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Japan proposes the revision of MRLs for 7 agricultural chemicals

Report Categories:
Sanitary/Phytosanitary/Food Safety
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Report Highlights:
On Thursday, April 13, 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 Isoxathion, Glyphosate, Clethodim, and Flutolanil. MHLW also announced changes to the MRLs of Oxytetracycline/Chlortetracycline/Tetracycline as pesticides/veterinary drugs/feed additives. The Embassy comment period for these proposals is open until Thursday, April 27, 2017. MHLW will also notify those MRLs to the WTO becoming more restrictive except for Oxytetracycline/Chlortetracycline/ Tetracycline, which will allow another opportunity for interested parties to comment on these changes.

Keyword: JA7053

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 **Thursday, April 27, 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 and 3, the SPS notification will be made for the setting or revision of the MRL for the agricultural chemicals except for Oxytetracycline/ Chlortetracycline/Tetracycline 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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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 System[1] 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: Isoxathion, Glyphosate, Clethodim, Flutolanil
Pesticide, Veterinary drug and Feed additive:
Oxytetracycline/Chlortetracycline/Tetracycline

[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

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

Glyphosate (herbicide): 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 Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan (Shokuan No. 0205001, 5 February 2004). Furthermore the MHLW is going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Clethodim (herbicide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting import tolerances based on the Guideline for 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 MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Flutolanil (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.

Oxytetracycline/Chlortetracycline/Tetracycline (fungicide, antibiotic): 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. This action will not strengthen the current regulation for any commodities.

Isoxathion

Commodity	MRL (draft) ppm		MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Rice (brown rice)	●		0.2				
Wheat	●		0.02				
Barley	●		0.02				
Rye	●		0.02				
Corn (maize, including pop	○	0.03	0.02	§			
Buckwheat	●		0.02				
Other cereal grains	●		0.02				
Soybeans, dry	●	0.02	0.05	§			
Beans, dry	●	0.02	0.05	§			
Peas	●	0.02	0.05	§			
Broad beans	●	0.02	0.05	§			
Peanuts, dry	●	0.02	0.05	§			
Other pulses	●	0.02	0.05	§			
Potato	●		0.05				
Taro	●	0.03	0.05	§			
Sweet potato	●		0.05				
Yam	●		0.05				
Konjac	●		0.05				
Other potatoes	●		0.05				
Sugarcane	●	0.03	0.05	§			
Japanese radish, roots	○	0.1	0.1	§			
Japanese radish, leaves	○	0.1	0.1	§			
Turnip, roots (including	●	0.05	0.1	§			
Turnip, leaves (including	●	0.05	0.1	§			
Horseradish	●		0.1				
Watercress	●		0.1				
Chinese cabbage	●	0.03	0.1	§			
Cabbage	●	0.02	0.1	§			
Brussels sprouts	●		0.1				
Kale	●		0.1				
Komatsuna(Japanese	●		0.1				
Kyona	●		0.1				
Qing-geng-cai	●		0.1				
Cauliflower	●		0.1				
Broccoli	●	0.02	0.1	§			
Other cruciferous	○	0.1	0.1	§			
Burdock	●	0.02	0.1	§			
Salsify	●		0.1				
Artichoke	●		0.1				
Chicory	●		0.1				
Endive	●	0.02	0.1	§			
Shungiku	●	0.05	0.1	§			
Lettuce (including cos	○	0.1	0.1	§			
Other composite	○	0.1	0.1	§			
Onion	●	0.01	0.1	§			
Welsh (including leek)	●	0.05	0.1	§			
Garlic	●		0.1				
Nira	●		0.1				
Asparagus	●		0.1				
Multiplying onion (including	●	0.05	0.1	§			
Other liliaceous vegetables	●		0.1				

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Carrot	● 0.05	0.1	§			
Parsnip	●	0.1				
Parsley	●	0.1				
Celery	●	0.1				
Mitsuba	●	0.1				
Other umbelliferous	●	0.1				
Tomato	● 0.01	0.1	§			
Pimiento (sweet	●	0.1				
Egg plant	● 0.02	0.1	§			
Other solanaceous	●	0.1				
Cucumber (including	● 0.01	0.1	§			
Pumpkin (including	● 0.01	0.1	§			
Oriental pickling melon	●	0.1				
Water melon	● 0.01	0.2	§			
Melons	●	0.2				
Makuwauri melon	●	0.2				
Other cucurbitaceous	●	0.1				
Spinach	● 0.05	0.1	§			
Bamboo shoots	●	0.1				
Okra	●	0.1				
Ginger	●	0.1				
Peas, immature (with	○ 0.2	0.1	§			
Kidney beans,	● 0.02	0.1	§			
Green soybeans	○ 0.1	0.1	§			
Button mushroom	●	0.1				
Shiitake mushroom	●	0.1				
Other mushrooms	●	0.1				
Other vegetables	○ 0.1	0.1	§			
Unshu orange, pulp	● 0.02	0.2	§			
Citrus natsudaidai,	●	0.2				
Lemon	●	0.2				
Orange (including navel	●	0.2				
Grapefruit	●	0.2				
Lime	●	0.2				
Other citrus fruits	●	0.2				
Apple	● 0.02	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	●	0.2				
Mume plum	●	0.2				
Cherry	●	0.2				
Strawberry	○ 0.2	0.2	§			
Raspberry	●	0.2				
Blackberry	●	0.2				
Blueberry	●	0.2				
Cranberry	●	0.2				

Commodity	MRL (draft) ppm		MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Huckleberry	●		0.2				
Other berries	●		0.2				
Grape	●		0.2				
Japanese	●		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				
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	●	0.1	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	5	§			
Other spices	○	10	0.2	§			
Other herbs	●	0.05	0.1	§			
Fish	○	0.2		Request			

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

Glyphosate

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Rice (brown rice)	○	0.1	0.1	§			
Wheat	○	30	5.0	§・Request	30		
Barley	○	30	20	§	30		
Rye	○	30	0.2	§	30		
Corn (maize, including pop	○	5	1.0	§・IT	5		
Buckwheat	○	30	0.2	§	30		
Other cereal grains	○	30	20	§	30		
Soybeans, dry	○	20	20	§・IT	20		
Beans, dry	○	10	2.0	§・IT	2	10	Australia
Peas	○	5	5.0	§	5		
Broad beans	○	2	2.0	§			
Peanuts, dry	○	0.1	0.1				
Other pulses	○	5	2.0	§	5		
Potato	○	0.2	0.2	§			
Taro	○	0.1	0.1	§			
Sweet potato	○	0.2	0.2	§			
Yam	○	0.2	0.2	§			
Konjac	○	0.1	0.1	§			
Other potatoes	○	0.1	0.1	§			
Sugar beet	○	15	0.2		15		
Sugarcane	○	2	2.0	§	2		
Japanese radish, roots	○	0.2	0.2	§			
Japanese radish, leaves	○	0.2	0.2	§			
Turnip, roots (including	○	0.2	0.2	§			
Turnip, leaves (including	○	0.2	0.2	§			
Horseradish	○	0.2	0.2	§			
Watercress	○	0.2	0.2	§			
Chinese cabbage	○	0.2	0.2	§			
Cabbage	○	0.2	0.2	§・Request			
Brussels sprouts	○	0.2	0.2	§			
Kale	○	0.2	0.2	§			
Komatsuna(Japanese	○	0.2	0.2	§			
Kyona	○	0.2	0.2	§			
Qing-geng-cai	○	0.2	0.2	§			
Cauliflower	○	0.2	0.2	§			
Broccoli	○	0.2	0.2	§			
Other cruciferous	○	0.2	0.2	§			
Burdock	○	0.2	0.2	§			
Salsify	○	0.2	0.2	§			
Artichoke	○	0.2	0.2	§			
Chicory	○	0.2	0.2	§			
Endive	○	0.2	0.2	§			
Shungiku	○	0.2	0.1	§			
Lettuce (including cos	○	0.2	0.2	§			
Other composite	○	0.2	0.2	§			
Onion	○	0.2	0.2	§・Request			
Welsh (including leek)	○	0.2	0.2	§			
Garlic	○	0.2	0.2	§			
Nira	○	0.2	0.1	§			
Asparagus	○	0.5	0.5	§			
Multiplying onion (including	○	0.2	0.2	§			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Other liliaceous	○ 0.2	0.2	§			
Carrot	○ 0.2	0.2	§			
Parsnip	○ 0.2	0.2	§			
Parsley	○ 0.2	0.2	§			
Celery	○ 0.2	0.2	§			
Mitsuba	○ 0.2	0.1	§			
Other umbelliferous	○ 0.2	0.1	§			
Tomato	○ 0.2	0.2	§			
Pimiento (sweet	○ 0.1	0.1	§			
Egg plant	○ 0.2	0.2	§			
Other solanaceous	○ 0.1	0.1	§			
Cucumber (including	○ 0.5	0.5	§			
Pumpkin (including	○ 0.5	0.5	§			
Oriental pickling melon	○ 0.2	0.2	§			
Water melon	○ 0.5	0.5	§			
Melons	○ 0.5	0.5	§			
Makuwauri melon	○ 0.2	0.2	§			
Other cucurbitaceous	○ 0.5	0.5	§			
Spinach	○ 0.2	0.2	§			
Bamboo shoots	○ 0.2	0.2	§			
Okra	○ 0.2	0.2	§			
Ginger	○ 0.2	0.2	§			
Peas, immature (with	● 0.2	3	§			
Kidney beans,	● 0.2	2	§			
Green soybeans	○ 0.2	0.2	§			
Button mushroom	○ 0.2	0.2				
Shiitake mushroom	●	0.1				
Other mushrooms	●	30				
Other vegetables	○ 0.2	0.2	§			
Unshu orange, pulp	○ 0.5	0.5	§ ・Request			
Citrus natsudaidai,	○ 0.5	0.5	§ ・Request			
Lemon	○ 0.5	0.5	§ ・Request			
Orange (including navel	○ 0.5	0.5	§ ・Request			
Grapefruit	○ 0.5	0.5	§ ・Request			
Lime	○ 0.5	0.5	§ ・Request			
Other citrus fruits	○ 0.5	0.5	§ ・Request			
Apple	○ 0.2	0.2	§ ・Request			
Japanese pear	○ 0.2	0.2	§ ・Request			
Pear	○ 0.2	0.2	§ ・Request			
Quince	○ 0.2	0.2	§			
Loquat	○ 0.2	0.2	§			
Peach	○ 0.2	0.2	§			
Nectarine	○ 0.2	0.2	§			
Apricot	○ 0.2	0.2	§			
Japanese plum	○ 0.2	0.2	§			
Mume plum	○ 0.2	0.2	§			
Cherry	○ 0.2	0.2	§			
Strawberry	○ 0.2	0.2	§			
Raspberry	○ 0.2	0.2	§			
Blackberry	○ 0.2	0.2	§			
Blueberry	○ 0.2	0.2	§			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Cranberry	○ 0.2	0.2	§			
Huckleberry	○ 0.2	0.2	§			
Other berries	○ 0.2	0.2	§			
Grape	○ 0.5	0.2	§ ・IT		0.5	EU
Japanese persimmon	○ 0.2	0.2	§			
Banana	○ 0.2	0.2	§	0.05		
Kiwifruit	○ 0.1	0.1	§			
Papaya	○ 0.2	0.2	§			
Avocado	○ 0.2	0.2	§			
Pineapple	○ 0.1	0.1	§			
Guava	○ 0.2	0.2	§			
Mango	○ 0.2	0.2	§			
Passion fruit	○ 0.2	0.2	§			
Date	○ 0.2	0.2	§			
Other fruits	○ 0.2	0.2	§			
Sunflower seeds	○ 40	0.1	IT	7	40	USA
Sesame seeds	○ 40	0.2	IT		40	USA
Safflower seeds	○ 40	0.1	IT		40	USA
Cotton seeds	○ 40	10	IT	40		
Rapeseeds	○ 30	10	IT	30		
Other oil seeds	○ 40	0.1	IT		40	USA
Ginkgo nut	○ 0.2	0.2	§			
Chestnut	○ 1	1.0	§			
Pecan	○ 1	1.0	§			
Almond	○ 1	1.0	§			
Walnut	○ 1	1.0	§			
Other nuts	○ 1	1.0	§			
Tea	○ 1	1.0	§			
Coffee beans	○ 1	1.0				
Cacao beans	○ 0.2	0.2				
Hop	○ 0.1	0.1				
Other spices	● 0.2	2	§ ・Request			
Other herbs	○ 0.2	0.2	§			
Cattle, muscle	● 0.05	0.1		0.05		
Pig, muscle	● 0.05	0.1		0.05		
Other terrestrial	● 0.05	0.4		0.05		
Cattle, fat	● 0.05	0.5				
Pig, fat	● 0.05	0.3				
Other terrestrial	● 0.05	0.5				
Cattle, liver	○ 5	2		5		
Pig, liver	● 0.5	1		0.5		
Other terrestrial	○ 5	1		5		
Cattle, kidney	○ 5	2		5		
Pig, kidney	● 0.5	1		0.5		
Other terrestrial	○ 5	3		5		
Cattle, edible offal	○ 5	2		5		
Pig, edible offal	● 0.5	1		0.5		
Other terrestrial	○ 5	1		5		
Milk	● 0.05	0.1		0.05		
Chicken, muscle	● 0.05	0.1		0.05		
Other poultry, muscle	● 0.05	0.1		0.05		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Chicken, fat	● 0.05	0.08				
Other poultry, fat	● 0.05	0.08				
Chicken, liver	● 0.5	0.6		0.5		
Other poultry, liver	● 0.5	0.6		0.5		
Chicken, kidney	● 0.5	1		0.5		
Other poultry, kidney	● 0.5	1		0.5		
Chicken, edible offal	● 0.5	0.7		0.5		
Other poultry, edible offal	● 0.5	0.7		0.5		
Chicken eggs	● 0.05	0.1		0.05		
Other poultry, eggs	● 0.05	0.1		0.05		
Salmoniformes (such as	●	0.3				
Anguilliformes (such as eel)	●	0.3				
Perciformes (such as bonito, horse mackerel,	●	0.3				
Other fish	●	0.3				
Shelled molluscs	●	3				
Crustaceans	●	3				
Other aquatic animals	●	3				
Cottonseed oil, (limited to refined cottonseed oil and cottonseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and	●	0.05				
Cottonseed oil (except refined cottonseed oil and cottonseed salad oil that meet the JAS for Edible Vegetable Fats and Oils,	●	0.05				

Note: The residue definition for agricultural products (limited to soybeans, corn and rapeseeds)and animal products will be changed to the sum of Glyphosate and N-acetylglyphosate, expressed as Glyphosate. The residue definition for agricultural products (except soybeans, corn and rapeseeds) is Glyphosate only.
The current residue definition is Glyphosate only, and Glyphosate includes Glyphosate, Glyphosate-ammonium, Glyphosate-isopropylammonium, Glyphosatetrimecium and Glyphosate-sodium.

* The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.
* Shaded figures indicate provisional MRLs.
* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

● : Commodities for which MRLs are to be lowered or deleted.
○ : Commodities for which MRLs are to be maintained, increased or newly set. (*It should be noted that the residue definition for animal products will be changed.)
§ : Permitted for use in Japan.
Request : The MRL is to be modified in response to MAFF request
IT : Import tolerance

Clethodim

Commodity	MRL (draft) ppm		MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Wheat	●		0.1				
Barley	●		0.1				
Corn (maize, including pop	●		1				
Soybeans, dry	○	10	10	§	10		
Beans, dry	○	2	0.2	§	2		
Peas	○	2	2		2		
Broad beans	○	2	0.1		2		
Peanuts, dry	○	5	5		5		
Other pulses	○	2	0.5		2		
Potato	○	1	0.2	§	0.5	1.0	USA
Taro	●		1				
Sweet potato	○	1	0.2	§		1.0	USA
Yam	○	1	1			1.0	USA
Konjac	●		1				
Other potatoes	●		1				
Sugar beet	○	0.1	0.1	§	0.1		
Japanese radish, roots	○	1	1	§		1.0	USA
Japanese radish, leaves	○	1	0.9	§		1.0	USA
Turnip, roots (including	●		1				
Turnip, leaves (including	●		2				
Horseradish	●		1				
Watercress	●		1				
Chinese cabbage	●		2				
Cabbage	○	0.3	0.2	§			
Brussels sprouts	●		0.2				
Kale	●		2				
Komatsuna(Japanese	●		2				
Kyona	●		1				
Qing-geng-cai	●		3				
Cauliflower	●		2				
Broccoli	●		2				
Other cruciferous	●		2				
Burdock	●		1				
Salsify	●		1				
Artichoke	●		1				
Chicory	●		1				
Endive	●		0.5				
Shungiku	●		1				
Lettuce (including cos	●		0.1				
Other composite	●		1				
Onion	○	0.5	0.5	§	0.5		
Welsh (including leek)	●	0.2	1	§			
Garlic	○	0.5	0.5	§	0.5		
Nira	●		0.1				
Asparagus	●	0.2	1	§			
Multiplying onion (including	●		0.2				
Other liliaceous vegetables	●		0.1				
Carrot	○	0.1	0.1	§			
Parsnip	●		1				
Parsley	●		0.1				
Celery	●		0.1				

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Other umbelliferous	●	1				
Tomato	○ 1	1		1		
Pimiento (sweet	○ 1	1			1.0	USA
Egg plant	●	1				
Other solanaceous	●	1				
Cucumber (including	○ 0.5	0.5			0.5	USA
Pumpkin (including	○ 0.5	0.5	§		0.5	USA
Oriental pickling melon	●	0.5				
Water melon	●	1				
Melons	●	1				
Makuwauri melon	●	1				
Other cucurbitaceous	●	1				
Spinach	●	1				
Bamboo shoots	●	1				
Okra	●	1				
Ginger	●	1				
Peas, immature (with	●	0.6				
Kidney beans,	○ 0.5	0.5		0.5		
Green soybeans	● 2	6	§			
Button mushroom	●	1				
Shiitake mushroom	●	1				
Other mushrooms	●	1				
Other vegetables	○ 0.5	0.5	§	0.5		
Strawberry	●	2				
Cranberry	○ 0.5	0.5			0.5	USA
Other fruits	●	0.6				
Sunflower seeds	○ 0.5	0.2	§	0.5		
Cotton seeds	○ 0.5	0.5		0.5		
Rapeseeds	○ 0.5	0.5		0.5		
Other oil seeds	●	0.2				
Almond	●	0.5				
Hop	○ 0.5		IT		0.5	USA
Other spices	●	1				
Other herbs	●	2				
Cattle, muscle	○ 0.2	0.2		0.2		
Pig, muscle	○ 0.2	0.2		0.2		
Other terrestrial	○ 0.2	0.2		0.2		
Cattle, fat	○ 0.2	0.2		0.2		
Pig, fat	○ 0.2	0.2		0.2		
Other terrestrial	○ 0.2	0.2		0.2		
Cattle, liver	○ 0.2	0.2		0.2		
Pig, liver	○ 0.2	0.2		0.2		
Other terrestrial	○ 0.2	0.2		0.2		
Cattle, kidney	○ 0.2	0.2		0.2		
Pig, kidney	○ 0.2	0.2		0.2		
Other terrestrial	○ 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	○ 0.2	0.2		0.2		
Milk	○ 0.05	0.05		0.05		
Chicken, muscle	○ 0.2	0.2		0.2		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Other poultry, muscle	○ 0.2	0.2		0.2		
Chicken, fat	○ 0.2	0.2		0.2		
Other poultry, fat	○ 0.2	0.2		0.2		
Chicken, liver	○ 0.2	0.2		0.2		
Other poultry, liver	○ 0.2	0.2		0.2		
Chicken, kidney	○ 0.2	0.2		0.2		
Other poultry, kidney	○ 0.2	0.2		0.2		
Chicken, edible offal	○ 0.2	0.2		0.2		
Other poultry, edible offal	○ 0.2	0.2		0.2		
Chicken eggs	○ 0.05	0.05		0.05		
Other poultry, eggs	○ 0.05	0.05		0.05		
Soybean oil, (limited to edible soybean oil that meets the JAS for Edible Vegetable Fats and Oils,	●	0.5		0.5		
Soybean oil (except edible soybean oil that meets the JAS for Edible Vegetable Fats and Oils, and other	●	1				
Sunflower oil (except refined cottonseed oil and cottonseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and	●	0.1		0.1		
Cottonseed oil, (limited to refined cottonseed oil and cottonseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and	●	0.5		0.5		
Cottonseed oil (except refined cottonseed oil and cottonseed salad oil that meet the JAS for Edible Vegetable Fats and Oils,	●	0.5				
Cottonseed oil	○ 0.5					
Rapeseed oils, (limited to refined rapeseed oil and rapeseed salad oil that meet the JAS for Edible Vegetable Fats and Oils,	●	0.5		0.5		
Rapeseed oils, crude (except refined rapeseed oil and rapeseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and other	●	0.5				
Rapeseed oils	○ 0.5					

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

* The uniform limit 0.01 ppm will be applied to commodities for which draft MRLs are not given in this table and to commodities not listed above.
* Shaded figures indicate provisional MRLs.
* In the Commodity column, for the food categories to which the word other is added, refer to the Notes given in the last two pages of the Attachment.

● : Commodities for which MRLs are to be lowered or deleted.
○ : Commodities for which MRLs are to be maintained, increased or newly set. (*It should be noted that the residue definition will be changed.)
§ : Permitted for use in Japan. IT : Import tolerance

※For soybean oil and sunflower oil, the MRLs of their raw commodities (soybean and sunflower seeds, respectively) will be applied taking into account each processing factor.
JMPR estimated their processing factors as following: 0.1 for soybean oil and 0.2 for sunflower seeds.

Flutolanil

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Rice (brown rice)	○ 2	2.0	§	2		
Wheat	● 0.05	2.0	§			
Soybeans, dry	○ 0.5	0.5	§			
Peanuts, dry	○ 0.5	0.5			0.5	USA
Potato	○ 0.2	0.2	§		0.20	USA
Konjac	○ 0.2	0.2	§			
Sugar beet	● 0.2	1.0	§			
Turnip, leaves (including	○ 0.07			0.07		
Chinese cabbage	○ 0.07			0.07		
Cabbage	○ 2	2.0	§	0.05		
Brussels sprouts	○ 0.07			0.07		
Kale	○ 0.07			0.07		
Komatsuna(Japanese	○ 0.07			0.07		
Kyona	○ 0.07			0.07		
Qing-geng-cai	○ 0.07			0.07		
Cauliflower	○ 0.05			0.05		
Broccoli	○ 0.05			0.05		
Other cruciferous	○ 10		Request	0.07		
Lettuce (including cos	○ 3	3.0	§			
Other composite	○ 2	2.0	§			
Welsh (including leek)	○ 1	1	§			
Other liliaceous	○ 5		Request			
Mitsuba	○ 2	2	§			
Tomato	● 0.03	0.05	§			
Pimiento (sweet pepper)	○ 0.7	0.7	§			
Egg plant	●	0.05				
Other solanaceous	○ 0.1		Request			
Cucumber (including	○ 0.05	0.05	§			
Spinach	○ 2	2.0	§			
Ginger	○ 5	1	§ ・ Request			
Green soybeans	○ 2	2.0	§			
Other vegetables	○ 1	1.0			1	Korea
Japanese pear	●	2				
Pear	●	2				
Strawberry	○ 3	3			5	Korea
Other herbs	○ 10	2	§ ・ Request	0.07		
Cattle, muscle	○ 0.05	0.05		0.05		
Pig, muscle	○ 0.05	0.05		0.05		
Other terrestrial	○ 0.05	0.05		0.05		
Cattle, fat	○ 0.1	0.1		0.05	0.10	USA
Pig, fat	○ 0.1	0.1		0.05		
Other terrestrial	○ 0.1	0.1		0.05		
Cattle, liver	○ 0.5	0.2		0.5		
Pig, liver	○ 0.5	0.2		0.5		
Other terrestrial	○ 0.5	0.2		0.5		
Cattle, kidney	○ 0.5	0.1		0.5		
Pig, kidney	○ 0.5	0.1		0.5		
Other terrestrial	○ 0.5	0.1		0.5		
Cattle, edible offal	○ 0.5	0.05		0.5		
Pig, edible offal	○ 0.5	0.05		0.5		
Other terrestrial	○ 0.5	0.05		0.5		

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Milk	○	0.05	0.05		0.05		
Chicken, muscle	○	0.05	0.05		0.05		
Other poultry,	○	0.05	0.05		0.05		
Chicken, fat	○	0.05	0.05		0.05		
Other poultry, fat	○	0.05	0.05		0.05		
Chicken, liver	○	0.05	0.05		0.05		
Other poultry, liver	○	0.05	0.05		0.05		
Chicken, kidney	○	0.05	0.05		0.05		
Other poultry,	○	0.05	0.05		0.05		
Chicken, edible	○	0.05	0.05		0.05		
Other poultry,	○	0.05	0.05		0.05		
Chicken eggs	○	0.05	0.05		0.05		
Other poultry, eggs	○	0.05	0.05		0.05		
Fish	○	2	2				
Rice bran	○	10	10		10		
Milled rice※	●		1		1		

Note: The residue definition for agricultural products and aquatic products is Flutolanil only. The residue definition for animal products will be changed to the sum of Flutolanil and metabolites which are transformed to 2-trifluoromethylbenzoic acid moiety by hydrolysis, expressed as Flutolanil.
The current residue definition for animal products is sum of Flutolanil and α,α,α-trifluoro-3'-hydroxy-*o*-toluanilide, expressed as Flutolanil, and for other commodities is Flutolanil only.
α,α,α-trifluoro-3'-hydroxy-*o*-toluanilide includes its free form, glucuronic acid conjugates and sulfate conjugates.

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

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

● : Commodities for which MRLs are to be lowered or deleted.
○ : Commodities for which MRLs are to be maintained, increased or newly set. (*It should be noted that the residue definition will be changed.)
§ : Permitted for use in Japan.
Request : The MRL is to be modified in response to MAFF request

※For milled rice, the MRL of its raw commodity will be applied taking into account its processing factor. JMPR estimated a processing factor of ＜0.5 for milled rice.

Oxytetracycline, Chlortetracycline and Tetracycline

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Potato	○ 0.2	0.2	§			
Konjac	○ 0.2	0.2	§			
Japanese radish, roots	○ 0.2	0.2	§			
Japanese radish, leaves	○ 0.2	0.2	§			
Chinese cabbage	○ 0.05	0.05	§			
Cabbage	○ 0.2	0.2	§			
Broccoli	○ 0.2		Request			
Lettuce (including cos	○ 0.2	0.2	§			
Onion	○ 0.2	0.2	§			
Garlic	○ 0.2	0.2	§			
Tomato	○ 0.3		Request			
Cucumber (including	○ 0.2	0.2	§			
Unshu orange, pulp	○ 0.05	0.05	§			
Citrus natsudaidai, whole	○ 0.2	0.2	§			
Lemon	○ 0.2	0.2	§			
Orange (including navel	○ 0.2	0.2	§			
Grapefruit	○ 0.2	0.2	§			
Lime	○ 0.2	0.2	§			
Other citrus fruits	○ 0.2	0.2	§			
Apple	○ 0.2	0.2	§			
Japanese pear	○ 0.2	0.2	§			
Pear	○ 0.2	0.2	§			
Peach	○ 0.2	0.2	§			
Nectarine	○ 0.2	0.2	§			
Apricot	○ 0.2	0.2	§			
Japanese plum	○ 0.2	0.2	§			
Mume plum	○ 0.2	0.2	§			
Cherry	○ 0.2	0.2	§			
Kiwifruit	○ 0.2	0.2	§			
Other spices	○ 0.1	0.1	§			
Cattle, muscle	○ 0.2	0.2	§	0.2		
Pig, muscle	○ 0.2	0.2	§	0.2		
Other terrestrial	○ 0.2	0.2		0.2		
Cattle, fat	○ 0.2	0.2	§			
Pig, fat	○ 0.2	0.2	§			
Other terrestrial	○ 0.2	0.2				
Cattle, liver	○ 0.6	0.6	§	0.6		
Pig, liver	○ 0.6	0.6	§	0.6		
Other terrestrial	○ 0.6	0.6		0.6		
Cattle, kidney	○ 1	1	§	1.2		
Pig, kidney	○ 1	1	§	1.2		
Other terrestrial	○ 1	1		1.2		
Cattle, edible offal	○ 1	1	§			
Pig, edible offal	○ 1	1	§			
Other terrestrial	○ 1	1				
Milk	○ 0.1	0.1	§	0.1		
Chicken, muscle	○ 0.2	0.2	§	0.2		
Other poultry, muscle	○ 0.2	0.2				
Chicken, fat	○ 0.2	0.2	§			
Other poultry, fat	○ 0.2	0.2				

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Chicken, liver	○	0.6	0.6	§	0.6		
Other poultry, liver	○	0.6	0.6				
Chicken, kidney	○	1	1	§	1.2		
Other poultry, kidney	○	1	1				
Chicken, edible offal	○	1	1	§			
Other poultry, edible offal	○	1	1				
Chicken eggs	○	0.4	0.4	§	0.4		
Other poultry, eggs	○	0.4	0.4				
Salmoniformes (such as	○	0.2	0.2		0.2		
Anguilliformes (such as eel)	○	0.2	0.2	§	0.2		
Perciformes (such as bonito, horse mackerel,	○	0.2	0.2	§	0.2		
Other fish	○	0.2	0.2	§	0.2		
Shelled molluscs	○	0.2	0.2		0.2		
Crustaceans	○	0.2	0.2	§	0.2		
Other aquatic animals	○	0.2	0.2		0.2		
Honey (including royal-jelly)	○	0.3	0.3			0.3	Australia

Note: The residue definition for agricultural products, aquatic products and honey is Oxytetracycline only. The residue definition for animal products is sum of Oxytetracycline, Chlortetracycline and Tetracycline. Because these three compounds are antibiotics, the compound shall not be included in any commodity for which the MRL is not given and in any commodity not listed above. Therefore, agricultural products, aquatic products and honey shall not contain Chlortetracycline or Tetracycline.

* 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

Notes:

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

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

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

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

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

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

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

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

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

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

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

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

“Other citrus fruits” refers to all citrus fruits, except *unshu* orange (pulp), citrus *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 Diethylstilbestrol

Notification (draft)
Analytical Method for Diethylstilbestrol (Targeted to Animal and Fishery Products)

The target compounds to be determined are diethylstilbestrol and diethylstilbestrol glucuronide.

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 compounds.

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

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

-Glucuronidase solution: Contains 100,000 unit/mL of -glucuronidase derived from *Helix pomatia*. One unit of this reagent is the amount of enzyme that liberates 1.0 μg of phenolphthalein per hour at pH 5.0 at 37-38ºC using phenolphthalein -D-glucuronide as the substrate. Or use a reagent equivalent to the specified one in enzyme activity. The reagent should not contain any substance that may interfere with the analysis of the target compounds.

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

0.1 mol/L sodium acetate solution (pH 5.0)

Solution 1: Dissolve 0.82 g of sodium acetate in water to make exactly 100 mL. Solution 2: Dissolve 0.60 g of Acetic acid in water to make exactly 100mL.

Add solution 2 to solution 1, mix and adjust pH to 5.0.

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

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

3. Reference standard

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

4. Procedure

a. Extraction

Weigh 10.0 g of sample, add 50 mL of ethanol/water (9:1, v/v), homogenize, centrifuge at 3,000 rpm for 5 minutes, and collect the supernatant. Add 30 mL of ethanol/water (9:1, v/v) to the residue, homogenize, and centrifuge as described above. Collect the supernatant, combine the resulting supernatants, and add ethanol/water (9:1, v/v) to make exactly 100 mL. Take exactly 10 mL of the solution and concentrate to about 5 mL at below 40ºC. Add 10 mL of 0.1 mol/L sodium acetate solution (pH 5.0) and mix well.

b. Hydrolysis

Add 0.1 mL of -glucuronidase solution to the solution obtained in "a Extraction", mix, let stand for 60 minutes at 37ºC with occasional shaking. Extract with shaking twice with 10 mL each of ethyl acetate/*n*-hexane (3:1, v/v). Combine the resulting extracts, concentrate at below 40ºC, and remove the solvent. Dissolve the residue in 2 mL of ethyl acetate.

c. Clean-up

Add 5 mL of ethyl acetate to an ethylenediamine-*N*-propylsilanized silica gel cartridge (1,000 mg), and discard the effluent. Transfer the solution obtained in "b. Hydrolysis", add 10 mL of ethyl acetate, and discard the effluent. Elute with 10 mL of ethanol/ethyl acetate (1:9, v/v), concentrate the eluate at below 40ºC, and remove the solvent. Dissolve the residue in acetonitrile/water (1:1, v/v) to make exactly 1 mL, and use this solution as the test solution.

5. Measurement

a. Calibration curve

Prepare diethylstilbestrol standard solution (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 diethylstilbestrol gives the test solution of 0.0005 mg/L in concentration.

b. Quantification

Inject the test solution to LC-MS/MS, and calculate the concentration of diethylstilbestrol 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: Acetonitrile/2 mmol/L ammonium acetate (3:2, v/v) Ionization mode: ESI (–)

Major monitoring ions (*m/z*): Precursor ion 267, product ion 237, 222 Injection volume: 5 μL

Expected retention time: 3 minutes

6. Limit of Quantification 0.0005 mg/kg

Item 3. Revision of the Standards and Specifications for Foods and Food Additives under the Food Sanitation Law

Background

Any food or food additive for which compositional specifications or standards are established based on Article 11, Paragraph 1 of the Food Sanitation Law of Japan and published in the Ministry of Health, Labour and Welfare Notification (Ministry of Health and Welfare Notification No. 370, 1959) shall not be used or marketed unless it meets the standards or specifications.

Non-alcoholic beverages are classified into four categories: 1) mineral waters (non-alcoholic beverages consisting only of water), 2) frozen fruit beverages, 3) fruit juices for ingredients, and 4) beverages other than those listed in 1) through 3). Compositional specifications and standards are established for individual categories.

In the exiting standards, arsenic is not permitted to be detected in beverages listed in 2) through 4) as determined by either of Gutzeit method or silver diethyldithiocarbamate method.

Outline of revision

Gutzeit method, which is regulated as a method to detect arsenic in non-alcoholic beverages except for mineral waters, will be deleted.

Item4. Revising Specifications and Standards (Updating the Official Compilation of Food Additives), etc.

The government of Japan will revise the existing specifications and standards for food additives.

Summary

The Food Sanitation Act of Japan ("the Act"), in Article 10, prohibits the use and sale of food additives that the Minister of Health, Labour and Welfare ("the Minister") does not designate as approved. In addition, when specifications or standards for food additives are established based on Article 11 of the Act, those additives shall not be used or sold unless they meet the standards or specifications.

The specifications and standards established based on Article 11 of the Act are stipulated in the Ministry of Health, Labour and Welfare Notification (Ministry of Health and Welfare Notification No. 370, 1959,"Notification"). The Notification contains general notices, general tests, and reagents and solutions required for the testing of food additives as well as compositional specifications for additives and standards for the storage, manufacturing, and use thereof.

On the other hand, the Act requires the Minister and the Prime Minister, in Article 21, to prepare the Official Compilation of Food Additives containing compositional specifications and standards and labeling for food additives. The compilation contains almost all items for food additives stipulated in the Notification. In 1960 the first edition of the compilation was prepared. Since then the compilation had been updated regularly until the eighth edition in 2007.

The Ministry of Health, Labour and Welfare ("the MHLW") is working to prepare the ninth edition. Specifically, the MHLW has listed substances that have been designated since the publication of the eighth edition, reviewed existing testing methods and compositional specifications, and newly set specifications for some existing food additives (food additives from natural origins).

In August 2016, as for the draft of revised Notification based on the result of the work, the Committee on Food Additives of the Food Sanitation Council that is established under the Pharmaceutical Affairs and Food Sanitation Council ("the committee") concluded that the revision of the specifications and standards was adequate.

Since the committee's discussion in August, specifications have been newly established for six substances: Asparaginase (*A. oryzae* NZYM-SP-derived), Sodium selenite, Octanoic acid, Peracetic acid composition, Hypobromous acid water, and 1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP). In March 2017, the committee discussed the description of specifications for the six additives to align them with the description requirements for the ninth edition of the Official Compilation of food additives.

The committee has concluded that the Minister should revise the specifications and standards based on Article 11 of the Act in step with the updating of the compilation. For details, see Attachment 4-1.

In addition, the committee has discussed the revision of the specifications and standards for peracetic acid and peracetic acid composition, and then has concluded that the Minister should revise the specifications and standards based on Article 11 of the Act. For details, see Attachment 4-2.

<Additional Information>

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

As of April 13, 2017, all flavorings and 41 non-flavoring additives are designated. See Attachment 4-3.

Attachment 4-1

Revising Specifications and Standards (Updating the Official Compilation of Food Additives) (Additional parts)

Outline of the revision

The specifications for the six additives (Asparaginase (*A. oryzae* NZYM-SP-derived), Sodium selenite, Octanoic acid, Peracetic acid composition, Hypobromous acid water, and 1-Hydroxyethylidene-1,1-diphosphonic acid (HEDP)) will be revised.

1. Conversion of arsenic specification limits

In the Arsenic Limit Test, the specification limit, currently expressed as As_2O_3, will be expressed as As. Following this change in conversion, specifications for the three additives will be revised as follows:

Substance Name	Change of specifications limit for Arsenic($As_2O_3 \rightarrow As$) (μg／g)
Asparaginase (asparaginase (*A. oryzae*	4.0 → 3
Sodium selenite	4.0 → 3
HEDP	6.7 → 5

The change in the description of the specification limit is to harmonize with JECFA arsenic standards expressed as As. Please note that this change is simply conversion and there will be no substantial change in specification limit.

2. Others

Some descriptions will be aligned for consistency in wording including examples.

Attachment 4-2

Revising Specifications and Standards

Peracetic Acid and Peracetic Acid Composition

Outline of the revision

As for the revision of specifications for peracetic acid and specifications and standards for manufacturing of peracetic acid composition, they will be revised as below.

(The underlined parts are to be revised)

	Revised standards and specifications (draft)	Current standards and specifications
Standards for manufacturing	Peracetic acid: It shall be made of glacial acetic acid or its dilution and hydrogen peroxide. Peracetic acid composition: It shall be a product manufactured by mixing 1-hydroxyethylidene-1,1-diphosphonic acid with glacial acetic acid or its dilution or with glacial acetic acid or its dilution and hydrogen peroxide, or a product manufactured by adding octanoic acid to the above mixture. Glacial acetic acid, hydrogen peroxide, 1-hydroxyethylidene-1,1-diphosphonic acid, and octanoic acid that are used as ingredients of peracetic acid composition shall meet the existing specifications.	Peracetic acid: It shall be made of acetic acid and hydrogen peroxide. Peracetic acid composition: It shall be a product manufactured by mixing 1-hydroxyethylidene-1,1-diphosphonic acid with peracetic acid or with acetic acid and hydrogen peroxide, or a product manufactured by adding octanoic acid to the above mixture. Acetic acid, hydrogen peroxide, 1-hydroxyethylidene-1,1-diphosphonic acid, and octanoic acid that are used as ingredients of peracetic acid composition shall meet the existing specifications.
specifications	Peracetic acid composition: Definition Peracetic Acid Composition is an aqueous solution containing Peracetic Acid, "Glacial Acetic Acid," "Hydrogen Peroxide," and "1-Hydroxyethylidene-1,1-diphosphonic Acid" or an aqueous solution containing these four substances and "Octanoic Acid." Peroctanoic acid may be produced from "Octanoic Acid" contained in "Peracetic Acid Composition."	Peracetic acid composition: Definition Peracetic Acid Composition is an aqueous solution containing Peracetic Acid, "Acetic Acid," "Hydrogen Peroxide," and "1-Hydroxyethylidene-1,1-diphosphonic Acid" or an aqueous solution containing these four substances and "Octanoic Acid." Peroctanoic acid may be produced from "Octanoic Acid" contained in "Peracetic Acid Composition."