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Date: 1/25/2016

GAIN Report Number: 6001

Japan

Post: Tokyo

Japan Issues New Safety Standards for Agriculture and Food

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

On January 20, 2016, Japan's Ministry of Health, Labor and Welfare (MHLW) issued the 190th Conference for the Promotion of Food Import Facilitation report. The report informs of regulatory actions on maximum residue levels (MRLs), veterinary drugs, food containers, food additives, and standards for raw or frozen fish and shellfish.

MHLW will revise the existing standards and specifications for food as shown in this document. Comments should be provided in writing by Wednesday, February 3, 2016, after which comments should be directed to the enquiry point in accordance with the sanitary and Phytosanitary (SPS) Agreement or the technical barriers to trade (TBT) Agreement.

General Information:

The Ministry of Health, Labour and Welfare (MHLW) will revise the existing standards and specifications for food as shown in this document. Please provide comments in writing by **Wednesday, February 3, 2016**. After the given date, comments should be directed to the enquiry point in accordance with the SPS Agreement or TBT Agreement.

Agenda:

Item 1: Establishment of the Standards for Agricultural Chemicals in Food

(1) Establishment of the Maximum Residue Limits for Agricultural Chemicals in Food

Pesticide: Phenmedipham, Picoxystrobin, Thiamethoxam

Veterinary drug: Tulathromycin

(2) Deletion of the Maximum Residue Limits for Agricultural Chemicals in Food

Pesticide: 4-Aminopyridine, Chlorobenzilate, Dinoseb, Thifensulfuron, Thiometon, Sodium TCA

(3) Designation of Substances Used as Ingredients of Agricultural Chemicals and Other Chemical Substances That Are Stipulated to be "Not Detected" in Food

Veterinary drug: Dimetridazole, Iprnidazole, Metronidazole, Ronidazole

(4) Confirmation of the intention concerning the handling of provisional MRLs for Agricultural chemicals

Item 2: Establishment of Specifications and Standards for Utensils, Containers, and Packaging Made of Polyethylene Naphthalate Resins.

Item 3: Revision of the Standards for Evaporated Skimmed Milk

Item 4: Revision of Processing Standards for Fresh Fish, Shellfish and Oysters Intended To Be Eaten Raw and Frozen Foods

Item 5: Designation of a Food Additive and Revision of Compositional Specifications Designation: Sodium selenite

Revision: Asparaginase

With regard to item 1, the SPS notification will be made for the setting or revision of the MRL for the agricultural chemicals. However, the setting or revision of the MRLs for Picoxystrobin and Thiamethoxam will NOT be notified to the WTO because their regulations will not be strengthened by this amendment.

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

With regard to item 2, the SPS notification as well as the TBT notification will be made for the establishment of specifications and standards for utensils, containers, and packaging made of polyethylene naphthalate resins.

With regard to item 3 and 4, the SPS notification will be made for the revision of the standards for evaporated skimmed milk and the revision of processing standards for fresh fish, shellfish and oysters intended to be eaten raw and frozen foods.

With regard to item 5, the SPS notification will be made for information only because this amendment will not strengthen the regulation on food additives.

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Item 1. Establishment of the Standards for Agricultural Chemicals in Food

The Food Sanitation Act authorizes the Minister 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 chemicals”) that may remain in foods. Any food for which standards are established pursuant to the provisions in Article 11, Paragraph 1 of the act is not permitted to be marketed in Japan unless it complies with the established standards.

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

The MHLW has comprehensively reviewed existing MRLs to modify those that were provisionally set at the introduction of the system. In addition, the MHLW is going to establish MRLs for some commodities. This activity has been targeted at three pesticides (Phenmedipahm, Picoxystrobin, Thiamethoxam) and one veterinary drug (Tulathromycin).

The MHLW is going to delete the MRLs for six pesticides (4-Aminopyridine, Chlorobenzilate, Dinoseb, Thifensulfuron, Thiometon and Sodium TCA).

The MHLW has decided to maintain the risk management for three veterinary drugs (Dimetridazole, Metronidazole and Ronidazole) designated as substances used as ingredients of agricultural chemicals and other chemical substances that are stipulated to be "Not detected" in foods. In addition, the MHLW is going to designate Ipronidazole as a substance used as an ingredient of agricultural chemicals and other chemical substances that is stipulated to be "Not detected" in foods.

¹The 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

(1) Establishment of Maximum Residue Limits for Agricultural Chemicals in Food

Phenmedipham (pesticide: herbicide): Permitted for use in Japan.

The MHLW is going to modify MRLs in some commodities in response to a request for setting MRLs by the Ministry of Agriculture, Forestry and Fisheries (MAFF). The MHLW is also going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Picoxystrobin (pesticide: fungicide): Not permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF and 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.

Thiametoxam (pesticide: insecticide): 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.

Tulathromycin (veterinary drug: synthetic antimicrobial): Permitted for use in Japan. The MHLW is going to modify the MRLs in response to the application for the manufacture and sales approval as a veterinary drug under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics.

(2) Deletion of the Maximum Residue Limits for Agricultural Chemicals in Food

The MHLW is going to delete the MRLs for all commodities for six pesticides (4-Aminopyridine, Chlorobenzilate, Dinoseb, Thifensulfuron, Thiometon, Sodium TCA) as a result of consideration for the revision of the provisional MRLs for these pesticides. The uniform limit 0.01 ppm will be applied to all commodities for these pesticides under the Positive List System.

(3) Designation of Substances Used as Ingredients of Agricultural Chemicals and Other Chemical Substances That Are Stipulated to be "Not Detected" in Foods

Dimetridazole (veterinary drug: parasiticide, antiprotozoal agent): Not permitted for use in Japan. The MHLW has decided to maintain the risk management for Dimetridazole designated as a substance used as an ingredient of agricultural chemicals and other chemical substances that is stipulated to be "Not detected" in foods.

Ipronidazole (veterinary drug: parasiticide, antiprotozoal agent): Not permitted for use in Japan.

The MHLW is going to designate Ipronidazole as a substance used as an ingredient of agricultural chemicals and other chemical substances that is stipulated to be "Not detected" in foods.

Metronidazole (veterinary drug: antiprotozoal agent): Not permitted for use in Japan. The MHLW has decided to maintain the risk management for Metronidazole designated as a substance used as an ingredient of agricultural chemicals and other chemical substances that is stipulated to be "Not detected" in foods.

Ronidazole (veterinary drug: parasiticide, antiprotozoal agent): Not permitted for use in Japan. The MHLW has decided to maintain the risk management for Ronidazole designated as a substance used as an ingredient of agricultural chemicals and other chemical substances that is stipulated to be "Not detected" in foods.

Phenmedipham

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Sugar beet	○ 0.1	0.05	§•Request		0.1: EU
Lettuce (including cos lettuce and leaf lettuce)	●	0.2			
Spinach	○ 0.5	0.5			0.5: EU
Other vegetables	●	0.2			
Other spices	●	0.2			
Other herbs	●	0.2			
Cattle, muscle	●	0.1			
Pig, muscle	●	0.1			
Other terrestrial mammals, muscle	●	0.1			
Cattle, fat	●	0.1			
Pig, fat	●	0.1			
Other terrestrial mammals, fat	●	0.1			
Cattle, liver	●	0.1			
Pig, liver	●	0.1			
Other terrestrial mammals, liver	●	0.1			
Cattle, kidney	●	0.1			
Pig, kidney	●	0.1			
Other terrestrial mammals, kidney	●	0.1			
Cattle, edible offal	●	0.1			
Pig, edible offal	●	0.1			
Other terrestrial mammals, edible offal	●	0.1			
Milk	●	0.1			

Note: The residue definition is Phenmedipham only.

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

* Shaded figures indicate provisional MRLs.

* 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 were lowered

○ : Commodities for which MRLs were maintained or increased

§ : Permitted for use in Japan

Request : MRL was modified in response to MAFF request

Picoxystrobin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Wheat	o 0.04		IT		0.04 USA
Barley	o 0.3		IT		0.3 USA
Rye	o 0.04		IT		0.04 USA
Corn (maize, including pop corn and sweet corn)	o 0.04		IT		0.04 USA
Buckwheat	o 0.04		IT		0.04 USA
Other cereal grains	o 0.04		IT		0.04 USA
Soybeans, dry	o 0.05		IT		0.05 USA
Beans, dry	o 0.06		IT		0.06 USA
Peas	o 0.06		IT		0.06 USA
Broad beans	o 0.06		IT		0.06 USA
Other pulses	o 0.06		IT		0.06 USA
Chinese cabbage	o 2		Request		
Cabbage	o 1		Request		
Lettuce (including cos lettuce and leaf lettuce)	o 15		Request		
Onion	o 0.05		Request		
Welsh (including leek)	o 2		Request		
Other vegetables	o 0.08		IT		0.08 USA
Unshu orange, pulp	o 0.1		Request		
Citrus natsudaidai, whole	o 3		Request		
Lemon	o 3		Request		
Orange (including navel orange)	o 3		Request		
Grapefruit	o 3		Request		
Lime	o 3		Request		
Other citrus fruits	o 3		Request		
Apple	o 2		Request		
Japanese pear	o 1		Request		
Pear	o 1		Request		
Peach	o 0.3		Request		
Cherry	o 5		Request		
Sesame seeds	o 0.08		IT		0.08 USA
Rapeseeds	o 0.08		IT		0.08 USA
Other oil seeds	o 0.08		IT		0.08 USA
Other spices	o 10		Request		

Note: The residue definition is Picoxystrobin only.

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

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

o : Commodities for which MRLs were increased

IT : Import tolerance

Request : The MRL was modified in response to MAFF request

Thiamethoxam

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	0.3	0.3	§		
Wheat	0.05	0.05		0.05	
Barley	0.4	0.4		0.4	
Corn (maize, including pop corn and sweet corn)	0.7	0.05	§	0.7	
Other cereal grains	0.02	0.02			0.02 USA
Soybeans, dry	0.04	0.04	§	0.04	
Beans, dry	0.05	0.05	§	0.04	
Peas	0.04	0.04	§	0.04	
Broad beans	0.04	0.04	§	0.04	
Peanuts, dry	0.02	0.02		0.02	
Other pulses	0.04	0.04	§	0.04	
Potato	0.3	0.3	§	0.3	
Taro	0.3	0.3	§	0.3	
Sweet potato	0.3	0.3	§	0.3	
Yam	0.3	0.3	§	0.3	
Konjac	0.3	0.3	§	0.3	
Other potatoes	0.3	0.3		0.3	
Sugar beet	0.3	0.3	§	0.3	
Japanese radish, roots (including radish)	0.3	0.3	§	0.3	
Japanese radish, leaves (including radish)	3	3	§	3	
Turnip, roots (including rutabaga)	0.5	0.5	§	0.3	
Turnip, leaves (including rutabaga)	10	10	§	3	
Horseradish	0.3	0.3		0.3	
Watercress	3	3		3	
Chinese cabbage	3	3	§	3	
Cabbage	5	5	§	5	
Brussels sprouts	5	5		5	
Kale	3	3		3	
Komatsuna(Japanese mustard spinach)	5	5	§	3	
Kyona	3	3	§	3	
Qing-geng-cai	5	5	§	3	
Cauliflower	5	5	§	5	
Broccoli	5	5	§	5	
Other cruciferous vegetables	5	5	§	5	
Burdock	0.3	0.3		0.3	
Salsify	0.3	0.3		0.3	
Artichoke	0.5	0.5		0.5	
Chicory	3	3		3	
Endive	3	3		3	
Shungiku	3	3	§	3	
Lettuce (including cos lettuce and leaf lettuce)	3	3	§	3	
Other composite vegetables	3	3		3	
Onion	0.02		IT		0.03 USA
Welsh (including leek)	2	2	§		
Nira	2	2	§		
Asparagus	0.1	0.1	§		
Multiplying onion (including shallot)	10	10	§		
Carrot	0.3	0.3	§	0.3	
Parsnip	0.3	0.3		0.3	
Parsley	3	3			4.0 USA
Celery	1	1	§	1	
Other umbelliferous vegetables	3	3		0.3	4.0 USA

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Tomato	0.2	2	☑	0.7	
Pimiento (sweet pepper)	1	1	☑	0.7	
Egg plant	0.7	0.7	☑	0.7	
Other solanaceous vegetables	3	2	☑	3	
Cucumber (including gherkin)	0.5	0.5	☑	0.5	
Pumpkin (including squash)	0.5	0.5		0.5	
Oriental pickling melon (vegetable)	0.5	0.5		0.5	
Water melon	0.2	0.2	☑		
Melons	0.3	0.3	☑		
Makuwauri melon	0.2	0.2			
Other cucurbitaceous vegetables	3	3		3	
Spinach	10	10	☑	3	
Okra	0.7	0.7	☑	0.7	
Peas, immature (with pods)	0.3	0.3	☑	0.01	
Kidney beans, immature (with pods)	0.3	0.3	☑	0.3	
Green soybeans	0.3	0.3		0.01	
Button mushroom	0.7	0.7		0.7	
Shiitake mushroom	0.7	0.7		0.7	
Other mushrooms	0.7	0.7		0.7	
Other vegetables	3	3		3	
Unshu orange, pulp	0.3	0.3	☑		
Citrus natsudaidai, whole	1	1	☑	0.5	
Lemon	1	1	☑	0.5	
Orange (including navel orange)	1	1	☑	0.5	
Grapefruit	1	1	☑	0.5	
Lime	1	1	☑	0.5	
Other citrus fruits	1	1	☑	0.5	
Apple	0.3	0.3	☑	0.3	
Japanese pear	1	1	☑	0.3	
Pear	1	1		0.3	
Quince	0.3	0.3		0.3	
Loquat	0.2	0.2			
Peach	0.5	0.5	☑		
Nectarine	1	1	☑	1	
Apricot	3	3	☑	1	
Japanese plum (including prune)	1	1	☑	1	
Mume plum	3	3	☑	1	
Cherry	5	5	☑	1	
Strawberry	2	2	☑	0.5	
Raspberry	0.5	0.5		0.5	
Blackberry	0.5	0.5		0.5	
Blueberry	0.5	0.5		0.5	
Cranberry	0.5	0.5		0.5	
Huckleberry	0.5	0.5		0.5	
Other berries	0.5	0.5		0.5	
Grape	2	2	☑	0.5	
Japanese persimmon	1	1	☑		
Banana	0.7	0.7	☑	0.02	
Papaya	0.01	0.01		0.01	
Avocado	0.5			0.5	
Pineapple	0.01	0.01		0.01	
Guava	0.2	0.2	☑		
Mango	0.2	0.2	☑	0.2	
Other fruits	2	2		0.3	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Sunflower seeds	○ 0.02	0.02		0.02	
Sesame seeds	○ 0.02	0.02		0.02	
Safflower seeds	○ 0.02	0.02		0.02	
Cotton seeds	○ 0.1	0.1		0.02	0.1 USA
Rapeseeds	○ 0.02	0.02		0.02	
Other oil seeds	○ 0.02	0.02		0.02	
Pecan	○ 0.02	0.02		0.01	0.02 USA
Other nuts	○ 0.02	0.02		0.02	
Tea	○ 20	20	§	20	
Coffee beans	○ 0.2	0.2		0.2	
Cacao beans※1	○ 0.02	0.02		0.02	
Hop	○ 0.1	0.1		0.09	0.1 USA
Other spices	○ 5	5		0.5	
Other herbs	○ 5	5		3	
Cattle, muscle	○ 0.02	0.02		0.02	
Pig, muscle	○ 0.02	0.02		0.02	
Other terrestrial mammals, muscle	○ 0.02	0.02		0.02	
Cattle, fat	○ 0.02	0.02		0.02	
Pig, fat	○ 0.02	0.02		0.02	
Other terrestrial mammals, fat	○ 0.02	0.02		0.02	
Cattle, liver	○ 0.01	0.01		0.01	
Pig, liver	○ 0.01	0.01		0.01	
Other terrestrial mammals, liver	○ 0.01	0.01		0.01	
Cattle, kidney	○ 0.01	0.01		0.01	
Pig, kidney	○ 0.01	0.01		0.01	
Other terrestrial mammals, kidney	○ 0.01	0.01		0.01	
Cattle, edible offal	○ 0.01	0.01		0.01	
Pig, edible offal	○ 0.01	0.01		0.01	
Other terrestrial mammals, edible offal	○ 0.01	0.01		0.01	
Milk	○ 0.05	0.05		0.05	
Chicken, muscle	○ 0.01	0.01		0.01	
Other poultry animals, muscle	○ 0.01	0.01		0.01	
Chicken, fat	○ 0.01	0.01		0.01	
Other poultry animals, fat	○ 0.01	0.01		0.01	
Chicken, liver	○ 0.01	0.01		0.01	
Other poultry animals, liver	○ 0.01	0.01		0.01	
Chicken, kidney	○ 0.01	0.01		0.01	
Other poultry animals, kidney	○ 0.01	0.01		0.01	
Chicken, edible offal	○ 0.01	0.01		0.01	
Other poultry animals, 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	○	7		7	

Note: The residue definition is Thiamethoxam only.

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

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

※1 The portion to which an MRL applies is cacao bean excluding shell.

※2 For dried pepper, the MRL of Other solanaceous vegetables (raw commodity) will be applied taking into account the processing factor.

● : Commodities for which MRLs were lowered

○ : Commodities for which MRLs were maintained or increased

IT : Import tolerance

§ : Permitted for use in Japan

Tulathromycin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cattle, muscle	● 0.3	0.3	Request		0.3 EU
Pig, muscle	● 2	2	§		
Cattle, fat	● 0.2	0.2	Request		
Pig, fat	● 0.3	0.3	§		
Cattle, liver	● 5	5	Request		
Pig, liver	● 4	4	§		
Cattle, kidney	● 3	3	Request		
Pig, kidney	● 9	9	§		
Cattle, edible offal	● 3	3	Request		
Pig, edible offal	● 5	5	§		

Note: The residue definition will be changed to "the sum of Tulathromycin(A and B) and its metabolite M1 [(2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-2-ethyl-3,4,10,13-tetrahydroxy-3,5,8,10,12,14-hexamethyl-11-[[3,4,6-trideoxy-3-(dimethylamino)-β-D-xylo-hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one], expressed as Tulathromycin."

The current residue definition is "Tulathromycin" only.

* Foods shall not contain any antibiotics or chemically synthesized antibacterial substances except for the commodities listed above.

● : Commodities for which MRLs were lowered

§ : Permitted for use in Japan

Request : The MRL was modified in response to MAFF request

4-Aminopyridine

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Corn (maize, including pop corn and sweet corn)	●	0.1			
Sunflower seeds	●	0.1			

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

* Shaded figures indicate provisional MRLs.

● : Commodities for which MRLs were lowered

Chlorobenzilate

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Corn (maize, including pop corn and sweet corn)	•	0.02			
Soybeans, dry	•	0.02			
Beans, dry	•	0.02			
Peas	•	0.02			
Broad beans	•	0.02			
Peanuts, dry	•	0.02			
Other pulses	•	0.02			
Potato	•	0.02			
Taro	•	0.02			
Sweet potato	•	0.02			
Yam	•	0.02			
Konjac	•	0.02			
Other potatoes	•	0.02			
Sugar beet	•	0.02			
Japanese radish, roots (including radish)	•	0.02			
Japanese radish, leaves (including radish)	•	0.02			
Turnip, roots (including rutabaga)	•	0.02			
Turnip, leaves (including rutabaga)	•	0.02			
Horseradish	•	0.02			
Watercress	•	0.02			
Chinese cabbage	•	0.02			
Cabbage	•	0.02			
Brussels sprouts	•	0.02			
Kale	•	0.02			
Komatsuna(Japanese mustard spinach)	•	0.02			
Kyona	•	0.02			
Qing-geng-cai	•	0.02			
Cauliflower	•	0.02			
Broccoli	•	0.02			
Other cruciferous vegetables	•	0.02			
Burdock	•	0.02			
Salsify	•	0.02			
Artichoke	•	0.02			
Chicory	•	0.02			
Endive	•	0.02			
Shungiku	•	0.02			
Lettuce (including cos lettuce and leaf lettuce)	•	0.02			
Other composite vegetables	•	0.02			
Onion	•	0.02			
Welsh (including leek)	•	0.02			
Garlic	•	0.02			
Nira	•	0.02			
Asparagus	•	0.02			
Multiplying onion (including shallot)	•	0.02			
Other liliaceous vegetables	•	0.02			
Carrot	•	0.02			
Parsnip	•	0.02			
Parsley	•	0.02			
Celery	•	0.02			
Mitsuba	•	0.02			
Other umbelliferous vegetables	•	0.02			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Tomato	•	0.02			
Pimiento (sweet pepper)	•	0.02			
Egg plant	•	0.02			
Other solanaceous vegetables	•	0.02			
Cucumber (including gherkin)	•	0.02			
Pumpkin (including squash)	•	0.02			
Oriental pickling melon (vegetable)	•	0.02			
Water melon	•	0.02			
Melons	•	0.02			
Makuwauri melon	•	0.02			
Other cucurbitaceous vegetables	•	0.02			
Spinach	•	0.02			
Bamboo shoots	•	0.02			
Okra	•	0.02			
Ginger	•	0.02			
Peas, immature (with pods)	•	0.02			
Kidney beans, immature (with pods)	•	0.02			
Green soybeans	•	0.02			
Button mushroom	•	0.02			
Shiitake mushroom	•	0.02			
Other mushrooms	•	0.02			
Other vegetables	•	0.02			
Unshu orange, pulp	•	5.0			
Citrus natsudaikai, whole	•	5.0			
Lemon	•	5.0			
Orange (including navel orange)	•	5.0			
Grapefruit	•	5.0			
Lime	•	5.0			
Other citrus fruits	•	5.0			
Apple	•	0.02			
Japanese pear	•	0.02			
Pear	•	0.02			
Quince	•	0.02			
Loquat	•	0.02			
Peach	•	0.02			
Nectarine	•	0.02			
Apricot	•	0.02			
Japanese plum (including prune)	•	0.02			
Mume plum	•	0.02			
Cherry	•	0.02			
Strawberry	•	0.02			
Raspberry	•	0.02			
Blackberry	•	0.02			
Blueberry	•	0.02			
Cranberry	•	0.02			
Huckleberry	•	0.02			
Other berries	•	0.02			
Grape	•	0.02			
Japanese persimmon	•	0.02			
Banana	•	0.02			
Kiwifruit	•	0.02			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Avocado	●	0.02			
Pineapple	●	0.02			
Guava	●	0.02			
Mango	●	0.02			
Passion fruit	●	0.02			
Date	●	0.02			
Other fruits	●	0.02			
Sunflower seeds	●	0.02			
Sesame seeds	●	0.02			
Safflower seeds	●	0.02			
Cotton seeds	●	0.02			
Rapeseeds	●	0.02			
Other oil seeds	●	0.02			
Ginkgo nut	●	0.02			
Chestnut	●	0.02			
Pecan	●	0.02			
Almond	●	0.02			
Walnut	●	0.02			
Other nuts	●	0.02			
Tea	●	0.1			
Hop	●	0.1			
Other spices	●	5			
Other herbs	●	0.02			
Cattle, muscle	●	0.1			
Pig, muscle	●	0.1			
Other terrestrial mammals, muscle	●	0.1			
Cattle, fat	●	0.1			
Pig, fat	●	0.1			
Other terrestrial mammals, fat	●	0.1			
Cattle, liver	●	0.1			
Pig, liver	●	0.1			
Other terrestrial mammals, liver	●	0.1			
Cattle, kidney	●	0.1			
Pig, kidney	●	0.1			
Other terrestrial mammals, kidney	●	0.1			
Cattle, edible offal	●	0.1			
Pig, edible offal	●	0.1			
Other terrestrial mammals, edible offal	●	0.1			
Milk	●	0.1			
Chicken, muscle	●	0.1			
Other poultry animals, muscle	●	0.1			
Chicken, fat	●	0.1			
Other poultry animals, fat	●	0.1			
Chicken, liver	●	0.1			
Other poultry animals, liver	●	0.1			
Chicken, kidney	●	0.1			
Other poultry animals, kidney	●	0.1			
Chicken, edible offal	●	0.1			
Other poultry animals, edible offal	●	0.1			
Chicken, eggs	●	0.1			
Other poultry, eggs	●	0.1			

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

* Shaded figures indicate provisional MRLs.

* 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 were lowered

Dinoseb

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	○	0.01			
Wheat	○	0.01			
Barley	○	0.01			
Rye	○	0.01			
Corn (maize, including pop corn and sweet corn)	●	0.05			
Buckwheat	○	0.01			
Other cereal grains	○	0.01			
Soybeans, dry	●	0.05			
Beans, dry	●	0.05			
Peas	●	0.05			
Broad beans	●	0.05			
Peanuts, dry	●	0.05			
Other pulses	●	0.05			
Potato	●	0.05			
Taro	●	0.05			
Sweet potato	●	0.05			
Yam	●	0.05			
Konjac	●	0.05			
Other potatoes	●	0.05			
Sugar beet	●	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	●	0.05			
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	●	0.05			
Burdock	●	0.05			
Salsify	●	0.05			
Artichoke	●	0.05			
Chicory	●	0.05			
Endive	●	0.05			
Shungiku	●	0.05			
Lettuce (including cos lettuce and leaf lettuce)	●	0.05			
Other composite vegetables	●	0.05			
Onion	●	0.05			
Welsh (including leek)	●	0.05			
Garlic	●	0.05			
Nira	●	0.05			
Asparagus	●	0.05			
Multiplying onion (including shallot)	●	0.05			
Other liliaceous vegetables	●	0.05			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Carrot	•	0.05			
Parsnip	•	0.05			
Parsley	•	0.05			
Celery	•	0.05			
Mitsuba	•	0.05			
Other umbelliferous vegetables	•	0.05			
Tomato	•	0.05			
Pimiento (sweet pepper)	•	0.05			
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	•	0.05			
Shiitake mushroom	•	0.05			
Other mushrooms	•	0.05			
Other vegetables	•	0.05			
Unshu orange, pulp	•	0.05			
Citrus natsudaidai, whole	•	0.05			
Lemon	•	0.05			
Orange (including navel orange)	•	0.05			
Grapefruit	•	0.05			
Lime	•	0.05			
Other citrus fruits	•	0.05			
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	•	0.05			
Raspberry	•	0.05			
Blackberry	•	0.05			
Blueberry	•	0.05			
Cranberry	•	0.05			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Huckleberry	•	0.05			
Other berries	•	0.05			
Grape	•	0.05			
Japanese persimmon	•	0.05			
Banana	•	0.05			
Kiwifruit	•	0.05			
Avocado	•	0.05			
Pineapple	•	0.05			
Guava	•	0.05			
Mango	•	0.05			
Passion fruit	•	0.05			
Date	•	0.05			
Other fruits	•	0.05			
Sunflower seeds	•	0.05			
Sesame seeds	•	0.05			
Safflower seeds	•	0.05			
Cotton seeds	•	0.05			
Rapeseeds	•	0.05			
Other oil seeds	•	0.05			
Ginkgo nut	•	0.05			
Chestnut	•	0.05			
Pecan	•	0.05			
Almond	•	0.05			
Walnut	•	0.05			
Other nuts	•	0.05			
Tea	•	0.1			
Hop	•	0.1			
Other spices	•	0.05			
Other herbs	•	0.05			
Cattle, muscle	○	0.01			
Pig, muscle	○	0.01			
Other terrestrial mammals, 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	○	0.01			
Pig, edible offal	○	0.01			
Other terrestrial mammals, edible offal	○	0.01			
Milk	○	0.01			
Chicken, muscle	○	0.01			
Other poultry animals, muscle	○	0.01			
Chicken, fat	○	0.01			
Other poultry animals, fat	○	0.01			
Chicken, liver	○	0.01			
Other poultry animals, liver	○	0.01			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Chicken, kidney	○	0.01			
Other poultry animals, kidney	○	0.01			
Chicken, edible offal	○	0.01			
Other poultry animals, edible offal	○	0.01			
Chicken, eggs	○	0.01			
Other poultry, eggs	○	0.01			

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● : Commodities for which MRLs were lowered

○ : Commodities for which MRLs were maintained or increased

Thiometon

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	•	0.02			
Wheat	•	0.02			
Barley	•	0.02			
Rye	•	0.02			
Corn (maize, including pop corn and sweet corn)	•	0.02			
Buckwheat	•	0.02			
Other cereal grains	•	0.02			
Soybeans, dry	•	0.02			
Beans, dry	•	0.02			
Peas	•	0.02			
Broad beans	•	0.02			
Peanuts, dry	•	0.02			
Other pulses	•	0.02			
Potato	○	0.01			
Taro	○	0.01			
Sweet potato	○	0.01			
Yam	○	0.01			
Konjac	○	0.01			
Other potatoes	○	0.01			
Sugar beet	•	0.05			
Japanese radish, roots (including radish)	•	0.10			
Japanese radish, leaves (including radish)	•	0.10			
Turnip, roots (including rutabaga)	•	0.10			
Turnip, leaves (including rutabaga)	•	0.10			
Horseradish	•	0.10			
Watercress	•	0.10			
Chinese cabbage	•	0.10			
Cabbage	•	0.10			
Brussels sprouts	•	0.10			
Kale	•	0.10			
Komatsuna(Japanese mustard spinach)	•	0.10			
Kyona	•	0.10			
Qing-geng-cai	•	0.10			
Cauliflower	•	0.20			
Broccoli	•	0.20			
Other cruciferous vegetables	•	0.10			
Burdock	•	0.10			
Salsify	•	0.10			
Artichoke	•	0.10			
Chicory	•	0.10			
Endive	•	0.10			
Shungiku	•	0.10			
Lettuce (including cos lettuce and leaf lettuce)	•	0.10			
Other composite vegetables	•	0.10			
Onion	•	0.10			
Welsh (including leek)	•	0.10			
Garlic	•	0.10			
Nira	•	0.10			
Asparagus	•	0.10			
Multiplying onion (including shallot)	•	0.10			
Other liliaceous vegetables	•	0.10			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Carrot	•	0.10			
Parsnip	•	0.10			
Parsley	•	0.10			
Celery	•	0.10			
Mitsuba	•	0.10			
Other umbelliferous vegetables	•	0.10			
Tomato	•	0.10			
Pimiento (sweet pepper)	•	0.10			
Egg plant	•	0.30			
Other solanaceous vegetables	•	0.10			
Cucumber (including gherkin)	•	0.30			
Pumpkin (including squash)	•	0.10			
Oriental pickling melon (vegetable)	•	0.10			
Water melon	•	0.05			
Melons	•	0.05			
Makuwauri melon	•	0.05			
Other cucurbitaceous vegetables	•	0.10			
Spinach	•	0.10			
Bamboo shoots	•	0.10			
Okra	•	0.10			
Ginger	•	0.10			
Peas, immature (with pods)	•	0.10			
Kidney beans, immature (with pods)	•	0.10			
Green soybeans	•	0.10			
Button mushroom	•	0.10			
Shiitake mushroom	•	0.10			
Other mushrooms	•	0.10			
Other vegetables	•	0.10			
Unshu orange, pulp	•	0.02			
Citrus natsudaikai, whole	•	0.05			
Lemon	•	0.05			
Orange (including navel orange)	•	0.05			
Grapefruit	•	0.05			
Lime	•	0.05			
Other citrus fruits	•	0.05			
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	•	0.05			
Raspberry	•	0.05			
Blackberry	•	0.05			
Blueberry	•	0.05			
Cranberry	•	0.05			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Huckleberry	•	0.05			
Other berries	•	0.05			
Grape	•	0.05			
Japanese persimmon	•	0.05			
Banana	•	0.05			
Kiwifruit	•	0.05			
Papaya	•	0.05			
Avocado	•	0.05			
Pineapple	•	0.05			
Guava	•	0.05			
Mango	•	0.05			
Passion fruit	•	0.05			
Date	•	0.05			
Other fruits	•	0.05			
Sunflower seeds	•	0.05			
Sesame seeds	•	0.05			
Safflower seeds	•	0.05			
Cotton seeds	•	0.05			
Rapeseeds	•	0.05			
Other oil seeds	•	0.05			
Ginkgo nut	•	0.05			
Chestnut	•	0.05			
Pecan	•	0.05			
Almond	•	0.05			
Walnut	•	0.05			
Other nuts	•	0.05			
Hop	•	0.20			
Other spices	•	0.1			
Other herbs	•	0.1			
Cattle, muscle	•	0.05			
Pig, muscle	•	0.05			
Other terrestrial mammals, muscle	•	0.05			
Cattle, fat	•	0.05			
Pig, fat	•	0.05			
Other terrestrial mammals, fat	•	0.05			
Cattle, liver	•	0.05			
Pig, liver	•	0.05			
Other terrestrial mammals, liver	•	0.05			
Cattle, kidney	•	0.05			
Pig, kidney	•	0.05			
Other terrestrial mammals, kidney	•	0.05			
Cattle, edible offal	•	0.05			
Pig, edible offal	•	0.05			
Other terrestrial mammals, edible offal	•	0.05			
Milk	•	0.05			
Chicken, muscle	•	0.05			
Other poultry animals, muscle	•	0.05			
Chicken, fat	•	0.05			
Other poultry animals, fat	•	0.05			
Chicken, liver	•	0.05			
Other poultry animals, liver	•	0.05			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Chicken, kidney	●	0.05		
Other poultry animals, kidney	●	0.05		
Chicken, edible offal	●	0.05		
Other poultry animals, edible offal	●	0.05		
Chicken, eggs	●	0.05		
Other poultry, eggs	●	0.05		

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● : Commodities for which MRLs were lowered

○ : Commodities for which MRLs were maintained or increased

Thifensulfuron

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Wheat	●	0.1			
Barley	●	0.1			
Rye	●	0.1			
Corn (maize, including pop corn and sweet corn)	●	0.1			
Buckwheat	●	0.1			
Other cereal grains	●	0.1			
Soybeans, dry	●	0.1			
Beans, dry	●	0.1			
Peas	●	0.1			
Broad beans	●	0.1			
Peanuts, dry	●	0.1			
Other pulses	●	0.1			
Sugar beet	●	0.05			
Cotton seeds	●	0.02			
Rapeseeds	●	0.02			
Other oil seeds	●	0.02			
Other spices	●	0.1			
Cattle, muscle	○	0.01			
Pig, muscle	○	0.01			
Other terrestrial mammals, 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	○	0.01			
Pig, edible offal	○	0.01			
Other terrestrial mammals, edible offal	○	0.01			
Milk	○	0.01			
Chicken, muscle	○	0.01			
Other poultry animals, muscle	○	0.01			
Chicken, fat	○	0.01			
Other poultry animals, fat	○	0.01			
Chicken, liver	○	0.01			
Other poultry animals, liver	○	0.01			
Chicken, kidney	○	0.01			
Other poultry animals, kidney	○	0.01			
Chicken, edible offal	○	0.01			
Other poultry animals, edible offal	○	0.01			
Chicken, eggs	○	0.01			
Other poultry, eggs	○	0.01			

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* Shaded figures indicate provisional MRLs.

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● : Commodities for which MRLs were lowered

○ : Commodities for which MRLs were maintained or increased

Sodium TCA

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Barley	•	0.5		
Other cereal grains	•	0.5		

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* Shaded figures indicate provisional MRLs.

* 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 were lowered

Notes:

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

“Beans, dry” including butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya

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

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

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

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

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

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

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

“Other cucurbitaceous vegetables” refers to all cucurbitaceous vegetables, except

cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and *makuwauri* melon.

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

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

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

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

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

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

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

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

“Other 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 animals” 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.

MINISTRY OF HEALTH, LABOUR AND WELFARE
STANDARDS AND EVALUATION DIVISION
DEPARTMENT OF ENVIRONMENTAL HEALTH AND FOOD SAFETY
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January 20, 2016

Confirmation of the intention concerning the handling of provisional MRLs for Agricultural chemicals

Thank you very much for your cooperation in the promotion of Japan's activities on food safety.

Japan introduced the Positive List System for pesticides, veterinary drugs, and feed additives ("Agricultural chemicals") in 2006. For the protection of public health and smooth operation of the new system, prior to its enforcement, Japan provisionally established maximum residue limits ("provisional MRLs") for chemical-commodity combinations without specific MRLs for 758 Agricultural chemicals. These MRLs were set without carrying out safety assessment legally required, based on Codex standards and some countries' standards. Since the enforcement of the system, Japan has been reviewing the provisional MRLs based on assessment by the Food Safety Commission ("FSC") to examine whether they are appropriate. As of December 22, 2015, Japan completed reviewing of 308 Agricultural chemicals.

Agricultural chemicals that have yet to be assessed include:

Ones for which it is unknown whether they are still in use in foreign countries,

Ones for which enough information required for assessment is not available because they are not used in Japan.

Unless there are any problems, Japan intends to withdraw the current provisional MRLs for Agricultural chemicals that cannot be assessed. If some of the Agricultural chemicals listed in Attachment 1 are in use in your country and you consider that the

MRLs should be kept, please contact the following addresses using the form given each Agricultural chemicals in Attachment 2 by April 30, 2016. The form should be accompanied by a document giving:

1. Names of Agricultural chemicals,
2. Reasons why the MRLs should be kept, including statement as to whether they are in use in your country,

*The names of the bureau and department changed as of October 1, 2015. Previous names are Pharmaceutical Safety and Environmental Health Bureau and Department of Food Safety.

3. Types/contents (e.g., toxicity and residue data) of data and timing (until the end of 2016) of provision if you can provide data required for assessment by the FSC.

If you do not contact us by the given data or even though you have contacted us if safety assessment cannot be carried out by the FSC due to insufficiency or lack of data (including the case not offered by the end of 2016), unfortunately, we will have to consider withdrawing the MRLs.

If you have any questions about this matter, please do not hesitate to contact our division.

Contact

Pesticides

Mr. W. Iizuka, Mr. A. Iino (ex. 2921, 2487)

Veterinary drugs and feed additives

Mr. Y. Ogawa, Mr. R. Nakamura (ex. 2486, 2487)

Standards and Evaluation Division
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75 chemicals to be reviewed

No.	Substance Name	Japanese Name
1	2-(1-NAPHTHYL)ACETAMIDE	2-(1-ナフチル)アセタミド
2	2,2-DPA	2,2-DPA (DPA)
3	2,6-DIISOPROPYLNAPHTHALENE	2,6-ジイソプロピルナフタレン
4	ALIPHATIC ALCOHOL ETHOXYLATES	脂肪族アルコールエトキシレート
5	ASPOXICILLIN	アスポキシリン
6	AZAMETHIPHOS	アザメチホス
7	BAQUILOPRIM	バクイロプリム
8	BENSULIDE	ベンスリド (SAP)
9	BUPIRIMATE	ブピリメート
10	BUQUINOLATE	バクイノレート
11	BUTROXYDIM	ブトロキシジム
12	CARBETAMIDE	カルベタミド
13	CARBONYL SULPHIDE	硫化カルボニル
14	CEFACETRILE	セファセトリル
15	CHLORONEB	クロロネブ
16	CLODINAFOP ACID	クロジナホップ酸
17	CLOPIDOL	クロピドール
18	CYCLOATE	シクロエート
19	ENDOTHAL	エンドタール
20	ETHYLENE DICHLORIDE	二塩化エチレン
21	FAMPHUR	ファミフル
22	FENPROSTALENE	フェンプロスタレン
23	FLORASULAM	フロラスラム
24	FLUMICLORAC PENTYL	フルミクロラックペンチル
25	FLUPROPANATE	フルプロパネート
26	FURATHIOCARB	フラチオカルブ
27	HALOXON	ハロクソン
28	HEXACHLOROBENZENE	ヘキサクロロベンゼン
29	IMAZAMETHABENZ METHYL ESTER	イマザメタベンズメチルエステル
30	ISOFENPHOS	イソフェンホス
31	KITASAMYCIN	キタサマイシン
32	LAIDLAMYCIN	ライドロマイシン
33	METHABENZTHIAZURON	メタベンズチアズロン
34	METHOXYCHLOR	メキシクロール
35	METHYLBENZOQUATE (NEQUINATE)	メチルベンゾクエート (ネクイネート)
36	METOSERPATE HYDROCHLORIDE	塩酸メトセルベイト
37	METOSULAM	メスラム

38	NAPHTHALOPHOS	ナフタロホス
39	NAPROPAMIDE	ナプロバミド
40	NITARSONE	ニタルソン
41	NOVOBIOCIN	ノボピオシン
42	ORYZALIN	オリザリン
43	OXABETRINIL	オキサベトリニル
44	OXACILLIN	オキサシリン
45	OXADIXYL	オキサジキシル
46	OXYCARBOXIN	オキシカルボキシソ
47	PEBULATE	ペブレート
48	PHENOTHRIN	フェノトリン
49	PHOSPHAMIDON	ホスファミドン
50	POLYMYXINE B	ポリミキシンB
51	PROPANIL	プロパニル (DCPA)
52	PYRACLOFOS	ピラクロホス
53	PYRITHIOBAC-SODIUM	ピリチオバックナトリウム塩
54	QUINALPHOS	キナルホス
55	ROXARSONE	ロキサソ
56	Sec-BUTYLAMINE	Sec-ブチルアミン
57	SODIUM NIFRUSTYRENATE	ニフルスチレン酸ナトリウム
58	SULFABENZAMIDE	スルファベンズアミド
59	SULFABROMOMETHAZINE SODIUM	スルファブromoメタジンナトリウム
60	SULFACETAMIDE	スルファセタミド
61	SULFAETHOXYPYRIDAZINE	スルファエトキシピリダジン
62	SULFAGUANIDINE	スルファグアニジン
63	SULFAMERAZINE	スルファメラジン
64	SULFAMETHOXYPYRIDAZINE	スルファメトキシピリダジン
65	SULFANILAMIDE	スルファニルアミド
66	SULFANITRAN	スルファニトラン
67	SULFAPYRIDINE	スルファピリジン
68	SULFATROXAZOLE	スルファトロキサゾール
69	TEBUTHIURON	テブチウロン
70	TEMEPHOS	テメホス
71	TERBUTRYN	テルブトリン
72	TETRACHLORVINPHOS	テトラクロルビンホス (CVMP)
73	TOLYFLOXYSULFURON	トリフロキシスルフロ
74	TRIFLUMURON	トリフルムロン
75	TRIPLENNAMINE	トリペレナミン

Confirmation of the intention concerning the handling of
provisional MRLs for Agricultural chemicals

1. Country	
2. Agency responsible	
3. Names of Agricultural chemicals	
4. Reasons why the MRLs should be kept	
5. Types/contents of data and timing of provision	
6. Note	

Item 2. Establishment of Specifications and Standards for Utensils, Containers, and Packaging Made of Polyethylene Naphthalate Resins

Purpose

This activity is to develop specifications and standards for food utensils, containers, and packaging made of synthetic resins and ensure the safety of these products.

The Food Sanitation Act (“Act”), in Article 18, authorizes the Minister of Health, Labour and Welfare to establish 1) specifications for food contact utensils, containers, and packaging, and their materials and 2) standards for the production methods of these products. The established specifications and standards appear in the Ministry of Health and Welfare Notification (No. 370, 1959), titled “Specifications and Standards for Food, Food Additives, Etc.”

When specifications or standards are established for food utensils, containers, or packaging based on Article 18, these products shall not be used or marketed unless they meet the standards or specifications.

Synthetic resins whose main component is polyethylene naphthalate (PEN) are already in commercial use in Japan as eating utensils for school and hospital meals. In Europe and the United States, PEN resins are used for utensils such as returnable drink bottles. They are expected to be widely used in Japan as well. Given such situation, the Ministry of Health, Labour and Welfare (“MHLW”) has decided to newly establish specifications and standards for food utensils, containers, and packaging made of PEN resins.

Outline of establishment

The Act specifies two types of specifications—general specifications and individual specifications—in Item 2 “Utensils, Containers and Packaging Made of Synthetic Resins” in Section D “Specifications for Utensils, Containers and Packaging According to Material” in Part 3 “Utensils, Containers and Packaging” in the Specifications and Standards for Food, Food Additives, Etc. This time, the MHLW will newly establish individual specifications for the new category, “utensils, containers, and packaging made of synthetic resins whose main component is polyethylene naphthalate.” See the attachment for details.

When the drafted revision is finalized and implemented, the PEN resins will be subject to the individual specifications in addition to the existing general specifications for synthetic resins.

Attachment

Part 3. Utensils, Containers and Packaging

D. Material Specifications

<Synthetic resins>

Individual specifications

Item 14. Polyethylene naphthalate resins

Utensils, containers, and packaging made of synthetic resins whose main component is polyethylene naphthalate shall pass the following tests.

a. Migration tests

i. Germanium: Not more than 0.1 µg/ml

The specification for germanium shall be met when the test is performed as directed under Atomic Absorption Spectrometry or Inductively Coupled Plasma Atomic Emission Spectrometry—specified in Section B “General Tests,” in Part 3 “Utensils, Containers, and Packaging” in the Specifications and Standards for Food, Food Additives, Etc.— using 4% acetic acid as a stimulant. The germanium in the sample solution is not more than 0.1 µg/ml, if the product meets the requirement.

ii. Residue on evaporation: Not more than 30 µg/ml

The residue shall be not more than 30 µg/ml, when the test is performed as directed in the residue on evaporation test in Section B.

Item 3. Revision of the Standards for Evaporated Skimmed Milk

Summary

As stipulated in Article 11 Paragraph 1 of the Food Sanitation Act, from the public health viewpoint, the Minister of Health, Labour and Welfare is authorized to establish standards for producing, processing, using, cooking, or preserving food or additives intended for marketing; or to establish specifications for the compositions of food or additives intended for marketing, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

Compositional standards for milk and milk products are stipulated in the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc. (“Ministerial Ordinance”) based on the Article 11 Paragraph 1 of the Act.

This time, Japan will revise the Ministerial Ordinance to modify the existing standards for processing and storing and other standards for evaporated skimmed milk, taking into account the development of manufacturing technologies and the variation of forms of product distribution.

Proposed revision

1. Processing standards

To newly establish processing standards for evaporated skimmed milk.

The new standards are the same as the existing standards for skimmed milk powder, as specified in the Ministerial Ordinance. The new standards include the requirements of disinfection: Raw milk for skimmed milk powder shall be pasteurized by heating either at 63°C for 30 minutes (the holding method) or using a method equivalent or superior in pasteurization effect to the former method, and shall be maintained at a temperature of not more than 10°C or more than 48°C in the whole process of manufacturing.)

2. Storing standard

To add a condition, taking into account the case in which products are pasteurized after concentration.

Existing standard: Evaporated skimmed milk shall be cooled to a temperature not higher than 10°C immediately after concentration and stored.

Revised standard: Evaporated skimmed milk shall be cooled to a temperature not higher than 10°C immediately after concentration (after pasteurization, when pasteurization is done after concentration) and stored.

3. Other standards

To allow the use of lactose and milk retentate or permeate (the product obtained by filtering raw milk, cow’s milk, special milk, composition modified milk, low fat milk or skimmed milk) to adjust the protein content in evaporated skimmed milk.

Item 4. Revision of Processing Standards for Fresh Fish, Shellfish and Oysters Intended To Be Eaten Raw and Frozen Foods

Summary

As stipulated in Article 11 Paragraph 1 of the Food Sanitation Act, from the public health viewpoint, the Minister of Health, Labour and Welfare is authorized to establish standards for producing, processing, using, cooking, or preserving food or additives intended for marketing; or to establish specifications for the compositions of food or additives intended for marketing, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

This time, Japan will revise the processing standards for fresh fish, shellfish and oysters intended to be eaten raw and frozen foods (hereafter, limited to frozen fish and shellfish intended to be eaten raw) to allow the use of carbon dioxide as a pH regulator for sodium hypochlorite used as a disinfectant.

Proposed revision

Currently, Japan allows the use of hypochlorous acid water and sodium hypochlorite as disinfectants for fresh fish, shellfish and oysters intended to be eaten raw and frozen foods. In addition, Japan allows the use of hydrochloric acid in sodium hypochlorite for adjusting the pH of sodium hypochlorite. By the revision of the processing standards, Japan will allow the use of carbon dioxide as a pH regulator for sodium hypochlorite in addition to hydrochloric acid.

Item 5. Designation of a Food Additive and Revision of Compositional Specifications

The government of Japan will designate sodium selenite and revise the existing specifications for asparaginase.

Summary

The Food Sanitation Act, in Article 10, prohibits the use and sale of food additives the Minister of Health, Labour and Welfare (hereinafter referred as “the Minister”) does not designate. In addition, when specifications or standards for food additives are established based on Article 11 of the act and stipulated in the Ministry of Health, Labour and Welfare Notification (Ministry of Health and Welfare Notification No. 370, 1959), those additives shall not be used or sold unless they meet the standards or specifications.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council that is established under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the designation of sodium selenite [CAS: 26970-82-1]¹ and the revision of the existing specifications for asparaginase [CAS: 9015-68-3]².

The committee has concluded that based on Article 10 of the act, the Minister should designate sodium selenite as an additive unlikely to harm human health and establish specifications and standards for this additive based on Article 11. The committee has also concluded that the Minister should revise the specifications for asparaginase based on Article 11 of the act. For details, see Attachment 5-1 and 5-2.

Note

1. Selenium is an essential nutrient as a constituent of proteins containing selenium, which are involved in the anti-oxidizing system and thyroid hormone metabolism. Some European countries and the United States require the infant formula and follow-up milk producers to add selenium to their products.

2. Asparaginase (*Aspergillus oryzae* NZYM-SP-derived) is derived from *A. oryzae*, in which asparaginase productivity is improved by amplifying the asparaginase gene intrinsically occurring in *A. oryzae*. It is an enzyme that hydrolyzes asparagine into aspartic acid and ammonia. It is used in food production to reduce acrylamide formulation on the reaction with the asparagine. Japan permits the use of *Aspergillus niger* ASP-72 derived asparaginase.

<Additional Information>

Progress in the designation procedure of food additives (54 flavorings and 45 non-flavoring additives) that have been proven safe by JECFA (Joint FAO/WHO Expert Committee on Food Additives) and that are widely used in countries other than Japan.

As of January 20, 2016, all flavorings and 41 non-flavoring additives were already approved. See Attachment 5-3.

Attachment 5-1

Sodium Selenite

亜セレン酸ナトリウム

Standards for use

Sodium Selenite is permitted only in powdered formulated breast milk substitutes [(cow's milk-based powdered formulated milk (infant formula and follow-up formula) and other breast milk substitutes*].

When used in other breast milk substitutes, it shall not be contained at a level exceeding 5.5 µg as Se per 100 kcal for each product.

*Other breast milk substitutes include non-milk based formula, such as soy milk

Compositional specifications

Substance name Sodium Selenite

Molecular formula $\text{Na}_2\text{SeO}_3 \cdot 5\text{H}_2\text{O}$

Molecular weight 263.01

Chemical name [CAS number]

Disodium Selenite Pentahydrate [26970-82-1]

Content Sodium Selenite contains 98.5–101.5% of sodium selenite ($\text{Na}_2\text{SeO}_3 \cdot 5\text{H}_2\text{O}$).

Description Sodium Selenite occurs as a white crystalline powder.

Identification

(1) Dissolve 0.05 g of Sodium Selenite by adding 2.5 ml of water and 2.5 ml of dilute hydrochloric acid, and boil. When 0.05 g of L-ascorbic acid is added, the resulting solution produces a red precipitate. When left to stand for a few minutes, the color of the precipitate changes to red-brown to black.

(2) Dissolve 0.05 g of Sodium Selenite by adding 5 ml of water and 1 ml of dilute hydrochloric acid. When 1 ml of barium chloride solution (3 in 50) is added, no precipitate is produced.

(3) Sodium selenite responds to all tests for Sodium Salt in the Qualitative Tests.

Purity

(1) Clarity of solution Colorless and clear (2.0 g, carbon dioxide-free water 20 ml).

(2) pH 9.8–10.8 (2.0 g, carbon dioxide-free water 20 ml).

(3) Chloride Not more than 0.005% as Cl.

Sample Solution Place 2.0 g of sodium selenite into a Nessler tube, and dissolve it by adding about 30 ml of water. Add 4 ml of nitric acid and mix.

Control Solution Use 0.30 ml of 0.01 mol/L hydrochloric acid.

(4) Sulfate Not more than 0.03% as SO_4 (0.8 g, Control solution: 0.005 mol/L sulfuric acid 0.50 ml).

(5) Lead Not more than 2.0 µg/g as Pb.

Standard Solution Measure exactly 2 ml of Lead Standard Stock Solution, 5 ml of Iron Standard Stock Solution, and 3 ml of Arsenic Standard Stock Solution (for inductive coupled plasma-atomic emission spectrometry) in to a 100-ml volumetric flask, and add nitric acid (1 in 200) to volume.

Test Solution Weigh 1.00 g of sodium selenite into a 10-ml volumetric flask, dissolve it by adding nitric acid (1 in 200) to make 10 ml.

Standard Test Solutions Weigh 1.00 g of sodium selenite into each of three 10-ml volumetric flasks. To the flasks, add 0.5 ml, 1 ml, and 2 ml of the standard solution separately, and dissolve them by adding nitric acid (1 in 200) to make 10 ml of each.

Procedure Determine the emission intensity of lead, iron and arsenic in the test

solution and standard test solutions by inductive coupled plasma-atomic emission spectrometry. Plot the values obtained on a graph, with the amount (μg) in each solution on the x axis and emission intensity on the y axis, to prepare regression lines for the three elements. Determine the amount of lead, iron, and arsenic in the sample from the distance between the origin and the intersection of the regression line and the x axis.

(6) Iron Not more than $50 \mu\text{g/g}$ as Fe.

Procedure Proceed as directed in Purity (5).

(7) Arsenic Not more than $4.0 \mu\text{g/g}$ as As_2O_3 .

Procedure Proceed as directed in Purity (5).

Assay Weigh accurately about 0.1 g of sodium selenite into a stoppered flask, and dissolve it by adding 100 ml of water. To this solution, add 3 g of potassium iodide and 5 ml of diluted hydrochloric acid (2 in 3), immediately stopper tightly, and allow to stand in a dark place for 5 minutes. Titrate the liberated iodine with 0.1 mol/L sodium thiosulfate (indicator: 3 ml of starch TS). Add starch TS near the endpoint of the titration, when the solution is pale yellow-red. The endpoint is when the blue color produced disappears. Separately perform a blank test to make a correction.

Each ml of 0.1 mol/L sodium thiosulfate = 6.575 mg of $\text{Na}_2\text{SeO}_3 \cdot 5\text{H}_2\text{O}$

Reagents and Test Solutions (TS)

Iron Standard Stock Solution Weigh exactly 8.63 g of ammonium iron(III) sulfate dodecahydrate, dissolve it by adding 25 ml of diluted nitric acid and water, and add water to this solution to make exactly 1000 ml of solution. Each ml of this solution contains 1 mg of iron (Fe). Store, protected from light.

Arsenic Standard Stock Solution (for inductive coupled plasma-atomic emission spectrometry) Weigh exactly 0.10 g diarsenic trioxide, previously powdered finely and dried for 4 hours at 105°C , dissolve it by adding 6 ml of sodium hydroxide solution (1 in 10), and add 500 ml of water. Adjust the pH to 3 to 5 with diluted hydrochloric acid (1 in 4), and add water to make exactly 1000 ml of solution. Each ml of this solution contains 0.1 mg of arsenic trioxide (As_2O_3).

Attachment 5-2

Asparaginase
アスパラギナーゼ

Revision of regulations

Part of the definition and the specifications for Asparaginase (*A. oryzae* NZYM-SP-derived) will be added by revision this time. The reagents and test solutions (TS) newly added for testing of *A. oryzae* NZYM-SP-derived asparaginase are given in the last part of this document.

Standards for Use

Not established.

Compositional specifications

Definition Asparaginase is derived from the filamentous fungi (limited to *Aspergillus niger* ASP-72 and *Aspergillus oryzae* NZYM-SP), in which asparaginase productivity is improved by amplifying the asparaginase gene intrinsically occurring in *A. niger* and *A. oryzae*. It is an enzyme that hydrolyzes asparagine into aspartic acid and ammonia. There are two types of Asparaginase: *A. niger* ASP-72-derived and *A. oryzae* NZYM-SP-derived products. It may contain glycerine, dextrin, maltodextrin, salt, or wheat flour.

Asparaginase (*A. oryzae* NZYM-SP-derived)

Enzyme Activity Asparaginase has an enzyme activity of not less than 3,500 units per gram or milliliter.

Description Asparaginase occurs as a light brown liquid or as white to grayish white granules.

Identification When tested by the enzyme activity determination, Asparaginase shows activity.

Purity

(1) Lead Not more than 5.0 µg/g as Pb.

Weigh 0.8 g of Asparaginase, and proceed as directed in Purity (1) for Asparaginase (*A. niger* ASP-72-derived).

(2) Arsenic Not more than 4.0 µg/g as As₂O₃ (0.50 g, Method 3, Apparatus B).

Microbial Limits Proceed as directed under Microbial Limit Tests. The total bacterial count is not more than 50,000/g. *Escherichia coli* and *Salmonella* are negative. For the *Salmonella* test, proceed as directed in the microbial limit test for Nisin.

Enzyme Activity Determination

(i) **Substrate Solution** Weigh 0.25 g of L-asparagine monohydrate, add 15 ml of MOPS buffer (0.1 mol/L, pH7.0), and dissolve it completely by stirring. Cover the container to block out light. Refer the resulting solution to as Solution A. To Solution A, add 0.011 g of β-nicotinamide adenine dinucleotide disodium salt hydrate (reduced form), 0.063 g of disodium 2-ketoglutarate, and an appropriate amount of L-glutamic acid dehydrogenase (bovine liver-derived) equivalent to not less than 1680 units, and stir well to dissolve them. Add MOPS buffer (0.1 mol/L, pH7.0) to make exactly 25 ml. Prepare fresh before use.

- (ii) *Sample Solution* Weigh accurately about 1.0 g of Asparaginase, and dissolve it in acetate buffer (0.1 mol/L, pH5.0, containing polyoxyethylene(23) lauryl ether) to make exactly 100 ml. Dilute this solution with acetate buffer (0.1 mol/L, pH5.0, containing polyoxyethylene(23) lauryl ether) to prepare a solution containing about 0.6 units/ml.
- (iii) *Standard Stock Solutions* Weigh an amount of *A. oryzae*-derived asparaginase (for enzyme activity determination) equivalent to 775 units, dissolve in acetate buffer (0.1 mol/L, pH5.0, containing polyoxyethylene(23) lauryl ether) to make exactly 100 ml. Dilute this solution with acetate buffer (0.1 mol/L, pH5.0, containing polyoxyethylene(23) lauryl ether) 8, 10, 15, 20, and 30 times to prepare five solutions containing 0.9688, 0.7750, 0.5167, 0.3875, and 0.2583 units/ml, respectively.

(iv) Procedure

Test Solution Transfer 4.6 ml of the substrate solution into a test tube, and warm at $37.0 \pm 0.5^\circ\text{C}$ for 8 minutes. Add exactly 0.4 ml of the sample solution, shake, and warm at $37.0 \pm 0.5^\circ\text{C}$ for 90 seconds.

Standard Solutions Transfer 4.6 ml portions of the substrate solution into five separate test tubes, and warm at $37.0 \pm 0.5^\circ\text{C}$ for 8 minutes. To each test tube, add 4 ml of the appropriate one of the standard stock solutions with different concentrations, instead of the sample solution, and proceed as directed for the test solution.

Calibration Curve Measure the absorbance of the standard solutions against water at 340 nm and prepare the calibration curve from the absorbance values obtained and the enzyme activity in 1 ml (unit/ml) of each standard stock solution.

Determination Measure the absorbance, *A*, of the test solution against water at 340 nm. Determine the enzyme activity, *U* (unit/ml), of the sample solution from absorbance *A* and the calibration curve. Then calculate the enzyme activity of the sample by the following formula. One unit of enzyme activity is equivalent to the amount of the enzyme required to liberate 1 μmol of ammonia per minute from L-asparagine when the enzyme activity is determined as directed in the procedure.

$$\text{Enzyme activity (unit/g)} = \frac{U \times D \times 100}{\text{Weight (g) of the sample}}$$

U = the enzyme activity of the sample solution.

D = the dilution factor of the sample solution.

Asparaginase (*A. niger* ASP-72-derived)

Enzyme Activity Asparaginase has an enzyme activity of not less than 2375 units per gram or milliliter.

Description Asparaginase occurs as a clear, yellow to brown liquid or as pale gray or slightly yellowish white granules.

Identification When tested by the enzyme activity determination, Asparaginase shows activity.

Purity

(1) Lead Not more than 5.0 µg/g as Pb.

Test Solution Weigh 0.8 g of Asparaginase into a platinum, quartz, or porcelain crucible or a quartz beaker, and moisten it with a small amount of diluted sulfuric acid (1 in 4). Heat it by increasing the temperature gradually until the sample is carbonized and the white fumes of sulfuric acid are no longer evolved. If necessary, add diluted sulfuric acid (1 in 4) again, and heat until the sample is almost carbonized. For a liquid sample or a sample that is hard to be carbonized, concentrated sulfuric acid may be used, instead of diluted sulfuric acid (1 in 4). After the sample is carbonized, lid the crucible or beaker loosely if necessary, heat in an electric furnace by increasing the temperature gradually, and ignite at 450–600°C to incinerate. If any carbonized residue is present, crush the residue with a glass rod if necessary, moisten with 1 ml of diluted sulfuric acid (1 in 4) and 1 ml of nitric acid, heat until the white fumes of sulfuric acid are no longer evolved, and ignite in the electric furnace to completely incinerate it. To residue, add 10 ml of diluted hydrochloric acid (1 in 4), heat on a water bath, and evaporate to dryness. To the residue, add a small amount of diluted nitric acid (1 in 100), and warm to dissolve it. After cooling, add diluted nitric acid (1 in 100) to make exactly 10 ml.

When incineration is done at 500°C or below, a heat-resistant glass beaker can be used.

Control Solution - To 1 ml of Lead Standard Stock Solution, exactly measured, add water to make exactly 100 ml. To exactly measured 4 ml of this solution, add diluted nitric acid (1 in 100) to make 10 ml.

Procedure - Proceed as directed in Method 1 of the Lead Limit Test.

(2) Arsenic Not more than 4.0 µg/g as As₂O₃ (0.50 g, Method 3, Apparatus B).

Microbial Limits Proceed as directed under Microbial Limit Tests. The total bacterial count is not more than 50,000/g. Escherichia coli and Salmonella are negative. For the Salmonella test, proceed as directed in the microbial limit tests for Nisin.

Enzyme Activity Determination

- (i) *Substrate Solution* Weigh 1.50 g of L-asparagine monohydrate, add citric acid–sodium hydroxide buffer (pH 5.0), and dissolve it completely by stirring. Add citric acid–sodium hydroxide buffer (pH 5.0) again to make exactly 100 ml. Prepare fresh before use.
- (ii) *Sample Solution* Weigh accurately about 2.5 g of Asparaginase, dissolve in 20 ml of citric acid–sodium hydroxide buffer (pH 5.0), and then add citric acid–sodium hydroxide buffer (pH 5.0) to make exactly 25 ml. Dilute this solution with citric acid–sodium hydroxide buffer (pH 5.0) to prepare a solution containing 6 units/ml.
- (iii) *Control Stock Solution* Weigh an amount of asparaginase (for enzyme activity determination) equivalent to 4000 units, dissolve in 20 ml of citric acid–sodium hydroxide buffer (pH 5.0), and then add citric acid–sodium hydroxide buffer (pH 5.0) to make exactly 25 ml. Dilute this solution with citric acid–sodium hydroxide buffer (pH 5.0) to prepare a solution containing 6 units/ml.
- (iv) *Ammonium Sulfate Standard Solutions* Weigh accurately about 3.9 g of ammonium sulfate, add 40 ml of citric acid–sodium hydroxide buffer (pH 5.0), and shake for 15 minutes. Again add citric acid–sodium hydroxide buffer (pH 5.0) to make 50 ml. Dilute this solution with citric acid–sodium hydroxide buffer (pH 5.0) 4, 6, 10, 30, and 60 times, respectively, to prepare five standard solutions.
- (v) *Procedure*

Test Solution and Control Solution - Place 2.0 ml portions of the substrate solution into two separate test tubes, and warm them at 37°C for 10 minutes. Add 0.100 ml of the sample solution to one test tube and 0.100 ml of the control stock solution to the other, and stir. Warm them at 37°C exactly for 30 minutes, add 0.400 ml portions of trichloroacetic acid solution (1 in 4) to them, stir, and add 2.5 ml of water to each, and again stir. Take 0.100 ml from each test tube, and add 4.0 ml of water and 0.850 ml of basic phenol–nitroprusside TS, and stir. Add 0.850 ml of sodium hypochlorite–sodium hydroxide TS for asparaginase activity test to each, and allow them to stand at 37°C for 10 minutes. Use them as the test solution and the control solution, respectively.

Reference Solutions - Place 2.0 ml portions of the substrate solution into two separate test tubes, and add 0.400 ml portions of trichloroacetic acid solution (1 in 4) to them, and stir. Add 0.100 ml of the sample solution to one test tube and 0.100 ml of the control stock solution to the other, stir, and warm them at 37°C for 30 minutes. Add 2.5 ml of water to each, and stir again. Take 0.100 ml from each test tube, and add 4.00 ml of water and 0.850 ml of phenol-nitroprusside (basic), and stir. Add 0.850 ml of sodium hypochlorite–sodium hydroxide TS for asparaginase activity test to each, allow them stand at 37°C for 10 minutes. Use them as the reference solutions for the test solution and the control solution, respectively.

Calibration Curve - Place 2.0 ml portions of the substrate solution into five separate test tubes, and warm them at 37°C for 10 minutes. To each test tube, add 0.100 ml portion of the appropriate one of the ammonium sulfate standard solutions with different concentrations, instead of the sample solution, and proceed as directed for the test solution. Measure the absorbance of them against water at 600 nm. Prepare a calibration curve using the absorbance values obtained and the ammonium sulfate concentrations in the ammonium sulfate standard solutions.

Determination - Measure the absorbance (A_T and A_C) of the test solution and the control solution against water at 600 nm. Also measure the absorbance (A_{BT} and A_{BC}) of the reference solutions for the test solution and the control solution against water at 600 nm. Measure the slope, a (ml/mg), of the calibration curve. Calculate the enzyme activity of asparaginase for enzyme activity determination used for the preparation of the control solution by the formula given below. When the obtained activity is in the range of 91 to 109% of the labeled value, determine the enzyme activity of the sample also by the formula. One unit of enzyme activity is equivalent to the amount of the enzyme required to liberate 1 μ mol of ammonia per minute from L-asparagine when the enzyme activity is determined as directed in the Procedure.

$$\text{Enzyme activity (unit/g)} = \frac{A \times D_f \times 25 \times 2 \times 10^3}{a \times W \times 132.14 \times 30}$$

A = the value obtained by deducting the absorbance (A_{BT} or A_{BC}) of the corresponding reference solution from the absorbance (A_T or A_C) of the test solution or the control solution, whichever is appropriate.

D_f = the dilution factor of the sample solution or the control stock solution.

W = the weight (g) of the sample or asparaginase (for enzyme activity determination).

Reagents and Test Solutions (TS)

Asparaginase (A. oryzae-derived) for Enzyme Activity Determination Obtained from the filamentous fungi, *A. oryzae* NZYM-SP, in which asparaginase productivity is improved by amplifying the asparaginase gene intrinsically occurring in *Aspergillus oryzae*. Occurs as a light brown liquid or as white to grayish white granules. It has an enzyme activity whose number of units is known. One unit of this substance is equivalent to the amount of the enzyme required to liberate 1 μmol of ammonia in one minute at pH 5.0 and at 37°C when L-asparagine as the substrate is used.

3-(N-Morpholino)propanesulfonic Acid $\text{C}_7\text{H}_{15}\text{NO}_4\text{S}$ A white crystalline powder. Freely soluble in water and practically insoluble in ethanol (99.5). Melting point 275–280°C.

Polyoxyethylene(23) Lauryl Ether $(\text{C}_2\text{H}_4\text{O})_n\text{C}_{12}\text{H}_{26}\text{O}$ Use lauromacrogol specified in the Japanese Pharmacopoeia.

Polyoxyethylene(23) Lauryl Ether TS Add water to 15 g of polyoxyethylene(23) lauryl ether to make 100 ml.

β -Nicotinamide Adenine Dinucleotide Disodium Salt Hydrate (reduced form)
 $\text{C}_{21}\text{H}_{27}\text{N}_7\text{Na}_2\text{O}_{14}\text{P}_2$ A white to pale yellow powder. Soluble in water.

Disodium 2-ketoglutarate $\text{C}_5\text{H}_4\text{Na}_2\text{O}_5$ A white powder. Soluble in water.

L-Glutamic Acid Dehydrogenase (bovine liver-derived) Obtained from bovine liver. It has an enzyme activity whose number of units is known. One unit of enzyme activity is equivalent to the amount of the enzyme required to liberate 1 μmol of L-glutamic acid per minute at pH 7.3 and at 25°C when 2-ketoglutaric acid as the substrate is used.

Acetate Buffer (0.1 mol/L, pH5.0, containing polyoxyethylene(23) lauryl ether)

To 500 ml of acetate buffer (1 mol/L, pH 5.0), add 3500 ml of water and 7.5 ml of polyoxyethylene(23) lauryl ether TS. Adjust the pH to 5.0 with sodium hydroxide solution of an appropriate concentration, and dilute with water exactly to 5000 ml.

Acetate buffer (1 mol/L, pH 5.0) Dissolve 88.8 g of sodium acetate trihydrate in 1800 ml of water. Adjust the pH to 5.0 with acetic acid and dilute with water to exactly 2000 ml.

MOPS Buffer (0.1 mol/L, pH7.0) Dissolve 21 g of 3-(N-morpholino)propanesulfonic acid in 900 ml of water. Adjust the pH to 7.0 with sodium hydroxide solution of an appropriate concentration, and dilute with water to exactly 1000 ml.

Progress of evaluation of food additives that have been proven safe and are widely used in the world

20 Jan, 2016

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee ¹	Notification of result ²	Discussion by subcommittee ³	Closing date for comments ⁴	Date of designation as food additives
Isobutanol	21 Nov 2003	24 Mar 2004(fin.)	27 May 2004	23 Apr 2004(fin.)	19 Aug 2004	24 Dec 2004
2-Ethyl-3, (5 or 6)-dimethylpyrazine		3 Mar 2004(fin.)	27 May 2004	8 Apr 2004(fin.)	26 Jul 2004	24 Dec 2004
2,3,5,6-Tetramethylpyrazine		3 Mar 2004(fin.)	27 May 2004	8 Apr 2004(fin.)	26 Jul 2004	24 Dec 2004
Calcium stearate	4 Mar 2004	20 May 2004(fin.)	29 Jul 2004	24 Jun 2004(fin.)	21 Oct 2004	24 Dec 2004
Propanol	21 Nov 2003	24 Mar 2004 20 May 2004 28 Jul 2004(fin.)	9 Sep 2004	26 Aug 2004(fin.)	14 Dec 2004	24 Feb 2005
Nitrous oxide	20 Oct 2003	17 Dec 2003 5 Oct 2004(fin.)	9 Dec 2004	17 Dec 2004(fin.)	19 Feb 2005	22 Mar 2005
Isopropanol	15 Dec 2003	24 Mar 2004 9 Apr 2004 8 Sep 2004 5 Oct 2004(fin.)	9 Dec 2004	28 Oct 2004(fin.)	4 Mar 2005	28 Apr 2005
Hydroxypropyl cellulose	16 Aug 2004	22 Dec 2004(fin.)	10 Mar 2005	24 Feb 2005(fin.)	14 Jun 2005	19 Aug 2005
Isoamylalcohol	5 Nov 2004	14 Jan 2005(fin.)	17 Mar 2005	24 Feb 2005(fin.)	14 Jun 2005	19 Aug 2005
2,3,5-Trimethylpyrazine						
Amylalcohol						
Natamycin	20 Oct 2003	9 Jan 2004 16 Nov 2004 26 Jan 2005(fin.)	6 May 2005	24 Mar 2005(fin.)	7 Sep 2005	28 Nov 2005
Acetaldehyde	21 Nov 2003	3 Mar 2004 9 Apr 2004 27 Apr 2004 23 Feb 2005 13 Apr 2005(fin.)	21 Jul 2005	23 Jun 2005(fin.)	12 Oct 2005	16 May 2006

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee ¹	Notification of result ²	Discussion by subcommittee ³	Closing date for comments ⁴	Date of designation as food additives
2 Ethyl 3 methylpyrazine	7 Mar 2005	14 Jun 2005(fin.)	18 Aug 2005	28 Jul 2005(fin.)	19 Dec 2005	16 May 2006
5 Methylquinoxaline		14 Jun 2005 22 Jul 2005(fin.)	22 Sep 2005	27 Oct 2005 24 Nov 2005(fin.)	26 Apr 2006	12 Sep 2006
Butanol		2 Dec 2005 14 Dec 2005(fin.)	30 Mar 2006	23 Mar 2006(fin.)	5 Sep 2006	26 Dec 2006
Ammonium alginate	28 Mar 2005	2 Dec 2005 14 Dec 2005(fin.)	30 Mar 2006	23 Mar 2006(fin.)	5 Sep 2006	26 Dec 2006
Potassium alginate		14 Jul 2006 11 Aug 2006(fin.)	12 Oct 2006	8 Dec 2006 16 Jan 2007 (Fin.)	22 May 2007	3 Aug 2007
Calcium alginate		28 Jun 2006 14 Jul 2006 11 Aug 2006 13 Sep 2006 13 Oct 2006(fin.)	7 Dec 2006	8 Dec 2006 16 Jan 2007 (Fin.)	22 May 2007	3 Aug 2007
2 Methylbutanol	19 Dec 2005	14 Jul 2006 11 Aug 2006(fin.)	12 Oct 2006	8 Dec 2006 16 Jan 2007 (Fin.)	22 May 2007	3 Aug 2007
Isobutyraldehyde	19 Dec 2005	28 Jun 2006 14 Jul 2006 11 Aug 2006 13 Sep 2006 13 Oct 2006(fin.)	7 Dec 2006	8 Dec 2006 16 Jan 2007 (Fin.)	22 May 2007	3 Aug 2007
Butyraldehyde	19 Dec 2005	19 Dec 2006 26 Jan 2007(fin.)	22 Mar 2007	20 Mar 2007(fin.)	27 Aug 2007	26 Oct 2007
Polysorbate 20, 60, 65, 80	8 Oct 2003	29 Oct 2003 27 Apr 2004 28 Jul 2004 23 Mar 2007(fin.)	7 Jun 2007	4 Jul 2007 9 Aug 2007(fin.)	16 Dec 2007	30 Apr 2008
Calcium silicate	15 Aug 2005	28 Feb 2007 23 Mar 2007 17 Apr 2007 29 May 2007(fin.)	26 Jul 2007	9 Aug 2007(fin.)	16 Dec 2007	30 Apr 2008
Calcium ascorbate	3 Oct 2005	23 Mar 2007 17 Apr 2007 29 May 2007 22 Jun 2007(fin.)	23 Aug 2007	9 Aug 2007(fin.)	16 Dec 2007	30 Apr 2008
Nisin	20 Oct 2003	9 Apr 2004 16 Nov 2004 26 Jan 2005 30 Jul 2007 27 Aug 2007(fin.)	31 Jan 2008	26 Sep 2007 24 Oct 2007 28 Feb 2008(fin.) 24 Sep 2008(fin.)	18 Jul 2008	2 Mar 2009

Substance name	Request for evaluation	Food Safety Commission		MHLW		
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Acetylated distarch adipate Acetylated distarch phosphate Acetylated oxidized starch Starch sodium octenylsuccinate Hydroxypropyl starch Hydroxypropyl distarch phosphate Phosphated distarch phosphate Monostarch phosphate Distarch phosphate Oxidized starch Starch acetate	26 Nov 2004	23 Mar 2005 17 May 2005 27 Aug 2007 28 Sep 2007(fin.)	29 Nov 2007	28 Nov 2007(fin.) 4 Jul 2008(fin.)	29 May 2008	1 Oct 2008
Magnesium hydroxide	9 Mar 2006	22 Jun 2007 30 Jul 2007 27 Aug 2007(fin.)	1 Nov 2007	24 Oct 2007(fin.)	7 Feb 2008	4 Jul 2008
Magnesium Monohydrogen Phosphate	28 Mar 2005	31 May 2006 28 Jun 2006 14 Jul 2006 11 Aug 2006 13 Sep 2006 28 Nov 2006 25 Oct 2011 29 Nov 2011 16 Dec 2011(fin.)	22 Mar 2012	6 Mar 2012(fin.)	22 Jul 2012	2 Nov 2012
Polyvinylpyrrolidone	20 Jun 2005	13 Sep 2006 13 Oct 2006 28 Nov 2006 19 Dec 2006 26 Jan 2007 18 Dec 2012 22 Jan 2013 22 Feb 2013 27 Mar 2013 25 Apr 2013(fin.)	30 Jul 2013	21 Jun 2013 30 Oct 2013 29 Jan 2014(fin.)	—	18 Jun 2014

Substance name	Request for evaluation	Food Safety Commission		MHLW		
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Magnesium silicate(synthetic)	15 Aug 2005	28 Feb 2007 23 Mar 2007 17 Apr 2007 28 Sep 2009 17 Nov 2009(fin.)	21 Jan 2010	25 Dec 2009(fin)	6 Jun 2010	20 Oct 2010
Sodium aluminium silicate	15 Aug 2005	28 Feb 2007 30 May 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013 (under consideration)				
Calcium aluminium silicate	15 Aug 2005	28 Feb 2007 30 May 2012 27 Jul 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013 (under consideration)				
Calcium saccharin	22 May 2006	27 Aug 2007 28 Sep 2007 26 Oct 2007 26 Apr 2011 31 May 2011 28 Jun 2011(fin)	25 Aug 2011	2 Nov 2011 (fin)	12 May 2012	28 Dec 2012
Ammonium L- glutamate	22 May 2006	15 Jan 2008(fin.)	13 Mar 2008	11 Apr 2008 (fin.)	10 Oct 2008	20 Oct 2010
Sodium stearoyl-2 lactylate	6 Feb 2007	24 Mar 2008 15 Apr 2008(fin.)	10 Jul 2008	4 Jul 2008(fin.)	1 Dec 2008	28 May 2010
Potassium lactate	6 Feb 2007	17 Jun 2008 29 Sep 2008 21 Aug 2012 26 Sep 2012 25 Oct 2012(fin.)	21 Jan 2013	6 Dec 2012	11 Mar 2013	15 May 2013

Substance name	Request for evaluation	Food Safety Commission		MHLW		
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Calcium sorbate	19 Mar 2007	26 Mar 2008 17 Jun 2008 29 Aug 2008(fin.)	20 Nov 2008	25 Nov 2008(fin.)	25 Apr 2009	28 May 2010
Valeraldehyde	19 Mar 2007	1 Feb 2008(fin.)	27 Mar 2008	4 Jul 2008(fin.)	1 Dec 2008	4 Jun 2009
Isovaleraldehyde	19 Mar 2007	1 Feb 2008(fin.)	27 Mar 2008	4 Jul 2008(fin.)	1 Dec 2008	4 Jun 2009
2,3-Dimethylpyrazine	7 Feb 2008	15 Apr 2008 26 May 2008(fin.)	31 Jul 2008	24 Sep 2008(fin.)	3 Feb 2009	4 Jun 2009
2,5-Dimethylpyrazine	7 Feb 2008	15 Apr 2008 26 May 2008(fin.)	31 Jul 2008	24 Sep 2008(fin.)	3 Feb 2009	4 Jun 2009
2,6-Dimethylpyrazine	7 Feb 2008	15 Apr 2008 26 May 2008(fin.)	31 Jul 2008	24 Sep 2008(fin.)	3 Feb 2009	4 Jun 2009
2-Ethylpyrazine	22 May 2008	29 Sep 2008(fin.)	27 Nov 2008	22 Oct 2008(fin.)	25 Apr 2009	28 May 2010
2-Methylpyrazine	22 May 2008	29 Sep 2008(fin.)	27 Nov 2008	22 Oct 2008(fin.)	25 Apr 2009	28 May 2010
2-Pentanol	14 Oct 2008	11 Nov 2008(fin.)	22 Jan 2009	28 Apr 2009(fin.)	20 Sep 2009	28 May 2010
2-Methylbutyraldehyde	14 Oct 2008	11 Nov 2008(fin.)	22 Jan 2009	22 Dec 2008(fin.)	29 May 2009	28 May 2010
Propionaldehyde	20 Nov 2008	2 Feb 2009(fin.)	2 Apr 2009	28 Apr 2009(fin.)	20 Sep 2009	28 May 2010
6-Methylquinoline	20 Nov 2008	23 Mar 2009(fin.)	21 May 2009	28 Apr 2009(fin.)	20 Sep 2009	28 May 2010
2-Ethyl-5-methylpyrazine	12 Mar 2009	29 Jun 2009 28 Sep 2009(fin.)	8 Oct 2009	25 Dec 2009(fin.)	6 Jun 2010	20 Oct 2010
5,6,7,8-Tetrahydroquinoxaline	12 Mar 2009	29 Jun 2009(fin.)	27 Aug 2009	3 Sep 2009(fin.)	2 Feb 2010	28 May 2010
3-Methyl-2-butanol	12 Mar 2009	18 May 2009(fin.)	23 Jul 2009	3 Sep 2009(fin.)	2 Feb 2010	28 May 2010
Isopentylamine	12 Aug 2009	7 Sep 2009(fin.)	12 Nov 2009	25 Dec 2009(fin.)	6 Jun 2010	20 Oct 2010
Butylamine	10 Sep 2009	20 Oct 2009 17 Nov 2009(fin.)	4 Mar 2010	5 Mar 2010(fin.)	30 Aug 2010	10 Nov 2010
Phenethylamine	5 Nov 2009	17 Nov 2009(fin.)	18 Mar 2010	5 Mar 2010(fin.)	30 Aug 2010	10 Nov 2010
Trimethylamine	26 Nov 2009	15 Dec 2009(fin.)	29 Jul 2010	2 Nov 2011 (fin.)	19 Mar 2012	28 Dec 2012
1-Penten-3-ol	2 Feb 2010	23 Feb 2010(fin.)	28 Apr 2010	9 Feb 2011(fin.)	24 May 2011	19 Jul 2011
3-Methyl-2-butenol	2 Feb 2010	23 Feb 2010(fin.)	28 Apr 2010	9 Feb 2011(fin.)	24 May 2011	19 Jul 2011
Piperidine	15 Mar 2010	30 Mar 2010(fin.)	20 May 2010	23 Jun 2010(fin.)	23 Oct 2010	13 Dec 2010
Pyrrolidine	5 Apr 2010	20 Apr 2010(fin.)	3 Jun 2010	23 Jun 2010(fin.)	23 Oct 2010	13 Dec 2010
2,6-Dimethylpyridine	13 May 2010	2 Jun 2010(fin.)	15 Jul 2010	9 Sep 2010(fin.)	3 Jan 2011	15 Mar 2011
3-Ethylpyridine	14 Jun 2010	29 Jun 2010 23 Aug 2011 15 Nov 2012(fin.)	18 Feb 2013	18 Jan 2013	18 May 2013	6 Aug 2013

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee ¹	Notification of result ²	Discussion by subcommittee ³	Closing date for comments ⁴	Date of designation as food additives
5-Ethyl-2-methylpyridine	14 Jun 2010	29 Jun 2010(fin)	26 Aug 2010	9 Sep 2010(fin)	3 Jan 2011	15 Mar 2011
2-(3-Phenylpropyl)pyridine	9 Jul 2010	27 Jul 2010(fin)	7 Oct 2010	22 Dec 2010(fin)	1 Apr 2011	28 Jun 2011
2,3-Diethyl-5-methylpyrazine	9 Jul 2010	27 Jul 2010(fin)	7 Oct 2010	22 Dec 2010(fin)	1 Apr 2011	28 Jun 2011
5-methyl-6,7-Dihydro-5H-cyclopentapyrazine	12 Aug 2010	31 Aug 2010(fin)	27 Jan 2011	22 Dec 2010(fin)	1 Apr 2011	28 Jun 2011
Pyrazine	12 Aug 2010	31 Aug 2010(fin)	4 Jan 2011	9 Feb 2011(fin)	24 May 2011	19 Jul 2011
3-Methyl-2-butenal	9 Sep 2010	27 Sep 2010(fin)	27 Jan 2011	9 Feb 2011(fin)	24 May 2011	19 Jul 2011
<i>trans</i> -2-Pentenal	29 Oct 2010	12 Nov 2010 21 Dec 2010 27 Sep 2011(fin)	1 Dec 2011	6 Mar 2012(fin)	22 Jul 2012	2 Nov 2012
Isoquinolin	29 Oct 2010	12 Nov 2010(fin)	3 Feb 2011	11 May 2011(fin)	8 Aug 2011	27 Dec 2011
2-Ethyl-6-methylpyrazine	6 Dec 2010	21 Dec 2010(fin)	31 Mar 2011	2 Nov 2011 (fin)	19 Mar 2012	28 Dec 2012
<i>trans</i> -2-Methyl-2-butenal	4 Jan 2011	18 Jan 2011(fin)	21 Apr 2011	2 Nov 2011 (fin)	19 Mar 2012	28 Dec 2012
Pyrrrole	4 Jan 2011	18 Jan 2011(fin)	31 Mar 2011	11 May 2011(fin)	8 Aug 2011	27 Dec 2011
(3-Amino-3-carboxypropyl)dimethylsulfonium chloride	17 Feb 2011	22 Feb 2011(fin)	12 May 2011	2 Nov 2011 (fin)	19 Mar 2012	28 Dec 2012
Ammonium isovalerate	3 Mar 2011	26 Apr 2011 31 May 2011 15 Nov 2012(fin.)	18 Feb 2013	16 Feb 2015	21 May 2015	29 Jul 2015
	28 Nov 2014	—	9 Dec 2014			
β-apo-8'-carotenal	19 Apr 2011	27 Mar 2012 27 Jul 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013(fin.)	25 Nov 2013	27 Nov 2013	—	18 Jun 2014
Carmine	19 Apr 2011	26 Jul 2011 23 Aug 2011 30 May 2012 (under consideration)				

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee ¹	Notification of result ²	Discussion by subcommittee ³	Closing date for comments ⁴	Date of designation as food additives
Canthaxanthin	19 Apr 2011	27 Mar 2012 27 Jul 2012 20 Aug 2013 24 Sep 2013 17 Oct 2013 20 Nov 2013 25 Dec 2013 30 Jun 2014(fin)	14 Oct 2014	5 Sep 2014	18 Nov 2014	20 Feb 2015
Sodium aluminium phosphate,acidic	19 Apr 2011	30 May 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013 (under consideration)				
Calcium acetate	19 Apr 2011	24 Apr 2012 15 Nov 2012 18 Dec 2012 22 Jan 2013(fin)	15 Apr 2013	13 Mar 2013	22 Jun 2013	4 Dec 2013
Calcium oxide	19 Apr 2011	24 Apr 2012 15 Nov 2012 18 Dec 2012 22 Jan 2013(fin)	15 Apr 2013	13 Mar 2013	22 Jun 2013	22 Oct 2013
Potassium sulfate	19 Apr 2011	24 Apr 2012 26 Sep 2012 25 Oct 2012(fin.)	21 Jan 2013	6 Dec 2012	11 Mar 2013	15 May 2013
Triethyl citrate	19 Apr 2011	30 May 2012 18 Dec 2012 22 Jan 2013 22 Feb 2013 29 Sep 2014 29 Oct 2014(fin.)	17 Feb 2015	25 Dec 2014	3 Mar 2015	19 May 2015

Substance name	Request for evaluation	Food Safety Commission		MHLW		
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Isopropanol	19 Apr 2011	29 Nov 2011 16 Dec 2011(fin)	29 Mar 2012	31 May 2013	8 Oct 2013	4 Dec 2013
	16 May 2013	—	27 May 2013			
2,3-Diethylpyrazine	12 Feb 2014	13 Mar 2014 22 May 2014(fin)	26 Aug 2014	20 Jun 2014	23 Oct 2014	17 Nov 2014
1-Methylnaphthalene	5 Nov 2014	12 Dec 2014 14 Jan 2015 5 Feb 2015(fin.)	19 May 2015	24 Apr 2015	12 Jun 2015	18 Sep 2015

flavouring agents

1. Date when discussion was conducted by the expert committee.
2. Date when the evaluation result was filed with the MHLW.
3. Date when discussion was conducted by the Subcommittee on Food Additives under the Pharmaceutical Affairs and Food Sanitation Council.
4. Closing date for comment on WTO notification