

## **A. GENERAL NOTICES**

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1. The title of this book is *Japan's Specifications and Standards for Food Additives, Ninth Edition*, which may be abbreviated as JSFA-IX.
2. Unless otherwise specified, determination of the compliance of food additives shall be based on the provisions, specifications, and standards as directed under the headings "General Notices," "General Tests," and "Monographs." The physical form of each solid substance indicated under "Description" in each monograph is given merely as reference information and not as a requirement for determination.
3. In this English translation, substances whose names are indicated with an initial capital letter and enclosed with quotation marks mean food additives that meet the requirements specified in the Monographs.
4. Any substance whose name is followed by its molecular formula or compositional formula enclosed in parentheses means that the substance is a chemically pure substance. The atomic weights used in this publication comply with the Standard Atomic Weights 2010 (the Chemical Society of Japan). The molecular weights are expressed to two decimal places, rounded off to the nearest hundredth.

### Units and Abbreviations

5. The following abbreviations are used as the main measurement units:

meter	m
centimeter	cm
millimeter	mm
micrometer	μm
nanometer	nm
kilogram	kg
gram	g
milligram	mg
microgram	μg
nanogram	ng
degrees Celsius	°C
mole	mol
millimole	mmol
square centimeter	cm <sup>2</sup>
liter	L
milliliter	mL

microliter	$\mu\text{L}$
megahertz	MHz
per centimeter	$\text{cm}^{-1}$
newton	N
kilopascal	kPa
pascal	Pa
pascal second	$\text{Pa} \times \text{s}$
millipascal second	$\text{mPa} \times \text{s}$
square millimeter per second	$\text{mm}^2/\text{s}$
mol per liter	$\text{mol/L}$
millimol per liter	$\text{mmol/L}$
microsiemens per centimeter	$\mu\text{S/cm}$
degree (angle)	$^{\circ}$

6. Mass percentage is expressed using the symbol “%.” The mass (g) of a substance in 100 mL of a liquid or gas is expressed using the symbol “% (w/v).” The volume (mL) of a substance in 100 g of a substance is expressed using the symbol “% (v/w).” The volume (mL) of a substance in 100 mL of a liquid or a gas is expressed using the symbol “% (vol).” Unless otherwise specified, the mass (g) of a solid in percentage is expressed on the anhydrous basis.

7. The potency of a food additive shall be expressed using the unit specified in the individual monograph.

8. Temperatures are expressed in centigrade (Celsius) degrees with Arabic numerals followed by the symbol “°C”. Where a temperature is expressed in integer numbers in the individual procedures, its acceptable range shall usually be  $\pm 1^{\circ}\text{C}$  or  $\pm 5\%$  of the specified temperature, whichever is larger. When a temperature controller is used to maintain temperature, its temperature control accuracy at the temperature set is acceptable.

### Tests

9. An alternative testing method that is equal or superior in precision and accuracy to a method specified in JSFA-IX may replace the specified method. However, if there is any doubt about the results, the final determination shall be made by the corresponding methods specified in JSFA-IX.

10. Unless otherwise specified, each test directed in the Monographs or other sections in JSFA-IX shall be performed by the corresponding method specified in the General Tests,

based on the directions given in the individual monograph or other corresponding sections.

11. Where judgment for conformity is made by comparing a value obtained by a test (measured value) with a specified value (standard value), comparison shall be made between the standard value and the measured value that is obtained to one more digit than required and rounded off to the nearest indicated digit. An expression “a–b” or “a to b” for a standard value means the standard value is not less than “a” and not more than “b.”

12. Unless otherwise specified, the water to be used in the tests specified in JSFA-IX shall be “water for food manufacturing”<sup>1</sup> that is purified through hyperfiltration (inverse osmosis or ultrafiltration), ion-exchanging, distillation, or a combination thereof. The water shall be used immediately after purification. If it is placed in an appropriate container to control contamination by microorganisms or chemical compounds, it may be used even after it is stored for a certain period.

13. “Standard temperature,” “ordinary temperature,” “room temperature,” and “lukewarm temperature” mean 20°C, 15–25°C, 1–30°C, and 30–40°C, respectively. Unless otherwise specified, “cold place” means a place where the temperature is 1–15°C. “Cold water” means water at a temperature of not higher than 10°C, and “lukewarm water” means water at a temperature of 30–40°C. “Warm water” means water at a temperature of 60–70°C, and “hot water” means water at a temperature of about 100°C. “To warm” means to raise the temperature to 60–70°C, unless otherwise specified.

14. Unless otherwise specified, the temperature of the testing room shall be 15–30°C. A procedure described as “immediately” normally means that the procedure is performed within 30 seconds after the previous procedure is finished.

15. The term “heated solvent” or “hot solvent” means a solvent heated almost to the boiling point of the solvent, and the term “warmed solvent” or “warm solvent” means a solvent heated to 60–70°C, unless otherwise specified.

16. The expression “to heat on a water bath” means to heat the substance on a boiling water bath, and a steam bath at about 100°C may replace the boiling water bath. The expression “to heat in a water bath” means to heat the substance by placing the vessel containing the substance in a boiling water bath, unless otherwise specified. The

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<sup>1</sup> “Water for food manufacturing” is water supplied by the water-supply system specified by Article 3 Paragraph 2 of the Water Supply Act, the private water-supply system specified by Paragraph 6 of the same article, or small-size private water-supply specified by Paragraph 7 of the same article.

expression “to heat under a reflux condenser” means, unless otherwise specified, to heat the substance in a solvent by boiling and refluxing the solvent. The expression “after cooling” means after the temperature of a heated or warmed substance falls to room temperature.

17. When the amount of a liquid is specified by the number of drops, a device capable of supplying 20 drops of water that weigh 0.90–1.10 g at 20°C shall be used.

18. Unless otherwise specified, the term “reduced pressure” means a pressure not exceeding 2.0 kPa.

19. Unless otherwise specified, the desiccant in a desiccator shall be silica gel.

20. Unless otherwise specified, when the nature of a solution is indicated just as “acidic,” “alkaline,” or “neutral,” the solution shall be tested using litmus paper. The terms “slightly acidic,” “weakly acidic,” “strongly acidic,” “slightly alkaline,” “weakly alkaline,” and “strongly alkaline” indicate the approximate degrees of acidity or alkalinity obtained when a solution is tested using pH test paper. The ranges of the corresponding pH values are given below. When the nature of a solution is indicated by pH values, testing shall be done as directed under pH Determination in the General Tests.

<u>Descriptive term</u>	<u>Range of pH</u>
Strongly Acidic	less than 3
Weakly Acidic	from 3 to less than 5
Slightly Acidic	from 5 to less than 6.5
Slightly Alkaline	from 7.5 to less than 9
Weakly Alkaline	from 9 to less than 11
Strongly Alkaline	11 and more

21. Any solution indicated by a solute name along with the word “solution” is an aqueous solution, unless the name of a specific solvent is given.

22. Where a liquid reagent is indicated only with its concentration, like 1 mol/L hydrochloric acid, diluted sulfuric acid (1 in 10), or 50% (vol) ethanol, it means that the reagent is diluted with water, unless otherwise specified.

23. An expression such as “(1 in 5)” or “(1 in 100)” for solutions means the concentration ratio whereby 1 g of a solid substance or 1 mL of a liquid substance is dissolved in a solvent to make 5 mL or 100 mL, respectively. An expression such as “10:1” or “5:3:1” for a liquid mixture means a mixture of two different liquids in the ratio of 10 to 1 by

volume, or a mixture of three different liquids in the ratio of 5 to 3 to 1 by volume, respectively.

24. The expression “to weigh” means to weigh a substance so that the quantity actually taken is within the range of values in which each value rounded off to the nearest indicated digit makes the specified value. For example, “to weigh 1 g” means to take an amount between 0.5 and 1.4 g, “to weigh 1.0 g” means to take an amount between 0.95 and 1.04 g, and “to weigh 1.00 g” means to take an amount between 0.995 g and 1.004 g.

25. The expression “to weigh accurately” means to weigh the mass to the required accuracy, taking into account the number of decimal digits of the standard value. Usually, when the mass is weighed to the 0.1-mg accuracy, 10- $\mu$ g accuracy, or 1- $\mu$ g accuracy, a chemical balance, semimicro chemical balance, or micro chemical balance is used, respectively.

26. When the quantity of sample to be taken for assays or other tests is indicated with the term “about,” the quantity actually taken may deviate within the range of  $\pm 10\%$  of the specified quantity.

27. Unless otherwise specified, the expression “to measure exactly,” means to measure the specified quantity using a whole pipet, buret, or other measuring device equal or superior in precision and accuracy to the aforementioned volumetric devices. Where the expression “to make exactly 100 mL” is given, a volumetric flask shall be used unless otherwise specified.

28. The term “white” means white or practically white, and the term “colorless” means colorless or practically colorless. When the tone of a color is tested, unless otherwise specified, in the case of a solid sample, 1 to 3 g of the sample shall be placed on a watch glass and observed against a white background; in the case of a liquid sample, the sample shall be placed into a colorless test tube with about 1.5-mm internal diameter to 3 mm in depth and observed from above and from the side against a white background. When the fluorescence of a liquid sample is observed, a black background shall be used.

29. The term “odorless” means odorless or practically odorless. Unless otherwise specified, tests for odor shall be performed by placing about 1 g for a solid sample or 1 mL for a liquid sample in a beaker. For a substance with a strong or pungent odor, it is acceptable to dilute it as necessary or use a filter paper.

30. The terms to describe solubilities are given below. The solubility of a substance,

unless specified otherwise, means the degree to which the substance dissolves within 30 minutes when the test is performed by placing the powdered sample into the specified solvent and shaking vigorously for 30 seconds at a time at 5-minute intervals at  $20 \pm 5^{\circ}\text{C}$ .

<u>Volume of solvent required</u>	
<u>Descriptive term</u>	<u>to dissolve 1 g or 1 mL of solute</u>
Very soluble	less than 1 mL
Freely soluble	from 1 mL to less than 10 mL
Soluble	from 10 mL to less than 30 mL
Sparingly soluble	from 30 mL to less than 100 mL
Slightly soluble	from 100 mL to less than 1000 mL
Very slightly soluble	from 1000 mL to less than 10 L
Practically insoluble	10 L and more

31. Unless otherwise specified, filtration shall be done through filter paper.

32. Identification tests are necessary to identify the main ingredients of a food additive based on their specific properties.

33. Unless otherwise specified, identification tests shall be performed by placing 2 to 5 mL of the specified solution into a test tube having an internal diameter of 8.0 to 18 mm.

34. Under the heading "Identification," for example, the expression "responds to the tests for Carbonate" or "responds to the tests for Sodium Salt" means that the specified reactions occur when the tests are performed as directed under Carbonate or Sodium Salt under the Qualitative Tests in the General Tests.

35. Purity tests are intended to detect impurities in a food additive, and these tests usually specify the types and quantitative limits of possible impurities.

36. Unless otherwise specified, the clarity of a solution shall be examined for a solution obtained by placing the sample into the specified solvent and shaking the mixture for 30 seconds to 5 minutes. Where the term "clear," "almost clear," "very slightly turbid," "slightly turbid," or "turbid" is used under the heading "Clarity of solution" in Purity, determination shall be based on the Clarity of Solution Test in the General Tests

37. The requirement "no turbidity appears" means that the clarity of the solution does not change.

38. “A Nessler tube” shall be a colorless, glass-stoppered test tube with a flat-bottom, with the dimensions of 20 mm in internal diameter, 24 mm in external diameter, and 20 cm in height from the bottom of the tube to the bottom of the stopper. It shall be marked with 5-mL graduations up to 50 mL, and the difference of the height at the 50 mL graduation mark between tubes shall not exceed 2 mm.

39. Unless otherwise specified, the term “constant weight” in drying or ignition means that when drying or ignition is continued for an additional hour, the difference between two consecutive weighings (before and after the additional hour) is not more than 0.1% of the preceding weighing of the dried substance or the residue on ignition. Where the difference is not more than 0.5 mg by a chemical balance, not more than 50 µg by a semimicro chemical balance, or not more than 5 µg by a micro chemical balance, the difference is taken as negligible and the weight obtained is deemed to be a constant weight.

40. An assay is a method to determine the content of an active component of a food additive or its potency. The limit of the content of a component or the potency declared in each monograph means the limit of the value obtained by the specified assay. Unless otherwise specified, the upper limit is 101.0%.

41. Where the instruction “to dry the sample” or “to ignite the sample” is given alone, the conditions for drying or ignition shall be the same as those given under Loss on Drying or Residue on Ignition in the individual monograph. Under the heading “Content” in the individual monographs, the expression “when dried” means that the additive is dried under the conditions given under Loss on Drying in the corresponding individual monograph. The expression “when calculated on the dried basis” means that calculation is carried out based on the value actually obtained by the test for Loss on Drying in the corresponding individual monograph. The expression “when calculated on the anhydrous basis” means that calculation is carried out based on the value actually obtained by the test for Water Content in the corresponding individual monograph.

### **Containers**

42. Hermetic containers are those capable of protecting the contents from intrusion by extraneous air or other gases during handling and storage under ordinary conditions.

43. Light-resistant containers are those capable of preventing the transmission of light or those wrapped so that the transmission of light is prevented.