

Guidelines for the Designation of Flavoring Agents

This document was issued on May 17, 2016, as an attachment to Notification of Director-General of Department of Environmental Health and Food Safety, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, No. 0517-1, titled “Concerning Guidelines for the Designation of Flavoring Agents”.

This document is the English translation of “香料の指定に関する指針.” The Ministry of Health, Labour and Welfare offers this translation as a service to a broad international audience/readers. While the ministry has attempted to obtain translation that is as faithful as possible to the Japanese version, we recognize that the translated version may not be as precise, clear, or complete as the original version. The official version of this document is the Japanese version.

Attachment

Guidelines for the Designation of Flavoring Agents

I Purpose

The guidelines provide the procedures required to apply to the Minister of Health, Labour and Welfare for the designation of flavoring agents as food additives to be listed in Table1 of the Ordinance for Enforcement of the Food Sanitation Act (Ordinance of the Ministry of Health and Welfare, No. 23, 1948) as well as the scope of documents that should be submitted with the application, such as results of safety studies.

The flavoring agents subject to the Guidelines are food additives defined in Article 4-2 of the Act and intended to be used for the flavoring of food.

Thus, if additives designated based on the Guidelines are used for purposes other than the flavoring of food, the procedures for revising the specifications and standards will be required in accordance with the “Guidelines for the Designation of Food Additives and for Revision of Standards for Use of Food Additives” (Notification of the Director-General of Environmental Health Bureau, No. 29, March 22, 1996).

II Basic policies on the designation of flavoring agents

Flavoring agents are intentionally added to food for the purpose of flavoring it, and therefore, they must be ensured as safe.

Thus, in designating flavoring agents, it is important that the points shown below are scientifically assessed.

For this reason, deliberation needs to be made by the Pharmaceutical Affairs and Food Sanitation Council (“the Council”) of the Ministry of Health, Labour and Welfare (“the MHLW”) from a scientific perspective, in consideration of food consumptions in Japan as well as the overseas food additive standards, such as those of JECFA (Joint FAO/WHO Expert Committee on Food Additives). In addition, assessment is made by the Food Safety Commission of Japan in the Cabinet Office (“the FSC”) on the effect of flavoring agents on human health through food.

1. Safety

It shall be proven or confirmed that the substance for which designation is requested (hereinafter the “substance for which designation is requested” is referred to as the “target substance”) is safe when it is used for the flavoring of food.

2. Effectiveness/Necessity

It shall be proven or confirmed that the target substance improves the organoleptic properties, such as food taste.

III Procedures for the designation of flavoring agents

1. Application

Those who apply for designation of a flavoring agent may submit an application to the Minister of Health, Labour and Welfare using the form as described in the appendix (Place of submission: Standards and Evaluation Division, Department of Environmental Health and Food Safety, Pharmaceutical Safety and Environmental Health Bureau, the MHLW). The application must be accompanied by documents, such as on draft specifications and standards for the flavoring agent and its safety.

Further, if the applicant resides overseas, a person who is able to respond responsibly in Japanese to matters concerning the application should be specified in the application.

2. Procedures of the designation

When receiving an application for the designation of a flavoring agent, the MHLW asks the FSC to assess the effect of the flavoring agent on human health through food based on the provisions of Article 24 of the Food Safety Basic Act (Act No. 48 of 2003). The FSC conducts assessment based mainly on documents on safety.

When notified by the FSC of the assessment result, the MHLW consults the Council on the designation.

Following discussion on the matters referred, the Council submits a report to the Minister of Health, Labour and Welfare. Based on the report, the MHLW takes necessary measures, including the revision of the Ordinance for Enforcement of the Food Sanitation Act. When necessary, the FSC and Council may request the additional information to the applicant in the course of assessment by the FSC and the process of deliberation by the Council.

IV Documents to accompany application for the designation of flavoring agents

1. Scope of accompanying documents

(1) For application for the designation of a flavoring agent, in principle, the documents listed in the Table should be submitted.

(2) Notwithstanding the requirement of (1), the applicant may be exempted from the submission of some documents with the provision of the reason, when the flavoring agent is identical to an already designated flavoring agent with exception in different bases, when the flavoring agent is an isomer of an already designated flavoring agent, or when any other legitimate reason exists.

(3) Documents that would raise doubts about the quality, safety, or effectiveness of the flavoring agent for application of the designation should be submitted, without regard to the reliability of the submitted documents.

2. General considerations for preparation of accompanying documents

(1) Applicants should submit documents for application on their responsibility and assume full responsibility for the reliability of the information given in the documents.

(2) The main part of accompanying documents (“overview documentation”) must be written in Japanese. However, documents other than the overview documentation (quoted documents listed in categories 2 to 5 in the Table) may be submitted in English. Quoted documents in languages other than Japanese or English must be accompanied by their Japanese translations.

(3) Studies necessary to prepare the required documents should be conducted at laboratories that have facilities, equipment, and personnel adequate to ensure the credibility of the study results, and that are recognized as appropriately managed.

3. Specific considerations on the preparation of accompanying documents

(1) Overview documentation

① The overview documentation must be prepared in consideration of the Procedure for Preparing Application Documents for Designation of Food Additives and Revision of Use Standards for Food Additives—an attachment to the Notification of Director of the Standards and Evaluation Division, Department

of Food Safety, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, No. 0909-2, September 9, 2014, titled “Concerning the Procedure for Preparing Application Documents for Designation of Food Additives and Revision of Use standards for Food Additives.”

② The overview documentation should be described concisely, according to the document category. To identify the documents related, the number of the document being referenced should appear on the upper left or right corner of the corresponding page. In addition, sequential page numbers must be entered on all pages.

③ If any quoted documents listed in the Table are omitted from description, the reason for the omission should be stated.

④ In principle, draft specifications and standards should accompany the application with them contained in the overview documentation.

⑤ The draft standard for use should be stated as follows: It shall not to be used for purposes other than the flavoring of food.

(2) Documents on the origin or details of development and use status in other countries

① Origin or details of development

The background that led to application should be described to the extent possible, including examples showing that the target substance occurs in nature and information on when and in which country it was developed and subsequently in which country it came to be used as a flavoring agent.

② Use status in other countries

Overseas status of the target substance should be described, including authorization status, the names of the foods in which it is permitted for use, and specifications and standards. Also, safety assessments, specifications, and standards of international organizations should be described.

(3) Documents on the physiochemical properties and specifications

Documents should be prepared based on results of tests appropriately conducted in accordance with A. *General Notices* and B. *General Tests*, under Part 2 *Additives* in Ministry of Health and Welfare Notification No. 370, titled “*Specifications and Standards for Food, Food Additives, Etc.*” (Ministry of Health and Welfare Notification No. 370, 1959, hereinafter referred to as “Notification”).

① Name

The general name, chemical name (IUPAC name), and other appropriate name should be indicated.

② Structural or rational formula

This item should be described referring to Part 2 of Notification.

③ Molecular formula and molecular weight

These items should follow Part 2-A of the Notification.

④ Assay

Assay should be established to guarantee constant quality in safety and effectiveness, based on the manufacturing processes, quantitative error, stability, and other conditions.

The content of an effective ingredient as a flavoring agent should be described in percentage. When two or more effective ingredients exist, the content should be described for individual ingredients.

⑤ Manufacturing methods

Since different manufacturing processes could result in different type or amount of impurities, the manufacturing methods should be described concisely.

⑥ Description

Information on description should include items that are required for identification and handling at the time of use, such as the odor, color, and form of the target substance.

⑦ Identification tests

Identification tests are conducted to confirm whether the substance concerned is the target flavoring agent, based on its characteristics. The tests, therefore, should be specific to the characteristics of the substance's chemical structure.

Ordinarily, conceivable test methods for identification are based on spectral analysis and chemical reaction. Methods based on chemical reaction should be set if they are appropriate for confirming the characteristics of the chemical structure.

⑧ Specific properties

Specific properties are expressed as numeral values measured by physical and chemical methods, such as absorbance, optical rotation, pH, and melting point. Parameters that are essential to ensure the quality shall be specified.

⑨ Purity tests

Purity tests are conducted to determine impurities in the flavoring agent. The purity tests as well as assay define the purity of the flavoring agent. Tests should be set for necessary substances among those that may be present as contaminants in the flavoring agent (raw materials, intermediates, by-products, decomposition products, reagents/catalysts, heavy metals/inorganic salts, and solvents).

⑩ Loss on drying, loss on ignition, or water content

A loss on drying test is conducted to measure the amount of the substances in the flavoring agent that are lost by drying, including free water, all or part of the crystal water, and volatile substances. A loss on ignition test is conducted on the inorganic substances that lose a part of the structural components or inclusions by ignition. Water determination is conducted to identify the water content in the flavoring agent.

⑪ Ignition residue (Residue on ignition)

A residue on ignition test is generally conducted to identify the content of the inorganic substances present as impurities in organic substances. In some cases, the test is conducted to measure the amount of the inorganic substances present in organic substances as the structural components, or the impurities in inorganic substances that volatilize when heated.

⑫ Methods of assay

Assay is a test to measure the content of effective components by physical, chemical, or biological methods. A commonly employed method is directed under *Gas Chromatographic Assay of Flavoring Agents, Flavoring Substances Tests* in Part 2B in the Notification.

When it is impossible to establish a testing method with sufficient reproducibility or specificity, an appropriate method that is able to measure the absolute amount with good reproducibility may be established. When the limit of the inclusion is regulated, there is a need to establish a method with high specificity for other tests, such as purity tests, to complement the lack of specificity of the assay method.

If constituents to be determined are more than one, they should be described in the order of importance.

⑬ Stability of flavoring agents

The stability of flavoring agents should be examined, including the retrieved information on decomposition products.

⑭ Analytical methods of flavoring agents in food

If necessary, a method to be able to qualitatively and quantitatively identify the addition of the flavoring agent should be established, for example, including chemical analysis, for foods in which the flavoring agent is likely to be used. Examination should be made as to whether the flavoring agent can be quantitatively separated from other flavoring agents.

⑮ Grounds for establishing draft specifications

(i) The draft specifications should be established as necessary to ensure a certain level of quality concerning safety and effectiveness of the flavoring agent, based on the information shown in ①–⑫, taking into consideration the specifications established by international organizations.

(ii) A table comparing the draft specifications with the specifications established by international organizations and foreign countries should be attached.

(4) Documents on effectiveness

① Documents on effectiveness are required to proven or confirm that the use of the substance adds flavors to food or positively changes the original flavor of food.

② The stability of the flavoring agent in food should be examined. If it is not stable, the type and quantity of the primary decomposition products generated should be examined.

③ The effect of the flavoring agent on the main nutritional components of the food should be also examined.

(5) Documents on safety

Documents that are required in accordance with the “Guideline for Assessment of the Effect of Food on Human Health Regarding Flavoring Agents” (Decision by the FSC in May 2016) should be attached.

Table Documents to accompany the application for designation of flavoring agents

Document category
1. Overview documentation
2. Documents on the origin or details of development and use status in other countries
(1) Origin or details of development
(2) Use status in other countries
3. Documents on the physiochemical properties and specifications
(1) Name
(2) Structural or rational formula
(3) Molecular formula and molecular weight
(4) Assay
(5) Manufacturing methods
(6) Description
(7) Identification tests
(8) Specific properties
(9) Purity tests
(10) Loss on drying, loss on ignition, or water content
(11) Ignition residue (Residue on ignition)
(12) Methods of assay
(13) Stability of food additives
(14) Analytical methods of food additives in food
(15) Grounds for establishing draft specifications
4. Documents on effectiveness
(1) Effectiveness as food additives
(2) Stability in food
(3) Effects on nutritional components in food
5. Documents on safety

(Appendix)

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)

Seal

I/We hereby apply for the designation of the substance below, pursuant to Article 10 of the Food Sanitation Act, as a food additive unlikely to cause damage to human health.

(Name of the substance)

(Note)

1. Use JIS A4-size paper.
2. Use black ink. Type in clear block letters, if in Japanese.
3. If the applicant resides outside Japan, specify the name and contact information of a person who is able to responsibly respond in Japanese to matters regarding the application. The seal may be replaced by the applicant's signature,