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 ammonium hydrogen sulfite water as an authorized food additive and establish compositional specifications and use standards for this additive.

<u>Background</u>

Japan prohibits the sale of food additives that are not designated by the Minister of Health, Labour and Welfare (hereinafter referred to as "the Minister") under Article 12 of the Food Sanitation Act (Act No. 233 of 1947; hereinafter referred to as "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), Japan prohibits the sale of those additives unless they meet the specifications or the standards pursuant to Article 13 of the Act.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council under the Pharmaceutical Affairs and Food Sanitation Council (hereinafter referred to as "the Committee") has discussed the adequacy of the designation of ammonium hydrogen sulfite water as a food additive. The conclusion of the Committee is outlined below.

Outline of conclusion

The Minister should designate ammonium hydrogen sulfite water 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).

Attachment

Ammonium Hydrogen Sulfite Water

亜硫酸水素アンモニウム水

Standards for Use (draft)

Permitted for use in grape juice used for wine production and grape wine only.

Shall be used at not more than 0.2 g/L in grape wine as ammonium hydrogen sulfite. When Ammonium Hydrogen Sulfite Water is used in grape juice used for wine production, this additive is considered to be used in grape wine.

Shall not remain at a level not less than 0.35 g/kg as sulfur dioxide in grape wine (excluding squeezed grape juice used for wine production containing not less than 1 % (volume) of ethanol and the concentrate of squeezed grape juice).

Compositional Specifications (draft)

Substance Name Ammonium Hydrogen Sulfite Water

Definition

Ammonium Hydrogen Sulfite Water is a solution consisting mainly of ammonium hydrogen sulfite.

Content

Ammonium Hydrogen Sulfite Water contains not less than 13.0% of ammonium hydrogen sulfite (NH₄HSO₃ = 99.11).

Description Ammonium Hydrogen Sulfite Water occurs as a light yellow liquid.

Identification

- (1) Ammonium Hydrogen Sulfite Water responds to all the tests for Sulfite and Bisulfite and the test for Ammonium Salt in the Qualitative Tests.
- (2) Ammonium Hydrogen Sulfite Water contains not less than 2.2 % as ammonia (NH₃=17.03).

Weigh accurately about 0.5 g of Ammonium Hydrogen Sulfite Water, add 25 mL of water to dissolve it, and add 10 mL of sodium hydroxide solution (2 in 5). Immediately connect the flask containing this solution to a previously assembled distillation apparatus. The apparatus is equipped with a condenser joined to a delivery tube with a spray trap and the lower end of the condenser is immersed in 30 mL of 0.1 mol/L sulfuric acid, exactly measured, in a receiver. Heat and distill

ammonia into the sulfuric acid until about 25 mL of the distillate is obtained. Titrate the excess sulfuric acid in the receiver with 0.2 mol/L sodium hydroxide (indicator: 3 drops of methyl red TS). Determine the amount of ammonia by the formula.

Each mL of 0.1 mol/L sulfuric acid = 3.406 mg of NH₃

Purity

(1) <u>Lead</u> Not more than 5 μg/g of NH₄HSO₃ as Pb (an amount equivalent to 8.0 g of ammonium hydrogen sulfite (NH₄HSO₃), Method 5, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).

Sample Solution To the specified amount of Ammonium Hydrogen Sulfite Water, add 20mL of diluted hydrochloric acid (1 in 4), and boil gently for 5 minutes with a watch glass covering it. Allow to cool. Use this solution as the sample solution. If the sample does not dissolve completely, evaporate it to dryness, and add 20 mL of diluted hydrochloric acid (1 in 4) to the residue. Boil gently for 5 minutes, allow to cool, and use this solution as the sample solution.

(2) <u>Arsenic</u> Not more than 3 μg/g of NH₄HSO₃ as As (an amount equivalent to 5.0 g of ammonium hydrogen sulfite (NH₄HSO₃), Standard Color: Arsenic Standard Solution 3.0 mL, Apparatus B).

Test Solution To the specified amount of Ammonium Hydrogen Sulfite Water, add water to make 50 mL. Measure 10 mL of this solution, add 2 mL of sulfuric acid, and heat on a water bath until sulfur dioxide is no longer evolved. Evaporate to about 2 mL, and add water to make 10 mL. Use 5 mL of this solution as the test solution.

Residue on Ignition Not more than 0.2% per ammonium hydrogen sulfite (NH₄HSO₃) (10 g).

Assay Weigh accurately about 0.3 g of Ammonium Hydrogen Sulfite Water, and proceed as directed under Sulfite Determination.

Each mL of 0.05 mol/L iodine = 4.955 mg of NH_4HSO_3