

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY.

Voluntary - Public

Date: 9/3/2019

GAIN Report Number: JA9110

Japan

Post: Tokyo

Japan 226th Food Safety Group

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

On August 29, 2019, Japan's Ministry of Health, Labor and Welfare (MHLW) announced revisions to Japan's Maximum Residue Levels (MRLs) for five pesticides (Chloropicrin, Dichlobentiazo, Fenpicoxamid, Flutianil, Prothiofos) and a veterinary drug (Cephapirin) in foods. In addition, MHLW intends to designate Psicose Epimerase (also known as Allulose Epimerase) as a food additive. MHLW also presented a new standard for buffalo milk and processed products containing buffalo milk. Lastly, MHLW shared proposed specifications and standards for utensils, containers and packaging (UCP) intended for milk and milk products. The embassy comment period for these proposals is open until September 12, 2019. MHLW will then notify these revisions to the World Trade Organization (WTO), which will provide another opportunity for interested parties to comment.

Keyword: JA9110, Chloropicrin, Dichlobentiazo, Fenpicoxamid, Flutianil, Prothiofos, Cephapirin, Psicose Epimerase, Utensils, Containers, Packaging, Buffalo, Milk

General Information:

(The following is taken from Japan's documents at the Food Safety Group)

<The manner of submitting comments>

The Ministry of Health, Labour and Welfare (MHLW) will amend the existing standards and specifications for food as shown in this document. Please provide comments in writing by **Thursday, September 12, 2019**. After the given date, comments should be directed to the enquiry point in accordance with the WTO/SPS Agreement.

If you wish to request Japan to adopt the same limits as your country's MRLs, you are requested to submit data supporting your country's MRLs, such as risk assessment and residue data.

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Item 1. Establishment of the Maximum Residue Limits for Agricultural and Veterinary Chemicals in Foods

The Food Sanitation Act authorizes the Ministry of Health, Labour and Welfare (MHLW) to establish residue standards (maximum residue limits, “MRLs”) for pesticides, feed additives, and veterinary drugs (hereafter referred to as “agricultural and veterinary chemicals”) that may remain in foods. Any food for which standards are established pursuant to the provisions in Article 11, Paragraph 1 of the act is not permitted to be marketed in Japan unless it complies with the established standards.

On May 29, 2006, Japan introduced the Positive List System¹ for agricultural and veterinary chemicals in food. All foods distributed in the Japanese marketplace are subject to regulation of the system.

The MHLW is going to modify or newly set MRLs in some commodities for the following substances:

Pesticides : Chloropicrin , Dichlobentiazox , Fenpicoxamid , Flutianil, Prothiofos

Veterinary drug : Cephapirin

¹ The aim of the positive list system is to prohibit the distribution of any foods which contain agricultural chemicals at amounts exceeding a certain level (0.01 ppm) in the Japanese marketplace unless specific maximum residue limits (MRLs) have been set.

Summary

Chloropicrin (pesticide: fungicide, insecticide, herbicide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRL by the Ministry of Agriculture, Forestry and Fisheries (MAFF) with the intention to expand its use pattern. This action will not strengthen the current regulation for any commodities.

Dichlobentiazox (pesticide: fungicide): Not permitted for use in Japan. The MHLW is going to establish MRLs in a commodity in response to a request for setting MRLs by the MAFF with the intention to newly register this substance as a pesticide. This action will not strengthen the current regulation for any commodities.

Fenpicoxamid (pesticide: fungicide): Not permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting import tolerances based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan (Shokuan No. 0205001, 5 February 2004). This action will not strengthen the current regulation for any commodities.

Flutianil (pesticide: fungicide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting import tolerances based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan (Shokuan No. 0205001, 5 February 2004). This action will not strengthen the current regulation for any commodities.

Prothiofos (pesticide: insecticide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRL by the MAFF with the intention to expand its use pattern. The MHLW is also going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Cephapirin (veterinary drug: synthetic antibiotics): Not permitted for use in Japan. The MHLW is going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System. This action will not strengthen the current regulation for any commodities.

Chloropicrin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	0.01		§		
Wheat	0.01		§		
Barley✕	0.01		§		
Rye✕	0.01		§		
Corn (maize, including pop corn and sweet corn)✕	0.01		§		
Other cereal grains✕	0.01		§		
Soybeans, dry	0.01		§		
Beans, dry	0.01		§		
Peas✕	0.01		§		
Broad beans	0.01		§		
Peanuts, dry	0.01		§		
Other pulses	0.01		§		
Potato	0.01		§		
Taro	0.01		§		
Sweet potato	0.01		§		
Japanese yam (including Chinese yam)	0.01		§		
Konjac	0.01		§		
Sugar beet✕	0.01		§		
Japanese radish, roots (including radish)	0.01		§		
Japanese radish, leaves (including radish)	0.01		§		
Turnip, roots (including rutabaga)	0.01		§		
Turnip, leaves (including rutabaga)	0.01		§		
Horseradish✕	0.01		§		
Watercress✕	0.01		§		
Chinese cabbage	0.01		§		
Cabbage	0.01		§		
Brussels sprouts	0.01		§		
Kale✕	0.01		§		
Komatsuna (Japanese mustard spinach)	0.01		§		
Kyona	0.01		§		
Qing-geng-cai	0.01		§		
Cauliflower✕	0.01		§		
Broccoli	0.01		§		
Other cruciferous vegetables	0.01		§		
Burdock	0.01		§		
Lettuce (including cos lettuce and leaf lettuce)	0.01		§		
Other composite vegetables	0.01		§		
Onion	0.01		§		
Welsh (including leek)	0.01		§		
Garlic	0.01		§		
Nira	0.01		§		
Asparagus	0.01		§		
Multiplying onion (including shallot)✕	0.01		§		
Other liliaceous vegetables	0.01		§		
Carrot	0.01		§		
Parsley	0.01		§ • Request		
Celery	0.01		§		
Mitsuba	0.01		§ • Request		
Other umbelliferous vegetables	0.01		Request		
Tomato	0.01		§		
Pimiento (sweet pepper)	0.01		§		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Egg plant	○ 0.01		§		
Other solanaceous vegetables	○ 0.01		§		
Cucumber (including gherkin)	○ 0.01		§		
Pumpkin (including squash)	○ 0.01		§		
Oriental pickling melon (vegetable)	○ 0.01		§		
Water melon(whole commodity after removal of stems.)	○ 0.01		§		
Melons(whole commodity after removal of stems.)	○ 0.01		§		
Makuwauri melon(whole commodity after removal of stems.)※	○ 0.01		§		
Other cucurbitaceous vegetables	○ 0.01		§		
Spinach	○ 0.01		§		
Okra	○ 0.01		§		
Ginger	○ 0.01		§		
Peas, immature (with pods)	○ 0.01		§		
Kidney beans, immature (with pods)	○ 0.01		§		
Green soybeans	○ 0.01		§		
Other vegetables	○ 0.01		§		
Apple※	○ 0.01		§		
Strawberry	○ 0.01		§		
Other herbs	○ 0.01		§・Request		

The residue definition is chloropicrin only.

* The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.

* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

○: Commodities for which MRLs are to be maintained, increased or newly set. (*It should be noted that the residue definition (for agricultural / animal products) will be changed.)

§ : Permitted for use in Japan.

Request: Request for setting/revising MRL was made by the MAFF.

※ The MHLW sets an MRL of 0.01 ppm, same as uniform limit, without residue trial data when the pesticide is permitted for use for the commodity in Japan and it is theoretically clear that no pesticide residues remains.

Dichlobentiazox

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	○ 0.01		Request		

The residue definition is dichlobentiazox only.

- * The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.
- * In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

○: Commodities for which MRLs are to be maintained, increased or newly set. (*It should be noted that the residue definition (for agricultural / animal products) will be changed.)

Request: Request for setting/revising MRL was made by the MAFF.

Fenpicoxamid

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Wheat	○ 0.6		IT		0.6 EU
Rye	○ 0.6		IT		0.6 EU
Banana	○ 0.2		IT	0.15	

The residue definition is fenpicoxamid only.

- * The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.
- * In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

○ : Commodities for which MRLs are to be maintained, increased or newly set. (*It should be noted that the residue definition (for agricultural / animal products) will be changed.)

IT : Import tolerance

Flutianil

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Tomato	○ 0.3	0.3	§			
Egg plant	○ 0.2	0.2	§			
Cucumber (including gherkin)	○ 0.2	0.2	§			
Pumpkin (including squash)	○ 0.2	0.2	§			
Water melon	○ 0.05	0.05	§			
Melons	○	0.05				
Melons(whole commodity after removal of stems.)	○ 0.07		§·IT		0.07	USA
Peas, immature (with pods)	○ 0.5	0.5	§			
Apple	○ 0.2		IT		0.15	USA
Cherry	○ 0.4		IT		0.40	USA
Strawberry	○ 0.5	0.5	§			
Grape	○ 0.7		IT		0.70	USA

The residue definition is flutianil only.

- * The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.
- * Diagonal line means deletion of a food category to which an MRL applies.
- * In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.
 - : Commodities for which MRLs are to be lowered or deleted.
 - : Commodities for which MRLs are to be maintained, increased or newly set. (*It should be noted that the residue definition (for agricultural / animal products) will be changed.)
 - § : Permitted for use in Japan.
 - IT : Import tolerance

Prothiofos

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Soybeans, dry	○ 0.05	0.05	§		
Beans, dry	● 0.03	0.05	§		
Peanuts, dry	● 0.02	0.05	§		
Potato	● 0.02	0.05	§		
Sweet potato	○ 0.05	0.05	§		
Sugar beet	○ 0.5	0.5	§		
Sugarcane	● 0.05	0.5	§		
Chinese cabbage	●	0.1			
Cabbage	● 0.03	0.2	§		
Brussels sprouts	●	0.2			
Qing-geng-cai	●	0.2			
Cauliflower	●	0.2			
Broccoli	●	0.2			
Other cruciferous vegetables	●	0.2			
Burdock	○ 0.1	0.1	§		
Onion	○ 0.1	0.1	§		
Welsh (including leek)	○ 2		Request		
Garlic	● 0.03	0.1	§		
Nira	○ 0.2	0.1	§		
Other liliaceous vegetables	○ 0.2	0.1	§-Request		
Ginger	●	1.0			
Unshu orange, pulp	/	0.05	§		
Unshu orange(whole commodity.)	○ 2		§		
Citrus natsudaidai, whole	●	0.1			
Lemon	●	0.1			
Orange (including navel orange)	●	0.1			
Grapefruit	●	0.1			
Lime	●	0.1			
Other citrus fruits	●	0.1			
Apple	●	0.3			
Japanese pear	○ 0.2	0.1	§		
Pear	○ 0.2	0.1	§		
Quince	●	0.05			
Loquat	●	0.05			
Strawberry	○ 0.3	0.3	§		
Grape	● 1	2.0	§		
Japanese persimmon	○ 0.2	0.2	§		
Banana	●	0.01			
Chestnut	● 0.01	0.1	§		
Tea	○ 5	5.0	§		
Other spices	○ 10	0.1	§		
Other herbs	●	0.2			

The residue definition is prothiofos only.

- * The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.
- * Shaded figures indicate provisional MRLs.
- * Diagonal line means deletion of a food category to which an MRL applies.
- * In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.
- : Commodities for which MRLs are to be lowered or deleted.

○ : Commodities for which MRLs are to be maintained, increased or newly set. (*It should be noted that the residue definition (for agricultural / animal products) will be changed.)

§ : Permitted for use in Japan.

Request: Request for setting/revising MRL was made by the MAFF.

Cephapirin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cattle, muscle	○ 0.03	0.03			
Cattle, fat	○ 0.03	0.03			
Cattle, liver	○ 0.03	0.03			
Cattle, kidney	○ 0.03	0.03			
Cattle, edible offal	○ 0.03	0.03			
Milk	○ 0.03	0.03			

The residue definition is cephalosporin only.

* The compound shall not be included in any commodity for which MRL is not given in the above table and in any commodity not listed above.

* Shaded figures indicate provisional MRLs.

○ : Commodities for which MRLs are to be maintained, increased or newly set.

Notes:

“Other cereal grains” refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat.

“Beans, dry” includes butter beans, cowbeans (red beans), lentil, lima beans, pedia, sultani, sultapya and white beans.

“Other legumes/pulses” refers to all legumes/pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry), and spices.

“Other potatoes” refers to all potatoes, except potato, taro, sweet potato, yam, and konjac.

“Other cruciferous vegetables” refers to all cruciferous vegetables, except Japanese radish roots and leaves (including radish), turnip roots and leaves, horseradish, watercress, Chinese cabbage, cabbage, brussels sprouts, kale, *komatsuna* (Japanese mustard spinach), *kyona*, qing-geng-cai, cauliflower, broccoli, and herbs.

“Other composite vegetables” refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, *shungiku*, lettuce (including cos lettuce and leaf lettuce), and herbs.

“Other liliaceous vegetables” refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, *nira*, asparagus, multiplying onion, and herbs.

“Other umbelliferous vegetables” refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, *mitsuba*, spices, and herbs.

“Other solanaceous vegetables” refers to all solanaceous vegetables, except tomato, pimienta (sweet pepper), and egg plant.

“Other cucurbitaceous vegetables” refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and *makuwauri* melon.

“Other mushrooms” refers to all mushrooms, except button mushroom, and *shiitake* mushroom.

“Other vegetables” refers to all vegetables, except potatoes, sugar beet, sugarcane, cruciferous vegetables, composite vegetables, liliaceous vegetables, umbelliferous vegetables, solanaceous vegetables, cucurbitaceous vegetables, spinach, bamboo shoots, okra, ginger, peas (with pods, immature), kidney beans (with pods, immature), green soybeans, mushrooms, spices, and herbs.

“Other citrus fruits” refers to all citrus fruits, except *unshu* orange (pulp), citrus *natsudaidai* (pulp), citrus *natsudaidai* (peel), citrus *natsudaidai* (whole), lemon, orange (including navel orange), grapefruit, lime, and spices.

“Other berries” refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.

“Other fruits” refers to all fruits, except citrus fruits, apple, Japanese pear, pear, quince, loquat, peach, nectarine, apricot, Japanese plum (including prune), mume plum, cherry, berries, grape, Japanese persimmon, banana, kiwifruit, papaya, avocado, pineapple, guava, mango, passion fruit, date and spices.

“Other oil seeds” refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.

“Other nuts” refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.

“Other spices” refers to all spices, except horseradish, *wasabi* (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), *yuzu* (Chinese citron) peels and sesame seeds.

“Other spices (limited to roots and rhizome)” includes asafoetida roots, turmeric root, galangal rhizome and licorice root.

“Other herbs” refers to all herbs, except watercress, *nira*, parsley stems and leaves, celery stems and leaves.

“Edible offal” refers to all edible parts, except muscle, fat, liver, and kidney.

“Other terrestrial mammals” refers to all terrestrial mammals, except cattle and pig.

“Other poultry” refers to all poultry, except chicken.

“Other fish” refers to all fish, except salmoniformes, anguilliformes, and perciformes.

“Other aquatic animals” refers to all aquatic animal, except fish, shelled molluscs and crustaceans.

Item 2. Designation of a Food Additive

The government of Japan will designate Psicose epimerase as a food additive and establish compositional specifications for this substance.

Summary

Japan prohibits the sale etc. of food additives which are not designated by the Minister of Health, Labour and Welfare (hereinafter referred to as “the Minister”) under Article 10 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. (Ministry of Health and Welfare Notification No. 370, 1959) pursuant to Article 11 of the Act, the sale etc. of those additives are prohibited unless they meet the specifications or the standards.

On July 29, 2019, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council (hereinafter referred to as “the Committee”) deliberated on Psicose epimerase. The Committee concluded that the Minister should designate this substance as a food additive that is unlikely to harm human health pursuant to Article 10 of the Act and should establish the specifications and the standards for the additive pursuant to Article 11 of the Act (See Attachment 2-1 for the details).

Regulatory situation in other countries

Psicose epimerase is an enzyme to isomerize fructose into psicose. Its intended use in Japan is as a processing agent. Processing agents include additives categorized as processing aids. Processing aids (including enzymes) are not subject to the Codex General Standard for Food Additives and Psicose epimerase has not been evaluated by the Joint FAO/WHO Expert Committee on Food Additives.

In 2016 the United States Food and Drug Administration responded with no objection to GRAS (generally recognized as safe) notification for this enzyme.

The European Union (except for Denmark and France) has no regulation of enzymes used as processing aids as of September 2018. Although Psicose epimerase is legally usable, it has no history of use in food production. Denmark and France separately regulate enzymes and the distribution of them requires permission. Psicose epimerase is not authorized for distribution and the enzyme has no history of use in food production. In addition, the enzyme has not been evaluated by the European Food Safety Authority.

Australia and New Zealand regulate food-use enzymes as processing aids and the distribution of them requires permission. Psicose epimerase is not authorized for distribution and the enzyme has no history of use. The enzyme has not been evaluated by the Food Standard Australia New Zealand.

Psicose Epimerase

プシコースエピメラー
ゼ

Standard for use (draft)

Not established.

Compositional specifications (draft)

Substance name Psicose Epimerase, Allulose Epimerase

CAS number [1618683-38-7]

Definition Psicose Epimerase is an enzyme that mutually isomerizes fructose and psicose to each other. It is derived from the culture of *Escherichia coli* (limited to *E. coli* K12 W3110 strain) in which the psicose epimerase gene, intrinsically occurring in the bacterium (limited to *Arthrobacter globiformis*), is introduced.

It may contain foods used exclusively for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its activity. Also, it may also contain food additives used for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its pH or activity.

Enzyme Activity Psicose Epimerase has an enzyme activity of not less than 230 units per gram.

Description Psicose Epimerase occurs as a light to dark brown liquid or as a gray powder.

Identification When tested by the enzyme activity determination specified below, Psicose Epimerase shows activity.

Purity

(1) Lead Not more than 5 µg/g as Pb (0.80 g, Method 1, Control Solution: Lead Standard Solution 4.0 mL, Flame Method). If the residue does not dissolve in 5 mL of diluted nitric acid (1 in 100) in the preparation of the test solution, proceed as directed in Method 3.

(2) Arsenic Not more than 3 µg/g as As (0.50 g, Method 5, Standard Color: Arsenic Standard Solution 3.0 mL, Apparatus B).

Microbial Limits Proceed as directed under Microbial Limit Tests.

Total plate count: Not more than 50,000 per gram.

Escherichia coli: Negative per test.

Salmonella: Negative per test.

Sample Fluid Prepare as directed in Method 3 for total plate count.

Pre-enrichment Culture Prepare as directed in Method 3 for the *Escherichia coli* test and

Method 2 for the *Salmonella* test.

Enzyme Activity Determination

(i) Substrate Solution Weigh 0.18 g of D(+)-psicose, dissolve it in water, and add water to make exactly 5 mL. Prepare fresh before use.

(ii) Sample Solution Weigh accurately about 1.0 g of Psicose Epimerase, and dissolve it in the diluent prepared as directed below to make a constant volume so that the resulting solution has 4–10 units per mL. The diluent: Mix phosphate buffer (0.05 mol/L) at pH 8.0 and magnesium chloride (1 mol/L) at a rate of 199 : 1.

(iii) D(–)-Fructose Standard Solutions Weigh accurately about 0.27 g of D(–)-fructose, dissolve it in water to make exactly 100 mL. Use this solution as the standard stock solution. Prepare four standard solutions with different concentrations—10 μmol, 5 μmol, 3 μmol, and 1 μmol of D(–)-fructose ($C_6H_{12}O_6 = 180.16$) per mL—by exactly diluting the standard stock solution to 1.5, 3, 5, and 15 times, respectively.

(iv) Procedure

Test Solution Place 0.100 mL of the sample solution into a test tube, mix it with 0.400 mL of the diluent prepared in (ii), lid the test tube, and equilibrate at $50^\circ\text{C} \pm 0.5^\circ\text{C}$ for 5 minutes. Add 0.500 mL of the substrate solution to the test tube, mix, incubate at $50^\circ\text{C} \pm 0.5^\circ\text{C}$ for exactly 10 minutes, and then heat in a water bath for 2 minutes. After cooling, add about 100 mg of strongly acidic cation-exchange resin and about 100 mg of weakly basic anion- exchange resin (free-form), both whose surface water was previously removed with a filter paper, shake for 15 minutes, and filter through a membrane filter (pore size: 0.2 μm).

For strongly acidic cation-exchange resin, before use wash with water as directed in the Strongly Acidic Cation-exchange Resin section under C. REAGENTS, SOLUTIONS, AND OTHER REFERENCE MATERIALS, beginning with “Weigh about 50 g of strongly acidic cation-exchange resin,” and confirm that the pH of the effluent is 5.0–6.5.

Reference Solution Place 0.100 mL of the diluent into a test tube instead of the sample solution, and proceed as directed for the test solution.

Determination Analyze 10 μL portions of the test solution, the reference solution, and the four D(–)-fructose standard solutions by liquid chromatography using the operating conditions given below. Prepare a calibration curve from the peak area and the concentration (μmol/mL) of each D(–)-fructose standard solution. Measure the peak areas of the test solution and the reference solution, and then determine the concentration (μmol/mL) of D(–)-fructose in each solution from the calibration curve. Calculate the enzyme activity by the following formula. One unit of the enzyme activity is equivalent to the amount of the enzyme required to liberate 1 μmol of D(–)-fructose per minute when determined as directed in the Procedure.

$$\text{Enzyme activity (unit/g)} = \frac{(C_T - C_B) \times V_T}{M}$$

C_T = concentration (μmol/mL) of D(–)-fructose in the test solution,

C_B = concentration (μmol/mL) of D(–)-fructose in the reference solution, V_T = whole volume (mL) of the sample solution prepared,

M = weight (g) of the sample.

Operating conditions

Detector: Differential refractometer.

Column: A stainless steel tube (8 mm internal diameter and 30 cm length).

Column packing material: About 9- μ m cation-exchange resin for liquid chromatography (Ca-form).

Column temperature: 80°C.

Mobile phase: Water.

Flow rate: 0.4 mL/min.

Reagents, Solutions, and Other Reference Materials

Magnesium Chloride TS (1 mol/L) Dissolve 203 g of magnesium chloride hexahydrate in water to make 1000 mL.

D(+)-Psicose C₆H₁₂O₆ [551-68-8] A white to slightly pale yellow crystallized powder or powder.

Specific rotation $[\alpha]_D^{20}$: +2.0 to +6.0° (0.1 g, water, 10 mL).

Purity Related substances Prepare a test solution by dissolving 20 mg of D(+)-psicose in 2 mL of water. Prepare a control solution by diluting exactly measured 1 mL of the test solution with water to exactly 50 mL. Analyze 10 μ L portions of the test solution and the control solution by liquid chromatography using the operating conditions given below. Continue the chromatography for about three times the retention time of the main peak, and measure the peak areas. The sum of the areas of all peaks from the test solution, other than the main peak, is not greater than the area of main peak from the control solution.

Operating conditions

Detector: Differential refractometer.

Column: A stainless steel tube (3–8 mm internal diameter and 15–30 cm length).

Column packing material: 5–10 μ m aminopropyl-bonded silica gel for liquid chromatography.

Column temperature: A constant temperature of 35–40°C. Mobile

phase: A 7 : 3 mixture of acetonitrile/water.

Flow rate: Adjust the retention time of D(+)-psicose to 6–9 minutes.

D(–)-Fructose C₆H₁₂O₆ [57-48-7] Colorless to white crystals or powder.

Specific rotation $[\alpha]_D^{20}$: –90.0 to –94.0° Weigh accurately about 4 g of D(–)-fructose, add 0.2 mL of ammonia TS and 80 mL of water to dissolve it, allow to stand for 30 minutes, and add water to make exactly 100 mL. Measure the optical rotation of the resulting solution.

Purity (1) Clarity of solution Clear (1.0 g, water 20 mL).

(2) Loss of drying Not more than 2.0% (reduced pressure, 18 hours).

(3) Related substances Prepare a test solution by dissolving 20 mg of D(+)-psicose in 2 mL of water. Prepare a control solution by diluting exactly measured 1 mL of the test solution with water to exactly 50 mL. Analyze 10 μ L portions of the test solution and the control solution by liquid chromatography using the operating conditions given below. Continue the chromatography for about three times the retention time of the main peak, and measure the

peak areas. The sum of the areas of all peaks from the test solution, other than the main peak, is not greater than the area of main peak from the control solution.

Operating conditions

Detector: Differential refractometer.

Column: A stainless steel tube (3–8 mm internal diameter and 15–30 cm length).

Column packing material: 5–10 μm aminopropyl-bonded silica gel for liquid chromatography.

Column temperature: A constant temperature of 35–40°C. Mobile

phase: A 7 : 3 mixture of acetonitrile/water.

Flow rate: Adjust the retention time of D(-)-fructose to 4–7 minutes.

Item 3. Setting of Standards for Buffalo's Milk

Summary

Pursuant to the stipulation in Article 11, Paragraph 1 of the Food Sanitation Act, and from the viewpoint of public health, the Minister of Health, Labour and Welfare is authorized to establish standards for the methods of producing, processing, using, cooking, or preserving food or additives to be served for the purpose of marketing; or to establish specifications for the ingredients of food or additives to be served for the purpose of marketing by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council ("the PAFSC").

Specifications and standards for milk, milk products and food mostly made from milk and milk products are stipulated in the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc. (hereinafter referred to as "the Ministerial Ordinance on Milk, etc.") pursuant to the stipulation in Article 11, Paragraph 1 of the Food Sanitation Act.

The Ministry of Health, Labour and Welfare amends the Ministerial Ordinance on Milk, etc. to establish specifications and standards for buffalo's milk based on the deliberation result of the expert committee of the Food Sanitation Council that is established under the PAFSC as follows.

Amendments

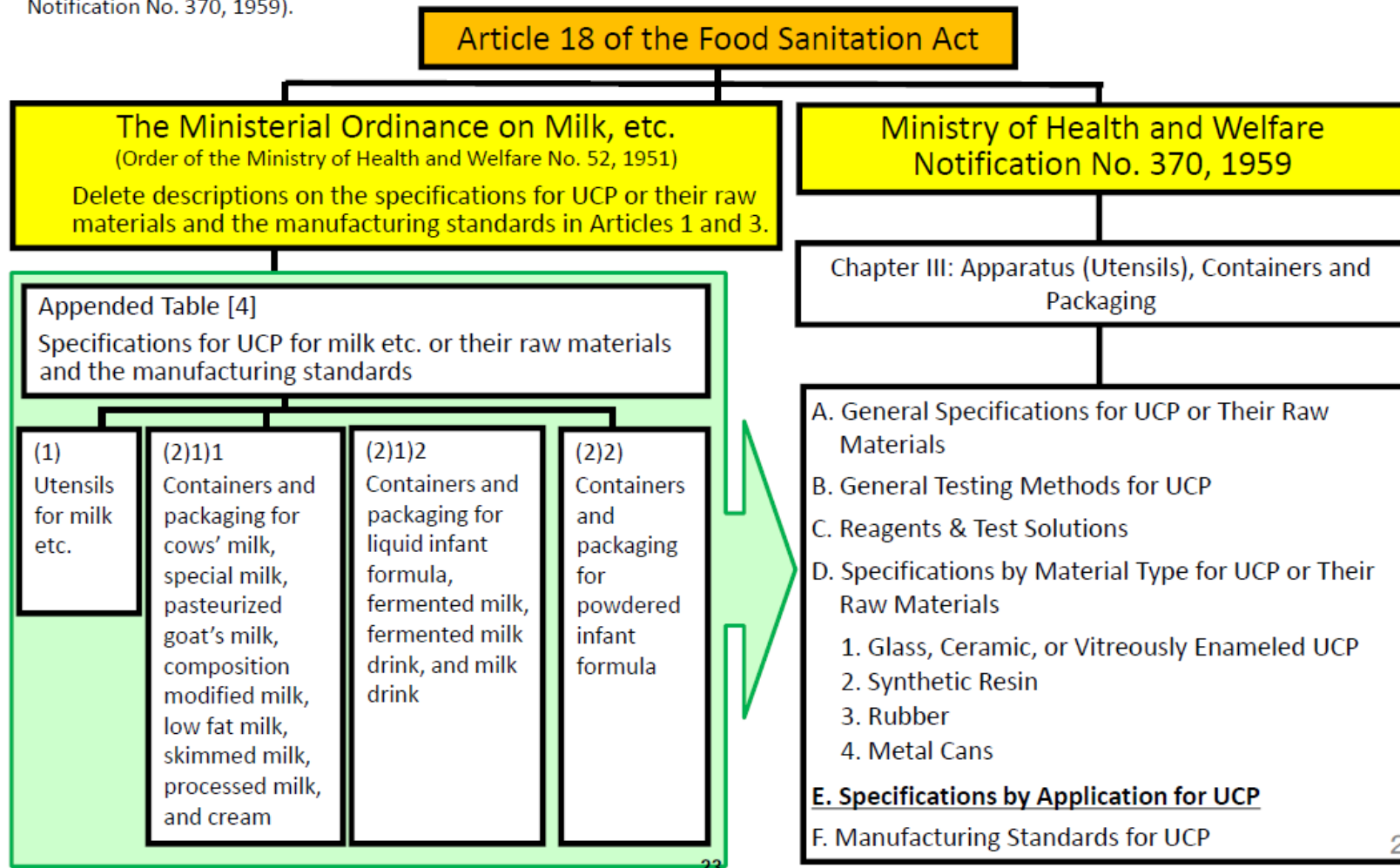
1. For buffalo's milk, those similar to the existing specifications and standards for milk and milk products are newly established in the Ministerial Ordinance on Milk, etc.

By this amendment, "raw buffalo's milk" is newly added to the definition of "milk." The amended definition is as follows: "milk" means raw milk, cow's milk, special milk, raw goat's milk, pasteurized goat's milk, raw sheep's milk, raw buffalo's milk, composition modified milk, low fat milk, skimmed milk, and processed milk.

2. The scope of the amendment is as follows:
 - a. Raw buffalo's milk (newly defined)
 - b. Processed milk
 - c. Milk products: in the Ministerial Ordinance on Milk, etc., "milk products" means cream, butter, butter oil, cheese, concentrated whey, ice cream products, concentrated milk, concentrated skimmed milk, evaporated milk, evaporated skimmed milk, sweetened condensed milk, sweetened condensed skimmed milk, whole milk powder, skimmed milk powder, cream powder, whey powder, protein concentrated whey powder, buttermilk powder, sweetened milk powder, powdered infant formula, liquid infant formula, fermented milk, fermented milk drinks (limited to products containing not less than 3.0% of non-fat milk solids) and milk drinks.
 - d. Foods mainly made from milk or milk product

Incorporation of Specifications and Standards for Utensils, Containers, and Packaging for Milk etc.

Japan is preparing specific stipulations to incorporate the specifications and the standards for utensils, containers, and packaging (UCP) for milk etc.— which are currently prescribed in the Ministerial Ordinance on Milk and Milk Products Concerning Compositional Standards, Etc. (the Ministerial Ordinance on Milk, etc.) —into the Specifications and Standards for Foods, Food Additives, Etc. (Ministry of Health and Welfare Notification No. 370, 1959).



Incorporation of Specifications and Standards for UCP for Milk etc.

Details of the incorporation

1. Delete descriptions on the specifications for UCP or their raw materials and the manufacturing standards prescribed in Articles 1 and 3 of the Ministerial Ordinance on Milk, etc.
2. Consider transferring the descriptions that prescribe the specifications and the standards for UCP in Appended Table [4] of the Ministerial Ordinance on Milk, etc. to **E. Specifications by Application for UCP** of the Ministry of Health and Welfare Notification No. 370, 1959 taking into consideration the following items.
 - a. Aiming at clear and specific descriptions by aligning with the form of Ministry of Health and Welfare Notification No. 370, 1959 for easier understanding.
 - b. Simplifying duplication of descriptions of testing methods etc.