nut and seed – purees, spreads (e.g. peanut butter)

C. CONFECTIONERY

Chocolate with nuts

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 <u>in whole or cuts</u>
    a. Heat-treated processed meat, poultry and game products (canned)
    b. Frozen processed meat, poultry and game products (marinated pork/ beef/ chicken cuts)
2. Processed <u>comminuted</u> meat, poultry and game products
    a. Heat-treated processed meat, poultry and game products (canned)
    b. Frozen processed meat, poultry and game products (nuggets, patties, dumplings, salami, meat loaf, hotdog)

F. PROCESSED FISH AND FISH PRODUCTS, INCLUDING MOLLUSCS, CRUSTACEANS AND ECHINODERMS

1. Processed fish and fish products, including mollusks, crustaceans and echinoderms
    a. Frozen fish, fish fillets and fish products, including mollusks, crustaceans and echinoderms
    b. Frozen battered fish, fish fillets and fish products, including mollusks, crustaceans and echinoderms; including value added products (battered, marinated, smoked, spiced, fish and squid balls preparations)
    c. Frozen minced and creamed fish products, including mollusks, crustaceans and echinoderms
    d. Cooked and/or fried fish and fish products, including mollusks, crustaceans and echinoderms
        i. Cooked fish and fish products
        ii. Cooked mollusks, crustaceans and echinoderms
        iii. Fried fish and fish products, including mollusks, crustaceans and echinoderms
2. Fully preserved, including canned or fermented fish and fish products, including mollusks, crustaceans and echinoderms

G. EGG AND EGG PRODUCTS

1. Liquid egg products
2. Frozen egg products (e.g. frozen eggs, frozen egg whites, frozen egg yolks)
3. Dried and/or heat coagulated egg products (e.g. dried eggs, dried egg whites, dried egg yolks and powdered egg products)

H. FOODSTUFFS INTENDED FOR PARTICULAR NUTRITIONAL USES

1. Infant formula, follow-on formula and formula for special medical purposes for infants
2. Complementary foods for infants and young children
3. Dietetic foods intended for special medical purposes (excluding products under HR Letter H.1)
4. Dietetic formula for slimming purposes and weight reduction
5. Dietetic foods (e.g. supplementary foods for dietary use) excluding products under HR Letter H.1 to 4 and Letter J, Food supplements)
6. Weaning foods for infants and growing children
7. Dietetic foods for special medical purpose
8. Dietetic formulas for weight control

I. PROCESSED WATER

1. Bottled Water
2. Ice

J. FOOD SUPPLEMENT/ HERBAL FOOD/ HERBAL DIETARY SUPPLEMENTS

1. Herbs and botanicals and/or products with other nutritional substances and/or combination as Food Supplement
2. Herbs and botanicals and/or Products with other nutritional substances and/or combination as Conventional Food Products (Excluding products under LR Letter I.1.b)

K. NOVEL / INNOVATIONS in FOOD

New in the international or local market

*As listed in the Codex General Standard for Food Additives (GSFA) latest revision.

ANNEX C

ACTIVITIES ALLOWED UNDER A SINGLE LICENSE

Primary Activity	Activities that may be added to LTO						
	Manufacturer/ Toll-Manufacturer	Repacker	Exporter of Own Products	Importer of RM for Own Use	Exporter	Importer	Wholesaler
					of products produced by other manufacturers		
Manufacturer/ Toll-Manufacturer	n/a	✓	✓	✓	□	□	□
Repacker	✓	n/a	✓	✓	□	□	□
Trader	□	□	✓	✓	□	□	□
Distributor-Importer	□	□	□	□	✓	n/a	✓
Distributor-Exporter	□	□	□	□	n/a	✓	✓
Distributor-Wholesaler	□	□	□	□	✓	✓	n/a

Legend:
✓ = may be added to LTO
□ = cannot be added to existing LTO and will require a new LTO
n/a = Not applicable, existing activity

ANNEX D

Requirements for Application of License to Operate

A. Requirements for Initial Licensing – The following are the requirements for application by an establishment:

1. Accomplished Online Application Form as prescribed by current FDA regulations;
2. Proof of Payment of Fees as prescribed by current FDA regulations;
3. Proof of Business Registration
    a. If Single Proprietorship: Valid Certificate of Business Name Registration with the Department of Trade and Industry indicating the same name, address and ownership as the establishment applying for a license;
    b. If a Corporation or Partnership:
        i. Valid Registration with Securities and Exchange Commission (SEC) indicating the same name, address, and ownership as the establishment applying for a license;
        ii. Articles of Incorporation; and
        iii. Other pertinent documents, as applicable;
    c. If a Cooperative: Certificate of Cooperative Development Authority (CDA) indicating the same name, address, and ownership as the establishment applying for a license;
4. If the business name and/or and address is different from the registered name and/or address in the DTI-, SEC-, or CDA-issued certificate, the following shall be submitted in addition to the documents specified above as applicable:
    a. If a Corporation or Partnership, SEC Certificate shall reflect "Doing business under the name and style of (Name of Establishment)
    b. Valid Mayor's Business Permit or Barangay Business Permit indicating the same name, address and ownership as the establishment applying for a license;
5. Proof of Occupancy (per facility and/or address declared as part of the establishment);
    a. If the facility and/or address declared as part of application is **not owned** by the applicant:
        i. Notarized valid Contract of Lease of the space or building occupied; and
        ii. If the applicant is engaged in distribution (i.e. third-party logistics):
            - Duly notarized warehousing agreement;
    b. If the facility and/or address declared as part of application is **owned** by the applicant:
        - Copy of Transfer Certificate of Title;
6. Product List
    a. The list of food products to be manufactured, processed with proposed brand name per product
    b. The list of products to be distributed, sold, or offered for sale or use, as appropriate, including the following information per product:
        i. Business name and address of direct source;
        ii. Business name and address of facility where the product is last packaged, if different from source;

iii. Business name and address of facility where product is last processed, if different from last packaging site and direct source;
iv. If product is to be imported, a unique global product identification number;

7. Location Map – a graphic illustration indicating the address, landmarks, immediate environment, type of building, and Global Positioning System (GPS) coordinates (if available) for each facility and/ or address declared part of the establishment;
8. Floor plan/ layout with dimensions
9. Specific requirements – The following are the requirements for application in addition to the General Requirements (Nos. 1-8 above) as applicable:
    a. Manufacturer/Processor
        i. Description of the products to be manufactured (e.g. list of ingredients, physico-chemical, and/or microbiological specifications)
        ii. Description of manufacturing process or food processing/preparation, including a flowchart with quality control points, as appropriate to the size of operation
        iii. Quality control procedures, as appropriate to the size of operation
        iv. Results of analysis of Finished Product /s showing compliance with applicable standards
        v. Facsimile of proposed product label, compliant with FDA standards
    b. Repacker

        i. Description of the product to be repacked (e.g. name of product, physico-chemical, and/or microbiological specifications)
        ii. Description of repacking process, including a flowchart with quality control points
        iii. Quality control procedures
        iv. Photocopy of duly notarized valid contract or agreement with the manufacturer, and, as appropriate, the License to Operate (LTO) of the manufacturer where the product will be sourced for repacking
        v. Facsimile of proposed label, compliant with FDA labeling requirements
    c. Importer-Distributor of Raw Materials/Finished Products/ Ingredients/ Additives for Distribution and/or Retail

        i. Each item declared in the list of food product(s) to be imported shall be identified in <u>any</u> of the following:
            - Pro forma invoice,
            - Foreign agency agreement,
            - Appointment letter, or
            - Distributorship agreement
        ii. All establishments from which the applicant sources its imports shall be supported by at least one of the following documents issued by the health or regulatory 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

iii. All certification issued by a private organization should be attested by a recognized business association or chamber of commerce.

iv. Appropriate test result or certificate of analysis routinely conducted in the country of origin or source that would indicate or show safety of the product. For test or analysis conducted in the Philippines, the applicant shall be guided by appropriate FDA standards as published in the FDA Website in addition to the recognition or accreditation of laboratories.

d. Distributor-Exporter

i. Any of the following documents issued to the applicant by the establishment from which it sources the products it exports:
   - Valid notarized distributorship agreement; or
   - Letter of appointment between FDA-licensed manufacturer and exporter

ii. Copy of valid CPR if already registered by the FDA-licensed manufacturer

e. Distributor-Wholesaler

i. Any of the following 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 FDA-licensed source

ii. Valid Certificate(s) of Product Registration if already registered by the FDA-licensed source

f. Food Trader
   - Valid and notarized toll manufacturing and/or repacking agreement with FDA-licensed toll manufacturer and/or repacker.

10. For local food products covered by Republic Act No. 8172 otherwise known as "*An Act for Salt Iodization Nationwide (ASIN)"* and Republic Act No. 8976 or the *"Philippine Food Fortification Act of 2000"*, the Certificate of Analysis attesting its conformity to prescribed fortification levels shall be uploaded in the eServices Portal System. Levels of iodine shall conform to the latest acceptable level of fortification based on FDA Circular 2013-007 or its amendment.

B. **Requirements for Renewal of a License**

1. Regular renewal

a. Accomplished Online Application Form as prescribed by current FDA regulations;
b. Proof of Payment of Fees as prescribed by current FDA regulations; and
c. Requirements in support of amendments, if applicable, included in the renewal application, including Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);

2. Automatic renewal – where there is no need for inspection or re-submission of requirements as required for initial applications, automatic renewal may be granted only if the following conditions are met:

    a. Submission of an affidavit of undertaking for automatic renewal with a sworn statement indicating no change or variation or, as applicable, no violation of FDA rules and regulations or non-compliance to the requirements of GMP have been committed
    b. The application for renewal was filed before the expiration date of the license; and
    c. The prescribed renewal fee was paid upon filing of the application.

C. Requirements for Amendment of a License

1. The following changes are equivalent to an initial licensing application and shall satisfy all applicable requirements as specified in Section V Part A and Section V Part B or Part C, of main text of this Issuance, and surrender the previously issued license:

    a. Change of Ownership
    b. Change of Location of Manufacturing Site or Distribution Office
2. The following amendments shall satisfy applicable requirements and upon approval, LTO will be re-issued:

    a. Change of Business Name
        i. Accomplished Online Application Form as prescribed by current FDA regulations;
        ii. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
        iii. New Business Name registration from DTI/SEC. If registered address with DTI/ SEC is different from the address of the establishment, a photocopy of Business/ Mayor's Permit; and
        iv. Proof of Payment of Fees as prescribed by current FDA regulations
    b. Additional Product Line(s), for manufacturers

        i. Accomplished Online Application Form as prescribed by current FDA regulations;
        ii. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);
        iii. Compliance to GMP verified during inspection; and
        iv. Proof of Payment of Fees as prescribed by current FDA regulations
    c. Additional activity(ies):

        i. Accomplished Online Application Form as prescribed by current FDA regulations;
        ii. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made);

iii. Compliance to GMP verified during inspection; if for additional activity as Toll Manufacturer for a Licensed Food Manufacturer; and
iv. Proof of Payment of Fees as prescribed by current FDA regulations

3. The following amendments shall be made known to the FDA through notification:

    a. Deletion of activity(ies);
    b. Deletion of Source(s);
    c. Deletion of Warehouse Address; and
    d. Deletion of Manufacturing Plant Address

4. Requirements for notification of amendments are as follows:

    a. Accomplished Online Application Form and Notarized Declaration page in the FDA website as prescribed by current FDA regulations;
    b. Scanned Application Letter stating the intended changes (indicate changes/ amendments to be made); and
    c. Proof of Payment of Fees as prescribed by current FDA regulations

5. The following amendments shall be made known to FDA through notification, submission of applicable Proof of Occupancy, and payment of appropriate fees:

    a. Addition of Warehouse Address not involving transfer of location
    b. Any change requiring modification of the submitted Proof of Occupancy

6. All other changes not identified previously, including but not limited to, the following:

    a. Change in Distribution Agreement not previously covered;
    b. Change of Manufacturing Process; and
    c. Change of Quality Control Procedure

    Shall be reflected in the appropriate document that was required during initial application and shall be submitted during renewal;

7. Amendments requiring notification shall be made known to the FDA within 30 calendar days of effect.
8. Amendments requiring satisfaction of initial licensing requirements shall be done within 60 calendar days of effect.
9. Amendments taking effect within 90 days prior to expiration of a current license shall be declared along with the renewal, and shall pay the corresponding fees as prescribed by current FDA regulations.

D. Re-issuance of a License – for additional original copies

1. Accomplished Online Application Form as prescribed by current FDA regulations; and

2. Proof of Payment of Fees as prescribed by current FDA regulations.

ANNEX E

Requirements for Application of Certificate of Product Registration

A. **Requirements for Initial Registration** – The following are the requirements for product registration:

1. Accomplished Food Product Online Application Form as prescribed by FDA Circular 2020-033 or its latest revision;

2. Proof of Payment of Fees as prescribed by FDA Administrative Order No. 50. s. 2001 or its latest revision ;

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

4. 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;

5. A sample in actual commercial presentation for food supplement products only.

6. In case of label claims, documents to substantiate the same, such as technical, nutritional or health studies or reports, market-research studies, Certificate of Analysis (E.g. physical, chemical, microbiological and nutrient analysis of the finished product), quantitative analysis and computations, scientific report or studies published in peer-reviewed scientific journals, certificates or certification to support use of logo/seal.

7. For imported food products covered by Republic Act No. 8172 otherwise known as "*An Act for Salt Iodization Nationwide (ASIN)"* and Republic Act No. 8976 or the *"Philippine Food Fortification Act of 2000"*, the Certificate of Analysis attesting its conformity to prescribed fortification levels shall be required. Levels of iodine shall conform to the latest acceptable level of fortification based on FDA Circular 2013-007 or its amendment.

8. Source Documents

    a. For locally produced products, Certificate of Distributorship or Appointment letter or Memorandum of Agreement from each supplier

    b. For imported products:

        i. Foreign Agency Agreement or Certificate of Distributorship or Appointment letter or Proforma Invoice or Memorandum of Agreement **from each supplier**

ii. any of the following valid[1] documents are hereby accepted:

1) Certificate of Registration with GMP Compliance or its equivalent
2) Sanitary Phyto-Sanitary Certificate
3) Health Certificate or FSSC Certificate or HACCP Certificate issued by the Regulatory/ Health Authority/ Attested by recognized Association
4) ISO 22000 Certificate
5) Certificate of Free Sale indicating that the product is freely sold and fit for human consumption issued by the Regulatory/ Health Authority/ Attested by recognized Association or duly authenticated by the Philippine Consulate or with affixed Apostille from the country of origin (from Manufacturer or Supplier).

8. In addition to the requirements for initial registration, any of the following documents or the prevailing guidelines or policies shall be required for the following products, as necessary:

8.1 Ice

Parameters	**Method of Determination**	**Value**	**Units of Measurement**
Total coliform	Multiple Tube Fermentation Technique (MTFT)	< 1.1	MPN/100 mL
	Chromogenic substrate test (Presence-Absence)	Absent < 1.1	 MPN/100 mL
	Membrane Filter (MF) Technique	< 1	Total coliform colonies/ 100 mL
Fecal coliform	Multiple Tube Fermentation Technique (MTFT)	< 1.1	MPN/100 mL
	Membrane Filter (MF) Technique	< 1	Fecal coliform colonies/100 mL
	Chromogenic substrate test (Presence-Absence)	< 1.1	MPN/100 mL
Heterotrophic Plate Count	● Pour Plate ● Spread Plate	< 500	CFU/mL

[1] 1 month prior to expiry or if less submit proof of renewal application along with the required document

	• Membrane Filter Technique		

Chemical Constituents	Max. Accept. Level (MAL)
Arsenic	0.05 mg/L
Cadmium	0.003 mg/L
Lead	0.01 mg/L
Nitrate	50 mg/L
Benzene	0.01 mg/L

Physical-Chemical Constituents		Max. Accept. Level (MAL)
Color	Apparent	10 Color Units
	True	5 Color Units
Turbidity		5 NTU
Iron		1.0 mg/L
Manganese		0.4 mg/L
pH		6.5 – 8.5 5 – 7 (for product water that undergone reverse osmosis or distillation process)
Sulfate		250 mg/L
Total Dissolved Solids (TDS)		500 mg/L <10 (for product water that undergone reverse osmosis or distillation process)

Directly from the source:

Radiological Constituents	Activity Level (Bq/L)
Gross Alpha activity	0.1 (excluding radon)
Gross Beta	1.0
Radon	11 (MCL)

8.2 Food Supplement

a. Technical specifications of an ingredient
b. Computation for conversion of vitamins and elemental minerals
c. Certificate of Analysis (i.e. Vitamins/Minerals Quantitative Assay)
d. Safety data (Toxicity Study, LD50) with corresponding conclusion on safety (i.e. Certificate for Absence of TSE/BSE, Scientific Study)
e. Stability Data / Shelf-life Study 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

f. Standards for the following tests shall be based on AO 184 s. 2004 or its future amendments:

i. For Dried plants (limits for adults):

Heavy Metals	Unit	Limits
Lead	ppm	maximum 10
Cadmium	ppm	maximum 0.3
Arsenic	ppm	maximum 0.3
Mercury	ppm	maximum 0.5

ii. For untreated plant material harvested under acceptable hygienic conditions intended for further processing:

Microorganisms	Unit	Limits
Escherichia coli	cfu/g	negative
Moulds propagules	cfu/g	maximum 10^5
Staphylococcus	cfu/g	negative

iii. Plant materials that will undergo pre-treatment (e.g. with boiling water as used for herbal teas and infusions):

Microorganisms	Unit	Limits
Aerobic bacteria	cfu/g	maximum 10^7
Yeast and moulds	cfu/g	Maximum 10^4
Escherichia coli	cfu/g	negative
Salmonellae	cfu/g	negative
Staphylococcus	cfu/g	negative
Other Enterobacteria	cfu/g	maximum 10^4

iv. The following tests and standards shall be required to determine the quality of the finished product:

- Moisture Content – not more than 10%
- pH
- Microbial Limits shall be based on the following:

For Solid Products

Microorganisms	Unit	Limits
Aerobic bacteria	cfu/g	maximum 10^4
Yeast and moulds	cfu/g	maximum 10^3

Escherichia coli	cfu/g	negative
Salmonellae	cfu/g	negative
Staphylococcus	cfu/g	negative
Other Enterobacteria	cfu/g	maximum 10^2

For Liquid Products

Microorganisms	Unit	Limits
Aerobic bacteria	cfu/g	maximum 10^2
Yeast and moulds	cfu/g	maximum 10^2
Escherichia coli	cfu/g	negative
Salmonellae	cfu/g	negative
Staphylococcus	cfu/g	negative
Other Enterobacteria	cfu/g	maximum 10^2

8.3 Low Risk food products

Certificate of Analysis* of finished product to determine compliance with RA 8976, RA 8172, and F.M. 2011-028 for 3-MCPD

8.4 Medium and High risk food products

a. Certificate of Analysis of finished product to determine compliance with applicable standards of identity such as, but not limited to, Codex Standards (i.e. infant formula, milk supplement, other foods for infants and young children, foods for special medical purposes, foods for special dietary uses), Philippine National Standards, RA 8976, and RA 8172
b. Certificate of Analysis to determine compliance with FDA Circular No. 2013-010 "Revised Guidelines for the Assessment of Microbiological Quality of Processed Foods" and its future revision;
c. Relevant validated scientific studies (peer reviewed and/or published) to support the use of products for specific purposes (e.g. foods for special medical purposes, foods for special dietary uses); and/or
d. Validated scientific researches or studies published in peer-reviewed scientific journals to support declaration of health and nutrition claims, and other relevant supporting documents.

C. Automatic Renewal of CPR

1. Select “Renewal” and upload a sworn statement indicating no change or variation in the product

2. Proof of payment of fees as prescribed by FDA AO No.50 s.2001 or its latest revision

3. The application for renewal shall be filed within 90 working days before the date of its expiration

4. Renewal of the CPR may be automatic provided that the following conditions are met:

    a. The prescribed automatic renewal fee shall be paid; and
    b. Product label is compliant with Labeling requirements as stipulated in Administrative Order No. 2014-0030 or its latest revisions, R. A. No. 10611, R. A. No. 3720, as amended RA 9711, and other pertinent laws, rules and regulations associated with food labeling.
    c. Valid and appropriate FDA License to Operate (required for all types of CPR application)
    d. The marketing authorization holder has no violations on the scope of authority of the previous approval of registration and the terms and conditions in the CPR thereof (including APPROVED AMENDMENTS during the validity of the prior registration)
    e. The compliance by the company of the Checklist of Requirements below will not preclude the CFRR from implementing Section 4, Article I, Book II of the IRR of RA No. 9711, as may be warranted

5. Requests for amendment shall not be allowed to be filed simultaneously with an application for automatic renewal.

5. Below shall be the specific cases wherein the Automatic Renewal will <u>not</u> apply:

    a. If the application for registration is filed after the expiry date of the CPR but within 120 calendar days, the application shall not be qualified for automatic renewal and is subject to corresponding surcharges prescribed in Administrative Order 50 s.2001 or its latest revisions
    b. If the previously approved application has undergone any changes without prior FDA approval, it shall not be qualified for automatic renewal.
    c. If there are any changes in product formulation (reformulation), this is treated as an application for initial registration.
    d. No application for renewal shall be accepted unless the prescribed renewal fee is paid.

7. For renewal of applications initially approved in the old e-portal, the application shall be filed in the Modified E-Registration Version by starting a new case number and by selecting "Renewal" as the type of application. The applicant shall accomplish the online application form, upload revised labels, indicate the correct case number and use the same user account to automatically transfer initially submitted documents from the old portal.

D. Amendments to the Product Registration

1. The following changes are equivalent to an initial registration application:

    a. Change in manufacturer or repacker and change in manufacturer's or repacker's address shall be treated as initial registration; and
    b. Change of product formulation.

2. Types of Amendments

    a. Change in/Additional Commercial Presentation (i.e. Packaging Size)
    b. Change in/Additional Packaging Design
    c. Change/Extension in Shelf-Life
    d. Change in/Additional Packaging Type or Packaging Material
    e. Exportation of previously registered product initially for local distribution/ Additional design of the product intended for local distribution initially registered for exportation

    f. Change in Brand Name
    g. Change in Product Name/ Additional Product Description
    h. Change in Business/Company Name
    i. Change in Business/Company Address (Not Applicable to Manufacturer and Repacker)
    j. Transfer of ownership of a registered product
    k. Change in/Additional Supplier
    l. Change in Importer/Distributor/Wholesaler/Trader
    m. Other cases as declared in succeeding FDA issuances

3. Requirements for Amendment shall follow Annex D of the FDA Circular 2020-033 "Procedure for the Use of E-Portal Version 2 for Prepackaged Processed Food Products" and FDA CFRR Citizen's Charter or its latest revisions.

E. Printing of Certificate of Product Registration

If the application filed in the Modified E-portal Version 2 is approved, a system-generated email notification shall be sent to the applicant's registered email. The applicant can download and print the system-generated CPR by opening the case number in the Inbox of the E-portal account holder.

F. Cancellation of CPR

The FDA shall be notified for cancellation of CPR through the modified e-portal version 2 with simultaneous submission of a request letter.

For applications approved in the old e-portal, the hard copy of original CPR shall also be submitted to the FDA.

ANNEX F

Requirements for Application of Import Permit for Samples

The following are the requirements for Import Permit:

1. Application Letter stating the purpose of importations, products to be imported and their quantity shall be sent to fdac.letters@fda.gov.ph.

2. Notarized Affidavit of Undertaking (refer to Annex H & I, can be downloaded from the FDA website)

    a. Certificate of Analysis (E.g. physical, chemical, microbiological and nutrient analysis of the finished product) or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by a recognized Association or duly authenticated by the Philippine Consulate from the country of origin.

3. Proforma or Commercial Invoice

4. If available, these documents may be attached to the application dossier: Packing List, Airway Bill or Bill of Lading

5. Valid License to Operate issued by FDA-CFRR

6. Proof of Payment of Fees as prescribed by current FDA regulations;

ANNEX G

Requirements for Application of Import Permit for Exhibits

The following are the requirements for Import Permit:

1. Application Letter stating details of the exhibit (date, venue, event name), products to be imported and their quantity shall be sent to fdac.letters@fda.gov.ph.

2. Notarized Affidavit of Undertaking (can be downloaded from the FDA website)

   b. Certificate of Analysis (E.g. physical, chemical, microbiological and nutrient analysis of the finished product) or Certificate of Free Sale issued by the Regulatory/ Health Authority/ Attested by a recognized Association or duly authenticated by the Philippine Consulate from the country of origin.

3. Proforma or Commercial Invoice

4. If available, these documents may be attached to the application dossier: Packing List, Airway Bill or Bill of Lading

5. Proof of Payment of Fees as prescribed by current FDA regulations;

ANNEX H

AFFIDAVIT FOR EXHIBITS

Affidavit of Undertaking

I, (Name of Applicant) of legal age, (Position in the Company) and/or duly authorized representative of (Name of Company and Address), after having been sworn in accordance with law, hereby declare that:

1. The (Company Name) has imported products from (Country of Origin).

2. The said importation is covered by Proforma Invoice No. ____ dated _____ of (Source of the Importer).

3. The applicant company will participate in (Name of Exhibit) on (Date of Exhibit).

4. The products are not adulterated, nor misbranded, and contain ingredients and additives that are permitted for use in human and in accordance with relevant regulations issued by FDA.

5. The said product/s is for use by (Company Name) for (State Purpose) Moreover, it will not find its way in the market for sale or for distribution.

6. The company understands and agrees that the products may be subjected to FDA Laboratory examination at any time to verify the food product safety and quality and that the cost of laboratory examination shall be charged to the importing company.

7. This Affidavit is executed to confirm the truth of the foregoing.

IN TRUTH WHEREOF, I am affixing my signature below this _____ day of _____, 20___ at _____.

_____
Affiant Name

SUBSCRIBED AND SWORN TO BEFORE ME, this _____ day of _____, 20___ at _____. Affiant exhibited to me his/her (Government Issued ID and Number).

Notary Public

Doc. No. : _____

Book No.: _____

Page No.: _____

Series of _____

ANNEX I

AFFIDAVIT OF UNDERTAKING FOR SAMPLES

Affidavit of Undertaking

(Name of Applicant) of legal age, (Position in the Company) and/or duly authorized representative of (Name of Company and Address), after having been sworn in accordance with law, hereby declare that:

1. The aforementioned company has imported from (Country of Origin) the food products: see attached product list.

2. The said importation is covered by Proforma Invoice No. ____ dated _____ of (Source/Principal of the Importer), copy of which is cross-checked with the original.

3. The applicant company has a valid License to Operate as an importer, with LTO No. _____ covering the said shipment.

4. The products are not adulterated nor misbranded, and contain ingredients and additives that are permitted for use in human and in accordance with relevant regulations issued by FDA.

5. The said product is for use by (Company Name) for sampling purposes and product development only. Moreover, it will not find its way in the market for sale or for distribution.

6. The company understands and agrees that the products may be subjected to FDA Laboratory examination at any time to verify the food product safety and quality and that the cost of laboratory examination shall be charged to the importing company.

7. This Affidavit is executed to confirm the truth of the foregoing.

(Date) at (Place of Execution)

(Affiant)

Subscribed and sworn to before me this (date) day of (month), (year) at _____.

Notary Public