Draft as of 14 Nov 2023

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ADMINISTRATIVE ORDER
No. _____

SUBJECT : Adoption of the Philippine National Standards (PNS) and its Recommended Code of Practices (RCP) for Processed Food Products as Technical Regulation

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I. BACKGROUND

The Food and Drug Administration is mandated by Article IV Section 9 of the Republic Act (RA) No. 10611 in establishing food safety standard through the basis of science, risk analysis, scientific advice from expert body/bodies, standards of other countries, existing Philippine National Standards (PNS) and the standards of the Codex Alimentarius Commission (Codex).

The PNS and its Recommended Code of Practice for processed products have been issued by the Food and Drug Administration (FDA) in partnership with other concerned agencies through Technical Working Groups (TWGs) comprised of experts from various institutions that developed the draft standards. The PNS and RCP are used as reference for the quality and safety standards for the product and its processing procedure.

Consistent with the FDA's mandate to ensure safe and quality food products as prescribed in RA No. 9711 or the FDA Act of 2009 and its Implementing Rules and Regulations (IRR), as well as provisions stated in RA No. 10611 or the Food Safety Act of 2013 and its IRR, this Administrative Order is hereby issued to utilize the quality and safety standards developed for the PNS processed food products to serve as a guide to all food business operators (FBOs) and the general public for the standards of specific food products that are to be sold in the local market; and to demonstrate compliance to food safety and quality prior to issuance of FDA authorizations and ultimately protect consumer interest.

Hence, the adoption of PNS as technical regulation is deemed imperative.

II. OBJECTIVE

This Order aims to adopt PNS of processed food products as part of FDA technical regulations. Specifically, this Order aims:

A. To adopt the standards of identity of the applicable processed products; and
B. To adopt the recommended code of practice for the manufacture of the applicable products.

III. SCOPE

This shall cover all imported and locally manufactured processed food products under the jurisdiction of the FDA.

IV. DEFINITION OF TERMS

For the purpose of implementing this Order, the following terms shall be defined as follows:

A. **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 and may take the form of a permit, license, certificate of registration, and certificate of compliance or exemption or any similar document.

B. **Code of Practice** refers to a document stating the minimum standard for the processing and handling of a specific commodity.

C. **Codex Alimentarius** refers to the collection of international standards, guidelines and codes of practice to protect the health of consumers and ensure fair practices in the food trade.

D. **Food Standard** refers to 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 processed foods.

E. **Philippine National Standard** refers to a document stating the minimum standard for a specific commodity established to help industries produce quality products, raise productivity, protect consumers, and facilitate trade.

F. **Processed Food** refers to 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.

G. **Technical Regulation** refers to the legal instrument that gives effect to a government policy intervention and includes licensing, compliance to standards or any other statutory and regulatory requirements necessary to carry out activity.

V. GENERAL GUIDELINES

A. The PNS and RCP of processed food products finalized by the FDA and/or DA-BAFS and promulgated by the Bureau of Philippine Standards, such as but not limited to Annex A, shall be adopted as technical regulation.

B. Compliance with these standards shall be made mandatory and shall be a requirement prior to approval of registration application.

C. In the absence of a Philippine National Standard for a specific processed food, the Codex Alimentarius's latest commodity standards shall be adopted, except when these conflict with what is necessary to protect consumers and scientific justification exists for the action taken.

D. All other succeeding approved, amended or revised PNS-FDA of processed food products that will be developed by the FDA- Center for Food Regulation and Research (CFRR) shall be automatically adopted as technical regulations.

VI. SPECIFIC GUIDELINES

A. The processed food product may only be labeled as prescribed in the standard of identity if it conforms to the specifications indicated in the PNS prior to its manufacture with the intention of sale, offering for sale, promotion, advertisement, or donation.

B. Specifications of the product complying with the standard shall be declared in the data entry in applications for registration of both locally produced and imported processed food products.

C. A recent (within twelve months from the date of application) Certificate of Analysis (COA) for medium and high risk processed food products shall be submitted as part of the registration requirements for both local and imported processed food products.

D. All processed food products shall conform to the microbiological parameters based on the FDA Circular No. 2022-012 entitled "Revised Guidelines for the Assessment of Microbiological Quality of Processed Foods" or its latest revision.

E. The registration process and requirements shall be in accordance with Administrative Order 2014-0029 and FDA Circular 2020-033, and their latest revisions.

F. The labeling shall be in accordance with Administrative Order No. 2014-0030 and its latest revisions.

VIII. TRANSITORY PROVISION

The following transitory provision shall be provided for the affected FBOs distributing the processed food products under this Circular:

A. All FBOs shall be given a maximum of two (2) years transitory period to comply with this Circular upon its effectivity.

B. All affected FBOs granted CPRs with a validity of three (3) to five (5) years from the effectivity of this Circular shall use a maximum of two (2) years of the CPR validity and shall file initial application complying with this Circular after the given period.

C. Those CPRs granted with remaining validity and are qualified for renewal with validity of less than thirty (30) days upon effectivity of this Circular shall be renewed for a maximum of two (2) years to give ample time to comply with the new guidelines.

D. In the event where stocks of the label of the previous CPR still be available upon the filing of the new CPR, request for exhaustion for a maximum of six (6) months may be submitted and a copy of its inventory to the FDA.

IX. REPEALING CLAUSE

Other FDA issuances inconsistent with this Order are hereby repealed and/or modified accordingly.

X. MONITORING AND REVIEW CLAUSE

This Order shall be reviewed and evaluated within three (3) years of its implementation to determine whether the policy's objectives, impact, and effectiveness are achieved.

XI. PENALTY CLAUSE

Any food product that is non-compliant to, or in violation of, the indicated guidelines in this Order shall be deemed not in conformity with the applicable food quality or safety standard or either adulterated, misbranded, mislabeled or both, as applicable.

The authorized sanctions shall be imposed following Republic Act No. 3720, as amended by Executive Order No. 175 and Republic Act No. 9711 or Republic Act No. 10611, as far as applicable, and following the proceedings under Book III of the Implementing Rules and Regulations of R.A. No. 9711.

XII. SEPARABILITY CLAUSE

If any part, term, of provision of this Order shall be declared invalid or unenforceable, the validity or enforceability of the remaining portions or provisions shall not be affected and this Order shall be construed as if it did not contain the particular invalid or unenforceable or unconstitutional part, term, or provision.

XIII. EFFECTIVITY

This Order shall take effect after fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation and filing with the Office of the National Administrative Register of the UP Law Center.

DR. TEODORO J. HERBOSA
SECRETARY OF HEALTH

DTN 20230518064819