

CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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GENERAL STANDARD FOR FOOD ADDITIVES

CODEX STAN 192-1995

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2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019

PREAMBLE

1. SCOPE

1.1 Food Additives Included in this Standard

Only the food additives listed herein are recognized as suitable for use in foods in conformance with the provisions of this Standard.¹ Only food additives that have been assigned an Acceptable Daily Intake (ADI) or determined, on the basis of other criteria, to be safe² by the Joint FAO/WHO Expert Committee on Food Additives (JECFA)³ and an International Numbering System (INS) designation by Codex will be considered for inclusion in this Standard. The use of additives in conformance with this Standard is considered to be technologically justified.

1.2 Foods in Which Additives May Be Used

This Standard sets forth the conditions under which food additives may be used in all foods, whether or not they have previously been standardized by Codex. The use of additives in foods standardized by Codex is subject to the conditions of use established by the Codex commodity standards and this Standard. The *General Standard for Food Additives* (GSFA) should be the single authoritative reference point for food additives. Codex commodity committees have the responsibility and expertise to appraise and justify the technological need for the use of additives in foods subject to a commodity standard. The information given by the commodity committees may also be taken into account by the Codex Committee on Food Additives (CCFA) when considering food additive provisions in similar non-standardized foods. When a food is not covered by a commodity committee, CCFA will appraise the technological need.

1.3 Foods in Which Additives May Not Be Used

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.

1.4 Maximum Use Levels for Food Additives

The primary objective of establishing maximum use levels for food additives in various food groups is to ensure that the intake of an additive from all its uses does not exceed its ADI.

The food additives covered by this Standard and their maximum use levels are based in part on the food additive provisions of previously established Codex commodity standards, or upon the request of governments after subjecting the requested maximum use levels to an appropriate method for verifying the compatibility of a proposed maximum level with the ADI.

Annex A of this Standard may be used as a first step in this regard. The evaluation of actual food consumption data is also encouraged.

2. DEFINITIONS

- a) **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.⁴

¹ Notwithstanding the provisions of this Section of the General Standard, the lack of reference to a particular additive or to a particular use of an additive in a food in the General Standard as currently drafted, does not imply that the additive is unsafe or unsuitable for use in food. The Commission shall review the necessity for maintaining this footnote on a regular basis, with a view to its deletion once the General Standard is substantially complete.

² For the purpose of this standard "determined, on the basis of other criteria, to be safe" means that the use of a food additive does not pose a safety concern under conditions of use described by JECFA as being of no toxicological concern (e.g. use levels defined circumstances).

³ A data base of food additive specifications with their current ADI status, the year of their most recent JECFA evaluation, their assigned INS numbers, etc. are available in English at the JECFA website at FAO <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>. The database has a query page and background information in English, French, Spanish, Arabic and Chinese. The reports of JECFA are available at the JECFA website at WHO <http://apps.who.int/food-additives-contaminants-jecfa-database/search.aspx>

⁴ Codex Alimentarius Procedural Manual.

- b) **Acceptable Daily Intake (ADI)** is an estimate by 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.⁵
- c) **Acceptable Daily Intake "Not Specified" (NS)**⁶ 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, 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 3.3 below.

- d) **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.

3. GENERAL PRINCIPLES FOR THE USE OF FOOD ADDITIVES

The use of food additives in conformance with this Standard requires adherence to all the principles set forth in Sections 3.1 – 3.4.

3.1 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, present 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 and its probable daily intake⁷ 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 Annex A, the intake assessment of Codex members or upon a request by the CCFA to JECFA for an independent evaluation of national intake assessments.

3.2 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 set out by Codex 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;

⁵ 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.

⁶ For purposes of this Standard, the phrase acceptable daily intake (ADI) "not limited" (NL) has the same meaning 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.

⁷ Codex members may provide the CCFA with intake information that may be used by the Committee in establishing maximum use levels. Additionally, the JECFA, at the request of the CCFA, will evaluate intakes of additives based on intake assessments submitted by Codex members responding to a call for data. The CCFA will consider the JECFA evaluations when establishing the maximum use levels for additives.

- 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.

3.3 Good Manufacturing Practice (GMP)⁸

All food additives subject to the provisions of this Standard shall be used under conditions of good manufacturing practice, 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.

3.4 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 Commission⁹ 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.

4. CARRY-OVER OF FOOD ADDITIVES INTO FOODS

4.1 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.

4.2 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.

⁸ For additional information, see the Codex Alimentarius Commission Procedural Manual. Relations Between Commodity Committees and General Committees - Food Additives and Contaminants.

⁹ 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/>). These specifications, prepared by the JECFA, are also being published in 2006 in the "Combined Compendium of Food Additive Specifications," FAO JECFA Monographs No. 1, which consists of four volumes and in subsequent JECFA Monographs. The specifications are also available at the JECFA website (<http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>). Although specifications for flavourings are not included in the printed compendium, with the exception of those few which have an additional non-flavour technological function, they are included in an online searchable database at the JECFA website at FAO. <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-flav/en/>

4.3 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 Tables 1 and 2 of this standard.

- 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.

5. FOOD CATEGORY SYSTEM¹⁰

The food category system is a tool for assigning food additive uses in this Standard. 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 sub-categories 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.

6. DESCRIPTION OF THE STANDARD

This Standard consists of three main components:

- a) Preamble
- b) Annexes
 - i. Annex A is a guideline for considering maximum use levels for additives with numerical JECFA ADIs.
 - ii. Annex B is a listing of the food category system used to develop and organize Tables 1, 2, and 3 of the standard. Descriptors for each food category and sub-category are also provided.
 - iii. Annex C is a cross-reference of the food category system and Codex commodity standards.
- c) Food Additive Provisions
 - i. Table 1 specifies, for each food additive or food additive group (in alphabetical order) with a numerical JECFA ADI, the food categories (or foods) in which the additive is recognized for use, the maximum use levels for each food or food category, and its technological function. Table 1 also includes the uses of those additives with non-numerical ADIs for which a maximum use level is specified.
 - ii. Table 2 contains the same information as Table 1, but the information is arranged by food category number.
 - iii. Table 3 lists 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 good manufacturing practice described in Section 3.3 of this Preamble.

The Annex to Table 3 lists food categories and individual food items excluded from the general conditions of Table 3. The provisions in Tables 1 and 2 govern the use of additives in the food categories listed in the Annex to Table 3.

¹⁰ Annex B to this Standard.

Unless otherwise specified, maximum use levels for additives in Tables 1 and 2 are set on the final product as consumed.

Tables 1, 2, and 3 do not include references to the use of substances as processing aids.¹¹

¹¹ 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: Codex Alimentarius Commission Procedural Manual.