Ⅱ. Synthetic Additives, Natural Additives and Mixed Preparations

Article 1. Standards for Manufacturing and Preparation

A. Standards applying generally to all food additives

Unless it is absolutely indispensable, insoluble minerals such as acidic white clay, china clay, bentonite, talc, sand, diatomite, magnesium carbonate, and their similar minerals should not be used in the manufacturing of additives.

B. Alkali Additives for Noodles

When alkali additives for noodles(restricted to approved synthetic food additives) are prepared, one of the following suitable to the specification is to be used. One or a mixture of two or more of appropriate ingredients such as sodium carbonate, potassium carbonate, sodium hydrogen carbonate, or potassium salts can be used, and is allowable in the form of hydro liquid or wheat flour blends.

C. Mixed Preparations

1. Additives, which are used to prepare mixed preparations, must be one listed in the Food Additives Codes and be suitable to the individual specifications. A natural substance recognized as a food additive on the status of product specific individual specification and standard with time-limit in use can be a

component of additive mix preparation.

2. When additives mix preparations are prepared, the purpose of the preparation should be appropriate for use in foods, and the composition of preparation should not be to alter chemically the original components.
3. Diluent, which are used to prepare mixed dilution or diluted mixed preparations, must be one of starch (excluding starches modified and classified as food additives), wheat flour, glucose, sugar and others recognized generally as food ingredients.
4. When preparing mixed preparations, additives such as antioxidant, preservatives, emulsifiers, stabilizers, or dissolving agents may be used if it is indispensable to maintain the stability in quality and to form necessary shape. The amount of addition must be kept at a minimum level, where the required technical effects can be achieved.

D. Ingredients for Natural Additives

1. As for raw materials such as bovine split, etc. used in manufacturing gelatin, those that underwent the hardening process such as chromium treatment, etc should not be used.
2. The ingredients of chitin, chitosan, glucosamine, crayfish pigment, carageenan, alginic acid, cochineal extracted pigment, and carmin should be handled in a sanitary way in the process of collecting, storing, and transporting.

E. Food Additives Manufactured by Manufacturing Equipment

1. Food Additives manufactured by manufacturing equipment should be suitable to standards and specification.
2. The concentration of ozone emitted from ozone solution manufacturing equipment should be suitable to the standard in the relevant rule such as

Management of Indoor Air Quality in Crowd Facilities.

F. Genetically Modified Organisms Food Additives

Food additives prepared by using microorganism acquired by genetically modified organisms technology should be approved on 「Regulation for Examination of Genetically Modified Organisms Safety Evaluation」(KFDA Notification) under Article 18 of 「Food Sanitation Law」and suitable to standards and specification.

G. Extraction Solvents for Natural Food Additives

Extraction solvents, which are used to prepare natural additives, must be listed in the Food Additive Codes and be suitable for individual specifications. Solvents such as trichloroethylene or methylene chloride can also be used as extraction solvents for natural food additives. These solvents must conform to the following individual specifications.

Trichloroethylene

Ethylene Trichloride

1,1,2-Trichloroethylene

Chemical Formula C_2HCl_3

Molecular Weight 131.39

Compositional Specifications of Trichloroethylene

Description This is a colorless transparent fluidal liquid with a characteristic scent and sweet taste that are similar those of chloroform.

Purity (1) Specific Gravity : Specific gravity of Trichloroethylene should be a range of 1.454 ~ 1.458.

(2) Acidity and alkalinity : Add 2 drops of phenolphthalein standard solution to 25 ml of water, then 0.01 N sodium hydroxide solution is added until pale red color appears. Approximately 25 ml (approximately 36 g) of sample is added to the solution, which is then shaken for 30 seconds. If the pale red color persists, the solution is titrated with 0.01 N hydrochloric acid while shaking until the color disappears. The amount of 0.01 N hydrochloric acid consumed must be not more than 0.9 ml. When the color disappears, the solution is titrated with 0.01 N sodium hydroxide solution until the pale red color appears, where the amount of consumed 0.01 N sodium hydroxide solution should not be more than 1.0 ml.

(3) Heavy Metals : 14 ml of Trichloroethylene (approximately 20 g) is dried by evaporation in a water bath and then cooled. 2 ml of hydrochloric acid is added and then slowly dried again by evaporation in a water bath. Remaining residues are wetted with 1 drop of hydrochloric acid and decomposed with 10 ml of hot water for 2 minutes. After filtering, if necessary, test solution is prepared by adding 2 ml of dilute acetic acid and water, where the total volume of the final solution is brought up to 50 ml. This solution test by Heavy Metal Limit Test, the content of heavy metals should not be more than 1 ppm.

(4) Distillation Range : When sample is tested for boiling point and amount of distillate, 95%(v/v) or more should be extracted at 86～88°.

(5) Free Halogen : When 10 ml of sample is vigorously stir-mixed for 2 minutes with 10 ml of potassium iodide solution (1→10) and 1 ml of starch standard solution, the aqueous layer should not turn blue.

(6) Residue on Evaporation : 69 ml (approximately 100 g) of sample is dried in a water bath and is further dried at 105° for 30 minutes. The weight of the residue after cooling should not be more than 10 ppm.

Water Content Water content of this item is measured by water determination (Karl-Fisher Titration) and should not be more than Methylene Chloride 0.05%.

Methylene Chloride

Dichloromethane

Chemical Formula CH_2Cl_2
Molecular Weight 84.93

Compositional Specifications of Methylene Chloride

Description This is a colorless transparent nonflammable liquid.

Purity (1) Specific Gravity : Specific gravity of Methylene Chloride should be within a range of 1.318 ~ 1.323.

(2) Acidity (as hydrochloric acid) : After adding 100 ml of water to 100 ml (approximately 132 g) of sample in a separatory funnel with a stop cock, the mixture is vigorously shaken for 2 minutes. Two layers are separated and the aqueous portion is titrated with 0.01 N sodium hydroxide solution. The amount of titrant consumed should not be more than 3.6 ml. (indicator : 4 drops of bromothymol blue solution).

(3) Heavy Metals : 15 ml of sample (approximately 20 g) is dried by evaporation in a water bath and then cooled. 2 ml of hydrochloric acid is added and then slowly dried again by evaporation in a water bath. Remaining residues are wetted with 1 drop of hydrochloric acid and decomposed with 10 ml of hot water for 2 minutes. After filtering, if necessary, test solution is prepared by adding 2 ml of dilute acetic acid and water, where the total volume of the final solution is brought up to 50 ml. Test solution is tested by Heavy Metal Limit Test, the content of heavy metals should not be more than 1 ppm.

(4) Distillation Range : When sample is tested for boiling point and amount of distillate, 95%(v/v) or more should be extracted at 39.5~40.5°.

(5) Free Halogen : After adding 25 ml of water to 10 ml of sample in a separatory funnel with a stop cock, the mixture is vigorously shaken for 1 minute. After settling, the sub phase is decanted out. To the aqueous phase, 1 ml of potassium iodide solution and a few drops of starch standard

solution are added and the mixture is set-aside for 5 minutes. This aqueous phase should not turn blue.

(6) Residue on Evaporation : 38 ml (approximately 50 g) of sample is dried by evaporation in a water bath and is further dried at 105° for 30 minutes. The weight of the residue after cooling should not be more than 20 ppm.

Water Content Water content of this item is measured by water determination (Karl-Fisher Titration) and should not be more than 0.02%.