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POLICY

Voluntary Public

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Japan to Revise MRLs for 5 Agricultural Chemicals

Report Categories:

Sanitary/Phytosanitary/Food Safety

Approved By:

Jess K. Paulson

Prepared By:

Suguru Sato

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 Cyclaniliprole, Nitenpyram, Paclobutrazol, Fenpyrazamine, and Boscalid as well as the revision of analytical methods for Melengestrol Acetate. The Embassy comment period for these proposals is open until Thursday, March 23, 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:

**THE 201st CONFERENCE FOR PROMOTION
OF FOOD IMPORT FACILITATION**

(FOOD SAFETY GROUP)

Standards and Evaluation Division
Department of Environmental Health and Food Safety
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

Date: Thursday, March 9, 2017 (10:00 - 12:00)

Place: Ministry of Health, Labour and Welfare
Temporary Meeting Room No. 2
1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo

Agenda:

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

Pesticide: Cyclaniliprole, Nitenpyram, Paclobutrazol, Fenpyrazamine,
Boscalid

Item 2. Revision of Analytical Methods for Agricultural and Veterinary Chemicals in Foods

Melengestrol Acetate

<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 **Thursday, March 23, 2017**. After the given date, comments should be directed to the enquiry point in accordance with the WTO/SPS Agreement.

With regard to item 1, the SPS notification will be made for the setting or revision of the MRL for the agricultural chemicals except for Cyclaniliprole and Fenpyrazamine 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.

<Contact>

Standards and Evaluation Division,
Department of Environmental Health and Food Safety,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916
Tel: 03-5253-1111 Fax: 03-3501-4868

Pesticide/Veterinary drug/Feed additive
Mr. Ryota NAKAMURA (nakamura-ryouta@mhlw.go.jp)
Tel: 03-5253-1111 (ex 4289)

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:

Pesticide: Cyclaniliprole, Nitenpyram, Paclobutrazol, Fenpyrazamine, Boscalid

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

Cyfluprolle (insecticide): 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 Ministry of Agriculture, Forestry and Fisheries (MAFF). This action will not strengthen the current regulation for any commodities.

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

Paclobutrazol (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.

Fenpyrazamine (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. 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). This action will not strengthen the current regulation for any commodities.

Boscalid (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.

Cyclaniliprole

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Apple	○ 0.3		Request		
Japanese pear	○ 0.3		Request		
Pear	○ 0.3		Request		
Peach	○ 0.05		Request		
Nectarine	○ 0.5		Request		
Japanese plum (including prune)	○ 0.3		Request		
Cherry	○ 1		Request		
Grape	○ 1		Request		
Tea	○ 40		Request		

Note: The residue definition is Cyclaniliprole 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.

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

Request: The MRL is to be modified in response to MAFF request

Nitenpyram

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Code x ppm	National ppm
Rice (brown rice)	• 0.3	0.5	§		
Wheat	•	0.03			
Barley	•	0.03			
Rye	•	0.03			
Corn (maize, including pop corn and sweet corn)	•	0.03			
Buckwheat	•	0.03			
Other cereal grains	•	0.03			
Soybeans, dry	•	0.03			
Beans, dry	•	0.03			
Peas	•	0.03			
Broad beans	•	0.03			
Peanuts, dry	•	0.03			
Other pulses	•	0.03			
Potato	○ 0.2	0.2	§		
Taro	•	0.2			
Sweet potato	•	0.2			
Yam	•	0.2			
Konjac	•	0.2			
Other potatoes	•	0.2			
Sugar beet	•	0.03			
Sugarcane	•	0.03			
Japanese radish, roots (including radish)	○ 0.2	0.2	§		
Japanese radish, leaves (including radish)	○ 5	5	§		
Turnip, roots (including rutabaga)	•	0.2			
Turnip, leaves (including rutabaga)	•	5			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Code x ppm	National ppm
Horseradish	•	0.2			
Watercress	•	5			
Chinese cabbage	•	0.03			
Cabbage	•	0.03			
Brussels sprouts	•	5			
Kale	•	5			
Komatsuna(Japanese mustard spinach)	•	5			
Kyona	•	5			
Qing-geng-cai	•	5			
Cauliflower	• 2	5	Request		
Broccoli	• 2	5	Request		
Other cruciferous vegetables	• 0. 5	5	§		
Burdock	•	0.2			
Salsify	•	0.2			
Artichoke	•	5			
Chicory	•	5			
Endive	•	5			
Shungiku	• 2	5	§		
Lettuce (including cos lettuce and leaf lettuce)	• 3	5	§		
Other composite vegetables	• 3	5	§ • Request		
Onion	○ 0. 1	0.03	Request		
Welsh (including leek)	• 2	5	§		
Garlic	•	0.03			
Nira	•	5			
Asparagus	• 2	5	§		
Multiplying onion (including shallot)	○ 5	5	§		
Other liliaceous vegetables	•	5			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Code x ppm	National ppm
Carrot	•	0.2			
Parsnip	•	0.2			
Parsley	•	5			
Celery	•	5			
Mitsuba	•	5			
Other umbelliferous vegetables	• 3	5	§		
Tomato	• 1	5	§		
Pimiento (sweet pepper)	• 0.5	1	§		
Egg plant	• 2	5	§		
Other solanaceous vegetables	○ 5	5	§		
Cucumber (including gherkin)	• 2	5	§		
Pumpkin (including squash)	• 0.2	5	§		
Oriental pickling melon (vegetable)	• 0.3	5	§		
Water melon	• 0.5	5	§		
Melons	• 0.7	5	§		
Makuwauri melon	•	1			
Other cucurbitaceous vegetables	• 0.3	5	§		
Spinach	•	5			
Bamboo shoots	•	0.2			
Okra	•	1			
Ginger	•	0.2			
Peas, immature (with pods)	•	0.03			
Kidney beans, immature (with pods)	•	0.03			
Green soybeans	•	0.03			
Button mushroom	•	0.03			
Shiitake mushroom	•	0.03			
Other mushrooms	•	0.03			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Code x ppm	National ppm
Other vegetables	• 3	5	§		
Unshu orange, pulp	• 3	0.5	§		
Citrus natsudaidai, whole	• 1	2	§		
Lemon	○ 2	2	§		
Orange (including navel orange)	○ 2	2	§		
Grapefruit	○ 2	2	§		
Lime	○ 2	2	§		
Other citrus fruits	○ 2	2	§		
Apple	○ 0.5	0.5	§		
Japanese pear	○ 0.5	0.5	§		
Pear	○ 0.5	0.5	§		
Quince	•	1			
Loquat	•	1			
Peach	○ 0.5	0.5	§		
Nectarine	•	1			
Apricot	•	5			
Japanese plum (including prune)	•	5			
Mume plum	•	5			
Cherry	•	5			
Strawberry	• 2	5	§		
Raspberry	•	5			
Blackberry	•	5			
Blueberry	•	5			
Cranberry	•	5			
Huckleberry	•	5			
Other berries	•	5			
Grape	○ 5	5	§		

Japanese persimmon	● 0.7	1	§			
Banana	●	1				
Kiwifruit	●	1				
Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Code x ppm	National ppm	
Papaya	●	1				
Avocado	●	1				
Pineapple	●	1				
Guava	●	1				
Mango	○ 1	1	Request			
Passion fruit	●	1				
Date	●	5				
Other fruits	●	5				
Sunflower seeds	●	0.03				
Sesame seeds	●	0.03				
Safflower seeds	●	0.03				
Cotton seeds	●	0.03				
Rapeseeds	●	0.03				
Other oil seeds	●	0.03				
Ginkgo nut	●	0.03				
Chestnut	●	0.03				
Pecan	●	0.03				
Almond	●	0.03				
Walnut	●	0.03				
Other nuts	●	0.03				
Tea	○ 10	10	§			
Coffee beans	●	0.03				
Cacao beans	●	0.03				
Hop	●	0.03				

Other spices	○ 10	5				
Other herbs	● 3	5	§			

Note: The residue definition is sum of Nitenpyram and its metabolites CPMA 【2-[N-(6-Chloro-3-pyridylmethyl)-N-ethyl]amino-2-methylimino acetic acid】 and CPMF 【N-(6-Chloro-3-pyridylmethyl)-N-ethyl-N'-methyl formamidine】 , expressed as Nitenpyram.

* 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: The MRL is to be modified in response to MAFF request

Paclobutrazol

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Code x ppm	National ppm
Rice (brown rice)	● 0.0 2	0.05	§		
Tomato	○ 0.0 5		Request		
Unshu orange, pulp	○ 0.0 2	0.02	§		
Apple	○ 0.5	0.5			
Japanese pear	○ 1	1		1	Australia
Pear	○ 1	1		1	Australia
Quince	○ 1	1		1	Australia
Loquat	○ 1	1		1	Australia
Peach	○ 0.2	0.2	§		
Nectarine	●	0.05			
Apricot	●	0.05			
Japanese plum (including prune)	●	0.05			
Mume plum	●	0.05			
Cherry	○ 0.5	0.5	§		
Other berries	● 0.3	0.5	§		
Banana	○ 0.0 1	0.01		0.0 1	Australia
Kiwifruit	○ 0.0 1	0.01		0.0 1	Australia
Papaya	○ 0.0 1	0.01		0.0 1	Australia
Avocado	○ 0.0 1	0.01			
Pineapple	○ 0.0 1	0.01		0.0 1	Australia

Guava	○	0.0 1	0.01			0.0 1	Australia
Mango	○	0.0 1	0.01				
Passion fruit	○	0.0 1	0.01			0.0 1	Australia
Date	○	0.0 1	0.01			0.0 1	Australia
Other fruits	○	0.0 1	0.01			0.0 1	Australia
Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Code x ppm	National ppm	
Almond	●		0.05				
Other spices	○	0.2	0.2	§			
Fish	○	0.0 4	0.04				

Note: The residue definition is Paclobutrazol 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.

§ : Permitted for use in Japan.

Request: The MRL is to be modified in response to MAFF request

Fenpyrazamine

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Code x ppm	National ppm	
Lettuce (including cos lettuce and leaf lettuce)	○ 2		IT		2.0	US A
Tomato	○ 5	5	§			
Egg plant	○ 2	2	§			
Cucumber (including gherkin)	○ 0.7	0.7	§			
Water melon	○ 0.0 5		Request			
Melons	○ 0.0 5		Request			
Other vegetables	○ 0.7		IT		0.7	US A
Unshu orange, pulp	○ 0.1	0.1	§			
Citrus natsudaidai, whole	○ 5	5	§			
Lemon	○ 5	5	§			
Orange (including navel orange)	○ 5	5	§			
Grapefruit	○ 5	5	§			
Lime	○ 5	5	§			
Other citrus fruits	○ 5	5	§			
Peach	○ 0.3		Request			
Strawberry	○ 10	10	§			
Raspberry	○ 5		IT		5.0	US A
Blackberry	○ 5		IT		5.0	US A
Blueberry	○ 5		IT		5.0	US

						A
Cranberry	○ 5		IT		5.0	US A
Huckleberry	○ 5		IT		5.0	US A
Other berries	○ 5		IT		5.0	US A
Grape	○ 10	10	§			
Almond	○ 0.0 2		IT		0.0 2	US A
Other nuts	○ 0.0 2		IT		0.0 2	US A
Other spices	○ 15	15	§			

Note: The residue definition is Fenpyrazamine 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: The MRL is to be modified in response to MAFF request

IT : Import tolerance

Boscalid

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Code x ppm	National ppm	
Wheat	0.7	0.7	§	0.5		
Barley	3	3		0.5	3	EU
Rye	0.5	0.5		0.5		
Corn (maize, including pop corn and sweet corn)	0.1	0.1		0.1		
Buckwheat	0.1	0.1		0.1		
Other cereal grains	0.5	0.5		0.5		
Soybeans, dry	3	3	§	3		
Beans, dry	3	3	§	3		
Peas	3	3		3		
Broad beans	3	3		3		
Peanuts, dry	1	1		1		
Other pulses	3	3		3		
Potato	2	2		2		
Taro	2	2		2		
Sweet potato	2	2		2		
Yam	2	2		2		
Konjac	2	2		2		

Other potatoes	○	2	2		2		
Sugar beet	○	2	2		2		
Japanese radish, roots (including radish)	○	2	2		2		
Japanese radish, leaves (including radish)	○	40	40		40		
Turnip, roots (including rutabaga)	○	2	2		2		
Turnip, leaves (including rutabaga)	○	40	40		40		
Horseradish	○	2	2		2		
Watercress	○	40	40		40		
Chinese cabbage	○	40	40	§	40		
Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Code x ppm	National ppm	
Cabbage	○	5	5	§	5		
Brussels sprouts	○	5	5		5		
Kale	○	40	40		40		
Komatsuna(Japanese mustard spinach)	○	40	40		40		
Kyona	○	40	40		40		
Qing-geng-cai	○	40	40		40		
Cauliflower	○	5	5		5		
Broccoli	○	5	5	§	5		
Other cruciferous vegetables	○	40	40	§	40		
Burdock	○	2	2		2		
Salsify	○	2	2		2		
Artichoke	○	30	30		30		
Chicory	○	40	40		40		
Endive	○	40	40		40		
Shungiku	○	40	40		40		
Lettuce (including cos lettuce and leaf lettuce)	○	40	40	§	40		
Other composite vegetables	○	40	40	§	40		
Onion	○	5	5	§	5		

Welsh (including leek)	○ 5	5		5		
Garlic	○ 5	5	§	5		
Nira	○ 5	3		5		
Asparagus	○ 30	30		30		
Multiplying onion (including shallot)	○ 5	5		5		
Other liliaceous vegetables	○ 30	30	§	30		
Carrot	○ 2	2	§	2		
Parsnip	○ 2	2		2		
Celery	○ 30	30		30		
Other umbelliferous vegetables	○ 5	5		5		
Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Code x ppm	National ppm	
Tomato	○ 5	5	§	3		
Pimiento (sweet pepper)	○ 10	10	§	3		
Egg plant	○ 3	3	§	3		
Other solanaceous vegetables	○ 40	40	§	40		
Cucumber (including gherkin)	○ 5	5	§	3		
Pumpkin (including squash)	○ 3	3	§	3		
Oriental pickling melon (vegetable)	○ 3	3		3		
Water melon	● 0.2	2	§			
Melons	● 0.2	2	§			
Makuwauri melon	● 0.2	2				
Other cucurbitaceous vegetables	○ 40	40		40		
Spinach	○ 40	40		40		
Bamboo shoots	○ 30	30		30		
Okra	○ 3	3		3		
Ginger	○ 0.0 5	0.05			0.0 5	US A
Peas, immature (with pods)	○ 5	5	§	3		
Kidney beans, immature (with pods)	○ 5	5	§	3		

Green soybeans	o	3	3		3		
Other vegetables	o	40	40		40		
Unshu orange, pulp	o	1	1	§			
Citrus natsudaidai, whole	o	10	10	§	2		
Lemon	o	10	10	§	2		
Orange (including navel orange)	o	10	10	§	2		
Grapefruit	o	10	10	§	2		
Lime	o	10	10	§	2		
Other citrus fruits	o	10	10	§	2		
Apple	o	2	2	§	2		
Japanese pear	o	3	3	§		3.0	US A
Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Code x ppm	National ppm	
Pear	o	3	3	§		3.0	US A
Quince	o	3	3			3.0	US A
Loquat	o	3	3			3.0	US A
Peach	o	0.2	0.2	§			
Nectarine	o	3	3	§	3		
Apricot	o	3	3	§	3		
Japanese plum (including prune)	o	10	10	§	10		
Mume plum	o	3	3	§	3		
Cherry	o	3	3	§	3		
Strawberry	o	15	15	§	3		
Raspberry	o	10	10		10		
Blackberry	o	10	10		10		
Blueberry	o	10	10		10		
Cranberry	o	10	10		10		
Huckleberry	o	10	10		10		
Other berries	o	10	10		10		

Grape	○ 10	10	§	5		
Japanese persimmon	○ 1	1	§			
Banana	○ 0.6	0.6		0.6		
Kiwifruit	○ 0.1		Request			
Other fruits	○ 10	10		10		
Sunflower seeds	○ 1	1		1		
Sesame seeds	○ 1	1		1		
Safflower seeds	○ 1	1		1		
Cotton seeds	○ 1	1		1		
Rapeseeds	○ 4	4		1	3.5	US A
Other oil seeds	○ 1	1		1		
Ginkgo nut	○ 0.0 5	0.05		0.05		
Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Code x ppm	National ppm	
Chestnut	○ 0.7	0.7		0.05	0.7	US A
Pecan	○ 0.7	0.7		0.05	0.7	US A
Almond	○ 0.7	0.7		0.05	0.7	US A
Walnut	○ 0.7	0.7		0.05	0.7	US A
Other nuts	○ 1	1		1		
Tea	○ 60	10	§ · Request			
Coffee beans	○ 0.0 5	0.05		0.05		
Hop	○ 60	60	§	60		
Other spices	○ 40	40	§	10		
Other herbs	○ 40	40		40		
Cattle, muscle	○ 0.2	0.2				
Pig, muscle	○ 0.2	0.2				
Other terrestrial mammals, muscle	○ 0.2	0.2				
Cattle, fat	○ 0.7	0.7		0.7		

Pig, fat	○ 0.7	0.7		0.7		
Other terrestrial mammals, fat	○ 0.7	0.7		0.7		
Cattle, liver	○ 0.2	0.2		0.2		
Pig, liver	○ 0.2	0.2		0.2		
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	○ 0.1	0.1		0.1		
Chicken, muscle	○ 0.0 2	0.02		0.02		
Other poultry, muscle	○ 0.0 2	0.02		0.02		
Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Code x ppm	National ppm	
Chicken, fat	○ 0.0 2	0.02		0.02		
Other poultry, fat	○ 0.0 2	0.02		0.02		
Chicken, liver	○ 0.0 2	0.02		0.02		
Other poultry, liver	○ 0.0 2	0.02		0.02		
Chicken, kidney	○ 0.0 2	0.02		0.02		
Other poultry, kidney	○ 0.0 2	0.02		0.02		
Chicken, edible offal	○ 0.0 2	0.02		0.02		
Other poultry, edible offal	○ 0.0 2	0.02		0.02		
Chicken eggs	○ 0.0 2	0.02		0.02		
Other poultry, eggs	○ 0.0 2	0.02		0.02		

Peanut oils, (limited to refined peanut oil and peanut 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)	○ 0.2	0.2			0.1 5	US A
Pepper,dried	○ 10	10		10		
Raisin※1	●	10		10		
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)※2	●	5			5.0	US A

Note: The residue definition is Boscalid 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.

§ : Permitted for use in Japan.

Request: The MRL is to be modified in response to MAFF request

*For some foods such as peanut oils and pepper dried, draft MRLs are based on JMPR standards by applying a conversion processing factor as 10 for peanut oils and 9.2 for pepper dried.

※1 For raisin, The MRL of its raw commodity will be applied taking into account its processing factor. JMPR estimated a processing factor of 0.5 for raisin.

※2 For rapeseed oils, the MRL of its raw commodity will be applied taking into account its processing factor. JMPR estimated a processing factor of 1.3 for rapeseed oils.

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, pedia, 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 *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 any ingredients of agricultural chemicals or other chemical substances shall not be detected by the methods.

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

- Analytical Method for Melengestrol Acetate

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

The target compound to be determined is melengestrol acetate.

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.

Acetonitrile: 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.

Anhydrous sodium sulfate: 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 melengestrol acetate: Contains not less than 98% of melengestrol acetate.

4. Procedure

a. Extraction

i. Muscle, fat, liver and kidney

Weigh 10.0 g of sample. Add 50 mL of acetonitrile saturated with *n*-hexane, 50 mL of *n*-hexane and 1 mL of acetic acid, and homogenize for 1 minute. Add 20 g of anhydrous sodium sulfate, and homogenize for 2 minutes. Centrifuge at 3,000 rpm for 5 minutes, discard the *n*-hexane layer, and collect the acetonitrile layer. Add 50 mL of acetonitrile to the residue, homogenize for 2 minutes, and centrifuge as described above. Collect the acetonitrile layer, combine the resulting acetonitrile layers, and add acetonitrile to make exactly 100 mL. Take exactly 5 mL of the solution, concentrate at below 40°C, and remove the solvent. Dissolve the residue in 1 mL of 0.1 vol% formic acid/methanol (1:4, v/v).

ii. Foods except those listed in i above

Extract according to the method described in “i. Muscle, fat, liver and kidney.”

b. Clean-up

Add 5 mL each of methanol and 0.1 vol% formic acid/methanol (1:4, v/v) to an octadecylsilanized silica gel cartridge (1,000 mg) sequentially, and discard the effluents. Transfer the solution obtained in “a. Extraction” to the cartridge and elute with 15 mL of 0.1 vol% formic acid/methanol (1:4, v/v). Collect the total eluate, concentrate at below 40°C, and remove the solvent. Dissolve the residue in acetonitrile/0.1 vol% formic acid (1:3, v/v) to make exactly 1 mL, and use this solution as the test solution.

5. Measurement

a. Calibration curve

Prepare melengestrol acetate standard solutions (acetonitrile/0.1 vol% formic acid (1:3, 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 0.0005 mg/kg of melengestrol acetate gives the test solution of 0.00025 mg/L in concentration.

b. Quantification

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

c. Confirmation

Confirm using LC-MS/MS.

d. Measurement conditions

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

Column temperature: 40°C

Mobile phase: Linear gradient from 0.1 vol% formic acid/0.1 vol% formic acid-acetonitrile solution (1:3, v/v) to (1:9, v/v) in 5 min and hold at (1:99, v/v) for 5 min.

Ionization mode: ESI (+)

Major monitoring ions (m/z): Precursor ion 397, product ion 337, 279

Injection volume: 5 μL

Expected retention time: 4 min

6. Limit of quantification

0.0005 mg/kg