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Voluntary - Public

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Report Highlights:

On Thursday, September 13, 2018, Japan's Ministry of Health, Labor and Welfare (MHLW) announced revisions to Japan's Maximum Residue Levels (MRLs) for the following agricultural chemicals and veterinary drugs: Simeconazole, Tebufenpyrad, Triflumizole, Pyriofenone, Fluazifop-butyl, Fluensulfone, Metaflumizone and Thymol. Further, MHLW proposes to designate Glucan extracted from brewing yeast as an exempted substance that does not require a MRL. Lastly, MHLW proposes to approve Argon, Isobutylamine, Isopropylamine, *sec*-Butylamine, Propylamine, Hexylamine, Pentylamine, and 2-Methylbutylamine as designated food additives. The Embassy comment period for these proposals is open until Thursday, September 27, 2018. MHLW will notify revisions with stricter standards to the World Trade Organization, which will provide another opportunity for interested parties to comment on these proposed changes.

Keyword: JA8068

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, September 27, 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 Simeconazole, Triflumizole, Pyriofenone, Fluensulfone, Metaflumizone and Thymol for which regulations will not be strengthened by this amendment.

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

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Item 1. Establishment of the Maximum Residue Limits for Agricultural and Veterinary Chemicals in 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 System¹ for agricultural and veterinary chemicals in food. All foods distributed in the Japanese marketplace are subject to regulation of the system.

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

Pesticides : Simeconazole, Tebufenpyrad, Triflumizole, Pyriofenone,

Fluazifop-butyl, Fluensulfone, Metaflumizone

Veterinary drugs : Thymol

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

Simeconazole (pesticide: fungicide): Permitted for use in Japan. The MHLW is going to establish MRL in one commodity in response to a request for setting MRL by the Ministry of Agriculture, Forestry and Fisheries (MAFF) with the intention to expand its use pattern. This action will not strengthen the current regulation for any commodities.

Tebufenpyrad (pesticide: insecticide/miticide): 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). The MHLW is also going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

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

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

Fluazifop-butyl (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.

Fluensulfone (pesticide: insecticide): 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.

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

Thymol (veterinary drug: ectoparasiticide): Not permitted for use in Japan. The Minister of Agriculture, Forestry and Fisheries asked the minister of Health, Labour and Welfare for comments about application for manufacture and sales approval as a veterinary drug, and modification of the application of this substance, under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics. In response to this, the MHLW is going to establish MRLs in some commodities. This action will not strengthen the current regulation for any commodities.

Simeconazole

Commodity	MRL (draft)	MRL (current)	Registration	Reference MRL	
				Codex	National ppm
Rice (brown rice)	○ 0.1	0.1	§		
Corn (maize, including pop corn and sweet)	○ 0.05		Request		
Soybeans, dry	○ 0.2	0.2	§		
Konjac	○ 0.1	0.1	§		
Cabbage	○ 0.05	0.05	§		
Burdock	○ 0.3	0.3	§		
Lettuce (including cos lettuce and leaf)	○ 0.7	0.7	§		
Welsh (including leek)	○ 0.2	0.2	§		
Garlic	○ 0.1	0.1	§		
Nira	○ 0.1	0.1	§		
Tomato	○ 0.2	0.2	§		
Other solanaceous vegetables	○ 2	2			2 Kor
Cucumber (including gherkin)	○ 0.3	0.3	§		
Pumpkin (including squash)	○ 0.2	0.2	§		
Water melon	○ 0.1	0.1	§		
Melons	○ 0.1	0.1	§		
Spinach	○ 0.1	0.1	§		
Ginger	○ 0.3	0.3	§		
Unshu orange, pulp	○ 0.1	0.1	§		
Citrus natsudaidai, whole	○ 0.3	0.3	§		
Lemon	○ 0.3	0.3	§		
Orange (including navel orange)	○ 0.3	0.3	§		
Grapefruit	○ 0.3	0.3	§		
Lime	○ 0.3	0.3	§		
Other citrus fruits	○ 0.3	0.3	§		
Apple	○ 0.5	0.5	§		
Japanese pear	○ 0.5	0.5	§		
Pear	○ 0.5	0.5	§		
Peach	○ 0.7	0.7	§		
Nectarine	○ 0.5	0.5	§		
Apricot	○ 1	1	§		
Japanese plum (including prune)	○ 0.2	0.2	§		
Mume plum	○ 1	1	§		
Cherry	○ 3	3	§		
Strawberry	○ 3	3	§		
Grape	○ 0.2	0.2	§		
Japanese persimmon	○ 0.2	0.2	§		
Tea	○ 10	10	§		
Other spices	○ 0.3	0.3	§		
Other herbs	○ 30	30	§		
Fish	○ 0.02	0.02			

The residue definition is simeconazole only.

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

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

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

§ : Permitted for use in Japan.

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

Tebufenpyrad

Com m	MRL (draft)	MRL (current)	Registration	Reference MRL		
				Codex	Natio nal	
Beans, dry	○ 0.2	0.2	§			
Peas	●	0.2				
Broad beans	●	0.2				
Peanuts, dry	●	0.2				
Other pulses	●	0.2				
Taro	○ 0.05		Request			
Tomato	○ 0.8	0.5	IT		0.8	EU
Pimiento (sweet pepper)	●	0.5				
Egg plant	○ 0.5	0.5	§			
Other solanaceous vegetables	●	0.5				
Cucumber (including gherkin)	○ 0.5	0.5	§		0.5	EU
Pumpkin (including squash)	●	0.5				
Oriental pickling melon (vegetable)	●	0.5				
Water melon	● 0.05	0.1	§			
Melons	● 0.05	0.1	§			
Makuwauri melon	●	0.1				
Other cucurbitaceous vegetables	●	0.5				
Other vegetables	○ 3	0.5	IT		5.0	Korea
Unshu orange, pulp	● 0.05	0.1	§			
Citrus natsudaidai, whole	● 0.7	1	§			
Lemon	○ 1	1	§			
Orange (including navel orange)	○ 1	1	§			
Grapefruit	○ 1	1	§			
Lime	○ 1	1	§			
Other citrus fruits	○ 1	1	§			
Apple	○ 1	0.5	§ - Requ			
Japanese pear	○ 0.5	0.5	§			
Pear	○ 0.5	0.5	§			
Quince	●	0.1				
Loquat	●	0.1				
Peach	● 0.03	0.5	§ - IT			
Nectarine	● 0.4	0.5	IT		0.4	EU
Apricot	● 0.4	2	IT		0.4	EU
Japanese plum (including prune)	● 0.2	2			0.2	EU
Mume plum	●	2				
Cherry	● 1	2	§			
Strawberry	○ 1	1	§			
Raspberry	● 0.2	2			0.15	EU
Blackberry	●	2				
Blueberry	●	2				
Cranberry	●	2				
Huckleberry	●	2				
Other berries	○ 2	2			1.5	EU
Grape	○ 0.5	0.5	§			
Japanese persimmon	● 0.3	0.5	§			
Banana	●	0.5				
Kiwifruit	●	0.1				
Papaya	○ 0.5	0.5	§			
Avocado	●	0.5				
Pineapple	●	0.5				
Guava	●	0.5				

Commodity	MRL (draft)	MRL (current)	Registration	Reference MRL		
				Code x	National	
Mango	● 0.2	0.5	§			
Passion fruit	●	0.5				
Date	●	2				
Other fruits	● 0.3	0.5	§			
Tea	○ 2	2	§			
Other spices	○ 5	1	§			
Other herbs	●	0.5				

The residue definition is tebufenpyrad only.

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

* Shaded figures indicate provisional MRLs.

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

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

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

§ : Permitted for use in Japan.

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

Triflumizole

Com m	MRL (draft)	MRL (current)	Registration	Reference MRL		
				Codex	National	
Rice (brown rice)	0.05	0.05	§			
Wheat	0.7	0.7	§			
Barley	0.7	0.7	§			
Rye	0.7	0.7	§			
Corn (maize, including pop corn and sweet)	0.5	0.5	§			
Other cereal grains	0.7	0.7	§			
Konjac	1	1	§			
Burdock	0.3	0.3	§			
Other composite vegetables	0.5	0.5	§			
Onion	0.2	0.2	§			
Welsh (including leek)	0.5	0.5	§			
Garlic	0.3	0.3	§			
Nira	3	3	§			
Asparagus	0.5	0.5	§			
Other liliaceous vegetables	2	2	§			
Carrot	0.5	0.5	§			
Parsley	1	1	§			
Celery	15	15	§			
Tomato	2	2	§			
Pimiento (sweet pepper)	3	3	§			
Egg plant	1	1	§			
Other solanaceous vegetables	1	1	§			
Cucumber (including gherkin)	0.7	0.7	§	0.5		
Pumpkin (including squash)	0.5	0.5	§			
Oriental pickling melon (vegetable)	0.3	0.3	§			
Water melon	0.2	0.2	§			
Melons	0.3	0.3	§			
Other cucurbitaceous vegetables	1	1	§			
Okra	0.5	0.5	§			
Ginger	0.5	0.5	§			
Peas, immature (with pods)	5	5	§			
Apple	0.7	0.7	§			
Japanese pear	1	1	§			
Pear	1	1	§			
Quince	2	2	§			
Peach	0.7	0.7	§			
Japanese plum (including prune)	1	1	§			
Mume plum	1	1	§			
Cherry ※1	3	3	§	4		
Strawberry	1	1	§			
Grape ※1	2	2	§	3		
Japanese persimmon	1	1	§			
Papaya ※1	1	1		2		
Pineapple ※2	2	2				
Mango	0.7	0.7	§			
Other fruits	1	0.7	§- Requ			
Tea	15	15	§			
Hop ※3	8	8		30	50	US
Other herbs	0.5	0.5	§			
Cattle, muscle	0.03	0.03		0.03		
Pig, muscle	0.03	0.03		0.03		

Commodity	MRL (draft)	MRL (current)	Registration	Reference MRL	
				Code x	National
Other terrestrial mammals, muscle	○ 0.03	0.03		0.03	
Cattle, fat	○ 0.03	0.03			
Pig, fat	○ 0.03	0.03			
Other terrestrial mammals, fat	○ 0.03	0.03			
Cattle, liver	○ 0.1	0.1		0.1	
Pig, liver	○ 0.1	0.1		0.1	
Other terrestrial mammals, liver	○ 0.1	0.1		0.1	
Cattle, kidney	○ 0.1	0.1		0.1	
Pig, kidney	○ 0.1	0.1		0.1	
Other terrestrial mammals, kidney	○ 0.1	0.1		0.1	
Cattle, edible offal	○ 0.1	0.1		0.1	
Pig, edible offal	○ 0.1	0.1		0.1	
Other terrestrial mammals, edible offal	○ 0.1	0.1		0.1	
Milk	○ 0.02	0.02		0.02	
Chicken, muscle	○ 0.02		Request		
Other poultry, muscle	○ 0.02		Request		
Chicken, fat	○ 0.02		Request		
Other poultry, fat	○ 0.02		Request		
Chicken, liver	○ 0.05		Request		
Other poultry, liver	○ 0.05		Request		
Chicken, kidney	○ 0.05		Request		
Other poultry, kidney	○ 0.05		Request		
Chicken, edible offal	○ 0.05		Request		
Other poultry, edible offal	○ 0.05		Request		
Chicken eggs	○ 0.02		Request		
Other poultry, eggs	○ 0.02		Request		
Fish	○ 0.3	0.3			

The residue definition for agricultural products is sum of triflumizole and metabolite FM-6-1 [(E)-4-Chloro- α,α,α -Trifluoro-*N*-(1-amino-2-propoxyethylidene)-*o*-toluidine], expressed as triflumizole. For animal products, the residue definition is sum of triflumizole and metabolites converted to FA-1-1 [4-Chloro- α,α,α -Trifluoro-*o*-toluidine] in basic condition, expressed as triflumizole. For aquatic products, triflumizole only.

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

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

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

§ : Permitted for use in Japan.

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

※1 The MRLs for cherries, papayas, and grapes are based on the Codex MRLs. Japan's MRLs are derived by multiplying the Codex MRLs by the corresponding factors (0.66 for cherries and papayas, 0.72 for grapes) which are calculated based on the plant metabolism studies because different residue definitions are used between Japan and Codex (The residue definition is residues analysed as FA-1-1 and expressed as parent triflumizole in Codex).

※2 The MRL for pineapple maintain the formal MRL set in before the positive list system because there was detected record.

※3 The MRL for hop is set based on the residue data from the supervised residue trials in which analysed residue definition in Japan.

Pyriofenone

Commodity	MRL (draft)	MRL (current)	Registration	Reference MRL		
				Codex	National	
Wheat	○ 1	1	§			
Tomato	○ 1		Request			
Pimiento (sweet pepper)	○ 1	1	§			
Egg plant	○ 1	1	§			
Cucumber (including gherkin)	○ 1	1	§			
Pumpkin (including squash)	○ 0.7	0.7	§			
Water melon	○ 0.05	0.05	§			
Melons	○ 0.2	0.2	§			
Other cucurbitaceous vegetables	○ 0.3		IT		0.30	USA
Peas, immature (with pods)	○ 2		Request			
Apple	○ 1	1	§			
Japanese pear	○ 1	1	§			
Strawberry	○ 2	2	§			
Raspberry	○ 0.9		IT		0.90	USA
Blackberry	○ 0.9		IT		0.90	USA
Blueberry	○ 2		IT		1.5	USA
Huckleberry	○ 2		IT		1.5	USA
Other berries	○ 2		IT		1.5	USA
Grape	○ 3	3	§			
Japanese persimmon	○ 0.7		Request			
Guava	○ 2		IT		1.5	USA
Passion fruit	○ 2		IT		1.5	USA
Other fruits	○ 2		IT		1.5	USA

The residue definition is pyriofenone only.

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

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

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

§ : Permitted for use in Japan.

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

Fluazifop-butyl

Com m	MRL (draft)	MRL (current)	Registration	Reference MRL [®]		
				Cod ex	Natio nal	
Soybeans, dry ※2	○ 3	3	§	15	2.5	USA
Beans, dry ※3	○ 47	5	§	40		
Peas ※3	○ 4	0.2		3		
Broad beans	○ 0.2	0.2			0.15	Canada
Peanuts, dry	○ 2	2			1.5	USA
Other pulses ※3	○ 47	0.1		40		
Potato ※3	○ 0.7	0.1	§	0.6		
Sweet potato	○ 0.05	0.05	§			
Yam	○ 0.05	0.05	§			
Sugar beet ※3	○ 0.6	0.2	§	0.5		
Sugarcane ※4				0.01		
Japanese radish, roots (including radish)	○ 0.2	0.2	§			
Japanese radish, leaves (including radish)	○ 0.2	0.2	§			
Turnip, roots (including rutabaga) ※3	○ 5			4		
Cabbage ※3	○ 4	2	§	3		
Broccoli	○ 1	1	§			
Lettuce (including cos lettuce and leaf)				0.01		
Onion ※2	○ 0.3	0.3	§	0.3		
Garlic ※2	○ 0.3	0.3	§	0.3		
Asparagus	○ 3	3	§		3.0	USA
Carrot	○ 1	1	§	0.6		
Other umbelliferous vegetables ※3	○ 0.5			0.4		
Tomato ※3	○ 0.5	0.05	§	0.4		
Egg plant ※3	○ 0.5			0.4		
Peas, immature (with pods) ※3	○ 2			2		
Kidney beans, immature (with pods) ※3	○ 7			6		
Green soybeans	○ 2	0.1	§- Requ			
Unshu orange, pulp	○ 0.05	0.05	§			
Citrus natsudaidai, whole	○ 0.05	0.05	§	0.01		
Lemon	○ 0.05	0.05	§	0.01		
Orange (including navel orange)	○ 0.05	0.05	§	0.01		
Grapefruit	○ 0.05	0.05	§	0.01		
Lime	○ 0.05	0.05	§	0.01		
Other citrus fruits	○ 0.05	0.05	§	0.01		
Apple ※4				0.01		
Japanese pear ※3	● 0.01	0.05		0.01		
Pear ※3	● 0.01	0.05		0.01		
Quince ※4				0.01		
Nectarine ※4				0.01		
Apricot ※4				0.01		
Japanese plum (including prune) ※4				0.01		
Cherry ※4				0.01		
Strawberry ※3	○ 0.4			0.3		
Other berries ※4				0.01		
Grape ※4				0.01		
Banana	○ 0.1	0.1		0.01		
Pineapple	○ 0.05	0.05				
Other Fruits ※4				0.01		
Sunflower seeds ※3	○ 8			7		
Cotton seeds ※3	○ 0.8			0.7		
Pecan ※4				0.01		
Almond ※4				0.01		

Commodity	MRL (draft)	MRL (current)	Registration	Reference MRL		
				Codex	National ppm	
Walnut ※4				0.01		
Other nuts ※4				0.01		
Coffee beans ※3	● 0.01	0.1		0.01		
Other spices	○ 0.3	0.3	§		0	Cana
Other herbs ※3	○ 0.4			0.3		
Cattle, muscle	○ 0.04	0.03				
Pig, muscle	○ 0.04	0.03				
Other terrestrial mammals, muscle	○ 0.04	0.03				
Cattle, fat ※3	○ 0.1	0.03		0.09		
Pig, fat ※3	○ 0.1	0.03		0.09		
Other terrestrial mammals, fat ※3	○ 0.1	0.03		0.09		
Cattle, liver ※3	○ 0.2	0.03		0.2		
Pig, liver ※3	○ 0.2	0.03		0.2		
Other terrestrial mammals, liver ※3	○ 0.2	0.03		0.2		
Cattle, kidney ※3	○ 0.2	0.03		0.2		
Pig, kidney ※3	○ 0.2	0.03		0.2		
Other terrestrial mammals, kidney ※3	○ 0.2	0.03		0.2		
Cattle, edible offal ※3	○ 0.2	0.03		0.2		
Pig, edible offal ※3	○ 0.2	0.03		0.2		
Other terrestrial mammals, edible offal ※3	○ 0.2	0.03		0.2		
Milk ※5	○ 0.03	0.03		0.2		
Chicken, muscle ※3	○ 0.04	0.02		0.03		
Other poultry, muscle ※3	○ 0.04	0.02		0.03		
Chicken, fat ※3	○ 0.04	0.02		0.03		
Other poultry, fat ※3	○ 0.04	0.02		0.03		
Chicken, liver ※3	○ 0.1	0.04		0.09		
Other poultry, liver ※3	○ 0.1	0.04		0.09		
Chicken, kidney ※3	○ 0.1	0.04		0.09		
Other poultry, kidney ※3	○ 0.1	0.04		0.09		
Chicken, edible offal ※3	○ 0.1	0.04		0.09		
Other poultry, edible offal ※3	○ 0.1	0.04		0.09		
Chicken eggs ※3	● 0.04	0.05		0.03		
Other poultry, eggs ※3	● 0.04	0.05		0.03		

The residue definition is sum of fluzifop-butyl and metabolite D【2-[4-(5-trifluoromethyl-2-pyridyloxy)phenoxy]propionic acid】(including metabolites that can be hydrolyzed to metabolite D), expressed as fluzifop-butyl. Fluzifop-butyl includes fluzifop-P-butyl and metabolite D includes metabolite E【(R)-2-[4-(5-trifluoromethyl-2-pyridyloxy)phenoxy]propionic acid】(including metabolites that can be hydrolyzed to metabolite E).

* 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.

※1 Reference MRLs are expressed as metabolite D or metabolite E.

※2 For soybeans, dry, onion and garlic in which Codex has set MRLs, the dietary exposure of fluzifop-butyl estimated by using the STMR of the supervised residue trials submitted to the JMPR and national food consumption data of these commodities would exceed an ADI of 0.0024 mg/kg bw/day which was set by the Food Safety Commission of Japan.

Therefore, the MHLW has decided to set the MRLs for these commodities based on the residue data from the USA or domestic supervised residue trials.

※3 Regarding food citing Codex MRL, MRL is set by multiplying Codex MRL by a conversion factor of 1.17 in order to take into account differences in residue definition.

※4 For sugarcane, lettuce (including cos lettuce and leaf lettuce), apple, quince, nectarine, apricot, japanese plum (including prune), cherry, other berries, grape, other fruits pecan, almond, walnut and other nuts in which Codex has set MRLs, the dietary exposure of fluazifop-butyl estimated by using the STMR of the supervised residue trials submitted to the JMPR and national food consumption data of these commodities would exceed an ADI of 0.0024 mg/kg bw/day which was set by the Food Safety Commission of Japan. Therefore, the MHLW has decided to maintain the current MRLs (i.e. the uniform limit of 0.01 ppm) in these commodities.

※5 For milk in which Codex has set MRL, the dietary exposure of fluazifop-butyl estimated by using the STMR of the supervised residue trials submitted to the JMPR and national food consumption data of milk would exceed an ADI of 0.0024 mg/kg bw/day which was set by the Food Safety Commission of Japan. Therefore, the MHLW has decided to set the MRL for milk based on the residue data estimated from the domestic maximum dietary burden (MDB).

Fluensulfone

Commo	MRL (draft)	MRL (current)	Registration	Reference MRL		
				Codex	National**	
Potato	0.8		IT	0.8	0.50	USA
Taro	3		IT	3		
Sweet potato	5	3	§	3		
Yam	3		IT	3		
Other potatoes	3		IT	3		
Japanese radish, roots (including radish)	4	3		4		
Japanese radish, leaves (including radish)	50	30		50		
Turnip, roots (including rutabaga)	4	3		4		
Turnip, leaves (including rutabaga)	30	30		10	30	USA
Horseradish	4	3		4		
Watercress	3	2		1	2.0	USA
Chinese cabbage	2	2		1	1.50	USA
Cabbage	2	2		1.5	1.50	USA
Brussels sprouts	2	2		1.5	1.50	USA
Kale	15	9		1	9.0	USA
Komatsuna(Japanese mustard spinach)	15	9		9	9.0	USA
Kyona	15	9		1	9.0	USA
Qing-geng-cai	15	9		1	9.0	USA
Cauliflower	2	2		1.5	1.50	USA
Broccoli	2	2		1.5	1.50	USA
Other cruciferous vegetables	15	9		1.5	9.0	USA
Burdock	3	3		3	3.0	USA
Salsify	3	3		3	3.0	USA
Endive	3	2		1	2.0	USA
Shungiku	3	2		1	2.0	USA
Lettuce (including cos lettuce and leaf)	3	2		2	2.0	USA
Other composite vegetables	30	30		30	30	USA
Carrot	4	3		4		
Parsnip	4	3		4		
Parsley	3	2			2.0	USA
Celery	3	2		2	2.0	USA
Other umbelliferous vegetables	30	30		4	30	USA
Tomato	1	0.7	§	0.7		
Pimiento (sweet pepper)	0.7	0.5	§	0.7		
Egg plant	0.7	0.3	§	0.7		
Other solanaceous vegetables	0.7	0.5		0.7		
Cucumber (including gherkin)	1	0.7	§	0.7		
Pumpkin (including squash)	2	1	§	0.7		
Water melon	0.2	0.1	§			
Melons	2	1	§			
Other cucurbitaceous vegetables	3	0.5		3		
Spinach	4	2		4		
Okra	0.7	0.5		0.7		
Ginger	0.8		IT		0.50	USA
Other vegetables	30	30		4	30	USA
Strawberry	0.5	0.3		0.5		
Blueberry	0.5	0.3		0.5		
Cranberry	0.5	0.3		0.5		
Other berries	0.5	0.3		0.5		
Other fruits	0.7	0.5		0.7		
Other spices	0.5		IT	0.5		

Commodity	MRL (draft)	MRL (current)	Registration	Reference MRL	
				Code x	National
Other herbs	○ 20	9		20	
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	

The residue definition for agricultural products is sum of fluensulfone and metabolite BSA【3,4,4-trifluorobut-3-ene-1-sulfonic acid】, expressed as fluensulfone. For animal products, fluensulfone only. The current residue definition is metabolite BSA【3,4,4-trifluorobut-3-ene-1-sulfonic acid】 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 should be noted that the residue definition will be changed.)

§ : Permitted for use in Japan.

IT: Import tolerance

※ USA MRLs are expressed as metabolite BSA.

Metaflumizone

Com m	MRL (draft)	MRL (current)	Registration	Reference MRL	
				Code x	Natio nal
Corn (maize, including pop corn and sweet	0.2	0.2	§		
Soybeans, dry	0.5	0.5	§		
Potato	0.02	0.02		0.02	
Taro	0.2	0.2	§		
Sweet potato	0.2	0.2	§		
Japanese radish, roots (including radish)	0.5	0.5	§		
Japanese radish, leaves (including radish)	30	30	§		
Turnip, roots (including rutabaga)	0.5		Request		
Turnip, leaves (including rutabaga)	30		Request		
Chinese cabbage	10	10	§	6	
Cabbage	5	5	§		
Brussels sprouts	0.8	0.8		0.8	
Kale	40	40	§		
Komatsuna (Japanese mustard spinach)	40	40	§		
Kyona	40	40	§		
Qing-geng-cai	10	10	§		
Broccoli	10	10	§		
Other cruciferous vegetables	40	40	§		
Burdock	0.2	0.2	§		
Lettuce (including cos lettuce and leaf	50	50	§	7	
Welsh (including leek)	10	10	§		
Asparagus	0.7	0.7	§		
Carrot	0.3	0.3	§		
Tomato	5	5	§	0.6	
Pimiento (sweet pepper)	5	5	§	0.6	
Egg plant	3	3	§	0.6	
Other solanaceous vegetables	0.6	0.6		0.6	
Spinach	70	70	§		
Ginger	0.3	0.3	§		
Green soybeans	10	10	§		
Unshu orange, pulp	0.3		Request		
Citrus natsudaidai, whole	5		Request		
Lemon	5		Request		
Orange (including navel orange)	5		Request		
Grapefruit	5		Request		
Lime	5		Request		
Other citrus fruits	5		Request		
Mume plum	10	10	§		
Strawberry	0.2	0.2	§		
Kiwifruit	0.3		Request		
Other spices	25		Request		
Other herbs	40	40	§		
Cattle, muscle	0.02	0.02		0.02	
Pig, muscle	0.02	0.02		0.02	
Other terrestrial mammals, muscle	0.02	0.02		0.02	
Cattle, fat	0.02	0.02			
Pig, fat	0.02	0.02			
Other terrestrial mammals, fat	0.02	0.02			
Cattle, liver	0.02	0.02		0.02	
Pig, liver	0.02	0.02		0.02	
Other terrestrial mammals, liver	0.02	0.02		0.02	

Commodity	MRL (draft)	MRL (current)	Registration	Reference MRL		
				Code x	National	
Cattle, kidney	○ 0.02	0.02		0.02		
Pig, kidney	○ 0.02	0.02		0.02		
Other terrestrial mammals, kidney	○ 0.02	0.02		0.02		
Cattle, edible offal	○ 0.02	0.02		0.02		
Pig, edible offal	○ 0.02	0.02		0.02		
Other terrestrial mammals, edible offal	○ 0.02	0.02		0.02		
Milk	○ 0.01	0.01		0.01		
Fish	○ 2	2				
Pepper,dried ※				6		

The residue definition for agricultural products is sum of *E* and *Z* isomers of metaflumizone and metabolite D【p-[m-(trifluoromethyl)phenacyl]benzotrile】, expressed as metaflumizone. For animal and aquatic products, the residue definition is sum of *E* and *Z* isomers of metaflumizone.

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

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

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

§ : Permitted for use in Japan.

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

※ For food category “Pepper,dried”, MRL will not be set, and hereafter, MRL in its raw commodity (i.e. other solanaceous vegetables) will also apply to such processed commodity, taking into account its processing factor. For this substance, JMPR estimated processing factor of 10 for pepper,dried.

Thymol

Commodity	MRL (draft)	MRL (current)	Registration	Reference MRL	
				Code x	National
Honey	o		Request		

The residue definition is thymol 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.

* 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.

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:

Pesticide : Glucan extracted from brewing yeast

Summary

Glucan extracted from brewing yeast (pesticide: 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. The FSC concluded that glucan extracted from brewing yeast 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 glucan extracted from brewing yeast as an exempt substance.

Item 3. Designation of Food Additives

Summary

The Food Sanitation Act (hereinafter referred to as “the Act”), in Article 10, prohibits the use and sale of the food additives that the Minister of Health, Labour and Welfare (hereinafter referred to as “the Minister”) has not designated. In addition, when specifications and standards for food additives are established pursuant to Article 11 of the Act and the Standards and Regulations of Foods, Food Additives, etc. (Ministry of Health and Welfare Notification No. 370, 1959), those additives shall not be used or sold unless they meet the standards and the specifications.

1. Argon

In August 2, 2018, the Committee on Food Additives of the Pharmaceutical Affairs and Food Sanitation Council deliberated on Argon, and concluded that the Minister should designate Argon as a food additive that is unlikely to harm human health pursuant to Article 10 of the Act and should establish specifications and standards for the additive pursuant to Article 11 of the Act (See Attachment 3-1).

Situations in other countries and Japan:

The Codex Alimentarius Commission listed Argon in the inventory of processing aids as a packaging gas in 1991, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established the specifications in 1999.

The United States has classified Argon as a GRAS (Generally Recognized as Safe) substance and has permitted to use it in fruit juice, vegetable juice, and wine. The European Union (EU) has permitted to use it in basically all food products. The Scientific Committee on Food (SCF) also permitted to use Argon as a packaging gas and propellant, and concluded that there is no need to set acceptable daily intake for Argon in 1990.

In Japan, Argon has not been designated as a food additive at the present.

2. Isobutylamine, Isopropylamine, *sec*-Butylamine, Propylamine, Hexylamine, Pentylamine and 2-Methylbutylamine

In August 2, 2018, the Committee on Food Additives of the Pharmaceutical Affairs and Food Sanitation Council deliberated on Isobutylamine, Isopropylamine, *sec*-Butylamine, Propylamine, Hexylamine, Pentylamine and 2-Methylbutylamine (hereinafter referred to as “the requested flavorings”), and concluded that the Minister should designate the requested flavorings as food additives that are unlikely to harm human health pursuant to Article 10 of the Act and should establish specifications and standards for the additives pursuant to Article 11 of the Act (See Attachment 3-2).

Situations in other countries and Japan:

JECFA and the European Food Safety Authority have evaluated some flavorings including the requested flavorings as a group of aliphatic and aromatic amines and amides. Among these amines, the Food Safety Commission of Japan (FSCJ) evaluated Isopentylamine in 2009 and Butylamine in 2010 on aliphatic primary amines; and Phenethylamine, Trimethylamine, Piperidine and Pyrrolidine in 2010 on the amines other than aliphatic primary ones. FSCJ has concluded that these amines are unlikely to harm human health when used as flavoring enhancers.

The EU, the United States, Australia, and New Zealand have permitted to use the requested flavorings as food additives, and have not established standards for use such as concentrations. In the United States, the requested flavorings are used in processed foods including baked goods, icings, snack foods, cheese, milk products, and dried fruit.

In Japan, the requested flavorings have not been permitted to use at the present.

Additional Information

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

As of September 13, 2018, all flavorings and 41 non-flavoring additives are designated. See Attachment 3-3 for the details.

Argon

Standards for use (draft)

Not specified Compositional

Specifications (draft)

Argon

アルゴン

Argon gas

Ar

Mol. Wt. 39.95

Argon [7440-37-1]

Definition Argon is a substance produced using the air liquefaction separation method.

Content Argon contains not less than 99.0% (vol) of argon (Ar).

Description Argon is a colorless gas having no odor.

Identification

- (1) When a burning wood chip with a flame is placed in a test tube containing Argon, the flame goes off.
- (2) Introduce Argon into a 1-mL gas measuring tube for gas chromatography, and analyze it by gas chromatography using the operation conditions given in Purity (ii) below. The retention time of the main peak corresponds to that of the main peak obtained when the reagent argon is analyzed in the same manner.

Purity Oxygen and Nitrogen Not more than 1.0% (vol) as the total amount.

(i) Oxygen

Measure oxygen in Argon using a yellow phosphor luminescent oxygen analyzer and determine the amount (% (vol)). If the amount of oxygen obtained exceeds the measurement range of the meter, exactly dilute the sample gas with oxygen-free nitrogen, and determine the amount.

(ii) Nitrogen

Introduce Argon into a 1-mL gas measuring tube for gas chromatography at constant flow rate of 50–150 mL/min, analyze it using the operating conditions below, and obtain the peak area (A_T) of nitrogen. Separately, prepare a constant amount of a uniform gas mixture with the nitrogen concentration of about 0.5% (vol) by mixing a constant amount of nitrogen, measured exactly, with the carrier gas given below. Use this as the standard gas mixture. Introduce the standard gas mixture into a gas measuring tube with same amount at the same flow rate, proceed as directed for Argon, and obtain the peak area (A_S) of nitrogen in the gas mixture. Determine the amount (% (vol)) of nitrogen in Argon by the formula:

$$\text{Amount (\% (vol)) of nitrogen (N}_2\text{)} = V_S \times \frac{A_T}{A_S}$$

V_S : Amount (% (vol)) of nitrogen in the standard gas mixture

Operating Conditions

Detector: Thermal conductivity detector

Column: A stainless steel tube (about 3 mm internal diameter and about 3 m length)

Column packing material: 180–250 μm zeolite for gas chromatography

Column temperature: A constant temperature of 50–150°C

Carrier gas: Hydrogen or helium

Flow rate: A constant rate of 20–40 mL/min Injection:

Loop injection using a gas measuring tube

(iii) Total amount

Determine the total amount of oxygen and nitrogen from the amount (% (vol)) of oxygen obtained in (i) and the amount (% (vol)) of nitrogen obtained in (ii) by the formula:

Total amount (% (vol)) of oxygen and nitrogen (% (vol)) = $V_O + V_N$

V_O : Amount (% (vol)) of oxygen obtained in (i)

V_N : Amount (% (vol)) of nitrogen obtained in (ii)

Water content Not more than 0.05% (vol)

Measure using capacitance moisture meter and determine the amount (% (vol)) of the water content from the obtained value.

Assay Calculate the content of Argon from the total amount of oxygen and nitrogen, and water content obtained in Purity (iii) by the formula:

Content of argon (% (vol)) = $100 - V_{O\ N} - V_W$

$V_{O\ N}$: Total amount (% (vol)) of oxygen and nitrogen

V_W : Amount (% (vol)) of water content

Reagent and Test Solutions Argon Ar [K1105, Second grade] [7440-37-1]

Measurement instruments

Yellow phosphor luminescent oxygen analyzer

Use a unit meeting with the performance of the yellow phosphor luminescent oxygen analyzer specified in Japanese Industrial Standards K1105.

Capacitance moisture meter

Use a unit meeting with the performance of the capacitance moisture meter specified in Japanese Industrial Standards K1105.

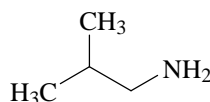
Isobutylamine

Standard for use (draft)

Only for flavoring Compositional

Specifications (draft)

Isobutylamine イソブチルアミン



C₄H₁₁N

Mol. Wt. 73.14

2-Methylpropan-1-amine [78-81-9]

Content Isobutylamine contains not less than 95.0% of isobutylamine (C₄H₁₁N).

Description Isobutylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of Isobutylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

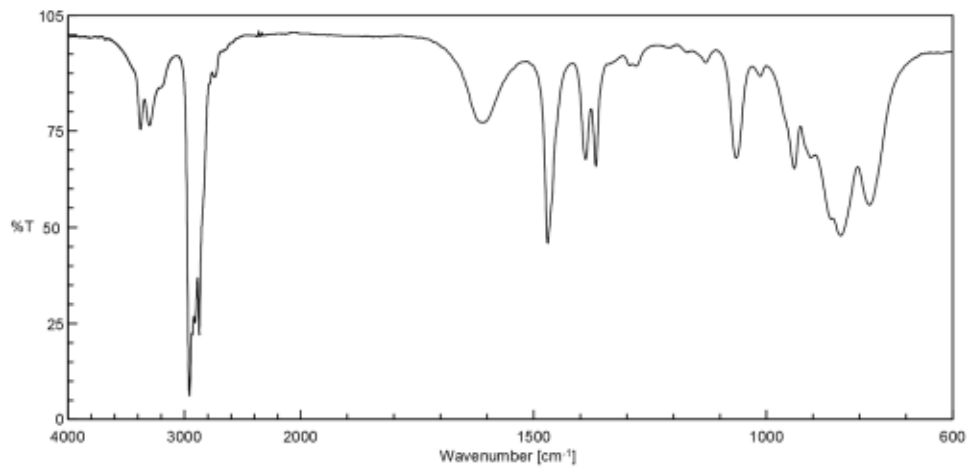
Refractive Index n_D^{20} : 1.391–1.400

Specific Gravity d_4^{25} : 0.724–0.737

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum

Isobutylamine



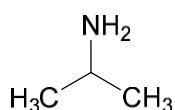
Isopropylamine

Standard for use (draft)

Only for flavoring Compositional

Specifications (draft)

Isopropylamine イソプロピルアミン



C₃H₉N

Mol. Wt. 59.11

Propan-2-amine [75-31-0]

Content Isopropylamine contains not less than 95.0% of isopropylamine (C₃H₉N).

Description Isopropylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.

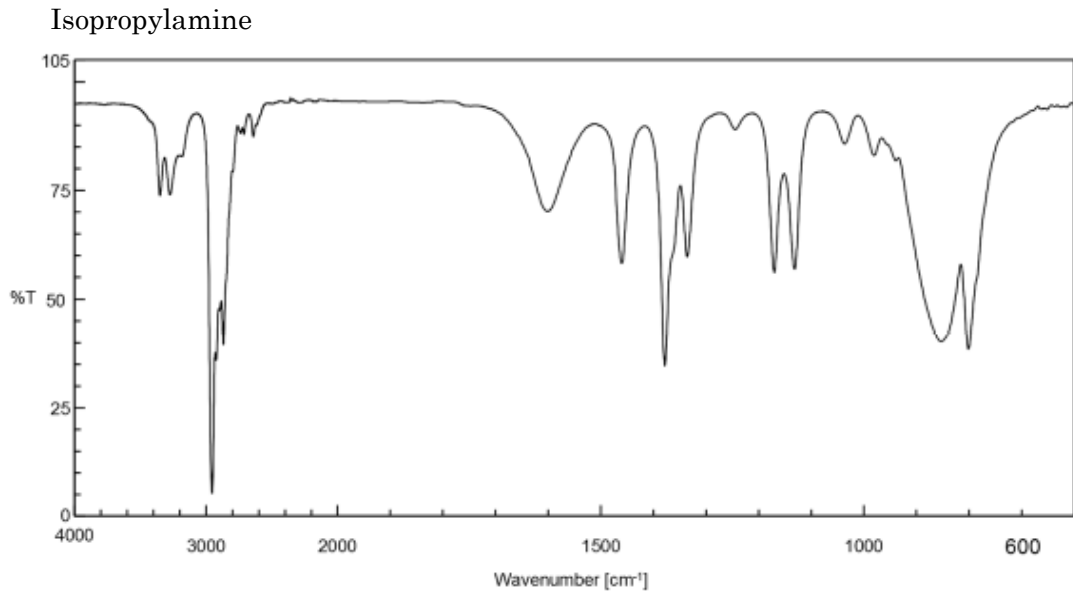
Identification Determine the infrared absorption spectrum of Isopropylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

Refractive index n_D^{20} : 1.367–1.378 **Specific**

Gravity d_4^{25} : 0.681–0.693

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum



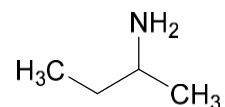
sec-Butylamine

Standard for use (draft)

Only for flavoring Compositional

Specifications (draft)

sec-Butylamine
sec-ブチルアミン



C₄H₁₁N

Mol. Wt. 73.14

Butan-2-amine [13952-84-6]

Content *sec*-Butylamine contains not less than 95.0% of *sec*-butylamine (C₄H₁₁N).

Description *sec*-Butylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of *sec*-Butylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

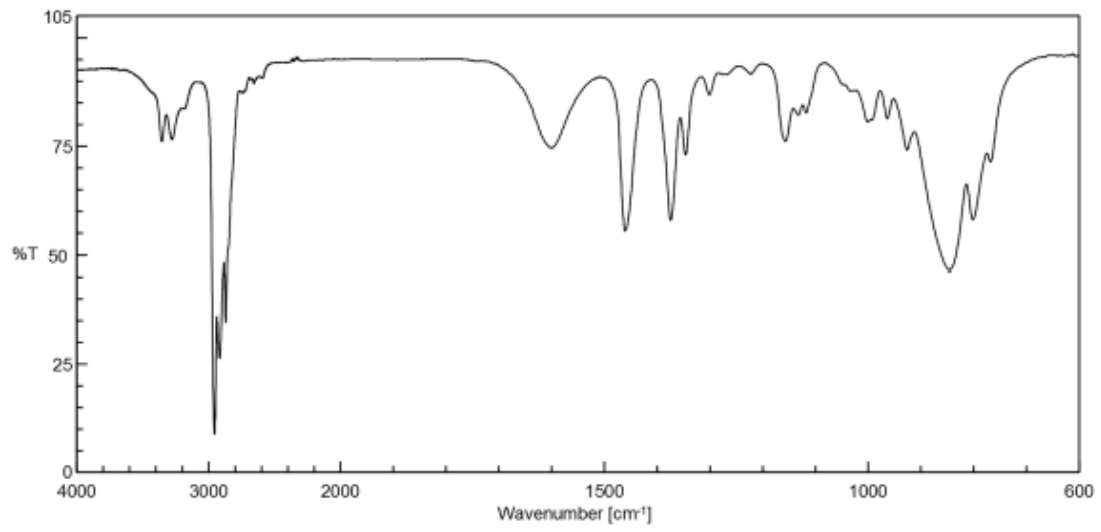
Refractive Index n_D^{20} : 1.387–1.396

Specific Gravity d_4^{25} : 0.715–0.724

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum

sec-Butylamine



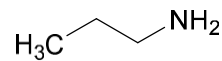
Propylamine

Standard for use (draft)

Only for flavoring Compositional

Specifications (draft)

Propylamine
プロピルアミン



C₃H₉N

Mol. Wt. 59.11

Propan-1-amine [107-10-8]

Content Propylamine contains not less than 95.0% of propylamine (C₃H₉N).

Description Propylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of Propylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

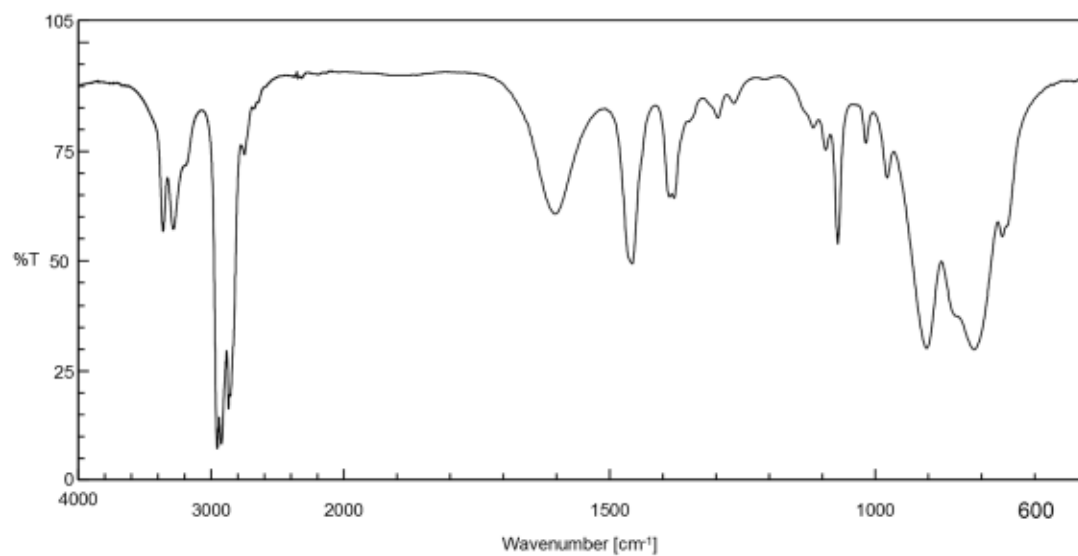
Refractive Index n_D^{20} : 1.384–1.392

Specific Gravity d_4^{25} : 0.710–0.720

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum

Propylamine



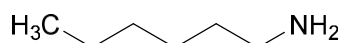
Hexylamine

Standard for use (draft)

Only for flavoring Compositional

Specifications (draft)

Hexylamine
ヘキシルアミン



C₆H₁₅N

Mol. Wt. 101.19

Hexan-1-amine [111-26-2]

Content Hexylamine contains not less than 95.0% of hexylamine (C₆H₁₅N).

Description Hexylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of Hexylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

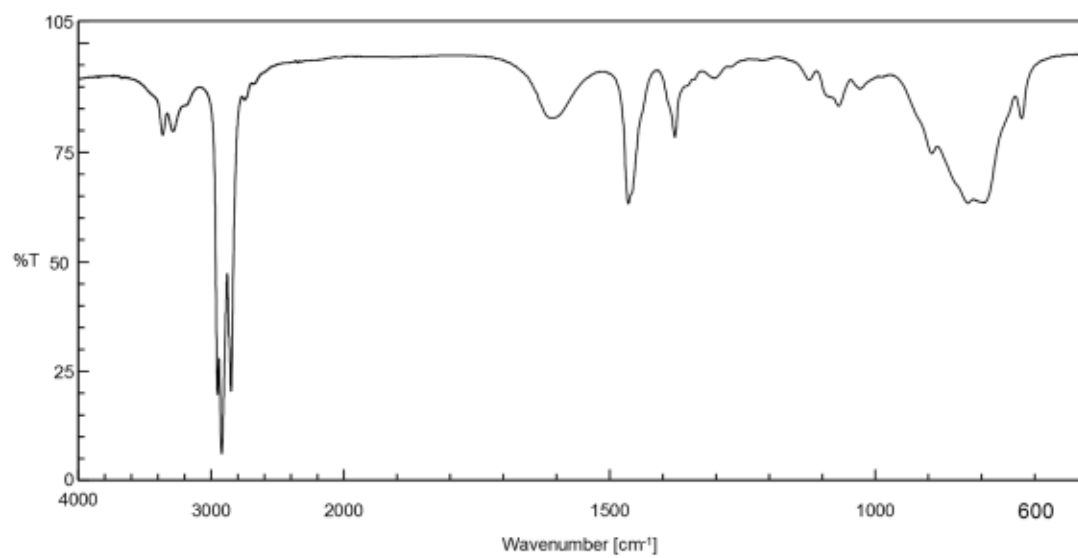
Refractive Index n_D^{20} : 1.415–1.421

Specific Gravity d_4^{25} : 0.761–0.767

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum

Hexylamine



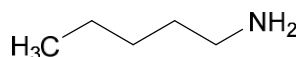
Pentylamine

Standard for use (draft)

Only for flavoring Compositional

Specifications (draft)

Pentylamine
ペンチルアミン



$C_5H_{13}N$

Mol. Wt. 87.16

Pentan-1-amine [110-58-7]

Content Pentylamine contains not less than 95.0% of pentylamine ($C_5H_{13}N$).

Description Pentylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of Pentylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

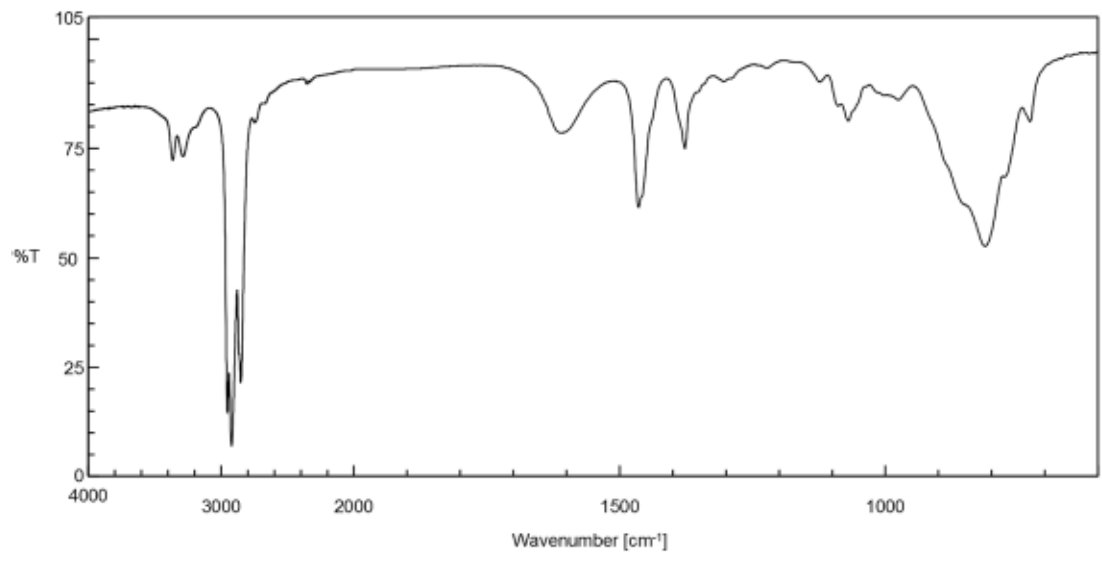
Refractive Index n_D^{20} : 1.408–1.424

Specific Gravity d_4^{25} : 0.750–0.759

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum

Pentylamine



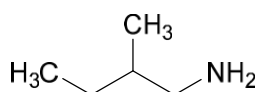
2-Methylbutylamine

Standard for use (draft)

Only for flavoring Compositional

Specifications (draft)

2-Methylbutylamine
2-メチルブチルアミン



C₅H₁₃N

Mol. Wt. 87.16

2-Methylbutan-1-amine [96-15-1]

Content 2-Methylbutylamine contains not less than 95.0% of 2-methylbutylamine (C₅H₁₃N).

Description 2-Methylbutylamine occurs as a colorless to yellow, clear liquid having a characteristic odor.

Identification Determine the infrared absorption spectrum of 2-Methylbutylamine as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit similar intensities of absorption at the same wavenumbers.

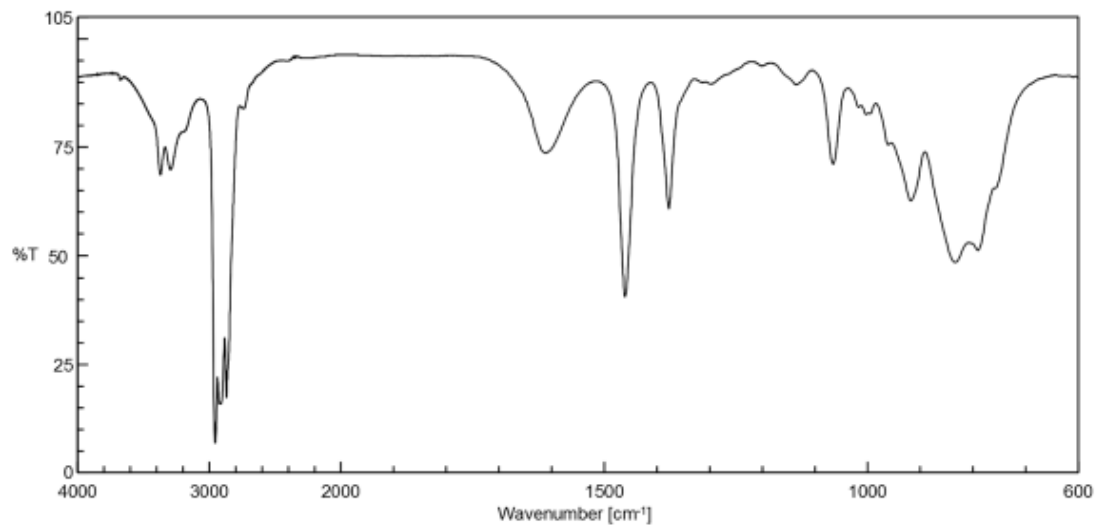
Refractive Index n_D^{20} : 1.408–1.423

Specific Gravity d_4^{25} : 0.752–0.779

Assay Proceed as directed in the Peak Area Percentage Method in the Gas Chromatographic Assay of Flavoring Agents under the Flavoring Substances Tests. Use operating conditions (2) except for the column. Use a fused silica tube (0.25–0.53 mm in internal diameter and 30–60 m in length) coated with a 0.25–1 μm thick layer of dimethylpolysiloxane for gas chromatography.

Reference Spectrum

2-Methylbutylamine



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

13
September,
2018

Substance name	Request for evaluation	Food Safety		MHLW		
		Evaluation by expert committee ¹	Notification of result ²	Discussion by subcommittee ³	Closing date for comments ⁴	Date of designation as
Isobutanol 2-Ethyl-3, (5 or 6)- 2,3,5,6-	21 Nov 2003	24 Mar	27 May	23 Apr 2004(fin.)	19 Aug 2004	24 Dec 2004
		3 Mar	27 May	8 Apr 2004(fin.)	26 Jul 2004	24 Dec 2004
		3 Mar	27 May	8 Apr 2004(fin.)	26 Jul 2004	24 Dec 2004
Calcium stearate	4 Mar 2004	20 May	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	9 Sep 2004	26 Aug 2004(fin.)	14 Dec 2004	24 Feb 2005
Nitrous oxide	20 Oct 2003	17 Dec 2003 5 Oct	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	9 Dec 2004	28 Oct 2004(fin.)	4 Mar 2005	28 Apr 2005
Hydroxypropyl cellulose	16 Aug	22 Dec	10 Mar 2005	24 Feb 2005(fin.)	14 Jun 2005	19 Aug 2005
Isoamylalcohol 2,3,5- 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	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	21 Jul 2005	23 Jun 2005(fin.)	12 Oct 2005	16 May 2006
2-Ethyl-3- 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	28 Mar 2005	2 Dec 2005	30 Mar	23 Mar 2006(fin.)	5 Sep 2006	26 Dec 2006

Calcium alginate		14 Dec	2006			
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Substance name	Request for evaluation	Food Safety		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	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	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	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	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	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	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	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		MHLW		
		Evaluation by expert committee ¹	Notification of result ²	Discussion by subcommittee ³	Closing date for comments ⁴	Date of designation as
Acetylated distarch	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
Acetylated distarch						
Acetylated oxidized						
Starch sodium						
Hydroxypropyl starch						
Hydroxypropyl distarch						
Phosphated distarch						
Monostarch phosphate						
Distarch phosphate						
Oxidized starch						
Starch acetate						
Magnesium hydroxide	9 Mar 2006	22 Jun 2007 30 Jul 2007 27 Aug	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	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	30 Jul 2013	21 Jun 2013 30 Oct 2013 29 Jan 2014(fin.)	—	18 Jun 2014

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

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

Substance name	Request for evaluation	Food Safety		MHLW		
		Evaluation by expert committee ¹	Notification of result ²	Discussion by subcommittee ³	Closing date for ⁴	Date of designation as
5-Ethyl-2-methylpyridine	14 Jun	29 Jun	26 Aug	9 Sep 2010(fin)	3 Jan 2011	15 Mar
2-(3-Phenylpropyl)pyridine	9 Jul 2010	27 Jul	7 Oct 2010	22 Dec 2010(fin)	1 Apr 2011	28 Jun
2,3-Diethyl-5-methylpyrazine	9 Jul 2010	27 Jul	7 Oct 2010	22 Dec 2010(fin)	1 Apr 2011	28 Jun
5-methyl-6,7-Dihydro-5 <i>H</i> -cyclopentapyrazine	12 Aug 2010	31 Aug 2010(fin)	27 Jan 2011	22 Dec 2010(fin)	1 Apr 2011	28 Jun 2011
Pyrazine	12 Aug	31 Aug	4 Jan 2011	9 Feb 2011(fin)	24 May 2011	19 Jul
3-Methyl-2-butenal	9 Sep	27 Sep	27 Jan	9 Feb 2011(fin)	24 May 2011	19 Jul
<i>trans</i> -2-Pentenal	29 Oct 2010	12 Nov 2010 21 Dec 2010	1 Dec 2011	6 Mar 2012(fin)	22 Jul 2012	2 Nov 2012
Isoquinolin	29 Oct	12 Nov	3 Feb 2011	11 May 2011(fin)	8 Aug 2011	27 Dec
2-Ethyl-6-methylpyrazine	6 Dec	21 Dec	31 Mar	2 Nov 2011 (fin)	19 Mar 2012	28 Dec
<i>trans</i> -2-Methyl-2-butenal	4 Jan	18 Jan	21 Apr	2 Nov 2011 (fin)	19 Mar 2012	28 Dec
Pyrrole	4 Jan	18 Jan	31 Mar	11 May 2011(fin)	8 Aug 2011	27 Dec
(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	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	25 Nov 2013	27 Nov 2013	–	18 Jun 2014
Carmine	19 Apr 2011	26 Jul 2011 23 Aug 2011 30 May 2012 (under				

Substance name	Request for evaluation	Food Safety		MHLW		
		Evaluation by expert committee ¹	Notification of result ²	Discussion by subcommittee ³	Closing date for comments ⁴	Date of designation as
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	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				
Calcium acetate	19 Apr 2011	24 Apr 2012 15 Nov 2012 18 Dec 2012 22 Jan	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	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	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	17 Feb 2015	25 Dec 2014	3 Mar 2015	19 May 2015

Substance name	Request for evaluation	Food Safety		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	29 Mar 2012	31 May 2013	8 Oct 2013	4 Dec 2013
	16 May	—	27 May			
2,3-Diethylpyrazine	12 Feb 2014	13 Mar 2014 22 May	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