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Japan to revise 10 MRLs and 5 analytical methods

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Sanitary/Phytosanitary/Food Safety

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Report Highlights:

On Tuesday, January 24, 2017, the Ministry of Health, Labor and Welfare (MHLW) of the Government of Japan (GOJ) announced changes to the Maximum Residue Levels (MRLs) for the pesticides Imidacloprid, Oxathiapiprolin, Quinclorac, Clethodim, Clofentezine, Fludioxonil, and Prohexadione-calcium as well as veterinary drugs Abamectin, Spiramycin, and Tylosin. MHLW also revised analytical methods for agricultural and veterinary chemicals in food for 2,4,5-T, Daminozide, Malachite green as well as the standards for food additives, Calcium carbonate and Magnesium stearate. The Embassy comment period for these proposals is open until Tuesday, February 7, 2017. MHLW will also notify these MRLs to the WTO, which will allow another opportunity for interested parties to comment on these changes.

General Information:

Item 1. Establishment of the Maximum Residue Limits for Agricultural and Veterinary 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 and veterinary chemicals”) that may remain in foods. Any food for which standards are established pursuant to the provisions in Article 11, Paragraph 1 of the act is not permitted to be marketed in Japan unless it complies with the established standards.

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

MHLW has comprehensively reviewed existing MRLs to modify those that were provisionally set at the introduction of the system. In addition, MHLW is going to establish MRLs for some commodities. This activity has been targeted for the following agricultural chemicals:

Pesticide: Bicyclopyrone, 1,3-Dichloropropene, Ethofumesate, Etofenprox, Fluazifop-butyl, Isopyrazam

Veterinary drug: Erythromycin, Flumethrin, Metoclopramide, Piperazine, Vedaprofen

Summary

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

Imidacloprid (insecticide): Permitted for use in Japan. MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the Ministry of Agriculture, Forestry and Fisheries (MAFF).

Oxathiapiprolin (fungicide): Permitted for use in Japan. 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 Used outside Japan (Shokuan No. 0205001, 5 February 2004). This action will not strengthen the current regulation for any commodities.

Quinclorac (herbicide): Not permitted for use in Japan. 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 Used outside Japan (Shokuan No. 0205001, 5 February 2004). This action will not strengthen the current regulation for any commodities.

Clethodim (herbicide): Permitted for use in Japan. MHLW is going to establish MRLs in some commodities in response to a request for setting import tolerances based on the Guideline for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan (Shokuan No. 0205001, 5 February 2004). MHLW is also going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Clofentezine (acaricide): Permitted for use in Japan. MHLW is going to establish MRLs in some commodities in response to a request for setting import tolerances based on the Guideline for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan (Shokuan No. 0205001, 5 February 2004). MHLW is also going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Fludioxonil (fungicide): Permitted for use in Japan. MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF. MHLW is also 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).

Prohexadione-calcium (plant growth regulator): Permitted for use in Japan. MHLW is going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Abamectin (insecticide, parasiticide): Permitted for use in Japan. MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the

MAFF. The MHLW is also 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).

Spiramycin (antibiotic): Permitted for use in Japan. MHLW is going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System. MHLW is also going to modify the existing MRLs in some commodities that were set before the introduction of the Positive List System.

Tylosin (antibiotic): Permitted for use in Japan. 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 Used outside Japan (Shokuan No. 0205001, 5 February 2004). This action will not strengthen the current regulation for any commodities.

Imidacloprid

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Rice (brown rice)	○ 1	1	§			
Wheat	○ 0.2	0.05	§ · Request	0.05		
Barley	● 0.04	0.05		0.05		
Rye	● 0.04	0.05		0.05		
Corn (maize, including pop corn and sweet corn)	○ 0.05	0.05	§	0.05		
Buckwheat	● 0.04	0.05		0.05		
Other cereal grains	○ 3	3	§	0.05		
Soybeans, dry	○ 3	3	§	2	4.0	USA
Beans, dry	○ 3	3	§	2	4.0	USA
Peas	○ 3	3	§	2	4.0	USA
Broad beans	○ 3	3	§	2	4.0	USA
Peanuts, dry	○ 0.7	0.7	§	1		
Other pulses	○ 3	3	§	2	4.0	USA
Potato	● 0.4	0.5	§	0.5		
Taro	○ 0.4	0.4	§	0.5		
Sweet potato	○ 0.4	0.4	§	0.5		
Yam	○ 0.4	0.4	§	0.5		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Konjac	○ 0.4	0.4	§	0.5		
Other potatoes	○ 0.4	0.4		0.5		
Sugar beet	○ 0.4	0.4	§	0.5		
Sugarcane	○ 0.04	0.04			0.05	Australia
Japanese radish, roots (including radish)	○ 0.4	0.4	§	0.5		
Japanese radish, leaves (including radish)	○ 4	4	§	5		
Turnip, roots (including rutabaga)	○ 0.4	0.4	§	0.5		
Turnip, leaves (including rutabaga)	○ 3	3	§		4.0	USA
Horseradish	○ 0.4	0.4		0.5		
Watercress	○ 3	3			3.5	USA
Chinese cabbage	○ 0.5	0.5	§			
Cabbage	○ 0.5	0.5	§	0.5		
Brussels sprouts	○ 0.5	0.5	§	0.5		
Kale	○ 5	5	§			
Komatsuna(Japanese mustard spinach)	○ 5	5	§			
Kyona	○ 5	5	§			
Qing-geng-cai	○ 5	5	§			
Cauliflower	○ 0.4	0.4		0.5		
				Reference MRL		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	National	
				Codex ppm	ppm
Broccoli	○ 5	5	§	0.5	
Other cruciferous vegetables	○ 5	5	§	0.5	
Burdock	○ 0.4	0.4	§	0.5	
Salsify	○ 0.4	0.4		0.5	
Artichoke	○ 2	2			2.5 USA
Chicory	○ 3	3			4.0 USA
Endive	○ 5	5	§		
Shungiku	○ 3	3			3.5 USA
Lettuce (including cos lettuce and leaf lettuce)	○ 3	3	§	2	3.5 USA
Other composite vegetables	○ 5	5	§	0.5	
Onion	○ 0.07	0.07	§	0.1	
Welsh (including leek)	○ 0.7	0.7	§	0.05	
Nira	● 0.7	1	§		
Asparagus	○ 0.7	0.7	§		
Multiplying onion (including shallot)	○ 2	2	§		
Other liliaceous vegetables	○ 0.2		Request		

					Reference MRL
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Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Carrot	○ 0.4	0.4	§	0.5		
Parsnip	○ 0.4	0.4		0.5		
Parsley	○ 3	3	§			
Celery	○ 4	4	§	6		
Mitsuba	○ 5	5	§			
Other umbelliferous vegetables	○ 4	4	§	0.5	6.0	USA
Tomato	○ 2	2	§	0.5		
Pimiento (sweet pepper)	○ 3	3	§	1		
Egg plant	○ 2	2	§	0.2		
Other solanaceous vegetables	○ 5	5	§	1		
Cucumber (including gherkin)	○ 1	1	§	1		
Pumpkin (including squash)	○ 1	1	§	1		
Oriental pickling melon (vegetable)	○ 1	1	§			
Water melon	○ 0.5	0.5	§			
Melons	● 0.2	0.4	§			
Makuwauri melon	● 0.1	0.4	§			
Other cucurbitaceous vegetables	○ 1	1	§	0.5		
Spinach	○ 15	15	§			
Okra	○ 0.7	0.7	§			
				Reference MRL		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Ginger	○ 0.3	0.3			0.4	USA
Peas, immature (with pods)	○ 4	4	§	5		
Kidney beans, immature (with pods)	○ 3	3	§	2	4.0	USA
Green soybeans	○ 3	3	§		4.0	USA
Other vegetables	○ 5	5	§	5		
Unshu orange, pulp	○ 0.3	0.3	§			
Citrus natsudaidai, whole	○ 0.7	0.7	§	1		
Lemon	○ 0.7	0.7	§	1		
Orange (including navel orange)	○ 0.7	0.7	§	1		
Grapefruit	○ 0.7	0.7	§	1		
Lime	○ 0.7	0.7	§	1		
Other citrus fruits	○ 0.7	0.7	§	1		
Apple	○ 0.5	0.5	§	0.5		
Japanese pear	○ 0.7	0.7	§	1		
Pear	○ 0.7	0.7	§	1		
Quince	● 0.4	0.5			0.6	USA
Loquat	○ 0.5	0.5	§			
Peach	○ 0.5	0.5	§			
Nectarine	○ 2	2	§	0.5	3.0	USA
				Reference MRL		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	National ppm		
				Codex ppm		USA
Apricot	○ 2	2	§	0.5	3.0	USA
Japanese plum (including prune)	○ 2	2	§	0.2	3.0	USA
Mume plum	○ 0.3	0.3	§			
Cherry	○ 2	2		0.5	3.0	USA
Strawberry	● 0.4	0.5	§	0.5		
Raspberry	○ 4	4		5		
Blackberry	○ 4	4		5		
Blueberry	○ 4	4		5		
Cranberry	○ 0.04	0.04		0.05		
Huckleberry	○ 4	4		5		
Other berries	○ 4	4		5		
Grape	○ 3	3	§	1		
Japanese persimmon	○ 1	1	§			
Banana	○ 0.04	0.04		0.05		
Kiwifruit	○ 0.2	0.2	§			
Papaya	○ 0.7	0.7			1.0	USA
Avocado	○ 0.7	0.7			1.0	USA
Guava	○ 0.7	0.7			1.0	USA
Mango	○ 1	1	§	0.2		
				Reference MRL		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Passion fruit	○ 0.7	0.7	§			
Other fruits	○ 4	4	§	5		
Sunflower seeds	○ 0.04	0.04		0.05		
Sesame seeds	○ 0.05		Request			
Safflower seeds	○ 0.04	0.04			0.05	USA
Cotton seeds	○ 4	4			6.0	USA
Rapeseeds	○ 0.04	0.04		0.05	0.05	USA
Other oil seeds	○ 0.04	0.04			0.05	USA
Ginkgo nut	○ 0.05	0.05	§	0.01		
Chestnut	○ 0.05	0.05	§	0.01		
Pecan	○ 0.04	0.04		0.01	0.05	USA
Almond	○ 0.04	0.04		0.01	0.05	USA
Walnut	○ 0.04	0.04		0.01	0.05	USA
Other nuts	○ 0.04	0.04		0.01	0.05	USA
Tea	○ 10	10	§			
Coffee beans	○ 0.7	0.7		1		
Cacao beans	○ 0.05	0.05				
Hop	○ 7	7		10		
Other spices	○ 5	5	§	5		
				Reference MRL		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Other herbs	○ 15	15	§	0.5		
Cattle, muscle	○ 0.3	0.3		0.1	0.30	USA
Pig, muscle	○ 0.3	0.3		0.1	0.30	USA
Other terrestrial mammals, muscle	○ 0.3	0.3		0.1	0.30	USA
Cattle, fat	○ 0.3	0.3		0.1	0.30	USA
Pig, fat	○ 0.3	0.3		0.1	0.30	USA
Other terrestrial mammals, fat	○ 0.3	0.3		0.1	0.30	USA
Cattle, liver	○ 0.3	0.3		0.3		
Pig, liver	○ 0.3	0.3		0.3		
Other terrestrial mammals, liver	○ 0.3	0.3		0.3		
Cattle, kidney	○ 0.3	0.3		0.3		
Pig, kidney	○ 0.3	0.3		0.3		
Other terrestrial mammals, kidney	○ 0.3	0.3		0.3		
Cattle, edible offal	○ 0.3	0.3		0.3		
Pig, edible offal	○ 0.3	0.3		0.3		
Other terrestrial mammals, edible offal	○ 0.3	0.3		0.3		
Milk	○ 0.1	0.1		0.1		
Chicken, muscle	○ 0.02	0.02		0.02		
Other poultry animals, muscle	○ 0.02	0.02		0.02		
				Reference MRL		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	National	
				Codex ppm	ppm
Chicken, fat	○ 0.02	0.02			
Other poultry animals, fat	○ 0.02	0.02			
Chicken, liver	● 0.05	0.1		0.05	
Other poultry animals, liver	● 0.05	0.1		0.05	
Chicken, kidney	● 0.05	0.1		0.05	
Other poultry animals, kidney	● 0.05	0.1		0.05	
Chicken, edible offal	● 0.05	0.1		0.05	
Other poultry animals, edible offal	● 0.05	0.1		0.05	
Chicken, eggs	○ 0.02	0.02		0.02	
Other poultry, eggs	○ 0.02	0.02		0.02	
Wheat flour (except whole grain)	●	0.02		0.03	
Wheat bran	●	0.2		0.3	
Pepper, dried	●	7		10	

Note: The residue definition for agricultural products is Imidacloprid only. The residue definition for animal products is sum of Imidacloprid and its metabolites containing the 6-chloropyridinyl moiety, expressed as Imidacloprid.

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

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

● : Commodities for which MRLs are to be lowered or deleted.

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

§ : Permitted for use in Japan.

Request : The MRL was modified in response to MAFF request

*For wheat flour (except whole grain), wheat bran and dried pepper, the MRLs of their raw commodities (wheat and other solanaceous vegetables, respectively) will be applied taking into account each processing factor. JMPR estimated their processing factors as following: 0.5 for wheat flour (except whole grain); 3.5 for wheat bran and 7 for dried pepper.

*For some foods such as Barley, draft MRLs are based on Codex or overseas standards by applying a conversion factor of 0.7, taking into consideration the difference of residue definition between Japan and Codex/overseas.

Oxathiapiprolin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Potato	○ 0.05	0.05	§			
Watercress	○ 15		IT		15	USA
Chinese cabbage	○ 2	0.2	§ · IT		1.5	USA
Cabbage	○ 2		IT		1.5	USA
Brussels sprouts	○ 2		IT		1.5	USA
Cauliflower	○ 2		IT		1.5	USA
Broccoli	○ 2		IT		1.5	USA
Other cruciferous vegetables	○ 2		IT		1.5	USA
Endive	○ 15		IT		15	USA
Shungiku	○ 15		IT		15	USA
Lettuce (including cos lettuce and leaf lettuce)	○ 15	0.5	§ · IT		15	USA
Other composite vegetables	○ 15		IT		15	USA
Onion	○ 0.04		IT		0.04	USA
Welsh (including leek)	○ 2		IT		2.0	USA
Garlic	○ 0.04		IT		0.04	USA
Nira	○ 2		IT		2.0	USA
Other liliaceous vegetables	○ 2		IT		2.0	USA

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Parsley	○ 15		IT		15	USA
Tomato	○ 0.5	0.3	§ · IT		0.50	USA
Pimiento (sweet pepper)	○ 0.5		IT		0.50	USA
Egg plant	○ 0.5		IT		0.50	USA
Other solanaceous vegetables	○ 0.5		IT		0.50	USA
Cucumber (including gherkin)	○ 0.2	0.2	§			
Pumpkin (including squash)	○ 0.2		IT		0.20	USA
Water melon	○ 0.01		IT		0.20	USA
Melons	○ 0.01		IT		0.20	USA
Other cucurbitaceous vegetables	○ 0.2		IT		0.20	USA
Spinach	○ 15		IT		15	USA
Okra	○ 0.5		IT		0.50	USA
Peas, immature (with pods)	○ 1		IT		1.0	USA
Other vegetables	○ 15		IT		15	USA
Grape	○ 0.7	0.5	§ · IT		0.70	USA
Other fruits	○ 0.5		IT		0.50	USA
Other herbs	○ 15		IT		15	USA

Note: The residue definition is Oxathiapiprolin only.

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

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

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

§ : Permitted for use in Japan.

IT : Import tolerance

*Draft MRLs for watermelon and melon fruits are based on the US MRL of 0.2 ppm for cantaloupe (whole fruit) by applying a conversion factor (0.069) of residue concentration in whole fruit to that in pulp flesh.

Quinclorac

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Rice (brown rice)	○ 5	5				
Wheat	○ 0.5	0.5			0.5	USA
Barley	○ 2	2			2.0	USA
Other cereal grains	○ 0.8	0.8				
Blueberry	○ 2		IT		1.5	USA
Cranberry	○ 2		IT	1.5	1.5	USA
Other berries	○ 2		IT		1.5	USA
Sesame seeds	○ 2	2			1.5	USA
Rapeseeds	○ 2	2			1.5	USA
Other oil seeds	○ 2	2			1.5	USA
Other spices	○ 2	2			1.5	USA
Other herbs	○ 0.5		IT	0.5	0.5	USA
Cattle, muscle	○ 0.05	0.05			0.05	USA
Pig, muscle	○ 0.05	0.05			0.05	USA
Other terrestrial mammals, muscle	○ 0.05	0.05			0.05	USA
Cattle, fat	○ 0.7	0.7			0.7	USA
				Reference MRL		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Pig, fat	○ 0.7	0.7			0.7 USA
Other terrestrial mammals, fat	○ 0.7	0.7			0.7 USA
Cattle, liver	○ 2	2			1.5 USA
Pig, liver	○ 2	2			1.5 USA
Other terrestrial mammals, liver	○ 2	2			1.5 USA
Cattle, kidney	○ 2	2			1.5 USA
Pig, kidney	○ 2	2			1.5 USA
Other terrestrial mammals, kidney	○ 2	2			1.5 USA
Cattle, edible offal	○ 2	2			1.5 USA
Pig, edible offal	○ 2	2			1.5 USA
Other terrestrial mammals, edible offal	○ 2	2			1.5 USA
Milk	○ 0.05	0.05			0.05 USA
Chicken, muscle	○ 0.05	0.05			0.05 USA
Other poultry animals, muscle	○ 0.05	0.05			0.05 USA
Chicken, fat	○ 0.05	0.05			0.05 USA
Other poultry animals, fat	○ 0.05	0.05			0.05 USA
Chicken, liver	○ 0.05	0.05			
Other poultry animals, liver	○ 0.05	0.05			
	MRL	MRL		Reference MRL	

Commodity	(draft) ppm	(current) ppm	Registration	Codex ppm	National ppm	
Chicken, kidney	○ 0.05	0.05				
Other poultry animals, kidney	○ 0.05	0.05				
Chicken, edible offal	○ 0.05	0.05				
Other poultry animals, edible offal	○ 0.05	0.05				
Chicken, eggs	○ 0.05	0.05			0.05	USA
Other poultry, eggs	○ 0.05	0.05			0.05	USA

Note: The residue definition for agricultural products is sum of Quinclorac and metabolite C **【Methyl-3,7-dichloroquinoline-8-carboxylate】** , expressed as Quinclorac. The residue definition for animal products is Quinclorac only.

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

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

● : Commodities for which MRLs are to be lowered or deleted.

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

IT : Import tolerance

Clethodim

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Wheat	●	0.1			
Barley	●	0.1			
Corn (maize, including pop corn and sweet corn)	●	1			
Soybeans, dry	○ 10	10	§	10	
Beans, dry	○ 2	0.2	§	2	
Peas	○ 2	2		2	
Broad beans	○ 2	0.1		2	
Peanuts, dry	○ 5	5		5	
Other pulses	○ 2	0.5		2	
Potato	○ 0.5	0.2	§	0.5	
Taro	●	1			
Sweet potato	○ 0.3	0.2	§		
Yam	●	1			
Konjac	●	1			
Other potatoes	●	1			
Sugar beet	○ 0.1	0.1	§	0.1	
Japanese radish, roots (including radish)	○ 1	1	§		1.0 USA

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Japanese radish, leaves (including radish)	○ 1	0.9	§		1.0 USA
Turnip, roots (including rutabaga)	●	1			
Turnip, leaves (including rutabaga)	●	2			
Horseradish	●	1			
Watercress	●	1			
Chinese cabbage	●	2			
Cabbage	○ 0.3	0.2	§		
Brussels sprouts	●	0.2			
Kale	●	2			
Komatsuna(Japanese mustard spinach)	●	2			
Kyona	●	1			
Qing-geng-cai	●	3			
Cauliflower	●	2			
Broccoli	●	2			
Other cruciferous vegetables	●	2			
Burdock	●	1			
Salsify	●	1			
Artichoke	●	1			
Chicory	●	1			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Endive	●	0.5			
Shungiku	●	1			
Lettuce (including cos lettuce and leaf lettuce)	●	0.1			
Other composite vegetables	●	1			
Onion	○ 0.5	0.5	§	0.5	
Welsh (including leek)	● 0.2	1	§		
Garlic	○ 0.5	0.5	§	0.5	
Nira	●	0.1			
Asparagus	● 0.2	1	§		
Multiplying onion (including shallot)	●	0.2			
Other liliaceous vegetables	●	0.1			
Carrot	○ 0.1	0.1	§		
Parsnip	●	1			
Parsley	●	0.1			
Celery	●	0.1			
Other umbelliferous vegetables	●	1			
Tomato	○ 1	1		1	
Pimiento (sweet pepper)	○ 1	1			1.0 USA
Egg plant	●	1			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other solanaceous vegetables	•	1			
Cucumber (including gherkin)	•	0.5			
Pumpkin (including squash)	• 0.3	0.5	§		
Oriental pickling melon (vegetable)	•	0.5			
Water melon	•	1			
Melons	•	1			
Makuwauri melon	•	1			
Other cucurbitaceous vegetables	•	1			
Spinach	•	1			
Bamboo shoots	•	1			
Okra	•	1			
Ginger	•	1			
Peas, immature (with pods)	•	0.6			
Kidney beans, immature (with pods)	○ 0.5	0.5		0.5	
Green soybeans	• 2	6	§		
Button mushroom	•	1			
Shiitake mushroom	•	1			
Other mushrooms	•	1			
Other vegetables	○ 0.5	0.5	§	0.5	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Strawberry	•	2			
Cranberry	•	0.5			
Other fruits	•	0.6			
Sunflower seeds	○ 0.5	0.2	§	0.5	
Cotton seeds	○ 0.5	0.5		0.5	
Rapeseeds	○ 0.5	0.5		0.5	
Other oil seeds	•	0.2			
Almond	•	0.5			
Hop	○ 0.5		IT		0.5 USA
Other spices	•	1			
Other herbs	•	2			
Cattle, muscle	○ 0.2	0.2		0.2	
Pig, muscle	○ 0.2	0.2		0.2	
Other terrestrial mammals, muscle	○ 0.2	0.2		0.2	
Cattle, fat	○ 0.2	0.2		0.2	
Pig, fat	○ 0.2	0.2		0.2	
Other terrestrial mammals, fat	○ 0.2	0.2		0.2	
Cattle, liver	○ 0.2	0.2		0.2	
Pig, liver	○ 0.2	0.2		0.2	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other terrestrial mammals, liver	○ 0.2	0.2		0.2	
Cattle, kidney	○ 0.2	0.2		0.2	
Pig, kidney	○ 0.2	0.2		0.2	
Other terrestrial mammals, kidney	○ 0.2	0.2		0.2	
Cattle, edible offal	○ 0.2	0.2		0.2	
Pig, edible offal	○ 0.2	0.2		0.2	
Other terrestrial mammals, edible offal	○ 0.2	0.2		0.2	
Milk	○ 0.05	0.05		0.05	
Chicken, muscle	○ 0.2	0.2		0.2	
Other poultry animals, muscle	○ 0.2	0.2		0.2	
Chicken, fat	○ 0.2	0.2		0.2	
Other poultry animals, fat	○ 0.2	0.2		0.2	
Chicken, liver	○ 0.2	0.2		0.2	
Other poultry animals, liver	○ 0.2	0.2		0.2	
Chicken, kidney	○ 0.2	0.2		0.2	
Other poultry animals, kidney	○ 0.2	0.2		0.2	
Chicken, edible offal	○ 0.2	0.2		0.2	
Other poultry animals, edible offal	○ 0.2	0.2		0.2	
Chicken, eggs	○ 0.05	0.05		0.05	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other poultry, eggs	○ 0.05	0.05		0.05	
Soybean oil, (limited to edible soybean oil that meets the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	●	0.5		0.5	
Soybean oil (except edible soybean oil that meets the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	●	1			
Sunflower oil, (except 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)	●	0.1		0.1	
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)		0.5		0.5	
Cottonseed oil (except 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)		0.5			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cottonseed oil	○ 0.5				
Rapeseed oils, (limited to refined rapeseed oil and rapeseed 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)		0.5		0.5	
Rapeseed oils, crude (except refined rapeseed oil and rapeseed 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)		0.5			
Rapeseed oils	○ 0.5				

Note: The residue definition will be changed to the sum of Clethodim and its metabolites which are oxidized with m-chloroperoxybenzoic acid to Clethodim sulfoxide **【(±)-2-[(EZ)-1-[(E)-3-Chloroallyloxyimino]propyl]-5-[2-(ethylsulphonyl)propyl]-3-hydroxycyclohex-2-en】** and metabolite O **【(±)-2-[(EZ)-1-[(E)-3-Chloroallyloxyimino]propyl]-5-[2-(ethylsulphonyl)propyl]-3,5-dihydroxycyclohex-2-en】**, expressed as Clethodim. The current residue definition is sum of Clethodim, Clethodim sulfoxide and Clethodim sulfon, expressed as Clethodim.

* 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.

* Items with diagonal lines drawn represent foods deleted since the food categories are reorganized. For example, several kinds of cottonseed oil (edible vegetable oil and refined cotton seed oil in Japan Agriculture Standards) are integrated into cottonseed oil.

● : Commodities for which MRLs are to be lowered or deleted.

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

§ : Permitted for use in Japan.

IT : Import tolerance

For soybean oil and sunflower oil, the MRLs of their raw commodities (soybean and sunflower seeds, respectively) will be applied taking into account each processing factor.

JMPR estimated their processing factors as following: 0.1 for soybean oil and 0.2 for sunflower seeds.

Clofentezine

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)	•	0.05			
Buckwheat	•	0.02			
Other cereal grains	•	0.02			
Soybeans, dry	•	0.05			
Beans, dry	•	0.2			
Peas	•	0.02			
Broad beans	•	0.02			
Peanuts, dry	•	0.05			
Other pulses	•	0.02			
Potato	•	0.02			
Taro	•	0.02			
Sweet potato	•	0.02			
Yam	•	0.02			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Konjac	•	0.02			
Other potatoes	•	0.02			
Sugar beet	•	0.05			
Sugarcane	•	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			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
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			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Celery	•	0.02			
Mitsuba	•	0.02			
Other umbelliferous vegetables	•	0.02			
Tomato	• 0.5	1.0		0.5	
Pimiento (sweet pepper)	•	0.2			
Egg plant	•	1.0			
Other solanaceous vegetables	•	0.02			
Cucumber (including gherkin)	• 0.5	1.0		0.5	
Pumpkin (including squash)	•	0.2			
Oriental pickling melon (vegetable)	•	0.02			
Water melon	•	0.05			
Melons	• 0.05	0.2			
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			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Kidney beans, immature (with pods)	●	0.02			
Green soybeans	●	0.04			
Button mushroom	●	0.02			
Shiitake mushroom	●	0.02			
Other mushrooms	●	0.02			
Other vegetables	●	0.02			
Unshu orange, pulp	●	1.0			
Citrus natsudaidai, whole	○ 0.5	0.5		0.5	
Lemon	○ 0.5	0.5		0.5	
Orange (including navel orange)	○ 0.5	0.5		0.5	
Grapefruit	○ 0.5	0.5		0.5	
Lime	○ 0.5	0.5		0.5	
Other citrus fruits	○ 0.5	0.5		0.5	
Apple	○ 1	1.0	§	0.5	
Japanese pear	○ 0.7	0.5	§	0.5	
Pear	○ 0.7	0.5	§	0.5	
Quince	○ 0.5	0.5		0.5	
Loquat	○ 0.5	0.5		0.5	
Peach	○ 0.2	0.2	§		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Nectarine	○ 0.5	0.2		0.5	
Apricot	○ 0.5	0.2		0.5	
Japanese plum (including prune)	○ 0.5	0.2		0.5	
Mume plum	○ 0.5	0.2		0.5	
Cherry	○ 0.5	0.2	§	0.5	
Strawberry	○ 2	2.0		2	
Raspberry	●	2.0			
Blackberry	●	2.0			
Blueberry	●	2.0			
Cranberry	●	2.0			
Huckleberry	●	2.0			
Other berries	● 0.2	2.0		0.2	
Grape	○ 2	1.0		2	
Japanese persimmon	○ 0.05	0.04			0.05 USA
Banana	○ 2	0.01	IT		2 EU
Kiwifruit	●	0.02			
Papaya	●	0.02			
Avocado	●	0.02			
Pineapple	●	0.02			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Guava	●	0.02			
Mango	●	0.02			
Passion fruit	●	0.02			
Date	●	0.02			
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	○ 0.5	0.05		0.5	
Pecan	○ 0.5	0.05		0.5	
Almond	○ 0.5	0.5		0.5	
Walnut	○ 0.5	0.02		0.5	
Other nuts	○ 0.5	0.05		0.5	
Tea	○ 20	20	§		
Coffee beans	●	0.02			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cacao beans	●	0.02			
Hop	●	0.2			
Other spices	●	1			
Other herbs	●	0.02			
Cattle, muscle	○ 0.05	0.05		0.05	
Pig, muscle	○ 0.05	0.05		0.05	
Other terrestrial mammals, muscle	○ 0.05	0.05		0.05	
Cattle, fat	○ 0.05	0.05		0.05	
Pig, fat	○ 0.05	0.05		0.05	
Other terrestrial mammals, fat	○ 0.05	0.05		0.05	
Cattle, liver	● 0.05	0.1		0.05	
Pig, liver	● 0.05	0.2		0.05	
Other terrestrial mammals, liver	● 0.05	0.2		0.05	
Cattle, kidney	● 0.05	0.1		0.05	
Pig, kidney	○ 0.05	0.05		0.05	
Other terrestrial mammals, kidney	○ 0.05	0.05		0.05	
Cattle, edible offal	● 0.05	0.1		0.05	
Pig, edible offal	○ 0.05	0.05		0.05	
Other terrestrial mammals, edible offal	○ 0.05	0.05		0.05	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Milk	○ 0.05	0.01		0.05	
Chicken, muscle	○ 0.05	0.05		0.05	
Other poultry animals, muscle	○ 0.05	0.05		0.05	
Chicken, fat	○ 0.05	0.05		0.05	
Other poultry animals, fat	○ 0.05	0.05		0.05	
Chicken, liver	○ 0.05	0.05		0.05	
Other poultry animals, liver	○ 0.05	0.05		0.05	
Chicken, kidney	○ 0.05	0.05		0.05	
Other poultry animals, kidney	○ 0.05	0.05		0.05	
Chicken, edible offal	○ 0.05	0.05		0.05	
Other poultry animals, edible offal	○ 0.05	0.05		0.05	
Chicken, eggs	○ 0.05	0.05		0.05	
Other poultry, eggs	○ 0.05	0.05		0.05	

The residue definition for agricultural products is Clofentezine only. The residue definition for animal products will be changed to sum of Clofentezine and all metabolite converted to 2-clorobenzoic acid, expressed as Clofentezine.

The current residue definition for agricultural and animal products are Clofentezine 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 are to be lowered or deleted.

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

§ : Permitted for use in Japan.

IT : Import tolerance

Fludioxonil

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	○ 0.05	0.05	§		
Wheat	○ 0.05	0.05		0.05	
Barley	○ 0.05	0.05		0.05	
Rye	○ 0.05	0.05		0.05	
Corn (maize, including pop corn and sweet corn)	○ 0.05	0.05		0.05	
Buckwheat	○ 0.05	0.05		0.05	
Other cereal grains	○ 0.05	0.05		0.05	
Soybeans, dry	○ 0.5	0.07	§	0.5	
Beans, dry	○ 0.5	0.4	§	0.5	
Peas	● 0.07	0.3		0.07	
Broad beans	○ 0.5	0.4		0.5	
Peanuts, dry	●	0.3			
Other pulses	○ 0.5	0.4		0.5	
Potato	○ 0.02	0.02	§		
Taro	○ 0.02	0.02			
Other potatoes	○ 0.02	0.02			
Japanese radish, roots (including radish)	○ 0.5	0.5		0.3	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Japanese radish, leaves (including radish)	○ 20	20		20	
Turnip, roots (including rutabaga)	○ 0.5	0.5			
Turnip, leaves (including rutabaga)	○ 20	20			
Horseradish	○ 0.5	0.5			
Watercress	○ 10	10		10	
Chinese cabbage	○ 2	2			2.0 USA
Cabbage	○ 2	2	§	2	
Brussels sprouts	○ 2	2			2.0 USA
Kale	○ 10	10			10 USA
Komatsuna(Japanese mustard spinach)	○ 10	10			10 USA
Kyona	○ 10	10			10 USA
Qing-geng-cai	○ 10	10			10 USA
Cauliflower	○ 2	2			2.0 USA
Broccoli	○ 2	2		0.7	2.0 USA
Other cruciferous vegetables	○ 10	10		10	
Burdock	○ 0.5	0.5			
Salsify	○ 0.5	0.5			
Chicory	○ 30	20		30	
Endive	○ 30	30			30 USA

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Shungiku	○ 30	30			30	USA
Lettuce (including cos lettuce and leaf lettuce)	○ 40	30		40		
Other composite vegetables	○ 30	2	§ · IT	9	30	USA
Onion	○ 0.5	0.5	§	0.5		
Welsh (including leek)	○ 7	7	§		7.0	USA
Garlic	○ 0.2	0.2	§			
Nira	○ 10	10	§	9		
Multiplying onion (including shallot)	○ 0.2	0.2				
Other liliaceous vegetables	○ 10	10	§	10		
Carrot	○ 5	5	§	0.7		
Parsnip	○ 0.5	0.5				
Parsley	○ 10	10		9		
Other umbelliferous vegetables	○ 20	20		9		
Tomato	○ 5	5	§			
Pimiento (sweet pepper)	○ 5	5	§	1		
Egg plant	○ 1	1	§	0.3		
Other solanaceous vegetables	○ 1	0.5		1		
Cucumber (including gherkin)	○ 2	2	§	0.5		
Pumpkin (including squash)	○ 0.5	0.3		0.5		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Oriental pickling melon (vegetable)	○ 0.5	0.5		0.5		
Water melon	○ 0.2	0.2	§			
Melons	○ 0.1	0.1	§			
Other cucurbitaceous vegetables	○ 0.5	0.5		0.5		
Spinach	○ 30	0.02	§	30		
Ginger	○ 0.02	0.02				
Peas, immature (with pods)	○ 5	5	§	0.6		
Kidney beans, immature (with pods)	○ 5	5	§	0.6		
Green soybeans	○ 5	5	§			
Other vegetables	○ 10	10	§	9		
Unshu orange, pulp	○ 0.1	0.1	§			
Citrus natsudaidai, whole	○ 10	10	§	10	10	USA
Lemon	○ 10	10	§	10	10	USA
Orange (including navel orange)	○ 10	10	§	10	10	USA
Grapefruit	○ 10	10	§	10	10	USA
Lime	○ 10	10	§	10	10	USA
Other citrus fruits	○ 10	10	§	10	10	USA
Apple (including base of flower, shin and fruit)	○ 5	5.0		5	5.0	USA
Pear (including base of flower, shin and fruit)	○ 5	5.0		5	5.0	USA

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Quince (including base of flower, shin and fruit)	○ 5	5.0		5	5.0	USA
Loquat (including fruit, pericarp and seed)	○ 5	5.0		5	5.0	USA
Peach (including pericarp)	○ 5	5.0		5	5.0	USA
Nectarine (including fruit flowers)	○ 5	5.0		5	5.0	USA
Apricot (including fruit flowers)	○ 5	5.0		5	5.0	USA
Japanese plum (including prune and fruit flowers)	○ 5	5.0		5	5.0	USA
Mume plum	○ 0.5	0.5	§			
Cherry (including fruit flowers)	○ 5	5.0		5	5.0	USA
Strawberry	○ 5	5	§	3		
Raspberry	○ 5	5		5		
Blackberry	○ 5	5		5		
Blueberry	○ 2	2		2		
Huckleberry	○ 2	2			2.0	USA
Other berries	○ 5	5		5		
Grape	○ 5	5	§ • Request	2		
Kiwifruit (including pericarp)	○ 20	20			20	USA
Avocado	○ 0.4			0.4		
Other fruits	○ 5	5.0		2	5.0	USA
Sunflower seeds	○ 0.01	0.01		0.01		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cotton seeds	○ 0.05	0.05		0.05	
Rapeseeds	○ 0.02	0.02		0.02	
Other oil seeds	○ 0.05	0.05			0.05 USA
Other nuts	○ 0.2	0.2		0.2	
Other spices	○ 10	10	§		
Other herbs	● 40	50	§	9	
Cattle, muscle	○ 0.01	0.01		0.01	
Pig, muscle	○ 0.01	0.01		0.01	
Other terrestrial mammals, muscle	○ 0.01	0.01		0.01	
Cattle, fat	○ 0.05	0.05		0.05	
Pig, fat	○ 0.05	0.05		0.05	
Other terrestrial mammals, fat	○ 0.05	0.05		0.05	
Cattle, liver	○ 0.05	0.05		0.05	
Pig, liver	○ 0.05	0.05		0.05	
Other terrestrial mammals, liver	○ 0.05	0.05		0.05	
Cattle, kidney	○ 0.05	0.05		0.05	
Pig, kidney	○ 0.05	0.05		0.05	
Other terrestrial mammals, kidney	○ 0.05	0.05		0.05	
Cattle, edible offal	○ 0.05	0.05		0.05	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Pig, edible offal	○ 0.05	0.05		0.05	
Other terrestrial mammals, edible offal	○ 0.05	0.05		0.05	
Milk	○ 0.01	0.01		0.01	
Chicken, muscle	○ 0.01	0.01		0.01	
Other poultry animals, muscle	○ 0.01	0.01		0.01	
Chicken, fat	○ 0.05	0.05		0.05	
Other poultry animals, fat	○ 0.05	0.05		0.05	
Chicken, liver	○ 0.05	0.05		0.05	
Other poultry animals, liver	○ 0.05	0.05		0.05	
Chicken, kidney	○ 0.05	0.05		0.05	
Other poultry animals, kidney	○ 0.05	0.05		0.05	
Chicken, edible offal	○ 0.05	0.05		0.05	
Other poultry animals, edible offal	○ 0.05	0.05		0.05	
Chicken, eggs	● 0.01	0.05		0.01	
Other poultry, eggs	● 0.01	0.05		0.01	
Fish	○ 0.04		Request		
NIRA, dried	●	50			
Basil, dried	●	50			

The residue definition for agricultural products and aquatic products is Fludioxonil only.

The residue definition for animal products is sum of Fludioxonil and Benzopyrrole metabolite which is transformed to metabolite K **【2,2-Difluoro-1,3-benzodioxol-4-carboxylic acid】** expressed as Fludioxonil.

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

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

● : Commodities for which MRLs are to be lowered or deleted.

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

§ : Permitted for use in Japan.

Request : The MRL was modified in response to MAFF request

IT : Import tolerance

Prohexadione-calcium

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	○ 0.2	0.2	§		
Wheat	○ 0.5	0.5	§		
Barley	● 0.1	0.2	§		
Rye	● 0.1	0.2			0.1 EU
Corn (maize, including pop corn and sweet corn)	●	0.2			
Buckwheat	●	0.2			
Other cereal grains	● 0.1	0.2			0.1 EU
Soybeans, dry	●	0.1			
Beans, dry	●	0.05			
Peas	●	0.05			
Broad beans	●	0.05			
Peanuts, dry	○ 1	0.6			1.0 USA
Other pulses	●	0.05			
Potato	●	0.05			
Taro	●	0.05			
Sweet potato	●	0.05			
Yam	●	0.05			
Konjac	●	0.05			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other potatoes	●	0.05			
Sugar beet	●	0.05			
Sugarcane	●	0.02			
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	●	0.2			
Cabbage	○ 0.2	0.2	§		
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			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
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			
Carrot	•	0.05			
Parsnip	•	0.05			
Parsley	•	0.05			
Celery	•	0.05			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
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			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
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	○ 3	2			3.0 USA
Japanese pear	○ 3	2	§		3.0 USA
Pear	○ 3	2			3.0 USA
Quince	●	2			
Loquat	●	2			
Peach	●	0.05			
Nectarine	●	0.05			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Apricot	•	2			
Japanese plum (including prune)	•	2			
Mume plum	•	2			
Cherry	• 0.4	2			0.40 USA
Strawberry	○ 2	2	§		
Raspberry	•	2			
Blackberry	•	2			
Blueberry	•	2			
Cranberry	•	2			
Huckleberry	•	2			
Other berries	•	2			
Grape	•	2			
Japanese persimmon	•	0.05			
Banana	•	0.05			
Kiwifruit	•	0.05			
Papaya	•	0.05			
Avocado	•	0.05			
Pineapple	•	0.05			
Guava	•	0.05			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Mango	•	0.05			
Passion fruit	•	0.05			
Date	•	2			
Other fruits	•	2			
Sunflower seeds	•	0.1			
Sesame seeds	•	0.1			
Safflower seeds	•	0.1			
Cotton seeds	•	0.1			
Rapeseeds	•	0.1			
Other oil seeds	•	0.1			
Ginkgo nut	•	0.05			
Chestnut	•	0.05			
Pecan	•	0.05			
Almond	•	0.05			
Walnut	•	0.05			
Other nuts	•	0.05			
Tea	•	0.1			
Coffee beans	•	0.02			
Cacao beans	•	0.02			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Hop	●	0.1			
Other spices	●	2			
Other herbs	●	0.05			
Cattle, muscle	● 0.01	0.05			
Pig, muscle	● 0.01	0.05			
Other terrestrial mammals, muscle	● 0.01	0.05			
Cattle, fat	○ 0.05	0.05		0.05	USA
Pig, fat	○ 0.05	0.05		0.05	USA
Other terrestrial mammals, fat	○ 0.05	0.05		0.05	USA
Cattle, liver	○ 0.05	0.05		0.05	USA
Pig, liver	○ 0.05	0.05		0.05	USA
Other terrestrial mammals, liver	○ 0.05	0.05		0.05	USA
Cattle, kidney	○ 0.1	0.08		0.10	USA
Pig, kidney	○ 0.1	0.08		0.10	USA
Other terrestrial mammals, kidney	○ 0.1	0.08		0.10	USA
Cattle, edible offal	○ 0.05	0.05		0.05	USA
Pig, edible offal	○ 0.05	0.05		0.05	USA
Other terrestrial mammals, edible offal	○ 0.05	0.05		0.05	USA
Milk	○ 0.01	0.01			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
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			
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			

Note: The residue definition is sum of Prohexadione calcium and its free form, Prohexadione (acid), expressed as Prohexadione calcium. The current residue definition is Prohexadione calcium salt, expressed as Prohexadione.

* 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 are to be lowered or deleted.

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

§ : Permitted for use in Japan.

Abamectin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Soybeans, dry	○ 0.005			0.005		
Beans, dry	○ 0.005			0.005		
Peanuts, dry	○ 0.005			0.005		
Other pulses	○ 0.005			0.005		
Potato	○ 0.01	0.01		0.005	0.01	USA
Taro	○ 0.01	0.01			0.01	USA
Sweet potato	○ 0.01	0.01		0.005	0.01	USA
Yam	○ 0.01	0.01		0.005	0.01	USA
Other potatoes	○ 0.01	0.01			0.01	USA
Lettuce (including cos lettuce and leaf lettuce)	○ 0.2	0.05	IT	0.15	0.1	USA
Onion	○ 0.005			0.005		
Welsh (including leek)	○ 0.1	0.1	§	0.005		
Garlic	○ 0.005			0.005		
Celery	○ 0.03			0.03		
Other umbelliferous vegetables	○ 0.05	0.05			0.05	USA
Tomato	○ 0.3	0.02	Request	0.05		
Pimiento (sweet pepper)	○ 0.5	0.5	§	0.09		
Egg plant	○ 0.2	0.2	§	0.05		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Other solanaceous vegetables	○ 0.2	0.2		0.005	0.2	Korea
Cucumber (including gherkin)	○ 0.2	0.01	Request	0.03		
Pumpkin (including squash)	○	0.01				
Water melon	○ 0.05	0.05	§			
Melons	○ 0.05	0.05	§			
Other cucurbitaceous vegetables	○ 0.01	0.01			0.01	USA
Ginger	○ 0.01	0.01			0.01	USA
Kidney beans, immature (with pods)	○ 0.08			0.08		
Other vegetables	○ 0.08	0.01		0.08		
Unshu orange, pulp	○ 0.02		Request			
Citrus natsudaidai, whole	○ 0.1	0.01	Request	0.02		
Lemon	○ 0.1	0.01	Request	0.02		
Orange (including navel orange)	○ 0.1	0.01	Request	0.02		
Grapefruit	○ 0.1	0.01	Request	0.02		
Lime	○ 0.1	0.01	Request	0.02		
Other citrus fruits	○ 0.1	0.01	Request	0.02		
Apple	○ 0.02	0.02		0.01	0.02	USA
Japanese pear	○ 0.02	0.02		0.01	0.02	USA
Pear	○ 0.02	0.02		0.01	0.02	USA

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Quince	○ 0.01			0.01		
Nectarine	○ 0.09	0.09		0.03	0.09	USA
Apricot	○ 0.09	0.09		0.03	0.09	USA
Japanese plum (including prune)	○ 0.09	0.09		0.005	0.09	USA
Cherry	○ 0.09	0.09		0.07	0.09	USA
Strawberry	○ 0.2	0.02	IT	0.15	0.15	EU
Raspberry	○ 0.05			0.05		
Blackberry	○ 0.05			0.05		
Grape	○ 0.02		IT	0.01	0.02	USA
Papaya	○ 0.02			0.015		
Avocado	○ 0.02			0.015		
Mango	○ 0.01			0.01		
Other fruits	○ 0.005			0.005		
Cotton seeds	○ 0.02	0.01		0.015		
Ginkgo nut	○ 0.005			0.005		
Chestnut	○ 0.01	0.01		0.005	0.01	USA
Pecan	○ 0.01	0.01		0.005	0.01	USA
Almond	○ 0.01	0.01		0.005	0.01	USA
Walnut	○ 0.01	0.01		0.005	0.01	USA

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Other nuts	○ 0.01	0.01		0.005	0.01	USA
Tea	○ 1	1	§			
Hop	○ 0.2	0.2		0.15		
Other spices	○ 1		Request	0.02		
Other herbs	○ 0.03	0.03		0.005	0.03	USA
Cattle, muscle	○ 0.02	0.01			0.02	USA
Pig, muscle	○ 0.02				0.02	Australia
Other terrestrial mammals, muscle	○	0.01				
Cattle, fat	○ 0.1	0.1		0.1		
Pig, fat	○ 0.02	0.02			0.02	Australia
Other terrestrial mammals, fat	○	0.01				
Cattle, liver	○ 0.1	0.1		0.1		
Pig, liver	○ 0.02	0.02			0.02	Australia
Other terrestrial mammals, liver	●	0.1				
Cattle, kidney	○ 0.06	0.06		0.05	0.06	USA
Pig, kidney	○ 0.01	0.01			0.01	Australia
Other terrestrial mammals, kidney	●	0.1				
	MRL	MRL		Reference MRL		

Commodity	(draft) ppm	(current) ppm	Registration	Codex ppm	National ppm	
Cattle, edible offal	○ 0.06	0.06			0.06	USA
Pig, edible offal	○ 0.02	0.02			0.02	USA
Other terrestrial mammals, edible offal	●	0.1				
Milk	○ 0.02	0.02			0.02	Australia
Pepper, dried	○ 0.5	0.2		0.5		

Note: The residue definition is sum of Abamectin B1a, Abamectin B1b and metabolite b【8,9-Z- Abamectin B1a】expressed as Abamectin.

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

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

● : Commodities for which MRLs are to be lowered or deleted.

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

§ : Permitted for use in Japan.

Request : The MRL was modified in response to MAFF request

IT : Import tolerance

Spiramycin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cattle, muscle	○ 0.2	0.2		0.2	
Pig, muscle	○ 0.2	0.2		0.2	
Cattle, fat	○ 0.3	0.3		0.3	
Pig, fat	○ 0.3	0.3		0.3	
Cattle, liver	○ 0.6	0.6		0.6	
Pig, liver	○ 0.6	0.6		0.6	
Cattle, kidney	○ 0.3	0.3		0.3	
Pig, kidney	○ 0.3	0.3		0.3	
Cattle, edible offal	○ 0.6	0.1			
Pig, edible offal	● 0.6	1			
Milk	○ 0.2	0.2		0.2	
Chicken, muscle	○ 0.2	0.2		0.2	
Other poultry, muscle	●	0.1			
Chicken, fat	○ 0.3	0.3		0.3	
Other poultry, fat	●	0.1			
Chicken, liver	○ 0.6	0.6		0.6	
Other poultry, liver	●	1			
Chicken, kidney	○ 0.8	0.8		0.8	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other poultry, kidney	●	1			
Chicken, edible offal	● 0.8	1			
Other poultry, edible offal	●	1			
Fish	●	0.2			
Perciformes (such as bonito, horse mackerel, mackerel, sea bass, sea bream and tuna)	○ 0.2		§		

Note: The residue definition will be changed to the sum of Spiramycin I and Neospiramycin I, expressed as Spiramycin I. The current residue definition is “the sum of Spiramycin, antimicrobially equivalent to Spiramycin I, and its metabolites, expressed as Spiramycin I” for swine, and “the sum of Spiramycin I and Neospiramycin I, expressed as Spiramycin I” for foods except for swine.

* The compound shall not be included in any commodity for which the MRL is not given in the above table and in any commodity 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 are to be lowered or deleted.

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

§ : Permitted for use in Japan.

Tylosin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cattle, muscle	○ 0.1	0.1	§	0.1	
Pig, muscle	○ 0.1	0.1	§	0.1	
Other terrestrial mammals, muscle	○ 0.1	0.1		0.1	
Cattle, fat	○ 0.1	0.1	§	0.1	
Pig, fat	○ 0.1	0.1	§	0.1	
Other terrestrial mammals, fat	○ 0.1	0.1			
Cattle, liver	○ 0.1	0.1	§	0.1	
Pig, liver	○ 0.1	0.1	§	0.1	
Other terrestrial mammals, liver	○ 0.1	0.1		0.1	
Cattle, kidney	○ 0.1	0.1	§	0.1	
Pig, kidney	○ 0.1	0.1	§	0.1	
Other terrestrial mammals, kidney	○ 0.1	0.1		0.1	
Cattle, edible offal	○ 0.1	0.1	§		
Pig, edible offal	○ 0.1	0.1	§		
Other terrestrial mammals, edible offal	○ 0.1	0.1			
Milk	○ 0.1	0.1	§	0.1	
Chicken, muscle	○ 0.1	0.1	§	0.1	
Chicken, fat	○ 0.1	0.1	§	0.1	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Chicken, liver	○ 0.1	0.1	§	0.1		
Chicken, kidney	○ 0.1	0.1	§	0.1		
Chicken, edible offal	○ 0.1	0.1	§			
Chicken eggs	○ 0.3	0.3		0.3		
Honey (including royal-jelly)	○ 0.2		IT		0.2	Canada

Note: The residue definition is "the sum of Tylosin A and Tylosin B, expressed as Tylosin A" for honey, and "Tylosin A" for foods excluding honey.

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

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

● : Commodities for which MRLs are to be lowered or deleted.

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

§ : Permitted for use in Japan.

IT : Import tolerance

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, pimiento (sweet pepper), and egg plant.

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

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

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

“Other citrus fruits” refers to all citrus fruits, except unshu orange (pulp), citrus natsudaïdai (pulp), citrus natsudaïdai (peel), citrus natsudaïdai (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.

Item 2. Establishment of Analytical Methods for Agricultural and Veterinary Chemicals in Food

MHLW notifies analytical methods for certain agricultural and veterinary chemicals in the Ministry of Health and Welfare Notification No. 370. The Food Sanitation Act stipulates that any ingredients of agricultural chemicals or other chemical substances shall not be detected by the methods.

MHLW is going to revise the following analytical methods in the Notification No. 370:

- Analytical Method for 2,4,5-T
- Analytical Method for Daminozide
- Analytical Method for Malachite Green

Notification (draft)
Analytical Method for 2, 4, 5-T
(Targeted to Agricultural, Animal and Fishery Products)

The target compound to be determined is 2, 4, 5-T.

1. Instrument

Liquid Chromatograph-tandem mass spectrometer (LC-MS/MS)

2. Reagents

Use the reagents listed in Section C *Reagents/Test Solutions, Etc.*, Part II *Food Additives*, except the following.

Acetonitrile: Use a reagent not containing any substance that may interfere with the analysis of the target compound.

Acetone: Use a reagent not containing any substance that may interfere with the analysis of the target compound.

Ether: Diethyl ether. Use a reagent not containing any substance that may interfere with the analysis of the target compound.

Octadecylsilanized silica gel column (1,000 mg): A polyethylene tube of 12-13 mm in inside diameter packed with 1,000 mg of octadecylsilanized silica gel, or a cartridge equivalent to the specified one in separation capability.

Graphitized carbon black/ethylenediamine-*N*-propylsilanized silica gel layered cartridge (500 mg/500 mg): A polyethylene tube of 12-13 mm in inside diameter packed with 500 mg of graphitized carbon black in the upper layer and 500 mg of ethylenediamine-*N*-propylsilanized silica gel in the lower layer, or a cartridge equivalent to the specified one in separation capability.

Ethyl acetate: Use a reagent not containing any substance that may interfere with the analysis of the target compound.

Toluene: Use a reagent not containing any substance that may interfere with the analysis of the target compound.

n-Hexane: Use a reagent not containing any substance that may interfere with the analysis of the target compound.

Water: Use water suitable for chemical analysis, including distilled water, purified water, or pure water. If it contains any substance that may interfere with the analysis of the target compound, wash with a solvent such as *n*-hexane before use.

Sodium sulfate (anhydrous): Use a reagent not containing any substance that may interfere with the analysis of the target compound.

Methanol: Use a reagent not containing any substance that may interfere with the analysis of the target compound.

3. Reference standard

Reference standard of 2,4,5-T : Contains not less than 98% of 2,4,5-T.

4. Procedure

a. Extraction

i. Grains, legumes, nuts and seeds

Add 20 mL of water to 10.0 g of sample, and let stand for 30 minutes. Add 5 mL of 4 mol/L hydrochloric acid and 100 mL of acetone, homogenize, and filter with suction. Add 50 mL of acetone to the residue on the filter paper, homogenize, and treat as described above. Combine the resulting filtrates, and add acetone to make exactly 200 mL.

Take exactly a 10 mL aliquot of the solution, add 100 mL of 10 w/v% sodium chloride solution, and extract with shaking twice with 100 mL and 50 mL of ethyl acetate/*n*-hexane (1:1, v/v). Combine the extracts, dehydrate with sodium sulfate (anhydrous), filter out the sodium sulfate (anhydrous), concentrate the filtrate at below 40°C, and remove the solvent.

Add 30 mL of *n*-hexane to the residue, and extract with shaking three times with 30 mL of acetonitrile/water (99:1, v/v). Combine the extracts, concentrate at below 40°C and remove the solvent.

ii. Fruits and vegetables

Add 5 mL of 4 mol/L hydrochloric acid and 100 mL of acetone to 20.0 g of sample, homogenize, and filter with suction. Add 50 mL of acetone to the residue on the filter paper, homogenize, and filter as described above. Combine the resulting filtrates, and add acetone to make exactly 200 mL.

Take exactly a 5 mL aliquot of the solution, add 100 mL of 10 w/v% sodium chloride solution, and extract with shaking twice with 100 mL and 50 mL of ethyl acetate/*n*-hexane (1:1, v/v). Combine the extracts, dehydrate with sodium sulfate (anhydrous), filter out the sodium sulfate (anhydrous), concentrate the filtrate at below 40°C, and remove the solvent.

iii. Tea and hops

Add 20 mL of water to 5.00 g of the sample, and let stand for 30 minutes. Add 5 mL of 4 mol/L hydrochloric acid and 100 mL of acetone, homogenize, and filter with suction. Add 50 mL of acetone to the residue on the filter paper, homogenize, and filter as described above. Combine the resulting filtrates, and add acetone to make exactly 200 mL.

Take exactly a 10 mL aliquot of the solution, add 100 mL of 10 w/v% sodium chloride solution, and extract with shaking twice with 100 mL and 50 mL of ethyl acetate/*n*-hexane (1:1, v/v). Combine the extracts, dehydrate with sodium sulfate (anhydrous), filter out the sodium sulfate (anhydrous), concentrate the filtrate at below 40°C, and remove the solvent.

Add 30 mL of *n*-hexane to the residue, and extract with shaking three times with 30 mL of acetonitrile/water (99:1, v/v). Combine the extracts, concentrate at below 40°C, and remove the solvent.

iv. Muscle, liver, kidney, milk, egg and fish/shellfish

Add 5 mL of 4 mol/L hydrochloric acid and 100 mL of acetone to 10.0 g of sample, homogenize, and filter with suction. Add 50 mL of acetone to the residue on the filter paper, homogenize, and treat as described above. Combine the resulting filtrates, and add acetone to make exactly 200 mL.

Take exactly a 10 mL aliquot of the solution, add 100 mL of 10 w/v% sodium chloride solution, and extract with shaking twice with 100 mL and 50 mL of ethyl acetate/*n*-hexane (1:1, v/v). Combine the extracts, dehydrate with sodium sulfate (anhydrous), filter out the sodium sulfate (anhydrous), concentrate the filtrate at below 40°C, and remove the solvent.

Add 30 mL of *n*-hexane to the residue, and extract with shaking three times with 30 mL of acetonitrile/water (99:1, v/v). Combine the extracts, concentrate at below 40°C, and remove the solvent.

v. Fat

Add 5 mL of 4 mol/L hydrochloric acid and 100 mL of acetone to 5.00 g of sample, homogenize, and filter with suction. Add 50 mL of acetone to the residue on the filter paper, homogenize, and filter as described above. Combine the resulting filtrates, and add acetone to make exactly 200 mL.

Take exactly a 20 mL aliquot of the solution, add 100 mL of 10 w/v% sodium chloride solution, and extract with shaking twice with 100 mL and 50 mL of ethyl acetate/*n*-hexane (1:1, v/v). Combine the extracts, dehydrate with sodium sulfate (anhydrous), filter out the sodium sulfate (anhydrous), concentrate the filtrate at below 40°C, and remove the solvent.

Add 30 mL of *n*-hexane to the residue, and extract with shaking three times with 30 mL acetonitrile/water (99:1, v/v). Combine the extracts, concentrate at below 40°C, and remove the solvent.

vi. Honey

Dissolve 10.0 g of sample in 20 mL of water. Add 5 mL of 4 mol/L hydrochloric acid and 100 mL of acetone, homogenize, and filter with suction. Add 50 mL of acetone to the residue on the filter paper, homogenize, and filter as described above. Combine the resulting filtrates, and add acetone to make exactly 200 mL.

Take exactly a 10 mL aliquot of the solution, add 100 mL of 10 w/v% sodium chloride solution, extract with shaking twice with 100 mL and 50 mL of ethyl acetate/*n*-hexane (1:1, v/v). Combine the extracts, dehydrate with sodium sulfate (anhydrous), filter out the sodium sulfate (anhydrous), concentrate the filtrate at below 40°C, and remove the solvent.

b. Hydrolysis

Dissolve the residue obtained in “a. Extraction” in 2 mL of methanol, add 1 mL of a 1.5 mol/L sodium hydroxide solution. Attach a reflux condenser to the flask, heat at 80°C for 30 minutes in a water bath, and allowed to cool. Add 1.5 mol/L hydrochloric acid to adjust pH 7.5 - 8.0, then add 16 mL of 0.1 w/v% sodium hydrogen carbonate solution.

c. Clean-up

i. Octadecylsilanized silica gel column chromatography

Add 10 mL each of methanol and water to an octadecylsilanized silica gel cartridge (1,000 mg) sequentially, and discard the effluents. Transfer the solution obtained in “b. Hydrolysis” to the cartridge

and discard the effluent. Elute with 20 mL of 0.1 w/v% sodium hydrogen carbonate/methanol (1:1, v/v), add 5 mL of 4 mol/L hydrochloric acid to the eluate, and adjust pH 1.0 or less. Add 100 mL of 10 w/v% sodium chloride solution to the resulting solution and extract with shaking twice with 50 mL ether. Combine the extracts, dehydrate with sodium sulfate (anhydrous), and filter out the sodium sulfate (anhydrous), concentrate the filtrate at below 40°C and remove the solvent. Dissolve the residue in 3 mL of acetonitrile/toluene (3:1, v/v).

ii. Graphitized carbon block/ethylenediamine-*N*-propylsilylated silica gel layered column chromatography

Add 10 mL of acetonitrile/toluene (3:1, v/v) to a graphitized carbon black/ethylenediamine-*N*-propylsilylated silica gel layered cartridge (500 mg/500 mg) and discard the effluent. Transfer the solution obtained in “i. Octadecylsilylated silica gel column chromatography”, add 7 mL of acetonitrile/toluene (3:1, v/v), and discard the effluent. Elute with 30 mL of acetonitrile/formic acid/toluene (75:1:25, v/v/v), concentrate the eluate at below 40°C and remove the solvent. Dissolve the residue in methanol to make exactly 1 mL (exactly 0.5 mL for tea and hops) and use this solution as the test solution.

5. Measurement

a. Calibration curve

Prepare 2, 4, 5-T standard solution (methanol) of several concentrations. Inject each standard solution to LC-MS/MS, and make a calibration curve by peak-height or peak-area method. When the test solution is prepared following the above procedure, the sample containing 0.01 mg/kg of 2, 4, 5-T gives the test solution of 0.005 mg/L in concentration.

b. Quantification

Inject the test solution to LC-MS/MS and calculate the concentration of 2, 4, 5-T from the calibration curve made in “a. Calibration curve”.

c. Confirmation

Confirm using LC-MS/MS.

d. Measurement conditions

(Example)

Column: Octadecylsilylated silica gel, 2.1 mm in inside diameter, 150 mm in length, 3 µm in particle diameter
Column temperature: 40°C

Mobile phase: Linear gradient from 5 mmol ammonium acetate solution/5 mmol/L ammonium acetate-methanol solution (7:3, v/v) to (1:9, v/v) in 20 min.

Ionization mode: ESI (-)

Major monitoring ions (*m/z*): Precursor ion 253, product ion 195

Precursor ion 255, product ion 197

Injection volume: 5 µL

Expected retention time: 12 min

6. Limit of Quantification

0.01 mg/kg

Notification (draft)
Analytical Method for Daminozide
(Targeted to Agricultural, Animal and Fishery Products)

The target compounds to be determined are daminozide and 1,1-dimethylhydrazine.

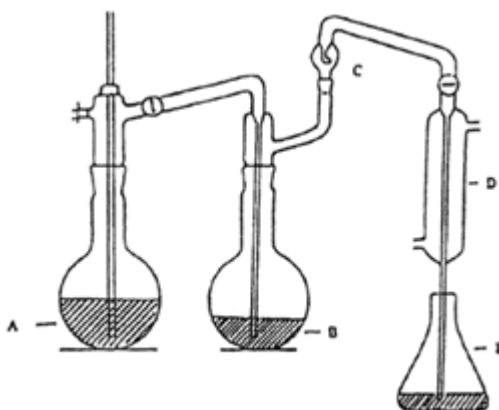
1. Instruments

Gas chromatograph-flame thermionic detector (GC-FTD)

Gas chromatograph-nitrogen phosphorus detector (GC-NPD)

Gas chromatograph-mass spectrometer (GC-MS)

Steam distillation apparatus: Use the apparatus made of glass and roughly as the following figure.



A: 500-1,000 mL round-bottom flask
(for steam generation)

B: 500-1,000 mL round-bottom flask
(for distillation)

C: Distillation trap

D: Condenser

E: 100-mL conical flask

2. Reagents

Use the reagents listed in Section C *Reagents/Test Solutions, Etc.*, Part II *Food*

Additives, except the following. Reagents designated as “special grade” in this section must meet the requirements for “special grade” specified in the Japan Industrial Standards for the reagents.

Acetone: Use a reagent not containing any substance that may interfere with the analysis of the target compounds.

Alumina (basic) cartridge (1,710 mg): A polyethylene tube of 8-9 mm in inside diameter packed with 1,710 mg of alumina (basic) or a cartridge equivalent to the specified one in separation capability.

Phase-separator filter paper: Use a siliconized filter paper for chemical analysis.

Defoaming silicone: Use a silicone produced for defoaming.

o-Nitrobenzaldehyde: *o*-Nitrobenzaldehyde (special grade).

1 w/v% *o*-Nitrobenzaldehyde-methanol solution: Dissolve 100 mg of *o*-nitrobenzaldehyde in 10 mL of methanol. Prepare each time before use.

n-Hexane: Use a reagent not containing any substance that may interfere with the analysis of the target compounds.

Water: Use water suitable for chemical analysis, including distilled water, purified water, or pure water. If it contains any substance that may interfere with the analysis of the target compounds, wash with a solvent such as *n*-hexane before use.

Methanol: Use a reagent not containing any substance that may interfere with the analysis of the target compounds.

Phosphate buffer solution (pH 5): Dissolve 13.15 g of potassium dihydrogen phosphate and 0.59 g of dipotassium hydrogen phosphate in water to make 100 mL.

3. Reference standard

Reference standard of 1,1-dimethylhydrazine: Contains not less than 97% of 1,1-dimethylhydrazine.

4. Procedure

a. Extraction

i. Agricultural products

For grains, legumes, nuts and seeds, grind sample to pass through a standard sieve (425 μm) and weigh 10.0 g of the sample. If it difficult to pass through the sieve, cut-up sample into about 2 mm square and weigh 10.0 g of the sample.

For fruits and vegetables, weigh about 1 kg of sample accurately, add an appropriate quantity of water (if necessary), homogenize, and then take the sample equivalent to 20.0 g.

For powdered tea, weigh 5.00 g of sample.

For tea leaves and hops, grind sample to pass through a standard sieve (425 μm) and weigh 5.00 g of the sample.

Add 80 mL of water, homogenize, and filter with suction using a glass fiber filter.

Add 40 mL of water to the residue on the filter paper, homogenize, and filter as described above.

Combine the resulting filtrates, and add water to make exactly 200 mL.

For grains, legumes, nuts and seeds, fruits and vegetables, take exactly a 20 mL aliquot of the solution (exactly a 40 mL aliquot for tea and hops) to a round-bottom flask (for distillation), and add 80 mL of water.

ii. Animal and fishery products (except for milk, egg and honey)

Homogenize sample and weigh 10.0 g (5.00 g for fat) of the sample. Add 80 mL of water and 40 mL of *n*-hexane, homogenize, filter with suction using a glass fiber filter, and take aqueous and *n*-hexane layers. Add the *n*-hexane layer to the residue on the filter, add 40 mL of water, homogenize, and filter as described above. Combine the obtained aqueous layers, and add water to make exactly 200 mL. Take exactly a 20 mL aliquot of the solution (exactly a 40 mL aliquot for fat) to a round-bottom flask (for distillation), and add 80 mL of water.

iii. Milk, egg and honey

Homogenize sample by thoroughly mixing, take 10.0 g of the sample to a round-bottom flask (for distillation), and add 80 mL of water.

b. Distillation

Add gradually and dissolve 60 g of sodium hydroxide cooling with water to the round-bottom flask used in "a. Extraction ". Add 1-2 drops of defoaming silicone and boiling stones, and attach the flask immediately to a steam distillation apparatus. Also attach a 100 mL conical flask containing 5 mL of phosphate buffer solution (pH 5) and 1 drop of phenolphthalein reagent. Heat a round-bottom flask (for steam generation) attached with the steam distillation apparatus. Distill the solution until the distillate becomes 45 mL, confirming that the distillate remains colorless. Adjust the heat so that the distillation finishes in about 15 minutes.

c. Derivatization

Add 1 mL of 1 w/v% *o*-nitrobenzaldehyde-methanol solution to the distillate obtained in "b. Distillation ", shake, and let stand at 40°C for 16 hours. Add 50 mL of *n*-hexane to the distillate, shake for 5 minutes, let stand, take the *n*-hexane layer, and filter using a phase-separator filter paper. Add 50 mL of *n*-hexane to the aqueous layer, treat as described above, and combine the obtained *n*-hexane layers. Wash the residue on the filter paper with 10 mL of *n*-hexane, transfer the washing to the *n*-hexane layer, concentrate at below 40°C and remove *n*-hexane. Dissolve the residue in 5 mL of acetone/*n*-hexane (1:19, v/v).

d. Clean-up

Add 10 mL of acetone/*n*-hexane (1:19, v/v) to an alumina (basic) cartridge (1,710 mg) and discard the effluent. Transfer the solution obtained in "c. Derivatization" to the cartridge, elute with 10 mL of acetone/*n*-hexane (1:19, v/v), collect the total eluate, concentrate at below 40°C and remove the solvent. Dissolve the residue in acetone to make exactly 1 mL for grains, legumes, nuts and seeds, tea, hops and animal and fishery products (except for milk, egg and honey), 2 mL for fruits and vegetables, 10 mL for milk, egg and honey, and use this solution as the test solution.

5. Measurement

a. Calibration curve

Prepare a 500 mg/L 1,1-dimethylhydrazine standard solution (water). Take a 1 mL aliquot of the solution, add 5 mL of phosphate buffer solution (pH 5) and 40 mL of water, and then add 1 mL of 1 w/v% *o*-nitrobenzaldehyde-methanol solution. Shake, and let stand at 40°C for 16 hours. Add 50 mL of *n*-hexane to the solution, shake for 5 minutes, let stand, take the *n*-hexane layer, and filter using a phase-separator filter paper.

Add 50 mL of *n*-hexane to the aqueous layer, treat as described above, and combine the obtained *n*-hexane layers. Wash the residue on the filter paper with 10 mL of *n*-hexane, transfer the washing to the *n*-hexane layer, concentrate at below 40°C and remove *n*-hexane. Dissolve the residue and prepare standard solutions (acetone) of several concentrations, inject each standard solution to GC, and make a calibration curve by peak-height or peak-area method. When the test solution is prepared following the above procedure, the sample containing 0.1 mg/kg of daminozide gives the test solution of 0.1 mg/L (as daminozide) in concentration.

b. Quantification

Inject the test solution to GC, and calculate the concentration of 1,1-dimethylhydrazine from the calibration curve made in “a. Calibration curve”. Use the following equation to calculate the concentration of daminozide.

$$\text{Concentration of daminozide (ppm)} = \text{concentration of 1,1-dimethylhydrazine (ppm)} \times 2.655$$

c. Confirmation

Confirm using GC-MS.

d. Measurement conditions

(Example)

i. GC

Instruments: GC-FTD or GC-NPD

Column: Silicate glass capillary column 0.25 mm in inside diameter, 30 m in length coated with (trifluoropropyl) methylcyclotetrasiloxane for gas chromatography 0.25 µm in film thickness

Column temperature: The column temperature is held at 60°C for two minutes, followed by an increase of 10°C every minute until reaching 280°C, where it is held for 8 minutes.

Inlet temperature: 250°C

Detector: Should be operated at 280°C

Carrier gas: Helium

Injection volume: 2 µL

Expected retention time: 15 min

ii. GC-MS

Column: Silicate glass capillary column 0.25 mm in inside diameter, 30 m in length coated with (trifluoropropyl) methylcyclotetrasiloxane for gas chromatography 0.25 µm in film thickness

Column temperature: The column temperature is held at 80°C for 2 minutes, followed by an increase of 15°C every minute until reaching 200°C, after which the temperature is increased by 30°C every minute until reaching 250°C, where it is held for 3 minutes.

Inlet temperature: 250°C

Carrier gas: Helium

Ionization mode (ionization energy): EI (70 eV)

Major monitoring ions (*m/z*): 193, 77

Injection volume: 2 µL

Expected retention time: 9 min

6. Limit of Quantification

0.1 mg/kg

Notification (draft)
Analytical Method for Malachite Green
(Target to Animal and Fishery Products)

The target compounds to be determined are malachite green and leucomalachite green.

1. Instrument

Liquid chromatograph-tandem mass spectrometer (LC-MS/MS)

2. Reagents

Use the reagents listed in Section C *Reagents/Test Solutions, Etc.*, Part II *Food*

Additives, except the following. Reagents designated as “special grade” in this section must meet the requirements for “special grade” specified in the Japan Industrial Standards for the reagents.

Acetonitrile: Use a reagent not containing any substance that may interfere with the analysis of the target compounds.

Acetone: Use a reagent not containing any substance that may interfere with the analysis of the target compounds.

Ethanol: Use a reagent not containing any substance that may interfere with the analysis of the target compounds.

Ammonium formate: Ammonium formate (special grade).

Citric acid (anhydrous): Citric acid (anhydrous) (special grade).

Sulfonate-modified divinylbenzene-*N*-vinylpyrrolidone copolymer cartridge (500 mg):

A polyethylene tube of 12-13 mm in inside diameter packed with 500 mg of sulfonate-modified divinylbenzene-*N*-vinylpyrrolidone copolymer, or a cartridge equivalent to the specified one in separation capability.

Quaternary ammonium salt-modified divinylbenzene-*N*-vinylpyrrolidone copolymer cartridge (150 mg):

A polyethylene tube of 12-13 mm in inside diameter packed with 150 mg of quaternary ammonium salt-modified divinylbenzene-*N*-vinylpyrrolidone copolymer, or a cartridge equivalent to the specified one in separation capability.

50 mmol/L ammonium formate buffer (pH 3.5): Dissolve 3.15 g of ammonium formate in 990 mL of water. Adjust pH to 3.5 with formic acid, and add water to make exactly 1,000 mL.

3. Reference standard

Reference standard of malachite green oxalate: Contains not less than 98% of malachite green oxalate.

Reference standard of leucomalachite green: Contains not less than 98% of leucomalachite green.

4. Procedure

a. Extraction

Weigh sample accurately and add half amount in weight ratio of 15 w/w% of dibutylhydroxytoluene-ethanol solution and half amount in weight ratio of 50 w/w% of citric acid solution, respectively.

Homogenize and take the sample equivalent to 10.0 g (5.00 g for fat). Add 100 mL of acetone, homogenize, and filter with suction using glass fiber filter. Add 50 mL of acetone (10 mL of water and 50 mL of acetone for honey) to the residue on the filter, homogenize, and filter as described above.

Combine the resulting filtrates, and add acetone to make exactly 200 mL. Take exactly a 1 mL (2 mL for fat) aliquot of the solution and add 4 mL of 2 vol% formic acid.

b. Clean-up

Add 5 mL each of acetonitrile and 2 vol% formic acid to a sulfonate-modified divinylbenzene-*N*-vinylpyrrolidone copolymer cartridge (500 mg) sequentially and discard the effluents. Add 5 mL of acetonitrile/ammonia water (9:1, v/v) to a quaternary ammonium salt-modified divinylbenzene-*N*-vinylpyrrolidone copolymer cartridge (150 mg) and discard the effluent. Transfer the solution obtained in "a. Extraction" to the sulfonate-modified divinylbenzene-*N*-vinylpyrrolidone copolymer cartridge, add 5 mL of acetonitrile, and discard the effluent. Connect the quaternary ammonium salt-modified divinylbenzene-*N*-vinylpyrrolidone copolymer cartridge to the bottom of the sulfonate-modified divinylbenzene-*N*-vinylpyrrolidone copolymer cartridge, elute with 10 mL of acetonitrile/ammonia water (9:1, v/v), and take the eluate. Add acetonitrile/ammonia water (9:1, v/v) to the eluate to make exactly 10 mL, and use this solution as the test solution.

5. Measurement

a. Calibration curve

Dissolve reference standards of malachite green oxalate and leucomalachite green in acetone to make 500 mg/L respectively (for malachite green oxalate, adjust the concentration as malachite green), and use these solutions as stock standard solutions. Mix each stock standard solution appropriately, dilute with acetonitrile/ammonia water (9:1, v/v), and prepare standard solutions of several concentrations. Inject each standard solution to LC-MS/MS, and make calibration curves by peak-height or peak-area method. When the test solution is prepared following the above procedure, the sample containing 0.002 mg/kg of malachite green and leucomalachite green gives the test solution of 0.00001 mg/L in concentration.

b. Quantification

Inject the test solution in LC-MS/MS, and calculate the concentration of malachite green and leucomalachite green from the calibration curve made in "a. Calibration curve".

c. Confirmation

Confirm using LC-MS/MS.

d. Measurement conditions

(Example)

Column: Octadecylsilanized silica gel, 2.1 mm in inside diameter, 150 mm in length and 5 µm in particle diameter

Column temperature: 40°C

Mobile phase: Linear gradient from acetonitrile/50 mmol/L ammonium formate buffer (pH 3.5) (3:7, v/v) to (9:1, v/v) in 15 min and hold for 10 min.

Ionization mode: ESI (+)

Major monitoring ions (*m/z*):

Malachite green: Precursor ion 329, product ions 313, 165

Leucomalachite green: Precursor ion 331, product ions 316, 239

Injection volume: 10 µL

Expected retention time

Malachite green: 8 min

Leucomalachite green: 16 min

6. Limit of Quantification

Malachite green: 0.002 mg/kg

Leucomalachite green: 0.002 mg/kg

Item 3. Revision of Standards for Calcium Carbonate and Magnesium Stearate

The government of Japan will revise the existing standards for use of calcium carbonate and magnesium stearate.

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 whether it is adequate to revise the existing standards for use of calcium carbonate [CAS: 471-34-1] and magnesium stearate [CAS: 557-04-0].

The committee has concluded that the Minister should revise the standards based on Article 11 of the act. For details, see Attachments 3-1 and 3-2.

Note

Calcium carbonate, which is used for various uses, such as a nutrient supplement and a chewing gum base, was designated as a food additive in July 1957 in Japan.

In the Codex Alimentarius Commission’s General Standards for Food Additives (GSFA), the substance is permitted for use in food under good manufacturing practice (GMP), except in some categories of food. In the United States, the substance is categorized as a generally-recognized-as-safe (GRAS) substance by the US Food and Drug Administration (FDA) and permitted for use in food under GMP. In the European Union (EU), it is permitted for use in food under GMP, except in some categories of food.

Magnesium stearate, which is used as a processing agent (a lubricant or anti-sticking agent in manufacturing capsules and tablets), was designated as a food additive in January 2004 in Japan.

In the United States, it is categorized as a GRAS substance and used as a lubricant, mold release agent or processing aid. On the other hand, it is authorized in the EU as a food additive as a magnesium salt of fatty acids and used as a thickener.

**Revision of Standards for Use
Calcium Carbonate**

Current regulations

Calcium Carbonate is permitted for use only when indispensable for manufacturing or processing the food, or when used for nutritive purposes.

The maximum use limit (as calcium) is 10% by weight in chewing gum and 0.1% in the other foods. These limits are, however, not applied to foods approved to be labeled as “special dietary use”.

Revised regulations

The existing use standards will be withdrawn.

Revision of Standards for Use Magnesium Stearate

Current regulations

Magnesium Stearate is permitted only for use in capsule- and tablet-form foods for specified health uses and with nutrient function claims.

Revised regulations

The use of the additive is expanded for foods not in conventional food form, like those in capsule- or tablet-form* and tablet confectioneries.

* In addition to foods for specified health uses and foods with nutrient function claims, in which the substance is permitted by the current regulations, Magnesium Stearate will be able to be used in foods that are not in conventional food form such as foods with functional claims.