Amendment to the Ordinance for Enforcement of the Food Sanitation Act and the Specifications and Standards for Foods, Food Additives, Etc.

The government of Japan will designate Calcium Phytate as an authorized food additive and establish compositional specifications and standards for use of this additive.

Background

Japan prohibits the sale of food additives that are not designated by the Minister of Health, Labour and Welfare ("the Minister") under Article 12 of the Food Sanitation Act (Act No. 233 of 1947; "the Act"). In addition, when specifications or standards for food additives are stipulated in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370, 1959) pursuant to Article 13 of the Act, the sale of those additives are prohibited unless they meet the specifications or the standards .

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the designation of Calcium Phytate as a food additive. The conclusion of the committee is outlined below.

Outline of conclusion

The Minister should designate Calcium Phytate as a food additive unlikely to cause harm to human health pursuant to Article 12 of the Act and should establish compositional specifications and use standards for this additive pursuant to Article 13 of the Act (see Attachment for the details).

Calcium Phytate

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Standards for Use (draft)

Permitted for use only in grape wine. Must be used at not more than 0.08 g/L in grape wine as calcium phytate.

Compositional Specifications (draft)

Substance Name Calcium Phytate

CAS number [3615-82-5]

Definition Calcium Phytate consists mainly of the calcium salt of inositol hexaphosphate (including double salt of calcium and magnesium).

Content Calcium Phytate, when dried, contains 15–30% of calcium phytate as total phosphorus.

Description Calcium Phytate occurs as a white powder.

Identification

(1) Neutralize 2 mL of Solution A prepared in Assay with sodium hydroxide solution (1 in 25). The resulting solution responds to test (2) for Phosphorous Salt in the Qualitative Tests.

(2) Boil 0.1 g of Calcium Phytate with 5 mL of acetic acid (1 in 4). After cooling, filter it, and add 5 mL of a solution of ammonium oxalate monohydrate (1 in 30) to the filtrate. A white precipitate is formed. The separated precipitate dissolves in hydrochloric acid (1 in 4).

Purity

(1) Lead Not more than 5 μg/g as Pb (0.80 g of a died sample, Method 3, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).

(2) Arsenic Not more than 3 μg/g as As (0.50 g of a dried sample, Method 3, Standard Color: Arsenic Standard Solution 3.0 mL, Apparatus B).

(3) Free inorganic phosphorus Not more than 1.0% (dried sample).

Test Solution Weigh accurately about 0.5 g of Calcium Phytate, previously dried, add about 150 mL of water, gently shake 2 to 3 times, and filter. To the filtrate, add water to make exactly 200 mL. To exactly 3 mL of the resulting solution, add 5 mL of L (+)-ascorbic acid solution (1 in 100). Add 5 mL of a solution prepared by dissolving 1 g of hexaammonium heptamolybdate tetrahydrate in 100 mL of sulfuric acid TS (0.025mol/L). Then add acetic buffer (pH 4.0) to make exactly 50 mL, and allow to stand for 15 minutes.

Reference Solution To 5 mL of L (+)-ascorbic acid solution (1 in 100), add 5 mL of a

solution prepared by dissolving 1 g of hexaammonium heptamolybdate tetrahydrate in 100 mL of sulfuric acid TS (0.025 mol/L). Then add acetic acid buffer (pH 4.0) to make exactly 50 mL.

Procedure Measure the absorbance of the test solution at a wavelength of 750 nm against the reference solution. Prepare a calibration curve by measuring the absorbance of the following three solutions. Determine the concentration of free inorganic phosphorus from the calibration curve and the absorbance of the test solution, and then calculate the amount (%) of free inorganic phosphorus in the sample.

Solutions for Calibration Curve To exactly 5 mL of Phosphorus Standard Solution, add water to make 1000 mL. Transfer exactly 5 mL, 10 mL, and 20 mL of this solution into separate volumetric flasks, add 5 mL of L (+)-ascorbic acid solution (1 in 100) to each, and proceed as directed for the test solution to develop the color.

Loss on Drying Not more than 12% (1 g, 105°C, 4 hours).

Assay

Test Solution Weigh accurately about 0.6 g of Calcium Phytate, previously dried, into a Kjeldahl flask or heat-resistant glass beaker, and add 4 mL each of sulfuric acid and nitric acid. For a beaker, cover by a watch glass. Heat it by gradually increasing the temperature from about 150°C. Continue heating until brown fumes of nitric acid almost cease to be evolved, the liquid is transparent, and then white fumes are evolved; and decompose it. If the contents become blackened while heating, add about 2 mL of nitric acid and keep heating. After cooling, add 100 mL of water, mix, and filter. Wash the filter with water, combine the filtrate with the washings, and then add water to make 200 mL. Designate it as Solution A. Transfer exactly 2 mL of Solution A into a 100-mL volumetric flask, add 1 drop of phenol phthalein TS, neutralize with ammonia solution (1 in 4), and add nitric acid (1 in 10) until the solution is colorless to make the solution slight acidic. To this solution, add 20 mL of vanadic acid–molybdic acid TS, and make up to exactly 100 mL with water. Shake it well, and allow to stand for 30 minutes.

Procedure Measure the absorbance of the test solution at a wavelength of 420 nm. Prepare a calibration curve by measuring the absorbance of the following three solutions. Determine the total phosphorus concentration in the test solution from the calibration curve and the absorbance of the test solution, and then calculate the total phosphorus amount (%) in the sample.

Solutions for Calibration Curve To exactly 10 mL of Phosphorus Standard Solution, add water to make exactly 100 mL. Transfer exactly 5 mL, 10 mL, and 20 mL of this solution into separate 100-mL separate volumetric flasks, proceed as directed for the test solution, and develop the color.