



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

DRAFT AS OF 12 Jan 2023

Administrative Order

No. - _____

SUBJECT: Revised Guidelines on Food Additives and Processing Aids, Repealing Administrative Order 88-A s. 1984

I. RATIONALE

The 1987 Philippines Constitution, Article II, Section 15 declares to “protect and promote the right to health of the people and instill health consciousness among them” Republic Act (RA) No. 9711 or the “Food and Drug Administration (FDA) 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 aims, 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 registration and monitoring of health products.”

The Implementing Rules and Regulation of RA No. 9711 further states that the 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.

Further, RA No. 10611 or the Food Safety Act of 2013, Section 9 states that the Department of Health – 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-As.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, 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:

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

III. SCOPE OF APPLICATION

This Order shall apply to all manufacturers, distributors (importer, exporter, wholesaler), and traders of food products which shall include food additives listed herein as well as their maximum use levels, and foods in which additives may or may not be used.

IV. DEFINITION OF TERMS

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

A. **Adulterated** refers to the food products which:

- 1. Bears or contains any poisonous or deleterious substance that may render it injurious to the health of the public;
- 2. Bears or contains any added poisonous or deleterious substance in amounts exceeding established maximum limits or standards for good manufacturing practice;
- 3. Contains in whole or in part filthy, putrid or decomposed substance that is unfit for human consumption;
- 4. Has been prepared, packed or held under unsanitary conditions;
- 5. In whole or in part, is the product of a diseased animal or an animal which has died through ways other than slaughter;
- 6. Is in a container having in whole or in part any poisonous or deleterious substance;
- 7. Has been intentionally subjected to radiation unless the use of radiation is in conformity with an existing regulation or exemption;
- 8. Becomes injurious to health because of the omission or abstraction of a valuable constituent; or if any substance has been substituted wholly or in part; or if damaged or made inferior which has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its strength or to make it appear better or greater than it is;

9. Has not been prepared in accordance with current Good Manufacturing Practice (GMP) as promulgated by way of regulation; and
10. Uses expired ingredients.

B. Acceptable Daily Intake “Not Specified” (NS) is a term applicable to a food substance of very low toxicity for which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background levels in food, does not, in the opinion of Joint FAO/WHO Experts Committee on Food Additives (JECFA), represent a hazard to health. For the above reason, and for reasons stated in individual JECFA evaluations, establishments of an acceptable daily intake expressed in numerical form are not deemed necessary by JECFA. An additive meeting the above criterion must be used within the bounds of good manufacturing practice as defined below.

C. 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 (60 kg-man), that can be ingested daily over a lifetime without appreciable health risk. (Codex Stan 192-1995 Rev. 2012, (WHO Environmental Health Criteria No. 70, 1987)

D. Artificial Synthetic Colors are substances derived from coal-tar dyes or other synthetic Chemical compounds.

E. Natural Colors are derived from or identical with substances derived from plant materials.

F. Cyclamates refer to cyclamic acids and its sodium and calcium salts.

G. Enzymes are proteins capable of catalyzing biochemical processes, acting on specific substrates and in relative low amounts.

H. Flavor is the sum of those characteristics of any material taken in the mouth, perceived principally by the senses of taste and smell, and also the general pain and tactile receptors in the mouth, as received and interpreted by the brain. The perception of flavor is a property of flavorings.

I. Flavorings are products that are added to food to impart, modify, or enhance the flavor of food (with the exception of flavor enhancers considered as food additives under the Codex Class Names and the International Numbering System for Food Additives – CAC/GL 36-1989). Flavorings do not include substances that have an exclusively sweet, sour, or salty taste (e.g. sugar, vinegar, and table salt). Flavorings may consist of natural flavoring substances and complexes, thermal process flavorings or smoke flavorings and mixtures of them and may contain non-flavoring food ingredients. They are not intended to be consumed as such.

1. **Flavoring substances** are chemically-defined substances either formed by Chemical synthesis, or obtained from the materials of plant or animal origin.

- a. **Natural flavoring substances** are flavoring substances obtained by physical processes that may result in unavoidable but unintentional changes in the chemical structure of the components of the flavoring (e.g. distillation and solvent extraction), or by enzymatic or microbiological processes, from material plant or animal origin. Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, roasting and fermentation). This means substances that have been identified /detected in a natural material of animal or vegetable origin.
 - b. **Synthetic/artificial flavoring substances** are flavoring substances formed by chemical synthesis.
2. **Natural flavoring complexes** are preparations that contain flavoring substances obtained by physical processes that may result in unavoidable but unintentional changes in the chemical structure of the flavoring (e.g. distillation and solvent extraction), or by enzymatic or microbiological processes, from material of plant or animal origin. Such material may be unprocessed, or processed for human consumption by traditional food-preparation processes (e.g. drying, roasting and fermentation). Natural flavoring complexes include the essential oil, essence, or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis.
3. **Smoke flavorings** are complex mixtures of components of smoke obtained by subjecting untreated wood to pyrolysis in a limited and controlled amount of air, dry distillation, or superheated steam, then subjecting the wood smoke to an aqueous extraction system or to distillation, condensation, and separation for collection of the aqueous phase. The major flavoring principles of smoke flavorings are carboxylic acids, compounds with carbonyl groups and phenolic compounds.

J. 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.

K. Good manufacturing practices (GMP) refer 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 procedures.

L. Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).

M. Maximum Level or 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 a 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 additive would be used, taking into account the type of raw materials, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.

N. Misbranded/Misbranding means, in addition to definitions in existing laws, misinformation or misleading information on the label or other information materials authorized by the FDA. It shall not refer to copyright, trademark, or other intellectual property-like instruments.

O. Non-flavoring food ingredients are food ingredients, such as food additives, and foodstuffs that can be added to flavorings and are necessary for dissolving, dispersing, or diluting flavorings, or are necessary for the production, storage, handling and use of flavorings.

P. 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 fulfill 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.

V. GENERAL GUIDELINES

- A. Only those food additives adopted by Codex Alimentarius at the proposed level of use for specified food categories shall be included in this Order.
- B. The latest Codex General Standard for Food Additives (GSFA), and its future revisions/ amendments / updates, shall be adopted automatically through the mandated legal procedures, with a maximum of five (5) year transition period or until the validity of the existing CPR for those granted with CPRs, and shall be posted in the FDA website as upcoming regulations to update industries.
- C. Any food additive used not in accordance with the requirements of this Order shall be deemed to be an act which results in the food being misbranded or adulterated, as the case may be.

VI. SPECIFIC GUIDELINES

- A. The use of food additives is justified only when such use 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 the other means that are economically and technologically practicable:

1. 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;
2. To provide necessary ingredients or constituents for foods manufactured for groups of consumers having special dietary needs;
3. 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;
4. 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.

B. Where there is no national standard for specific food products, the food additive/s and its maximum level of use shall follow the Codex standard.

For products with PNS, the maximum level to be used shall be based on the latest GSFA with its corresponding Food Category for existing or listed food additive/s in the PNS.

However, if a specific food additive in a PNS is not listed in the latest GSFA under its corresponding Food Category, the food additive in the PNS may still be used within its maximum level until an updated GSFA list is adopted with its inclusion in the list and with corresponding updated maximum level. Otherwise, a specific food additive in a PNS shall be delisted if and when the Codex Alimentarius Commission approves its revocation, food safety-wise.

C. The use of Cyclamic acid and its salts listed in GSFA and its future revisions/amendments/updates is allowed.

D. If food additives are to be used as flavoring substances, they shall abide by the Codex Guidelines for the Use of Flavorings (CAC/GL66-2008) or as listed as safe in United States Flavor Extracts Manufacturers Association (US FEMA), International Organization for the Flavor Industry (IOFI) and/or Generally Recognized as Safe (GRAS).

E. The maximum level of caffeine used as flavor in cola-type beverages is 200 ppm. (United States Flavor Extracts Manufacturers Association (US FEMA))

F. All food additives covered by this Order shall be used under conditions of good manufacturing practice, which include the following:

1. The quantity of the additive 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 specific application;

2. 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,
 3. The food additive is of food grade quality and is prepared and handled in the same way as a food ingredient.
- G. Food additives used in accordance with this Order should 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 Commissions or, in the absence of such specifications, with appropriate specifications developed by responsible national or international bodies (E.g. ASEAN). In terms of safety, food grade quality is achieved by conformance of additives to their specification as a whole (not merely with individual criteria) and through their production, storage, transport, and handling in accordance with GMP.
- H. For Carry-Over of Food Additives from Ingredients and Raw Materials into Foods, the following conditions shall be applied:
1. The additive is acceptable for use in the raw materials or other ingredients (including food additives) according to this Order;
 2. The amount of the additive in the raw materials or other ingredients (including food additives) does not exceed the maximum use level specified in this Order;
 3. 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 this Order.
- I. Food Additives Not Directly Authorized in Food Ingredients and Raw Materials 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.
- J. 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 this Order:
1. 13.1 – Infant formula, follow-up formula, and formula for special medical purposes for infants; and
 2. Complementary foods for infants and young children.
- K. The food category system is a tool for assigning food additives used outlined in this Order. The food category system applies to all foodstuffs. The food category descriptors are not to be treated as a legal product designation or intended, in any way, for labeling 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 the 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 system takes 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.

L. All food manufacturers, traders, and distributors shall secure a Certificate of Product Registration (CPR) before engaging in sale, offer for sale, distribution, and where applicable the use of food additives.

M. The procedure for CPR application shall follow the Electronic Registration System as prescribed in FDA Circular 2020-033 Procedure for the Use of Electronic Registration System for Prepackaged Processed Food Products and its latest amendment thereof.

N. Processing Aids

1. The use of processing aids shall be guided by at least any one of the following latest revisions: Food Chemicals Codex, USFDA CFR Title 21, General Specifications and Considerations for Enzyme Preparations Used in Food Processing (Food and Agriculture Organization (FAO)), or Codex Guidelines on Substances Used as Processing Aids (CAC/GL75-2010).
2. For enzymes not listed in the Specifications and Considerations for Enzyme Preparations Used in Food Processing (FAO) or Codex Guidelines on Substances Used as Processing Aids (CAC/GL75-2010), there should be certification from competent authority of the country of origin.

VII. PENALTY CLAUSE

Any establishment found to be in violation of any provision of this issuance shall be a ground for disapproval of application and suspension or cancellation of CPR or Authorization pursuant to Section 4, Article 1, Book II of the Implementing Rules and Regulations (IRR) of RA No. 9711.

Notwithstanding the preceding paragraph, nothing in this section shall restrict the FDA in imposing the penalty and sanctions as prescribed under RA No. 10611 and its IRR.

VIII. TRANSITORY PROVISIONS

Affected manufacturers, traders and distributors of processed food products distributed in the Philippines are given a transition period as follows:

- A. Those granted CPRs expiring within a period of 5 years from effectivity of this Order shall file initial application complying with this Order after the expiration of the original registration;
- B. Those CPRs that have a validity of three years after the effectivity of this order shall file new application upon its expiration with the new formulation of the product.
- C. Those CPR with less than a year of validity upon effectivity of this Order shall be renewed for a maximum of two (2) years to give time for reformulation, after which, a new application shall be filed.
- D. In cases when there are still existing stocks of labels on the current CPR and stocks may be still available by the time of filing of new CPR and its approval, exhaustion may be allowed with a maximum of six months. Inventory shall be submitted to the FDA.

IX. PENALTY CLAUSE

Any establishment found to be in violation of any provision of this issuance shall be a ground for disapproval of application and suspension or cancellation of CPR or Authorization pursuant to Section 4, Article 1, Book II of the Implementing Rules and Regulations (IRR) of RA No. 9711.

Notwithstanding the preceding paragraph, nothing in this section shall restrict the FDA in imposing the penalty and sanctions after the transition period as prescribed under RA No. 10611 and its IRR.

X. SEPARABILITY CLAUSE

If any part or provision of this Order is rendered invalid by any court of law or competent authority, the remaining parts or provisions not affected shall remain valid and effective.

XI. REPEALING CLAUSE

Administrative Order No. 88-A s. 1984 or the “*Regulatory Guidelines Concerning Food Additives*”, Administrative Order No. 122 s. 1970 or the “*General Regulation Governing the Prohibition of the Use of Cyclamic Acid and its Salts (B-6.3. Food Additives and Preservatives)*”, Bureau Circular 2006-016 or the “*Updated List of Food Additives*” and other

related issuances inconsistent or contrary to the provisions of this Administrative Order are hereby repealed accordingly.

XII. EFFECTIVITY

This Order shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center Office of the National Administrative Register.

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<i>Keywords</i>	<i>Food Additives, Processing Aids</i>
<i>Related issuances, laws, directives from other government agencies</i>	<i>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</i>

ANNEX A

FOOD ADDITIVES FUNCTIONAL CLASSES, DEFINITIONS AND TECHNOLOGICAL PURPOSES

TABLE 1:

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 nutrients.	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
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 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	Humectant, moisture-

	food from drying out by counteracting the effect of a dry atmosphere.	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
27. Thickener	A food additive, which increases the viscosity of a food.	Binder, bodying agent, texturizing agent, thickener, thickener synergist

Reference: Class Name and the International Numbering System for Food Additives (CXST 36-1989) Revised 2021.

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ANNEX B

LIST OF FOOD PRODUCTS HIGHLY CONSUMED BY THE FILIPINO POPULATION IDENTIFIED BY THE DEPARTMENT OF SCIENCE AND TECHNOLOGY

– FOOD AND NUTRITION RESEARCH INSTITUTE (DOST-FNRI)

(The Philippine Nutrition Facts and Figures 2015*)

FOOD CATEGORY	SPECIFIC FOOD PRODUCTS
Cereal and Cereal Products	Corn-based products
	Pasta and Noodles
	Batters (e.g. for breading or batters for fish and poultry)
Bakery Wares	Biscuits, Crackers, Cookies
	Packaged Cakes, Muffins, donuts and breads
Confectionery	Decorations, Toppings and Sauces/ fillings for fine bakery wares/ products
Spices, Soups, Sauces	Seasonings and Condiments
	Mixes for Soups and Sauces
Beverages	Water-based flavored Drinks including concentrates
	Coffee, Tea, hot cereal and grain beverages
Dairy Products	Flavored Milk Drinks