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 metatartaric acid as an authorized food additive and establish compositional specifications and use standards for this additive.

Background

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 metatartaric acid as a food additive. The conclusion of the Committee is outlined below.

Outline of conclusion

The Minister should designate metatartaric acid 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

Metatartaric Acid メタ酒石酸

Standards for Use (draft)

Permitted for use in grape wine only. Shall be used at not more than 0.10 g/kg in grape wine.

Compositional Specifications (draft)

Substance Name Metatartaric Acid

CAS Number [39469-81-3]

Definition Metatartaric Acid consists mainly of molecules obtained by heating Ltartaric acid under atmospheric or vacuum pressure and esterifying the resulting fused substance. The molecules are of various chain lengths.

Content Metatartaric Acid contains the equivalent of 99.5-113% of L-tartaric acid (C₄H₆O₆ = 150.09).

Description Metatartaric Acid occurs as deliquescent, white to yellowish white crystals or powder. It has a slight odor like caramel.

- **Identification** Metatartaric Acid responds to all tests for Tartrate in the Qualitative Tests.
- **pH** 1.4–2.2 (1.0 g, water 100 mL).

Purity

(1) <u>Clarity of solution</u> Almost clear (1.0 g, water 10 mL). Almost clear (1.0 g, ethanol (95) 30 mL).

(2) <u>Degree of esterification</u> Not less than 32%.

Calculate the esterification value of Metatartaric Acid by the formula:

Degree of esterification (%) = $\frac{(20 - b)}{(a + 20 - b)} \times 100$

Determine a and b according to the procedure given in the Assay.

a = volume (mL) of 1 mol/L sodium hydroxide consumed,

b = volume (mL) of 0.5 mol/L sulfuric acid consumed.

(3)<u>Lead</u> Not more than 2 µg/g as Pb (2.0 g, Method 1, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).

(4) <u>Arsenic</u> Not more than 3 µg/g as As (0.50 g, Method 1, Standard Color: Arsenic Standard Solution 3.0 mL, Apparatus B).

Assay Weigh quickly and accurately about 2 g of Metatartaric Acid, and dissolve it in water to make exactly 100 mL. Transfer exactly 50 mL of this solution into a flask, and immediately titrate with 1 mol/L sodium hydroxide (indicator: 10 drops of bromothymol blue TS). The endpoint is when the color of the solution changes to bluish green. Refer to the volume of the sodium hydroxide consumed as a mL. Add 20 mL of 1 mol/L sodium hydroxide to the flask, stopper, allow to stand for 2 hours, and immediately titrate with 0.5 mol/L sulfuric acid. The endpoint is when the color of the solution changes to bluish green. Refer to the volume of the sulfuric acid consumed as b mL. Calculate the content of metatartaric acid by the formula:

Content (%) of metatartaric acid (as L-tartaric acid $C_4H_6O_6$)

 $= \frac{(a + 20 - b) \times 15.01}{\text{Weight (g) of the sample}}$

Storage Standards Store in a hermetic container, protected from moisture.