THE 212th CONFERENCE FOR PROMOTION OF FOOD IMPORT FACILITATION

(FOOD SAFETY GROUP)

Food Safety Standards and Evaluation Division

Pharmaceutical Safety and Environmental Health Bureau

Ministry of Health, Labour and Welfare

Date : Wednesday, April 11, 2018 (10:00－12:00)

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

Agenda :

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

Pesticides : Gibberellin, Dimethenamid, Fluxapyroxad, Fluxametamide, Heptachlor

Pesticides and Veterinary drugs : Teflubenzuron

Veterinary drugs : Monepantel

Item 2. Designation of Substances Having No Potential to Cause Damage to Human Health (exempt substance)

Pesticides : Glyceryl caprylate,

Citric acid esters of mono- and diglycerides of fatty acid

Veterinary drugs and Feed additives : Zinc

Item 3. Revision of Specifications and Standards for Food Additives, etc.

Item 4. Setting of the Standards for Liquid Infant Formula

Item 5. Renewed English Homepage Regarding Radioactive Materials in Foods

<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 **Wednesday, April 25, 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 Fluxametamide and Monepantel 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>

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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 : Gibberellin, Dimethenamid, Fluxapyroxad, Fluxametamide, Heptachlor

Pesticides and Veterinary drugs : Teflubenzuron

Veterinary drugs : Monepantel

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[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

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

Dimethenamid (pesticide: 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 with the intention to expand its use pattern.

Fluxapyroxad (pesticide: fungicide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF with the intention to expand its use pattern and in response to a request for setting import tolerances based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan (Shokuan No. 0205001, 5 February 2004).

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

Heptachlor (pesticide: insecticide): 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.

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

Monepantel (veterinary drug: parasiticide): Not 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 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.

Gibberellin

Commodity	MRL※1 (draft)		MRL (current) ppm	Registration	Reference MRL	
		ppm			Codex ppm	National ppm
Potato	○	0.05		Request		
Japanese radish, roots (including radish)	●		0.2	§		
Japanese radish, leaves (including radish)	●		0.2	§		
Turnip, roots (including rutabaga)	●		0.2	§		
Turnip, leaves (including rutabaga)	●		0.2	§		
Horseradish	●		0.2	§		
Watercress	●		0.2	§		
Chinese cabbage	●		0.2	§		
Cabbage	●		0.2	§		
Brussels sprouts	●		0.2	§		
Kale	●		0.2	§		
Komatsuna(Japanese mustard spinach)	●		0.2	§		
Kyona	●		0.2	§		
Qing-geng-cai	●		0.2	§		
Cauliflower	●		0.2	§		
Broccoli	●		0.2	§		
Other cruciferous vegetables ※1	●	0.05	0.2	§		
Burdock	●	0.1	0.2	§		
Salsify	●		0.2	§		
Artichoke	●		0.2	§		
Chicory	●		0.2	§		
Endive	●		0.2	§		
Shungiku	●		0.2	§		
Lettuce (including cos lettuce and leaf lettuce)	●		0.2	§		
Other composite vegetables ※2	●	0.1	0.2	§		
Onion	●		0.2	§		
Welsh (including leek)	●		0.2	§		
Garlic	●		0.2	§		
Nira	●		0.2	§		
Asparagus	●		0.2	§		
Multiplying onion (including shallot)	●		0.2	§		
Other liliaceous vegetables	●		0.2	§		
Carrot	●		0.2	§		
Parsnip	●		0.2	§		
Parsley	●		0.2	§		
Celery	○	2	0.2	Request		
Mitsuba	○	0.2	0.2	§		
Other umbelliferous vegetables	●		0.2	§		
Tomato	○	0.2	0.2	§		
Pimiento (sweet pepper)	●		0.2	§		
Egg plant	●	0.1	0.2	§		
Other solanaceous vegetables	●		0.2	§		
Cucumber (including gherkin)	●		0.2	§		
Pumpkin (including squash)	●		0.2	§		
Oriental pickling melon (vegetable)	●		0.2	§		
Water melon	●		0.2	§		
Melons	●	0.1	0.2	§		
Makuwauri melon	●		0.2	§		
Other cucurbitaceous vegetables	●		0.2	§		
Spinach	●		0.2	§		
Bamboo shoots	●		0.2	§		

Commodity	MRL (draft) ppm		MRL (current) ppm	Registration	Reference MRL	
					Codex ppm	National ppm
Okra	•		0.2	§		
Ginger	•		0.2	§		
Peas, immature (with pods)	•		0.2	§		
Kidney beans, immature (with pods)	•	0.1	0.2	§		
Green soybeans	•		0.2	§		
Button mushroom	•		0.2	§		
Shiitake mushroom	•		0.2	§		
Other mushrooms	•		0.2	§		
Other vegetables	○	0.3	0.2	§		
Unshu orange, pulp	•	0.1	0.2	§		
Citrus natsudaidai, whole	○	0.2	0.2	§		
Lemon	○	0.2	0.2	§		
Orange (including navel orange)	○	0.2	0.2	§		
Grapefruit	○	0.2	0.2	§		
Lime	○	0.2	0.2	§		
Other citrus fruits	○	0.2	0.2	§		
Apple	•		0.2			
Japanese pear	•	0.1	0.2	§		
Pear	•		0.2			
Quince	•		0.2			
Loquat	○	0.2	0.2	§		
Peach	•		0.2			
Nectarine	•		0.2			
Apricot	•		0.2			
Japanese plum (including prune)	•	0.1	0.2	§		
Mume plum	•		0.2			
Cherry	•		0.2			
Strawberry	•	0.1	0.2	§		
Raspberry	•		0.2			
Blackberry	•		0.2			
Blueberry	•		0.2			
Cranberry	•		0.2			
Huckleberry	•		0.2			
Other berries	•		0.2			
Grape	•	0.1	0.2	§		
Japanese persimmon	•	0.1	0.2	§		
Banana	•		0.2			
Kiwifruit	•		0.2			
Papaya	○	0.5	0.2	§		
Avocado	•		0.2			
Pineapple	•		0.2			
Guava	•		0.2			
Mango	•		0.2			
Passion fruit	•		0.2			
Date	•		0.2			
Other fruits ※3	•	0.1	0.2	§		
Sunflower seeds	•		0.2			
Sesame seeds	•		0.2			
Safflower seeds	•		0.2			
Cotton seeds	•		0.2			
Rapeseeds	•		0.2			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other oil seeds	●	0.2			
Ginkgo nut	●	0.2			
Chestnut	●	0.2			
Pecan	●	0.2			
Almond	●	0.2			
Walnut	●	0.2			
Other nuts	●	0.2			
Other spices	○ 0.2	0.2	§		
Other herbs	○ 0.3	0.2	§		

The residue definition is gibberellin A3 only.

Not the uniform limit of 0.01 ppm but the regulation that foods shall not exceed physiological level contained in each commodity will be applied to the commodities for which current MRLs are to be deleted, since this substance is contained in agricultural commodities naturally.

* Shaded figures indicate provisional MRLs.

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

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

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

§: Permitted for use in Japan.

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

※1: The MRL for other cruciferous vegetables will be applied to hatawasabi (farm-grown wasabi) only.

※2: The MRL for other composite vegetables will be applied to wipe only.

※3: The MRL for other fruits will be applied to acerola only.

Dimethenamid

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Corn (maize, including pop corn and sweet corn)	•	0.03	0.05	§	0.01		
Other cereal grains	○	0.01	0.01		0.01		
Soybeans, dry	•	0.03	0.05	§	0.01		
Beans, dry	○	0.01			0.01		
Peanuts, dry	○	0.01	0.01		0.01		
Other pulses	○	0.01			0.01		
Potato	○	0.01	0.01	§	0.01		
Sweet potato	○	0.01	0.01		0.01		
Sugar beet	○	0.05	0.05	§	0.01		
Turnip, roots (including rutabaga)	○	0.01	0.01			0.01	USA
Turnip, leaves (including rutabaga)	○	0.1	0.1			0.1	USA
Cabbage	○	0.05	0.05	§			
Broccoli	○	0.05		Request			
Onion	○	0.01	0.01	§	0.01		
Garlic	○	0.01	0.01		0.01		
Other liliaceous vegetables	•		0.01				
Cucumber (including gherkin)	•		0.01				
Pumpkin (including squash)	•		0.01				
Oriental pickling melon (vegetable)	•		0.01				
Water melon	•		0.01				
Melons	•		0.01				
Makuwauri melon	•		0.01				
Other cucurbitaceous vegetables	•		0.01				
Green soybeans	•	0.02	0.05	§			
Other vegetables	○	0.01	0.01		0.01		
Hop	○	0.05	0.05			0.05	USA
Other herbs	○	0.01			0.01		
Cattle, muscle	○	0.01	0.01		0.01		
Pig, muscle	○	0.01	0.01		0.01		
Other terrestrial mammals, muscle	○	0.01	0.01		0.01		
Cattle, fat	○	0.01	0.01		0.01		
Pig, fat	○	0.01	0.01		0.01		
Other terrestrial mammals, fat	○	0.01	0.01		0.01		
Milk	○	0.01	0.01		0.01		
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		
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		

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

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

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

●: Commodities for which MRLs are to be lowered or deleted.
○: Commodities for which MRLs are to be maintained, increased or newly set.
§: Permitted for use in Japan.
Request: Request for setting/revising MRL was made by the MAFF.

Fluxapyroxad

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Rice (brown rice)	o	3	1		3		
Wheat	o	2	0.3	Request	0.3		
Barley	o	3	3		2	3.0	USA
Rye	o	3	3		0.3	3.0	USA
Corn (maize, including pop corn and sweet corn)	o	0.2	0.2		0.15		
Buckwheat	o	3	3			3.0	USA
Other cereal grains	o	3	3		2	3.0	USA
Soybeans, dry	*	0.2	0.3		0.15		
Beans, dry	o	0.4	0.4		0.4		
Peas	o	0.4	0.4		0.4		
Broad beans	o	0.4	0.4			0.4	USA
Peanuts, dry	o	0.01	0.01		0.01		
Other pulses	o	0.4	0.4		0.4		
Potato	o	0.03	0.03	Request	0.03		
Taro	o	0.02	0.02			0.02	USA
Sweet potato	o	0.02	0.02			0.02	USA
Yam	o	0.02	0.02			0.02	USA
Other potatoes	o	0.02	0.02			0.02	USA
Sugar beet	o	0.2	0.2	Request	0.15		
Sugarcane	o	3	3			3.0	USA
Japanese radish, roots (including radish)	o	0.9	0.9		0.2	0.90	USA
Japanese radish, leaves (including radish)	o	8			8		
Turnip, roots (including rutabaga)	o	0.9	0.9			0.90	USA
Turnip, leaves (including rutabaga)	o	4			4		
Horseradish	o	0.9	0.9			0.90	USA
Watercress	o	30	30			30	USA
Chinese cabbage	o	4	4		4		
Cabbage	o	4	4		2	4.0	USA
Brussels sprouts	o	4	4		2	4.0	USA
Kale	o	4	4		4		
Komatsuna(Japanese mustard spinach)	o	4			4		
Kyona	o	4	4		4		
Qing-geng-cai	o	4	4		4		
Cauliflower	o	4	4		2	4.0	USA
Broccoli	o	4	4		2	4.0	USA
Other cruciferous vegetables	o	4	4		4		
Burdock	o	0.9	0.9			0.90	USA
Salsify	o	0.9	0.9			0.90	USA
Endive	o	30	30			30	USA
Shungiku	o	30	30			30	USA
Lettuce (including cos lettuce and leaf lettuce)	o	30	30		4	30	USA
Other composite vegetables	o	30	30			30	USA
Onion	o	2	2		0.6	1.5	USA
Welsh (including leek)	o	2	2			1.5	USA
Garlic	o	2	2		0.6	1.5	USA
Nira	o	2	2			1.5	USA
Other liliaceous vegetables	o	2	2			1.5	USA
Carrot	o	1	0.9		1		
Parsnip	o	1	0.9		1		
Parsley	o	30	30			30	USA
Celery	o	30	30		10	30	USA

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Other umbelliferous vegetables	o	30	30			30	USA
Tomato	o	0.7	0.7		0.6	0.7	USA
Pimiento (sweet pepper)	o	0.7	0.7		0.6	0.7	USA
Egg plant	o	0.7	0.7		0.6	0.7	USA
Other solanaceous vegetables	o	0.7	0.7		0.6	0.7	USA
Cucumber (including gherkin)	o	0.5	0.5		0.2	0.50	USA
Pumpkin (including squash)	o	0.5	0.5		0.2	0.50	USA
Oriental pickling melon (vegetable)	o	0.2			0.2		
Other cucurbitaceous vegetables	o	0.5	0.5		0.2	0.50	USA
Okra	o	0.7	0.7		0.6	0.7	USA
Ginger	o	0.02	0.02			0.02	USA
Peas, immature (with pods)	o	2	2		2		
Kidney beans, immature (with pods)	o	2	2		2		
Green soybeans	o	2	2		1.5		
Shiitake mushroom	o	0.6	0.6		0.6		
Other mushrooms	o	0.6	0.6		0.6		
Other vegetables	o	7	7		2	7.0	USA
Citrus natsudaidai, whole	o	1		IT		1.0	USA
Lemon	o	1		IT		1.0	USA
Orange (including navel orange)	o	1		IT	0.3	1.0	USA
Grapefruit	o	1		IT		1.0	USA
Lime	o	1		IT		1.0	USA
Other citrus fruits	o	1		IT	0.3	1.0	USA
Apple	o	0.9	0.9	Request	0.9		
Japanese pear	o	0.9	0.9	Request	0.9		
Pear	o	0.9	0.9	Request	0.9		
Quince	o	0.9	0.9		0.9		
Peach	o	0.2		Request			
Nectarine	o	3	3	Request	1.5	3.0	USA
Apricot	o	3	3		1.5	3.0	USA
Japanese plum (including prune)	•	2	5		1.5		
Mume plum	o	2	2		1.5		
Cherry	o	3	3		3		
Strawberry	o	7	4		7		
Raspberry	o	7	5		7		
Blackberry	o	7	5		7		
Blueberry	o	7	7		7		
Cranberry	o	7	7		7		
Huckleberry	o	7	7		7		
Other berries	o	7	7		7		
Grape	o	3	2		3		
Banana	o	3		IT	3		
Guava	o	7	7			7.0	USA
Mango	o	0.7		IT		0.7	USA
Passion fruit	o	2	2			2.0	USA
Other fruits	o	7	2		7		
Sunflower seeds	o	0.9	0.9		0.8	0.9	USA
Sesame seeds	o	0.9	0.9		0.8	0.9	USA
Safflower seeds	o	0.9	0.9		0.8	0.9	USA
Cotton seeds	o	0.3	0.01	IT	0.3		
Rapeseeds	o	0.9	0.9		0.8	0.9	USA

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Other oil seeds	o	0.9	0.9		0.8	0.9	USA
Ginkgo nut	o	0.04			0.04		
Chestnut	o	0.06	0.06		0.04	0.06	USA
Pecan	o	0.06	0.06		0.04	0.06	USA
Almond	o	0.06	0.06		0.04	0.06	USA
Walnut	o	0.06	0.06		0.04	0.06	USA
Other nuts	o	0.8	0.8		0.8		
Coffee beans	o	0.2		IT		0.2	USA
Other spices	o	7	0.8		7		
Other herbs	o	30	30		4	30	USA
Cattle, muscle	o	0.2	0.2		0.2		
Pig, muscle	o	0.2	0.2		0.2		
Other terrestrial mammals, muscle	o	0.2	0.2		0.2		
Cattle, fat	o	0.2	0.2		0.2		
Pig, fat	o	0.2	0.2		0.2		
Other terrestrial mammals, fat	o	0.2	0.2		0.2		
Cattle, liver	o	0.1	0.1		0.1		
Pig, liver	o	0.1	0.1		0.1		
Other terrestrial mammals, liver	o	0.1	0.1		0.1		
Cattle, kidney	o	0.1	0.1		0.1		
Pig, kidney	o	0.1	0.1		0.1		
Other terrestrial mammals, kidney	o	0.1	0.1		0.1		
Cattle, edible offal	o	0.1	0.1		0.1		
Pig, edible offal	o	0.1	0.1		0.1		
Other terrestrial mammals, edible offal	o	0.1	0.1		0.1		
Milk	o	0.02	0.02		0.02		
Chicken, muscle	o	0.02	0.02		0.02		
Other poultry, muscle	o	0.02	0.02		0.02		
Chicken, fat	o	0.05	0.05		0.05		
Other poultry, fat	o	0.05	0.05		0.05		
Chicken, liver	o	0.02	0.02		0.02		
Other poultry, liver	o	0.02	0.02		0.02		
Chicken, kidney	o	0.02	0.02		0.02		
Other poultry, kidney	o	0.02	0.02		0.02		
Chicken, edible offal	o	0.02	0.02		0.02		
Other poultry, edible offal	o	0.02	0.02		0.02		
Chicken eggs	o	0.02	0.02		0.02		
Other poultry, eggs	o	0.02	0.02		0.02		
Pepper,dried ※	●		6		6		
Wheat bran ※	●		1		1		
Raisin	o	15			15		

The residue definition is fluxapyroxad 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 lowered or deleted.

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

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

IT: Import tolerance

※For dried pepper and wheat bran, the MRL of the each raw commodity (i.e. peppers as other solanaceous vegetables, wheat, respectively) will be applied taking into account their processing factors.
JMPR estimated the processing factors of 10 for dried pepper and 2.90 for wheat bran.

Fluxametamide

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Soybeans, dry	o 0.02		Request		
Taro	o 0.05		Request		
Sweet potato	o 0.02		Request		
Japanese radish, roots (including radish)	o 0.1		Request		
Japanese radish, leaves (including radish)	o 5		Request		
Chinese cabbage	o 0.7		Request		
Cabbage	o 1		Request		
Cauliflower	o 2		Request		
Broccoli	o 2		Request		
Lettuce (including cos lettuce and leaf lettuce)	o 10		Request		
Onion	o 0.02		Request		
Welsh (including leek)	o 1		Request		
Tomato	o 1		Request		
Pimiento (sweet pepper)	o 2		Request		
Egg plant	o 0.3		Request		
Cucumber (including gherkin)	o 0.5		Request		
Water melon	o 0.02		Request		
Melons	o 0.05		Request		
Peas, immature (with pods)	o 3		Request		
Kidney beans, immature (with pods)	o 2		Request		
Green soybeans	o 5		Request		
Other vegetables	o 5		Request		
Strawberry	o 1		Request		
Tea	o 5		Request		
Fish	o 0.02		Request		

The residue definition is Fluxametamide only.

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

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

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

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

Heptachlor

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

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Other liliaceous vegetables	•	0.03			
Carrot	•	0.1			
Parsnip	•	0.03			
Parsley	•	0.01			
Celery	•	0.03			
Mitsuba	•	0.01			
Other umbelliferous vegetables	•	0.03			
Tomato	•	0.02			
Pimiento (sweet pepper)	•	0.03			
Egg plant	•	0.03			
Other solanaceous vegetables	•	0.03			
Cucumber (including gherkin)	•	0.03			
Pumpkin (including squash)	○ 0.2	0.03			
Oriental pickling melon (vegetable)	•	0.03			
Water melon	•	0.03			
Melons	•	0.03			
Makuwauri melon	•	0.03			
Other cucurbitaceous vegetables	•	0.03			
Spinach	•	0.03			
Bamboo shoots	•	0.03			
Okra	•	0.03			
Peas, immature (with pods)	•	0.03			
Kidney beans, immature (with pods)	•	0.03			
Green soybeans	○ 0.02	0.02		0.02	
Button mushroom	•	0.03			
Shiitake mushroom	•	0.03			
Other mushrooms	•	0.03			
Other vegetables	•	0.03			
Unshu orange, pulp	○ 0.01	0.01		0.01	
Citrus natsudaidai, whole	○ 0.01	0.01		0.01	
Lemon	○ 0.01	0.01		0.01	
Orange (including navel orange)	○ 0.01	0.01		0.01	
Grapefruit	○ 0.01	0.01		0.01	
Lime	○ 0.01	0.01		0.01	
Other citrus fruits	○ 0.01	0.01		0.01	
Apple	•	0.01			
Japanese pear	•	0.01			
Pear	•	0.01			
Quince	•	0.01			
Loquat	•	0.01			
Peach	•	0.01			
Nectarine	•	0.01			
Apricot	•	0.01			
Japanese plum (including prune)	•	0.01			
Mume plum	•	0.01			
Cherry	•	0.01			
Strawberry	•	0.01			
Raspberry	•	0.01			
Blackberry	•	0.01			
Blueberry	•	0.01			
Cranberry	•	0.01			

Commodity	MRL (draft) ppm		MRL (current) ppm	Registration	Reference MRL	
					Codex ppm	National ppm
Huckleberry	•		0.01			
Other berries	•		0.01			
Grape	•		0.01			
Japanese persimmon	•		0.01			
Banana	•		0.01			
Kiwifruit	•		0.01			
Avocado	•		0.01			
Pineapple	○	0.01	0.01		0.01	
Guava	•		0.01			
Mango	•		0.01			
Passion fruit	•		0.01			
Date	•		0.01			
Other fruits	•		0.03			
Sunflower seeds	•		0.01			
Sesame seeds	•		0.01			
Safflower seeds	•		0.01			
Cotton seeds	○	0.02	0.02		0.02	
Rapeseeds	•		0.01			
Other oil seeds	•		0.01			
Ginkgo nut	•		0.01			
Chestnut	•		0.01			
Pecan	•		0.01			
Almond	•		10			
Walnut	•		0.01			
Other nuts	•		0.01			
Tea	•		0.02			
Hop	•		0.01			
Other spices	•	0.01	0.03		0.01	
Other herbs	•		0.03			
Cattle, muscle	•		0.2			
Pig, muscle	•		0.2			
Other terrestrial mammals, muscle	•		0.2			
Cattle, fat	○	0.2	0.2		0.2	
Pig, fat	○	0.2	0.2		0.2	
Other terrestrial mammals, fat	○	0.2	0.2		0.2	
Cattle, liver	•		0.2			
Pig, liver	•		0.2			
Other terrestrial mammals, liver	•		0.2			
Cattle, kidney	•		0.2			
Pig, kidney	•		0.2			
Other terrestrial mammals, kidney	•		0.2			
Cattle, edible offal	•		0.2			
Pig, edible offal	•		0.2			
Other terrestrial mammals, edible offal	•		0.2			
Milk	○	0.006	0.006		0.006	
Chicken, muscle	•		0.2			
Other poultry, muscle	•		0.2			
Chicken, fat	○	0.2	0.2		0.2	
Other poultry, fat	○	0.2	0.2		0.2	
Chicken, liver	•		0.2			
Other poultry, liver	•		0.2			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Chicken, kidney	●	0.2			
Other poultry, kidney	●	0.2			
Chicken, edible offal	●	0.2			
Other poultry, edible offal	●	0.2			
Chicken eggs	○ 0.05	0.05		0.05	
Other poultry, eggs	○ 0.05	0.05		0.05	
Salmoniformes (such as salmon and trout)	●	0.05			
Anguilliformes (such as eel)	●	0.05			
mackerel, sea bass, sea bream and tuna)	●	0.05			
Other fish	●	0.05			
Shelled molluscs	●	0.05			
Crustaceans	●	0.05			
Other aquatic animals	●	0.05			
Whales	○ 0.02				
Honey (including royal-jelly)	●	0.006			
Soybean oil, (limited to edible soybean oil that meets the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)※	●	0.02			
Soybean oil (except edible soybean oil that meets the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)※	●	0.5			
Soybean oil	○ 0.5			0.5	

The residue definition is sum of heptachlor and heptachlor epoxide.

* 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.

* 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 lowered or deleted.

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

Teflubenzuron

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Rice (brown rice)	•		0.05				
Wheat	•		0.05				
Barley	•		0.05				
Rye	•		0.05				
Corn (maize, including pop corn and sweet corn)	•	0.01	0.1		0.01		
Buckwheat	•		0.05				
Other cereal grains	•		0.05				
Soybeans, dry	•	0.05	0.1	§	0.05		
Potato	•		0.1				
Sweet potato	•	0.05	0.1	§			
Sugar beet	•	0.3	0.5	§			
Sugarcane	○	0.01			0.01		
Japanese radish, roots (including radish)	•	0.05	0.1	§			
Japanese radish, leaves (including radish)	○	1	1	§			
Chinese cabbage	•	0.3	0.5	§			
Cabbage	•	0.3	0.5	§			
Brussels sprouts	•		0.5				
Qing-geng-cai	•	0.5	1	§			
Cauliflower	•	0.01	0.05		0.01		
Broccoli	•	0.5	1	§			
Other cruciferous vegetables	○	1	1	§			
Burdock	○	0.1	0.1	§			
Lettuce (including cos lettuce and leaf lettuce)	○	1	1	§			
Other composite vegetables	○	10	5	§ · Request			
Welsh (including leek)	○	1	1	§			
Asparagus	•	0.3	1	§			
Tomato	○	2	0.5	§	1.5		
Pimiento (sweet pepper)	•		0.5				
Egg plant	○	0.5	0.5	§			
Other solanaceous vegetables	○	0.2	0.2			0.2	Korea
Cucumber (including gherkin)	○	2	0.2		1.5		
Pumpkin (including squash)	•		0.2				
Melons	○	0.3	0.2		0.3		
Other cucurbitaceous vegetables	○	0.2	0.2	§			
Spinach	○	5	5	§			
Ginger	○	0.05	0.05	§			
Peas, immature (with pods)	○	3	3	§			
Green soybeans	○	1	1	§	0.2		
Button mushroom	•		0.2				
Unshu orange, pulp	•	0.05	0.1	§	0.05		
Citrus natsudaidai, whole	○	1	1	§	0.5		
Lemon	•	0.5	1		0.5		
Orange (including navel orange)	•	0.5	1		0.5		
Grapefruit	•	0.5	1		0.5		
Lime	•	0.5	1		0.5		
Other citrus fruits	•	0.5	1		0.5		
Apple	•	0.5	1	§	0.5		
Japanese pear	•	0.5	1	§			
Pear	•	0.5	1	§			
Quince	•		1				
Peach	•	0.2	0.3	§			

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Nectarine	●	0.5	1	§			
Apricot	●		0.3				
Japanese plum (including prune)	●		0.3				
Mume plum	●		0.3				
Cherry	●		0.3				
Strawberry	○	1	1	§			
Grape	●	0.7	1		0.7		
Japanese persimmon	○	0.5	0.5	§			
Papaya	○	0.4			0.4		
Sunflower seeds	○	0.3			0.3		
Tea	○	20	20	§			
Coffee beans	○	0.5	0.5		0.3	0.5	Brazil
Other spices	○	5	5	§			
Cattle, muscle	○	0.01			0.01		
Pig, muscle	○	0.01			0.01		
Other terrestrial mammals, muscle	○	0.01			0.01		
Cattle, fat	○	0.01			0.01		
Pig, fat	○	0.01			0.01		
Other terrestrial mammals, fat	○	0.01			0.01		
Cattle, liver	○	0.01			0.01		
Pig, liver	○	0.01			0.01		
Other terrestrial mammals, liver	○	0.01			0.01		
Cattle, kidney	○	0.01			0.01		
Pig, kidney	○	0.01			0.01		
Other terrestrial mammals, kidney	○	0.01			0.01		
Cattle, edible offal	○	0.01			0.01		
Pig, edible offal	○	0.01			0.01		
Other terrestrial mammals, edible offal	○	0.01			0.01		
Milk	○	0.01			0.01		
Chicken, muscle	○	0.01			0.01		
Other poultry, muscle	○	0.01			0.01		
Chicken, fat	○	0.01			0.01		
Other poultry, fat	○	0.01			0.01		
Chicken, liver	○	0.01			0.01		
Other poultry, liver	○	0.01			0.01		
Chicken, kidney	○	0.01			0.01		
Other poultry, kidney	○	0.01			0.01		
Chicken, edible offal	○	0.01			0.01		
Other poultry, edible offal	○	0.01			0.01		
Chicken eggs	○	0.01			0.01		
Other poultry, eggs	○	0.01			0.01		
Salmoniformes (such as salmon and trout)	○	0.4			0.4		

The residue definition is teflubenzuron only.

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

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

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

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

§: Permitted for use in Japan.

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

Monepantel

Commodity		MRL[1] (draft) ppm	MRL[1] (current) ppm	Registration	Reference MRL		
					Codex[2] ppm	National[1] ppm	
Cattle, muscle	○	0.3		IT		0.3	EU
Other terrestrial mammals, muscle	○	0.7	0.7		0.5	0.7	EU
Cattle, fat	○	7		IT		7	EU
Other terrestrial mammals, fat	○	13	7		13		
Cattle, liver	○	2		IT		2	EU
Other terrestrial mammals, liver	○	7	5		7		
Cattle, kidney	○	1		IT		1	EU
Other terrestrial mammals, kidney	○	2	2		1.7	2	EU
Cattle, edible offal	○	2		IT			
Other terrestrial mammals, edible offal	○	7	5				

The residue definition is monepantel sulfone only.

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

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

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

IT : Import tolerance

※1 The draft MRLs, the current MRLs and national MRLs are expressed as monepantel sulfone.

※2 Codex MRLs are expressed as monepantel. (The residue definition for Codex MRLs is monepantel sulfone

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. Designation of Substances Having No Potential to Cause Damage to Human Health (exempt substance)

The MHLW is going to designate the following agricultural and veterinary chemicals as substances having no potential to cause damage to human health, which is also referred to as "exempt substance," based on the provision of Paragraph 3, Article 11 of the Food Sanitation Act:

Pesticides: Glyceryl caprylate,

Citric acid esters of mono- and diglycerides of fatty acid

Veterinary drugs and Feed additives : Zinc

Summary

Glyceryl caprylate (pesticide: insecticide/fungicide): Not permitted for use in Japan. The MHLW requested the Food Safety Commission of Japan (FSC) to conduct a risk assessment for this substance in response to a request for setting MRLs by the MAFF with the intention to newly register this substance as a pesticide. The FSC concluded that Glyceryl caprylate is not considered to have no potential to cause damage to human health from its residue in foods. Based on the assessment, the MHLW has decided to designate Glyceryl caprylate as an exempt substance.

Citric acid esters of mono- and diglycerides of fatty acid (pesticide: insecticide): Not permitted for use in Japan. The MHLW requested the FSC to conduct a risk assessment for this substance in response to a request for setting MRLs by the MAFF with the intention to newly register this substance as a pesticide. The FSC concluded that Citric acid esters of mono- and diglycerides of fatty acid is not considered to have no potential to cause damage to human health from its residue in foods. Based on the assessment, the MHLW has decided to designate Citric acid esters of mono- and diglycerides of fatty acid as an exempt substance.

Zinc (Veterinary drug and Feed additive: minerals): Permitted for use in Japan. The Minister of Agriculture, Forestry and Fisheries asked the minister of Health, Labour and Welfare for comments about designation as a feed additive and establishment of standards and specifications of this substance, under the Act on Safety Assurance and Quality Improvement of Feeds. In response to this, The MHLW requested the FSC to conduct a risk assessment for this substance. The FSC concluded that Zinc is not considered to have no potential to cause damage to human health from its residue in foods. Based on the assessment, the MHLW has decided to designate Zinc as an exempt substance.

Item 3. Revision of Specifications and Standards for Food Additives

Summary

The Food Sanitation Act, in Article 10, prohibits the use and sale of 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 established based on Article 11 of the act and stipulated in the Ministry of Health, Labour and Welfare Notification (Ministry of Health and Welfare Notification No. 370, 1959), those additives shall not be used or sold unless they meet the standards or specifications.

1. Aluminum ammonium sulfate and Aluminum potassium sulfate

On 1 March 2018, the Committee on Food Additives of the Food Sanitation Council under the Pharmaceutical Affairs and Food Sanitation Council (hereinafter referred to as "the Committee") discussed whether it is adequate to revise the existing standards for use of Aluminum ammonium sulfate and Aluminum potassium sulfate. The committee has concluded that the Minister should revise the standards based on Article 11 of the act. For details, see Attachments 3-1.

Note

Aluminum ammonium sulfate and Aluminum potassium sulfate are used as raising agents or processing agents, such as color retention agents and firming agents.

In the Codex Alimentarius Commission's General Standards for Food Additives (GSFA), Aluminum ammonium sulfate is permitted for use in food, such as steamed bread and pickled vegetables. In the United States, Aluminum ammonium sulfate and Aluminum potassium sulfate are categorized as generally-recognized-as-safe (GRAS) substances by the US Food and Drug Administration (FDA) and permitted for use in food at levels necessary to achieve the desired effects under Good Manufacturing Practices (GMP). In the European Union (EU), these substances are permitted for use in candied cherries as aluminum sulfates.

2. Revising Specifications and Standards (Updating the Official Compilation of Food Additives)

On 1 March 2018, the Committee also discussed whether it is adequate to revise the existing specifications for β-Galactosidase and Fructosyl transferase. The committee concluded that the Minister should revise the specifications based on Article 11 of the act. For details, see Attachments 3-2

3. 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 11, 2018, all flavorings and 41 non-flavoring additives are designated. See Attachment 3-3.

As for Calcium aluminum silicate, Sodium aluminum phosphate (acidic), and Sodium aluminum silicate out of four non-designated additives, the MHLW will suspend the procedure for the designation because it is considered that these additives are no longer necessary in the global movement of reducing aluminum intake.

Attachment 3-1

Revision of Standards for Use

Aluminum ammonium sulfate and Aluminum potassium sulfate

Current regulations

(1) Aluminum ammonium sulfate
Aluminum ammonium sulfate is not permitted in *miso*.

(2) Aluminum potassium sulfate
Aluminum potassium sulfate is not permitted in *miso*.

Revised regulations

Use in bread and confectioneries will be limited for Aluminum ammonium sulfate and Aluminum potassium sulfate with a maximum use level of 0.1 g as aluminum per kg of each product.

Attachment 3-2
(The underlined parts are to be revised)

	Revised standards and specifications(draft)	Current standards and specifications
β－Galactosidase	**Definition** β-Galactosidase is an enzyme that hydrolyzes β-D-galactosidic linkages. It is derived from animal organs or the culture of filamentous fungi (limited to *Aspergillus niger*, *Aspergillus oryzae*, *Penicillium multicolor*, and *Rhizopus oryzae*), yeasts (*Cryptococcus laurentii*, *Kluyveromyces fragilis*, *Kluyveromyces lactis*, *Sporobolomyces singularis*, and species of the genus *Saccharomyces*), or bacteria (limited to *Bacillus circulans* and species of the genus *Streptococcus*). It may contain a food used exclusively for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its activity. It may also contain a food additive used for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its pH or activity.	**Definition** β-Galactosidase is an enzyme that hydrolyzes β-D-galactosidic linkages. It is derived from animal organs or the culture of filamentous fungi (limited to *Aspergillus niger*, *Aspergillus oryzae*, *Penicillium multicolor*, and *Rhizopus oryzae*), yeasts (*Kluyveromyces fragilis*, *Kluyveromyces lactis*, *Sporobolomyces singularis*, and species of the genus *Saccharomyces*), or bacteria (limited to *Bacillus circulans* and species of the genus *Streptococcus*). It may contain a food used exclusively for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its activity. It may also contain a food additive used for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its pH or activity.
Fructosyl Transferase	**Definition** Fructosyl Transferase is an enzyme that transfers the fructosyl group of sugars. It is derived from the culture of filamentous fungi (limited to *Penicillium roqueforti* and species of the genera *Aspergillus and Aureobasidium*) or bacteria (limited to *Microbacterium saccharophilum*, *Zymomonas mobilis*, and species of the genera *Arthrobacter* and *Bacillus*). It may contain a food used exclusively for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its activity. It may also contain a food additive used for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its pH or activity.	**Definition** Fructosyl Transferase is an enzyme that transfers the fructosyl group of sugars. It is derived from the culture of filamentous fungi (limited to *Penicillium roqueforti* and species of the genus *Aspergillus*) or bacteria (limited to *Microbacterium saccharophilum*, *Zymomonas mobilis*, and species of the genera *Arthrobacter* and *Bacillus*). It may contain a food used exclusively for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its activity. It may also contain a food additive used for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its pH or activity.

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

11 Apr. 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 2,3,5-Trimethylpyrazine Amylalcohol	5 Nov 2004	14 Jan 2005(fin.)	17 Mar 2005	24 Feb 2005(fin.)	14 Jun 2005	19 Aug 2005
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 5-Methylquinoxaline	7 Mar 2005	14 Jun 2005(fin.)	18 Aug 2005	28 Jul 2005(fin.)	19 Dec 2005	16 May 2006
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 Potassium alginate Calcium alginate	28 Mar 2005	2 Dec 2005 14 Dec 2005(fin.)	30 Mar 2006	23 Mar 2006(fin.)	5 Sep 2006	26 Dec 2006

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

Item 4. Setting of the Standards for Liquid Infant Formula

Summary

Pursuant to stipulation in Article 11, Paragraph 1 of the Food Sanitation Act, and from the viewpoint of public health, the Minister of Health, Labour and Welfare is authorized to establish standards for the methods of producing, processing, using, cooking, or preserving food or additives to be served for the purpose of marketing; or to establish standards for the ingredients of food or additives to be served for the purpose of marketing, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

In addition, pursuant to stipulation in Article 18, Paragraph 1 of the Food Sanitation Act, and from the viewpoint of public health, the Minister of Health, Labour and Welfare is authorized to establish standards for the utensils, containers and packaging, or the raw materials thereof to be served for the purpose of marketing or to be used in business, or establish standards for the production methods thereof, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

Compositional standards for milk and milk products, food principally made from milk and milk products, and containers and packaging thereof are stipulated in the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc. (hereinafter referred to as "the Ministerial Ordinance on Milk, etc.") pursuant to stipulation in Article 11, Paragraph 1 and Article 18, Paragraph 1 of the Food Sanitation Act.

MHLW intends to amend the Ministerial Ordinance on Milk, etc. to establish specifications and standards for liquid infant formula based on the deliberation result of the special committee of the Pharmaceutical Affairs and Food Sanitation Council as follows.

Amendments

Specifications and standards for liquid infant formula are stipulated as follows.

1. Definition

In the Ministerial Ordinance on Milk, etc., "liquid infant formula" means the products which are obtained from product made by processing food made from raw milk, cow's milk or special-type cow's milk or made from them as principal raw materials, by adding the necessary nutrients for infants, and by reducing to liquid.

2. Standards of manufacturing

(a) Liquid infant formula shall be packed in preservation containers and sterilized by heating at 120°C for 4 minutes or using a method superior or equivalent to the former

method in pasteurization effect.

(b) Liquid infant formula shall be sterilized using a continuous heat sterilizer and be filled aseptically in pre-sterilized container and packaging. (The liquid infant formula shall be authorized as shelf-stable food by the Minister of Health, Labor and Welfare.)

3. Compositional standards

(a) Viable bacterial cells: Negative (the test methods shall conform to that for food packed in containers and sterilized by pressurization and heating.)

(b) Bacterial count: 0 (per 1 mL by standard plate count method after incubation for 14 days at $30 \pm 1^{\circ}C$ or 7 days at $55 \pm 1^{\circ}C$)

4. Standards of storage

Liquid infant formula shall be stored at temperature not exceeding room temperature.

5. Standards of containers and packaging

Same standards as that of milk drink stipulated in the Ministerial Ordinance on Milk, etc. are established.

6. Other standards

The following stipulation is established in the same way as formulated milk powder.

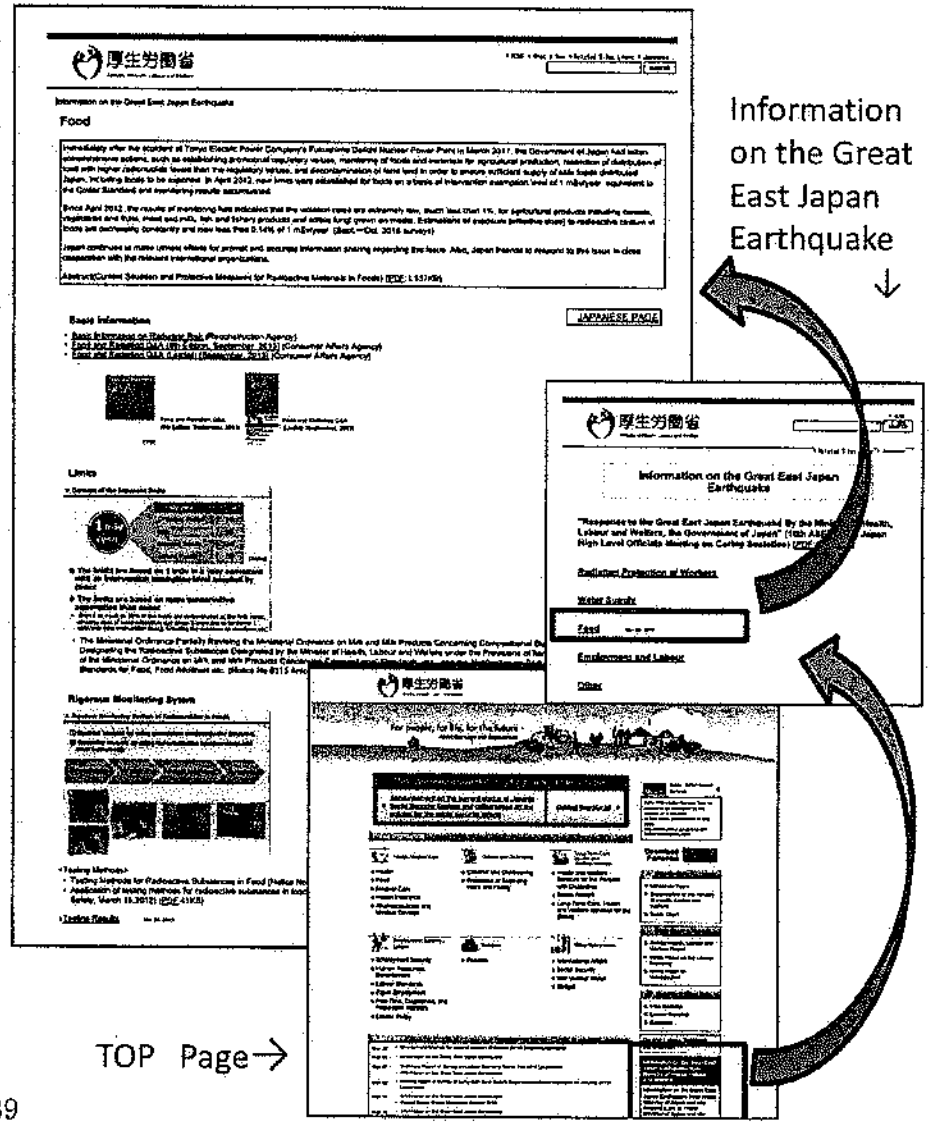
In liquid infant formula, nothing shall be used other than milk (excluding raw goat's milk, pasteurized goat's milk and raw sheep's milk), milk products or those that received the approval of the Minister of Health, Labour and Welfare for their types and mixing ratios.

Renewed English homepage regarding radioactive materials in foods

Information on the Great East Japan Earthquake (FOOD)

Disseminate relevant policy information of MHLW

- ◆The limits for radioactive materials in foods
- ◆Monitor radioactive materials in foods
  ※Timely update test results of radionuclide in foods
- ◆Recall and dispose of foods containing radioactive materials above the limits
  ※Timely update Press releases
- ◆Restrict the distribution of foods
- ◆Lift restrictions
- ◆Notifications

Information on the Great East Japan Earthquake (FOOD)

TOP>Information on the Great East Japan Earthquake>FOOD