37 III. SCOPE

 This Administrative Order covers food establishments engaged in the manufacture and/or distribution, trade and/or repacking of *salabat* or instant ginger drink in the Philippines.

# IV. DEFINITION OF TERMS

Acceptable Quality Level (AQL) is the quality level that or the purpose of sampling inspection is the limit of satisfactory process average in a continuing series of lots.

**Caking** is a phenomenon by which amorphous food powders are transformed into a sticky undesirable material, resulting in loss of functionality and lowered quality.

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.

**Defective** means a unit of product that contains one or more defects with respect to the quality characteristic(s) under consideration.

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.

**Food** is any substance, whether processed or semi-processed or raw which is intended for human consumption and including beverages, chewing gum and any substance, which has been used as an ingredient on the manufacture, preparation or treatment of food.

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.

**Food Standard** is a regulatory guideline that defines the identity of a given food product (i.e. its name and the ingredients used for its preparation) and specifies the minimum quality factors and, when necessary, the required fill of container. It may also include specific labeling requirements other than or in addition to the labeling requirements generally applicable to all prepackaged foods.

**Ginger Extract** is the liquid expressed from ginger rhizomes by any appropriate extraction method

manufacture or preparation of a food and present in the final product in its original or 85 modified form. 86 87 Instant is a characteristic of a food prepared and formulated to a form that dissolves in 88 water or other liquids. 89 90 Label includes any tag, brand, mark, pictorial, or other descriptive matter, written printed, 91 marked, embossed or impressed on, or attached to a container of food. 92 93 Labeling means any written, printed or graphic matter (1) upon any article or any of its 94 container or wrappers or (2) accompanying the packaged food. 95 96 Lot is food produced during a period of time and under more or less the same 97 manufacturing conditions as indicated by a specific code. 98 99 Moisture content is the level of moisture held in a substance, stated as a percentage of the 100 wet or dry weight. 101 102 Packaging is the process of packing that is part of the production cycle applied to a bulk 103 product to obtain the finished product. Any material, including painted material, employed 104 in the packaging of a product including any outer packaging used for transportation of 105 shipment. Packaging materials are referred to as primary or secondary according to 106 whether or not they are intended to be in direct contact with the product. 107 108 Prepackaged means packaged or made up in advance in a container, ready for sale to the 109 consumer, or for catering purposes. 110 111 Processed Food shall refer to food that has been subjected to some degree of processing 112 (e.g. milling, drying, concentration and canning, etc.), which partially or completely change 113 the physico-chemical and/or sensory characteristics of the raw material. 114 115 116 Rhizome a subterranean stem, horizontally elongated which form roots at lower side of the 117 nodes and shoots on the upper side. 118 Spray Drying is the transformation of a fluid from a liquid state into a dried particulate 119 form by spraying the fluid into a hot drying medium. 120 121 Water Activity (aw) is the ratio of vapor pressure of the substance to the vapor pressure 122

of pure water at the same temperature.

V. GENERAL GUIDELINES

**Ingredient** is any substance including food additives, used as a component in the

84

123

124

125126

## **Processing Operations**

Prior to introduction to processing line, raw materials and ingredients should be inspected and sorted as required to remove unfit materials. Such operations should be carried out in a clean and sanitary manner. Only clean, sound materials shall be used in further processing. The production process should be supervised by personnel with adequate technical training and experience.

Below (Figure 1) illustrates the general process flow of salabat production.

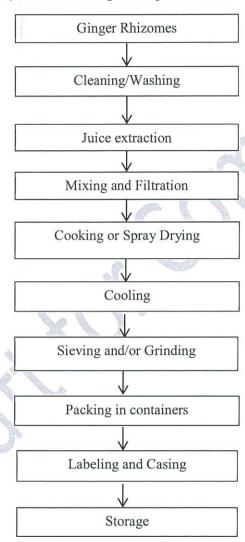


Figure 1. General process for salabat production

Appropriate HACCP plan may be developed for *salabat*. Prior to the development of HACCP plan, establishments shall have established, documented and implemented prerequisite programs (PRPs) based on the FDA's A.O. No. 153 s. 2004 (cGMP) and

Hygiene Control. Guidelines for the Application of the Hazard Analysis Critical Control Point (HACCP) System (CAC/GL 18-1993) present the recommended sequence and document formats for the application of the HACCP systems.

## 1. Preparation of raw materials and ingredients

# a. Raw Materials (ginger rhizomes)

 post-harvest defects, i.e. sprouting, softening, mold growth, excessive bruising, should be rejected. Moreover, those that are emitting objectionable odors shall likewise be rejected.

Fresh and mature ginger rhizomes that pass inspection but will not be processed immediately should be packed in clean plastic trays, nets or sacks, are to be stacked on pallets and properly stored in a clean and dry area, protected from moisture, heat, dirt, and other potential source of foreign matter or contaminants like pests and rodents.

Ginger rhizomes are physically examined and inspected upon receipt. Those that exhibit

## b. Other Ingredients

b.1 Dry ingredients in powdered or granulated forms, i.e. sugar, bulking agents, sweetener, and food colors, are separately weighed, then mixed together and packed in appropriate container.

b.2 Liquid ingredients, like water are measured by weight or volume.

## 2. Cleaning/Washing

 a. Ginger rhizomes are cleaned and washed with water using appropriate plastic brush or pressurized water jets to remove soil and other extraneous matters. Prior to washing, heavily soiled rhizomes maybe soaked in water to loosen the dirt.

b. The washed rhizomes are sanitized by soaking with chlorinated water (150-200 ppm residual chlorine) for at least 1 minute then thoroughly rinsed with tap water. A final rinse of chlorinated water containing 50 ppm residual chlorine is recommended.

c. Those ginger that have parts showing some bruising, discoloration or softening should be properly trimmed off using clean sharp knives.

d. The cleaned rhizomes are placed in appropriate perforated trays to drain off excess water.

## 3. Juice Extraction

The juice may be extracted manually by hand or by mechanical means using appropriate juice extracting equipment.

a. Manual extraction. The rhizomes are chopped or cut into pieces using sharp knives or any appropriate grinding/mincing machine, transferred in a filter cloth and squeezed to express the ginger juice. Water may be added to facilitate the extraction process.

211 212 213 214 215	b. Mechanical extraction. Whole or pre-cut rhizomes are passed through an appropriate mechanical press, like screw press or hydraulic press to extract the juice. Customized ginger extraction equipment may be equipped with a grinder or chopper and a screw press. The remaining juice in the residue may be recovered by the addition of water then passed again to the mechanical press or extractor.
216 217	The resulting ginger extract is filtered using a filter cloth or any filtering device to remove any suspended particles.
218	4. Mixing and Filtration
219	Accurately weighed sugar and/or other ingredients are added and thoroughly mixed to the
220	ginger extract. The mixture is then filtered or strained using appropriate devices, like nylon
221	nets, plastic or stainless steel filters or strainers. This will remove lumps or any undissolved
222	particles and other foreign matters.
223	
224	5. Cooking or Spray Drying
225	The mixture may undergo manual cooking or spray drying.
226	a. Cooking
227	The mixture is boiled with continuous mixing in an appropriate cooking vessel until sugar
228	crystallization occurs. Heat should be regulated to prevent over boiling and to avoid
229	scorching which will affect the quality of the final product.
230	Further air drying may be done to reduce the moisture content.
231	b. Spray Drying
232	The mixture is fed to a suitable spray dryer, resulting in the formation of powder or
233	granules.
234	If a spray dyer is used, sieving and/or grinding may no longer be necessary.
235	6. Cooling
236	The granules/powder are cooled to a room temperature. Continuous stirring during cooling
237	is recommended to prevent lumping or caking.
238	7. Sieving and/or grinding

The granules may be sieved through nylon net or metal screen of appropriate mesh size to separate the lumps. The lumps are also ground to a fine powder, which may be sieved if necessary.

## 8. Packing in containers

Salabat is packed in packaging materials with uniform net weight and are properly sealed. The packing process should be done under conditions that will prevent the introduction of contamination into the product.

Glass and plastic jars should be well filled with the product, which should occupy not less than 90% (minus any necessary head space according to good manufacturing practices).

Tamper-evident seals are highly recommended as added product security feature for glass and plastic jars. These include plastic shrink cap seals fitted to the jar caps and the use of an induction sealing device that heats and bonds the aluminum or plastic seal to the container rim.

## a. Glass jars

In preparing glass jars, these are manually cleaned by washing with appropriate detergent and rinsed with clean water. A final rinse of water containing appropriate sanitizer is recommended. The jars are dried upside down on racks or trays. For mechanical washing, jars are in an inverted position by suitable cleaning equipment using hot water jets or sprays, which usually makes the bottles dry after washing.

Inspection is particularly important in the case of glass jars which might possibly contain fragments of glass and glass defects which are difficult to see.

## b. Plastic jars

Only unused appropriate plastic jars that do not impart objectionable odor and flavor to the product should be used. They should be cleaned as those of glass jars and should be inspected for punctures, leakage and other abnormalities.

## c. Flexible containers

These shall be free from pinholes, scratches, blisters and gross closure defects that may affect the integrity of the package. The seal area must be free from contamination and wrinkles and shall provide a hermetic seal upon closure.

Flexible containers, including single serve packs should be filled as full as commercially practicable. The sealing surface should be free from defects, damage, or adhering ginger powder particles

## 9. Coding of Packed Products

Coding of packed products in sealed containers should be made with indelible markers with information details of production, date, batch code, product code, the product line in which the product was packed and other information necessary for product traceability. Whenever the container does not permit the code to be embossed or inked, the label shall be legibly perforated or otherwise marked, and securely affixed to the product package.

## 10. Post - process Handling

Care must be exercised in the handling and distribution of retail or bulk packaged products or as to prevent mechanical damage and spoilage to the products.

Storage and transport conditions of the finished products shall be such that the integrity of the product container is protected, and the safety and quality of the products are not adversely affected.

Cases and cartons must be thoroughly dry. They must be of proper size so that the containers fit properly and are not subject to damage from movement within the case. They must be strong enough to withstand normal transport and distribution conditions.

Extreme temperatures that are higher than 36°C, during storage and transport of the product must be avoided to prevent product deterioration.

#### VI. SPECIFIC GUIDELINES

## 1. Ingredients

# 1.1 Basic Ingredients

1. **Ginger Rhizomes** – shall be any acceptable ginger variety (*Zingiber* spp.) which are sound, wholesome, mature, firm with sufficiently dry shiny skin and fit for human consumption and shall meet the PNS Standards for Ginger (PNS/BAFPS No. 50:2007 – ICS 65.020.20) and/or applicable standards. Varieties of ginger to be used may include, but not limited to those listed in the table below:

Table 1. Varieties of ginger grown in the Philippines

Varieties	Size of rhizomes	Pungency	
1. Native	Small	Strongly pungent	
2. Taiwan	Medium	Moderately pungent	
3. Hawaiian	Large	Less pungent	

Source: Philippine National Standards for Ginger (PNS/BAFPS No. 50: 2007)

 2. **Sugar** – shall conform to the Philippine National Standards (PNS/BAFPS 82:2010) for sugars.

## 1.2 Optional Ingredients

These ingredients shall be of food grade quality and conform to all applicable standards, which may include other plant materials, other sweetening agents, fruit and vegetable juices, and, food flavors.

#### 2. Food Additives

Food additives when used shall be in accordance with the regulations prescribed by Food and Drug Administration (FDA) B.C. No. 016, s. 2006: Updated List of Food Additives) and the Codex General Standard for Food Additives (GSFA) Codex Stan 192-1995; 2013 Revision), and/or their future amendments. The food additives listed in Table 1 may be used for the manufacture of *salabat*.

Table 2. Food Additives for *salabat* in accordance with the regulations of the FDA and the Codex General Standard for Food Additives (GSFA)

Functional Class	Food Additives No.	Food Additive	Maximum Use Level
	Codex INS No.504(i)	Magnesium carbonate**	15000 mg/kg
	Codex INS No.551	Silicon dioxide, amorphous**	15000 mg/kg
Anti-caking	Codex INS No.552	Calcium silicate	15000 mg/kg
agent	Codex INS No.553 (i)	Magnesium silicate, synthetic	15000 mg/kg
	Codex INS No.170 (i)	Calcium carbonate	GMP
	Codex INS No.500 (i)	Sodium hydrogen carbonate*	GMP
	Codex INS No.341(iii)	Tricalcium phosphate**	6600 mg/kg*/300mg/kg*

<sup>\*</sup> Food Category System No. 14.1.5. Coffee, coffee substitutes, tea, herbal infusions, and other hot cereal and grain beverages, excluding cocoa (GFSA, 2013)

All others not included in the above list shall be allowed as carry-over, provided they are approved by the B.C. No. 2006-016 and its future updates, revisions and/or amendments, and shall be in accordance to the "Principle relating to the Carry-over of Food Additives into Foods" of the GSFA CODEX STAN 192-1995.

#### 3. Quality and Safety Criteria

Salabat shall conform to the following physico-chemical, microbiological and sensory properties:

## 3.1 Physico-chemical Properties

- a. Moisture content, % wet basis, maximum
- b. Water activity (a<sub>W</sub>) at 25°C, maximum

2.0 0.600

0.6

<sup>\*\*</sup> Based on the Food Category System No. 11.1.1. Powdered sugar, powdered dextrose (GFSA, 2013)

3.2 Microbiological Properties

Test/Microorganism	n	С	m	M
Coliform, cfu/g	5	3	10 <sup>2</sup>	$10^{3}$
SPC/APC, cfu/g	5	2	$3 \times 10^3$	$10^{3}$

- n Number of sample units selected from a lot of food to be examined
- m Acceptable level of microorganisms determined by a specified method; the values are generally based on levels that are achievable under GMP
- M Level which when exceeded in one or more samples would cause the lot to be rejected as this indicates potential health hazard or imminent spoilage
- c Maximum allowable number of defective or marginally acceptable samples

# 3.3 Sensory Properties

- a. It shall have a light to dark brown color
- b. It may have a sweet taste
- c. It shall have a pungent flavor and aroma, characteristic of ginger
- **3.4** To the extent possible in good manufacturing practices, the product shall be free from any objectionable matter and parasites harmful to humans.
- 3.5 The product should not contain any substances originating from microorganisms in amounts which may represent a hazard to health.
- **3.6** The product shall be free from chemical contaminants in amounts which may pose potential harm to consumer health.
- 3.7 The product shall comply with the requirements set forth by the Food and Drug Administration (FDA) and the Codex Alimentarius Commission on Pesticide Residues and Food Additives.

#### 4. Defects

A sample unit shall be considered defective when it exhibits any of the defects as defined and described in the following subsections.

#### 4.1 Types of Defects

#### 4.1.1 Foreign Matters

The presence in the sample unit of any matter which has not been derived from the components or constituents of ingredients used in the product and listed in

400 401 402

403 404

405 406

407 408 409

410 411 412

413 414

415 416

417 418

419 420

421 422 423

424 425

426 427

429 430

428

432 433

subsection 1.1.1; and, does not pose a threat to human health and can be recognized without magnification or is present at a level determined by any method including magnification that indicates non-compliance with good manufacturing and sanitation practices.

## 4.1.2 Appearance

- Caking or lumping
- Visible mold growth

#### 4.1.3 Odor and Flavor

Objectionable odors and/or flavors indicative of decomposition or deterioration

#### 4.1.4 Classification of Defectives

A container whose contents exhibit any of the defects described in subsections 4.1.1 to 4.1.3 and in which the number of defects observed per unit lot exceeds the acceptance number prescribed in the appropriate sampling plan (Section 9.1) shall be considered as "defective".

#### 5. Lot Acceptance

A lot shall be considered acceptable when it complies with the applicable Quality and Safety Criteria as prescribed in Sub-section 3 and the number of "defectives", as defined in Sub-section 4.1.4, does not exceed the acceptance number prescribed in the appropriate sampling plan (Section 9.1).

## 6. Contaminants

The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995).

## 7. Hygiene

It is recommended that the product covered by the provisions of this Order be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1–1969, Rev 4 (2003) and/or the FDA A.O. No. 153 s. 2004 - Guidelines, Current Good Manufacturing Practices in Manufacturing, Packing, Repacking or Holding Food, and/or their future amendments, covering the plant facilities and operations requirement including the construction and layout of processing plant, hygienic facilities, equipment, utensils and working surfaces.

#### 8. Packaging and Labeling 441 442 8.1 The product shall be packed in appropriate containers that will maintain their integrity 443 during storage and transport. 444 8.2 Labeling of retail packages/container - Each retail container shall be labeled and 445 marked with the information in accordance with FDA Administrative Order 2014-446 0030 its future updates, revisions and/or amendments. 447 448 9. Method of Sampling and Analysis 449 450 9.1. Method of Sampling 451 452 Sampling shall be in accordance with the FAO/WHO Codex Alimentarius Sampling 453 Plans for Prepackaged Foods (CAC/RM 42-1969), Codex Alimentarius Volume 13, 454 1994, and its series of subsequent amendments. 455 456 9.2. Recommended Methods of Analysis 457 458 Determination of Moisture Content, according to the AOAC Official Methods 459 of Analysis, 18th ed., 2005 Method No. 979.12 460 Water Activity Measurement, according to AOAC Official Methods of Analysis, 461 18th ed., 2005 Method No. 978.18 462 Enumeration of Standard Plate Count (SPC)/Aerobic Plate Count (APC), 463 according to the USFDA Bacteriological Analytical Method (BAM), 2001 464 Enumeration of Coliform Count according to the USFDA Bacteriological 465 Analytical Method (BAM), 2002 466 Determination of % Fill of the Container, according to the Food and Agriculture 467 Organization of the United Nations (FAO) Manuals of Food Quality Control: 8. 468 Food analysis: quality, adulteration, and tests of identity, 1986 469 470 TRANSITORY PROVISION 471 VII. 472 Manufacturers, importers, traders, wholesalers and distributors of instant ginger drinks 473 distributed in the Philippines are given a maximum of two (2) years transition period for 474 products with valid Certificate of Product Registration (CPR) starting from the effectivity 475 date of this order. 476 477 VIII. REPEALING CLAUSE 478 479 All issuances inconsistent or contrary to this order are hereby rescinded or modified 480

accordingly.

481 482

440

## IX. EFFECTIVITY

This Order shall be effective fifteen (15) days after filing at the UP Law Center and publication in a newspaper of general circulation.

FRANCISCO T. DUQUE III, MD, MSc Secretary of Health

573	
574	I ICTE OF ANNIEWED
575	LIST OF ANNEXES
576 577	ANNEX A – RECORD KEEPING
578	ANNEX B - LABORATORY CONTROL PROCEDURES
579	
580	
581	
582	
583	
584	
585	
586	
587	
588	
589	
590	
591	
592 593	
594	
595	
596	
597	
598	
599	
600	
601	
602	
603	
604	
605	
606 607	
608	
609	
610	
611	
612	
613	
614	
615	

616	ANNEX A
617	AINIEAA
618	
619	RECORD KEEPING
620	RECORD REEL ING
621	Permanent and legible dated records of production batches, code marks and other pertinent
622	details shall be kept concerning each load. Such records are essential as a check on
623	processing operations.
624	processing operations.
625	Written records of all package examinations shall specify the lot code and the date of package
626	inspections, the measurements obtained and all the corrective actions taken.
627	hispections, the measurements obtained and air the corrective actions taken.
628	Records identifying initial distribution of the finished product to facilitate, if necessary, the
629	segregation of specific food lots that may have been contaminated or otherwise unfit for
630	intended use, shall be kept and maintained.
631	intended use, shan oe kept and maintained.
632	All process deviations involving failure to satisfy the minimum requirements of the process
633	shall be recorded detailing those deviations and the actions taken.
634	Shall be recorded detailing those de rations and the details taken.
635	
636	
637	
638	
639	
640	
641	
642	
643	
644	
645	
646	
647	
648	
649	
650	
651	
652	
653	
654	
655	
656	
657	
658	
659	
660	

## ANNEX B LABORATORY CONTROL PROCEDURES Each food processing establishment shall have access to laboratory analyses and control of both the processes used and the finished products. All food ingredients and food products declared unfit for human consumption by the laboratory shall be rejected. Representative samples for each lot or batch shall be randomly taken to assess the safety and quality of the product. If capable of putting up a microbiological laboratory, it shall be separated from the processing area. No pathogens shall be handled within the premises of the manufacturing plant. Laboratory procedures for quality control of the processes and the product must follow recognized or standard methods for easy interpretation and recognition of the results.