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 13, 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 System[1] 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 : Ethaboxam, Tioxazafen, Fenbuconazole, Prochloraz
Veterinary drugs : Oxfendazole, Febantel and Fenbendazole

<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 Wednesday, November 25, 2020. 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.

<Contact person>
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[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

Ethaboxam (pesticides: Fungicide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the Ministry of Agriculture, Forestry and Fisheries (MAFF) with the intention to expand its use pattern.

Tioxazafen (pesticides: Nematocide): 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.

Fenbuconazole (pesticides: Fungicide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting them by the MAFF.

Prochloraz (pesticides: Fungicide): 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.

Oxfendazole, Febantel and Fenbendazole (veterinary drugs: parasiticide): Permitted for use in Japan. The MHLW is going to modify the MRLs in some commodities in response to an application to expand its usage as veterinary drugs..

Ethaboxam

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
					Codex ppm	National ppm
Potato		0.05	0.05	§		
Chinese cabbage		2	2	§		
Cabbage	○	4		Request		
Broccoli	○	9		Request		
Lettuce (including cos lettuce and leaf lettuce)	○	25		Request		
Tomato		1	1	§		
Cucumber (including gherkin)		0.5	0.5	§		
Grape	●	8	10	§		

The residue definition is Ethaboxam only.

* The uniform limit 0.01 ppm will be applied to commodities not listed above.

● : Commodities for which MRLs are to be lowered.
○ : Commodities for which MRLs are to be raised

§ : Permitted for use in Japan.

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

Tioxazafen

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Corn (maize, including pop corn and sweet corn)	○	0.02		IT	0.01	0.02	USA
Soybeans, dry	○	0.04		IT	0.04		
Cotton seeds	○	0.02		IT	0.01	0.02	USA
Cattle, muscle	○	0.02			0.02		
Pig, muscle	○	0.02			0.02		
Other terrestrial mammals, muscle	○	0.02			0.02		
Cattle, fat	○	0.03			0.03		
Pig, fat	○	0.03			0.03		
Other terrestrial mammals, fat	○	0.03			0.03		
Cattle, liver	○	0.03			0.03		
Pig, liver	○	0.03			0.03		
Other terrestrial mammals, liver	○	0.03			0.03		
Cattle, kidney	○	0.03			0.03		
Pig, kidney	○	0.03			0.03		
Other terrestrial mammals, kidney	○	0.03			0.03		
Cattle, edible offal	○	0.03			0.03		
Pig, edible offal	○	0.03			0.03		
Other terrestrial mammals, edible offal	○	0.03			0.03		
Milk	○	0.02			0.02		
Chicken, muscle	○	0.02			0.02		
Other poultry, muscle	○	0.02			0.02		
Chicken, fat	○	0.02			0.02		
Other poultry, fat	○	0.02			0.02		
Chicken, liver	○	0.02			0.02		
Other poultry, liver	○	0.02			0.02		
Chicken, kidney	○	0.02			0.02		
Other poultry, kidney	○	0.02			0.02		
Chicken, edible offal	○	0.02			0.02		
Other poultry, edible offal	○	0.02			0.02		
Chicken eggs	○	0.02			0.02		
Other poultry, eggs	○	0.02			0.02		

The residue definition is sum of Tioxazafen and metabolite TX2【benzamidine】, expressed as Tioxazafen.

* The uniform limit 0.01 ppm will be applied 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 raised.

IT：Import tolerance

Fenbuconazole

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Wheat	0.1	0.1	§	0.1		
Barley	0.2	0.2		0.2		
Rye	0.1	0.1		0.1		
Soybeans, dry	0.2	0.2	§			
Peanuts, dry	0.1	0.1		0.1		
Sugar beet	● 0.4	0.5	§			
Onion	0.05	0.05	§			
Pimiento (sweet pepper)	0.6	0.6		0.6		
Other solanaceous vegetables	0.6	0.6		0.6		
Cucumber (including gherkin)	0.2	0.2		0.2		
Pumpkin (including squash)	0.05	0.05		0.05		
Oriental pickling melon (vegetable)	○ 0.2			0.2		
Melons		0.2				
Melons (whole commodity after removal of stems)	0.2			0.2		
Makuwauri melon		0.2				
Makuwauri melon (whole commodity after removal of stems)	0.2			0.2		
Unshu orange, pulp		1				
Unshu orange (whole commodity)	1			0.5	1.0	USA
Citrus natsudaidai, whole	1	1		0.5	1.0	USA
Lemon	1	1		1		
Orange (including navel orange)	1	1		0.5	1.0	USA
Grapefruit	1	1		0.5	1.0	USA
Lime	1	1		1		
Other citrus fruits	1	1		1		
Apple	● 0.8	1	§	0.5		
Japanese pear	0.7	0.7	§	0.5		
Pear	0.7	0.7	§	0.5		
Quince	0.5	0.5		0.5		
Loquat		0.1				
Loquat (whole commodity after removal of stems)	0.5			0.5		
Peach		0.5	§			
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems)	2		§	0.5		
Nectarine	1	1	§		1.0	USA
Apricot	0.5	0.5	§	0.5		
Japanese plum (including prune)	1	1	§	0.3	1.0	USA
Mume plum	2	2	§	0.5		
Cherry	1	1	§	1		
Blueberry	0.7	0.7	§	0.5		
Cranberry	1	1		1		
Huckleberry	0.5	0.5		0.5		
Other berries	0.3	0.3			0.3	USA
Grape	3	3	§	1		
Japanese persimmon	0.7	0.7	§	0.5		
Banana	0.05	0.05		0.05		
Other fruits	○ 0.5	0.01		0.5		
Sunflower seeds	0.05	0.05		0.05		
Rapeseeds	0.05	0.05		0.05		
Ginkgo nut	0.01	0.01		0.01		
Chestnut	0.01	0.01		0.01		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Pecan	0.01	0.01		0.01		
Almond	0.05	0.05		0.01	0.05	USA
Walnut	0.01	0.01		0.01		
Other nuts	0.01	0.01		0.01		
Tea	○ 30	10	§・Request			
Other spices	1	1				
Other herbs	○ 0.6			0.6		
Cattle, muscle	0.01	0.01		0.01		
Pig, muscle	0.01	0.01		0.01		
Other terrestrial mammals, muscle	0.01	0.01		0.01		
Cattle, fat	0.01	0.01		0.01		
Pig, fat	0.01	0.01		0.01		
Other terrestrial mammals, fat	0.01	0.01		0.01		
Cattle, liver	0.1	0.1		0.1		
Pig, liver	0.1	0.1		0.1		
Other terrestrial mammals, liver	0.1	0.1		0.1		
Cattle, kidney	0.1	0.1		0.1		
Pig, kidney	0.1	0.1		0.1		
Other terrestrial mammals, kidney	0.1	0.1		0.1		
Cattle, edible offal	0.1	0.1		0.1		
Pig, edible offal	0.1	0.1		0.1		
Other terrestrial mammals, edible offal	0.1	0.1		0.1		
Milk	0.01	0.01		0.01		
Chicken, muscle	0.01	0.01		0.01		
Other poultry, muscle	0.01	0.01		0.01		
Chicken, fat	0.01	0.01		0.01		
Other poultry, fat	0.01	0.01		0.01		
Chicken, liver	0.01	0.01		0.01		
Other poultry, liver	0.01	0.01		0.01		
Chicken, kidney	0.01	0.01		0.01		
Other poultry, kidney	0.01	0.01		0.01		
Chicken, edible offal	0.01	0.01		0.01		
Other poultry, edible offal	0.01	0.01		0.01		
Chicken eggs	0.01	0.01		0.01		
Other poultry, eggs	0.01	0.01		0.01		
Pepper,dried ※				2		

The residue definition is Fenbuconazole only.

* The uniform limit 0.01 ppm will be applied to commodities not listed above.

* Diagonal line means a food category to which MRL applies is not set.

* 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.
○ : Commodities for which MRLs are to be raised

§ : Permitted for use in Japan.

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

※) For "Pepper, dried" as food category with MRL set by Codex, MRL of its raw commodity (Other solanaceous vegetables) will apply to the commodity, taking into account of its processing factor. For this substance, JMPR estimates it at 10 for Pepper, dried.

Prochloraz

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	● 0.05	2	§		
Wheat	○ 2	0.5	§	2	
Barley	○ 2	0.5		2	
Rye	○ 2	0.5		2	
Corn (maize, including pop corn and sweet corn)	2	2		2	
Buckwheat	2	2		2	
Other cereal grains	○ 2	0.5		2	
Soybeans, dry	●	0.1			
Beans, dry	●	0.05			
Peas	●	0.3			
Broad beans	●	0.05			
Peanuts, dry	●	0.1			
Other pulses	●	0.3			
Potato	●	0.05			
Taro	●	0.05			
Sweet potato	●	0.05			
Japanese yam (including Chinese yam)	●	0.05			
Konjac	●	0.05			
Other potatoes	●	0.05			
Sugar beet	●	0.05			
Sugarcane	●	0.05			
Japanese radish, roots (including radish)	●	0.05			
Japanese radish, leaves (including radish)	●	0.05			
Turnip, roots (including rutabaga)	●	0.05			
Turnip, leaves (including rutabaga)	●	0.05			
Horseradish	●	0.05			
Watercress	●	5			
Chinese cabbage	●	0.05			
Cabbage	●	0.05			
Brussels sprouts	●	0.05			
Kale	●	0.05			
Komatsuna (Japanese mustard spinach)	●	0.05			
Kyona	●	0.05			
Qing-geng-cai	●	0.05			
Cauliflower	●	0.05			
Broccoli	●	0.05			
Other cruciferous vegetables	●	5			
Burdock	●	0.05			
Salsify	●	0.05			
Artichoke	●	0.05			
Chicory	●	0.05			
Endive	●	5			
Shungiku	●	5			
Lettuce (including cos lettuce and leaf lettuce)	●	2			
Other composite vegetables	●	0.05			
Onion	●	0.05			
Welsh (including leek)	●	0.05			
Garlic	●	0.5			
Nira	●	5			
Asparagus	●	0.05			
Multiplying onion (including shallot)	●	0.05			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other liliaceous vegetables	● 0.4	5	§		
Carrot	●	0.05			
Parsnip	●	0.05			
Parsley	●	5			
Celery	●	5			
Mitsuba	●	5			
Other umbelliferous vegetables	●	5			
Tomato	●	0.05			
Pimiento (sweet pepper)	●	1			
Egg plant	●	0.05			
Other solanaceous vegetables	●	0.05			
Cucumber (including gherkin)	●	0.05			
Pumpkin (including squash)	●	0.05			
Oriental pickling melon (vegetable)	●	0.05			
Water melon	●	0.05			
Melons	●	0.05			
Makuwauri melon	●	0.05			
Other cucurbitaceous vegetables	●	0.05			
Spinach	●	0.05			
Bamboo shoots	●	0.05			
Okra	●	0.05			
Ginger	●	0.05			
Peas, immature (with pods)	●	0.05			
Kidney beans, immature (with pods)	●	0.05			
Green soybeans	●	0.05			
Button mushroom	○ 3	2		3	
Shiitake mushroom	●	2			
Other mushrooms	●	2			
Other vegetables	● 2	5		2	
Unshu orange, pulp	●	10			
Citrus natsudaidai, whole	●	10			
Lemon	●	10			
Orange (including navel orange)	●	5			
Grapefruit	●	10			
Lime	●	10			
Other citrus fruits	●	10			
Apple	●	0.05			
Japanese pear	●	0.05			
Pear	●	0.05			
Quince	●	0.05			
Loquat	●	0.05			
Peach	●	0.05			
Nectarine	●	0.05			
Apricot	●	0.05			
Japanese plum (including prune)	●	0.05			
Mume plum	●	0.05			
Cherry	●	0.05			
Strawberry	●	1			
Raspberry	●	0.05			
Blackberry	●	0.05			
Blueberry	●	0.05			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cranberry	●	0.05			
Huckleberry	●	0.05			
Other berries	●	0.05			
Grape	●	0.05			
Japanese persimmon	●	0.05			
Banana	5	5			
Kiwifruit	●	0.05			
Papaya	1	1			
Avocado	5	5			
Pineapple	2	2			
Guava	●	0.05			
Mango	2	2			
Passion fruit	●	0.05			
Date	●	0.05			
Other fruits	●	10			
Sunflower seeds	0.5	0.5		0.5	
Sesame seeds	●	0.1			
Safflower seeds	●	0.1			
Cotton seeds	●	0.1			
Rapeseeds	○ 0.7	0.5		0.7	
Other oil seeds	○ 2	0.05		2	
Ginkgo nut	●	0.1			
Chestnut	●	0.1			
Pecan	●	0.1			
Almond	●	0.1			
Walnut	●	0.1			
Other nuts	●	0.3			
Tea	●	0.1			
Coffee beans	●	0.2			
Hop	●	0.1			
Other spices	10	10		10	
Other herbs	●	5			
Cattle, muscle	○ 0.5	0.1			
Pig, muscle	○ 0.5	0.1			
Other terrestrial mammals, muscle	○ 0.5	0.1			
Cattle, fat	0.5	0.5		0.5	
Pig, fat	0.5	0.5		0.5	
Other terrestrial mammals, fat	0.5	0.5		0.5	
Cattle, liver	10	10		10	
Pig, liver	10	10		10	
Other terrestrial mammals, liver	10	10		10	
Cattle, kidney	10	10		10	
Pig, kidney	10	10		10	
Other terrestrial mammals, kidney	10	10		10	
Cattle, edible offal	10	10		10	
Pig, edible offal	10	10		10	
Other terrestrial mammals, edible offal	10	10		10	
Milk	0.05	0.05		0.05	
Chicken, muscle	0.05	0.05		0.05	
Other poultry, muscle	0.05	0.05		0.05	
Chicken, fat	● 0.05	0.1			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other poultry, fat	● 0.05	0.1			
Chicken, liver	0.2	0.2		0.2	
Other poultry, liver	0.2	0.2		0.2	
Chicken, kidney	0.2	0.2		0.2	
Other poultry, kidney	0.2	0.2		0.2	
Chicken, edible offal	0.2	0.2		0.2	
Other poultry, edible offal	0.2	0.2		0.2	
Chicken eggs	0.1	0.1		0.1	
Other poultry, eggs	0.1	0.1		0.1	
Wheat bran		7		7	
Sunflower oil (limited to refined sunflower oil that meet the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)		1			
Sunflower oil	1			1	

The residue definition for prochloraz is sum of prochloraz and its metabolites hydrolysed with pyridine hydrochloride to 2,4,6-trichlorophenol, expressed as prochloraz.
The current residue is sum of prochloraz, *N*-formyl-*N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]urea, *N*-propyl-*N*-[2-(2,4,6-trichlorophenoxy)ethyl]urea and 2,4,6-trichlorophenol, expressed as prochloraz.

* The uniform limit 0.01 ppm will be applied to commodities not listed above.

* Shaded figures indicate provisional MRLs.

* Diagonal line means a food category to which MRL applies is not set.

* 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.
○ : Commodities for which MRLs are to be raised.(*It should be noted that the residue definition will be changed.)

§ : Permitted for use in Japan.

※） For processed food, “Wheat bran”, the MRL in the raw commodity (Wheat) will be applied, taking into account of its processing factor. JMPR estimates it at 2 for Wheat bran.

Oxfendazole, Febantel and Fenbendazole

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cattle, muscle	0.1	0.1		0.1	
Pig, muscle	0.1	0.1	§	0.1	
Other terrestrial mammals, muscle	0.1	0.1		0.1	
Cattle, fat	0.1	0.1		0.1	
Pig, fat	0.1	0.1	§	0.1	
Other terrestrial mammals, fat	0.1	0.1		0.1	
Cattle, liver	0.5	0.5		0.5	
Pig, liver	0.5	0.5	§	0.5	
Other terrestrial mammals, liver	0.5	0.5		0.5	
Cattle, kidney	0.1	0.1		0.1	
Pig, kidney	0.1	0.1	§	0.1	
Other terrestrial mammals, kidney	0.1	0.1		0.1	
Cattle, edible offal	● 0.5	3			
Pig, edible offal	● 0.5	3	§		
Other terrestrial mammals, edible offal	● 0.5	3			
Milk	0.1	0.1		0.1	
Chicken, muscle	0.03	0.03			
Turkey, muscle		2			
Other poultry, except turkey, muscle		0.03			
Other poultry, muscle	○ 2				
Chicken, fat	0.01	0.01			
Other poultry, fat	0.01	0.01			
Chicken, liver	2	2			
Turkey, liver		6			
Other poultry, except turkey, liver		2			
Other poultry, liver	○ 6				
Chicken, kidney	0.01	0.01			
Other poultry, kidney	0.01	0.01			
Chicken, edible offal	0.01	0.01			
Other poultry, edible offal	0.01	0.01			
Perciformes (such as bonito, horse mackerel, mackerel, sea bass, sea bream and tuna)	0.01		Request		
Other fish	0.05	0.05	§		

The residue definition for Oxfendazole, Febantel and Fenbendazole is sum of Oxfenbendazole sulfone【Methyl [5-(Phenylsulfonyl)-1*H*-benzimidazol-2-yl]carbamate】, Oxfendazole, Fenbendazole, expressed as Oxfenbendazole sulfone.
The current residue definition is sum of Oxfenbendazole sulfone, Oxfendazole, Febantel and Fenbendazole, expressed as Oxfenbendazole sulfone.

* The uniform limit 0.01 ppm will be applied to commodities not listed above.

* Diagonal line means a food category to which MRL applies is not set.

* 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.
○ : Commodities for which MRLs are to be raised. (*It should be noted that the residue definition will be changed.)

§ : Permitted for use in Japan.

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

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, pegia, 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, pimiento (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 Food Additives and Establishment of Specifications and Standards (Ammonium hydrogen sulfite water, Chitin-glucan, Copolymer of vinylimidazole/vinylpyrrolidone, and Dipotassium DL-tartrate)

The government of Japan is taking necessary steps to designate four substances (Ammonium hydrogen sulfite water, Chitin-glucan, Copolymer of vinylimidazole/vinylpyrrolidone and Dipotassium DL-tartrate) as food additives.

Summary

Japan prohibits the sale etc. of food additives that are not designated by the Minister of Health, Labour and Welfare ("the Minister") under Article 12 of the Food Sanitation Act (Act No. 233 of 1947; "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 of 1959) pursuant to Article 13 of the Act, the sale etc. of those additives are prohibited unless they meet the specifications or the standards.

1. Ammonium Hydrogen Sulfite Water

On October 14, 2020, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council ("the Committee") deliberated on Ammonium hydrogen sulfite water and concluded that it is appropriate for this substance to be designated as a food additive that is unlikely cause harm to human health pursuant to Article 12 of the Act. The Committee also concluded that it is appropriate for compositional specifications and use standards to be established for the additive pursuant to Article 13 of the Act. See Attachment 2a for the details.

Notes

Ammonium hydrogen sulfite water is considered to work as an antioxidant, a preservative, and a fermentation aid when added to grape juice that is raw material of grape wine before or during fermentation. As an antioxidant, it prevents oxidation of grape juice through effects of sulfurous acid (sulfur dioxide and hydrogen sulfite ion). As a preservative, it inhibits the generation and increase of harmful microorganisms through the same effects. As a fermentation aid, it promote fermentation of grape juice through the effects of ammonium ion.

The European Union (the EU) permits the use of ammonium hydrogen sulfite in grapes, grape juice, and musts and wine during fermentation at a level not more than 0.2 g/L (as salt) only for fermentation purposes (the additive is not allowed to be used in wine after the completion of fermentation). The United States (the U.S.) allows the domestic distribution of ammonium hydrogen sulfite-treated wine products imported from EU countries. Australia lists this additive as the name ammonium bisulphite in the section "permitted processing aids" in the Food Standard Code and permits its use as a fermentation aid during wine production under the Good Manufacture Practice (GMP) compliance.

2. Chitin-glucan

On October 14, 2020, the Committee deliberated on Chitin-glucan and concluded that it is appropriate for this substance to be designated as a food additive that is unlikely cause harm to human health pursuant to Article 12 of the Act. The Committee also concluded that it is appropriate for compositional specifications and use standards to be established for the additive pursuant to Article 13 of the Act. See Attachment 2b for the details.

Notes

Chitin-glucan is derived from the culture of filamentous fungi (*Aspergillus niger*) as a by-product of citric acid production. It adsorbs contaminants; therefore, in the EU and other countries, it is used for clarifying or for the removal of heavy metals and contaminants especially ochratoxin A in wine.

The EU allows the use of chitin-glucan for wine production at a level up to 100 g per 100 L (1 g/L) to remove heavy metals and to prevent contamination of iron and copper, and at a level up to 500 g per 100 L (5 g/L) to remove ochratoxin A. The U.S approves chitin-glucan as a substance generally recognized as safe (GRAS) and permits its use within the range 10–500 g per 100 L (0.1–5 g/L) for the removal of contaminants and for clarifying during alcoholic beverage production. Australia approves chitin-glucan as a processing aid and permits its use as decolorant, clarifying, filtration, and absorbent agents for wine, sparkling wine, and fortified wine production under GMP compliance.

3. Copolymer of vinylimidazole/vinylpyrrolidone

On October 14, 2020, the Committee deliberated on Copolymer of

vinylimidazole/vinylpyrrolidone ("PVI/PVP") and concluded that it is appropriate for this substance to be designated as a food additive that is unlikely cause harm to human health pursuant to Article 12 of the Act. The Committee also concluded that it is appropriate for compositional specifications and use standards to be established for the additive pursuant to Article 13 of the Act. See Attachment 2c for the details.

Notes

PVI/PVP is a polymer forming insoluble complexes. It has imidazole groups, as functional parts, which selectively bind to metals such as iron and copper. PVI/PVP is therefore considered, as a filtration agent, to have adsorption effects on metals such as iron and copper in wine. This effects are considered to prevent browning, cloudiness, and precipitation caused by metallic ions, and to clarify wines.

The EU permits the use of PVI/PVP in musts or wine at a level up to 500 mg/L for the purpose of removing copper, iron and heavy metals. The U.S. permits the use of some PVI/PVP products based on a food contact substance notification (FCN) at a level not exceeding 80 g per 100 L (0.80 g/L) for the purpose of removing metallic ions and other substances from alcoholic beverage such as beer and wine. The U.S. also allows the domestic distribution of EU wine in which PVI/PVP was used. Australia approves PVI/PVP as a processing aid and permits its use in wine, sparkling wine, and fortified wine production under GMP compliance.

4. Dipotassium DL-tartrate

On October 14, 2020, the Committee deliberated on Dipotassium DL-tartrate and concluded that it is appropriate for this substance to be designated as a food additive that is unlikely cause harm to human health pursuant to Article 12 of the Act. The Committee also concluded that it is appropriate for compositional specifications and use standards to be established for the additive pursuant to Article 13 of the Act. See Attachment 2d for the details.

Notes

Dipotassium DL-tartrate is considered as racemate containing the equal amounts of two kinds of enantiomer: dipotassium D-tartrate and dipotassium L-tartrate. In wine, Dipotassium DL-tartrate is dissociated to dipotassium ions and tartrate ions (D-form and L-form) that are divalent anion. With calcium ions in wine, the tartrate ions form a poorly soluble racemic salt (calcium DL-tartrate) and then form crystals that eventually precipitate. Through above process, Dipotassium DL-tartrate is

considered to help to remove excess calcium in wine.

The EU permits the use of DL-tartrate acid or Dipotassium DL-tartrate during wine production to precipitate excess calcium. The U.S. and Australia allow the domestic distribution of wine products treated with Dipotassium DL-tartrate and imported from EU countries.

Attachment 2a

Ammonium Hydrogen Sulfite Water

亜硫酸水素アンモニウム水

Standards for Use (draft)

Permitted for use in grape juice used for wine production and grape wine only.

Shall be used at not more than 0.2 g/L in grape wine as ammonium hydrogen sulfite. When Ammonium Hydrogen Sulfite Water is used in grape juice used for wine production, this additive is considered to be used in grape wine.

Shall not remain at a level not less than 0.35 g/kg as sulfur dioxide in grape wine (excluding squeezed grape juice used for wine production containing not less than 1 % (volume) of ethanol and the concentrate of squeezed grape juice).

Compositional Specifications (draft)

Substance Name Ammonium Hydrogen Sulfite Water

Definition

Ammonium Hydrogen Sulfite Water is a solution consisting mainly of ammonium hydrogen sulfite.

Content

Ammonium Hydrogen Sulfite Water contains not less than 13.0% of ammonium hydrogen sulfite (NH_4HSO_3 = 99.11).

Description Ammonium Hydrogen Sulfite Water occurs as a light yellow liquid.

Identification

(1) Ammonium Hydrogen Sulfite Water responds to all the tests for Sulfite and Bisulfite and the test for Ammonium Salt in the Qualitative Tests.

(2) Ammonium Hydrogen Sulfite Water contains not less than 2.2 % as ammonia (NH_3=17.03).

Weigh accurately about 0.5 g of Ammonium Hydrogen Sulfite Water, add 25 mL of water to dissolve it, and add 10 mL of sodium hydroxide solution (2 in 5). Immediately connect the flask containing this solution to a previously assembled distillation apparatus. The apparatus is equipped with a condenser joined to a delivery tube with a spray trap and the lower end of the condenser is immersed in 30 mL of 0.1 mol/L sulfuric acid, exactly measured, in a receiver. Heat and distill

ammonia into the sulfuric acid until about 25 mL of the distillate is obtained. Titrate the excess sulfuric acid in the receiver with 0.2 mol/L sodium hydroxide (indicator: 3 drops of methyl red TS). Determine the amount of ammonia by the formula.

Each mL of 0.1 mol/L sulfuric acid = 3.406 mg of NH_3

Purity

(1) Lead Not more than 5 μg/g of NH_4HSO_3 as Pb (an amount equivalent to 8.0 g of ammonium hydrogen sulfite (NH_4HSO_3), Method 5, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).

Sample Solution To the specified amount of Ammonium Hydrogen Sulfite Water, add 20mL of diluted hydrochloric acid (1 in 4), and boil gently for 5 minutes with a watch glass covering it. Allow to cool. Use this solution as the sample solution. If the sample does not dissolve completely, evaporate it to dryness, and add 20 mL of diluted hydrochloric acid (1 in 4) to the residue. Boil gently for 5 minutes, allow to cool, and use this solution as the sample solution.

(2) Arsenic Not more than 3 μg/g of NH_4HSO_3 as As (an amount equivalent to 5.0 g of ammonium hydrogen sulfite (NH_4HSO_3), Standard Color: Arsenic Standard Solution 3.0 mL, Apparatus B).

Test Solution To the specified amount of Ammonium Hydrogen Sulfite Water, add water to make 50 mL. Measure 10 mL of this solution, add 2 mL of sulfuric acid, and heat on a water bath until sulfur dioxide is no longer evolved. Evaporate to about 2 mL, and add water to make 10 mL. Use 5 mL of this solution as the test solution.

Residue on Ignition Not more than 0.2% per ammonium hydrogen sulfite (NH_4HSO_3) (10 g).

Assay Weigh accurately about 0.3 g of Ammonium Hydrogen Sulfite Water, and proceed as directed under Sulfite Determination.

Each mL of 0.05 mol/L iodine = 4.955 mg of NH_4HSO_3

Attachment 2b

Chitin-Glucan

キチングルカン

Standards for Use (draft)

Permitted for use in grape juice used for wine production and grape wine only.

Shall be used at not more than 5 g/L in grape wine as chitin-glucan. When Chitin-Glucan is used in grape juice for wine production, this additive is considered to be used in grape wine.
Chitin-Glucan used shall be removed before the completion of the final product.

Compositional Specifications (draft)

Substance Name Chitin-Glucan

Definition
Chitin-Glucan is a copolymer composed of chitin and β-1,3-glucan that are derived from the culture of filamentous fungi (limited to *Aspergillus niger*).

Content
Chitin-Glucan contains not less than 95% of chitin-glucan.

Description Chitin-Glucan occurs as a white to light yellow-brown powder. It is odorless.

Identification
Chitin/glucan ratio 25：75 to 60：40.

Sample Place 2.0 g of Chitin-Glucan in a centrifuge tube, and add 40 mL of hydrochloric acid TS (1 mol/L). After shaking it for 30 minutes, centrifuge at 3000 rpm for 10 minutes, and remove the supernatant. Again add 40 mL of hydrochloric acid TS (1 mol/L), and perform the same step. Then, add 40 mL of water to the residue, agitate, centrifuge at 3000 rpm for 10 minutes, and remove the supernatant. Repeat the same step with 40 mL of water at each time until the electric conductivity of the supernatant is below 100 μS/cm. Then, add 40 mL of ethanol (99.5) to the residue, agitate, centrifuge at 3000 rpm for 10 minutes, and remove the supernatant. Again add 40 mL of ethanol (99.5) to the residue, and perform the same step. Then, add 40 mL of a 1：1 mixture of chloroform/methanol to the residue, shake for 30 minutes, centrifuge at 3000 rpm for 10 minutes, and remove the supernatant. Again

add 40 mL of a 1 : 1 mixture of chloroform/methanol to the residue, and perform the same step. Then, add 40 mL of acetone to the residue, shake for 30 minutes, and centrifuge at 3000 rpm for 10 minutes. Filter the supernatant through a filter paper (30 µm pore size), and discard the filtrate. Again add acetone to the residue in the centrifuge tube, shake, filter the whole content in the tube through the filter paper, and remove the filtrate. Place the residue with the filter paper on a watch glass, and dry it at room temperature in a draft chamber. Use the resulting residue on the filter paper as the sample.

Procedure Put the sample in a solid-state NMR tube (3–4 mm external diameter), and seal tightly. Measure the CP/MAS ^{13}C NMR spectrum using an NMR spectrometer— conditioned so that the carbon signal from adamantane in the high magnetic field is δ 29.5 ppm—with a proton resonance frequency of 400 MHz or more under the following operating conditions. Separately, measure the CP/MAS ^{13}C NMR spectrum of chitin as directed for the sample. For the obtained spectra, correct the baseline and conduct waveform separation treatment. Confirm that signals are detected in each CP/MAS ^{13}C NMR spectrum of the sample and chitin at SN ratio 50 or more in the regions of around δ 23 ppm, δ 55 ppm, δ 61 ppm, and δ104 ppm. Designate each signal area intensity as A_1, A_2, A_3, and A_4 for the sample; and B_1, B_2, B_3, and B_4 for chitin, respectively. Determine the chitin composition percentage (%) and the glucan composition percentage (%) by the following formulae. The chitin/glucan ratio is expressed as the ratio of chitin composition percentage (%) and the glucan composition percentage (%).

$$\text{Chitin composition ratio (\%)} = \frac{C_1 + C_2 + C_3 + C_4}{4} \times 100$$

$$\text{Glucan composition ratio (\%)} = 100 - \text{Chitin composition ratio (\%)}$$

A_1 = signal area intensity of Chitin-Glucan at around δ 23 ppm,
A_2 = signal area intensity of Chitin-Glucan at around δ 55 ppm,
A_3 = signal area intensity of Chitin-Glucan at around δ 61 ppm,
A_4 = signal area intensity of Chitin-Glucan at around δ 104 ppm,
B_1 = signal area intensity of Chitin at around δ 23 ppm,
B_2 = signal area intensity of Chitin at around δ 55 ppm,
B_3 = signal area intensity of Chitin-Glucan at around δ 61 ppm,
B_4 = signal area intensity of Chitin-Glucan at around δ 104 ppm,
$C_1 = (B_3/B_1)/(A_3/A_1)$,
$C_2 = (B_3/B_2)/(A_3/A_2)$,
$C_3 = (B_4/B_1)/(A_4/A_1)$,

$C_4 = (B_4/B_2)/(A_4/A_2)$.

Operating conditions

Spinning rate: Not less than 7 kHz.

Contact time: Constant time at around 2 milliseconds.

Delay time: Not less than 5 seconds.

Number of accumulation: Not less than 3000.

Purity

(1) Lead Not more than1 µg/g as Pb (an amount equivalent to 4.0 g on the dried basis, Method 1, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).

(2) Arsenic Not more than 1 µg/g as As (an amount equivalent to 1.0 g on the dried basis, Method 3, Standard Color: Arsenic Standard Solution 2.0 mL, Apparatus B).

Loss on Drying Not more than 10% (105°C, 3 hours).

Ash Not more than 3% (600°C, 6 hours, on the dried basis).

Microbial Limits Proceed as directed in the Microbial Limit Tests.

Total plate count: Not more than 1000 per gram.

Yeasts and molds: Not more than 200 per gram.

Escherichia coli: Negative per test.

Salmonella: Negative per test.

Sample Fluid Prepare as directed in Method 1 for the total plate count and the enumeration of yeasts and molds.

Pre-enrichment Culture Prepare as directed in Method 1 for the *Escherichia coli* test and the *Salmonella* test.

Assay Weigh accurately about 5 g of Chitin-Glucan, transfer it into a flask, add 100 mL of water, and stir for 2 minutes. Filter the resulting suspension by suction through a membrane filter (1 µm pore size). Place the filtrate in an evaporating dish, previously dried at 105°C for 30 minutes, cooled in a desiccator, and accurately weighed (the mass of the dish = m g), and evaporate it to dryness. Then, dry it at 105°C for 4 hours, leave to cool in the desiccator, accurately weigh the mass (M g), and calculate the content.

$$\text{Content (\%) of chitin-glucan} = \frac{\text{Weight (g) of the sample} - (\text{M (g)} - \text{m (g)})}{\text{Weight (g) of the sample}} \times 100$$

Reagents, Solutions, and Other Reference Materials

Adamantane $C_{10}H_{16}$ [281-23-2] White to light brown crystals or powder.

Purity Related substances Prepare a test solution by dissolving 0.5 g of adamantine in 10 mL of toluene. Prepare a control solution by diluting exactly measured 1.5 mL of the test solution with toluene to exactly 50 mL. Analyze 1.0 μL-portions of the test solution and the control solution by gas chromatography using the operating conditions given below. Continue the chromatography for two times the retention time of the main peak, and measure the peak areas. The sum of the areas of all peaks, excluding the main peak and solvent peaks, from the test solution is not greater than the area of main peak from the control solution.

Operating conditions
Detector: Frame-ionization detector.
Column: A fused silica tube (0.53 mm internal diameter and 15–30 m length) coated with a 5.0 μm thick layer of dimethylpolysiloxane for gas chromatography.
Column temperature: Raise the temperature at 10°C/minute from 100°C to 250°C and maintain the temperature at 250°C for 5 minutes.
Injection port temperature: 250°C.
Detector temperature: 250°C.
Carrier gas: Helium.
Flow rate: Adjust so that the peak of adamantine appears about 6–12 minutes after injection.
Injection method: Split.
Split ratio: 1 : 20.

Chitin $(C_8H_{13}NO_5)_n$ [1398-61-4] A white to light brown powder or scale-like substance.

Identification Add 1 g of chitin to 200 mL of diluted acetic acid (1 in 100). It does not solve.

Loss on drying Not more than 15.0% (1g, 105°C, 2 hours).

Attachment 2c

Copolymer of Vinylimidazole/Vinylpyrrolidone

PVI/PVP

ビニルイミダゾール・ビニルピロリドン共重合体

Standards for Use (draft)

Permitted for use in grape juice used for wine production and grape wine only.

Shall be used at not more than 0.50 g/L in grape wine as copolymer of vinylimidazole/vinylpyrrolidone. When Copolymer of Vinylimidazole/ Vinylpyrrolidone is used in grape juice used for wine production, this additive is considered to be used in grape wine.

Copolymer of Vinylimidazole/Vinylpyrrolidone used shall be removed before the completion of the final product.

Compositional Specifications (draft)

Substance Name Copolymer of Vinylimidazole/Vinylpyrrolidone

Definition

Copolymer of Vinylimidazole/Vinylpyrrolidone is produced by polymerization of 1-vinylimidazole and 1-vinyl-2-pyrrolidone, with a ratio of 9：1, in the presence of crosslinking agent 1,3-divinylimidazolin-2-one at a level of less than 2%.

Content

Copolymer of Vinylimidazole/Vinylpyrrolidone, when calculated on the dried basis, contains 26.0–29.0% of nitrogen (N = 14.01).

Description Copolymer of Vinylimidazole/Vinylpyrrolidone occurs as a white to yellowish-white powder.

Identification Determine the absorption spectrum of Copolymer of Vinylimidazole/Vinylpyrrolidone as directed in the Disk Method under Infrared Spectrophotometry, and compare with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

Purity

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

(2) Arsenic Not more than 2 μg/g as As (0.50 g, Method 3, Standard Color: Arsenic Standard Solution 2.0 mL, Apparatus B).

(3) Water-soluble substances Not more than 0.5%.

Weigh 10 g of Copolymer of Vinylimidazole/Vinylpyrrolidone, add it to 100 mL of water, shake, and allow to stand for 24 hours. Filter by suction through a membrane filter (2.5–3.0 μm pore size). Then, filter the filtrate by suction through a membrane filter (0.8 μm pore size), evaporate on a water bath to dryness, and weigh the residue.

(4) Acetic acid/ethanol-soluble substances Not more than 1%.

Weigh 1 g of Copolymer of Vinylimidazole/Vinylpyrrolidone, add 500 mL of a solution of 15 g of acetic acid and 50 mL of ethanol (95) in 500 mL of water, shake, and allow to stand for 24 hours. Filter the filtrate by suction through a membrane filter (2.5–3.0 μm pore size). Then, filter the filtrate by suction through a membrane filter (0.8 μm pore size), evaporate on a water bath to dryness, and weigh the residue.

(5) Organic impurities

Imidazole	Not more than 50 μg/g.
1,3-Divinylimidazolin-2-one	Not more than 2 μg/g.
1-Vinylimidazole	Not more than 10 μg/g.
1- Vinyl-2-pyrrolidone	Not more than 5 μg/g.
2-Pyrrolidone	Not more than 50 μg/g.

Test Solution Weigh 2.0 g of Copolymer of Vinylimidazole/Vinylpyrrolidone, add exactly 1 mL of internal standard solution, add 24 mL of acetone, and stir for 4 hours with a stirrer. Allow to stand, filter, and use the filtrate as the test solution.

Internal Standard Solution Use a solution of benzonitrile in acetone (1 in 4000).

Standard Solution Weigh separately 80 mg of imidazole, 3.2 mg of 1,3-divinylimidazolin-2-one, 16 mg of 1-vinylimidazole, 8.0 mg of 1-vinyl-2-pyrrolidone, and 80 mg of 2-pyrrolidone in a 200-mL volumetric flask, and add acetone to make 200 mL. Use the solution as the standard solution.

Control Solution Measure exactly 1 mL of the standard solution and 4 mL of the internal standard solution, and add acetone to make100 mL.

Procedure Analyze 1-μL portions of the test solution and the control solution by gas chromatography using the operating conditions given below. Determine the peak area ratio of each organic impurity to benzonitrile for the test solution and the control solution. The peak area ratio of each organic impurity to benzonitrile from the test solution is not greater than the peak area ratio of the corresponding organic impurity to benzonitrile from the control solution.

Operating Conditions

Detector: Nitrogen phosphorous detector.

Column: A fused silica tube (0.25 mm internal diameter and 30 m length) coated with a 0.5-µm thick layer of polyethylene glycol for gas chromatography.

Column temperature: Raise the temperature from 160°C to 210°C at a rate of 5°C/minute, and then maintain at 210°C for 7 minutes.

Injection port temperature: 220°C.

Detector temperature: 250°C.

Carrier gas: Helium.

Flow rate: Adjust so that the peak of benzonitrile appears 4–5 minutes after injection and the peak of each organic impurity is separated.

Injection method: Split.

Split ratio: 1 : 10.

Loss on Drying Not more than 5.0% (140°C, 1 hour).

Ash Not more than 0.3% (800°C, 6 hours).

Assay Weigh accurately about 10 mg of Copolymer of Vinylimidazole/Vinylpyrrolidone, and proceed as directed in the Semi-micro Kjeldahl Method under Nitrogen Determination. Determine the nitrogen content on the dried basis.

Reagents, Solutions, and Other Reference Materials

Benzonitrile C_7H_5N [100-47-0] A colorless, clear liquid.

Purity Related substances Prepare a test solution by dissolving 40 mg of benzonitrile in 25 mL of acetone. Prepare a control solution by diluting exactly 1 mL of the test solution with acetone to make exactly 50 mL. Analyze 1.0 µL each of the test solution and the control solution by gas chromatography using the operating conditions below. Continue the chromatography for two times the retention time of the main peak and measure the peak areas. The sum of the areas of all the peaks, excluding the main peak and solvent peaks, from the test solution is not greater than the area of the main peak from the control solution.

Operating conditions

Detector: Flame-ionization detector.

Column: A fused silica tube (0.25 mm internal diameter and 30 m length) coated with a 0.5-µm thick layer of polyethylene glycol for gas chromatography.

Column temperature: Raise the temperature from 160°C to 210°C at a rate of 5°C/minute, and then maintain at 210°C for 7 minutes.

Injection port temperature: 220°C.

Detector temperature: 250°C.

Carrier gas: Helium.

Flow rate: Adjust so that the peak of benzonitrile appears 4–5 minutes after injection.

Injection method: Split.

Split ratio: 1 : 10.

1,3-Divinylimidazolin-2-one $C_7H_{10}N_2O$ [13811-50-2]

Melting point 65–71°C.

Purity Related substances Prepare a test solution by mixing 6 mg of 1,3-divinylimidazolin-2-one with 2 mL of ethyl acetate. Prepare a control solution by diluting exactly 0.5 mL of the test solution with ethyl acetate to make exactly 10 mL. Analyze 2.0 µL each of the test solution and the control solution by gas chromatography using the operating conditions below. Continue the chromatography for 1.5 times the retention time of the main peak and measure the peak areas. The sum of the areas of all the peaks, excluding the main peak and solvent peaks, from the test solution is not greater than the area of the main peak from the control solution.

Operating conditions

Detector: Flame-ionization detector.

Column: A fused silica tube (0.25 mm internal diameter and 30 m length) coated with a 0.25-µm thick layer of 5% diphenyl/95% dimethylpolysiloxane for gas chromatography.

Column temperature: Maintain the temperature at 60°C for 5 minutes, raise to 280°C at a rate of 15°C/minute, and then maintain at 280°C for 1 minute.

Injection port temperature: 150°C.

Detector temperature: 250°C.

Carrier gas: Helium.

Flow rate: Adjust so that the peak of 1,3-divinylimidazolin-2-one appears 11–13 minutes after injection.

Injection method: Splitless.

Imidazole $C_3H_4O_2$ [288-32-4] White to light yellow crystals or powder. Very soluble in water and in methanol.

Content Not less than 98.0%.

Melting point 88–92°C.

Assay Weigh accurately about 0.1 g of imidazole, add 50 mL of acetic acid for nonaqueous titration, and titrate with 0.1 mol/L perchloric acid. To confirm the endpoint, use a potentiometer with a glass indicator electrode and silver-silver chloride reference electrode. A combined electrode can also be used for the indicator and reference electrodes. Separately, perform a blank test to make any necessary correction.

Each mL of 0.1 mol/L perchloric acid = 6.808 mg of $C_3H_4N_2$

2-Pyrrolidone C_4H_7NO [616-45-5] A colorless to pale yellow, clear liquid or white to pale yellow lumps or powder.

Melting point 22–27°C.

Purity Related substances Prepare a test solution by dissolving 1 g of 2-pyrrolidone in 10 mL of methanol. Prepare a control solution by diluting exactly 1 mL of the test solution with methanol to make exactly 50 mL. Analyze 1.0 µL each of the test solution and the control solution by gas chromatography using the operating conditions below. Continue the chromatography for two times the retention time of the main peak and measure the peak areas. The sum of the areas of all the peaks, excluding the main peak and solvent peaks, from the test solution is not greater than the area of the main peak from the control solution.

Operating conditions

Detector: Flame-ionization detector.

Column: A fused silica tube (0.53 mm internal diameter and 30 m length) coated with a 1.0-µm thick layer of polyethylene glycol for gas chromatography.

Column temperature: Maintain the temperature at 80°C for 1 minute, raise to 190°C at a rate of 10°C/minute, and then maintain at 190°C for 20 minutes.

Injection port temperature: A constant temperature of near 200°C.

Detector temperature: 250°C.

Carrier gas: Helium.

Flow rate: Adjust so that the peak of 2-pyrrolidone appears about 10 minutes after injection.

Injection method: Split.

Split ratio: 1 : 20.

1-Vinylimidazole $C_5H_6N_2$ [1072-63-5] A colorless to light yellow liquid.

Purity Related substances Prepare a test solution by dissolving 100 mg of 1-vinylimidazole in 25 mL of acetone. Prepare a control solution by diluting exactly 1 mL of the test solution with acetone to make exactly 50 mL. Analyze 1.0 µL each of

the test solution and the control solution by gas chromatography using the operating conditions below. Continue the chromatography for two times the retention time of the main peak and measure the peak areas. The sum of the areas of all the peaks, excluding the main peak and solvent peaks, from the test solution is not greater than the area of the main peak from the control solution.

Operating conditions

Detector: Flame-ionization detector.

Column: A fused silica tube (0.25 mm internal diameter and 30 m length) coated with a 0.5-µm thick layer of polyethylene glycol for gas chromatography.

Column temperature: Raise the temperature from 160°C to 210°C at a rate of 5°C/minute, and then maintain at 210°C for 7 minutes.

Injection port temperature: 220°C.

Detector temperature: 250°C.

Carrier gas: Helium.

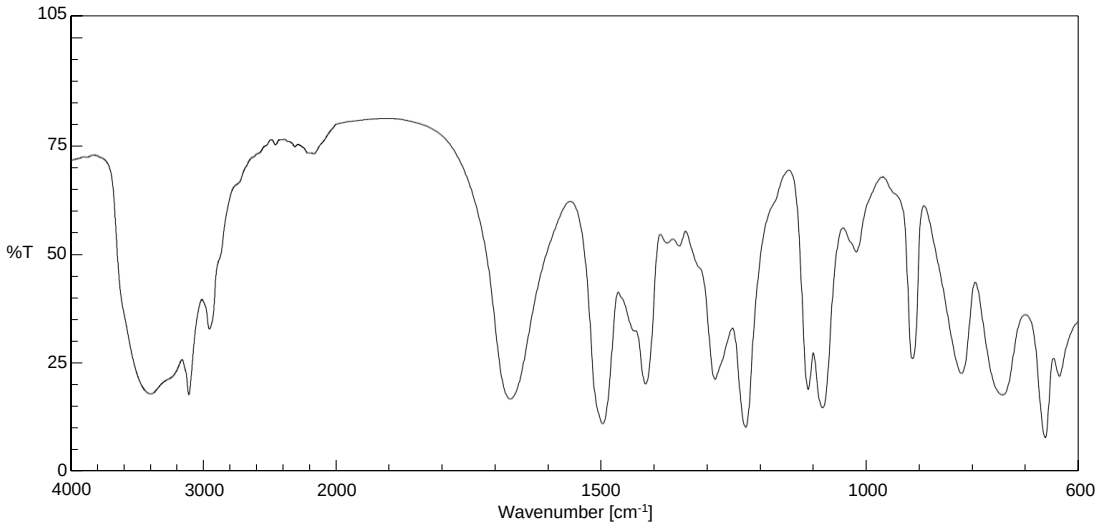
Flow rate: Adjust so that the peak of 1-vinylimidazole appears 4–5 minutes after injection.

Injection method: Split.

Split ratio: 1 : 10.

Infrared Reference Spectrum

Copolymer of Vinylimidazole/Vinylpyrrolidone



Attachment 2d

Dipotassium DL-Tartrate
DL-酒石酸カリウム

Standards for Use (draft)

Permitted for use in grape wine only.

Compositional Specifications (draft)

Substance Name Dipotassium DL-Tartrate

Structural Formula

Molecular Formula $C_4H_4K_2O_6$

Molecular Weight 226.27

Chemical Name
Dipotassium (2*RS*,3*RS*)-2,3-dihydroxybutanedioate

Definition
Dipotassium DL-Tartrate is a mixture of equal amounts of dipotassium L-tartrate and dipotassium D-tartrate.

Description Dipotassium DL-Tartrate occurs as colorless to white crystals, powder, or granules.

Identification

(1) A solution of Dipotassium DL-Tartrate (1 in 10) shows no optical activity.

(2) Dipotassium DL-Tartrate responds to test (1) for Potassium Salt and to all the tests for Tartrate in the Qualitative Tests.

Purity

(1) Lead Not more than 5 μg/g as Pb (0.80 g, Method 3, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).

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

(3) Oxalate Not more than 100 µg/g as $C_2H_2O_4$.

Test Solution Weigh 0.100 g of Dipotassium DL-Tartrate, previously dried, and add sulfuric acid TS (0.01 mol/L) to dissolve it and to make exactly 20 mL.

Control Solution Weigh 0.140 g of oxalic acid dihydrate, and add sulfuric acid TS (0.01 mol/L) to dissolve it and to make exactly 1000 mL. To exactly 1 mL of this solution, add sulfuric acid TS (0.01 mol/L) to make exactly 200 mL.

Procedure Analyze 10-µL portions of the test solution and the control solution by liquid chromatography using the operating conditions given below. Measure the peak area of oxalic acid for each of the test and control solutions by the automatic integration method. The peak area for the test solution is not greater than that for the control solution.

Operating Conditions

Detector: Ultraviolet spectrophotometer (wavelength: 210 nm).

Column: A stainless steel tube (6–8 mm internal diameter and 30 cm length). If necessary, two connected columns may be used.

Column packing material: 8-µm H-form cation-exchange resin for liquid chromatography.

Guard column: Use a column with the same internal diameter that is packed with the same packing material as for the column above.

Column temperature: 50°C.

Eluent: Sulfuric acid TS (0.01 mol/L).

Flow rate: 0.6 mL/min.

Loss on Drying Not more than 4.0% (105°C, 4 hours).

Storage Standards Store in an air-tight container.

Reagents, Solutions, and Other Reference Materials

Sulfuric Acid TS (0.01 mol/L) Add water to 10 mL of sulfuric acid TS (1 mol/L) to make 1000 mL. (This reagent has been already provided in the draft compositional specifications for Dipotassium L-Tartrate.)

Item 3. Revision of Specifications for Mineral Waters

The government of Japan will revise specifications for Di(2-ethylhexyl) phthalate in mineral waters.

Background

Japan prohibits, under Article 13, paragraph (2) of the Food Sanitation Act (Act No. 233 of 1947; "the Act"), the sale etc. of foods and food additives for which specifications or standards are stipulated in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370, 1959; "the Public Notice") pursuant to paragraph (1) of the same article of the Act when the foods or the food additives do not meet the specifications or the standards.

Specifications and standards for mineral waters stipulated in the Public Notice have been successively reviewed based on the assessment of the health effects of food by the risk assessment body, the Food Safety Commission of Japan under the Cabinet Office ("the FSCJ"), considering consistency with the water quality standards stipulated in Japan's Water Supply Act and international standards such as Codex. This time, Japan will revise the specifications for Di(2-ethylhexyl) phthalate in mineral waters as below based on the assessment report from the FSCJ.

Outline of revision

Compositional specifications for mineral waters (sterilized or filter sterilized)

(mg/l)

Substance name	Maximum level (current)	Maximum level (draft)
Di(2-ethylhexyl) phthalate	Not established	0.07

Note: The underlined part is the revised level (draft).

Item 4. Amendment to the Specifications and Standards for Foods, Food Additives, Etc.

The government of Japan will revise manufacturing standards for non-alcoholic beverages.

Background

The Minister of Health, Labour and Welfare can, under Article 13, paragraph (1) of the Food Sanitation Act (Act No. 233 of 1947; "the Act"), establish manufacturing standards or compositional specifications for food or food additives for sale after hearing opinion of the Pharmaceutical Affairs and Food Sanitation Council.

When specifications or standards foods or food additives are established and stipulated in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370, 1959; "the Public Notice"), Japan prohibits, under paragraph (2) of the same article of the Act, the sale etc. of foods and food additives if the foods or the food additives do not meet the specifications or the standards.

The specifications and standards for non-alcoholic beverages are established in the Public Notice. Japan does not approve the manufacturing of non-alcoholic beverages excluding mineral waters, frozen fruit beverages, and fruit juice used as ingredients ("other non-alcoholic beverages") by the following method: The method by mixing non-sterilized or non-filter sterilized ingredients into other non-alcoholic beverages that are already sterilized or filter sterilized.

This time, it has been confirmed that even if other non-alcoholic beverages are manufactured by mixing lactic bacteria, yeasts, fermented milks, or lactic-acid-bacteria beverages into other non-alcoholic beverages that are already sterilized or filter sterilized when the manufacturing process following the sterilization or filter-sterilization is controlled by an appropriate method that can prevent the process from being contaminated with pathogenic microorganisms, the obtained products do not have food hygiene problems. Japan has decided to revise the manufacturing standards

for non-alcoholic beverages, because the draft revision has been approved by the Food Specification Committee under the Pharmaceutical Affairs and Food Sanitation Council and the risk assessment body, the Food Safety Commission of Japan under the Cabinet Office.

Outline of revision

Japan will revise the manufacturing standards for non-alcoholic beverages and newly add the following standards for other non-alcoholic beverages to the Public Notice.

When other non-alcoholic beverages are manufactured by mixing lactic bacteria, yeasts, fermented milks, or lactic-acid-bacteria beverages into other non-alcoholic beverages that are sterilized or filter sterilized by the method specified in the Public Notice, the manufacturing process after the mixing shall be controlled by an appropriate method* that can prevent the process from being contaminated with pathogenic microorganisms and the obtained product shall be automatically filled in containers and stoppered or sealed tightly.

* To individually confirm that the process after the mixing of lactic bacteria, yeasts, fermented milks, or lactic-acid-bacteria beverages is controlled by an appropriate method, the Ministry of Health, Labour and Welfare requires the manufacturers of non-alcoholic beverages to submit documents to demonstrate that the product safety is ensured by hygiene control based on HACCP.