

E. STANDARDS FOR MANUFACTURING

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Standards applying generally to all food additives

1. Acid clay, bentonite, diatomaceous earth, kaolin, magnesium carbonate, sand, silicon dioxide, talc, or any other similar water-insoluble mineral substance shall not be used for manufacturing or processing any other food additive, except when the substance is indispensable for manufacturing or processing the additive.

2. Unless otherwise specified, preparations of additives shall not be manufactured from those other than additives (confined to substances designated under Article 10 of the Food Sanitation Act, natural flavoring agents, substances that are generally provided for eating or drinking as foods and that are used as additives, and substances appearing in the *List of Existing Food Additives*: Ministry of Health and Welfare Notification No. 120, April 1996) and foods (including water) (additives and foods shall meet corresponding specifications when they are established under Article 11 Paragraph 1 of the Act; water shall be water used for food production*).

3. When food additives are manufactured by making use of microorganisms obtained by recombinant DNA technologies, it shall be confirmed that the methods to be used meet the standards specified by the Minister of Health, Labour and Welfare.

4. When enzymes are manufactured by making use of microorganisms, the cultured strains to be used shall be nonpathogenic. If the strains to be used may produce toxins, the possible toxins shall be removed in purification process.

5. When food additives are manufactured or processed, no spinal column of specified cattle shall be used as ingredients of the food additives. However, this provision shall not apply to cases where ingredients to be used fall into one of the categories specified below:

i) Fat and oil derived from spinal columns of specified cattle that are hydrolyzed, saponified, or transesterified under the conditions of high temperature and high pressure.

ii) Spinal columns of specified cattle aged not more than 30 months that are defatted, decalcificated with acid, treated with acid or alkali, filtered, and sterilized at a temperature not lower than 138°C for 4 seconds or longer or that are treated with procedures comparable or superior in the reduction of infectivity to the above procedure.

* "Water used for food production" means drinking water that is specified by the Water Works Act or water that meet specifications established by the Food Sanitation Act.

Standards applying specifically to individual food additives and preparations

Chlorous Acid Water

Sodium chloride to be used as an ingredient to manufacture chlorous acid water shall be sodium chloride as specified in the Japanese Pharmacopoeia or sodium chloride with the same or higher quality standard than that of the Japanese Pharmacopoeia.

Kansui (confined to chemically synthesized substances)

Kansui shall be manufactured or processed by making use of potassium carbonate (anhydrous), sodium carbonate, sodium hydrogen carbonate, or potassium or sodium salts of phosphoric acids that meet the corresponding specifications, alone, or as a mixture of two or more of the compounds, as an aqueous solution of a single compound or mixture, or as a single compound or mixture diluted with wheat flour.

Peracetic Acid

Peracetic acid shall be manufactured from glacial acetic acid or its dilution and hydrogen peroxide. Glacial acetic acid and hydrogen peroxide to be used as ingredients of peracetic acid shall meet the corresponding compositional specifications.

Peracetic Acid Composition

Peracetic acid composition shall be manufactured by mixing 1-hydroxyethylidene-1,1-diphosphonic acid with peracetic acid alone or with glacial acetic acid or its dilution and hydrogen peroxide, or by further adding octanoic acid to the above mixture. Glacial acetic acid, hydrogen peroxide, 1-hydroxyethylidene-1,1-diphosphonic acid, and octanoic acid to be used as the ingredients of Peracetic Acid Composition shall meet the corresponding compositional specifications

Talc

Talc shall be manufactured or processed from water-insoluble mineral substances that do not contain asbestos.

Absinth Extract, Capsicum Water-soluble Extract, Carrot Carotene, Clove Extract, Essential Oil-removed Fennel Extract, Gardenia Yellow, Ginger Extract, Horseradish Extract, Licorice Extract, Licorice Oil Extract, Mustard Extract, Onion Color, Orange Color, Oregano Extract, Paprika Color, Perilla Extract, Rosemary Extract, Sage Extract, Sesame Seed Oil Unsaponified Matter, Spice Extracts, Tamarind Color, Tannin (extract), Turmeric Oleoresin, and natural flavoring agents (hereinafter referred to as the substances obtained only from ajowan, allspice, angelica, anise, asafetida, basil, caraway, cardamom, carrot, caper, capsicum, cassia, celery, chamomile, chervil,

Chinese pepper, chive, cinnamon, clove, coriander, cress, cumin, curry leaves, dill, fennel, fenugreek, gardenia, garlic, ginger, hemp seeds, horseradish, horsemint, hyssop, Japanese pepper, juniperberry, laurel, lavender, lemon balm, lemongrass, licorice, linden, marjoram, mint, mustard, *myoga* (*Zingiber mioga*), nigella, nutmeg, onion, orange peel, oregano, paprika, parsley, pepper, peppermint, perilla, poppy seeds, rose, rosemary, saffron, salvia, sassafras, savory, sesame seeds, shallot, sorrel, spearmint, star anise, tamarind, tarragon, thyme, turmeric, vanilla, *wasabi* (Japanese horseradish), or wormwood.)

When the food additives listed above are manufactured or processed, no solvents other than those appearing in the following list shall be used for extracting. In addition, methanol and 2-propanol shall not remain in any of the food additives at more than 50 µg/g each, acetone at more than 30 µg/g, dichloromethane and 1,1,2-trichloroethene at more than 30 µg/g as the total amount of both solvents, and hexane at more than 25 µg/g.

A list of usable solvents

Acetone; Butane; 1-Butanol; 2-Butanol; 2-Butanone; Carbon dioxide; Cyclohexane; Dichloromethane; Diethyl ether; Edible fats and oils, Ethanol; Ethyl acetate; Glycerol; Hexane; Methanol; Methyl acetate; Nitrous oxide; Propane; 1-Propanol; 2-Propanol; Propylene glycol; 1,1,1,2-Tetrafluoroethane; 1,1,2-Trichloroethene; and Water.