

Ninth Edition

Japan's  
Specifications and Standards  
for  
Food Additives

The Ministry of Health, Labour and Welfare  
The Consumer Affairs Agency

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Note: This document is an English translation of the official compilation of food additives, ninth edition. In the case of any discrepancy between the Japanese original and the English translation, the former will take priority.

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## Historical Background

In 1878 Japan initiated the nationwide control of food safety. This was based on the Notice concerning the Control of the Use of Aniline Dyes and Mineral Pigments in Food (No. 35, April 18, 1878), which was issued from the Minister of Home Affairs to the local governments.

In 1900 Japan first enacted the general act concerning food safety (Act No. 15, the Act for the Control of Foods and Things Relating to Foods). This act was established to provide comprehensive provisions for the control of food and beverages. Based on this act, the Minister of Home Affairs established successive enforcement regulations. These regulations were specialized for individual product categories, like milk, and non-alcoholic drinks, and coloring agents. These regulations were promulgated under the approval of the Central Food Sanitation Council. The regulations related to food additives are given below.

Enforcement Regulations for the Control of Poisonous Coloring Matters

(Ministry of Home Affairs Ordinance No. 17, April 17, 1900)

Enforcement Regulations for the Control of Artificial Sweetening Agents

(Ministry of Home Affairs Ordinance No. 31, October 16, 1901)

Enforcement Regulations for the Control of Food Preservatives

(Ministry of Home Affairs Ordinance No. 10, August 28, 1903)

Enforcement Regulations for the Control of Methyl Alcohol

(Ministry of Home Affairs Ordinance No. 8, May 28, 1912)

With some revisions, the Japanese act and regulations for food had been mostly formulated by the early 1930s. However, they had not yet fully covered all matters related to food.

In 1938 the Ministry of Health and Welfare was founded, and the food safety responsibilities have come under its jurisdiction.

After World War II, Japan enacted the comprehensive food act, entitled the Food Sanitation Act (Act No. 233, December 24, 1947), in the wake of the enactment of the new Japanese constitution. The next year, the Minister of Health and Welfare established the Enforcement Regulations of the Food Sanitation Act (Ministry of Health and Welfare Ordinance No. 23, July 13, 1948), and the Specifications and Standards for Foods, Food Additives, Equipment, Containers, and Packages (Ministry of Health and Welfare Notification No. 54, July 13, 1948), based on Articles 7 and 10 of the Food Sanitation Act.<sup>1</sup>

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<sup>1</sup> The Food Sanitation Act has been revised several times. Article 7 and Article 10 correspond to Article 11 and Article 18, respectively, of the current act.

In June 1957, the Food Sanitation Act was partially revised and a new provision (Article 13) concerning an official compilation of food additives was added. That revision was triggered by the arsenic-poisoning outbreaks in 1955, involving contaminated infant formula, resulting in a number of infant deaths.

Also, Article 25 was revised to include matters about the preparation of the official compilation of food additives in the scope of the matters on which the Food Sanitation Council shall deliberate upon request from the Minister.

**Article 13.** The Minister of Health and Welfare shall prepare the official compilation of food additives, which will contain the specifications and standards for the additives established pursuant to the provisions of Article 7 Paragraph 1, and the standards for the additives established pursuant to the provisions of Article 11 Paragraph 1.<sup>2</sup>

**Article 25 Paragraph 1.** The Minister of Health and Welfare shall establish the Food Sanitation Council under the supervision of the Minister of Health and Welfare, to deliberate matters relating to the prevention of food poisoning, matters relating to the preparation of the official compilation of food additives, and other important matters relating to food sanitation, in response to requests for consultation from the Minister of Health and Welfare.<sup>3</sup>

The Food Sanitation Council established the Subcommittee on the Official Compilation of Food Additives, in response to a request for opinion from the Minister of Health and Welfare, to draft and deliberate on a compilation. In November 1959, the subcommittee submitted its final report to the Minister of Health and Welfare.

Based on the report, the Minister published the first Japanese edition of the official compilation of food additives in March 1960. That edition contained standards and specifications for 198 additives. Since the publication of the first edition, the official compilations have been prepared fairly regularly. In August 2007 the eighth edition was published.

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<sup>2</sup> Article 11 corresponds to Article 4 of the Food Labeling Act (Act No. 70, June 28, 2013). Article 13 corresponds to Article 21 of the current Food Sanitation Act.

<sup>3</sup> Article 25 Paragraph 1 was repealed, and the Pharmaceutical Affairs and Food Sanitation Council was founded based on the Order for the Pharmaceutical Affairs and Food Sanitation Council (Cabinet Order No. 286, June 7, 2000).

## Introduction

In July 2009, the Ministry of Health, Labour and Welfare established a panel to draft the ninth edition of the official compilation of food additives. The panel was aimed to formulate the compilation corresponding to technological advances in manufacturing and quality control of food additives as well as analytical advances made since the publication of the eighth edition.

The panel worked to enhance compositional specifications for existing food additives (additives derived from natural sources, so-called natural additives) based on the 1995 revision of the Food Sanitation Act, to introduce new and improved test methods in step with the progress in science and technology, and to achieve international harmonization of standards.

In August 2016, the Minister of Health, Labour and Welfare referred the revision of Ministry of Health, Labour and Welfare Notification No. 370, 1959 (titled *Specifications and Standards for Food, Food Additives, Etc.*), based on the drafted official compilation (the ninth edition), to the Pharmaceutical Affairs and Food Sanitation Council. In October 2017, the Council submitted the affirmative report of the review to the Minister.

In response to the revision of the Ministerial Notification, the ninth edition was formulated. This edition carries General Notices (42 items); General Tests (45 items); Reagents, Solutions, and Other Reference Materials (11 categories); Monographs (683 monographs); Standards for Manufacturing; Standards for Use; and Standards for Labeling.

The following sections outline the revision.

### 1. General Notices

- (1) Several units and abbreviations have been added. The symbol for the unit “milliliter” has been changed from “ml” to “mL.”
- (2) The acceptable range of temperatures for testing has been revised. Definitions of some terms have been added.
- (3) Revisions have been added to some tests including tests to examine the nature of solutions and odors. The upper limit of assay has been revised.

### 2. General Tests

- (1) Methods to prepare test solutions and control solutions have been added in the Lead Limit Test.



- (2) Enumeration of yeasts and molds and tests for coliforms and *Salmonella* have been added in the Microbial Limit Tests.
- (3) The test using mercuric bromide test paper has been deleted in the Arsenic Limit Test because mercuric bromide test paper, which had been specified in Section C *Reagents, Solutions, and Other Reference Materials*, was deleted with mercuric bromide due to harmful reagents.
- (4) The names of tests have been changed: Turbidity of Solution Test to Clarity of Solution Test, and Specific Optical Rotation to Optical Rotation, respectively. In addition, the Japanese name of the analytical method using determination of the intensity of the atomic emission spectral line (Inductively Coupled Plasma-Atomic Emission Spectrometry) has been changed. However, its English name has remained unchanged.
- (5) Nuclear Magnetic Resonance Spectroscopy and Coloring Matter Preparations Tests have been added.

### 3. Reagents, Solutions, and Other References Materials

- (1) Some additions and deletions have been made in Section C *Reagents, Solutions, and Other References Materials* in the wake of revision of specifications in Section D *Monographs*.
- (2) The names of reagents appealing in the Japan Industrial Standards (JIS) have been based on the JIS nomenclature. The names of other reagents have been based on the IUPAC (International Union of Pure and Applied Chemistry) nomenclature. CAS (Chemical Abstracts Service) numbers have been added to individual reagents.

### 4. Monographs

- (1) Additions and deletions of monographs

A. Taking the opportunity of the revision of the eighth edition, specifications for the following existing food additives have been newly established.

#### Enzymes (62 monographs)

$\alpha$ -Acetolactate Decarboxylase, Acid Phosphatase, Acylase, Agarase, Alginate Lyase, Aminopeptidase,  $\alpha$ -Amylase,  $\beta$ -Amylase, Anthocyanase, Ascorbate Oxidase, Carboxypeptidase, Catalase, Cellulase, Chitinase, Chitosanase, Cyclodextringlucanotransferase, 5'-Deaminase, Dextranase, Esterase, Exomaltotetrahydrolase, Ficin, Fructosyl Transferase,  $\alpha$ -Galactosidase,  $\beta$ -Galactosidase, Glucanase, Glucoamylase, Glucose Isomerase, Glucose Oxidase,  $\alpha$ -Glucosidase,  $\beta$ -Glucosidase,  $\alpha$ -Glucosyltransferase, Glutaminase, Hemicellulase, Hesperidinase, Inulinase, Invertase, Isoamylase, Lactoperoxidase, Lipase, Lipoxygenase, Maltose Phosphorylase, Maltotriohydrolase, Muramidase, Naringinase, Pancreatin, Pectinase, Peptidase, Peroxidase, Phosphodiesterase, Phospholipase, Phytase, Polyphenol Oxidase, Protease, Pullulanase, Rennet, Tannase, Transglucosidase, Transglutaminase, Trehalose Phosphorylase, Urease, Xylanase

### Substances other than enzymes (27 monographs)

Annatto Extract, Cacao Color, Caffeine (Extract), Calcinated Bone Calcium [Calcinated Calcium]\*, Carob Germ Color, Cholesterol, Enzymatically Hydrolyzed Licorice Extract, Enzymatically Modified Rutin (Extract), Ferulic Acid,  $\alpha$ -Glucosyltransferase Treated Steviol Glycosides [ $\alpha$ -Glucosyltransferase Treated Stevia]\*, Grape Seed Extract, Hesperidin, Kaoliang Color, Lactoferrin concentrates, Monascus Yellow, Mustard Extract, Non-calcinated Coral Calcium [Non-calcinated Calcium]\*, Onion Color,  $\gamma$ -Oryzanol, Pectin Digests, Phytic Acid, L-Rhamnose, Rice Bran Oil Extract, Steviol Glycosides [Stevia Extract]\*, Tamarind Color, Vegetable Sterol, Welan Gum

B. Specifications for substances that have been designated since the publication of the eighth edition are added.<sup>§</sup> In addition, specifications for some additives have been deleted.

### Added (91 monographs including those for 43 flavoring agents)

Acetylated Distarch Adipate, Acetylated Distarch Phosphate, Acetylated Oxidized Starch, Advantame,  $\beta$ -Apo-8'-carotenal, Asparaginase, Azoxystrobin, Calcium Acetate, Calcium L-Ascorbate, Calcium Oxide, Calcium Saccharin, Calcium Silicate, Calcium Sorbate, Canthaxanthin, Chlorous Acid Water, Distarch Phosphate, Fludioxonil, Glutamyl-valyl-glycine, 1-Hydroxyethylidene-1,1-diphosphonic Acid, Hydroxypropyl Distarch Phosphate, Hydroxypropyl Starch, Hypobromous Acid Water, Magnesium Hydroxide, Magnesium Monohydrogen Phosphate, Magnesium Silicate, Monoammonium L-Glutamate, Monostarch Phosphate, Neotame, Nisin, Octanoic Acid, Oxidized Starch, Peracetic Acid Composition, Phosphated Distarch Phosphate, Polysorbate 20, Polysorbate 60, Polysorbate 65, Polysorbate 80, Polyvinylpyrrolidone, Potassium Lactate, Potassium Sulfate, Pyrimethanil, Sodium Selenite, Sodium Stearoyl Lactylate, Starch Acetate, Starch Sodium Ocetenyl Succinate, *all-rac*- $\alpha$ -Tocopheryl Acetate, *R,R,R*- $\alpha$ -Tocopheryl Acetate, Triethyl Citrate

#### *Flavoring agents*

(3-Amino-3-carboxypropyl)dimethylsulfonium Chloride, Ammonium Isovalerate, Butylamine, Butyraldehyde, 2,3-Diethyl-5-methylpyrazine, 2,3-Diethylpyrazine, 2,3-Dimethylpyrazine, 2,5-Dimethylpyrazine, 2,6-Dimethylpyrazine, 2,6-Dimethylpyridine, 2-Ethyl-5-methylpyrazine, 2-Ethyl-6-methylpyrazine, 5-Ethyl-2-methylpyridine, 2-Ethylpyrazine, 3-Ethylpyridine, Isobutyraldehyde, Isopentylamine, Isoquinoline, Isovaleraldehyde, 2-Methylbutanol, 3-Methyl-2-butanol, *trans*-2-Methyl-2-butenal, 3-Methyl-2-butenal, 3-Methyl-2-butenol, 2-Methylbutyraldehyde, 5-Methyl-6,7,-dihydro-5*H*-cyclopentapyrazine, 1-Methylnaphthalene,

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\* Substances marked with asterisk (calcinated bone calcium,  $\alpha$ -glucosyltransferase treated steviol glycosides, non-calcinated coral calcium, steviol glycosides) are listed under the corresponding names enclosed by the square brackets in the Existing Food Additives List. Separately, monographs for  $\alpha$ -glucosyltransferase treated stevia and stevia extract already appear in the eighth edition.

§ These substances have been designated since the publication of the eighth edition and have been published in the Official Gazette (*Kanpō*) by October 6, 2016.

2-Methylpyrazine, 6-Methylquinoline, *trans*-2-Pentenal, 1-Penten-3-ol, 2-Pentanol, Phenethyl Acetate, Phenethylamine, 2-(3-Phenylpropyl)pyridine, Piperidine, Propionaldehyde, Pyrazine, Pyrrole, Pyrrolidine, 5,6,7,8-Tetrahydroquinoxaline, Trimethylamine, Valeraldehyde

Deleted (3 monographs for a designated additive and 2 existing food additives)

Sodium Starch Phosphate (designated additives), *N*-Acetylglucosamine, Dammar Resin (existing food additives)

- (2) Revisions have been made in the purity tests in the Monographs.
  - A. Specifications for heavy metals have been replaced by those for lead.
  - B. The conversion mode of arsenic has been changed from diarsenic trioxide ( $\text{As}_2\text{O}_3$ ) to arsenic (As).

5. Standards for Manufacturing

- (1) Requirements for cultured strains of microorganisms that are used for the manufacturing of enzyme additives have been specified.
- (2) A requirement for talc to the effect that ingredients used for the manufacturing of talc shall not contain asbestos has been specified.

6. Besides specifications described in No. 1 through No. 5, modifications have been made concerning consistency in the way terminologies and examples are described.

## Explanatory Notes

**General Notices** This section gives general rules for performing tests in accordance with specifications and standards.

**General Tests** This section describes practical test methods common to certain additives.

**Reagents, Solutions, and Other Reference Materials** This section contains specifications concerning reagents, test solutions, and standards solutions in alphabetical order.

**Monographs** This section states specifications and standards for individual food additives listed in this publication. The section includes the definition, content, and description of each substance as well as the testing for identification, purity, and assay. It also includes specifications and standards necessary for corresponding substances, such as specific gravity, loss on drying, residue on ignition, and storage standards.

**Standards for Manufacturing** This section contains general and specific standards concerning the manufacture of food additives.

**Standards for Use** This section gives target foods, maximum use levels in each target food, and other restrictions for each of the additives with standards for use.

**Labeling Standards** This section specifies items to be declared for additives and relevant requirements. These standards are under the jurisdiction of the Consumer Affairs Agency.