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Japan

Agricultural Situation

Food Additive Update - 2-Ethylpyrazine, 2-Methylpyrazine et al.

2008

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Report Highlights:
On December 17, 2008, the Japanese Government announced designation of 2-Ethylpyrazine, 2-Methylpyrazine and Calcium Sorbate as food additives, and partial revision of the specification for Neotame. The comment period will close on January 9, 2009. After the given date, all comments should be directed to the enquiry point in accordance with the WTO/SPS Agreement.

Includes PSD Changes: No
Includes Trade Matrix: No
Trade Report
Tokyo [JA1]
[JA]

Summary
On December 17, 2008, the Japanese Government announced designation of 2-Ethylpyrazine, 2-Methylpyrazine and Calcium Sorbate as food additives, and partial revision of the specification for Neotame. The comment period will close on January 9, 2009.

If you have comments it is best to send directly to MHLW as soon as possible. However, MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a final report will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date, and this will constitute the final decision.

The comments can be either Japanese or English.

If you have comments, please send them directly to the Japanese Government at:

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Designation of Food Additives

Purpose and background
The Ministry of Health, Labour and Welfare is going to newly designate three substances as authorized food additives and partially revise the specifications of one substance.

Under Article 10 of the Food Sanitation Law, food additives can be used or marketed only when they are designated by the Minister of Health, Labour and Welfare. When use standards or compositional specifications are established for food additives based on Article 11 of the law, those additives are not permitted to be used or marketed unless they meet these standards or specifications.

In response to a request from the Minister, the Subcommittee on Food Additives under the Food Sanitation Committee under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the authorization of the three substances (2-Ethylpyrazine, 2-Methylpyrazine, Calcium Sorbate), and also discussed the adequacy of the partial revision of the specifications for Neotame. The subcommittee has concluded as follows.

Outline of conclusion
The Minister should designate 2-Ethylpyrazine, 2-Methylpyrazine, Calcium Sorbate, based on Article 10 of the Food Sanitation Law, as food additives unlikely to harm human health and establish compositional specifications for these substances, based on Article 11 of the law (see Attachments 2-1, 2-2, and 2-3).

Also, the Minister should partially revise the specification for Neotame based on Article 11 of the Food Sanitation Law (see Attachments 2-4).

Additional Information
Progress in the designation procedure of food additives that have been proven safe by JECFA (Joint FAO/WHO Expert Committee on Food Additives) and that are widely used in countries other than Japan (Attachment 2-5)

Attachment 2-1

2-Ethylpyrazine

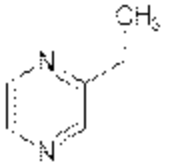
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name 2-Ethylpyrazine

Structural formula



Molecular formula $C_6H_8N_2$

Mol. Weight 108.14

Chemical name, CAS number 2-Ethylpyrazine [13925-00-3]

Content 2-Ethylpyrazine contains not less than 98.0% of 2-Ethylpyrazine ($C_6H_8N_2$).

Description 2-Ethylpyrazine occurs as a colorless to light yellow liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of 2-Ethylpyrazine, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

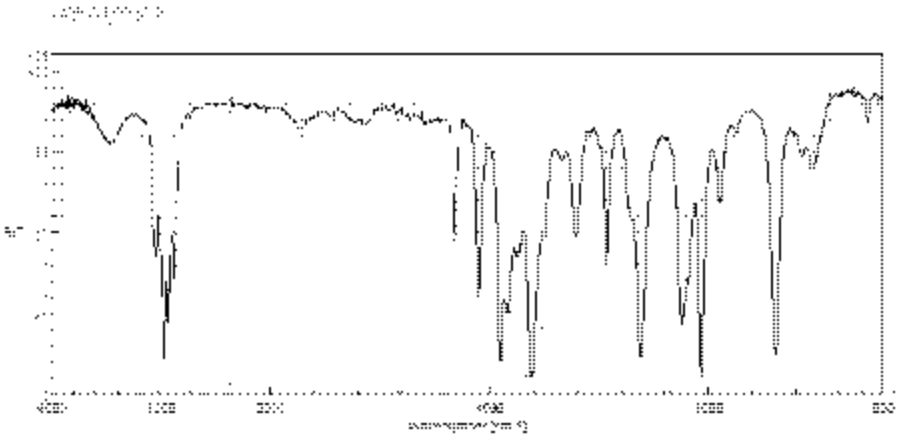
Purity

(1) Refractive index n_D^{20} : 1.493–1.505.

(2) Specific gravity d_{20}^{20}: 0.983–1.009

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (1).

Reference Spectrum



Attachment 2-2

2-Methylpyrazine

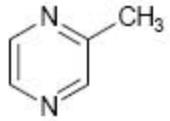
Standard for use

It shall not be used for purposes other than flavoring.

Compositional specifications

Substance name 2-Methylpyrazine

Structural formula



Molecular formula $C_5H_6N_2$

Mol. Weight 94.11

Chemical name, CAS number 2-Methylpyrazine [109-08-0]

Content 2-Methylpyrazine contains not less than 98.0% of 2-Ethylpyrazine ($C_5H_6N_2$).

Description 2-Methylpyrazine occurs as a colorless to light yellow liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of 2-Methylpyrazine, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wavenumbers.

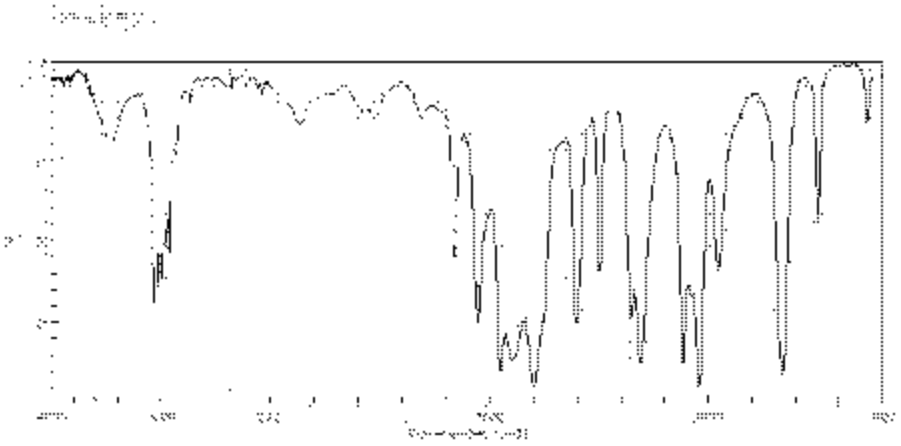
Purity

(1) Refractive index n_D^{20}: 1.501–1.509.

(2) Specific gravity d_{25}^{25}: 1.007–1.033

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2).

Reference Spectrum



Attachment 2-3

Calcium Sorbate

Standard for use

See the Annex.

Compositional specifications

Substance name Calcium Sorbate

Structural formula

Molecular formula $C_{12}H_{14}CaO_4$

Mol. Weight 262.32

Chemical name, CAS number Monocalcium bis[(2*E*,4*E*)-hexa-2,4-dienoate]
[7492-55-9]

Content Calcium Sorbate contains, when dried, contains 98.0–102.0% of calcium sorbate ($C_{12}H_{14}CaO_4$).

Description Calcium Sorbate occurs as a white, fine crystalline powder

Identification

(1) To 200 ml of a solution of Calcium Sorbate (1 in 200), add 2 drops of bromine TS, and shake. The color of the solution disappears immediately.

(2) A solution of Calcium Sorbate (1 in 200) responds to all tests for Calcium Salt in the Qualitative Tests.

(3) To 100 ml of a solution Calcium Sorbate (1 in 200), add 15 ml of diluted hydrochloric acid (1 in 4). Filter the resulting precipitate with suction, wash well with water, and dry in a vacuum desiccator for 4 hours. Its melting point is 132–135°C.

Purity

(1) Fluoride Not more than 10 μg/g as F.

Test Solution Weigh exactly 1.00 g of Calcium Sorbate transfer into a beaker, add 10 ml of water, and mix for a few minutes. Add 20 ml of diluted hydrochloric acid (1 in 20) gradually to dissolve. Boil this solution for 1 minute, transfer into a polyethylene beaker, and immediately cool with ice. Add 10 ml of a solution of disodium ethylenediaminetetraacetate (1 in 40) and 15 ml of a solution of sodium citrate (1 in 4), and mix. Adjust the pH of the solution to 5.4–5.6 with diluted hydrochloric acid (1 in 10) or a solution of sodium hydroxide (2 in 5). Transfer it into a 100-ml volumetric flask.

and dilute with water to volume. Place about 50 ml of this solution in a polyethylene beaker, and use as the test solution.

Control Stock Solution Weigh accurately 2.210 g of sodium fluoride, previously dried at 110°C for 2 hours, transfer into a polyethylene beaker, add 200 ml of water, and dissolve while stirring. Transfer this solution into a 1,000-ml volumetric flask, dilute with water to volume, and then store in a polyethylene bottle.

Control Solution Prepare fresh before use. Transfer exactly 5 ml of the control stock solution into a 1,000-ml volumetric flask, and dilute to volume with water. Transfer exactly 2.0 ml of this solution into a polyethylene beaker, add 10 ml of a solution of disodium ethylenediaminetetraacetate (1 in 40) and 15 ml of a solution of sodium citrate (1 in 4), and mix. Adjust the pH of the solution to 5.4–5.6 with diluted hydrochloric acid (1 in 10) or a solution of sodium hydroxide (2 in 5). Transfer this solution into a 100-ml volumetric flask, and dilute to volume with water. Place about 50 ml of the solution into a polyethylene beaker, and use as the control solution.

Procedure Measure the electric potentials of both solutions, using a potentiometer connected to a reference electrode and a fluorine ion electrode. The electric potential of the test solution is not lower than that of the control solution.

(2) Lead Not more than 2.0 μg/g as Pb

Test Solution Weigh 1.0 g of Calcium Sorbate into a 200-ml Kjeldahl flask, and heat with 10 ml of nitric acid and 5 ml of sulfuric acid until almost no red-brown fumes are produced. After cooling, heat again with an additional 3 ml of nitric acid until white fumes are produced. Cool, add 10 ml of diluted hydrochloric acid (1 in 2), boil for 10 minutes, and cool. To the resulting solution, add 10 ml of a solution of diammonium hydrogen citrate (1 in 3), and make weakly alkaline with ammonia solution, using thymol blue TS as the indicator. After cooling, transfer the content of the Kjeldahl flask to a 200-ml separating funnel, wash down its inside with water, add the washings to the funnel, and make about 100 ml. Add 5 ml of a solution of ammonium pyrrolidine dithiocarbamate (3 in 100), allow to stand for 5 minutes, add 10 ml of butyl acetate, shake for 5 minutes, and allow to stand. Use the butyl acetate layer as the test solution.

Control Solution Add water to exactly measured 1 ml of Lead Standard Stock Solution to make 100 ml. Measure exactly 2 ml of the resulting solution into a flask, add 10 ml of a solution of diammonium hydrogen citrate (1 in 3), and make the mixture weakly alkaline with ammonia solution, using thymol blue TS as the indicator. After cooling, transfer the contents of the flask to a 200-ml separating funnel, and wash down its inside with water. Proceed as directed for the test solution, beginning with "and add the washings to the funnel". Use the butyl acetate layer as the control solution.

Procedure With the test solution and the control solution, proceed as directed under Method 1 in the Lead Limit Test

(3) Arsenic Not more than 4.0 μg/g as As_2O_3 (0.50 g, Method 4, Apparatus B).

(4) Aldehyde Not more than 0.1% as formaldehyde.

Test Solution Adjust the pH of a solution of Calcium Sorbate (3 in 50) to 4 with diluted hydrochloric acid (1 in 12), and filter. Use 5 ml of the resulting solution as the test solution.

Control Solution Measure exactly 2.5 ml of formaldehyde solution, and add water to make exactly 1,000 ml. To exactly measured 3 ml of this solution, add water to make exactly 500 ml. Use exactly measured 5 ml of the resulting solution as the control solution.

Procedure Add 2.5 ml of fuchsin–sodium hydrogen sulfite TS to each of the test solution and control solution, and allow them to stand for 15–30 minutes. The color of the test solution is not darker than that of the control solution.

Loss on Drying Not more than 2.0% (105°C, 2 hours).

Assay Weigh accurately about 0.25 g of Calcium Sorbate, previously dried, add 35 ml of acetic acid and 4 ml of acetic anhydride, and dissolve while heating at 45–50°C. After cooling, titrate with 0.1 mol/L perchloric acid using 2 drops of a solution of crystal violet in acetic acid (1 in 100) as the indicator until the blue color of the solution changes to green. Each ml of 0.1 mol/L perchloric acid = 13.12 mg of $C_{12}H_{10}CaO_4$

Reagents

Fuchsin A green, lustrous crystalline powder or lumps. Hard to dissolve in water and in ethanol (95).

Loss on Drying 17.5–20.0% (1 g, 135°C, 4 hours).

Residue on Ignition Not more than 0.1% (1 g).

Fuchsin–sodium hydrogen sulfite TS Dissolve 0.2 g of fuchsin in 120 ml of hot water. After cooling, add 2 g of sodium hydrogen sulfite, 2 ml of hydrochloric acid, and water to make 200 ml. Allow to stand for at least 1 hour, and store in a brown bottle in a cold place.

Annex

1. Standards for use

A. Calcium Sorbate will be added to Column 1 of the following table.

Standards applying generally to all food additives

1. Unless otherwise specified, if standards for use are established for food additives used as ingredients of an additive preparation, the existing standards are deemed to be standards for the preparation.

2. When a food listed in column 2 of the following table, which contains additives listed in column 1 of the same table, is used in the process of the manufacturing or processing of one of the foods listed in column 3 in the same table, the additives contained in the food are considered to be used in the food listed in column 3

Column 1	Column 2	Column 3
Potassium Pyrosulfite Sodium Hydrosulfite Sodium Pyrosulfite Sodium Sulfite. Sulfur Dioxide	*Amanatto* (dried candied beans), Candied cherries (i.e., candied, pitted cherries, or such cherries which are frosted with crystal sugar or which are immersed in syrup), Dijon mustard, dried fruits (excluding raisin), dried potatoes, food molasses, frozen unheated crabs, fruit wines, gelatin, *Kanpyo* (dried gourd strips), *Konnyakuko* (Konjac powder), miscellaneous alcoholic beverages, natural fruit juice (confined to products to be consumed in 3-fold or more dilution), prawn, simmered beans, starch syrup, tapioca starch for saccharification.	All foods excluding those listed in column 2.
Sodium Saccharin.	Flour paste (hereinafter in section F, referred to as any paste food which is prepared by adding sugar, fats/oils, powder milk, eggs, or wheat flour to main ingredients such as wheat flour, starch, nuts or their processed products, cocoa, chocolate, coffee, fruit pulps, or fruit juice, pasteurized, and used for bread or confectionery as fillings or toppings).	Confections.
Calcium Sorbate Potassium Sorbate Sorbic Acid.	*Miso* (fermented soybean paste)	*Miso-zuke* (miso-pickled foods)
All food additives	All foods.	Milk and milk products (excluding ice cream) prescribed in Article 2 of the Ministerial Ordinance concerning Compositional Specifications for Milk and Milk Products, ETC. (Ministry of Health and Welfare Ordinance No. 52, 1951).

Annex

B. The following standards will be newly established.

	As sorbic acid	
Amazake (beverages made from rice fermented using *koji* (*Asp. oryzae*), confined to products to be coonsumed in 3-fold or more dilution).	0.30 g/kg	
An (sweetened bean paste).	1.0 g/kg	
Candied cherries.	1.0 g/kg	
Cheese.[1]	3.0 g/kg	1. For cheese, when the additive is used with Propionic Acid, Calcium Propionate, or Sodium Propionate, the total amount of them as propionic acid and as sorbic acid shall not be more than 3.0g/kg.
Dried fish/shellfish (excluding smoking cuttlefish & octopus).	1.0 g/kg	
Dried prune.	0.50 g/kg	
Fermented milk (as raw materials for lactic acid bacterial drinks).	0.30 g/kg	
Fish-paste products (excluding *surimi*).	2.0 g/kg	
Flour paste products confectionary.	1.0 g/kg	
Fruit juice for confection.	1.0 g/kg	
Fruit paste for confectionary.	1.0 g/kg	
Fruit wines (all kinds of wines).	0.20 g/kg	
Other miscellaneous alcoholic beverages.	0.20 g/kg	
Gnocchi.[2]	1.0 g/kg	2. Gnocchi: cooked dumplings made of boilded potatoes or wheat flour.
Jams.	1.0 g/kg	
Kasu-zuke (lees-pickled foods).	1.0 g/kg	
Ketchup.	0.50 g/kg	
Koji-zuke (koji (Asp. oryzae)-pickled foods).	1.0 g/kg	
Lactic acid bacterial beverages (excluding sterilized beverages).	0.050 g/kg	
Lactic acid bacterial beverages (as ingredients of lactic acid bacterial beverages, excluding sterilized beverages).	0.30 g/kg	
Margarine.[3]	1.0 g/kg	3. For margarine, when the additive is used with Benzoic Acid or Sodium Benzoate, the total amount of them as benzoic acid and as sorbic acid shall not be more than 1.0 g/kg.
Meat products.	2.0 g/kg	
Miso (fermented soy bean paste).	1.0 g/kg	
Miso-zuke (MISO-pickled foods).[4]	1.0 g/kg	
Salted foods.	1.0 g/kg	4. For *miso-zuke*, when the additive is used, the total amount of Sorbic Acid used in the product, and Sorbic Acid and its salts contained in miso as ingredient shall not be more than 1.0 g/kg.
Sea urchin products.	2.0 g/kg	
Shoyu-zuke (soy sauce-pickled foods).	1.0 g/kg	
Simmered beans.	1.0 g/kg	
Smoked cuttlefish/squid & octopus.	1.5 g/kg	
Soup (excluding potage-type soup).	0.50 g/kg	
Su-zuke (vinegar-pickled foods).	0.50 g/kg	
Syrup.	1.0 g/kg	
Takuan-zuke (rice bran-pickled radish).	1.0 g/kg	
Tare (a dip or sauce mainly for Japanese or Chinese foods).	0.50 g/kg	
Tsukudani (foods boiled down in soy sauce).	1.0 g/kg	
Tsuyu (a sauce mainly for Japanese noodles).	0.50 g/kg	
Whale meat products.	2.0 g/kg	

Attachment 2-4

Partial Revision of Specifications for Neotame

Outline

Neotame was designated as an approved food additive on December 28, 2007, based on an application from its importer, and compositional specifications were established for this substance. Based on the specifications for Aspartame, which has a similar chemical structure to Neotame, the limit and testing method for arsenic were set as "not more than 4.0 μg/g as As_2O_3 (0.5 g, Method 1, Apparatus B)." This means when determined by preparing a test solution from 0.50 g sample as directed in Method 1 and by proceeding as directed in the method using Apparatus B, the arsenic limit shall not be more than 4.0 μg/g. For the testing method, see "Extract of the testing method" on the next page.

The Minister has decided to revise the method. This action was based on a written request from the importer that Method 1 in the arsenic test be replaced with Method 3 because Method 3 had been found to be able to provide higher accuracy. As a result of discussion by the Subcommittee on Food Additives, based on Article 11 Paragraph 1 of the law, the method is going to be revised as follows:

Current Not more than 4.0 μg/g as As_2O_3 (0.5 g, **Method 1**, Apparatus B)
Revised Not more than 4.0 μg/g as As_2O_3 (0.5 g, **Method 3**, Apparatus B)

<Extract of the testing method>

Preparation of Test Solution Unless otherwise specified, proceed according to an appropriate method selected from among the following methods.

Method 1 Weigh the specified amount of the sample, add 5 ml of water, dissolve by heating if necessary, and use the resulting solution as the test solution.

Method 2 Weigh the specified amount of the sample, add 5 ml of water, and add 1 ml of sulfuric acid unless the samples are inorganic acids. Add 10 ml of sulfurous acid, transfer into a small beaker, and evaporate the mixture on a water bath until it is free from sulfurous acid and is reduced to about 2 ml. Dilute with water to make 5 ml, and use as the test solution.

Method 3 Weigh the specified amount of the sample, and place it in a crucible made of platinum, quartz, or porcelain. Add 10 ml of a solution of magnesium nitrate in ethanol (1 in 20), ignite the ethanol, and heat gradually to incinerate at 450–550°C. If carbonized matter still remains, moisten with a small quantity of a solution of magnesium nitrate in ethanol (1 in 50), ignite again, and heat again to incinerate at 450–550°C. After cooling, add 5 ml of hydrochloric acid, heat on a water bath to dissolve the residue, and use the resulting solution as the test solution.

Method 4 Weigh the specified amount of the sample, and place it in a crucible made of platinum, quartz, or porcelain. Add 10 ml of a solution of magnesium nitrate in ethanol (1 in 20), ignite the ethanol, and heat gradually to incinerate at 450–550°C. If carbonized matter still remains, moisten with a small quantity of a solution of magnesium nitrate in ethanol (1 in 50), and ignite again to incinerate at 450–550°C. After cooling, add 5 ml of hydrochloric acid, heat on a water bath to dissolve the residue, and use the resulting solution as the test solution.

Procedure Unless otherwise specified, proceed according to an appropriate method selected from among the following methods.

Method using Apparatus B Transfer the test solution into the generator bottle, proceed as directed for the Method using Apparatus A, add 5 ml of acidic stannous chloride TS, and allow to stand for 10 minutes. Next, add water to make 40 ml, add 2 g of arsenic-free zinc, and immediately connect the rubber stopper H, fitted with B and C, to the generator bottle. Insert the tip of C to the bottom of absorber tube D containing 5 ml of the absorbing solution for arsine, immerse the generator bottle up to the shoulder in water maintained at 25°C, and allow to stand for 1 hour. Disconnect the absorber tube, add pyridine to make 5 ml, if necessary, and examine the color of the absorbing solution. The color produced is not deeper than the standard color.

The standard color is prepared in parallel with the test directed above. Measure 2.0

ml of Arsenic Standard Solution, transfer into another generator bottle, add 5 ml of diluted hydrochloric acid (1 in 2) and 5 ml of potassium iodide TS, and allow to stand for 2 to 3 minutes. Add 5 ml of acidic stannous chloride TS, and allow to stand at room temperature for 10 minutes. Proceed in the same manner as for the test solution, and consider the color of the absorbing solution as the standard color.