Amendment to the Enforcement Ordinance of the Food Sanitation Law and the Standards and Specifications for Foods and Food Additives.

The government of Japan will designate Canthaxanthin as an authorized food additive.

Summary

Under Article 10 of the Food Sanitation Law (hereinafter referred to as the "Law"), food additives shall not be used or marketed without authorization by the Minister of Health, Labour and Welfare (hereinafter referred to as "the Minister"). In addition, when specifications or standards are established for food additives based on Article 11 of the Law and stipulated in the Ministry of Health, Labour and Welfare Notification (Ministry of Health and Welfare Notification No. 370, 1959), those additives shall not be used or marketed unless they meet the standards or specifications.

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

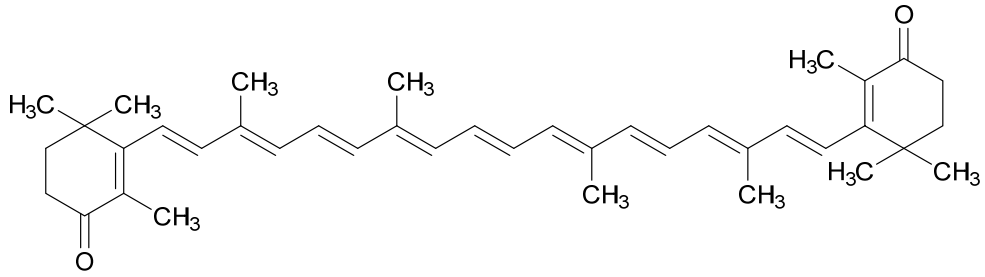
Outline of conclusion

The Minister, based on Article 10 of the Law, should designate Canthaxanthin, as a food additive unlikely to harm human health, and establish standards for use and compositional specifications, based on Article 11 of the Law (see Attachment).

Attachment

Canthaxanthin

カンタキサンチン



Standards for use

Only permitted for use in fish pastes products (*kamaboko* only) up to 0.035 g per kg of each product.

Compositional specifications

Substance name Canthaxanthin

Molecular formula $C_{40}H_{52}O_2$

Molecular weight 564.84

Chemical name [CAS number] β,β-Carotene-4,4'-dione ［514－78－3］

Content Canthaxanthin contains not less than 96.0% of canthaxanthin ($C_{40}H_{52}O_2$).

Description Canthaxanthin occurs as dark-purple crystals or crystalline powder.

Identification (1) A solution of Canthaxanthin in acetone (1 in 25,000) develops an orange color. To 5 ml of this solution, add 1 ml of sodium nitrite solution (1 in 20) and 1 ml of 0.5 mol/L sulfuric acid. The solution is immediately decolored.

(2) A solution of Canthaxanthin in cyclohexane (1 in 400,000) exhibits an absorption maximum at a wavelength of 470 nm.

Purity

(1) Lead Not more than 2.0 μg/g as Pb.

Test Solution Weigh 2.0 g of Canthaxanthin in a platinum, quartz, or porcelain crucible or a quartz beaker. Heat gradually, and stop heating before the sample starts to carbonize. Add 1 ml of sulfuric acid, and heat by increasing the temperature gradually until the sample is carbonized and white fumes are no longer evolved. If necessary, add sulfuric acid again, and heat until the sample is almost carbonized. Loosely lid the

crucible if necessary, heat in an electric furnace by increasing the temperature gradually, and incinerate at 450–600°C. If any carbonized matter still remains, crush the residue with a glass rod, moisten with 1 ml of diluted sulfuric acid (1 in 4) and 1 ml of nitric acid, and heat until white fumes are no longer evolved. Then, ignite in the electric furnace to complete incineration. To the residue, add 10 ml of diluted sulfuric acid (1 in 4), and evaporate on a water bath to dryness. To the residue, add a small amount of diluted nitric acid (1 in 100), and dissolve it while heating. After cooling, add diluted nitric acid (1 in 100) again to make exactly 10 ml. When incineration is done at 500°C or below, a heat-resistant glass beaker can be used.

Control Solution Add water to exactly measured 1 ml of Lead Standard Stock Solution to make exactly 100 ml. To exactly measured 4 ml of this solution, add diluted nitric acid (1 in 100) to make exactly 10 ml.

Procedure Proceed as directed under Method 1 in the Lead Limit Test.

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

(3) Subsidiary Colors Not more than 5%.

Test Solution Weigh 0.020 g of Canthaxanthin, and dissolve in 25 ml of dichloromethane.

Procedure Perform thin-layer chromatography. Use a thin-layer plate coated with silica gel for thin-layer chromatography and dried at 110°C for 1 hour. Apply 400 μl of the test solution in an about 3 mm-wide strip on the original line on the thin-layer plate. Develop using a 95:5 mixture of dichloromethane and diethyl ether as the developing solvent and using no control solution. Stop the development when the solvent front has ascended to a point about 15 cm above the original line, and air-dry the plate. Scrap the darkest colored part—which contains the main constituent—off the plate, and transfer in a centrifuging tube. Add exactly 40 ml of dichloromethane, and shake for 10 minutes, and centrifuge. Measure exactly 10 ml of the supernatant, and add dichloromethane to make exactly 50 ml. Refer to this solution as solution A. Similarly, scrap off the other colored part into a centrifuging tube, add exactly 20 ml of dichloromethane, shake for 10 minutes, and centrifuge. Refer to the resulting supernatant as solution B. Measure the absorbances of solutions A and B (A_A, and A_B) at a wavelength of 485 nm against dichloromethane. Determine the amount of the subsidiary colors by the following formula.

Note: The above procedure should be conducted while avoiding light exposure.

$$\text{Amount (\%)} = \frac{A_B}{A_A \times 10 + A_B} \times 100$$

Loss on Drying Not more than 0.10%.

Assay Weigh accurately about 0.05 g of Canthaxanthin, dissolve in 10 ml of chloroform, and add cyclohexane to make exactly 50 ml. Measure exactly 5 ml of this solution, and add cyclohexane to make exactly 100 ml. To 5 ml of the second solution, exactly measured, add cyclohexane to make exactly 100 ml. Measure the absorbance (A) of the resulting solution at the maximum at about 470 nm.

$$\text{Canthaxanthin } (C_{40}H_{52}O_2)(\%) = \frac{200}{\text{Weight (g) of the sample}} \times \frac{A}{2{,}200} \times 100$$

Storage standards Store in a hermetic container, protected from light, under inert gas.

Reagents and Solutions

Dichloromethane CH_2Cl_2 [K8161]