[DOH ADMINISTRATIVE ORDER NO. 2014-0029, September 08, 2014]

RULES AND REGULATIONS ON THE LICENSING OF FOOD ESTABLISHMENTS AND REGISTRATION OF PROCESSED FOOD, AND OTHER FOOD PRODUCTS, AND FOR OTHER PURPOSES

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I. Rationale/Background

Effective national food control systems are essential to protect the health and safety of consumers. The global environment for food trade places emphasizes on strengthening food control systems and to implement and enforce risk-based food control strategies.

The Department of Health (DOH) through the Food and Drug Administration (FDA) is mandated by Republic Act (RA) No. 10611, otherwise known as the Food Safety Act of 2013, to bear the specific responsibility of ensuring the safety of all food processing and product packaging activities, among others and to develop and issue appropriate authorizations in the form of a license and certificate or registration that would cover establishments, facilities engaged in production and distribution of products.

The FDA through the Center for Food Regulation and Research (CFRR), per RA 9711, shall adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to protect and promote the right to health of the Filipino people. It shall implement a performance-based food safety control management system which shall include, among others: a) the development of food standards and regulations; b) post-market monitoring; c) enforcement of Hazard Analysis Critical Control Points (HACCP) and other risk-based control measures; d) strong participation in Codex and other international standard setting bodies, e) communication of risks and development of interactive exchange among stakeholders; f) establishment and strengthening of food laboratories; g) development of a database on food-borne illness and epidemiological data; h) strengthening R&D capabilities food safety and quality standards; and i) certification of food safety inspectors.

Consistent with international food safety measures, FDA is adopting a risk-based approach on product and establishment risk categorization focusing on preventive, rather than corrective strategies. Consistent with this mandate, the FDA shall ensure food safety through the imposition of food quality standards in the country. Thus, the issuance of this Administrative Order on the Licensing of Food Establishments, and Registration of Processed Food to issue appropriate authorizations in the form of a permit, license and certificate of registration or compliance that would cover establishments, facilities engaged in packing, holding or producing food for

consumption in accordance with the mandated issuances of regulatory agencies issuing such authorizations.

II. Objectives

1. Adoption of risk-based classification of food establishments and food products as published by the Food and Agriculture Organization of the United Nations;

2. The issuance of License to Operate (LTO) to food establishments engaged in the manufacture or processing and distribution, i.e. import, export or wholesale, or trade and repacking of processed food and food products, and

3. The issuance of the Certificate of Product Registration (CPR) to FDA-licensed establishments before processed food and other food products are sold, offered for sale or use, distributed or supplied, among other marketing and promotional activities.

III. Scope and Coverage

This Administrative Order covers food establishments engaged in the manufacture and/or distribution, (i.e. import, export and/or wholesale) trade and/or repacking of processed food and food products.

This Administrative Order shall not cover fresh or raw food derived from plant, animal, fisheries and aquaculture products or foods in the primary production and post-harvest stages of the supply chain under the Department of Agriculture. It shall likewise not cover food businesses such as, but not limited to, activities in slaughter-houses, poultry dressing plants, fish ports, wet markets, supermarkets, school canteens, restaurants, catering establishments, water refilling stations, street food sale, including ambulant vending which are under the purview of the Local Government Units (LGUs).

IV. Definition of Terms

For the purpose of this issuance the following terms are defined:

1. Activity refers to either processing, packaging, repackaging, trading, import, wholesale, export, sale, promotion, or offer for sale, of a food product.
2. 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.
3. 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, postharvest 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.
4. Bottled Water means water that is placed in a sealed container or package and is offered for sale for human consumption as drinking water.
5. Certificate of Product Registration (CPR) is an authorization issued by the FDA for specific health products after evaluation and approval of submitted registration requirements.

6. 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) postharvest handling, manufacturing, processing, preparation, treatment, packing, packaging, transport or holding of such food as a result of environmental contamination.
7. 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.
8. 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.
9. 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.
10. Distributor/Importer/Exporter refers to any establishment that imports or exports raw materials, ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.
11. Distributor/wholesaler refers to any establishment that procures raw materials, and/or finished products from local establishments for local distribution on wholesale basis.
12. 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.
13. Export refers distribution outside of origin by crossing international borders.
14. 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.
15. 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.
16. Food-home illnesses refer to diseases, usually either infectious or toxic in nature, caused by agents that enter the body through the ingestion of food.
17. 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.
18. 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.
19. 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: 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, 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.

20. Fortification means the addition of nutrients to processed foods or food products at levels above the natural state.
21. Good Manufacturing Practice (GMP) refers to a quality assurance system aimed at ensuring that products are consistently manufactured, packed, repacked or held to quality standards appropriate for the intended use. It is thus concerned with both manufacturing and quality control procedure.
22. Good Distribution Practice (GDP) or Good Storage Practice (GSP) refers to a part of 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.
23. Hazard Analyses and Critical Control Points (HACCP) refer 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.
24. Import refers to the distribution into a local destination by crossing international borders.
25. Ingredient 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.
26. 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.
27. 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.
28. Licensing means the process of approval of an application to operate or establish an establishment prior to engaging in the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and where applicable the use, testing, promotion, advertisement, and/or sponsorship of health products.
29. 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.
30. 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 labelling with the end in view of its storage, sale or distribution. A trader shall be categorized as manufacturer. They may also manufacture products for institutional use. In case of imported food products,

the manufacturer's representative or, in his absence, the importer, shall be deemed the manufacturer.

31. 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.
32. Packaging refers to an activity where a product is contained AND SEALED with the intention of storage and/or transport.
33. Packer refers to food manufacturer engaged in packaging food products not previously packaged.
34. Permit refers to a form of authorization that is issued by the FDA to an establishment that has complied with the application requirements.
35. 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 producer/manufacture food.
36. Raw materials are all substances that are employed in the processing of a finished product, packed in bulk containers and not labelled as finished product. Raw Materials or ingredients would have product specifications that comply with the client requirements and not necessarily a single component.
37. 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.
38. Repacker means any establishment engaged in the process of packaging or changing of container, wrapper (that may include or not a changing of label) from a bulk material to retail packaging sizes in furtherance of distribution of food.
39. Retailer means any establishment which sells or offers to sell any health product directly to the general public.
40. Risk refers to a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.
41. Salt Iodization refers to the addition of iodine to salt intended for human consumption in accordance with specifications as to form, fortificant type, method, manner and composition as may be prescribed by the FDA.
42. Source refers to any establishment able to supply food products to another establishment through further importation, wholesale or export.
43. 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 product to a licensed manufacturer. In addition, a trader may also engage in the distribution and/or marketing of its products.
44. Toll Manufacturer refers to the manufacturer that conduct 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.
45. Wholesale refers to local distribution of pre-packaged food products in commercial quantity.

V. Guidelines for Licensing of Food Establishments

A. General Principles