

DRAFT FOR COMMENTS
as of 23 May 2017

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ADMINISTRATIVE ORDER

No. _____

**SUBJECT: REVISED REGULATORY GUIDELINES CONCERNING FOOD
ADDITIVES, AND PROCESSING AIDS**

I. RATIONALE

The 1987 Philippine Constitution declares under Article II, Section 15 to protect and promote the right to health of the people and instill health consciousness among them.

Republic Act 9711 or the Food and Drug Act of 2009, Section 3 declares that it is a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help 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. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capacity with regards to inspection, licensing and monitoring of establishments and the registration and monitoring of health products.

The Implementing Rules and Regulations of RA 9711 further states that Food and Drug Administration (FDA) is tasked to establish standards and quality measures for food and adopt measures to ensure quality and safe supply of food in the country.

Furthermore, Republic Act 10611 or the Food Safety Act of 2013, Section 9 states that the Department of Health or Food and Drug Administration (DOH-FDA) shall set the mandatory food safety standards and that Standards shall be established on 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), where these exist and are applicable.

Administrative Order (AO) No. 88-A s. 1984 and Bureau Circular (BC) No. 2006-0016 need updating to meet the current and emerging trends in food manufacturing. In view of the above and consistent with the requirements of the World Trade Organization on Technical Barriers to Trade in overcoming technical obstacles in world markets, these guidelines aim to update and put together the list of permitted food additives and prescribe standards for their use and application in food distributed in the Philippines whether locally manufactured or imported.

II. OBJECTIVES

These guidelines are meant to achieve the following objectives:

1. To establish guidelines prescribing:
 - a. The condition under which a food additive may be safely used; and
 - b. The maximum quantity food of additive which may be used or permitted to remain in or on such food;
2. To meet the demand for specific guidance on the use of food additives and ensure food safety, with the increasing awareness for safe food;
3. To harmonize local food regulation with international food control laws, rules and regulations and to ensure market access opportunities; and
4. To update the list of permitted food additives and prescribe guidelines for their use and application in food distributed in the Philippines.
5. To provide guidelines in the approval of proposed new Food Additives.

III. SCOPE

This Order shall apply to all manufacturers, importers, exporters, traders, wholesalers and distributors of food products.

IV. DEFINITION OF TERMS

As used in this document, the terms below shall be defined as follows:

1. **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.¹
2. **Flavoring Substances** refers to flavor preparations composed of substances derived from plant/ animal products and/or chemically synthesized substances whose significant function in food is flavoring rather than nutritional.²

¹ Codex Alimentarius Procedural Manual.

² Administrative Order 88-B s. 1984 (Rules and Regulations Governing the Labelling of Prepackaged Food Products Distributed in the Philippines)

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- 3. **Processing Aid** means any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.¹
- 4. **Enzymes** are proteins capable of catalyzing biochemical processes, acting on specific substrates and in relative low amounts.
- 5. **Artificial/synthetic Food Colors** are derived from petroleum distillates or coal tars and are essentially synthetic chemicals created in laboratories.
- 6. **Natural Food Colors** are derived from plant, animal or mineral sources which have been processed in some way.
- 7. **Acceptable Daily Intake** or **ADI** refers to an estimate by the JECFA of the amount of a food additive, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk.³
- 8. **Maximum Use Level** of an additive is the highest concentration of the additive determined to be functionally effective in a food or food category and agreed to be safe by the Codex Alimentarius Commission. It is generally expressed as mg additive/kg of food. The maximum use level will not usually correspond to the optimum, recommended, or typical level of use. Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.
- 9. **GMP** refers to Good Manufacturing Practice
- 10. **FAO** refers to Food and Agriculture Organization
- 11. **FCC** refers to Food Chemicals Codex
- 12. **GSFA** refers to General Standard for Food Additives
- 13. **CCFA** refers to Codex Committee on Food Additives
- 14. **IOFI** refers to International Organization for the Flavor Industry.
- 15. **JECFA** refers to Joint FAO/WHO Experts Committee on Food Additives.
- 16. **WHO** refers to World Health Organization.
- 17. **US FEMA** refers to United States Flavor Extracts Manufacturers Association.

¹ Codex Alimentarius Procedural Manual.

² Administrative Order 88-B s. 1984(Rules and Regulations Governing the Labelling of Prepackaged Food Products Distributed in the Philippines)

V. GENERAL GUIDELINES

A. General Principles for the Use of Food Additives

The use of food additives in conformance with this Order requires adherence to all the principles set forth in the following provision:

1. Food Additive Safety ó The safety of food additives must be guided by the following principles:
 - a. Only those food additives which present no appreciable risk to health of the consumer at the proposed level of use for specified food category as assessed by JECFA, present no appreciable health risk to consumers at the use levels proposed.
 - b. The inclusion of a food additive shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA and its probable daily intake from all food sources. Where the food additive is to be used in food eaten by special groups of consumers (e.g. diabetics, those on special medical diets, sick individuals on formulated liquid diets) account shall be taken of the probable daily intake of the food additive by those consumers.
 - c. The quantity of an additive added to food is at or below the maximum use level and is the lowest level necessary to achieve the intended technical effect. The maximum use level may be based on the application of procedures as recommended by JECFA, the intake assessment of Codex members or upon request by the CCFA to JECFA for an independent evaluation of national intake assessment.

2. Justification for the Use of Additives

The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions (see Annex A for the Food Additives Functional Classes, Definitions and Technological Purposes) and the needs set out below from (a) to (d), and only where these objectives cannot be achieved by other means that are economically and technologically practicable:

- a. To preserve the nutritional quality of the food; an intentional reduction in the nutritional quality of a food would be justified in the circumstances dealt with in (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;

³ Principles for the Safety Assessment of Food Additives and Contaminants in Food, World Health Organization, (WHO Environmental Health Criteria, No. 70), p. 111 (1987). For the purposes of this Standard, the phrase "without appreciable health risk" means that there is a reasonable certainty of no harm to consumers if an additive is used at levels that do not exceed those in this Standard. The provisions of this Standard do not sanction the use of an additive in a manner that would adversely affect consumer health.

- b. To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
- c. To enhance the keeping quality or stability of a food or to improve its sensory properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer; and
- d. To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food, provided that the additive is not used to disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices or techniques during the course of any of these activities.

3. The Permitted Levels of Use of Food Additives

The primary objective of establishing permitted levels of use of food additives in various food groups is to ensure that the intake of additives does not exceed the acceptable daily intake (ADI).

The maximum use level of food additives are based in part on FDA commodity standards, Codex and upon request of interested parties after subjecting their proposed maximum use level to internationally accepted scientific methods, ensuring that the same shall not exceed prescribed ADI.

4. Good Manufacturing Practice (GMP)

All food additives covered by these guidelines shall be used under conditions of good manufacturing practice, which include the following:

- a. The quantity of at the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect; unless specifically limited by these guidelines for or to a specific application;
- b. The quantity of the additive that becomes a component of food as a result of its use in the manufacturing, processing or packaging of a food and which is not intended to accomplish any physical, or other technical effect in the food itself, is reduced to the extent reasonably possible; and,
- c. The food additive is of food grade quality and is prepared and handled in the same way as a food ingredient.

5. Specifications for the Identity and Purity of Food Additives

Food additives used in accordance with these guidelinesshould be of appropriate food grade quality and should at all times conform with the applicable Specifications of Identity and Purity recommended by the Codex Alimentarius Commission or, in the absence of such specifications, with appropriate specifications developed by responsible national or international bodies. In terms of safety, food grade quality is achieved by conformance of additives to their specifications as a whole (not merely with individual criteria) and through their production, storage, transport, and handling in accordance with GMP.

B. Carry-Over of Food Additives into Foods

1. Conditions Applying to Carry-Over of Food Additives from Ingredients and Raw Materials into Foods

Other than by direct addition, an additive maybe present in food as a result of carry-over from a raw material or ingredient used to produce the food, provided that:

- a. The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to these guidelines;
- b. The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in these guidelines;
- c. The food into which the additive is carried over does not contain the additive in greater quantity than would be introduced by the use of raw materials, or ingredients under proper technological conditions or manufacturing practice, consistent with these guidelines.

2. Special Conditions Applying to the Use of Food Additives not Directly Authorized in Food Ingredients and Raw Materials

An additive may be used in or added to a raw material or other ingredient if the raw material or ingredient is used exclusively in the preparation of a food that is in conformity with these guidelines, provided that any maximum level applying to the food is not exceeded.

3. Foods for Which the Carry-Over of Food Additives is Unacceptable

Carry-over of a food additive from a raw material or ingredient is unacceptable for foods belonging to the following food categories; unless a food additive provision in the specified category is listed in these guidelines:

- a. 13.1 ó Infant formula, follow-up formula, and formula for special medical purposes for infants
- b. 13.2 ó Complementary foods for infants and young children.

C. Food Category System

The food category system is a tool for assigning food additives uses outlined in these guidelines and applies to all food stuffs. The food category system applies to all foodstuffs.

The food category descriptors are not to be treated as legal product designations or intended, in any way, for labelling purposes.

The food category system is based on the following principles:

1. The food category system is hierarchical, meaning that when an additive is recognized for use in a general category, it is recognized for use in all its sub-categories, unless otherwise stated.

Similarly, when an additive is recognized for use in a sub-category, its use is recognized in any further sub-categories or individual foodstuffs mentioned in a sub-category.

2. The food category system is based on product descriptors of foodstuffs as marketed, unless otherwise stated.
3. The food category systems take into consideration the carry-over principle. By doing so, the food category system does not need to specifically mention compound foodstuffs (e.g. prepared meals, such as pizza, because they may contain, *pro rata*, all the additives endorsed for use in their components), unless the compound foodstuff needs an additive that is not endorsed for use in any of its components.
4. The food category system is used to simplify the reporting of food additive uses for assembling and constructing these guidelines.

D. Provision for Mislabeled or Adulterated Food

Any food additive used not in accordance with the requirements of these guidelines shall be deemed to be an act which results in the food being misbranded or adulterated, as the case may be.

For violations under these guidelines, the sanctions provided under RA 9711 and its Implementing Rules and Regulations, and other allied laws and regulations may be imposed as far as applicable and after due notice and summary hearing.

E. Adoption of the Latest Codex General Standard for Food Additives (GSFA)

The latest Codex General Standard for Food Additives (GSFA), and its future revisions/ amendments/ updates, shall be adopted automatically.

F. Request / Proposal for New and/or Revision of Food Additive Provisions in the GSFA

Request or proposals for new and/or revision of Food Additives provisions in the GSFA shall follow the Codex "Procedure for Consideration for the Entry and Review of Food Additives Provisions in the GSFA" and shall accomplish the form in Annex B of this Order.

VII. FLAVORING SUBSTANCES

If food additives are to be used as flavoring substances, they shall abide by the Codex Guidelines for the Use of Flavorings (CAC/GL 66-2008) or as listed as safe in US FEMA and/or IOFI.

VIII. PROCESSING AIDS

The use of processing aids shall be guided by at least any one of the following latest revision: Food Chemicals Codex, USFDA CFR Title 21, the latest issuance of Codex Standard on Inventory of Processing Aids (CXA003e or CAC/MISC 3) and the latest issuance of Guidelines on Substances used as Processing Aids (CXG 075e/ CAC/GL 75-2010). For enzymes not listed in the Codex Inventory of Processing Aids, there should be certification from competent authority of country of origin.

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452 **X. TRANSITORY PROVISION**

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454 Manufacturers, importers, exporters, traders, wholesalers and distributors of processed

455 food products distributed in the Philippines are given a maximum of five (5) years

456 transition period for products with valid Certificate of Product Registration (CPR)

457 starting from the effectivity date of this order to phase out existing stocks and labels,

458 also to reformulate the product(s) to meet the standard specification for the food

459 additive.

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462 **XI. FINAL PROVISIONS**

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464 **A. Separability Clause**

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466 If any provision/s in this Order, or application of such provision to any

467 circumstances, is held invalid, the remainder of its provisions shall not be affected

468 thereby.

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471 **B. Repealing Clause**

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473 This Order repeals AO 88-A. s. 1984, BC 2006-0016, and other administrative

474 order, rules and regulations, and administrative issuances or parts thereof that is/are

475 inconsistent with its provisions.

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477 **C. Effectivity Clause**

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479 This Order shall take effect 15 days after its publication in an official gazette or in a

480 newspaper of general circulation and filing in the University of the Philippines Law

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486 **PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II**

487 Secretary of Health

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Keywords	Food Additives, Processing Aids
Related issuances, laws, directives	Administrative Order (AO) 88-A s. 1984 Bureau Circular (BC) 2006-0016 Administrative Order (AO) 103-A s. 1984 Administrative Order (AO) 112 s. 1985 Administrative Order (AO) 122 s. 1970

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500 ⁴ All Codex adopted new levels of specific food additives, additional food categories under each food additives and/ or other new food

501 additives included shall be adopted by FDA.

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LIST OF ANNEXES

- ANNEX A ó Food Additives Functional Classes, Definitions and Technological Purposes
- ANNEX B ó Form for the Submission of Proposals for New and/or Revision of Adopted Food Additive Provisions in the GSFA
- ANNEX C óList of Repealed DOH/ FDA Issuances

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ANNEX A

FOOD ADDITIVES FUNCTIONAL CLASSES,
DEFINITIONS AND TECHNOLOGICAL PURPOSES

TABLE 1: FOOD ADDITIVES FUNCTIONAL CLASSES, DEFINITIONS
AND TECHNOLOGICAL PURPOSES

Functional Classes	Definition	Technological Purpose
1. Acidity regulator	A food additive, which controls the acidity or alkalinity of a food.	Acidity regulator, acid, acidifier, alkali, base, buffer, buffering agent, pH adjusting agent
2. Anticaking agent	A food additive, which reduces the tendency of components of food to adhere to one another.	Anticaking agent, anti-stick agent, drying agent, dusting agent
3. Antifoaming agent	A food additive, which prevents or reduces foaming.	Antifoaming agent, defoaming agent
4. Antioxidant	A food additive, which prolongs the shelf-life of foods by protecting against deterioration caused by oxidation.	Antioxidant, antioxidant synergist, anti-browning agent
5. Bleaching agent	A food additive (non-flour use) used to decolorize food. Bleaching agents do not include pigments.	Bleaching agent
6. Bulking agent	A food additive, which contributes to the bulk of a food without contributing significantly to its available energy value.	Bulking agent, filler
7. Carbonating agent	A food additive used to provide carbonation in a food.	Carbonating agent
8. Carrier	A food additive used to dissolve, dilute, disperse or otherwise physically modify a food additive or nutrient without altering its function (and without exerting any technological effect itself) in order to facilitate its handling, application or use of the food additive or nutrient.	Carrier, carrier solvent, nutrient carrier, diluent for other food additives, encapsulating agent
9. Color	A food additive, which adds or restores color in a food.	Color, decorative pigment, surface colorant
10. Color retention agent	A food additive, which stabilizes, retains or intensifies the color of a food.	Color retention agent, color fixative, color stabilizer, color adjunct
11. Emulsifier	A food additive, which forms or maintains a uniform emulsion of two or more phases in a food.	Emulsifier, plasticizer, dispersing agent, surface active agent, crystallization inhibitor, density adjustment agent (flavoring oils in beverages), suspension agent, clouding agent
12. Emulsifying salt	A food additive, which, in the manufacture of processed food, rearranges proteins in order to prevent fat separation.	Emulsifying salt, melding salt
13. Firming agent	A food additive, which makes or keeps tissues of fruit or vegetables firm and crisp, or interacts with gelling agents to produce or strengthen a gel.	Firming agent

Functional Classes	Definition	Technological Purpose
14. Flavor enhancer	A food additive, which enhances the existing taste and/or odor of a food.	Flavor enhancer, flavor synergist
15. Flour treatment agent	A food additive, which is added to flour or dough to improve its baking quality or color.	Flour treatment agent, flour bleaching agent, flour improver, dough conditioner, dough strengthening agent
16. Foaming agent	A food additive, which makes it possible to form or maintain a uniform dispersion of a gaseous phase in a liquid or solid food.	Foaming agent, whipping agent, aerating agent
17. Gelling agent	A food additive, which gives a food texture through formation of a gel.	Gelling agent
18. Glazing agent	A food additive, which when applied to the external surface of a food, imparts a shiny appearance or provides a protective coating.	Glazing agent, sealing agent, coating agent, surface-finishing agent, polishing agent, film-forming agent
19. Humectant	A food additive, which prevents food from drying out by counteracting the effect of a dry atmosphere.	Humectant, moisture-retention agent, wetting agent
20. Packaging gas	A food additive gas, which is introduced into a container before, during or after filling with food with the intention to protect the food, for example, from oxidation or spoilage.	Packaging gas
21. Preservative	A food additive, which prolongs the shelf-life of a food by protecting against deterioration caused by micro-organisms.	Preservative, antimicrobial preservative, antimycotic agent, bacteriophage control agent, fungistatic agent, anti-mold and anti-rope agent, antimicrobial synergist
22. Propellant	A food additive gas, which expels a food from a container.	Propellant
23. Raising agent	A food additive or a combination of food additives, which liberate(s) gas and thereby increase(s) the volume of a dough or batter.	Raising agent
24. Sequestrant	A food additive, which controls the availability of a cation.	Sequestrant
25. Stabilizer	A food additive, which makes it possible to maintain a uniform dispersion of two or more components.	Stabilizer, foam stabilizer, colloidal stabilizer, emulsion stabilizer
26. Sweetener	A food additive (other than a mono- or disaccharide sugar), which imparts a sweet taste to a food.	Sweetener, intense sweetener, bulk sweetener

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ANNEX B

FORM FOR THE SUBMISSION OF PROPOSALS FOR NEW AND/OR REVISION
OF ADOPTED FOOD ADDITIVE PROVISIONS IN THE GSFA

In completing this form, only brief information is required. However, responsive information is required for each field. The form may be retyped if more space is needed under any one heading provided that the general format is maintained. A separate table should be completed for each food additive.

THE PROPOSAL IS SUBMITTED BY:			
IDENTITY OF THE FOOD ADDITIVE:			
Name of the Additive:			
As listed in Class Names and the International Numbering System (INS) – CAC/GL 36-1989			
INS NUMBER			
Functional Class		The proposal for:	
As listed Class Names and the International Numbering System (INS) - CAC/GL 36-1989		<input type="checkbox"/> a new revision; or <input type="checkbox"/> revising an existing provision; or <input type="checkbox"/> use and use levels of tocopherols (INS 307a, b, c) as antioxidant in FC 01.3.1 <input type="checkbox"/> Condensed milk (plain)); or <input type="checkbox"/> use and use levels of propylene glycol alginate (INS 405) and sucrose esters of fatty acids (INS 473) as emulsifier in FC 05.1.4 <input type="checkbox"/> Cocoa and chocolate products.	
Food Category No. (²)	Food Category Name (²)	Maximum Use Level (³)	Comments (⁴)
Is the proposal related to a FC with corresponding commodity standards? (If yes indicate the relevant FC)			
Is the proposal also intended to revise the products covered by the commodity standards (If yes indicate the relevant commodity standards)			
EVALUATION BY JECFA:			
Evaluation by JECFA			
Reference to the JECFA evaluation (including year and JECFA session of evaluation; full ADI (numerical or “not specified”); specifications monograph)			
JUSTIFICATION:			
Justification for use and technological need			
Supporting information based on the criteria in Section 3.2 of the Preamble of the General Standard for Food Additives (i.e. has an advantage, does not present an appreciable health risk, serves a technological function).			

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Safe use of additive: Dietary intake assessment <i>(as appropriate)</i>	Table 3 additive: <input type="checkbox"/> Yes <input type="checkbox"/> No (Please provide information on dietary intake assessment below)
Justification that the use does not mislead consumer	

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- (¹)For proposed revisions of adopted provisions, the current adopted provision should be provided, with deletions noted in ~~striketrough~~text, and changes or additions noted in **bold** font.
- (²)Food Category number and name, as listed in Annex B of the GSFA.
- (³)For consistency, the maximum use level should be reported on the same basis as the ADI. A numerical use level should be provided for a food additive assigned a non-numerical ADI. GMP or a numerical use level may be provided for a food additive assigned a non-numerical ADI (e.g. ñnot-specified).
- (⁴)Comments on specific restrictions on the use of the food additive to be included as Notes (e.g. limitation of use to specific products in a food category).

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ANNEX C

List of Repealed DOH/ FDA Issuances

1. *Administrative Order (AO) 88-A s. 1984* refers to *Regulatory Guidelines Concerning Food Additives*
2. *Bureau Circular (BC) 2006-0016* refers to *Updated List of Food Additives*
3. *Administrative Order (AO) 103-A s. 1984* refers to *Regulation on Non-nutritive Sweeteners Applicable to Both Food and Drug*
4. *Administrative Order (AO) 112 s. 1985* refers to *Regulation Governing Importation of Food Color Additives*
5. *Administrative Order (AO) 122 s. 1970* refers to *General Regulation Governing the Prohibition of the use of Cyclamic Acid and its Salts (B-6.3 Food Additives and Preservatives)*