Revision of Guidelines for the Designation of Food Additives and Revision of Standards for Use of Food Additives

Procedures for requesting designation of food additives and the scope of necessary materials attached to the request, based on the provisions of Article 12 and Article 13, paragraph 1 of the Food Sanitation Law (Law No. 233 in 1947) are shown in the "Food Additive Guideline for Designation and Revision of Usage Standards" (Eika No. 29 dated on March 22nd, 1996; hereinafter referred to as "the 1996 Guideline".

Based on recent revision of the "Guideline for Evaluation of the Health Effects of Food Additives" by Food Safety Commission, we have decided to revise the 1996 Guideline as shown in the attachment. It is appreciated for information sharing to related stakeholders.

(Attachment)

Guidelines for Designation of Food Additives and for Revision of Standards for Use of Food Additives

(Issued on March 22, 1996, as an attachment to Notification of Director- General of Environmental Health Bureau, Ministry of Health, Labour and Welfare (MHLW), No. 29)
(Partial amendment No.3 issued on September 29, 2022, by the Policy Planning Division for Environmental Health and Food Safety, Pharmaceutical Safety and Environmental Health Bureau, MHLW)

I Purpose

These Guidelines are designed to provide the procedures for application and the scope, etc., of accompanying documents of the application form for the designation of food additives which pose no hazard to human health, pursuant to Article 12 of the Food Sanitation Act (Act No. 233 of 1947) and for the revision of standards for use of food additives pursuant to Paragraph 1, Article 13 of the Act.

II Principles for the designation of food additives and the revision of standards for use of food additives

Food additives must pose no hazard to human health and also be effective. The use of them must benefit consumers.

In the case of designating food additives and revising standards for use, the points on safety and effectiveness should be scientifically confirmed. Therefore, based on these scientific viewpoints, evaluations should be conducted by the Pharmaceutical Affairs and Food Sanitation Council (PAFSC), MHLW from the view of public health. In these evaluations, standards of the Codex Alimentarius Commission, specifications, etc. of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and conditions of food intake in Japan should be considered. Risk assessment of the effect of food on health will also be conducted by the Food Safety Commission of Japan (FSCJ).

1. Safety information

The safety of the food additives should be confirmed based on requested use methods.

2. Effectiveness

It should be confirmed that the use of the food additive comes under one or more of the purposes given in (1) to (4) below. However, if manufacturing or processing method of the target food can be improved or modified at comparatively low cost without the food additive, request of the use of the food additive is not justified.

(1) To retain the nutritional value of food.

However, in case of (2) could apply and the food in question would not be important in the normal diet, it might be justified to intentionally reduce the nutritional value in the food.

(2) To supply raw materials or ingredients necessary for the manufacturing of specific food for consumers in special requirement.

However, the cases for the purpose of treatment of diseases or other medical effects are not be included in this exception.

(3) To maintain the quality of food or to improve its stability, or those that improve the sensory stimuli characteristics such as taste and vision.

However, the cases where there is a risk of changing the characteristics, essence or quality of the food and misleading consumers should be excluded.

(4) To provide aids in producing, processing, cooking, treatment, packing, transport, or storage of food.

However, the food additive is used to conceal the effects, caused by the use of inferior raw materials, or undesirable (including unhygienic) treatment or techniques during either of the processes above, should be excluded.

III Procedures for designation of food additives and revision of standards for use of food additives

1. Application

Those who wish to apply for the designation of a food additive or the revision of standards for use of a food additive (hereinafter referred to as "Designation") has to submit application form to the Minister of Health, Labour, and Welfare using Attachment No. 1 or No. 2, respectively (application form should be addressed to: Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW). The application form should be accompanied by any required documents on draft specifications and standards for use, and the safety of the food additive, as provided in IV. It should be noted that the Food Safety Standards and Evaluation Division would request submitting of the food additive sample at appropriate time to set appropriate specifications and execute tests on specifications.

If the applicant lives overseas, the one should stipulate a responsible contact person to handle the application in Japanese (its contact point in Japan).

2. Procedures for Designation

Pursuant to Article 24 of the Food Safety Basic Act (Act No. 48 of 2003), MHLW requests assessment of the effect of food on health to FSCJ. FSCJ will conduct Risk assessment of the effect of food on health based on documents, etc. on safety.

Based on the results of assessment by FSCJ, MHLW will conduct evaluations in PAFSC.

After completing evaluations on terms of reference, PAFSC will submit a report on the matters addressed to the Minister of MHLW. Based on the report of PAFSC will take necessary measures for the revision, etc. of the Enforcement Regulations of the Food Sanitation Act (Ministry of Health and Welfare Ordinance No. 23, 1948).

When necessary, during the procedures of Risk assessment of the effect of food on health in FSCJ and evaluations in PAFSC, MHLW, the applicant may be asked to submit additional documents.

IV Accompanying documents required for Designation

1. Scope of accompanying documents

(1) Application for Designation, in principle, requires the documents given in Attached Table.

(2) Notwithstanding (1), some of documents may be exempted when appropriate reasons are stated. The reasons may include the food additive is almost identical to a previously designated food additive other than different base, or is the isomer of a designated food additive, or when there are other rational reasons.

However, if a food additive is considered to have additive toxicity compared with designated food additives from the view of toxicity mechanism, all the required

documents should be provided.

2. General considerations for preparation of documents

(1) In preparing the required documents for application, applicants should assume full responsibility for the reliability of the documents.

(2) Document which summarizes the outline, effectiveness, safety, etc. of the food additive (hereinafter referred to as "Overview document") should be submitted in Japanese. "Draft specifications" and "Draft standards for use and contrasting list" should also be prepared in Japanese. The other documents could be submitted in English. If the documents were written in a language other than Japanese or English, Japanese translation of the documents should be attached.

(3) Studies required for the accompanying documents should be conducted in laboratories which have adequate facilities, equipment, and personnel which should be managed appropriately to ensure the data tested.

(4) References, etc. submitted as accompanying documents should be scientifically reliable.

(5) Notwithstanding (1), (3), and (4), documents that raise concerns about the quality, safety, or efficacy of the additive should be submitted, regardless of the reliability of the documents.

3. Specific considerations for preparation of accompanying documents

The outline of (4) to (11) listed in this article should be described as individual items in (3) Overview document. As documents other than Overview document, scientific evidence written in (4) to (11) should be attached respectively. The documents should be prepared with consideration of the Appendix 3 of the Procedure for Preparing Application Documents for Designation of Food Additives and Revision of Use Standards for Food Additives (No.2-0909 Notice of the director of Standards and Evaluation Division, Food Safety Department, Pharmaceutical and Food Safety Bureau, MHLW, issued on September 9, 2014).

(1) Draft specifications

Application for designation of a food additive, in principle, requires draft specifications attached to the application form.

(2) Draft standards for use

[1] In case of the application for designation of a food additive

Draft standards are required when target foods, in which the food additive is used, the amount of its use, and the way of use are restricted.

[2] In case of the application for revision of standards for use

Application should be accompanied by a list in tabular form contrasting the existing food additive standard(s) for use and the proposed standards for use.

(3) Overview document

Each item should be summarized, and the pages should be numbered consecutively throughout.

(4) Documents on name and purpose of use

[1] Name

The generic name (in Japanese and English), chemical name (pursuant to the International Union of Pure and Applied Chemistry Name) should be given.

[2] Purpose of use

Conditions on use in Japan and other countries and the purpose of use (e.g., provided by the Codex Alimentarius Commission) should be given.

(5) Documents on origin and details of development as food additives

The history of the food additive should be described. For example, when and where the food additives were developed.

(6) Documents on condition of use in overseas countries

Overseas conditions (including approval status of the food additive, target foods in which the food additive is used, standards for use, and specifications) should be described. Also, standards for use and specifications of international organizations such as Codex Alimentarius Commission should be described.

(7) Documents on safety evaluations by international organizations

The summary results of safety evaluations conducted in international organizations such as JECFA and overseas countries should be described.

(8) Documents on physicochemical properties and specifications

The documents should be described based on results of appropriate tests conducted in accordance with Japan's Specifications and Standards for Food Additives.

[1] Structural formula or rational formula

This formula should be described by referring to the official compilation of food additives.

[2] Molecular formula and formula weight

They should be described based on the section entitled "General Notice" in the Japan's Specifications and Standards for Food Additives.

[3] Methods of manufacturing

Methods of manufacturing should be clearly stated because types or amounts of impurities might vary with the methods for the food additive.

[4] Content

Assay requirements for the food additive should be established to ensure constant quality in safety and effectiveness based on the manufacturing process, assay error, and stability. The content should be expressed in the percentage (%) of each effective constituent of the food additive. Multiple effective constituents should be set separately.

[5] Description

Information necessary to identify or handle the food additive should be stated. Usually, the information includes taste, odor, color, and form.

[6] Identification

Identification tests are to identify whether the substance is the target food additive, based on its characteristics. Therefore, the tests should be specific to characteristics based on the chemical structure of the food additive. Tests other than those specified as identification tests may be employed if the conduct of these tests enables identification of the food additive. For example, if chromatography which has high specificity to the food additive is adopted as an assay method, the identification test may be simplified, and the setting of similar types of identification tests is not necessary. Generally, methods based on spectrum analyses and chemical reactions may be used for identification tests. Methods based on chemical reactions should be set when they were appropriate to identify characteristics of the chemical structure of the food additive.

[7] Specific properties

Specific properties are expressed as values measured using physical or chemical means. They include absorbance, optical rotation, pH, and melting point. Parameters necessary for quality assurance of the food additive should be described.

[8] Purity

Purity tests are required to determine levels of impurities in the food additive and specify the purity of the food additive in conjunction with assays. Necessary parameters should be chosen as targets of tests, such as substances (ingredients, intermediate products, by-products, breakdown products, regents/catalysts, heavy metals/inorganic bases, and solvents), which may be present in the food additive.

[9] Loss on drying, loss on ignition, or water content

A test for "loss on drying" is usually conducted to measure the amount of substances, which is present in the food additive and can be lost by drying. The substances include free water, all or part of the crystalline water, and volatile substances. A test for "loss on ignition" is usually conducted on an inorganic substance, which can lose a part of its components or admixed substances by igniting. Water determination is usually required to determine the water content in the food additive.

[10] Residues on ignition

This test is generally conducted to measure the total amount of inorganic impurities present in an organic compound. In some cases, this test may be conducted to measure the amount of inorganic substances present in an organic compound as its components or the amount of impurities present in an inorganic compound, which can volatilize by heating.

[11] Assay

An assay method is intended to determine the content of an effective component of the food additive using physical, chemical, or biological means. When a relative analytical method is established, specifications for the reference standard used in the quantitative test should be established. In establishing an analytical method, attention should be given to its accuracy, reproducibility, and specificity. If the limit of impurities in the food additive is controlled based on appropriate purity tests, an analytical method with relatively low specificity to the food additive but able to measure the absolute amount in high reproducibility may be employed. In such cases, however, methods with high specificity to the food additive should be used as purity tests to compensate for the lack of specificity to the food additive of the assay method. If there are multiple components to be determined, the descriptions of assay methods should be made in order of the importance of those components.

[12] Grounds for establishing draft specifications

a) Draft specifications should be appropriate to secure a constant quality concerning safety and effectiveness of the food additive. They should be based on documents given in (4) [1] and (8) [1] - [11], taking into account specifications established by international organizations.

b) A comparative table referring to the specifications established by international organizations and other major national institutions, and draft specifications should be prepared.

[13] Stability of food additives

The stability of the food additive including search for breakdown products should be evaluated.

[14] Analytical methods for food additives in food

Basically, analytical methods should be established for foods in which the food additive is likely to be used at high possibility. Methods should be able to identify the addition of the food additive quantitatively and qualitatively by chemically analyzing target foods. If other additives with similar purposes are used together with the food additive, the target additive should be separated from these additives analyzed. If the food additive does not require standards for use or it is determined not to remain in food, its assay method may be exempted from the description of the quantitative analytical methods of the food additive in food.

(9) Documents on draft standards for use

[1] When the applicant determines that standards for use of the food additive are necessary to restrict the target foods and the amount of use, as a result of comprehensive evaluation of the safety and effectiveness of the food additive, he or she should clarify the evidence to support the necessity of the standards for use, based on other documents attached. Standards for use should be established, according to those already established for other food additives.

[2] When the applicant determines that standards for use of the food additive are not necessary, he or she should clarify the evidence to support that determination, based on other documents attached.

[3] The documents should include evidence to support the necessity of the revision of standard(s) for use of the food additive, including the addition of target foods and the change of the amount of use.

(10) Documents on effectiveness

[1] Studies concerning effectiveness should be conducted to establish that the food additive has expected effects, according to its purpose.

For example, for an antioxidant, conduct studies which are capable of demonstrating the antioxidant effect of the food additive, based on the relationship with the amount of the food additive to be added and change in effect with time. Or, in the case of a preservative, conduct studies which demonstrate increase in preservative effects on target foods. Comparisons in effects with a widely used food additive, which has already been approved for the same use, are desirable.

[2] Studies on the stability of the food additive in foods should be conducted. For unstable food additives, breakdown products should be examined on kinds and generation extent.

[3] Effects of the food additive on main nutrients in foods should be examined.

(11) Documents on safety information

Information necessary for assessment of the effect of food on health should be described pursuant to the Guidelines for the Risk Assessment of Food Additives (determined by the Food Safety Commission in September 2021).

(Attached Table)

Documents required for application of designation and revision of standards for use of food additives

Type of documentation	Designation	Revision of standards
1. Draft specifications	○	
2. Draft standards for use and contrasting list	○	○
3. Overview document	○	○
4. Documents on name and purpose of use	○	○
5. Documents on origin or details of development	○	△
6. Documents on condition of use in overseas countries	○	○
7. Documents on safety evaluations by international organizations	○	△
8. Documents on physicochemical properties and specifications	○	△
9. Documents on draft standards for use	○	○
10. Documents on effectiveness		
(1) Effectiveness as a food additive and comparisons in effects with other food additives of the same category.	○	○
(2) Stability in foods	○	△
(3) Effects of the food additive on main nutrients in foods	○	△
11. Documents on safety information or safety evaluation	*	*

Note 1) Symbol ○ shows documentation to be attached and △ shows documentation to be attached when necessary, if there are available findings or new findings. For symbol *, documentation necessary for assessment of the effect of food on health should be attached pursuant to the Guidelines for the Risk Assessment of Food Additives (Revised Guidelines for Assessment of the Effect of Food on Human Health Regarding Food Additives) (determined by the Food Safety Commission in September 2021).

Note 2) Basically, food additives which have not undergone assessment of the effect of food on health by the Food Safety Commission require submission of documentation on “designation.” Revision of standards for use of food additives for which assessment of the effect of food on health by the Food Safety Commission has completed require submission of documentation on “revision of standards.”

(Attachment 1)

For new designation

Date

Minister of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)
Name of applicant (For a corporation, its name and the representative's name)

We hereby apply for designation of the substance given below as a food additive not injurious to human health, pursuant to Article 12 of the Food Sanitation Act.

(Name of substance)

(Notes)
1. Use JIS A4-size paper.
2. Use black ink and write in clear block letters for Japanese.
3. Give the contact in Japan if the applicant lives overseas.

(Attachment 2)

For revision of standards for use

Date

Minister of Health, Labour and Welfare

Address of applicant (For a corporation, principal place of business)
Name of applicant (For a corporation, its name and the representative's name)

We hereby apply for partial revision of the standards for use of food additives, as given below, pursuant to Paragraph 1, Article 13 of the Food Sanitation Act.

(Name of the food additive and proposed standards for use)

(Notes)
1. Use JIS A4-size paper.
2. Use black ink and write in clear block letters for Japanese.
3. Give the contact in Japan if the applicant lives overseas.