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Voluntary - Public

Date: 8/28/2017

GAIN Report Number: JA7109

Japan

Post: Tokyo

Japan proposes the revision of MRLs for 7 agricultural chemicals

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

On Friday, August 18, 2017, the Ministry of Health, Labor and Welfare (MHLW) of the Government of Japan (GOJ) announced revisions to Japan's Maximum Residue Levels (MRLs) for agricultural chemicals and veterinary drugs; Difenoconazole, Pyraziflumid, F;utianil, Folpet, Metaflumizone, Mepiquat chloride, and Abamectin. MHLW also proposed a revision of an analytical method for Propham in food. The Embassy comment period for these proposals is open until Friday, September 01, 2017. MHLW will also notify these revised MRLs to the World Trade Organization, which will allow for another opportunity for interested parties to comment on these proposed changes.

Keyword: JA7109

General Information:

<The manner of submitting comments>

The Ministry of Health, Labour and Welfare (MHLW) will amend the existing standards and specifications for food as shown in this document. Please provide comments in writing by **Friday, September 1, 2017**. After the given date, comments should be directed to the enquiry point in accordance with the WTO/SPS Agreement.

With regard to agenda item 1, the SPS notification will be made for the setting or revision of the MRL for the agricultural and veterinary chemicals except for Pyraziflumid and Flutianil for which regulations will not be strengthened by this amendment.

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

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Pesticides/Veterinary drugs/Feed additives

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Item 1. Establishment of the Maximum Residue Limits for Agricultural and Veterinary Chemicals in Food

The Food Sanitation Act authorizes the Ministry of Health, Labour and Welfare (MHLW) to establish residue standards (maximum residue limits, “MRLs”) for pesticides, feed additives, and veterinary drugs (hereafter referred to as “agricultural and veterinary chemicals”) that may remain in foods. Any food for which standards are established pursuant to the provisions in Article 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 of the system.

The MHLW is going to modify or newly set MRLs in some commodities for the following substances:

Pesticides: Difenoconazole, Pyraziflumid, Flutianil,

Folpet, Metaflumizone,

Mepiquat chloride

Pesticides and Veterinary drugs: Abamectin

¹

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

Summary

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

Pyraziflumid (pesticide: fungicide): Not permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF with the intention to newly register this substance as a pesticide. This action will not strengthen the current regulation for any commodities.

Flutianil (pesticide: fungicide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF with the intention to expand its use pattern. This action will not strengthen the current regulation for any commodities.

Folpet (pesticide: fungicide): Not permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF with the intention to newly register this substance as a pesticide. The MHLW is also going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Metaflumizone (pesticide: insecticide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF with the intention to expand its use pattern.

Mepiquat chloride (pesticide: plant growth regulator): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF with the intention to expand its use pattern. The MHLW is also going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Abamectin (pesticide/veterinary drug: insecticide/parasiticide): Permitted for use in Japan as a pesticide and veterinary drug. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the Ministry of Agriculture, Forestry and Fisheries (MAFF) with the intention to expand its use pattern. 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).

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	0.1 USA
Barley	○ 0.1	0.1			0.1 USA
Rye	●	0.1			
Corn (maize, including pop corn and sweet corn)	●	0.1			
Buckwheat	●	0.02			
Soybeans, dry	○ 0.1	0.05	§	0.1	
Peanuts, dry	● 0.01	0.1		0.01	
Potato	○ 0.1	0.1			
Sugar beet	○ 0.3	0.3	§	0.2	
Horseradish	○ 0.4	0.4			0.4 EU
Cabbage	○ 2	2	§	2	
Brussels sprouts	○ 2	2		2	
Cauliflower	○ 2	2		2	
Broccoli	○ 2	2		2	
Other cruciferous vegetables	○ 2	2		2	
Salsify	○ 0.4	0.4			0.4 EU
Chicory	○ 0.08	0.08			0.08 EU
Lettuce (including cos lettuce and leaf lettuce)	○ 2	2		2	
Other composite vegetables	○ 0.6	0.6			0.6 EU
Onion	○ 0.2	0.2		0.1	0.20 USA
Welsh (including leek)	○ 6	6		0.3	6.0 USA
Garlic	○ 0.2	0.2		0.02	0.20 USA
Asparagus	○ 0.03	0.03		0.03	
Other liliaceous vegetables	○ 9	9		9	
Carrot	○ 0.2	0.2		0.2	
Parsley	○ 25	10	§ • Request		
Celery	○ 10	10	§	3	
Other umbelliferous vegetables	○ 0.5	0.5		0.5	
Tomato	○ 0.6	0.6	§	0.6	
Pimiento (sweet pepper)	○ 2	2	§	0.6	
Egg plant	○ 0.6	0.6	§	0.6	
Other solanaceous vegetables	○ 1	1		0.6	1.0 Korea
Cucumber (including gherkin)	○ 0.7	0.7	§	0.2	0.70 USA
Pumpkin (including squash)	○ 0.7	0.7	§	0.2	0.70 USA
Water melon	○ 0.1	0.1	§		
Melons	○ 0.05	0.05	§		
Okra	○ 0.6	0.6		0.6	
Ginger	○ 0.05		Request		
Peas, immature (with pods)	○ 0.7	0.7		0.7	
Kidney beans, immature (with pods)	○ 0.7	0.7		0.7	
Shiitake mushroom	○ 0.6	0.6		0.6	
Other mushrooms	○ 0.6	0.6		0.6	
Other vegetables	○ 0.7	0.7		0.7	
Citrus natsudaidai, whole	○ 0.6	0.6		0.6	
Lemon	○ 0.6	0.6		0.6	
Orange (including navel orange)	○ 0.6	0.6		0.6	
Grapefruit	○ 0.6	0.6		0.6	
Lime	○ 0.6	0.6		0.6	
Other citrus fruits	○ 0.6	0.6		0.6	
Apple	○ 0.8	0.8	§	0.8	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Japanese pear	○ 0.8	0.8	§	0.8	
Pear	○ 0.8	0.8	§	0.8	
Quince	○ 0.8	0.8	§	0.8	
Loquat	● 0.2	0.5	§		
Peach	○ 0.2	0.2	§		
Nectarine	○ 0.7	0.7	§	0.5	
Apricot	○ 1	1	§		
Japanese plum (including prune)	○ 0.3	0.3	§	0.2	
Mume plum	○ 3	3	§		
Cherry	○ 3	3	§	0.2	
Strawberry	○ 2	2	§		
Blueberry	○ 4		IT		4 Canada
Grape	○ 4	4		3	4.0 USA
Japanese persimmon	○ 0.7	0.7	§		
Banana	○ 0.1	0.1		0.1	
Papaya	○ 0.2	0.2		0.2	
Avocado	○ 0.6	0.5		0.6	
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	
Sesame seeds	○ 0.1	0.1			0.1 Canada
Rapeseeds	○ 0.2	0.1		0.15	
Other oil seeds	○ 0.1	0.1			0.1 Canada
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			0.60 USA
Other herbs	○ 35	35			35 USA
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	○ 2	2		1.5	
Pig, liver	○ 2	2		1.5	
Other terrestrial mammals, liver	○ 2	2		1.5	
Cattle, kidney	○ 2	2		1.5	
Pig, kidney	○ 2	2		1.5	
Other terrestrial mammals, kidney	○ 2	2		1.5	
Cattle, edible offal	○ 2	2		1.5	
Pig, edible offal	○ 2	2		1.5	
Other terrestrial mammals, edible offal	○ 2	2		1.5	
Milk	○ 0.02	0.02		0.02	
Chicken, muscle	○ 0.01	0.01		0.01	
Other poultry, muscle	○ 0.01	0.01		0.01	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Chicken, fat	○ 0.01	0.01		0.01	
Other poultry, fat	○ 0.01	0.01		0.01	
Chicken, liver	○ 0.01	0.01		0.01	
Other poultry, liver	○ 0.01	0.01		0.01	
Chicken, kidney	○ 0.01	0.01		0.01	
Other poultry, kidney	○ 0.01	0.01		0.01	
Chicken, edible offal	○ 0.01	0.01		0.01	
Other poultry, edible offal	○ 0.01	0.01		0.01	
Chicken eggs	○ 0.03	0.03		0.03	
Other poultry, eggs	○ 0.03	0.03		0.03	

Note: The residue definition for agricultural products is Difenoconazole only. The residue definition for animal products is the sum of Difenoconazole and metabolite D 【1-[2-chloro-4-(4-chlorophenoxy)phenyl]-2-(1H-1,2,4-triazole-1-yl)ethanol】 , expressed as Difenoconazole.

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

IT : Import tolerance

Pyraziflumid

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Beans, dry	○ 0.3		Request		
Chinese cabbage	○ 2		Request		
Cabbage	○ 3		Request		
Broccoli	○ 3		Request		
Lettuce (including cos lettuce and leaf lettuce)	○ 20		Request		
Onion	○ 0.3		Request		
Welsh (including leek)	○ 5		Request		
Tomato	○ 2		Request		
Pimiento (sweet pepper)	○ 5		Request		
Egg plant	○ 0.7		Request		
Cucumber (including gherkin)	○ 0.7		Request		
Water melon	○ 0.02		Request		
Melons	○ 0.05		Request		
Other cucurbitaceous vegetables	○ 1		Request		
Peas, immature (with pods)	○ 5		Request		
Kidney beans, immature (with pods)	○ 5		Request		
Green soybeans	○ 10		Request		
Other vegetables	○ 10		Request		
Unshu orange, pulp	○ 0.1		Request		
Citrus natsudaikai, whole	○ 2		Request		
Lemon	○ 2		Request		
Orange (including navel orange)	○ 2		Request		
Grapefruit	○ 2		Request		
Lime	○ 2		Request		
Other citrus fruits	○ 2		Request		
Apple	○ 1		Request		
Japanese pear	○ 1		Request		
Pear	○ 1		Request		
Peach	○ 0.2		Request		
Nectarine	○ 2		Request		
Apricot	○ 3		Request		
Japanese plum (including prune)	○ 0.7		Request		
Mume plum	○ 3		Request		
Cherry	○ 3		Request		
Strawberry	○ 3		Request		
Grape	○ 2		Request		
Japanese persimmon	○ 0.5		Request		
Other spices	○ 10		Request		

Note: The residue definition is Pyraziflumid 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.

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

Flutianil

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Tomato	○ 0.3		Request		
Egg plant	○ 0.2	0.2	§		
Cucumber (including gherkin)	○ 0.2	0.2	§		
Pumpkin (including squash)	○ 0.2	0.05	§ • Request		
Water melon	○ 0.05	0.05	§		
Melons	○ 0.05	0.05	§		
Peas, immature (with pods)	○ 0.5		Request		
Strawberry	○ 0.5	0.5	§		

Note: The residue definition is Flutianil 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.

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

Folpet

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Beans, dry	○ 0.3		Request		
Potato	○ 0.1	0.02		0.1	
Lettuce (including cos lettuce and leaf lettuce)※	○ 2	2		50	
Onion	● 1	2	Request	1	
Welsh (including leek)	●	30			
Garlic	●	20			
Celery	●	30			
Tomato	○ 5	3	Request	3	
Cucumber (including gherkin)	○ 5	2	Request	1	
Pumpkin (including squash)	●	20			
Melons	● 0.3	2	Request		
Makuwauri melon	●	3			
Kidney beans, immature (with pods)	●	0.05			
Unshu orange, pulp	●	10			
Citrus natsudaikai, whole	●	10			
Lemon	●	10			
Orange (including navel orange)	●	10			
Grapefruit	●	10			
Lime	●	10			
Other citrus fruits	●	10			
Apple※	○ 5	5		10	
Cherry	●	30			
Strawberry	● 5	20		5	
Raspberry	●	20			
Blackberry	●	20			
Blueberry	●	20			
Cranberry	●	20			
Huckleberry	●	20			
Other berries	●	20			
Grape	○ 10	2		10	
Avocado	●	30			
Other fruits	●	30			
Hop	○ 120	120			120.0 USA
Other spices	●	30			
Raisin	○ 40			40	

Note: The residue definition is Folpet 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.

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

* For lettuce and apple in which the Codex has set MRLs, the dietary exposure of Folpet estimated by using the highest residues (HR) of the supervised residue trials submitted to the JMPR and national food consumption data of lettuce and apple would exceed an ARfD of 0.1 mg/kg which was set by the Food Safety Commission of Japan. Therefore, the MHLW has decided to maintain the current MRLs of 2 ppm for lettuce and 5 ppm for apple.

Metaflumizone

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Corn (maize, including pop corn and sweet corn)	○ 0.2		Request		
Soybeans, dry	○ 0.5	0.5	§		
Potato	○ 0.02	0.02		0.02	
Taro	○ 0.2	0.2	§		
Sweet potato	○ 0.2	0.2	§		
Japanese radish, roots (including radish)	○ 0.5	0.5	§		
Japanese radish, leaves (including radish)	● 30	40	§		
Chinese cabbage	○ 10	10	§	6	
Cabbage	○ 5	5	§		
Brussels sprouts	○ 0.8	0.8		0.8	
Kale	○ 40	40	§		
Komatsuna(Japanese mustard spinach)	○ 40	40	§		
Kyona	○ 40	40	§		
Qing-geng-cai	○ 10	10	§		
Broccoli	○ 10	10	§		
Other cruciferous vegetables	○ 40	40	§		
Burdock	○ 0.2		Request		
Lettuce (including cos lettuce and leaf lettuce)	○ 50	50	§	7	
Welsh (including leek)	○ 10		Request		
Asparagus	○ 0.7		Request		
Carrot	○ 0.3		Request		
Tomato	○ 5	0.6	Request	0.6	
Pimiento (sweet pepper)	○ 5	0.6	Request	0.6	
Egg plant	○ 3	0.6	Request	0.6	
Other solanaceous vegetables	○ 0.6	0.6		0.6	
Spinach	○ 70		Request		
Ginger	○ 0.3	0.3	§		
Green soybeans	○ 10	10	§		
Mume plum	○ 10		Request		
Strawberry	○ 0.2		Request		
Other herbs	○ 40	40	§		
Cattle, muscle	○ 0.02	0.02		0.02	
Pig, muscle	○ 0.02	0.02		0.02	
Other terrestrial mammals, muscle	○ 0.02	0.02		0.02	
Cattle, fat	○ 0.02	0.02			
Pig, fat	○ 0.02	0.02			
Other terrestrial mammals, fat	○ 0.02	0.02			
Cattle, liver	○ 0.02	0.02		0.02	
Pig, liver	○ 0.02	0.02		0.02	
Other terrestrial mammals, liver	○ 0.02	0.02		0.02	
Cattle, kidney	○ 0.02	0.02		0.02	
Pig, kidney	○ 0.02	0.02		0.02	
Other terrestrial mammals, kidney	○ 0.02	0.02		0.02	
Cattle, edible offal	○ 0.02	0.02		0.02	
Pig, edible offal	○ 0.02	0.02		0.02	
Other terrestrial mammals, edible offal	○ 0.02	0.02		0.02	
Milk	○ 0.01	0.01		0.01	
Fish	○ 2	2			
Pepper, dried ※1	● /	6		6	

Note: The residue definition for agricultural products is the sum of Metaflumizone *E*-isomer, Metaflumizone *Z*-isomer and its metabolite D $[p\text{-}[m\text{-(trifluoromethyl)phenacyl]benzonitril}]$, expressed as Metaflumizone. The residue definition for animal products and aquatic products is the sum of Metaflumizone *E*-isomer and Metaflumizone *Z*-isomer, expressed as Metaflumizone.

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

※1 For dried pepper, the MRL of the row commodities (peppers, Other solanaceous vegetables) will be applied taking into account the processing factor.

JMPR estimated the processing factors of 10 for dried pepper.

※2 Although the residue definition for agricultural commodities is different from the codex residue definition, the sum of metaflumizone *E*-isomer and metaflumizone *Z*-isomer (not including metabolite D). The codex MRLs for potatoes, brussels sprouts and peppers (other solanaceous vegetables) are acceptable because according to JMPR evaluation report, residues of metabolite D in these commodities are below LOQ.

Mepiquat chloride

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	•	2			
Wheat	○ 3	2			3 EU
Barley	○ 4	2			4 EU
Rye	○ 3	2			3 EU
Corn (maize, including pop corn and sweet corn)	•	2			
Buckwheat	•	2			
Other cereal grains	○ 3	2			3 EU
Water melon	•	2			
Melons	•	2			
Makuwauri melon	•	2			
Unshu orange, pulp	•	2			
Citrus natsudaikai, whole	•	2			
Lemon	•	2			
Orange (including navel orange)	•	2			
Grapefruit	•	2			
Lime	•	2			
Other citrus fruits	•	2			
Apple	•	2			
Japanese pear	•	2			
Pear	•	2			
Quince	•	2			
Loquat	•	2			
Peach	•	2			
Nectarine	•	2			
Apricot	•	2			
Japanese plum (including prune)	•	2			
Mume plum	•	2			
Cherry	•	2			
Strawberry	•	2			
Raspberry	•	2			
Blackberry	•	2			
Blueberry	•	2			
Cranberry	•	2			
Huckleberry	•	2			
Other berries	•	2			
Grape	○ 5	2	§ - Request		
Japanese persimmon	•	2			
Banana	•	2			
Kiwifruit	•	2			
Papaya	•	2			
Avocado	•	2			
Pineapple	•	2			
Guava	•	2			
Mango	•	2			
Passion fruit	•	2			
Date	•	2			
Other fruits	•	2			
Sunflower seeds	•	2			
Sesame seeds	•	2			
Safflower seeds	•	2			
Cotton seeds	○ 2	2			2.0 USA

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rapeseeds	○ 4	2			4 EU
Other oil seeds	●	2			
Ginkgo nut	●	2			
Chestnut	●	2			
Pecan	●	2			
Almond	●	2			
Walnut	●	2			
Other nuts	●	2			
Other spices	●	2			
Cattle, muscle	● 0.09	0.1			0.09 EU
Pig, muscle	● 0.05	0.1			0.05 EU
Other terrestrial mammals, muscle	● 0.09	0.1			0.09 EU
Cattle, fat	● 0.06	0.1			0.06 EU
Pig, fat	● 0.05	0.1			0.05 EU
Other terrestrial mammals, fat	● 0.06	0.1			0.06 EU
Cattle, liver	○ 0.5	0.1			0.5 EU
Pig, liver	● 0.05	0.1			0.05 EU
Other terrestrial mammals, liver	○ 0.5	0.1			0.5 EU
Cattle, kidney	○ 0.8	0.1			0.8 EU
Pig, kidney	● 0.05	0.1			0.05 EU
Other terrestrial mammals, kidney	○ 0.8	0.1			0.8 EU
Cattle, edible offal	○ 0.8	0.1			0.8 EU
Pig, edible offal	● 0.05	0.1			0.05 EU
Other terrestrial mammals, edible offal	○ 0.8	0.1			0.8 EU
Milk	○ 0.06	0.05			0.06 EU
Chicken, muscle	● 0.05	0.1			0.05 EU
Other poultry, muscle	● 0.05	0.1			0.05 EU
Chicken, fat	● 0.05	0.1			0.05 EU
Other poultry, fat	● 0.05	0.1			0.05 EU
Chicken, liver	● 0.05	0.1			0.05 EU
Other poultry, liver	● 0.05	0.1			0.05 EU
Chicken, kidney	● 0.05	0.1			0.05 EU
Other poultry, kidney	● 0.05	0.1			0.05 EU
Chicken, edible offal	● 0.05	0.1			0.05 EU
Other poultry, edible offal	● 0.05	0.1			0.05 EU
Chicken eggs	○ 0.05	0.05			0.05 EU
Other poultry, eggs	○ 0.05	0.05			0.05 EU

Note: The residue definition is Mepiquat chloride 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.

§ : Permitted for use in Japan.

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

Abamectin

Commodity	draft MRL		MRL (current) ppm	Registration	Reference MRL		
	Revised draft ppm	Previous draft* ppm			Codex ppm	National ppm	
Soybeans, dry	0.005	0.005			0.005		
Beans, dry	0.005	0.005			0.005		
Peanuts, dry	0.005	0.005			0.005		
Other pulses	0.005	0.005			0.005		
Potato	0.01	0.01	0.01		0.005	0.01	USA
Taro	0.01	0.01	0.01			0.01	USA
Sweet potato	0.01	0.01	0.01		0.005	0.01	USA
Yam	0.01	0.01	0.01		0.005	0.01	USA
Other potatoes	0.01	0.01	0.01			0.01	USA
Lettuce (including cos lettuce and leaf lettuce)	0.2	0.2	0.05	IT	0.15	0.1	USA
Onion	0.005	0.005			0.005		
Welsh (including leek)	0.1	0.1	0.1	\$	0.005		
Garlic	0.005	0.005			0.005		
Celery	0.03	0.03			0.03		
Other umbelliferous vegetables	0.05	0.05	0.05			0.05	USA
Tomato	0.3	0.3	0.02	Request	0.05		
Pimiento (sweet pepper)	0.5	0.5	0.5	\$	0.09		
Egg plant	0.2	0.2	0.2	\$	0.05		
Other solanaceous vegetables	0.2	0.2	0.2		0.005	0.2	Korea
Cucumber (including gherkin)	0.2	0.2	0.01	Request	0.03		
Pumpkin (including squash)			0.01				
Water melon	0.05	0.05	0.05	\$			
Melons	0.05	0.05	0.05	\$			
Other cucurbitaceous vegetables	0.01	0.01	0.01			0.01	USA
Ginger	0.01	0.01	0.01			0.01	USA
Kidney beans, immature (with pods)	0.08	0.08			0.08		
Other vegetables	0.08	0.08	0.01		0.08		
Unshu orange, pulp	0.02	0.02		Request			
Citrus natsudaidai, whole	0.1	0.1	0.01	Request	0.02		
Lemon	0.1	0.1	0.01	Request	0.02		
Orange (including navel orange)	0.1	0.1	0.01	Request	0.02		
Grapefruit	0.1	0.1	0.01	Request	0.02		
Lime	0.1	0.1	0.01	Request	0.02		
Other citrus fruits	0.1	0.1	0.01	Request	0.02		
Apple	0.02	0.02	0.02		0.01	0.02	USA
Japanese pear	0.02	0.02	0.02		0.01	0.02	USA
Pear	0.02	0.02	0.02		0.01	0.02	USA
Quince	0.01	0.01			0.01		
Nectarine	0.09	0.09	0.09		0.03	0.09	USA
Apricot	0.09	0.09	0.09		0.03	0.09	USA
Japanese plum (including prune)	0.09	0.09	0.09		0.005	0.09	USA
Cherry	0.09	0.09	0.09		0.07	0.09	USA
Strawberry	0.2	0.2	0.02	IT	0.15	0.15	EU
Raspberry	0.05	0.05			0.05		
Blackberry	0.05	0.05			0.05		
Grape	0.02	0.02		IT	0.01	0.02	USA
Papaya	0.02	0.02			0.015		
Avocado	0.02	0.02			0.015		
Mango	0.01	0.01			0.01		
Other fruits	0.005	0.005			0.005		
Cotton seeds	0.02	0.02	0.01		0.015		

Commodity	draft MRL		MRL (current) ppm	Registration	Reference MRL		
	Revised draft ppm	Previous draft* ppm			Codex ppm	National ppm	
Ginkgo nut	0.005	0.005			0.005		
Chestnut	0.01	0.01	0.01		0.005	0.01	USA
Pecan	0.01	0.01	0.01		0.005	0.01	USA
Almond	0.01	0.01	0.01		0.005	0.01	USA
Walnut	0.01	0.01	0.01		0.005	0.01	USA
Other nuts	0.01	0.01	0.01		0.005	0.01	USA
Tea	1	1	1	§			
Hop	0.2	0.2	0.2	§	0.15		
Other spices	1	1		Request	0.02		
Other herbs	0.03	0.03	0.03		0.005	0.03	USA
Cattle, muscle	0.02	0.02	0.01			0.02	USA
Pig, muscle	0.02	0.02				0.02	Australia
Other terrestrial mammals, muscle	○ 0.01		0.01			0.01	Australia
Cattle, fat	0.1	0.1	0.1		0.1		
Pig, fat	0.02	0.02	0.02			0.02	Australia
Other terrestrial mammals, fat	○ 0.1		0.01			0.1	Australia
Cattle, liver	0.1	0.1	0.1		0.1		
Pig, liver	0.02	0.02	0.02			0.02	Australia
Other terrestrial mammals, liver	○ 0.05		0.1			0.05	Australia
Cattle, kidney	0.06	0.06	0.06		0.05	0.06	USA
Pig, kidney	0.01	0.01	0.01			0.01	Australia
Other terrestrial mammals, kidney	○ 0.01		0.1			0.01	Australia
Cattle, edible offal	0.06	0.06	0.06			0.06	USA
Pig, edible offal	0.02	0.02	0.02			0.02	USA
Other terrestrial mammals, edible offal	○ 0.05		0.1				
Milk	0.02	0.02	0.02			0.02	Australia
Pepper, dried	0.5	0.5	0.2		0.5		

Note: The residue definition is sum of avermectin B_{1a}, avermectin B_{1b} and delta-8,9 isomer of avermectin B_{1a}.

* The WTO/SPS notification was made for those draft MRLs as G/SPS/N/JPN/506.

* 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 draft MRLs are modified in response to the comments and the submitted data on the previous

§ : Permitted for use in Japan.

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

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, pimienta (sweet pepper), and egg plant.

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

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

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

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

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

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

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

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

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

“Other herbs” refers to all herbs, except watercress, *nira*, parsley stems and leaves, celery stems and leaves.

“Edible offal” refers to all edible parts, except muscle, fat, liver, and kidney

“Other terrestrial mammals” refers to all terrestrial mammals, except cattle and pig.

“Other poultry animals” refers to all poultry, except chicken.

“Other fish” refers to all fish, except salmoniformes, anguilliformes, and perciformes.

“Other aquatic animals” refers to all aquatic animal, except fish, shelled molluscs and crustaceans.

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

The 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 these substances shall not be detected in any food and ingredients (limited to the commodities in which so called “no-detection limits” are established) by such analytical methods.

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

- Analytical Method for Protham

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

The target compound to be determined is propham.

1. Instrument

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

2. Reagents

Use the reagents listed in Section C *Reagent/Test Solution, 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 compound.

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

Ethylenediamine-*N*-propylsilanized silica gel cartridge (500 mg): A polyethylene tube of 8-9 mm in inside diameter packed with 500 mg of ethylenediamine-*N*-propylsilanized silica gel, or a cartridge equivalent to the specified one in separation capability.

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.

Ammonium formate: Ammonium formate (special grade)

Diethylene glycol: Contains not less than 98% of diethylene glycol.

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.

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

3. Reference standard

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

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 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 20 mL aliquot of the solution, and concentrate to about 3 mL at below 40°C. Add 100 mL of 10 w/v% sodium chloride solution, and extract with shaking twice with 100 mL and 50 mL of *n*-hexane. Combine the extracts, dehydrate with anhydrous sodium sulfate, filter out the anhydrous sodium sulfate, and add 0.2 mL of 2 vol% diethylene glycol-acetone solution. 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 each of acetonitrile saturated with *n*-hexane. Combine the extracts, concentrate at below 40°C, and remove the solvent. Dissolve the residue in 4 mL of acetone, and add 16 mL of water.

ii. Fruits and vegetables

Add 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 10 mL aliquot of the solution, concentrate to about 2 mL at below 40°C. Add 100 mL of 10 w/v% sodium chloride solution, and extract with shaking twice with 100 mL and 50 mL of *n*-hexane. Combine the extracts, dehydrate with anhydrous sodium sulfate, filter out the anhydrous sodium sulfate, and add 0.2 mL of 2 vol% diethylene glycol-acetone solution. Concentrate the filtrate at below 40°C, and remove the solvent. Dissolve the residue in 4 mL of acetone, and add 16 mL of water.

iii. Tea and hops

Add 20 mL of water to 5.00 g of sample, and let stand for 30 minutes. Add 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 40 mL aliquot of the solution, concentrate to about 6 mL at below 40°C. Add 100 mL of 10 w/v% sodium

chloride solution, and extract with shaking twice with 100 mL and 50 mL of *n*-hexane. Combine the extracts, dehydrate with anhydrous sodium sulfate, filter out the anhydrous sodium sulfate, and add 0.2 mL of 2 vol% diethylene glycol-acetone solution. Concentrate the filtrate at below 40°C, and remove the solvent. Dissolve the residue in 4 mL of acetone, and add 16 mL of water.

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

Add 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 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, concentrate to about 3 mL at below 40°C. Add 100 mL of 10 w/v% sodium chloride solution, and extract with shaking twice with 100 mL and 50 mL of *n*-hexane. Combine the extracts, dehydrate with anhydrous sodium sulfate, filter out the anhydrous sodium sulfate, and add 0.2 mL of 2 vol% diethylene glycol-acetone solution. 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 each of acetonitrile saturated with *n*-hexane. Combine the extracts, concentrate at below 40°C, and remove the solvent. Dissolve the residue in 4 mL of acetone, and add 16 mL of water.

v. Honey

Dissolve the 10.0 g of sample with 20 mL of water. Add 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 20 mL aliquot of the solution, concentrate to about 3 mL at below 40°C. Add 100 mL of 10 w/v% sodium chloride solution, and extract with shaking twice with 100 mL and 50 mL of *n*-hexane. Combine the extracts, dehydrate with anhydrous sodium sulfate, filter out the anhydrous sodium sulfate, and add 0.2 mL of 2 vol% diethylene glycol-acetone solution. Concentrate the filtrate at below 40°C, and remove the solvent. Dissolve the residue in 4 mL of acetone, and add 16 mL of water.

b. Clean-up

Add 10 mL each of acetonitrile and acetone/water (1:4, v/v) to an octadecylsilanized silica gel cartridge (1,000 mg) sequentially, and discard the effluents. Add 10 mL of acetonitrile/water (7:3, v/v) to an ethylenediamine-*N*-propylsilanized silica gel cartridge

(500 mg), and discard the effluents. Transfer the solution obtained in “a. Extraction” to the octadecylsilanized silica gel cartridge, add 10 mL of acetonitrile/water (1:4, v/v), and discard the effluents. Connect the ethylenediamine-*N*-propylsilanized silica gel cartridge to the bottom of the octadecylsilanized silica gel cartridge, elute with 10 mL of acetonitrile/water (7:3, v/v), collect the eluate. Add acetonitrile/water (7:3, v/v) to make exactly 10 mL, and use this solution as the test solution.

5. Measurement

a. Calibration curve

Prepare propham standard solutions (acetonitrile/water (7:3, 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 0.01 mg/kg of propham gives the test solution of 0.001 mg/L in concentration.

b. Quantification

Inject the test solution to LC-MS/MS, and calculate the concentration of propham 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,
3 µm in particle diameter

Column temperature: 40°C

Mobile phase: Linear gradient from 2 mmol/L ammonium formate/methanol (1:1, v/v)
to (1:9, v/v) in 10 min

Ionization mode: ESI (+)

Major monitoring ions (*m/z*): Precursor ion 180, product ion 138, 120

Injection volume: 5 µL

Expected retention time: 8 min

6. Limit of quantification

0.01 mg/kg