FDA CIRCULAR
No. _____

SUBJECT: Standard and Recommended Code of Practice for Processing of Distilled Fermented Coconut Sap (Lambanog)

I. BACKGROUND

The Republic Act No. 3720 (Food, Drug, and Cosmetic Act) as amended by Executive Order No. 175 and RA No. 9711 otherwise known as FDA Act of 2009 and RA No. 10611 otherwise known as Food Safety Act of 2013, as well as their implementing rules and regulations, mandated the FDA to protect and promote the right to health of Filipinos; and establish and maintain an effective health products regulatory system and undertake appropriate health manpower development and research, responsive to the country's health needs and problems.

Incidences of food poisoning related to consumption of lambanog has become a serious public health concern that necessitates updating of standard of identity and establishing recommended code of practice.

Consistent with the mandate of the FDA to protect the health of the public by regulating processed prepackaged food products, including lambanog, investigation, post-market surveillance, sampling, and laboratory testing were conducted, leading to review and revision of existing guidelines. A recommended code of practice (RCP) for the manufacture of lambanog is also deemed necessary to guide the manufacturers.

This Circular includes updated standard specifications based on PNS/BAFS 47:2021 on Distilled Fermented Coconut Sap (Lambanog) and corresponding RCP for the manufacture of lambanog to assure its safety and quality. Guidance on the integrity of the product through proper product naming and labeling is also provided to give consumers an informed choice and purchase, and enable fair trade based on the provisions of RA No. 10611.

II. OBJECTIVES

The objectives of this Circular are:

A. To prescribe the standard specifications for lambanog;

B. To prescribe the recommended code of practice for processing, handling, and labelling of lambanog; and

C. To provide guidelines in the inspection and application for FDA authorizations of lambanog manufacturers, traders and distributors.

III. SCOPE

This Circular covers the standard and COP for lambanog and pure lambanog for implementation by all food establishments engaged in the manufacture, trade, repacking, and distribution of lambanog products.

IV. DEFINITION OF TERMS

For the purpose of this Circular, the terminologies used shall be defined as follows:

A. **Alcohol content** is the alcoholic strength often expressed as percentage alcohol by volume**.**

B. **Coconut sap** is the liquid exuding from the tapped unopened inflorescence of the coconut palm, which is also called toddy.

C. **Container** means any form of packaging material, which completely or partially encloses the food (including 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.

D. **current Good Manufacturing Practices (cGMP)** is a quality assurance system aimed at ensuring that products are consistently manufactured, packed, repacked or held to a quality appropriate for the intended use. It is thus concerned with both manufacturing and quality control procedures.

E. **Distillation** is a process by which a low proof alcoholic beverage is heated in a controlled process to separate ethanol from water and other components, thereby, concentrating the ethanol into a high proof spirit.

F. **Ethanol or ethyl alcohol** is an organic compound with chemical formula C_2H_6O written also as CH_3CH_2OH or C_2H_5OH, abbreviated EtOH, derived from the natural fermentation of coconut sap, which is colorless, volatile, and flammable liquid.

G. **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.

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

I. **Label** includes any tag, brand, mark, pictorial, or other descriptive matter, written printed, marked, embossed or impressed on, or attached to a container of food.

J. **Labeling** is any written, printed or graphic matter: (1) upon any article or any of its container or wrappers or (2) accompanying the packaged food.

K. **Lambanog** is an alcoholic beverage obtained by distillation of naturally fermented sap collected from coconut inflorescence.

L. **Lot** is the food produced during a period of time and under more or less the same manufacturing conditions as indicated by a specific code.

M. **Methanol or methyl alcohol** is an organic compound with chemical formula CH_4O or CH_3OH, which is a colorless, flammable and volatile liquid. It is a by-product in the processing of naturally fermented alcoholic beverages caused by the action of naturally occurring microorganisms, which can be reduced or minimized through Good Manufacturing Practices (GMP), and not deliberately added.

N. **Naturally fermented coconut sap** is the coconut sap gathered from the inflorescence of the coconut palm that has undergone spontaneous fermentation before distillation, without the use of enzymes or subjecting to controlled air or temperature conditions.

O. **Primary packaging** is the packaging material that comes in direct contact with the product.

P. **Proof** is a statement of ethanol content, which is twice the percentage of alcohol by volume.

Q. **Pure lambanog** is an alcoholic beverage obtained by distillation of naturally fermented sap collected from coconut inflorescence without addition of any of the ingredients listed under Sec VII.B.2.

VI. GENERAL GUIDELINES

A. All covered manufacturers, trader, and distributors of lambanog shall ensure conformity to product identity, integrity and processing procedure as prescribed in this Circular.

B. The responsibility of ensuring the safety, quality and integrity of lambanog shall rest upon the food business operator and/or any person involved in the production, quality control, handling, packing, transport, trading, sale, advertising, storage, and distribution of the product.

C. Manufacturers, traders, and distributors of lambanog products shall be inspected by FDA in accordance with these guidelines in addition to the Quality Work Procedures implemented by the FDA - Field Regulatory Operations Office.

VII. SPECIFIC GUIDELINES

A. Product description

Lambanog shall be a colorless alcoholic beverage with the distinct taste and aroma of distilled fermented coconut sap and produced in conformance with the parameters set out in Section VII.B to J of this Circular. Its ethyl alcohol content shall be obtained solely from the distillation of naturally fermented coconut sap without a mixture of ethyl alcohol from other sources.

B. Raw materials

1. Pure lambanog contains only fermented and distilled coconut sap.

2. For lambanog, the major raw material is fermented and distilled coconut sap.

3. Lambanog may be added with optional ingredients as follows:

    a. Fruit bits or peel infusion may be used to impart distinct flavor/aroma.

    b. Potable water can be added to reduce the % alcohol content. The water to be used shall conform to DOH Administrative Order (AO) No. 2017-0010 entitled "Philippine National Standards (PNS) for Drinking Water of 2017" and its future amendments.

    c. Food additives such as colorants and flavors may be used at levels compliant with the latest revision of the Codex General Standard for Food Additives (CODEX Stan 192-1995).

C. Hygiene

The hygienic processing of lambanog shall conform with the appropriate sections of the FDA AO No. 153 s. 2004 "Revised Guidelines on Current Good Manufacturing Practices in Manufacturing, Packing, Repacking or Holding Food," and its future amendment and the Codex General Principles of Food Hygiene (CODEX CXC-1-1969 Rev. 2020).

D. Production and Process Control

1. The manufacture of lambanog should follow the general process flow as shown in Figure 1.

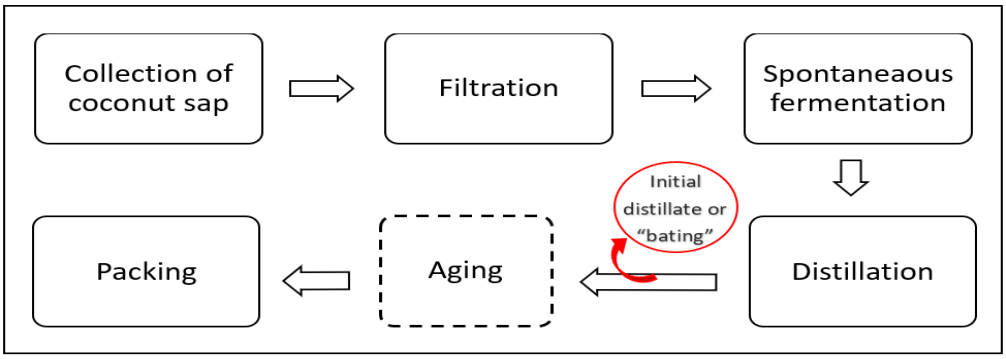

Figure 1. General process flow for lambanog manufacture

2. Coconut sap shall be collected in a clean smooth surfaced container and sufficiently covered to protect from possible contamination during sap collection and transport to distillation facility.

3. Upon receipt of coconut sap, it shall be checked and filtered with clean fine mesh cloth or strainer to remove filth and other physical contaminants.

4. Filtered coconut sap shall be placed in a clean container and covered appropriately to protect from contamination where it shall undergo natural or spontaneous fermentation for 24-72 hours at ambient temperature.

5. The naturally fermented coconut sap shall undergo distillation. There shall be a validated procedure to ensure that the initial distillate containing methanol (commonly called "bating") is excluded from the product lambanog. The succeeding distillate shall be the lambanog, also called "pure lambanog."

6. The food contact surfaces of the distillation equipment including pipes, fittings, heating/cooling tubes, connectors, and discharge outlet shall be made of stainless steel, smoothly welded, and maintained clean and sanitized.

7. The critical steps and control parameters during lambanog processing shall be identified, monitored, controlled and properly documented. These include, but not limited to: raw materials collection and preparation, time, temperature, % alcohol, sensory evaluation, and other physico-chemical test parameters.

8. Lambanog shall not be mixed with ethanol obtained from other sources, such as but not limited to: sugar cane, corn, sorghum, and wheat.

9. Lambanog may be subjected to aging prior to packing into final containers.

10. Lambanog shall not be added deliberately with methanol. Any methanol present should be derived only from the natural fermentation process and not purposely added.

11. There shall be enclosed and properly ventilated and marked areas designated for different stages of manufacture, such as, but not limited to: natural fermentation, distillation, mixing, aging (optional), packing, and storage. These areas shall be clean, orderly, and free from pests and any sources of contamination.

12. All containers and vessels for natural fermentation, distillation, aging, storage and transport shall be made of smooth surfaced, non-absorptive, and easily cleanable material.

F. Essential composition and quality factors

Lambanog shall conform with the following physico-chemical characteristics:

A. Pure Lambanog
   i. Alcohol content (expressed as ethanol) = 40-45 % v/v minimum
   ii. Methanol content (not deliberately added) = 0 ppm

B. Lambanog
   i. Alcohol content (expressed as ethanol) = 30 % v/v minimum
   ii. Methanol content (not deliberately added) = 0 ppm

G. Packaging

1. The primary packaging material of lambanog shall be made of food grade containers such as [glass] bottles and jars with tightly sealed caps.

2. For retail-sized containers, the use of primary packaging materials that were recycled from other beverage products shall not be allowed.

3. Primary packaging and caps shall be cleaned and sanitized prior to use.

4. Secondary packaging such as shrink wraps or cartons should be used for protection during storage and transport.

5. Packaging materials shall be durable enough to withstand the normal storage and distribution conditions.

6. Tamperproof seal, mark, or other similar materials should be used for added security against tampering or any deliberate contamination.

H. Product Naming and Labeling

1. Lambanog shall be labelled in accordance with the provisions of the FDA Administrative Order No. 2014-0030 entitled “Revised Rules and Regulations

Governing the Labeling of Prepackaged Food Products" and its future amendments.

2. The term "lambanog" shall be used as part of the product name only if it has been manufactured in accordance with the provisions of Section VI and VII of this Circular.

3. The term "pure lambanog" shall be used only if it is processed in accordance with this Circular and not mixed with any other ingredients like water, color, flavor, or any infusions.

4. The proof or % alcohol content shall be declared on the label. The declared % alcohol content on the label shall be obtained from the prescribed method of analysis for % ethyl alcohol in Section VII.J.2.

5. All ingredients (including food additives) used in the product shall be declared on the label under the list of ingredients in descending order.

5. Each lot or batch shall be properly identified to facilitate the traceability of the product.

6. Containers, cases or cartons shall be properly labeled to ensure traceability.

7. The phrase "Product of the Philippines" may be printed on the label depending on market requirement.

8. Lambanog shall be labelled in accordance with this Circular and applicable provisions of FDA AO No. 2014-0030 entitled Revised Rules and Regulations Governing the Labeling of Prepackaged Food Products and its future amendments.

I. Storage, transport and distribution

1. Lambanog shall be stored in designated cool, dry, and clean area, free from pests and sources of contamination. Extreme temperatures should be avoided to prevent product deterioration.

2. Transport and distribution facilities should protect the integrity of the product to ensure safety and quality.

3. Appropriate stock rotation system shall be applied, i.e. First-in, first-out system.

J. Methods of Sampling and Analysis

1. The sampling for lambanog should be in accordance with Codex General Guidelines on Sampling (CXS 50-2004).

2. The methods of analysis for % alcohol (expressed as ethanol) and ppm methanol content should be in accordance with AOAC 972.11 18th edition, 2005, Alcohol by % volume(v/v) (ethanol and methanol) in distilled liquors – Gas Chromatography Method or any updated version thereof.

3. For routine monitoring at the plant or manufacturer's level, the use of alcoholometer to determine the % alcohol may be allowed provided its equivalence with the prescribed Gas Chromatography Method has been established.

K. Inspection of Lambanog Manufacturers, Traders, and Distributors

1. All manufacturers, traders and distributors of lambanog shall be inspected by FDA prior to issuance of initial and major variation License to Operate (LTO). The LTO renewal and variation inspections shall be in accordance with the risk assessment of the FDA.

2. The actual processing of lambanog shall be observed during inspection to verify compliance with the recommended code of practice as a measure to prevent food poisoning incidents.

3. Batch manufacturing records and related documents shall be reviewed and verified by FDA during inspection to ensure integrity, safety, and quality of lambanog.

4. All documents related to manufacture, trade, and distribution (i.e., raw materials and ingredients sourcing and receiving, batch preparation, analysis, packaging, inspection, processing, lot/batch coding, storage, transport, and delivery, among others) of lambanog shall be made available during inspection for review of FDA. Failure to present requested documents shall be ground for non-issuance of initial/renewal/variation LTO, until the requested document is presented.

5. When necessary, samples of lambanog, pure lambanog, and other ingredients shall be collected for submission to the FDA Common Services Laboratory or accredited laboratories for verification of compliance to standard as provided in this Circular.

L. Application for FDA Authorizations

1. All lambanog and pure lambanog manufacturers, distributors, and traders shall obtain FDA License to Operate (LTO) and Certificate of product Registration (CPR) from the FDA CPR prior to distribution, selling, offer for sale, export, trading, advertising, and promotion, in accordance with applicable provisions of FDA AO No. 2024-0029 entitled Rules and Regulations on the Licensing of

Food Establishments and Registration of Processed Food, and Other Food Products, and For Other Purposes, and its amendments.

2. Application for initial CPR shall be supported by submission of Certificate of Analysis showing compliance to Section VII.F of this Circular, issued within 12 months from the date of CPR application conducted by a laboratory accredited by the FDA or Philippine Accreditation Bureau, indicating the method used for analysis and the limit of detection for the method used. The test method used for the analysis shall be in accordance with Section VII.J of this Circular.

3. Any change in the formulation of the product shall be applied for initial CPR.

VIII. PENALTY CLAUSE

Administrative penalties and sanctions shall be applied accordingly based on Implementing Rules and Regulations of Republic Act No. 9711 or the FDA Act of 2009 and Republic Act No. 10611 otherwise known as the Food Safety Act of 2013.

IX. SEPARABILITY CLAUSE

If any provision of this Circular is declared invalid or unenforceable, the validity and enforceability of the remaining portions or provisions shall remain in full force and effect.

X. TRANSITORY PROVISION

Twelve (12) months from date of effectivity, all applications for CPR for lambanog and pure lambanog shall conform with this Circular.

XI. EFFECTIVITY

This Circular shall take effect after fifteen (15) days following its publication in a newspaper of general circulation and upon filing of three (3) certified copies to the University of the Philippines Law Center.

DR. SAMUEL A. ZACATE
Director General