

# ASEAN Principles and Guidelines for the Establishment of Maximum Use Level for Food Additives

The ASEAN Secretariat  
Jakarta



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Jakarta

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# ASEAN Principles and Guidelines for the Establishment of Maximum Use Level for Food Additives

## Foreword

The Prepared Foodstuffs Product Working Group (PFPWG) was established by the Association of South East Asian Nations (ASEAN) Consultative Committee for Standards and Quality (ACCSQ) in 2003 and tasked to facilitate trade in the prepared foodstuffs sector in ASEAN. The PFPWG established a Task Force on Harmonisation of Prepared Foodstuff Standards (TF HPFS) to support the harmonisation of food safety standards as a part of its initiatives in removing technical barriers to trade in prepared foodstuffs.

The TF HPFS has been supporting the harmonisation of food safety standards for a number of years through an on-going exchange of information and discussion related to standards for food additives among ASEAN Member States (AMS). The PFPWG has recognised that for sustainability of the harmonisation of food additives an ASEAN reference standard that defines the objectives, principles, and methods of harmonising food additive standards is essential. The ASEAN Principles and Guidelines for the Establishment of Maximum Use Level for Food Additives has been developed to serve this need.

In keeping with the ASEAN policy for harmonisation on the basis of international standards, this standard adopts the principles for establishing requirements for food additives from the *Codex General Standard for Food Additives (GSFA) - CODEX STAN 192-1995*. In addition, the *Codex Guidelines, CAC/GL 36-1989 Class Names and the International Numbering System*, has been incorporated into this standard.

# ASEAN Principles and Guidelines for the Establishment of Maximum Use Level for Food Additives

## 1. Introduction

The ASEAN Principles and Guideline for the Establishment of Maximum Use Level for Food Additives establishes the principles and mechanism for ASEAN Member States (AMS) to establish and maintain, on an on-going basis, a listing of food additives and the prescribed maximum use levels that have been agreed to be harmonised by all Member States. Additionally, the leading role of the Joint Food and Agricultural Organization of the United Nations (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) is recognised and the determination of requirements relies on the data generated by JECFA whenever it is available.

The harmonised requirements for food additives will further contribute to the harmonisation of food safety regulations in AMS. When the Standard is incorporated into national legislation it will serve as a reference to the AMS in harmonising maximum use level of food additives to implement regulations.

The Standard will support ASEAN in the ongoing harmonisation process and applies to all food products and it is intended that all relevant ASEAN sectoral working groups will be consulted in the ongoing harmonisation process. It is intended that the Standard will provide a consolidated and uniform reference to all stakeholders, including food safety regulators, food business operators and consumers.

## 2. SCOPE

The ASEAN Principles and Guidelines for the Establishment of Maximum Use Level for Food Additives prescribes the principles and conditions for safe use of food additives and establishes a mechanism for the development, maintenance and updating of a list of food additives deemed to be safe. Only food additives for which the conditions of use have been harmonised through the prescribed mechanism are included in the list.

Format for ASEAN Maximum Use Levels of Food Additives are based on a review of the Codex General Standard for Food Additives - CODEX STAN 192-1995 (GSFA) and relevant Codex commodity standards, and will be updated taking into consideration changes in Codex standards and/or proposals from AMS. The ASEAN Standard fully adopts the Food Category system as in Annex B of the CODEX STAN 192-1995 (GSFA), and its amendments. A full description of the Format for ASEAN Maximum Use Levels of Food Additives is provided in Annex 1.

Other food additives not listed in the GSFA may be reviewed, harmonised and listed in this standard provided that the food additives have been assigned an Acceptable Daily Intake (ADI) or determined, on the basis of other criteria, to be safe by JECFA or ASEAN Risk Assessment Centre for Food Safety (ARAC), and assigned an International Numbering System (INS).

Food categories or individual food items in which the use of food additives is not acceptable, or where use should be restricted, are defined by this Standard.

Maximum use levels for food additives in this standard have been established taking into consideration that the intake of an additive from all its uses does not exceed its ADI. The scope of this standard does not include processing aids.

The Standard does not contain the full list of food additives permitted in AMS and does not contain a negative list of banned substances, these are for determination by each Member State.

### 3. DEFINITIONS

**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 manufacturing, 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.

**Acceptable Daily Intake (ADI)** is an estimate by JECFA<sup>1</sup> 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<sup>2</sup>.

**Acceptable Daily Intake “Not Specified” (NS)**<sup>3</sup> 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 JECFA<sup>4</sup>, represent a hazard to health.

For the above reason, and for reasons stated in individual JECFA evaluations, establishment of an acceptable daily intake expressed in numerical form is not deemed necessary by JECFA. An additive meeting the above criterion must be used within the bounds of good manufacturing practice as defined in section 6.3 below.

**ASEAN 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 ASEAN. It is generally expressed as mg additive/kg of food.

**Note:**

*The maximum use level will not usually correspond to the optimum, recommended, or typical level of use. Under Good Manufacturing Practice (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,*

<sup>1</sup> In case that JECFA has not published an ADI, an estimated ADI by recognised scientific body may be considered.

<sup>2</sup> 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.

<sup>3</sup> For the purpose of this standard, the phrase acceptable daily intake (ADI) “not limited” (NL) has the same meanings as ADI “not specified”. The phrase “acceptable ADI” refers to an evaluation by JECFA, which established safety on the basis of an acceptable level of treatment of food, limited numerically or by GMP, rather than on a toxicologically established ADI.

<sup>4</sup> Footnote 1 refers, in cases that JECFA has not published an ADI, an estimate by a recognized scientific body refers.



*food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.*

**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.

## 4. REFERENCES

The following documents are essential references to the interpretation and use and of this Standard.

1. General Standards for Food Additives (CODEX STAN 192-1995);
2. Class Names and the International Numbering System for Food Additives (CAC/GL 36-1989).

## 5. FUNCTIONAL CLASSES OF FOOD ADDITIVES

The technological purposes of food additives along with simple definitions of the functions performed are listed in Annex 2 (Table of Functional Classes, Definitions and Technological Purposes) of this standard. A single food additive can often be used for a range of technological purposes in a food and it remains the responsibility of the manufacturer to declare the most appropriate functional class in the list of ingredients.

## 6. GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES

The use of food additives in conformance with this Standard requires adherence to all principles set forth in Section 6.1 to 6.4.

### 6.1 Food Additive Safety

- a). Only those food additives shall be endorsed and included in this Standard that, so far as can be judged on the evidence presently available from JECFA or ARAC, presents no appreciable health risk to consumers at the use levels proposed;
- b). The inclusion of a food additive in this Standard shall have taken into account any ADI, or equivalent safety assessment established for the additive by JECFA<sup>5</sup> and its probable daily intake from all food sources. Where the food additive is to be used in foods 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 the procedures of Guidelines for the Development of Maximum Levels for the Use of Food Additives with Numerical Acceptable Daily Intakes (Annex A of CODEX STAN 192-1995) or the intake assessment of AMS.

<sup>5</sup> Footnote 1 refers.

## 6.2 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 as set out in **Annex 2** and the needs set out from (a) through (d) below, 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 sub-paragraph (b) and also in other circumstances where the food does not constitute a significant item in a normal diet;
- 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 organoleptic properties, provided that this does not change the nature, substance or quality of the food so as to deceive the consumer;
- 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.

## 6.3 Good Manufacturing Practice (GMP)

All food additives subject to the provisions of this Standard shall be used under conditions of GMP, which include the following:

- a) The quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect;
- 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 additive is of appropriate food grade quality and is prepared and handled in the same way as a food ingredient.

## 6.4 Specifications for the Identity and Purity of Food Additives

Food additives used in accordance with this Standard 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 Commission<sup>6</sup> 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.

<sup>6</sup> An index (CAC/MISC 6) of all specifications adopted by the Codex Alimentarius Commission, as well as the year of adoption, is available at the Codex website (<http://www.codexalimentarius.org/standards/en/>). The specifications are also available at the JECFA website (<http://www.fao.org/ag/agn/jecfaadditives/search.html?lang=en>). Specifications for flavourings are included in an online searchable database at the JECFA website at FAO. <http://www.fao.org/food/food-safety-quality/scientificadvice/jecfa/jecfa-flav/en/>

## **7. CARRY-OVER OF FOOD ADDITIVES INTO FOODS**

### **7.1 Conditions Applying to Carry-Over of Food Additives from ingredients and raw materials into foods**

Other than by direct addition, an additive may be present in a 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 this Standard;
- 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 this Standard;
- 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 the provisions of this Standard.

### **7.2 Special conditions applying to the use of food additives not directly authorised 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 the provisions of this Standard, including that any maximum level applying to the food is not exceeded.

### **7.3 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 as Format of ASEAN Maximum Use Level for Food Additives.

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

## **8. FOOD CATEGORY SYSTEM**

The food category system for assigning food additive uses in this Standard is adopted from Food Category System of Codex STAN 192-1995: Annex B. The food category system applies to all foodstuffs.

The food category descriptors are not to be legal product designations nor are they intended for labelling purposes.

The food category system is based on the following principles:

- a) 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 subcategories or individual foodstuffs mentioned in a sub-category;

- b) The food category system is based on product descriptors of foodstuffs as marketed, unless otherwise stated;
- c) 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;
- d) The food category system is used to simplify the reporting of food additive uses for assembling and constructing this Standard.

## 9. PROVISIONS FOR FOOD ADDITIVES WITH ADIs NOT SPECIFIED or NOT LIMITED

Reference is made to Table 3 of CODEX STAN 192 1995 with regard to additives with Not Specified or Not Limited JECFA ADIs that are acceptable for use in foods in general when used at *quantum satis* levels and in accordance with the principles of GMP described in Section 6.3.

The Annex to Table 3 of CODEX STAN 192 1995 lists food categories and individual food items excluded from the **general conditions of Table 3** of CODEX STAN 192-1995. The provision in ASEAN Maximum Use Level of Food Additives governs the use of additives in the food categories listed in the Annex to Table 3 of CODEX STAN 192 1995.

## Annex 1: FORMAT OF ASEAN MAXIMUM USE LEVELS OF FOOD ADDITIVES

Format:

**Additives Permitted for Use  
Under Specified Conditions in  
Certain Food Categories or  
Individual Food Items**

---

{Name of food additive}

INS xxx      {Name of food additive}

Functional Class: {aaaaaa, bbbbbb}

[e.g. Flavour enhancer, Sweetener]

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Food Cat No	Food Category	Max Level	Notes	Year Adopted

## Annex 2: TABLE OF 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, antibrowning agent
5. Bleaching agent	A food additive (non-flour use) used to decolourize 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. Colour	A food additive, which adds or restores colour in a food.	colour, decorative pigment, surface colourant

<b>FUNCTIONAL CLASSES</b>	<b>DEFINITION</b>	<b>TECHNOLOGICAL PURPOSE</b>
10. Colour retention agent	A food additive, which stabilizes, retains or intensifies the colour of a food.	colour retention agent, colour fixative, colour stabilizer, colour 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 (flavouring 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. Flavour enhancer	A food additive, which enhances the existing taste and/or odour of a food.	flavour enhancer, flavour synergist
15. Flour treatment agent	A food additive, which is added to flour or dough to improve its baking quality or colour.	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

FUNCTIONAL CLASSES	DEFINITION	TECHNOLOGICAL PURPOSE
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 microorganisms.	preservative, antimicrobial preservative, antimycotic agent, bacteriophage control agent, fungistatic agent, antimould and antirope 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, stabilizer synergist
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.	thickener, bodying agent, binder, texturizing agent, thickener synergist









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