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Japan proposes the revision of MRLs for 10 agricultural chemicals

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

On October 23, 2015, the Ministry of Health, Labor and Welfare (MHLW) of the Government of Japan (GOJ) announced changes to the Maximum Residue Levels (MRLs) for Acibenzolar-S-methyl, Cycloprothrin, Difenoconazole, Fluoxastrobin, Metrafenone, Oxathiapiprolin, Sulfoxaflor, Triafamone, and Norfloxacin. MHLW also proposed the revision of analytical methods for Brotizolam, a veterinary drug.

The Embassy comment period for these proposals is open until Friday, November 6, 2015. MHLW will also notify these MRLs to the WTO, which will allow another opportunity for interested parties to comment on these changes.

General Information:

On October 23, 2015, the Ministry of Health, Labor and Welfare (MHLW) of the Government of Japan (GOJ) announced changes to the Maximum Residue Levels (MRLs) for Acibenzolar-S-methyl, Cycloprothrin, Difenoconazole, Fluoxastrobin, Metrafenone, Oxathiapiprolin, Sulfoxaflor, Triafamone, and Norfloxacin. MHLW also proposed the revision of analytical methods for Brotizolam, a veterinary drug.

The Embassy comment period for these proposals is open until Friday, November 6, 2015. MHLW will also notify these MRLs to the WTO, which will allow another opportunity for interested parties to comment on these changes.

Pesticides: <http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/01.pdf>

Feed additives: <http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/02.pdf>

Veterinary drugs: <http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/03.pdf>

The WTO/SPS notifications can be found at the site below.

http://www.wto.org/english/tratop_e/sps_e/work_and_doc_e.htm

After the WTO comment period closes, a final report will be released based on the conclusions reached by a session of the Pharmaceutical Affairs and Food Sanitation Council scheduled to be held at a later date. The Council's report will constitute the final decision.

Comments to the GOJ can be made either in Japanese or English and can be sent to the below points of contact:

Mr. Ryouta Nakamura (nakamura-ryouta@mhlw.go.jp)
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Department of Environmental Health and Food Safety,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
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Post requests that the U.S. Embassy - Tokyo also be copied on any comments at agtokyo@usda.gov to allow them to be considered as part of the official U.S. Government comments to the WTO.

MHLW's draft proposal follows:

Item 1: Establishment of 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 eight pesticides (Acibenzolar-S-methyl, Cycloprothrin, Difenoconazole, Fluoxastrobin, Metrafenone, Oxathiapiprolin, Sulfoxaflor, Triafamone) and one veterinary drug (Norfloxacin).

The MHLW has decided to maintain the risk management for Chlorpromazine designated as substances used as ingredients of agricultural chemicals and other chemical substances that are stipulated to be "Not detected" in foods.

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

Acibenzolar-S-methyl (pesticide/fungicide): Not permitted for use in Japan.

The MHLW is going to establish MRLs for 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). The MHLW is also going to modify some MRLs that were provisionally set at the introduction of the Positive List System.

Cycloprothrin (pesticide/insecticide): Permitted for use in Japan.

The MHLW is going to establish MRLs for the fish/shellfish category in response to MAFF’s request, and modify some MRLs that were provisionally set at the introduction of the Positive List System.

Current provisional MRLs are based on domestic standards at the time of Positive List was introduced in 2006. Later, domestic MRLs were deleted.

Difenoconazole (pesticide/fungicide): Permitted for use in Japan

The MHLW is going to establish MRLs for 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).

Fluoxastrobin (pesticide/fungicide): Not permitted for use in Japan.

The MHLW is going to establish MRLs for 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.

Metrafenone (pesticide/fungicide): Not permitted for use in Japan.

The MHLW is going to establish MRLs for 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.

Oxathiapiprolin (pesticide/fungicide): Not permitted for use in Japan.

The MHLW is going to establish MRLs for some commodities in response to a request for setting MRLs by the Ministry of Agriculture, Forestry and Fisheries (MAFF). This action will not strengthen the current regulation for any commodities.

Sulfoxaflor (pesticide/insecticide): Permitted for use in Japan.

The MHLW is going to establish MRLs for 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 establish MRLs for 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.

Triafamone (pesticide/herbicide): Not permitted for use in Japan.

The MHLW is going to establish MRLs for 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 establish MRLs for 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.

Norfloxacin (veterinary drug/ synthetic antimicrobial): Permitted for use in Japan.

The MHLW is going to modify some MRLs that were provisionally set at the introduction of the Positive List System.

(2) Designation of substances used as ingredients of agricultural chemicals and other chemical

substances that are stipulated to be "Not detected" in foods

The MHLW has decided to maintain the risk management for Chlorpromazine designated as substances used as ingredients of agricultural chemicals and other chemical substances that are stipulated to be "Not detected" in foods.

Acibenzolar-S-methyl

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	0.1	0.1			
Wheat	0.05	0.05			
Barley	0.05	0.05			
Rye	0.05	0.05			
Corn (maize, including pop corn and sweet corn)	0.05	0.05			
Buckwheat	0.05	0.05			
Other cereal grains	0.05	0.05			
Watercress	0.3	0.3			0.25 USA
Chinese cabbage	1	1			1.0 USA
Cabbage	1	1			1.0 USA
Brussels sprouts	1	1			1.0 USA
Kale	1	1			1.0 USA
Komatsuna(Japanese mustard spinach)	1	1			1.0 USA
Kyona	1	1			1.0 USA
Qing-geng-cai	1	1			1.0 USA
Cauliflower	1	1			1.0 USA
Broccoli	1	1			1.0 USA
Other cruciferous vegetables	1	1			1.0 USA
Endive	0.3	0.3			0.25 USA
Shungiku	0.3	0.3			0.25 USA
Lettuce (including cos lettuce and leaf lettuce)	0.3	0.3			0.25 USA
Other composite vegetables	0.3	0.3			0.25 USA
Onion	0.1	0.05			0.1 USA
Parsley	0.3	0.3			0.25 USA
Celery	0.3	0.3			0.25 USA
Other umbelliferous vegetables	0.3	0.3			0.25 USA
Tomato	1	1			1.0 USA
Pimiento (sweet pepper)	1	1			1.0 USA
Egg plant	1	1			1.0 USA
Other solanaceous vegetables	1	1			1.0 USA
Spinach	1	1			1.0 USA
Other vegetables	0.3	0.3			0.25 USA
Strawberry	0.2		IT		0.15 USA
Blueberry	0.2		IT		0.15 USA
Cranberry	0.2		IT		0.15 USA

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other berries	○ 0.2		IT		0.15 USA
Banana	○ 0.1	0.1			0.1 USA
Cotton seeds	●	0.02			
Other spices	●	0.3			
Other herbs	○ 1	1			1.0 USA

Note: The residue definition is the sum of Acibenzolar-S-methyl, metabolite B [1,2,3-Benzothiadiazole-7-carboxylic acid] and its conjugates, expressed as Acibenzolar-S-methyl.

* 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
- IT: Import tolerance

Cycloprothrin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	● 0.05	0.1	§		
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	●	0.1			
Beans, dry	●	0.1			
Peas	●	0.1			
Broad beans	●	0.1			
Peanuts, dry	●	0.1			
Other pulses	●	0.1			
Potato	●	0.02			
Taro	●	0.02			
Sweet potato	●	0.02			
Yam	●	0.02			
Konjac	●	0.02			
Other potatoes	●	0.02			
Sugar beet	●	0.02			
Sugarcane	●	0.02			
Japanese radish, roots (including radish)	●	0.02			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
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			
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	•	0.2			

Melons	•		0.2			
Makuwauri melon	•		0.2			
Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
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	•		0.2			
Citrus natsudaidai, peels	•		20			
Citrus natsudaidai, whole	•		0.2			
Lemon	•		0.2			
Orange (including navel orange)	•		0.2			
Grapefruit	•		0.2			
Lime	•		0.2			
Other citrus fruits	•		0.2			
Apple	•		0.2			
Japanese pear	•		0.2			
Pear	•		0.2			
Quince	•		0.2			
Loquat	•		0.2			
Peach	•		0.2			
Nectarine	•		0.2			
Apricot	•		0.2			
Japanese plum (including prune)	•		0.2			
Mume plum	•		0.2			
Cherry	•		0.2			
Strawberry	•		0.2			
Raspberry	•		0.2			
Blackberry	•		0.2			
Blueberry	•		0.2			
Cranberry	•		0.2			
Huckleberry	•		0.2			
Other berries	•		0.2			
Grape	•		0.2			
Japanese persimmon	•		0.2			
Banana	•		0.2			
Kiwifruit	•		0.2			
Papaya	•		0.2			
Avocado	•		0.2			
Pineapple	•		0.2			

Guava	●		0.2			
Mango	●		0.2			
Passion fruit	●		0.2			
Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Date	●		0.2			
Other fruits	●		0.2			
Sunflower seeds	●		0.2			
Sesame seeds	●		0.2			
Safflower seeds	●		0.2			
Cotton seeds	●		0.2			
Rapeseeds	●		0.2			
Other oil seeds	●		0.2			
Ginkgo nut	●		0.2			
Chestnut	●		0.2			
Pecan	●		0.2			
Almond	●		0.2			
Walnut	●		0.2			
Other nuts	●		0.2			
Tea	●		0.5			
Coffee beans	●		0.02			
Cacao beans	●		0.02			
Hop	●		0.02			
Other spices	●		0.2			
Other herbs	●		0.02			
Fish	○	0.4		Request		

Note: The residue definition is Cycloprothrin 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; The MRL was modified in response to MAFF request

Difenoconazole

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Rice (brown rice)	○ 0.2	0.2			0.2	Korea
Wheat	○ 0.1	0.1		0.02		
Barley	○ 0.1	0.1				
Rye	○ 0.1	0.1				
Corn (maize, including pop	○ 0.1	0.1				

corn and sweet corn)							
Buckwheat	o	0.02	0.02				
Soybeans, dry	o	0.05	0.05	§	0.02		
Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Peanuts, dry	o	0.1	0.1				
Potato	o	0.1	0.1				
Sugar beet	●	0.3	0.5	§	0.2		
Horseradish	o	0.4		IT		0.4	EU
Cabbage	o	2	2	§	2		
Brussels sprouts	o	2	2		2		
Cauliflower	o	2	2		2		
Broccoli	o	2	2		2		
Other cruciferous vegetables	o	2	2		2		
Salsify	o	0.4		IT		0.4	EU
Chicory	o	0.08		IT		0.08	EU
Lettuce (including cos lettuce and leaf lettuce)	o	2	2		2		
Other composite vegetables	o	0.6		IT		0.6	EU
Onion	o	0.2	0.2		0.1	0.2	USA
Welsh (including leek)	o	6	6		0.3	6.0	USA
Garlic	o	0.2	0.2		0.02	0.2	USA
Asparagus	o	0.03	0.03		0.03		
Other liliaceous vegetables	o	9			9		
Carrot	o	0.2	0.2		0.2		
Parsley	o	10	10			10	EU
Celery	o	10	10	§	3		
Other umbelliferous vegetables	o	0.5	0.5		0.5		
Tomato	o	0.6	0.6	§	0.6		
Pimiento (sweet pepper)	o	2	2	§	0.6		
Egg plant	o	0.6	0.6	§	0.6		
Other solanaceous vegetables	o	1		IT	0.6	1	Korea
Cucumber (including gherkin)	o	0.7	0.7	§	0.2	0.7	USA
Pumpkin (including squash)	o	0.7	0.7	§	0.2	0.7	USA
Water melon	o	0.1	0.1	§			
Melons	o	0.05	0.05	§			
Okra	o	0.6			0.6		
Peas, immature (with pods)	o	0.7	0.7		0.7		
Kidney beans, immature (with pods)	o	0.7	0.7		0.7		
Shiitake mushroom	o	0.6			0.6		
Other mushrooms	o	0.6			0.6		
Other vegetables	o	0.7	0.7				
Citrus natsudaidai, whole	o	0.6			0.6		
Lemon	o	0.6	0.6		0.6		
Orange (including navel orange)	o	0.6	0.6		0.6		
Grapefruit	o	0.6	0.6		0.6		
Lime	o	0.6	0.6		0.6		

Other citrus fruits	○	0.6	0.6		0.6		
Apple	●	0.8	1	§	0.8		
Japanese pear	●	0.8	1	§	0.8		
Pear	●	0.8	1	§	0.8		
Quince	○	0.8	0.5	§	0.8		
Loquat	○	0.5	0.5				
Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Peach	●	0.2	1	§	0.5		
Nectarine	○	0.7	0.7	§			
Apricot	○	1	1	§			
Japanese plum (including prune)	○	0.3	0.3	§			
Mume plum	○	3	3	§	0.2		
Cherry	○	3	3	§			
Strawberry	○	2	2	§			
Grape	○	4	4		3	4	USA
Japanese persimmon	○	0.7	0.7	§			
Banana	●	0.1	0.5		0.1	0.5	Australia
Papaya	○	0.2	0.2		0.2		
Avocado	○	0.5	0.5				
Mango	○	0.07	0.07		0.07		
Passion fruit	○	0.05	0.05		0.05		
Other fruits	○	2	2		2		
Sunflower seeds	○	0.02	0.02		0.02	0.1	Canada
Sesame seeds	○	0.1		IT			
Rapeseeds	○	0.1	0.05	IT	0.05		
Other oil seeds	○	0.1		IT	0.1		
Ginkgo nut	○	0.03	0.03		0.03		
Chestnut	○	0.03	0.03		0.03		
Pecan	○	0.03	0.03		0.03		
Almond	○	0.03	0.03		0.03		
Walnut	○	0.03	0.03		0.03		
Other nuts	○	0.03	0.03		0.03		
Tea	○	15	15	§			
Other spices	○	0.6	0.6			0.6	USA
Other herbs	○	35	35		0.6	35	USA
Cattle, muscle	○	0.2	0.05		0.2		
Pig, muscle	○	0.2	0.05		0.2		
Other terrestrial mammals, muscle	○	0.2	0.05		0.2		
Cattle, fat	○	0.2	0.05		0.2		
Pig, fat	○	0.2	0.05		0.2		
Other terrestrial mammals, fat	○	0.2	0.05		0.2		
Cattle, liver	○	2	0.2		1.5		
Pig, liver	○	2	0.2		1.5		
Other terrestrial mammals, liver	○	2	0.2		1.5		
Cattle, kidney	○	2	0.2		1.5		

Pig, kidney	○	2	0.2		1.5		
Other terrestrial mammals, kidney	○	2	0.2		1.5		
Cattle, edible offal	○	2	0.2		1.5		
Pig, edible offal	○	2	0.2		1.5		
Other terrestrial mammals, edible offal	○	2	0.2		1.5		
Milk	○	0.02	0.005		0.02		
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		
Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
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	○	0.03	0.01		0.03		
Other poultry, eggs	○	0.03	0.01		0.03		

Note: Residue definition

For crops, Difenconazole only.

For terrestrial animal products (livestock and poultry), Difenconazole and metabolite D.
metabolite D: 1-[2-chloro-4-(4-chlorophenoxy)phenyl]-2-(1*H*-1,2,4-triazole-1-yl)ethanol

* 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 were lowered
- : Commodities for which MRLs were maintained or increased
- § : Permitted for use in Japan.
- IT : Import tolerance

Fluoxastrobin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Potato	○	0.01	IT		0.01	USA
Strawberry	○	2	IT		1.9	USA

Note: The residue definition is the sum of Fluoxastrobin and Z isomer [(Z)-{2-[6-(2-chlorophenoxy)-5-fluoropyrimidine-4-yloxy]phenyl}(5,6-dihydro-1,4,2-dioxazine-3-yl)methanone O-methylacetoxime].

* 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 were maintained or increased

IT : Import tolerance

Metrafenone

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Wheat	○ 0.06		IT	0.06	
Barley	○ 0.5		IT	0.5	0.5 EU
Rye	○ 0.1		IT	0.06	0.1 EU
Other cereal grains	○ 0.5		IT	0.5	0.5 EU
Tomato	○ 0.9		IT	0.4	0.9 USA
Pimiento (sweet pepper)	○ 2		IT	2	2 EU
Egg plant	○ 0.9		IT		0.9 USA
Other solanaceous vegetables	○ 2		IT	2	2 EU
Cucumber (including gherkin)	○ 0.5		IT	0.2	0.5 USA
Pumpkin (including squash)	○ 0.5		IT	0.06	0.5 USA
Oriental pickling melon (vegetable)	○ 0.5		IT		0.5 USA
Other cucurbitaceous vegetables	○ 0.5		IT		0.5 USA
Button mushroom	○ 0.5		IT	0.5	0.4 EU
Apple	○ 2		IT		1.5 USA
Japanese pear	○ 2		IT		1.5 USA
Pear	○ 2		IT		1.5 USA
Cherry	○ 2		IT		2 USA
Strawberry	○ 0.6		IT	0.6	0.6 EU
Grape	○ 5		IT	5	
Hop	○ 70		IT		70 USA
Cattle, muscle	○ 0.01		IT	0.01	
Pig, muscle	○ 0.01		IT	0.01	
Other terrestrial mammals, muscle	○ 0.01		IT	0.01	
Cattle, fat	○ 0.01		IT	0.01	
Pig, fat	○ 0.01		IT	0.01	
Other terrestrial mammals, fat	○ 0.01		IT	0.01	
Cattle, liver	○ 0.01		IT	0.01	
Pig, liver	○ 0.01		IT	0.01	
Other terrestrial mammals, liver	○ 0.01		IT	0.01	
Cattle, kidney	○ 0.01		IT	0.01	
Pig, kidney	○ 0.01		IT	0.01	

Other terrestrial mammals, kidney	○ 0.01		IT	0.01	
Cattle, edible offal	○ 0.01		IT	0.01	
Pig, edible offal	○ 0.01		IT	0.01	
Other terrestrial mammals, edible offal	○ 0.01		IT	0.01	
Milk	○ 0.01		IT	0.01	
Chicken, muscle	○ 0.01		IT	0.01	
Chicken, fat	○ 0.01		IT	0.01	
Chicken, liver	○ 0.01		IT	0.01	
Chicken, kidney	○ 0.01		IT	0.01	
Chicken, edible offal	○ 0.01		IT	0.01	
Chicken, eggs	○ 0.01		IT	0.01	
Flour, whole grain	○ 0.08			0.08	
Wheat bran, Unprocessed	○ 0.3			0.25	
Peppers Chili, dried	○		IT	20	
Raisin	○		IT	20	17 USA

Note: The residue definition is Metrafenone 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 were increased
- IT: Import tolerance

Oxathiapiprolin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Potato	○ 0.05		Request		
Chinese cabbage	○ 0.2		Request		
Lettuce (including cos lettuce and leaf lettuce)	○ 0.5		Request		
Tomato	○ 0.3		Request		
Cucumber (including gherkin)	○ 0.2		Request		
Grape	○ 0.5		Request		

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 were increased
- Request: The MRL was modified in response to MAFF request

Sulfoxaflor

	MRL	MRL		Reference MRL
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Commodity	(draft) ppm	(current) ppm	Registration	Codex ppm	National ppm	
Rice (brown rice)	○ 1		Request			
Wheat	○ 0.2			0.2		
Barley	○ 0.6			0.6		
Other cereal grains	○ 0.2			0.2		
Soybeans, dry	○ 0.3			0.3		
Broad beans	○ 0.2		IT		0.2	USA
Potato	○ 0.05		IT	0.03	0.05	USA
Taro	○ 0.03			0.03		
Sweet potato	○ 0.05		IT	0.03	0.05	USA
Yam	○ 0.05		IT	0.03	0.05	USA
Other potatoes	○ 0.03			0.03		
Sugar beet	○ 0.05		IT	0.03	0.05	USA
Japanese radish, roots (including radish)	○ 0.2		Request	0.03		
Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Japanese radish, leaves (including radish)	○ 10		Request	6		
Turnip, roots (including rutabaga)	○ 0.05		IT	0.03	0.05	USA
Turnip, leaves (including rutabaga)	○ 6			6		
Horseradish	○ 0.03			0.03		
Watercress	○ 6			6		
Chinese cabbage	○ 6			6		
Cabbage	○ 2		Request • IT	0.4	2.0	USA
Brussels sprouts	○ 2		IT		2.0	USA
Kale	○ 6			6		
Komatsuna(Japanese mustard spinach)	○ 6			6		
Kyona	○ 6			6		
Qing-geng-cai	○ 6			6		
Cauliflower	○ 0.08		IT	0.04	0.08	USA
Broccoli	○ 3			3		
Other cruciferous vegetables	○ 6			6		
Burdock	○ 0.03			0.03		
Salsify	○ 0.03			0.03		
Chicory	○ 6			6		
Endive	○ 6			6		
Lettuce (including cos lettuce and leaf lettuce)	○ 6		Request	6		
Other composite vegetables	○ 6			6		
Onion	○ 0.01			0.01		
Garlic	○ 0.01			0.01		
Other liliaceous vegetables	○ 0.7			0.7		
Carrot	○ 0.05		IT		0.05	USA
Parsnip	○ 0.03			0.03		
Parsley	○ 6		IT		6.0	USA
Celery	○ 2			1.5		

Other umbelliferous vegetables	o	0.03			0.03		
Tomato	o	2		Request	1.5		
Pimiento (sweet pepper)	o	2			1.5		
Egg plant	o	2			1.5		
Other solanaceous vegetables	o	6			6		
Cucumber (including gherkin)	o	0.7		Request	0.5		
Pumpkin (including squash)	o	0.5			0.5		
Other cucurbitaceous vegetables	o	6			6		
Spinach	o	6			6		
Okra	o	2			1.5		
Peas, immature (with pods)	o	4		IT		4.0	USA
Kidney beans, immature (with pods)	o	4		IT		4.0	USA
Shiitake mushroom	o	2			1.5		
Other mushrooms	o	2			1.5		
Other vegetables	o	6			6		
Unshu orange, pulp	o	0.2		Request			
Citrus natsudaidai, whole	o	2		Request			
Lemon	o	2		Request	0.4		
Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Orange (including navel orange)	o	2		Request	0.8		
Grapefruit	o	2		Request	0.15		
Lime	o	2		Request	0.4		
Other citrus fruits	o	2		Request	0.8		
Apple	o	0.7		Request	0.3		
Japanese pear	o	1		Request	0.3		
Pear	o	1		Request	0.3		
Quince	o	0.3			0.3		
Nectarine	o	3		IT	0.4	3.0	USA
Apricot	o	3		IT	0.4	3.0	USA
Japanese plum (including prune)	o	3		IT	0.5	3.0	USA
Cherry	o	3		IT	1.5	3.0	USA
Strawberry	o	0.7		IT	0.5	0.7	USA
Blueberry	o	0.7		IT		0.7	USA
Cranberry	o	0.7		IT		0.7	USA
Grape	o	2			2		
Other fruits	o	2			1.5		
Cotton seeds	o	0.4			0.4		
Rapeseeds	o	0.4		IT	0.15	0.4	USA
Chestnut	o	0.02		IT	0.015	0.015	USA
Pecan	o	0.02		IT	0.015	0.015	USA
Almond	o	0.02		IT	0.015	0.015	USA
Walnut	o	0.02		IT	0.015	0.015	USA
Other nuts	o	0.02		IT	0.015	0.015	USA
Other spices	o	10		Request	0.03		
Other herbs	o	6			6		

Cattle, muscle	○	0.3			0.3		
Pig, muscle	○	0.3			0.3		
Other terrestrial mammals, muscle	○	0.3			0.3		
Cattle, fat	○	0.1			0.1		
Pig, fat	○	0.1			0.1		
Other terrestrial mammals, fat	○	0.1			0.1		
Cattle, liver	○	0.6			0.6		
Pig, liver	○	0.6			0.6		
Other terrestrial mammals, liver	○	0.6			0.6		
Cattle, kidney	○	0.6			0.6		
Pig, kidney	○	0.6			0.6		
Other terrestrial mammals, kidney	○	0.6			0.6		
Cattle, edible offal	○	0.6			0.6		
Pig, edible offal	○	0.6			0.6		
Other terrestrial mammals, edible offal	○	0.6			0.6		
Milk	○	0.2			0.2		
Chicken, muscle	○	0.1			0.1		
Other poultry animals, muscle	○	0.1			0.1		
Chicken, fat	○	0.03			0.03		
Other poultry animals, fat	○	0.03			0.03		
Chicken, liver	○	0.3			0.3		
Other poultry animals, liver	○	0.3			0.3		
Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Chicken, kidney	○	0.3			0.3		
Other poultry animals, kidney	○	0.3			0.3		
Chicken, edible offal	○	0.3			0.3		
Other poultry animals, edible offal	○	0.3			0.3		
Chicken, eggs	○	0.1			0.1		
Other poultry, eggs	○	0.1			0.1		
Peppers Chili, dried	○				15		
Raisin	○				6		

Note: The residue definition is Sulfoxaflor 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 were maintained or increased

Request: The MRL was modified in response to MAFF request

IT : Import tolerance

Triafamone

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	○ 0.05		Request • IT		

Note: The residue definition is Triafamone 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 were increased

Request: The MRL was modified in response to MAFF request

IT : Import tolerance

Norfloxacin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Pig, muscle	○ 0.02	0.02	§		
Pig, fat	○ 0.02	0.02	§		
Pig, liver	○ 0.02	0.02	§		
Pig, kidney	○ 0.02	0.02	§		
Pig, edible offal	○ 0.02	0.02	§		
Chicken, muscle	○ 0.02	0.02	§		
Other poultry animals, muscle	●	0.1			
Chicken, fat	○ 0.02	0.02	§		
Other poultry animals, fat	●	0.1			
Chicken, liver	○ 0.02	0.02	§		
Other poultry animals, liver	●	0.1			
Chicken, kidney	○ 0.02	0.02	§		
Other poultry animals, kidney	●	0.1			
Chicken, edible offal	○ 0.02	0.02	§		
Other poultry animals, edible offal	●	0.1			

Note: The residue definition is Norfloxacin 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.

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 shiitakemushroom.

“**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.

Item 2: Revision of Analytical Methods for Veterinary Drugs

Brotizolam

Notification (draft)

Analytical Method for Brotizolam (Targeted to animal products)

The target compound to be determined is brotizolam.

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:

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

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

Octadecylsilanized silica gel cartridge (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.

Trimethylaminopropylsilanized silica gel/ethylenediamine-*N*-propylsilanized silica gel layered cartridge (500 mg/500mg): A polyethylene tube of 12–13 mm in inside diameter packed with 500 mg of trimethylaminopropylsilanized silica gel 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.

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

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

Anhydrous sodium sulfate: Use a reagent not containing any substance that may interfere with 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 analysis of the target compound, wash with a solvent such as *n*-hexane before use.

3. Reference standard

Reference standard of brotizolam: Contains not less than 98% of brotizolam.

4. Procedure

a. Extraction

(i) Muscle, fat, liver, kidney and fish/shellfish

For fat, weigh 5.00 g of sample. For muscle, liver, kidney and fish/shellfish, weigh 10.0g of sample.

Add 50 mL of acetone/*n*-hexane (1:1, v/v) to the sample, homogenize, and filter with suction. Add 25 mL of acetone/*n*-hexane (1:1, v/v) to the residue on the filter paper, homogenize, and filter as described above. Combine the resulting filtrates, and concentrate to about 15 mL at below 40°C. Add 100 mL of saturated sodium chloride solution, and extract with shaking twice with ethyl acetate (100 mL and then 50 mL). Combine the resulting extracts, dehydrate with anhydrous sodium sulfate, filter out the anhydrous sodium sulfate, concentrate the filtrate at below 40°C, and remove the solvent. Add 30 mL of *n*-hexane to the residue, and extract with shaking twice with 30 mL of acetonitrile saturated with *n*-hexane. Combine the resulting extracts, and concentrate to about 5 mL at below 40°C.

(ii) Milk, egg and honey

For milk and egg, weigh 5.00 g of sample. For honey, weigh 5.00 g of sample and dissolve with 5 mL of water.

Add 30 mL of acetonitrile to the sample, homogenize, centrifuge at 2,500 rpm for 5 minutes, and collect the acetonitrile layer. Add 20 mL of acetonitrile to the residue (the residue and the water layer for honey), homogenize, and centrifuge as described above. Combine the resulting acetonitrile layer, dehydrate with anhydrous sodium sulfate, filter out the anhydrous sodium sulfate, and concentrate the filtrate to about 5 mL at below 40°C.

b. Clean-up

Connect a trimethylaminopropylsilanized silica gel/ethylenediamine-*N*-propylsilanized silica gel layered cartridge (500 mg/500 mg) to the lower part of an octadecylsilanized silica gel cartridge (1,000 mg). Add 10 mL of acetonitrile to the cartridge and discard the effluent. Transfer the solution obtained in a. "Extraction" to the cartridge, elute with 10 mL of acetonitrile, collect the total eluate, concentrate at below 40°C and remove the solvent. Dissolve the residue in acetonitrile/water (1:1, v/v) to make exactly 5 mL (2.5 mL for fat, milk, egg and honey), and use this solution as the test solution.

5. Measurement

a. Calibration curve

Prepare brotizolam standard solutions (acetonitrile/water (1:1, v/v)) 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 0.0005 mg/kg of brotizolam gives the test solution of 0.001 mg/L in concentration.

b. Quantification

Inject the test solutions to LC-MS/MS and calculate the concentration of brotizolam from the calibration curve made in a. "Calibration curve".

c. Confirmation

Confirm using LC-MS/MS.

d. Measurement conditions

Column: Octadecylsilanized silica gel, 2.1 mm in inside diameter, 150 mm in length and 3 mm in particle diameter

Column temperature: 40°C

Mobile phase: Linear gradient from mobile phase acetonitrile/mobile phase 0.1 vol% formic acid (3:7, v/v) to (7:3, v/v) in 15 minutes.

Ionization mode: Electrospray ionization method (positive ion)

Major monitoring ions (m/z): Precursor ion 380, product ion 344, 314

Injection volume: 5 μ L

Expected retention time: 13 minutes

6. Limit of Quantification

0.0005 mg/kg