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Japan 218th Food Safety Group

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Approved By:
Jess Paulson

Prepared By:
Tomohiro Kurai

Report Highlights:
On November 29, 2018, Japan's Ministry of Health, Labor and Welfare (MHLW) announced revisions to Japan's Maximum Residue Levels (MRLs) for the following agricultural chemicals, veterinary drugs and feed additives: Isopyrazam, Etofenprox, Fenpyroximate, Mandestrobin, Flumequine, Mono- and bis- (trimethylammoniummethylene chloride)-alkyltoluene, and Butylated Hydroxyanisole. In addition, MHLW proposed the revision of standards for the feed additive Hypobromous Acid Water. Lastly, MHLW summarized revisions to Japan's Food Sanitation Act. The embassy comment period these proposals is open until December 13, 2018. MHLW will then notify the MRL revisions to the World Trade Organization (WTO), which will provide another opportunity for interested parties to comment. MHLW will prepare and provide information explaining how the Food Sanitation Act revisions will change import procedures.

Keyword: JA8103

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, December 13, 2018**. 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 Isopyrazam, Etofenprox, Mandestrobin and Butylated Hydroxyanisole 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 person>

Food Safety Standards and Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916

Pesticides/Veterinary drugs/Feed additives (Item 1)
Mr. Tomoaki MIURA (miura-tomoaki@mhlw.go.jp)
Tel : 03-3595-2423 (ex 4289) Fax: 03-3595-2432

Food Additives (Item 2)
Ms. Akane HAYASHI (hayashi-akane@mhlw.go.jp)
Tel : 03-3595-2341 (ex 4274) Fax: 03-3501-4868

Import Foods Safety (Item 3)
Ms. Mina Kojima (kojima-mina@mhlw.go.jp)
Tel : 03-3595-2337 (ex 2496) Fax: 03-3503-7964

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

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:

Pesticides : Isopyrazam, Etofenprox, Fenpyroximate,
Mandestrobin Veterinary
drugs : Flumequine,
Mono, bis (trimethylammoniummethylene chloride)-
alkyltoluene Feed additives : Butylated Hydroxyanisole

[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

Isopyrazam (pesticide: fungicide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to 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.

Etofenprox (pesticide: insecticide): Permitted for use in Japan. The MHLW is going to establish MRL for other composite vegetables 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.

Fenpyroximate (pesticide: acaricide): Permitted for use in Japan. The MHLW is going to establish MRLs in one commoditiy in response to requests for setting MRLs by the MAFF with the intention to expand its use pattern and 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).

Mandestrobin (pesticide: fungicide): Permitted for use in Japan. The MHLW is going to establish MRLs in one commoditiy in response to requests for setting MRLs by the MAFF with the intention to expand its use pattern and 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.

Flumequine (Veterinary drug: fungicide): Not permitted for use in Japan. The MHLW is going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

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Mono, bis (trimethylammoniummethylene chloride)-alkyltoluene (Veterinary drug: disinfectant): Permitted for use in Japan. The MHLW is going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Butylated Hydroxyanisole (Feed additive: antioxidizer): Permitted for use in Japan. The MHLW is going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System. This action will not strengthen the current regulation for any commodities.

Isopyrazam

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Wheat	○	0.2	0.2		0.03	0.2	EU
Barley	○	0.6	0.6		0.6	0.6	EU
Rye	○	0.2	0.2		0.03	0.2	EU
Other cereal grains	○	0.6	0.2		0.03	0.6	EU
Peanuts, dry	○	0.01			0.01		
Chinese cabbage	○	5	5	§			
Cabbage	○	3	3	§			
Lettuce (including cos lettuce and leaf lettuce)	○	10	10	§			
Carrot	○	0.2			0.15		
Tomato	○	3	3	§	0.4		
Pimiento (sweet pepper)	○	0.09			0.09		
Egg plant	○	2	2	§	0.4		
Cucumber (including gherkin)	○	1	1	§	0.06		
Pumpkin (including squash)	○	0.05	0.05			0.05	New Zealand
Melons	○	0.05	0.05	§			
Apple	○	5	5	§	0.4		
Japanese pear	○	3	3	§	0.4		
Pear	○	3	3	§	0.4		
Quince	○	0.4			0.4		
Peach	○	0.2	0.2	§			
Apricot	○	5	5	§			
Japanese plum (including prune)	○	2	2	§			
Mume plum	○	5	5	§			
Cherry	○	5		Request			
Strawberry	○	5	5	§			
Grape	○	10	10	§			
Japanese persimmon	○	2	2	§	0.4		
Banana	○	0.06	0.06		0.06		
Other fruits	○	0.4			0.4		
Rapeseeds	○	0.2			0.2		
Cattle, muscle	○	0.03	0.01				
Pig, muscle	○	0.03	0.01				
Other terrestrial mammals, muscle	○	0.03	0.01				
Cattle, fat	○	0.03	0.01		0.03		
Pig, fat	○	0.03	0.01		0.03		
Other terrestrial mammals, fat	○	0.03	0.01		0.03		
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	○	0.02	0.01		0.02		
Chicken, muscle	○	0.01	0.01		0.01		
Other poultry, muscle	○	0.01	0.01		0.01		
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		

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
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	○	0.01	0.01		0.01		
Other poultry, eggs	○	0.01	0.01		0.01		
Wheat bran ※	○				0.15		

The residue definition is sum of isopyrazam (*syn* -isomers) and isopyrazam (*anti* -isomers).

* 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.

* Diagonal line means deletion of a food category to which an MRL applies.

○: 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 the MAFF.

※ Food category "Wheat bran" will be deleted,and hereafter, MRLs in its raw commodity (i.e. Wheat) will also apply to such processed commodity, taking into account its processing factor. For this substance, JMPR estimated processing factor of 4.07 for Wheat.

Etofenprox

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Rice (brown rice)	○	0.5	0.5	§			
Wheat	○	0.5	0.5	§			
Barley	○	0.5	0.5			0.5	EU
Rye	○	0.5	0.5			0.5	EU
Corn (maize, including pop corn and sweet corn)	○	0.3	0.3	§	0.05		
Other cereal grains	○	5	5	§			
Soybeans, dry	○	0.2	0.2	§	0.05		
Beans, dry	○	0.05	0.05	§	0.05		
Peas	○	0.05	0.05	§			
Broad beans	○	0.05	0.05	§	0.05		
Peanuts, dry	○	0.05	0.05	§			
Other pulses	○	0.05	0.05	§	0.05		
Potato	○	0.05	0.05	§			
Taro	○	0.03	0.03	§			
Sweet potato	○	0.03	0.03	§			
Japanese yam (including Chinese yam)	○	0.02	0.02	§			
Sugar beet	○	0.3	0.3	§			
Sugarcane	○	0.03	0.03	§			
Japanese radish, roots (including radish)	○	0.2	0.2	§			
Japanese radish, leaves (including radish)	○	5	5	§			
Chinese cabbage	○	5	5	§			
Cabbage	○	1	1	§			
Brussels sprouts	○	2	2			2	EU
Broccoli	○	10	10	§			
Other cruciferous vegetables	○	1	1	§			
Lettuce (including cos lettuce and leaf lettuce)	○	2	2	§			
Other composite vegetables	○	10	2	§・Request			
Welsh (including leek)	○	2	2	§			
Mitsuba	○	5	5	§			
Other umbelliferous vegetables	○	2	2	§			
Tomato	○	2	2	§			
Pimiento (sweet pepper)	○	5	5	§			
Egg plant	○	2	2	§			
Other solanaceous vegetables	○	2	2			2.0	Korea
Cucumber (including gherkin)	○	1	1	§			
Pumpkin (including squash)	○	1	1	§			
Water melon	○	0.03	0.03	§			
Melons	○	0.2	0.2	§			
Other cucurbitaceous vegetables	○	1	1	§			
Okra	○	3	3	§			
Ginger	○	3	3	§			
Peas, immature (with pods)	○	2	2	§			
Kidney beans, immature (with pods)	○	3	3	§			
Green soybeans	○	3	3	§			
Other vegetables	○	10	10	§			
Unshu orange, pulp	○	0.2	0.2	§			
Citrus natsudaidai, whole	○	3	3	§			
Lemon	○	5	5	§			
Orange (including navel orange)	○	5	5	§			
Grapefruit	○	5	5	§			
Lime	○	5	5	§			

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Other citrus fruits	○	5	5	§			
Apple	○	2	2	§	0.6		
Japanese pear	○	2	2	§	0.6		
Pear	○	2	2	§	0.6		
Peach	○	0.1	0.1	§			
Nectarine	○	0.6	0.6		0.6		
Grape	○	4	4		4		
Japanese persimmon	○	2	2	§			
Mango	○	5	5	§			
Rapeseeds	○	0.01	0.01		0.01		
Chestnut	○	0.05	0.05	§			
Tea	○	10	10	§			
Other spices	○	20	20	§			
Other herbs	○	0.7	0.7	§			
Cattle, muscle	○	0.2	0.2				
Pig, muscle	○	0.2	0.2				
Other terrestrial mammals, muscle	○	0.2	0.2				
Cattle, fat	○	6	6		0.5		
Pig, fat	○	6	6		0.5		
Other terrestrial mammals, fat	○	6	6		0.5		
Cattle, liver	○	0.3	0.3		0.05		
Pig, liver	○	0.3	0.3		0.05		
Other terrestrial mammals, liver	○	0.3	0.3		0.05		
Cattle, kidney	○	0.4	0.4		0.05		
Pig, kidney	○	0.4	0.4		0.05		
Other terrestrial mammals, kidney	○	0.4	0.4		0.05		
Cattle, edible offal	○	0.4	0.4		0.05		
Pig, edible offal	○	0.4	0.4		0.05		
Other terrestrial mammals, edible offal	○	0.4	0.4		0.05		
Milk	○	0.4	0.4		0.02		
Chicken, muscle	○	0.02	0.02		0.01		
Other poultry, muscle	○	0.02	0.02		0.01		
Chicken, fat	○	1	1			1.0	USA
Other poultry, fat	○	1	1			1.0	USA
Chicken, liver	○	0.07	0.07		0.01		
Other poultry, liver	○	0.07	0.07		0.01		
Chicken, kidney	○	0.07	0.07		0.01		
Other poultry, kidney	○	0.07	0.07		0.01		
Chicken, edible offal	○	0.07	0.07		0.01		
Other poultry, edible offal	○	0.07	0.07		0.01		
Chicken eggs	○	0.4	0.4		0.01	0.40	USA
Other poultry, eggs	○	0.4	0.4		0.01	0.40	USA
Fish	○	0.8	0.8				
Raisin ※					8		

The residue definition is etofenprox 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.

* Diagonal line means deletion of a food category to which an MRL applies.

* 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 the MAFF.

※ Food category "Raisin" will be deleted,and hereafter, MRLs in its raw commodity (i.e. Grape) will also apply to such processed commodity, taking into account its processing factor. For this substance, JMPR estimated processing factor of 2.1 for Raisin.

Fenpyroximate

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Corn (maize, including pop corn and sweet corn)	○	0.01			0.01		
Soybeans, dry	○	0.05	0.05	§			
Beans, dry	○	0.05	0.05	§			
Peas	○	0.1	0.1	§			
Potato	○	0.05			0.05		
Sugar beet	○	0.02	0.02	§			
Other composite vegetables	●		0.5				
Parsley	●		0.5				
Mitsuba	●		2				
Other umbelliferous vegetables	●		0.5				
Tomato	●	0.5	0.7	§			
Pimiento (sweet pepper)	○	1	1	§	0.2		
Egg plant	○	0.5	0.5	§	0.3		
Other solanaceous vegetables	○	2	2	§	0.3		
Cucumber (including gherkin)	○	0.5	0.5	§	0.3		
Pumpkin (including squash)	○	0.06	0.05	IT	0.06	0.1	Brazil
Water melon	●	0.02	1	§			
Melons	●	0.02	1	§			
Other cucurbitaceous vegetables	○	0.5	0.5	§			
Spinach	○	0.5	0.5	§			
Bamboo shoots	●		5				
Okra	●		0.2				
Peas, immature (with pods)	●	0.5	2	§	0.5		
Kidney beans, immature (with pods)	●	0.7	2	§	0.5		
Green soybeans	○	2	2	§	0.5		
Shiitake mushroom	●		0.2				
Other mushrooms	●		0.2				
Other vegetables	○	5	5	§			
Unshu orange, pulp	●	0.1	0.5	§			
Citrus natsudaidai, whole	○	1	1	§	0.6		
Lemon	○	1	1	§	0.6		
Orange (including navel orange)	○	1	1	§	0.6		
Grapefruit	○	1	1	§	0.6		
Lime	○	1	1	§	0.6		
Other citrus fruits	○	1	1	§	0.6		
Apple	●	0.3	0.5	§	0.2		
Japanese pear	●	0.5	1	§	0.2		
Pear	●	0.5	1	§	0.2		
Quince	●		0.3				
Loquat	○	0.1	0.1	§			
Peach	●	0.03	0.1	§			
Nectarine	○	1	1	§	0.4		
Japanese plum (including prune)	○	1		Request	0.4		
Mume plum	○	2	2	§	0.4		
Cherry	○	2	0.7	§	2		
Strawberry	○	0.5	0.5	§	0.3		
Raspberry	○	0.2			0.2		
Other berries	●	0.5	1				
Grape	●	1	2	§	0.1		
Japanese persimmon	○	0.5	0.5	§			
Kiwifruit	○	0.05	0.05	§			

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Avocado	○	0.2			0.2		
Mango	○	1	1			0.5	Taiwan
Other fruits	○	0.5	0.5	§			
Cotton seeds	○	0.1	0.1				
Ginkgo nut	○	0.05	0.05		0.05		
Chestnut	○	0.05	0.05		0.05		
Pecan	○	0.05	0.05		0.05		
Almond	○	0.05	0.05		0.05		
Walnut	○	0.05	0.05		0.05		
Other nuts	○	0.05	0.05		0.05		
Tea	○	40	40	§	8		
Coffee beans	○	0.07			0.07		
Hop	○	15	15	§	15		
Other spices	○	5	5	§			
Other herbs	○	2	2	§			
Cattle, muscle	○	0.1	0.01				
Pig, muscle	○	0.1	0.01				
Other terrestrial mammals, muscle	○	0.1	0.01				
Cattle, fat	○	0.1	0.02		0.1		
Pig, fat	○	0.1	0.02		0.1		
Other terrestrial mammals, fat	○	0.1	0.02		0.1		
Cattle, liver	○	0.5	0.01		0.5		
Pig, liver	○	0.5	0.01		0.5		
Other terrestrial mammals, liver	○	0.5	0.01		0.5		
Cattle, kidney	○	0.5	0.01		0.5		
Pig, kidney	○	0.5	0.01		0.5		
Other terrestrial mammals, kidney	○	0.5	0.01		0.5		
Cattle, edible offal	○	0.5	0.01		0.5		
Pig, edible offal	○	0.5	0.01		0.5		
Other terrestrial mammals, edible offal	○	0.5	0.01		0.5		
Milk	○	0.01	0.005		0.01		
Pepper,dried ※	●		5		1		
Raisin ※	●		5		0.2		

The residue definition of fenpyroximate for plant commodities for compliance with the MRL is fenpyroximate. Residue definition of fenpyroximate for animal commodities for compliance with MRL is sum of fenpyroximate, G2【 1- hydroxylmethyl-1-methylethyl (*E*)-*α*-(1,3-dimethyl-5-phenoxypyrazol-4-ylmethyleneamino-oxy)-*p*-toluate】and M-3【(*E*)-4- [(1,3-dimethyl-5-phenoxypyrazol-4-yl)methyleneaminooxymethyl]benzoic acid】, expressed as fenpyroximate. Current residue definition: Fenpyroximate for compliance with the MRL (both for animal and plant commodities).

* 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.

* Diagonal line means deletion of a food category to which an MRL applies.

●: 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: Request for setting/revising MRL was made by the MAFF. IT : Import tolerance

※ Food category "Pepper,dried" and "Raisin" will be deleted,and hereafter, MRLs in its raw commodity (i.e. Other solanaceous vegetables,Grape) will also apply to such processed commodity, taking into account its processing factors. For this substance, JMPR estimated processing factors of 7 for Other solanaceous vegetables and 2.7 for Raisin.

Mandestrobin

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Soybeans, dry	○	0.3	0.3	§			
Beans, dry	○	0.2	0.2	§			
Peas	○	0.3	0.3	§			
Broad beans	○	0.3	0.3	§			
Other pulses	○	0.3	0.3	§			
Chinese cabbage	○	5		Request			
Cabbage	○	5	5	§			
Kale	○	40	40	§			
Komatsuna (Japanese mustard spinach)	○	40	40	§			
Kyona	○	25	25	§			
Qing-geng-cai	○	40	40	§			
Other cruciferous vegetables	○	40	40	§			
Shungiku	○	50		Request			
Lettuce (including cos lettuce and leaf lettuce)	○	40	40	§			
Tomato	○	10	10	§			
Egg plant	○	2	2	§			
Cucumber (including gherkin)	○	2	2	§			
Water melon	○	0.1	0.1	§			
Melons	○	0.05	0.05	§			
Peas, immature (with pods)	○	5	5	§			
Kidney beans, immature (with pods)	○	10	10	§			
Green soybeans	○	10	10	§			
Other vegetables	○	10	10	§			
Apple	○	5	5	§			
Japanese pear	○	2	2	§			
Pear	○	2	2	§			
Peach	○	0.2	0.2	§			
Nectarine	○	5	5	§			
Apricot	○	5	5	§			
Japanese plum (including prune)	○	2	2	§			
Mume plum	○	5	5	§			
Cherry	○	5	5	§			
Strawberry	○	3	3			3	USA
Grape	○	10	10	§			
Japanese persimmon	○	3	3	§			
Rapeseeds	○	0.5		IT		0.5	Canada
Tea	○	40	40	§			
Other herbs	○	40	40	§			

The residue definition is sum of R and L isomers of mandestrobin.

* 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 the MAFF. IT : Import tolerance

Flumequine

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Cattle, muscle	○	0.5	0.5		0.5		
Pig, muscle	○	0.5	0.5		0.5		
Other terrestrial mammals, muscle	○	0.5	0.5		0.5		
Cattle, fat	○	1	1		1		
Pig, fat	○	1	1		1		
Other terrestrial mammals, fat	○	1	1		1		
Cattle, liver	○	0.5	0.5		0.5		
Pig, liver	○	0.5	0.5		0.5		
Other terrestrial mammals, liver	○	0.5	0.5		0.5		
Cattle, kidney	○	3	3		3		
Pig, kidney	○	3	3		3		
Other terrestrial mammals, kidney	○	3	3		3		
Cattle, edible offal	○	3	0.2				
Pig, edible offal	○	3	0.2				
Other terrestrial mammals, edible offal	○	3	0.2				
Milk	●	0.05	0.1			0.05	EU
Chicken, muscle	○	0.5	0.5		0.5		
Chicken, fat	○	1	1		1		
Chicken, liver	○	0.5	0.5		0.5		
Chicken, kidney	○	3	3		3		
Chicken, edible offal	○	3	0.5				
Salmoniformes (such as salmon and trout)	○	0.6	0.5		0.5	0.6	EU
Anguilliformes (such as eel)	○	0.6	0.6			0.6	EU
Perciformes (such as bonito, horse mackerel, mackerel, sea bass, sea bream and tuna)	○	0.6	0.04			0.6	EU
Other fish	○	0.6	0.6			0.6	EU

The residue definition is flumequine only.

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

* Shaded figures indicate provisional MRLs.

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

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

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

Mono, bis (trimethylammoniummethylene chloride)]-alkyltoluene

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Cattle, muscle	○ 1	1	§			
Pig, muscle	○ 1	1	§			
Cattle, fat	○ 1	1	§			
Pig, fat	○ 1	1	§			
Cattle, liver	○ 2	2	§			
Pig, liver	○ 2	2	§			
Cattle, kidney	○ 1	1	§			
Pig, kidney	○ 1	1	§			
Cattle, edible offal	○ 2	2	§			
Pig, edible offal	○ 2	2	§			
Milk	● 0.1	1	§			
Chicken, muscle	○ 1	1	§			
Chicken, fat	○ 1	1	§			
Chicken, liver	○ 2	2	§			
Chicken, kidney	○ 1	1	§			
Chicken, edible offal	○ 2	2	§			
Chicken eggs	○ 1	1	§			

The residue definition for milk is sum of mono (trimethylammoniummethylene chloride)-alkyl ($C_{11}H_{23}$) toluene, mono (trimethylammoniummethylene chloride)-alkyl ($C_{12}H_{25}$) toluene, mono (trimethylammoniummethylene chloride)-alkyl ($C_{13}H_{27}$) toluene and bis (trimethylammoniummethylene chloride)-alkyl ($C_{12}H_{25}$) toluene. For animal products except for milk, the residue difiniton is mono, bis (trimethylammoniummethylene chloride)-alkyltoluene.

* 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.

Butylated Hydroxyanisole

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Pig, muscle	○ 0.03	0.03	§			
Pig, fat	○ 0.1	0.04	§			
Pig, liver	○ 0.04	0.03	§			
Pig, kidney	○ 0.05	0.02	§			
Pig, edible offal	○ 0.1	0.02	§			
Chicken, muscle	○ 0.02	0.02	§			
Chicken, fat	○ 0.05	0.02	§			
Chicken, liver	○ 0.02	0.02	§			
Chicken, kidney	○ 0.02	0.02	§			
Chicken, edible offal	○ 0.05	0.02	§			
Chicken eggs	○ 0.06	0.02	§			
Salmoniformes (such as salmon and trout)	○ 0.5	0.5	§			
Anguilliformes (such as eel)	○ 0.5	0.5	§			
Perciformes (such as bonito, horse mackerel, mackerel, sea bass, sea bream and tuna)	○ 0.5	0.5	§			
Other fish	○ 0.5	0.5	§			

The residue definition is butylated hydroxyanisole 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

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

§ : Permitted for use in Japan.

Notes:

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

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

“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. Revision of Standards for Food Additive

The government of Japan will revise the existing compositional specifications of Hypobromous acid water.

Summary

The Food Sanitation Act, in Article 10, prohibits the use and the sale of the food additives the Minister of Health, Labour and Welfare (hereinafter referred to as "the Minister") does not designate. In addition, when specifications or standards for food additives are stipulated in the Ministry of Health and Welfare Notification (Notification No. 370, 1959) pursuant to Article 11 of the Act, those additives shall not be used or sold unless they meet the standards or the specifications.

On October 24, 2018, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council (hereinafter referred to as "the Committee") discussed whether it is adequate to revise the existing compositional specifications of Hypobromous acid water. The Committee has concluded that the Minister should revise the standards pursuant to Article 11 of the Act. See Attachment 2-1 for the details.

Notes

Hypobromous acid water is an aqueous solution consisting mainly of hypobromous acid. In Japan, Hypobromous acid water is designated as a food additive consisting mainly of hypobromous acid that is obtained by hydrolyzing
1,3-dibromo-5,5-dimethylhydantoin. It is permitted for use in meat as a surface disinfectant.

The United States and Canada approve Hypobromous acid water obtained by mixing hydrogen bromide with chlorine sources, such as sodium hypochlorite, potassium hypochlorite or calcium hypochlorite besides Hypobromous acid water currently approved in Japan. In those countries, Hypobromous acid water is generally used as a processing aid to disinfect water and ices for treatment of meat.

The Codex Alimentarius Commission does not categorize processing aids as food additives. The Codex Committee on Food Additives, therefore, dose not established use standards for Hypobromous acid water, its precursor hydrogen bromid, and choline sources (sodium hypochlorite, potassium

hypochlorite, and calcium hypochlorite) in the General Standard for Food Additives.

In addition, Hypobromous acid water has not been evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Additional Information

Progress in the designation procedure of food additives (54 flavorings and 45 non-flavoring additives) that have been proven safe by JECFA and that are widely used in countries other than Japan.

As of November 29, 2018, all flavorings and 41 non-flavoring additives are designated. See Attachment 2-2 for the details.

Attachment 2-1

Revision of Compositional Specifications

Hypobromous Acid Water

Compositional Specifications (draft)

Compositional specifications of Hypobromous acid water will be revised as follows:

Revised regulations	Current regulations
Definition Hypobromous Acid Water is an aqueous solution consisting mainly of hypobromous acid. It is obtained by hydrolyzing 1,3-dibromo-5,5-dimethylhydantoin or by mixing hydrogen bromide with an aqueous solution of sodium hypochlorite, potassium hypochlorite or calcium hypochlorite.	**Definition** Hypobromous Acid Water is an aqueous solution consisting mainly of hypobromous acid. It is obtained by hydrolyzing 1,3-dibromo-5,5-dimethylhydantoin.

(The underlined part will be newly added.)

Progress of evaluation of food additives that have been proven safe and are widely used in the world

29 November, 2018

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee[1]	Notification of result[2]	Discussion by subcommittee[3]	Closing date for comments[4]	Date of designation as food additives
Isobutanol	21 Nov 2003	24 Mar 2004(fin.)	27 May 2004	23 Apr 2004(fin.)	19 Aug 2004	24 Dec 2004
2-Ethyl-3, (5 or 6)- dimethylpyrazine		3 Mar 2004(fin.)	27 May 2004	8 Apr 2004(fin.)	26 Jul 2004	24 Dec 2004
2,3,5,6-Tetramethylpyrazine		3 Mar 2004(fin.)	27 May 2004	8 Apr 2004(fin.)	26 Jul 2004	24 Dec 2004
Calcium stearate	4 Mar 2004	20 May 2004(fin.)	29 Jul 2004	24 Jun 2004(fin.)	21 Oct 2004	24 Dec 2004
Propanol	21 Nov 2003	24 Mar 2004 20 May 2004 28 Jul 2004(fin.)	9 Sep 2004	26 Aug 2004(fin.)	14 Dec 2004	24 Feb 2005
Nitrous oxide	20 Oct 2003	17 Dec 2003 5 Oct 2004(fin.)	9 Dec 2004	17 Dec 2004(fin.)	19 Feb 2005	22 Mar 2005
Isopropanol	15 Dec 2003	24 Mar 2004 9 Apr 2004 8 Sep 2004 5 Oct 2004(fin.)	9 Dec 2004	28 Oct 2004(fin.)	4 Mar 2005	28 Apr 2005
Hydroxypropyl cellulse	16 Aug 2004	22 Dec 2004(fin.)	10 Mar 2005	24 Feb 2005(fin.)	14 Jun 2005	19 Aug 2005
Isoamylalcohol	5 Nov 2004	14 Jan 2005(fin.)	17 Mar 2005	24 Feb 2005(fin.)	14 Jun 2005	19 Aug 2005
2,3,5-Trimethylpyrazine						
Amylalcohol						
Natamycin	20 Oct 2003	9 Jan 2004 16 Nov 2004 26 Jan 2005(fin.)	6 May 2005	24 Mar 2005(fin.)	7 Sep 2005	28 Nov 2005
Acetaldehyde	21 Nov 2003	3 Mar 2004 9 Apr 2004 27 Apr 2004 23 Feb 2005 13 Apr 2005(fin.)	21 Jul 2005	23 Jun 2005(fin.)	12 Oct 2005	16 May 2006
2-Ethyl-3-methylpyrazine	7 Mar 2005	14 Jun 2005(fin.)	18 Aug 2005	28 Jul 2005(fin.)	19 Dec 2005	16 May 2006
5-Methylquinoxaline						
Butanol		14 Jun 2005 22 Jul 2005(fin.)	22 Sep 2005	27 Oct 2005 24 Nov 2005(fin.)	26 Apr 2006	12 Sep 2006
Ammonium alginate	28 Mar 2005	2 Dec 2005 14 Dec 2005(fin.)	30 Mar 2006	23 Mar 2006(fin.)	5 Sep 2006	26 Dec 2006
Potassium alginate						
Calcium alginate						

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee[1]	Notification of result[2]	Discussion by subcommittee[3]	Closing date for comments[4]	Date of designation as food additives
2-Methylbutanol	19 Dec 2005	14 Jul 2006 11 Aug 2006(fin.)	12 Oct 2006	8 Dec 2006 16 Jan 2007 (Fin.)	22 May 2007	3 Aug 2007
Isobutyraldehyde	19 Dec 2005	28 Jun 2006 14 Jul 2006 11 Aug 2006 13 Sep 2006 13 Oct 2006(fin.)	7 Dec 2006	8 Dec 2006 16 Jan 2007 (Fin.)	22 May 2007	3 Aug 2007
Butyraldehyde	19 Dec 2005	19 Dec 2006 26 Jan 2007(fin.)	22 Mar 2007	20 Mar 2007(fin.)	27 Aug 2007	26 Oct 2007
Polysorbate 20, 60, 65, 80	8 Oct 2003	29 Oct 2003 27 Apr 2004 28 Jul 2004 23 Mar 2007(fin.)	7 Jun 2007	4 Jul 2007 9 Aug 2007(fin.)	16 Dec 2007	30 Apr 2008
Calcium silicate	15 Aug 2005	28 Feb 2007 23 Mar 2007 17 Apr 2007 29 May 2007(fin.)	26 Jul 2007	9 Aug 2007(fin.)	16 Dec 2007	30 Apr 2008
Calcium ascorbate	3 Oct 2005	23 Mar 2007 17 Apr 2007 29 May 2007 22 Jun 2007(fin.)	23 Aug 2007	9 Aug 2007(fin.)	16 Dec 2007	30 Apr 2008
Nisin	20 Oct 2003	9 Apr 2004 16 Nov 2004 26 Jan 2005 30 Jul 2007 27 Aug 2007(fin.)	31 Jan 2008	26 Sep 2007 24 Oct 2007 28 Feb 2008(fin.) 24 Sep 2008(fin.)	18 Jul 2008	2 Mar 2009

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee[1]	Notification of result[2]	Discussion by subcommittee[3]	Closing date for comments[4]	Date of designation as food additives
Acetylated distarch adipate Acetylated distarch phosphate Acetylated oxidized starch Starch sodium octenylsuccinate Hydroxypropyl starch Hydroxypropyl distarch phosphate Phosphated distarch phosphate Monostarch phosphate Distarch phosphate Oxidized starch Starch acetate	26 Nov 2004	23 Mar 2005 17 May 2005 27 Aug 2007 28 Sep 2007(fin.)	29 Nov 2007	28 Nov 2007(fin.) 4 Jul 2008(fin.)	29 May 2008	1 Oct 2008
Magnesium hydroxide	9 Mar 2006	22 Jun 2007 30 Jul 2007 27 Aug 2007(fin.)	1 Nov 2007	24 Oct 2007(fin.)	7 Feb 2008	4 Jul 2008
Magnesium Monohydrogen Phosphate	28 Mar 2005	31 May 2006 28 Jun 2006 14 Jul 2006 11 Aug 2006 13 Sep 2006 28 Nov 2006 25 Oct 2011 29 Nov 2011 16 Dec 2011(fin)	22 Mar 2012	6 Mar 2012(fin.)	22 Jul 2012	2 Nov 2012
Polyvinylpyrrolidone	20 Jun 2005	13 Sep 2006 13 Oct 2006 28 Nov 2006 19 Dec 2006 26 Jan 2007 18 Dec 2012 22 Jan 2013 22 Feb 2013 27 Mar 2013 25 Apr 2013(fin.)	30 Jul 2013	21 Jun 2013 30 Oct 2013 29 Jan 2014(fin)	—	18 Jun 2014

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee[1]	Notification of result[2]	Discussion by subcommittee[3]	Closing date for comments[4]	Date of designation as food additives
Magnesium silicate(synthetic)	15 Aug 2005	28 Feb 2007 23 Mar 2007 17 Apr 2007 28 Sep 2009 17 Nov 2009(fin.)	21 Jan 2010	25 Dec 2009(fin)	6 Jun 2010	20 Oct 2010
Sodium aluminium silicate	15 Aug 2005	28 Feb 2007 30 May 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013 (under consideration)				
Calcium aluminium silicate	15 Aug 2005	28 Feb 2007 30 May 2012 27 Jul 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013 (under consideration)				
Calcium saccharin	22 May 2006	27 Aug 2007 28 Sep 2007 26 Oct 2007 26 Apr 2011 31 May 2011 28 Jun 2011(fin)	25 Aug 2011	2 Nov 2011 (fin)	12 May 2012	28 Dec 2012
Ammonium L-glutamate	22 May 2006	15 Jan 2008(fin.)	13 Mar 2008	11 Apr 2008 (fin.)	10 Oct 2008	20 Oct 2010
Sodium stearoyl-2-lactylate	6 Feb 2007	24 Mar 2008 15 Apr 2008(fin.)	10 Jul 2008	4 Jul 2008(fin.)	1 Dec 2008	28 May 2010
Potassium lactate	6 Feb 2007	17 Jun 2008 29 Sep 2008 21 Aug 2012 26 Sep 2012 25 Oct 2012(fin.)	21 Jan 2013	6 Dec 2012	11 Mar 2013	15 May 2013

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee[1]	Notification of result[2]	Discussion by subcommittee[3]	Closing date for comments[4]	Date of designation as food additives
Calcium sorbate	19 Mar 2007	26 Mar 2008 17 Jun 2008 29 Aug 2008(fin.)	20 Nov 2008	25 Nov 2008(fin)	25 Apr 2009	28 May 2010
Valeraldehyde	19 Mar 2007	1 Feb 2008(fin.)	27 Mar 2008	4 Jul 2008(fin.)	1 Dec 2008	4 Jun 2009
Isovaleraldehyde	19 Mar 2007	1 Feb 2008(fin.)	27 Mar 2008	4 Jul 2008(fin.)	1 Dec 2008	4 Jun 2009
2,3-Dimethylpyrazine	7 Feb 2008	15 Apr 2008 26 May 2008(fin.)	31 Jul 2008	24 Sep 2008(fin.)	3 Feb 2009	4 Jun 2009
2,5-Dimethylpyrazine	7 Feb 2008	15 Apr 2008 26 May 2008(fin.)	31 Jul 2008	24 Sep 2008(fin.)	3 Feb 2009	4 Jun 2009
2,6-Dimethylpyrazine	7 Feb 2008	15 Apr 2008 26 May 2008(fin.)	31 Jul 2008	24 Sep 2008(fin.)	3 Feb 2009	4 Jun 2009
2-Ethylpyrazine	22 May 2008	29 Sep 2008(fin.)	27 Nov 2008	22 Oct 2008(fin.)	25 Apr 2009	28 May 2010
2-Methylpyrazine	22 May 2008	29 Sep 2008(fin.)	27 Nov 2008	22 Oct 2008(fin.)	25 Apr 2009	28 May 2010
2-Pentanol	14 Oct 2008	11 Nov 2008(fin.)	22 Jan 2009	28 Apr 2009(fin.)	20 Sep 2009	28 May 2010
2-Methylbutyraldehyde	14 Oct 2008	11 Nov 2008(fin.)	22 Jan 2009	22 Dec 2008(fin.)	29 May 2009	28 May 2010
Propionaldehyde	20 Nov 2008	2 Feb 2009(fin.)	2 Apr 2009	28 Apr 2009(fin.)	20 Sep 2009	28 May 2010
6-Methylquinoline	20 Nov 2008	23 Mar 2009(fin)	21 May 2009	28 Apr 2009(fin.)	20 Sep 2009	28 May 2010
2-Ethyl-5-methylpyrazine	12 Mar 2009	29 Jun 2009 28 Sep 2009(fin.)	8 Oct 2009	25 Dec 2009(fin)	6 Jun 2010	20 Oct 2010
5,6,7,8-Tetrahydroquinoxaline	12 Mar 2009	29 Jun 2009(fin)	27 Aug 2009	3 Sep 2009(fin.)	2 Feb 2010	28 May 2010
3-Methyl-2-butanol	12 Mar 2009	18 May 2009(fin.)	23 Jul 2009	3 Sep 2009(fin.)	2 Feb 2010	28 May 2010
Isopentylamine	12 Aug 2009	7 Sep 2009(fin.)	12 Nov 2009	25 Dec 2009(fin)	6 Jun 2010	20 Oct 2010
Butylamine	10 Sep 2009	20 Oct 2009 17 Nov 2009(fin)	4 Mar 2010	5 Mar 2010(fin)	30 Aug 2010	10 Nov 2010
Phenetylamine	5 Nov 2009	17 Nov 2009(fin)	18 Mar 2010	5 Mar 2010(fin)	30 Aug 2010	10 Nov 2010
Trimethylamine	26 Nov 2009	15 Dec 2009(fin)	29 Jul 2010	2 Nov 2011 (fin)	19 Mar 2012	28 Dec 2012
1-Penten-3-ol	2 Feb 2010	23 Feb 2010(fin)	28 Apr 2010	9 Feb 2011(fin)	24 May 2011	19 Jul 2011
3-Methyl-2-butenol	2 Feb 2010	23 Feb 2010(fin)	28 Apr 2010	9 Feb 2011(fin)	24 May 2011	19 Jul 2011
Piperidine	15 Mar 2010	30 Mar 2010(fin)	20 May 2010	23 Jun 2010(fin)	23 Oct 2010	13 Dec 2010
Pyrrolidine	5 Apr 2010	20 Apr 2010(fin)	3 Jun 2010	23 Jun 2010(fin)	23 Oct 2010	13 Dec 2010
2,6-Dimethylpyridine	13 May 2010	2 Jun 2010(fin)	15 Jul 2010	9 Sep 2010(fin)	3 Jan 2011	15 Mar 2011
3-Ethylpyridine	14 Jun 2010	29 Jun 2010 23 Aug 2011 15 Nov 2012(fin.)	18 Feb 2013	18 Jan 2013	18 May 2013	6 Aug 2013

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee[1]	Notification of result[2]	Discussion by subcommittee[3]	Closing date for comments[4]	Date of designation as food additives
5-Ethyl-2-methylpyridine	14 Jun 2010	29 Jun 2010(fin)	26 Aug 2010	9 Sep 2010(fin)	3 Jan 2011	15 Mar 2011
2-(3-Phenylpropyl)pyridine	9 Jul 2010	27 Jul 2010(fin)	7 Oct 2010	22 Dec 2010(fin)	1 Apr 2011	28 Jun 2011
2,3-Diethyl-5-methylpyrazine	9 Jul 2010	27 Jul 2010(fin)	7 Oct 2010	22 Dec 2010(fin)	1 Apr 2011	28 Jun 2011
5-methyl-6,7-Dihydro-5*H*-cyclopentapyrazine	12 Aug 2010	31 Aug 2010(fin)	27 Jan 2011	22 Dec 2010(fin)	1 Apr 2011	28 Jun 2011
Pyrazine	12 Aug 2010	31 Aug 2010(fin)	4 Jan 2011	9 Feb 2011(fin)	24 May 2011	19 Jul 2011
3-Methyl-2-butenal	9 Sep 2010	27 Sep 2010(fin)	27 Jan 2011	9 Feb 2011(fin)	24 May 2011	19 Jul 2011
trans-2-Pentenal	29 Oct 2010	12 Nov 2010 21 Dec 2010 27 Sep 2011(fin)	1 Dec 2011	6 Mar 2012(fin)	22 Jul 2012	2 Nov 2012
Isoquinolin	29 Oct 2010	12 Nov 2010(fin)	3 Feb 2011	11 May 2011(fin)	8 Aug 2011	27 Dec 2011
2-Ethyl-6-methylpyrazine	6 Dec 2010	21 Dec 2010(fin)	31 Mar 2011	2 Nov 2011 (fin)	19 Mar 2012	28 Dec 2012
trans-2-Methyl-2-butenal	4 Jan 2011	18 Jan 2011(fin)	21 Apr 2011	2 Nov 2011 (fin)	19 Mar 2012	28 Dec 2012
Pyrrole	4 Jan 2011	18 Jan 2011(fin)	31 Mar 2011	11 May 2011(fin)	8 Aug 2011	27 Dec 2011
(3-Amino-3-carboxypropyl)dimethylsulfonium chloride	17 Feb 2011	22 Feb 2011(fin)	12 May 2011	2 Nov 2011 (fin)	19 Mar 2012	28 Dec 2012
Ammonium isovalerate	3 Mar 2011	26 Apr 2011 31 May 2011 15 Nov 2012(fin.)	18 Feb 2013	16 Feb 2015	21 May 2015	29 Jul 2015
	28 Nov 2014	–	9 Dec 2014			
β-apo-8'-carotenal	19 Apr 2011	27 Mar 2012 27 Jul 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013(fin.)	25 Nov 2013	27 Nov 2013	—	18 Jun 2014
Carmine	19 Apr 2011	26 Jul 2011 23 Aug 2011 30 May 2012 (under consideration)				

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee[1]	Notification of result[2]	Discussion by subcommittee[3]	Closing date for comments[4]	Date of designation as food additives
Canthaxanthin	19 Apr 2011	27 Mar 2012 27 Jul 2012 20 Aug 2013 24 Sep 2013 17 Oct 2013 20 Nov 2013 25 Dec 2013 30 Jun 2014(fin)	14 Oct 2014	5 Sep 2014	18 Nov 2014	20 Feb 2015
Sodium aluminium phosphate,acidic	19 Apr 2011	30 May 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013 (under consideration)				
Calcium acetate	19 Apr 2011	24 Apr 2012 15 Nov 2012 18 Dec 2012 22 Jan 2013(fin)	15 Apr 2013	13 Mar 2013	22 Jun 2013	4 Dec 2013
Calcium oxide	19 Apr 2011	24 Apr 2012 15 Nov 2012 18 Dec 2012 22 Jan 2013(fin)	15 Apr 2013	13 Mar 2013	22 Jun 2013	22 Oct 2013
Potassium sulfate	19 Apr 2011	24 Apr 2012 26 Sep 2012 25 Oct 2012(fin.)	21 Jan 2013	6 Dec 2012	11 Mar 2013	15 May 2013
Triethyl citrate	19 Apr 2011	30 May 2012 18 Dec 2012 22 Jan 2013 22 Feb 2013 29 Sep 2014 29 Oct 2014(fin.)	17 Feb 2015	25 Dec 2014	3 Mar 2015	19 May 2015

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee[1]	Notification of result[2]	Discussion by subcommittee[3]	Closing date for comments[4]	Date of designation as food additives
Isopropanol	19 Apr 2011	29 Nov 2011 16 Dec 2011(fin)	29 Mar 2012	31 May 2013	8 Oct 2013	4 Dec 2013
	16 May 2013	—	27 May 2013			
2,3-Diethylpyrazine	12 Feb 2014	13 Mar 2014 22 May 2014(fin)	26 Aug 2014	20 Jun 2014	23 Oct 2014	17 Nov 2014
1-Methylnaphthalene	5 Nov 2014	12 Dec 2014 14 Jan 2015 5 Feb 2015(fin.)	19 May 2015	24 Apr 2015	12 Jun 2015	18 Sep 2015

flavouring agents

1. Date when discussion was conducted by the expert committee.
2. Date when the evaluation result was filed with the MHLW.
3. Date when discussion was conducted by the Subcommittee on Food Additives under the Pharmaceutical Affairs and Food Sanitation Council.
4. Closing date for comment on WTO notification

<Provisional Translation>

Ensuring safety of imported food

○ For the purpose to confirm that the inspections and control have properly been conducted in the exporting countries for insurance of safety of imported food, hygiene control based on HACCP and attachment of health certificates of milk products and aquatic food are required as a requisite of import.

Previous regulations

Confirmation of implementation of hygiene control based on HACCP

* Confirmation of implementation of hygiene control based on HACCP is not conducted under the existing regulation.

Obligation to attach health certificates ①
(Confirmation that the food is derived from healthy livestock)

Scope: Meat, offal, meat products

Obligation to attach health certificates ②
(Confirmation of the situation etc. of hygiene control at the places of production)

Scope: Puffer fish, oysters for eating raw

* Notification under the existing regulation

Hygiene control based on HACCP is required for a part of imported food.

Milk and milk products is added to the scope.

Obligation to attach health certificate is legislated.

Revision

Confirmation of implementation of hygiene control based on HACCP

Scope: Food that are required to be subject to hygiene control based on HACCP in Japan (Meat, poultry, etc. are considered.)
* Regulated by the ministerial order.

Obligation to attach health certificates ①
(Confirmation that the food is derived from healthy livestock)

Scope: Meat, offal, meat products, milk, milk products* ar considered
* Regulated by the Act (Article 10, Clause 2 of the Act)

* Appropriate risk management is especially required as they may contain bacteria having a risk of food poisoning, .

Obligation to attach health certificates ②
(Confirmation of the situation etc. of hygiene control at the places of production)

Scope: Puffer fish, oysters for eating raw* are considered.
*Regulated by the ministerial order.

* Certification that the status of hygiene control at the area is appropriate in terms of food sanitation is required for them, depending on the situation of its control.

Schedule for enforcement

Confirmation of implementation of hygiene control based on HACCP・・・from 2021（enforcement in 2020 + 1 year interval)

Obligation to attach health certificates ① and ② ・・・from 2020

→Ministerial orders etc. on these new measures are planning to be published by June 2019, following notification of the proposals to WTO and call for public comments. MHLW will explain the progress in a timely manner.

Ensuring safety of imported food <Provisional

1. Confirmation of implementation of hygiene control based on HACCP
(1. of Article 11, Revision of the Food Sanitation Act, 13 June 2018)

Designate foods requiring measures to control processes particularly important to prevent occurrence of adverse health effects (food hygiene control based on HACCP) in exporting country

○ Designation of food (Regulated by the ministerial order)
→ "meat and poultry meat" are considered, which require food hygiene control based on HACCP in Japan

Designated foods shall not be imported for sale, unless they are slaughtered or processed in countries and regions, or establishments where the Minister of Health, Labour and Welfare recognizes that such measures are taken.

○ Designation of countries, regions or establishments (Regulated by ministerial announcements)

- Recognition and supervision of establishments complying with criteria for exportation to Japan by exporting country's competent authorities
- Notification of a list on establishments eligible for exportation to Japan from the competent authorities to MHLW
- Regular audit and verification of the status of control in the exporting country by MHLW

➢ Before entering into force, MHLW needs to consult with an exporting country and conduct on-site inspection in order to make sure the equivalence of its control system (e.g. a mechanism to ensure hygiene control based on HACCP and a structure on how to supervise it) with Japan's system.

※If it is impossible for an exporting country's competent authority to follow the process, an establishment in the country which wishes for recognition as those eligible for exportation to Japan may request MHLW, through the competent authority to recognize them, to designate it in accordance with procedures set by MHLW.

→MHLW will develop guidelines on the basic principles, criteria and procedures for designation of countries and regions, or establishments.

Ensuring safety of imported food <Provisional

2. Obligation to attach certificates ①: Confirmation that the food is derived from healthy livestock
(2. of Article 10, Revision of the Food Sanitation Act, 13 June 2018)

When importing foods which may be at increased risk on food hygiene depending on hygiene control, request to attach to them health certificates issued by the exporting country's competent authorities which certify the status of food hygiene control.

○ Milk and milk products will be within the scope, in addition to meat, offal and meat products derived from healthy livestock

Scope of milk and milk products
(Regulated by the ministerial order)

→Select products within those which are provided in the Ministerial Ordinance for Milk and Milk Products Concerning Compositional Standards, etc.*, taking into account products currently requiring a certificate in terms of animal health (e.g. milk, cream, butter milk, whey, butter, cheese).

* Milk (cow's milk, special milk, pasteurized goat's milk, composition modified milk, low fat milk, skimmed milk and processed milk)
Milk products (cream, butter, butter oil, cheese, concentrated whey, ice cream products, concentrated milk, concentrated skimmed milk, evaporated milk, evaporated skimmed milk, sweetened condensed milk, sweetened condensed skimmed milk, whole milk powder, skimmed milk powder, cream powder, whey powder, protein concentrated whey powder, buttermilk powder, sweetened milk powder, formulated milk powder, fermented milk, fermented milk drink (only containing min. 3.0% of milk solids-not-fat) and milk drink)

Entries of health certificate for milk and milk products (Regulated by the ministerial order)

→Take into account the entries currently required for meat etc. and for milk and milk products in terms of animal health.

<Entries in certificates (under consideration)>

1. Types of milk or milk products and animal species of dairy ingredient[*1*2]
2. Country of origin[*2]
3. Quantity (No. of packages) and weight[*1*2]
4. Address and name of consignor (for a juridical person, its name and location) [*1*2]
5. Address and name of consignee (for a juridical person, its name and location) [*1*2]
6. Address and name of facilities where the products are manufactured[*1]
7. The fact that raw milk is not derived from livestock with diseases, abnormity or dead (i.e. raw milk is from clinically healthy livestock) [*1*2]
8. The fact that production was carried out in a sanitary manner based on equal or better criteria than those of Japan[*1]
9. Date when the production was carried out [*1*2]

[*1]Items required in the certificate for meat etc.
[*2i]Items required in the certificate for milk etc. in terms of animal health
Underline: requirements in addition to those on animal health.

Ensuring safety of imported food

<Provisional Translation>

3. Obligation to attach sanitation certificates ②: Confirmation of the situation etc. of hygiene control at the places of production (2. of Article 11, Revision of the Food Sanitation Act, 13 June 2018)

For certain foods, request to conduct hygiene control and attach health certificates in order to confirm that inspection and control in the exporting country is appropriate and to ensure safety of imported food

○ Require health certificates for puffer fish and oysters for eating raw by the Ministerial Order (currently by a notification) for confirmation of the status of hygiene control at the places of production

Previous regulations

【**Oysters for eating raw** (notification)】
countries which are able to export oysters for eating raw to Japan
U.S.A, Canada, Australia, New Zealand, Ireland and South Korea
※ These countries are subject to taking hygiene control measures in the harvest waters equivalent to those in Japan.

Obligation to attach health certificate is legislated

Revision

○ Requiring health certificates from the countries exporting oysters for eating raw to Japan by the Ministerial Order on Food Sanitation Act 《**The order will provide the targeted foods and entries in the certificate**》

[2. of Art. 11 of the Act] For food and food additives which require certification on the status of hygiene control at the places of production in terms of food sanitation and are designated by the Minister of Health, Labour and Welfare, anyone shall not import them for sale if a certificate or the copy issued by the competent authorities of the exporting country* and certifying such status is not attached.
* including local governments which have authorization to certify the status

【 Entries in certificates (under consideration) 】
1. Name and address of consignor and consignee
2. Name and address of processing facility
3. Waters where the product is harvested and the date
4. Quantity and weight
5. If purification is performed, name and address of the facility
6. The fact that production was processed in the facility authorized by the competent authority and the hygiene control is equivalent to those based on processing criteria in Japan, etc.

【**Puffer fish** notification)】
- In importation, need to attach a health certificate issued by the exporting country's competent authority
- For puffer fish exported to Japan, the harvest waters*1 and the types of fish*2 are limited.

*1 limited to fish which are caught at the Japan Sea (East Sea), the Bohai Sea, the Yellow Sea or the East China Sea
*2 limited to *Takifugu rubripes*, *Takifugu porphyreus*, *Takifugu pardalis*, *Lagocephalus wheeleri*, *Lagocephalus inermis* etc.

Obligation to attach health certificate is legislated

○ Requiring health certificates for puffer fish exported to Japan by the Ministerial Order on Food Sanitation Act 《**The order will provide the targeted foods and entries in the certificate**》

[Relevant Article of the Act] same as oysters for eating raw

【 Entries in certificates (under consideration) 】
1. Types of puffer fish (scientific name)
2. Name of sea
3. Name and address of consignor and consignee
4. Name and address of processing facility
5. Waters where the product is caught and the date
6. Quantity and weight, the status of storage
7. If processing is performed, the fact that production was processed properly and in a sanitary manner in the facility supervised by the competent authority, etc.

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