Items and Contact Information

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* 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, including modification of MRLs in some commodities that were provisionally set at the introduction of the Positive List System:

Pesticides: Iprodione, Metobromuron, Paraquat dichloride; Paraquat, Pyridachlometyl

Pesticide and Veterinary drug: Isoprothiolane

Veterinary drugs: Diminazene, Dipropyl isocinchomeronate, Mafoprazine, Pyrimethamine

(See the "MRL table" for details.)

Item 2. Designation of A Food Additive and Revision of Use Standards Calcium Phytate[§], Cupric Sulfate^{§§}

Japan prohibits the sale of food additives that are not designated by the MHLW 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 MHLW No. 370 of 1959) pursuant to Article 13 of the Act, the sale of those additives is prohibited unless they meet the specifications or the standards.

^{*:} The aim of the positive list system on "agricultural and veterinary chemicals" 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.

On December 23, 2022, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council ("the Committee") deliberated on Calcium Phytate and concluded that it is appropriate for this substance to be designated by the MHLW as a food additive that is unlikely to cause harm to human health pursuant to Article 12 of the Act. The Committee also concluded that it is appropriate for specifications and standards to be established for the additive pursuant to Article 13 of the Act. See Attachment 1 for the details.

The Committee also deliberated on revision of standards for Cupric Sulfate and concluded that it is appropriate for use standards to be revised for the additive pursuant to Article 13 of the Act. See <u>Attachment 2</u> for the details.

The MHLW takes necessary steps to designate Calcium Phytate as a food additive and establish specifications and standards for the additive, and to revise standards for Cupric Sulfate.

<The manner of submitting comments>

The MHLW will amend the existing standards and specifications for food as shown in this document. Please provide comments in writing by <u>Tuesday</u>, <u>February 21</u>, <u>2023</u>. 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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<u>Notes</u>

§: Calcium Phytate

An excess of iron ions in grape wine helps to form insoluble turbid substances, which lead to quality degradation. Calcium phytate can precipitate iron ions in grape wine due to its strong chelate effect, and the produced precipitates can be removed by racking. Addition of calcium phytate to grape wine can reduce the amount of iron ions in advance, resulting in the prevention of the quality degradation.

The European Union (the EU) permits the use of calcium phytate in red wine at a maximum level of 8 g/hL. The EU specifies that the wine must contain traces of iron after the treatment with calcium phytate.

Under an agreement with EU, the United States allows the domestic distribution of calcium-phytate-treated wine imported from EU countries.

Australia permits the use of this additive as a processing aid in wine.

§§: Cupric Sulfate

In Japan, cupric sulfate was designated in 1983 as a food additive. It can be used only in breast-milk substitutes.

When added to grape wine, cupric sulfate is dissociated into copper ions and sulfate ions. Copper ions reacts with hydrogen sulfide, which causes unpleasant smell in grape wine, and forms insoluble cupric sulfate, which precipitates. The precipitates are removed from wine through processes such as racking and filtration.

The EU specifies that the maximum use level applied is 1 g/hL and the concentration of copper in products after treatment must not exceed 1 mg/L (2 mg/L in some liqueur wine).

In the United States, cupric sulfate is approved as GRAS (generally recognized as safe) and can be used as a processing aid, a nutritional supplement, and other agents. The United States specifies that the maximum use level must be 6 mg/L as copper and the concentration of copper in final products must not exceed 1 mg/L.

Australia permits the use of cupric sulfate as a processing aid for all food categories including wine. Under the Australian-EU agreement, the use amount of cupric sulfate in wine that is intended to be distributed in the partner country is 1g/hL at a maximum under the condition that the copper concentration in cupric sulfate-treated products does not exceed 1 mg/L.

Iprodione

Commodity	MRL (draft) ppm	MRL (current) ppm
Rice (brown rice)	•	3.0
Wheat	•	10
Barley	•	2 10
Rye	•	10
Corn (maize, including pop corn and sweet corn)	•	10
Buckwheat	•	10
Other cereal grains ¹	1	0 10
Soybeans, dry	• 0.	1 0.2
Beans, dry ²	• 0.	2 1.0
Peas	• 0.	1 0.2
Broad beans	• 0.	1 0.2
Peanuts, dry	• 0.	1 0.5
Other pulses ³	• 0.	1 0.2
Potato	• 0.0	
Taro	•	0.1
Sweet potato	•	0.1
Japanese yam (including Chinese yam)	•	0.1
Konjac	•	0.1
Other potatoes ⁴	•	0.1
Sugar beet	• 0.	
Sugarcane	•	0.05
Japanese radish, roots (including radish)	• 0.0	
Japanese radish, leaves (including radish)	• 0.0	1 5.0
Turnip, roots (including rutabaga)	• 0.0	1 5.0
Turnip, leaves (including rutabaga)	• 0.0	1 5.0
Horseradish	• 0.	1 5.0
Watercress	• 0.0	1 5.0
Chinese cabbage	•	3 5.0
Cabbage	•	2 5.0
Brussels sprouts	• 0.0	1 5.0
Kale	• 0.0	1 5.0
Komatsuna (Japanese mustard spinach)	• 0.0	1 5.0
Kyona	0	5 5.0
Qing-geng-cai	• 0.0	1 5.0
Cauliflower	• 0.0	1 5.0
Broccoli	• 0.0	1 25
Other cruciferous vegetables ⁵	0	5.0
Burdock	• 0.	
Salsify	• 0.0	

Commodity		MRL (draft) ppm	MRL (current) ppm
Artichoke	•	0.01	5.0
Chicory	\bigcirc	1	1.0
Endive		0.01	5.0
Shungiku	•	0.01	5.0
Lettuce (including cos lettuce and leaf lettuce)	\circ	25	10
Other composite vegetables ⁶	\bigcirc	5	5.0
Onion		0.3	0.5
Welsh (including leek)		4	5.0
Garlic			0.1
Nira		0.01	5.0
Asparagus		3	5.0
Multiplying onion (including shallot)	•	3	5.0
Other liliaceous vegetables ⁷	\bigcirc	5	5.0
Carrot	•	1	5.0
Parsnip	•	0.01	5.0
Parsley		0.01	5.0
Celery		0.01	5.0
Mitsuba	\bigcirc	5	5.0
Other umbelliferous vegetables ⁸		3	5.0
Tomato	0	6	5.0
Pimiento (sweet pepper)	0	15	10
Egg plant	•	4	5.0
Other solanaceous vegetables ⁹	\bigcirc	5	5.0
Cucumber (including gherkin)	•	4	5.0
Pumpkin (including squash)	•	4	5.0
Oriental pickling melon (vegetable)	•	0.01	5.0
Water melon			10
Water melon (whole commodity after removal of stems)		2	
Melons			10
Melons (whole commodity after removal of stems)		8	
Makuwauri melon			10
Makuwauri melon (whole commodity after removal of stems)		0.01	
Other cucurbitaceous vegetables ¹⁰		0.2	5.0
Spinach		0.01	5.0
Bamboo shoots			20
Okra		2	5.0
Ginger		0.1	5.0
Peas, immature (with pods)		20	25
Kidney beans, immature (with pods)		2	5.0
Green soybeans	\bigcirc	6	5.0
Button mushroom	•		5.0

Commodity		MRL (draft) ppm	MRL (current) ppm
Shiitake mushroom	•		5.0
Other mushrooms ¹¹			5.0
Other vegetables ¹²	•	10	20
Unshu orange, pulp			10
Citrus natsudaidai, whole	•		10
Lemon	•		10
Orange (including navel orange)			10
Grapefruit			10
Lime			10
Other citrus fruits ¹³			10
Apple	•		10
Japanese pear	•	5	10
Pear	•	5	10
Quince	•		10
Loquat			10
Loquat (whole commodity after removal of stems)		15	
Peach			10
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems)		20	
Nectarine	0	15	10
Apricot	0	15	10
Japanese plum (including prune)		2	10
Mume plum		5	10
Cherry		20	10
Strawberry		10	20
Raspberry	0	30	5.0
Blackberry	0	30	12
Blueberry			15
Cranberry	•		12
Huckleberry	•		12
Other berries ¹⁴		5	25
Grape	0	30	25
Japanese persimmon		- 00	10
Banana	•	9	10
Kiwifruit			5.0
Kiwifruit (whole commodity)	\top	30	- 3.9
Papaya			10
Avocado			10
Pineapple			10
Guava	•		10
Mango		5	10
Passion fruit	•		10

Commodity		MRL (draft) ppm	MRL (current) ppm
Date	•		10
Other fruits ¹⁵	\circ	5	5.0
Sunflower seeds	•	0.5	20
Sesame seeds	•	0.05	10
Safflower seeds	•		10
Cotton seeds	•		10
Rapeseeds	•	0.5	10
Other oil seeds ¹⁶			10
Ginkgo nut	•		10
Chestnut			10
Pecan			10
Almond		0.2	10
Walnut	•		10
Other nuts ¹⁷			10
Tea	•	10	20
Coffee beans	•		0.05
Cacao beans	•		0.05
Нор	•		0.1
Other spices ¹⁸ (except for seeds and roots and rhizome)			20
Other spices		0.1	
Other herbs ¹⁹	•	15	20
Cattle, muscle	•	0.01	0.2
Pig, muscle	•	0.01	0.2
Other terrestrial mammals ²⁰ , muscle	•	0.01	0.2
Cattle, fat	•	0.01	0.3
Pig, fat	•	0.01	0.3
Other terrestrial mammals, fat	•	0.01	0.3
Cattle, liver	•	0.01	1
Pig, liver	•	0.01	1
Other terrestrial mammals, liver	•	0.01	1
Cattle, kidney	•	0.01	1
Pig, kidney	•	0.01	1
Other terrestrial mammals, kidney	•	0.01	0.9
Cattle, edible offal ²¹		0.01	0.2
Pig, edible offal		0.01	0.2
Other terrestrial mammals, edible offal		0.01	0.2
Milk		0.01	0.2
Chicken, muscle		0.01	0.5
Other poultry ²² , muscle		0.01	0.5
Chicken, fat		0.01	2
Other poultry, fat		0.01	2
Chicken, liver		0.01	3

Commodity	MRL (draft) ppm	MRL (current) ppm
Other poultry, liver	0.01	3
Chicken, kidney	0.01	0.5
Other poultry, kidney	0.01	0.5
Chicken, edible offal	0.01	0.5
Other poultry, edible offal	0.01	0.5
Chicken eggs	0.01	0.8
Other poultry, eggs	0.01	0.8
Other spices, dried (limited to seeds)	 	0.05
Other spices, dried (limited to roots or rhizome)	 	0.1

- : Commodities for which MRLs are to be lowered.
- O: Commodities for which MRLs are to be raised.(*It should be noted that the residue definition for agricultural/animal products will be changed.)

NOTE: The residue definition is to be Iprodione only.

The current residue definition is the sum of Iprodione and *N*-(3,5-dichlorophenyl)-3-isopropyl-2,4-dioxoimidazolidine-1carboxamideonly.

- * The uniform limit 0.01 ppm will be applied to commodities not listed above.
- * Shaded figures indicate provisional MRLs.
- * Diagonal line means the food category to which MRL applies is not set.
- * Regarding the MRLs in food categories, "Water melon", "Melons", "Makuwauri melon", "Loquat", "Peach" and "Kiwifruit" will be abolished, whereas new MRLs will be established in foods categorized as "Water melon (whole commodity after removal of stems)", "Melons (whole commodity after removal of stems)", "Loquat (whole commodity after removal of stems)", "Loquat (whole commodity after removal of stems)", "Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems)" and "Kiwifruit (whole commodity)", respectively.
- * Regarding the MRL in food category, "Unshu orange, pulp" will be abolished. Due to the revision of the scope of applied crops as agricultural chemicals.
- * Food category, "Other spices (except for seeds and roots and rhizome) will be abolished, whereas new MRLs will be established in food categorized as "Other spices".
- * Regarding the MRL in food category, "Other spices, dried (limited to seeds)" and "Other spices, dried (limited to roots or rhizome)" will be abolished, whereas new MRLs will be established in food categorized as "Other spices".
- 1. "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, kidney beans, lima beans, pegia, sultani, sultapya and white beans.
- 3. "Other pulses" refers to all pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry) and spices.
- 4. "Other potatoes" refers to all potatoes, except potato, taro, sweet potato, yam and konjac.

- 5. "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-qeng-cai, cauliflower, broccoli and herbs.
- 6. "Other composite vegetables" refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, shungiku, lettuce (including cos lettuce and leaf lettuce) and herbs.
- 7. "Other liliaceous vegetables" refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, nira, asparagus, multiplying onion and herbs.
- 8. "Other umbelliferous vegetables" refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, mitsuba, spices and herbs.
- 9. "Other solanaceous vegetables" refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper) and egg plant.
- 10. "Other cucurbitaceous vegetables" refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons and makuwauri melon.
- 11. "Other mushrooms" refers to all mushrooms, except button mushroom and shiitake mushroom.
- 12. "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.
- 13. "Other citrus fruits" refers to all citrus fruits, except unshu orange, citrus natsudaidai, lemon, orange (including navel orange), grapefruit, lime and spices.
- 14. "Other berries" refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry and huckleberry.
- 15. "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.
- 16. "Other oil seeds" refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.
- 17. "Other nuts" refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.
- 18. "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.
- 19. "Other herbs" refers to all herbs, except watercress, nira, parsley stems and leaves, celery stems and leaves.
- 20. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.
- 21. "Edible offal" refers to all edible parts, except muscle, fat, liver and kidney.
- 22. "Other poultry" refers to all poultry, except chicken.

Metobromuron

Commodity	MRL (draft) ppm	MRL (current) ppm
Wheat	0.01	
Soybeans, dry	0.01	
Beans, dry ¹	0.01	
Potato	0.01	

NOTE: The residue definition is Metobromuron only.

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

^{1. &}quot;Beans, dry" includes butter beans, cowbeans (red beans), lentil, kidney beans, lima beans, pegia, sultani, sultapya and white beans.

Paraquat dichloride, Paraquat

Commodity		MRL (draft) ppm	MRL (current) ppm
Rice (brown rice)	•	0.03	0.1
Wheat		0.02	0.05
Barley	•	0.02	0.05
Rye	•	0.02	0.05
Corn (maize, including pop corn and sweet corn)	•	0.03	0.1
Buckwheat	•		0.05
Other cereal grains ¹	•	0.03	0.5
Soybeans, dry	0	0.5	0.1
Beans, dry ²	0	0.5	0.05
Peas	0	0.5	0.05
Broad beans	0	0.5	0.05
Peanuts, dry	•	0.01	0.04
Other pulses ³	0	0.5	0.05
Potato	•	0.05	0.2
Taro		0.05	0.05
Sweet potato		0.05	0.05
Japanese yam (including Chinese yam)		0.05	0.05
Konjac		0.05	0.05
Other potatoes ⁴		0.05	0.05
Sugar beet		0.05	0.05
Sugarcane	•	0.02	0.3
Japanese radish, roots (including radish)		0.05	0.05
Japanese radish, leaves (including radish)	0	0.07	0.05
Turnip, roots (including rutabaga)		0.05	0.05
Turnip, leaves (including rutabaga)	0	0.07	0.05
Horseradish		0.05	0.05
Watercress	0	0.07	0.05
Chinese cabbage	0	0.07	0.05
Cabbage		0.05	0.05
Brussels sprouts		0.05	0.05
Kale	0	0.07	0.05
Komatsuna (Japanese mustard spinach)	0	0.07	0.05
Kyona	0	0.07	0.05
Qing-geng-cai	0	0.07	0.05
Cauliflower	•	0.02	0.05
Broccoli	•	0.02	0.05
Other cruciferous vegetables ⁵	\cap	0.07	0.05
Burdock		0.05	0.05
Salsify		0.05	0.05

Commodity	MRL (draft) ppm		MRL (current) ppm	
Artichoke	•	0.01	0.05	
Chicory	0	0.07	0.05	
Endive	0	0.07	0.05	
Shungiku	0	0.07	0.05	
Lettuce (including cos lettuce and leaf lettuce)	0	0.07	0.05	
Other composite vegetables ⁶	\bigcirc	0.07	0.05	
Onion	•	0.02	0.05	
Welsh (including leek)	•	0.02	0.05	
Garlic	•	0.02	0.05	
Nira	•	0.01	0.05	
Asparagus	•	0.03	0.05	
Multiplying onion (including shallot)	•	0.01	0.05	
Other liliaceous vegetables ⁷	•	0.01	0.05	
Carrot		0.05	0.05	
Parsnip		0.05	0.05	
Parsley	•	0.02	0.05	
Celery		0.01	0.05	
Mitsuba	\bigcirc	0.07	0.05	
Other umbelliferous vegetables ⁸		0.05	0.05	
Tomato		0.05	0.05	
Pimiento (sweet pepper)		0.05	0.05	
Egg plant		0.05	0.05	
Other solanaceous vegetables ⁹		0.05	0.05	
Cucumber (including gherkin)	•	0.02	0.05	
Pumpkin (including squash)	•	0.02	0.05	
Oriental pickling melon (vegetable)	•	0.02	0.05	
Water melon			0.05	
Water melon (whole commodity after removal of stems)		0.02		
Melons			0.05	
Melons (whole commodity after removal of stems)		0.02		
Makuwauri melon			0.05	
Makuwauri melon (whole commodity after removal of stems)		0.02		
Other cucurbitaceous vegetables ¹⁰	•	0.02	0.05	
Spinach	\circ	0.07	0.05	
Bamboo shoots	•	0.02	0.05	
Okra		0.05	0.05	
Ginger	•	0.02	0.05	
Peas, immature (with pods)	•	0.01	0.05	
Kidney beans, immature (with pods)	•	0.01	0.05	
Green soybeans	•	0.03	0.05	
Button mushroom	•		0.05	

Commodity	(MRL (draft) ppm	MRL (current) ppm
Shiitake mushroom			0.05
Other mushrooms ¹¹	•		0.05
Other vegetables ¹²	\bigcirc	0.07	0.05
Unshu orange, pulp			0.05
Unshu orange (whole commodity)		0.02	
Citrus natsudaidai, whole		0.02	0.05
Lemon		0.02	0.05
Orange (including navel orange)		0.02	0.05
Grapefruit		0.02	0.05
Lime		0.02	0.05
Other citrus fruits ¹³		0.02	0.05
Apple		0.01	0.05
Japanese pear	•	0.01	0.05
Pear	•	0.01	0.05
Quince	•	0.01	0.05
Loquat			0.05
Loquat (whole commodity after removal of stems)		0.01	
Peach			0.05
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity			
without stems)		0.01	
Nectarine	•	0.01	0.05
Apricot	•	0.01	0.05
Japanese plum (including prune)		0.01	0.05
Mume plum		0.01	0.05
Cherry		0.01	0.05
Strawberry		0.02	0.05
Raspberry		0.01	0.05
Blackberry		0.01	0.05
Blueberry		0.01	0.05
Cranberry		0.01	0.05
Huckleberry		0.01	0.05
Other berries ¹⁴		0.01	0.05
Grape		0.01	0.05
Japanese persimmon	•	0.01	0.05
Banana	•	0.01	0.05
Kiwifruit			0.05
Kiwifruit (whole commodity)		0.01	
Papaya	•	0.01	0.05
Avocado		0.01	0.05
Pineapple		0.01	0.05
Guava		0.01	0.05
Mango	•	0.01	0.05

Commodity		MRL (draft) ppm	MRL (current) ppm
Passion fruit		0.01	0.2
Date	•	0.01	0.05
Other fruits ¹⁵	•	0.1	1
Sunflower seeds		2	2
Sesame seeds			0.05
Safflower seeds	•		0.05
Cotton seeds	\circ	2	0.2
Rapeseeds	•		0.05
Other oil seeds ¹⁶	•		0.05
Ginkgo nut		0.05	0.05
Chestnut		0.05	0.05
Pecan		0.05	0.05
Almond		0.05	0.05
Walnut		0.05	0.05
Other nuts ¹⁷		0.05	0.05
Tea		0.2	0.3
Coffee beans		0.01	0.05
Cacao beans		0.01	0.05
Нор	•	0.1	0.2
Other spices ¹⁸		0.05	1
Other herbs ¹⁹	\bigcirc	0.07	0.05
Cattle, muscle	\circ	0.2	0.05
Pig, muscle	•	0.01	0.05
Other terrestrial mammals ²⁰ , muscle	0	0.2	0.05
Cattle, fat	•	0.03	0.05
Pig, fat	•	0.01	0.05
Other terrestrial mammals, fat	•	0.03	0.05
Cattle, liver	\circ	0.6	0.3
Pig, liver	•	0.05	0.3
Other terrestrial mammals, liver	0	0.6	0.3
Cattle, kidney	\circ	0.8	0.5
Pig, kidney		0.05	0.5
Other terrestrial mammals, kidney	\circ	0.8	0.5
Cattle, edible offal ²¹	\bigcirc	0.8	0.3
Pig, edible offal		0.05	0.3
Other terrestrial mammals, edible offal	0	0.8	0.3
Milk		0.01	0.01
Chicken, muscle	•	0.01	0.05
Other poultry ²² , muscle		0.01	0.05
Chicken, fat		0.01	0.05
Other poultry, fat		0.01	0.05

Commodity		MRL (draft) ppm	MRL (current) ppm
Chicken, liver		0.02	0.05
Other poultry, liver		0.02	0.05
Chicken, kidney		0.03	0.05
Other poultry, kidney		0.03	0.05
Chicken, edible offal		0.03	0.05
Other poultry, edible offal		0.03	0.05
Chicken eggs		0.01	0.01
Other poultry, eggs		0.01	0.01
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)	•		0.05
Sunflower oil (except 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)	•		0.05
Cottonseed oil (limited to refined cottonseed oil and cottonseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	•		0.05

- : 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.)

NOTE: The residue definition is to be Paraquat cation only.

The current residue definition is Paraquat only.

- * The uniform limit 0.01 ppm will be applied to commodities not listed above.
- * Shaded figures indicate provisional MRLs.
- * Diagonal line means the food category to which MRL applies is not set.
- * Regarding the MRLs in food categories, "Water melon", "Melons", "Makuwauri melon", "Unshu orange, pulp", "Loquat", "Peach" and "Kiwifruit" will be abolished, whereas new MRLs will be established in foods categorized as "Water melon (whole commodity after removal of stems)", "Melons (whole commodity after removal of stems)", "Unshu orange (whole commodity)", "Loquat (whole commodity after removal of stems)", "Peach (whole commodity after removal of stems) and stones but the residue calculated and expressed on the whole commodity without stems)", and "Kiwifruit (whole commodity)", respectively.
- 1. "Other cereal grains" refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize) and buckwheat.
- 2. "Beans, dry" includes butter beans, cowbeans (red beans), lentil, kidney beans, lima beans, pegia, sultani, sultapya and white beans.
- 3. "Other pulses" refers to all pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry) and spices.
- 4. "Other potatoes" refers to all potatoes, except potato, taro, sweet potato, yam and konjac.

- 5. "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.
- 6. "Other composite vegetables" refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, shungiku, lettuce (including cos lettuce and leaf lettuce) and herbs.
- 7. "Other liliaceous vegetables" refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, nira, asparagus, multiplying onion and herbs.
- 8. "Other umbelliferous vegetables" refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, mitsuba, spices and herbs.
- 9. "Other solanaceous vegetables" refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper) and egg plant.
- 10. "Other cucurbitaceous vegetables" refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons and makuwauri melon.
- 11. "Other mushrooms" refers to all mushrooms, except button mushroom and shiitake mushroom.
- 12. "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.
- 13. "Other citrus fruits" refers to all citrus fruits, except unshu orange, citrus natsudaidai, lemon, orange (including navel orange), grapefruit, lime and spices.
- 14. "Other berries" refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry and huckleberry.
- 15. "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.
- 16. "Other oil seeds" refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.
- 17. "Other nuts" refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.
- 18. "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.
- 19. "Other herbs" refers to all herbs, except watercress, nira, parsley stems and leaves, celery stems and leaves.
- 20. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.
- 21. "Edible offal" refers to all edible parts, except muscle, fat, liver and kidney.
- 22. "Other poultry" refers to all poultry, except chicken.

Pyridachlometyl

Commodity	MRL (draft) ppm	MRL (current) ppm
Wheat	0.01	
Barley	0.01	
Rye	0.01	
Other cereal grains ¹	0.01	
Soybeans, dry	O 0.2	
Sugar beet	O 0.2	
Tomato	O 2	
Pimiento (sweet pepper)	O 3	
Egg plant	O 2	
Cucumber (including gherkin)	O 2	
Water melon (whole commodity after removal of stems)	O 0.5	
Melons (whole commodity after removal of stems)	O 0.9	
Strawberry	O 4	
Cattle, muscle	0.01	
Pig, muscle	0.01	
Other terrestrial mammals ² , muscle	0.01	
Cattle, fat	0.01	
Pig, fat	0.01	
Other terrestrial mammals, fat	0.01	
Cattle, liver	0.01	
Pig, liver	0.01	
Other terrestrial mammals, liver	0.01	
Cattle, kidney	0.01	
Pig, kidney	0.01	
Other terrestrial mammals, kidney	0.01	
Cattle, edible offal ³	0.01	
Pig, edible offal	0.01	
Other terrestrial mammals, edible offal	0.01	
Milk	0.01	
Chicken, muscle	0.01	
Other poultry ⁴ , muscle	0.01	
Chicken, fat	0.01	
Other poultry, fat	0.01	
Chicken, liver	0.01	
Other poultry, liver	0.01	
Chicken, kidney	0.01	
Other poultry, kidney	0.01	
Chicken, edible offal	0.01	
Other poultry, edible offal	0.01	

Commodity	MRL (draft) ppm	MRL (current) ppm
Chicken eggs	0.01	
Other poultry, eggs	0.01	

 \bigcirc : Commodities for which MRLs are to be raised.

NOTE: The residue definition is to be Pyridachlometyl only.

- * The uniform limit 0.01 ppm will be applied to commodities not listed above.
- 1. "Other cereal grains" refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize) and buckwheat.
- 2. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.
- 3. "Edible offal" refers to all edible parts, except muscle, fat, liver and kidney.
- 4. "Other poultry" refers to all poultry, except chicken.

Isoprothiolane

Commodity	(0	MRL draft) opm	MRL (current) ppm
Rice (brown rice)	•	7	10
Unshu orange (whole commodity)		2	2
Apple		0.05	0.05
Japanese pear		0.05	0.05
Pear		0.05	0.05
Loquat (whole commodity after removal of stems)		0.02	0.02
Peach			0.02
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems)		0.02	
Mume plum		0.03	0.03
Cherry		0.05	0.05
Grape		0.02	0.02
Banana	\circ	0.9	
Other spices ¹	•	7	10
Cattle, muscle	0	0.04	0.02
Pig, muscle	0	0.04	0.01
Other terrestrial mammals ² , muscle	0	0.04	0.01
Cattle, fat	0	0.06	0.02
Pig, fat	0	0.06	0.01
Other terrestrial mammals, fat	0	0.06	0.01
Cattle, liver	\circ	1	0.02
Pig, liver	0	1	0.01
Other terrestrial mammals, liver	\bigcirc	1	0.01
Cattle, kidney	\bigcirc	0.9	0.02
Pig, kidney	\bigcirc	0.9	0.01
Other terrestrial mammals, kidney	\circ	0.9	0.01
Cattle, edible offal ³	\bigcirc	1	0.02
Pig, edible offal	0	1	0.01
Other terrestrial mammals, edible offal	0	1	0.01
Milk		0.02	0.02
Chicken, muscle		0.01	
Other poultry ⁴ , muscle		0.01	
Chicken, fat	0	0.07	
Other poultry, fat	0	0.07	
Chicken, liver		0.01	
Other poultry, liver		0.01	
Chicken, kidney	L	0.01	
Other poultry, kidney		0.01	
Chicken, edible offal		0.01	

Commodity	MRL (draft) ppm	MRL (current) ppm
Other poultry, edible offal	0.01	
Chicken eggs	0.03	
Other poultry, eggs	O.03	
Fish	3	3

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

NOTE: The residue definition for both agricultural and aquatic products is to be Isoprothiolane only. For animal products, the residue definition is to be the sum of Isoprothiolane and metablite C [Monoisopropyl, 1,3-dithiolan-2-ylidenemalonate]. The current residue definition is Isoprothiolane only.

- * The uniform limit 0.01 ppm will be applied to commodities not listed above.
- * Diagonal line means the food category to which MRL applies is not set.
- * Regarding the MRLs in food categories, "Peach" will be abolished, whereas new MRL will be established in food categorized as "Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems)", respectively.
- 1. "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.
- 2. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.
- 3. "Edible offal" refers to all edible parts, except muscle, fat, liver and kidney.
- 4. "Other poultry" refers to all poultry, except chicken.

Diminazene

Commodity	MRL (draft) ppm	MRL (current) ppm
Cattle, muscle	0.5	0.5
Cattle, fat	0.5	0.5
Cattle, liver	12	12
Cattle, kidney	6	6
Cattle, edible offal ¹	O 12	6
Milk	0.2	0.15

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

NOTE: The residue definition is to be Diminazene diaceturate only. The current residue definition is Diminazene only.

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

^{*} Shaded figures indicate provisional MRLs.

^{1. &}quot;Edible offal" refers to all edible parts, except muscle, fat, liver and kidney.

Dipropyl isocinchomeronate

Commodity	MRL (draft) ppm	MRL (current) ppm
Cattle, muscle	0.1	0.1
Pig, muscle	0.1	0.1
Other terrestrial mammals ¹ , muscle	0.1	0.1
Cattle, fat	0.1	0.1
Pig, fat	0.1	0.1
Other terrestrial mammals, fat	0.1	0.1
Cattle, liver	0.1	0.1
Pig, liver	0.1	0.1
Other terrestrial mammals, liver	0.1	0.1
Cattle, kidney	0.1	0.1
Pig, kidney	0.1	0.1
Other terrestrial mammals, kidney	0.1	0.1
Cattle, edible offal ²	0.1	0.1
Pig, edible offal	0.1	0.1
Other terrestrial mammals, edible offal	0.1	0.1
Milk	0.004	0.004
Chicken, muscle	0.004	0.004
Other poultry ³ , muscle	0.004	0.004
Chicken, fat	0.004	0.004
Other poultry, fat	0.004	0.004
Chicken, liver	0.004	0.004
Other poultry, liver	0.004	0.004
Chicken, kidney	0.004	0.004
Other poultry, kidney	0.004	0.004
Chicken, edible offal	0.004	0.004
Other poultry, edible offal	0.004	0.004
Chicken eggs	0.004	0.004
Other poultry, eggs	0.004	0.004
Salmoniformes (such as salmon and trout)	0.004	0.004
Anguilliformes (such as eel)	0.004	0.004
Perciformes (such as bonito, horse mackerel, mackerel, sea bass, s	0.004	0.004
Other fish ⁴	0.004	0.004
Shelled molluscs	0.004	0.004
Crustaceans	0.004	0.004
Other aquatic animals ⁵	0.004	0.004
Honey (including royal-jelly)	0.004	0.004

NOTE:The residue definition is Dipropyl isocinchomeronate only. The residue definition will not be changed.

- * The uniform limit 0.01 ppm will be applied to commodities not listed above.
- * Shaded figures indicate provisional MRLs.
- 1. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.
- 2. "Edible offal" refers to all edible parts, except muscle, fat, liver and kidney.
- 3. "Other poultry" refers to all poultry, except chicken.
- 4. "Other fish" refers to all fish, except Salmoniformes, Anguilliformes and Perciformes.
- 5. "Other aquatic animals" refers to all aquatic animals, except fish, shelled molluscs and crustaceans.

Mafoprazine

Commodity	MRL (draft) ppm	MRL (current) ppm
Pig, muscle	0.03	0.03
Pig, fat	0.03	0.03
Pig, liver	0.03	0.03
Pig, kidney	0.03	0.03
Pig, edible offal ¹	0.03	0.03

NOTE:The residue definition is Mafoprazine only. The residue definition will not be changed.

- * Shaded figures indicate provisional MRLs.
- 1. "Edible offal" refers to all edible parts, except muscle, fat, liver and kidney.

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

Pyrimethamine

Commodity	MRL (draft) ppm	MRL (current) ppm
Pig, muscle	0.05	0.05
Pig, fat	0.05	0.05
Pig, liver	0.05	0.05
Pig, kidney	0.05	0.05
Pig, edible offal ¹	0.05	0.05
Chicken, muscle	0.05	0.05
Chicken, fat	0.05	0.05
Chicken, liver	0.05	0.05
Chicken, kidney	0.05	0.05
Chicken, edible offal	0.05	0.05

NOTE:The residue definition is Pyrimethamine only.

The residue definition will not be changed.

synthesized substances will be applied to the commodities for which current MRLs are to be deleted, since this substance is considered to be an antibiotic or chemically synthesized antibacterial substance.

^{*} Not the uniform limit of 0.01 ppm but the regulation that foods shall not contain any antibiotics or chemically

^{*} Shaded figures indicate provisional MRLs.

^{1. &}quot;Edible offal" refers to all edible parts, except muscle, fat, liver and kidney.

Supplementary information on each pesticide in this report.

<u>Pesticides</u>

Iprodione:

The international standards for rice and broccoli could not be referenced because they exceeded the standard values as a result of risk assessment. Other than that, there are no standards lower than international standards.

Metobromuron:

N/A

Paraquat dichloride, Paraquat:

N/A

Pyridachlometyl:

N/A

Pesticide and Veterinary drug

Isoprothiolane:

N/A

Veterinary drugs

Diminazene:

N/A

Dipropyl isocinchomeronate:

N/A

Mafoprazine:

N/A

Pyrimethamine:

N/A

Calcium Phyate

Standards for Use (draft)

Permitted for use only in grape wine. Must be used at not more than 0.08 g/L in grape wine as calcium phytate.

Compositional Specifications (draft)

Substance Name Calcium Phytate

CAS number [3615-82-5]

Definition Calcium Phytate consists mainly of the calcium salt of inositol hexaphosphate (including double salt of calcium and magnesium).

Content Calcium Phytate, when dried, contains 15–30% of calcium phytate as total phosphorus.

Description Calcium Phytate occurs as a white powder.

Identification

- (1) Neutralize 2 mL of Solution A prepared in Assay with sodium hydroxide solution (1 in 25). The resulting solution responds to test (2) for Phosphorous Salt in the Qualitative Tests.
- (2) Boil 0.1 g of Calcium Phytate with 5 mL of acetic acid (1 in 4). After cooling, filter it, and add 5 mL of a solution of ammonium oxalate monohydrate (1 in 30) to the filtrate. A white precipitate is formed. The separated precipitate dissolves in hydrochloric acid (1 in 4).

Purity

- (1) <u>Lead</u> Not more than 5 µg/g as Pb (0.80 g of a died sample, Method 3, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).
- (2) <u>Arsenic</u> Not more than 3 µg/g as As (0.50 g of a dried sample, Method 3, Standard Color: Arsenic Standard Solution 3.0 mL, Apparatus B).
 - (3) <u>Free inorganic phosphorus</u> Not more than 1.0% (dried sample).

Test Solution Weigh accurately about 0.5 g of Calcium Phytate, previously dried, add about 150 mL of water, gently shake 2 to 3 times, and filter. To the filtrate, add water to make exactly 200 mL. To exactly 3 mL of the resulting solution, add 5 mL of L (+)-ascorbic acid solution (1 in 100). Add 5 mL of a solution prepared by dissolving 1 g of hexaammonium heptamolybdate tetrahydrate in 100 mL of sulfuric acid TS (0.025mol/L). Then add acetic buffer (pH 4.0) to make exactly 50 mL, and allow to stand for 15 minutes.

Reference Solution To 5 mL of L (+)-ascorbic acid solution (1 in 100), add 5 mL of a solution prepared by dissolving 1 g of hexaammonium heptamolybdate tetrahydrate in 100 mL of sulfuric acid TS (0.025 mol/L). Then add acetic acid buffer (pH 4.0) to make exactly 50 mL.

Procedure Measure the absorbance of the test solution at a wavelength of 750 nm against the reference solution. Prepare a calibration curve by measuring the absorbance of the following three solutions. Determine the concentration of free inorganic phosphorus from the calibration curve and the absorbance of the test solution, and then calculate the amount (%) of free inorganic phosphorus in the sample.

Solutions for Calibration Curve To exactly 5 mL of Phosphorus Standard Solution, add water to make 1000 mL. Transfer exactly 5 mL, 10 mL, and 20 mL of this solution into separate volumetric flasks, add 5 mL of L (+)-ascorbic acid solution (1 in 100) to each, and proceed as directed for the test solution to develop the color.

Loss on Drying Not more than 12% (1 g, 105°C, 4 hours).

Assay

Test Solution Weigh accurately about 0.6 g of Calcium Phytate, previously dried, into a Kjeldahl flask or heat-resistant glass beaker, and add 4 mL each of sulfuric acid and nitric acid. For a beaker, cover by a watch glass. Heat it by gradually increasing the temperature from about 150°C. Continue heating until brown fumes of nitric acid almost cease to be evolved, the liquid is transparent, and then white fumes are evolved; and decompose it. If the contents become blackened while heating, add about 2 mL of nitric acid and keep heating. After cooling, add 100 mL of water, mix, and filter. Wash the filter with water, combine the filtrate with the washings, and then add water to make 200 mL. Designate it as Solution A. Transfer exactly 2 mL of Solution A into a 100-mL volumetric flask, add 1 drop of phenol phthalein TS, neutralize with ammonia solution (1 in 4), and add nitric acid (1 in 10) until the solution is colorless to make the solution slight acidic. To this solution, add 20 mL of vanadic acid—molybdic acid TS, and make up to exactly 100 mL with water. Shake it well, and allow to stand for 30 minutes.

Procedure Measure the absorbance of the test solution at a wavelength of 420 nm. Prepare a calibration curve by measuring the absorbance of the following three solutions. Determine the total phosphorus concentration in the test solution from the calibration curve and the absorbance of the test solution, and then calculate the total phosphorus amount (%) in the sample.

Solutions for Calibration Curve To exactly 10 mL of Phosphorus Standard Solution, add water to make exactly 100 mL. Transfer exactly 5 mL, 10 mL, and 20 mL of this solution into separate 100-mL separate volumetric flasks, proceed as directed for the test solution, and develop the color.

Revision of Standards for Use Cupric Sulfate

<u>Current regulations</u>

Cupric Sulfate is permitted for use only in breast-milk substitutes.

It must be used at not more than 0.60 mg/L as copper when breast-milk substitutes are formulated into a standard concentration. This does not apply to cases where the additive is used in formulated liquid or powdered milk under the approval of the Minister of Health, Labour and Welfare.

Revised regulations (draft)

The use of the additive is expanded to include grape wine as a target food. The current regulations are changed as follows:

Cupric Sulfate is permitted for use only in grape wine and breast-milk substitutes. In grape wine, it must be used at not more than 10 mg/L as copper(II) sulfate pentahydrate ($CuSO_4 \cdot 5H_2O$), and it must not remain at levels exceeding 2 mg/L as copper.

In breast-milk substitutes, it must be used at not more than 0.60 mg/L as copper (Cu) when they are formulated into a standard concentration. This does not apply to cases where the additive is used in formulated liquid or powdered milk under the approval of the Minister of Health, Labour and Welfare.