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Japan 220th Food Safety Group

Report Categories:
Sanitary/Phytosanitary/Food Safety

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Report Highlights:
On March 15, 2019, Japan's Ministry of Health, Labor and Welfare (MHLW) announced revisions to Japan's Maximum Residue Levels (MRLs) for the following agricultural chemicals, veterinary drugs and feed additives: Cyanophos, Tetradifon, Tetraniliprole, Picoxystrobin, Bifenazate, Neomycin, Fluralaner, and Tylosin. In addition, MHLW proposed the revision of analytical methods for Chlorpromazine. Furthermore, MHLW proposes a new designation of Dimethyl dicarbonate as a food additive as well as revision of specifications for the following food additives; Isomaltodextranase, Japanese persimmon color, Enju extract and dl-a-Tocopherol. Lastly, MHLW proposes withdrawal of 10 food additives from Japan's list of existing food additives. The embassy comment period for these proposals is open until March 29, 2019. MHLW will then notify these revisions to the World Trade Organization (WTO), which will provide another opportunity for interested parties to comment.

Keyword: JA9029

General Information:

FAS/Tokyo has included below the 220th Food Safety Group report, without revision, except as necessary to meet the format of this report.

THE 220th 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 ：Friday, March 15, 2019（10:00－12:00）

Place：Ministry of Health, Labour and Welfare Temporary Meeting Room No. 3
1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo

Agenda：

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

Pesticides：Cyanophos , Tetradifon , Tetraniliprole , Picoxystrobin , Bifenazate

Veterinary drugs：Neomycin, Fluralaner

Veterinary drugs and Feed additives：Tylosin

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

Chlorpromazine

Item 3. Designation of a food additive and revision of specifications for food additives

Designation: Dimethyl dicarbonate

Revision of specifications: Isomaltodextranase, Japanese persimmon color, Enju extract, and dl-α-Tocopherol

<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 **Friday, March 29, 2019**. After the given date, comments should be directed to the enquiry point in accordance with the WTO/SPS Agreement.

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

<Contact person>

Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare
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Pesticides/Veterinary drugs (Item 1)
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Food Additives (Items 3&4)
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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 : Cyanophos , Tetradifon , Tetraniliprole , Picoxystrobin , Bifenazate

Veterinary drugs : Neomycin, Fluralaner

Veterinary drugs and Feed additives : Tylosin

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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

Cyanophos (pesticide: insecticide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities 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. The MHLW is also going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System

Tetradifon (pesticide: acaricide): 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.

Tetraniliprole (pesticide: insecticide): Not permitted for use in Japan. The MHLW is going to establish MRLs in some commodities and for also fish, 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.

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

Bifenazate (pesticide: acaricide): 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 MAFF with the intention to expand its use pattern.

Neomycin (Veterinary drug: antibiotic): 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.

Fluralaner (Veterinary drug: ectoparasiticide): 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.

Tylosin (Veterinary drug and Feed additive: antibiotic): Permitted for use in Japan.The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF. This action will not strengthen the current regulation for any commodities.

Cyanophos

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Soybeans, dry	○ 0.1	0.1	§			
Beans, dry	○ 0.1	0.1	§			
Peas	●	0.1				
Broad beans	●	0.1				
Peanuts, dry	●	0.1				
Other pulses	●	0.1				
Japanese radish, roots (including radish)	○ 0.05	0.05	§			
Japanese radish, leaves (including radish)	● 0.03	0.05	§			
Turnip, roots (including rutabaga)	● 0.01	0.05	§			
Turnip, leaves (including rutabaga)	● 0.02	0.05	§			
Horseradish	●	0.05				
Watercress	●	0.05				
Chinese cabbage	○ 0.05	0.05	§			
Cabbage	● 0.02	0.05	§			
Brussels sprouts	●	0.05				
Kale	●	0.05				
Komatsuna (Japanese mustard spinach)	●	0.05				
Kyona	●	0.05				
Qing-geng-cai	●	0.05				
Cauliflower	●	0.05				
Broccoli	●	0.05				
Other cruciferous vegetables	●	0.05				
Burdock	●	0.05				
Salsify	●	0.05				
Artichoke	●	0.05				
Chicory	●	0.05				
Endive	●	0.05				
Shungiku	●	0.05				
Lettuce (including cos lettuce and leaf lettuce)	●	0.05				
Other composite vegetables	●	0.05				
Onion	○ 0.05	0.05	§			
Welsh (including leek)	● 0.03	0.05	§			
Garlic	●	0.05				
Nira	●	0.05				
Asparagus	●	0.05				
Multiplying onion (including shallot)	●	0.05				
Other liliaceous vegetables	●	0.05				
Carrot	●	0.05				
Parsnip	●	0.05				
Parsley	●	0.05				
Celery	●	0.05				
Mitsuba	●	0.05				
Other umbelliferous vegetables	●	0.05				
Tomato	●	0.05				
Pimiento (sweet pepper)	●	0.05				
Egg plant	○ 0.05	0.05	§			
Other solanaceous vegetables	●	0.05				
Cucumber (including gherkin)	● 0.01	0.05	§			
Pumpkin (including squash)	●	0.05				
Oriental pickling melon (vegetable)	●	0.05				
Water melon	●	0.2				

Commodity	MRL (draft) ppm		MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Melons	●		0.2				
Makuwauri melon	●		0.2				
Other cucurbitaceous vegetables	●		0.05				
Spinach	●		0.05				
Bamboo shoots	●		0.05				
Okra	●		0.05				
Ginger	●		0.05				
Peas, immature (with pods)	●		0.05				
Kidney beans, immature (with pods)	●		0.05				
Green soybeans	●		0.05				
Button mushroom	●		0.05				
Shiitake mushroom	●		0.05				
Other mushrooms	●		0.05				
Other vegetables	●		0.05				
Unshu orange, pulp	●		0.2	§			
Unshu orange(whole commodity.)	○	3		§			
Citrus natsudaidai, whole	●		0.2				
Lemon	●		0.2				
Orange (including navel orange)	●		0.2				
Grapefruit	●		0.2				
Lime	●		0.2				
Other citrus fruits	●		0.2				
Apple	○	0.5	0.2	§・Request			
Japanese pear	●	0.1	0.2	§			
Pear	●	0.1	0.2	§			
Quince	○	0.2	0.2	§			
Loquat	●		0.2				
Peach	●		0.2	§			
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems.)	○	0.3		§			
Nectarine	●	0.1	0.2	§			
Apricot	●		0.2				
Japanese plum (including prune)	●	0.05	0.2	§			
Mume plum	●		0.2				
Cherry	○	0.2	0.2	§			
Strawberry	●		0.2				
Raspberry	●		0.2				
Blackberry	●		0.2				
Blueberry	●	0.1	0.2	§			
Cranberry	●		0.2				
Huckleberry	●		0.2				
Other berries	●		0.2				
Grape	●	0.1	0.2	§			
Japanese persimmon	●	0.05	0.2	§			
Banana	●		0.2				
Kiwifruit	●		0.2				
Papaya	●		0.2				
Avocado	●		0.2				
Pineapple	●		0.2				
Guava	●		0.2				
Mango	●		0.2				
Passion fruit	●		0.2				

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Date	●	0.2				
Other fruits	●	0.2				
Sunflower seeds	●	0.2				
Sesame seeds	●	0.2				
Safflower seeds	●	0.2				
Cotton seeds	●	0.2				
Rapeseeds	●	0.2				
Other oil seeds	●	0.2				
Ginkgo nut	●	0.2				
Chestnut	●	0.2				
Pecan	●	0.2				
Almond	●	0.2				
Walnut	●	0.2				
Other nuts	●	0.2				
Other spices	○ 15	0.2	§			
Other herbs	●	0.05				

The residue definition is cyanophos 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.

* 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, incresed or newly set.

§ : Permitted for use in Japan.

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

Tetradifon

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Corn (maize, including pop corn and sweet corn)	●	5				
Soybeans, dry	●	5				
Beans, dry	●	5				
Peas	●	5				
Broad beans	●	5				
Other pulses	●	5				
Potato	●	5				
Taro	●	5				
Sweet potato	●	5				
Japanese yam (including Chinese yam)	●	5				
Konjac	●	5				
Other potatoes	●	5				
Sugar beet	●	5				
Japanese radish, roots (including radish)	●	1				
Japanese radish, leaves (including radish)	●	1				
Turnip, roots (including rutabaga)	●	1				
Turnip, leaves (including rutabaga)	●	1				
Horseradish	●	1				
Watercress	●	1				
Chinese cabbage	●	1				
Cabbage	●	1				
Brussels sprouts	●	1				
Kale	●	1				
Komatsuna (Japanese mustard spinach)	●	1				
Kyona	●	1				
Qing-geng-cai	●	1				
Cauliflower	●	1				
Broccoli	●	1				
Other cruciferous vegetables	●	1				
Burdock	●	1				
Salsify	●	1				
Artichoke	●	1				
Chicory	●	1				
Endive	●	1				
Shungiku	●	1				
Lettuce (including cos lettuce and leaf lettuce)	●	1				
Other composite vegetables	●	1				
Onion	●	1				
Welsh (including leek)	●	1				
Garlic	●	1				
Nira	●	1				
Asparagus	●	1				
Multiplying onion (including shallot)	●	1				
Other liliaceous vegetables	●	1				
Carrot	●	1				
Parsnip	●	1				
Parsley	●	1				
Celery	●	1				
Mitsuba	●	1				
Other umbelliferous vegetables	●	1				
Tomato	●	1				

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Pimiento (sweet pepper)	●	1				
Egg plant	○ 1	1	§			
Other solanaceous vegetables	●	1				
Cucumber (including gherkin)	● 0.5	1	§			
Pumpkin (including squash)	●	1				
Oriental pickling melon (vegetable)	●	1				
Water melon	●	1	§			
Water melon(whole commodity after removal of stems.)	○ 0.3		§			
Melons	●	1	§			
Melons(whole commodity after removal of stems.)	○ 2		§			
Makuwauri melon	●	1				
Other cucurbitaceous vegetables	●	1				
Spinach	●	1				
Bamboo shoots	●	1				
Okra	●	1				
Ginger	●	1				
Peas, immature (with pods)	●	1				
Kidney beans, immature (with pods)	●	1				
Green soybeans	●	1				
Button mushroom	●	1				
Shiitake mushroom	●	1				
Other mushrooms	●	1				
Other vegetables	●	1				
Unshu orange, pulp	●	3	§			
Unshu orange(whole commodity.)	○ 2		§			
Citrus natsudaidai, whole	● 2	3	§			
Lemon	● 2	3	§			
Orange (including navel orange)	● 2	3	§			
Grapefruit	● 2	3	§			
Lime	● 2	3	§			
Other citrus fruits	● 2	3	§			
Apple	○ 1	1	§			
Japanese pear	○ 1	1	§			
Pear	○ 1	1	§			
Quince	●	1				
Loquat	●	1				
Peach	●	1				
Nectarine	●	1				
Apricot	●	1				
Japanese plum (including prune)	●	1				
Mume plum	●	1				
Cherry	●	1				
Strawberry	● 0.7	1	§			
Raspberry	●	1				
Blackberry	●	1				
Blueberry	●	1				
Cranberry	●	1				
Huckleberry	●	1				
Other berries	●	1				
Grape	●	1				
Japanese persimmon	●	1				

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Banana	●		1				
Kiwifruit	●		1				
Papaya	●		1				
Avocado	●		1				
Pineapple	●		5				
Guava	●		1				
Mango	●		1				
Passion fruit	●		1				
Date	●		1				
Other fruits	●		1				
Sunflower seeds	●		1				
Sesame seeds	●		1				
Safflower seeds	●		1				
Cotton seeds	●		1				
Rapeseeds	●		1				
Other oil seeds	●		1				
Ginkgo nut	●		1				
Chestnut	●		1				
Pecan	●		1				
Almond	●		1				
Walnut	●		1				
Other nuts	●		1				
Tea	●	0.7	1	§			
Hop	●		60				
Other spices	○	10	5	§			
Speamint	●		100				
Peppermint	●		100				
Other herbs(except speamint and peppermint)	●		1				

The residue definition is tetradifon 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.

* 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.

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§ : Permitted for use in Japan.

Tetraniliprole

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Rice (brown rice)	○	0.01		Request			
Corn (maize, including pop corn and sweet corn)	○	0.05		Request			
Soybeans, dry	○	0.2		Request			
Taro	○	0.05		Request			
Chinese cabbage	○	3		Request			
Cabbage	○	2		Request			
Kale	○	15		Request			
Komatsuna (Japanese mustard spinach)	○	15		Request			
Kyona	○	10		Request			
Qing-geng-cai	○	5		Request			
Broccoli	○	10		Request			
Other cruciferous vegetables	○	15		Request			
Lettuce (including cos lettuce and leaf lettuce)	○	20		Request			
Welsh (including leek)	○	2		Request			
Tomato	○	2		Request			
Pimiento (sweet pepper)	○	2		Request			
Egg plant	○	0.7		Request			
Cucumber (including gherkin)	○	0.5		Request			
Water melon(whole commodity after removal of stems.)	○	0.3		Request			
Melons(whole commodity after removal of stems.)	○	0.5		Request			
Green soybeans	○	2		Request			
Apple	○	1		Request			
Japanese pear	○	0.5		Request			
Pear	○	0.5		Request			
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems.)	○	1		Request			
Apricot	○	1		Request			
Japanese plum (including prune)	○	0.1		Request			
Mume plum	○	1		Request			
Cherry	○	1		Request			
Strawberry	○	2		Request			
Grape	○	2		Request			
Japanese persimmon	○	0.5		Request			
Tea	○	50		Request			
Other herbs	○	15		Request			
Fish	○	0.05		Request			

The residue definition is tetraniliprole only.

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

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

Picoxystrobin

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Wheat	○	0.04	0.04		0.04		
Barley	○	0.3	0.3		0.3		
Rye	○	0.04	0.04		0.04		
Corn (maize, including pop corn and sweet corn)	○	0.04	0.04		0.02	0.04	USA
Buckwheat	○	0.04	0.04			0.04	USA
Other cereal grains	○	0.3	0.04		0.3		
Soybeans, dry	○	0.06	0.05		0.06		
Beans, dry	○	0.2	0.06	Request	0.06		
Peas	○	0.06	0.06		0.06		
Broad beans	○	0.06	0.06		0.06		
Other pulses	○	0.06	0.06		0.06		
Japanese yam (including Chinese yam)	○	0.05		Request			
Japanese radish, roots (including radish)	○	0.1		Request			
Japanese radish, leaves (including radish)	○	15		Request			
Turnip, roots (including rutabaga)	○	0.5		Request			
Turnip, leaves (including rutabaga)	○	40		Request			
Chinese cabbage	○	2	2	§			
Cabbage	○	1	1	§			
Broccoli	○	5		Request			
Lettuce (including cos lettuce and leaf lettuce)	○	15	15	§			
Onion	○	0.05	0.05	§			
Welsh (including leek)	○	2	2	§			
Garlic	○	0.05		Request			
Nira	○	15		Request			
Asparagus	○	0.3		Request			
Carrot	○	0.5		Request			
Other vegetables	○	0.08	0.08			0.08	USA
Unshu orange, pulp	●		0.1	§			
Unshu orange(whole commodity.)	○	2		§			
Citrus natsudaidai, whole	○	3	3	§			
Lemon	○	3	3	§			
Orange (including navel orange)	○	3	3	§			
Grapefruit	○	3	3	§			
Lime	○	3	3	§			
Other citrus fruits	○	3	3	§			
Apple	○	2	2	§			
Japanese pear	○	1	1	§			
Pear	○	1	1	§			
Peach	●		0.3	§			
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems.)	○	5		§			
Cherry	○	5	5	§			
Sesame seeds	○	0.08	0.08			0.08	USA
Rapeseeds	○	0.08	0.08			0.08	USA
Other oil seeds	○	0.08	0.08			0.08	USA
Other spices	○	10	10	§			
Cattle, muscle	○	0.02			0.02		
Pig, muscle	○	0.02			0.02		
Other terrestrial mammals, muscle	○	0.02			0.02		
Cattle, fat	○	0.02			0.02		
Pig, fat	○	0.02			0.02		
Other terrestrial mammals, fat	○	0.02			0.02		

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Cattle, liver	○ 0.02			0.02		
Pig, liver	○ 0.02			0.02		
Other terrestrial mammals, liver	○ 0.02			0.02		
Cattle, kidney	○ 0.02			0.02		
Pig, kidney	○ 0.02			0.02		
Other terrestrial mammals, kidney	○ 0.02			0.02		
Cattle, edible offal	○ 0.02			0.02		
Pig, edible offal	○ 0.02			0.02		
Other terrestrial mammals, edible offal	○ 0.02			0.02		
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		
Wheat germ	○ 0.2			0.15		
Wheat bran	○ 0.2			0.15		
Corn oil	●			0.15		
Soybean oil	○ 0.2			0.2		

The residue definition is picoxystrobin 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.

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

※1 Food categories “Corn oil” will be deleted, and hereafter, MRLs in their raw commodities (i.e. corn) will also apply to such processed commodities, respectively, taking into account their processing factors. For this substance, JMPR estimated processing factors of 6.9 for Corn.

Bifenazate

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Soybeans, dry	○ 0.3	0.3		0.3	
Beans, dry	○ 0.3	0.3		0.3	
Broad beans	○ 0.3	0.3		0.3	
Other pulses	○ 0.3	0.3		0.3	
Potato	○ 0.05	0.05			
Taro	○ 0.05	0.05	§		
Sweet potato	○ 0.05	0.05	§		
Japanese yam (including Chinese yam)	○ 0.05	0.05	§		
Asparagus	○ 0.5		Request		
Tomato	○ 1	1	§	0.5	
Pimiento (sweet pepper)	○ 2	2	§	2	
Egg plant	○ 2	2	§		
Other solanaceous vegetables	○ 3	3	§	3	
Cucumber (including gherkin)	● 0.5	0.8	§	0.5	
Pumpkin (including squash)	● 0.5	0.7		0.5	
Oriental pickling melon (vegetable)	● 0.5	0.8		0.5	
Water melon	●	0.3	§		
Water melon(whole commodity after removal of stems.)	○ 0.5		§	0.5	
Melons	●	0.3	§		
Melons(whole commodity after removal of stems.)	○ 0.7		§	0.5	
Makuwauri melon	●	0.8			
Makuwauri melon(whole commodity after removal of stems.)	○ 0.5			0.5	
Other cucurbitaceous vegetables	○ 0.5	0.5		0.5	
Okra	○ 2	2			
Peas, immature (with pods)	○ 7	7		7	
Kidney beans, immature (with pods)	○ 7	7		7	
Green soybeans	○ 7	7		7	
Other vegetables	○ 7	7		7	
Unshu orange, pulp	●	0.2	§		
Unshu orange(whole commodity.)	○ 2		§		
Citrus natsudaidai, whole	○ 0.7	0.7	§		
Lemon	○ 0.7	0.7	§		
Orange (including navel orange)	○ 0.7	0.7	§		
Grapefruit	○ 0.7	0.7	§		
Lime	○ 0.7	0.7	§		
Other citrus fruits	○ 0.7	0.7	§		
Apple	○ 2	2	§	0.7	
Japanese pear	○ 2	2	§	0.7	
Pear	○ 2	2	§	0.7	
Quince	● 0.7	1		0.7	
Loquat	●	1			
Loquat(whole commodity after removal of stems.)	○ 0.7			0.7	
Peach	●	2	§		
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems.)	○ 5		§	2	
Nectarine	○ 2	2	§	2	
Apricot	○ 3	3	§	2	
Japanese plum (including prune)	○ 2	2	§	2	
Mume plum	○ 3	3	§	2	
Cherry	○ 2	2	§	2	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Strawberry	○ 5	5	§	2		
Raspberry	○ 7	7		7		
Blackberry	○ 7	7		7		
Other berries	○ 7	7		7		
Grape	○ 3	3	§	0.7		
Japanese persimmon	○ 1	1	§	0.7		
Mango	○ 0.2	0.2	§			
Other fruits	○ 2	2	§	0.7		
Cotton seeds	● 0.3	1		0.3		
Ginkgo nut	○ 0.2	0.2		0.2		
Chestnut	○ 0.2	0.2		0.2		
Pecan	○ 0.2	0.2		0.2		
Almond	○ 0.2	0.2		0.2		
Walnut	○ 0.2	0.2		0.2		
Other nuts	○ 0.2	0.2		0.2		
Tea	○ 2	2	§			
Hop	○ 20	20		20		
Other spices	○ 10	10	§			
Other herbs	○ 40	40	§	40		
Cattle, muscle	○ 0.01	0.01				
Pig, muscle	○ 0.01	0.01				
Other terrestrial mammals, muscle	○ 0.01	0.01				
Cattle, fat	○ 0.05	0.05		0.05		
Pig, fat	○ 0.05	0.05		0.05		
Other terrestrial mammals, fat	○ 0.05	0.05		0.05		
Cattle, liver	○ 0.01	0.01		0.01		
Pig, liver	○ 0.01	0.01		0.01		
Other terrestrial mammals, liver	○ 0.01	0.01		0.01		
Cattle, kidney	○ 0.01	0.01		0.01		
Pig, kidney	○ 0.01	0.01		0.01		
Other terrestrial mammals, kidney	○ 0.01	0.01		0.01		
Cattle, edible offal	○ 0.01	0.01		0.01		
Pig, edible offal	○ 0.01	0.01		0.01		
Other terrestrial mammals, edible offal	○ 0.01	0.01		0.01		
Milk	○ 0.01	0.01		0.01		
Chicken, muscle	○ 0.01	0.01				
Other poultry, muscle	○ 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		
Raisin※	●	10		2		

The residue definition is sum of bifenazate and metabolite B【isopropyl（4-methoxybiphenyl-3-yl）diazenylformate】, expressed as bifenazate.

* 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.

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

※ Food category "Raisin" will be deleted,and hereafter, MRLs in its raw commodity (i.e. Grape) will also apply to such processed commodity, taking into account its processing factor. For this substance, JMPR estimated processing factor of 3.2 for Raisin

Neomycin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Cattle, muscle	○ 0.5	0.5	§	0.5		
Pig, muscle	○ 0.5	0.5	§	0.5		
Sheep, muscle	●	0.5				
Goat, muscle	●	0.5				
Other terrestrial mammals, muscle(except sheep and goat)	●	0.5				
Other terrestrial mammals, muscle	○ 0.5			0.5		
Cattle, fat	○ 0.5	0.5	§	0.5		
Pig, fat	○ 0.5	0.5	§	0.5		
Sheep, fat	●	0.5				
Goat, fat	●	0.5				
	●	0.5				
Other terrestrial mammals, fat	○ 0.5			0.5		
Cattle, liver	○ 0.5	0.5	§	0.5		
Pig, liver	○ 0.5	0.5	§	0.5		
Sheep, liver	●	0.5				
Goat, liver	●	0.5				
Other terrestrial mammals, fat(except sheep and goat)	●	0.5				
Other terrestrial mammals, liver	○ 0.5			0.5		
Cattle, kidney	○ 10	10.0	§	10		
Pig, kidney	○ 10	10.0	§	10		
Sheep, kidney	●	10.0				
Goat, kidney	●	10.0				
Other terrestrial mammals, kidney(except sheep and goat)	●	5				
Other terrestrial mammals, kidney	○ 10			10		
Cattle, edible offal	○ 10	0.5	§			
Pig, edible offal	○ 10	0.5	§			
Other terrestrial mammals, edible offal	○ 10	0.5				
Milk	○ 2	0.5	§	1.5		
Chicken, muscle	○ 0.5	0.5	§	0.5		
Duck, muscle	●	0.5				
Turkey, muscle	●	0.5				
Other poultry, muscle(except duck and turkey)	●	0.5				
Other poultry, muscle	○ 0.5			0.5		
Chicken, fat	○ 0.5	0.5	§	0.5		
Duck, fat	●	0.5				
Turkey, fat	●	0.5				
Other poultry, fat(except duck and turkey)	●	0.5				
Other poultry, fat	○ 0.5			0.5		
Chicken, liver	○ 0.5	0.5	§	0.5		
Duck, liver	●	0.5				
Turkey, liver	●	0.5				
Other poultry, liver(except duck and turkey)	●	0.5				
Other poultry, liver	○ 0.5			0.5		
Chicken, kidney	○ 10	10.0	§	10		
Duck, kidney	●	10.0				
Turkey, kidney	●	10.0				
Other poultry, kidney(except duck and turkey)	●	8				
Other poultry, kidney	○ 10			10		
Chicken, edible offal	○ 10	0.5	§			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
				Codex ppm	National ppm	
Other poultry, edible offal	○ 10	0.5				
Chicken eggs	○ 0.5	0.5		0.5		
Other poultry, eggs	○ 0.5	0.5				
Salmoniformes (such as salmon and trout)	●	0.5				
Anguilliformes (such as eel)	●	0.5				
Perciformes (such as bonito, horse mackerel, mackerel, sea bass, sea bream and tuna)	●	0.5				
Other fish	●	0.5				
Shelled molluscs	●	0.5				
Crustaceans	●	0.5				
Other aquatic animals	●	0.5				

The residue definition is neomycinB.

* The compound shall not be included in any commodity for which the MRL is not given in the above table and in any commodity 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, incresed or newly set.

§: Permitted for use in Japan.

Fluralaner

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Chicken, muscle	○	0.07		IT		0.065	EU
Chicken, fat	○	0.7		IT		0.65	EU
Chicken, liver	○	0.7		IT		0.65	EU
Chicken, kidney	○	0.4		IT		0.42	EU
Chicken, edible offal	○	0.7		IT			
Chicken eggs	○	1		IT		1.3	EU

The residue definition is fluralaner 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, incresed or newly set.

IT : Import tolerance

Tylosin

Commodity		MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL		
					Codex ppm	National ppm	
Cattle, muscle	○	0.1	0.1	§	0.1		
Pig, muscle	○	0.1	0.1	§	0.1		
Other terrestrial mammals, muscle	○	0.1	0.1		0.1		
Cattle, fat	○	0.1	0.1	§	0.1		
Pig, fat	○	0.1	0.1	§	0.1		
Other terrestrial mammals, fat	○	0.1	0.1				
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	§			
Pig, edible offal	○	0.1	0.1	§			
Other terrestrial mammals, edible offal	○	0.1	0.1				
Milk	○	0.1	0.1	§	0.1		
Chicken, muscle	○	0.1	0.1	§	0.1		
Chicken, fat	○	0.1	0.1	§	0.1		
Chicken, liver	○	0.1	0.1	§	0.1		
Chicken, kidney	○	0.1	0.1	§	0.1		
Chicken, edible offal	○	0.1	0.1	§			
Chicken eggs	○	0.3	0.3		0.3		
Honey (including royal-jelly)	○	0.7	0.2	§・Request			

The residue definition for honey is sum of tylosin A and tylosin B expressed as tylosin A. For other foods is tylosin A only.

* The compound shall not be included in any commodity for which the MRL is not given in the above table and in any commodity 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, incresed or newly set.

§ : Permitted for use in Japan.

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 and white beans.

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

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

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

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

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

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

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

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

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

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

“Other citrus fruits” refers to all citrus fruits, except *unshu* orange (pulp), citrus *natsudaidai* (pulp), citrus *natsudaidai* (peel), citrus *natsudaidai* (whole), lemon, orange (including navel orange), grapefruit, lime, and spices.

“Other berries” refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.

“Other fruits” refers to all fruits, except citrus fruits, apple, Japanese pear, pear, quince, loquat, peach, nectarine, apricot, Japanese plum (including prune), mume plum, cherry, berries, grape, Japanese persimmon, banana, kiwifruit, papaya, avocado, pineapple, guava, mango, passion fruit, date and spices.

“Other oil seeds” refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.

“Other nuts” refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.

“Other spices” refers to all spices, except horseradish, *wasabi* (Japanese horseradish) rhizomes, garlic, peppers chili, paprika, ginger, lemon peels, orange peels (including navel orange), *yuzu* (Chinese citron) peels and sesame seeds.

“Other herbs” refers to all herbs, except watercress, *nira*, parsley stems and leaves, celery stems and leaves.

“Edible offal” refers to all edible parts, except muscle, fat, liver, and kidney.

“Other terrestrial mammals” refers to all terrestrial mammals, except cattle and pig.

“Other poultry animals” refers to all poultry, except chicken.

“Other fish” refers to all fish, except salmoniformes, anguilliformes, and perciformes.

“Other aquatic animals” refers to all aquatic animal, except fish, shelled molluscs and crustaceans.

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

Notification (draft) Analytical Method for Chlorpromazine (Target to Animal and Fishery Products)

The target compound to be determined is chlorpromazine.

1. Instrument

Liquid chromatograph-tandem mass spectrometer (LC-MS/MS)

2. Reagents

Use the reagents listed in Section C ***Reagents/Test Solutions, Etc.***, Part II ***Food Additives***, except the following.

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

Sulfonate-modified methacrylate copolymer cartridge (1,000 mg): A polyethylene tube of 20-21 mm in inside diameter packed with 1,000 mg of sulfonate-modified methacrylate copolymer, or a cartridge equivalent to the specified one in separation capability.

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

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

3. Reference standard

Reference standard of chlorpromazine hydrochloride: Contains not less than 98% of chlorpromazine hydrochloride.

4. Procedure

a. Extraction

For muscle, fat, liver, kidney, milk, egg and fish/shellfish, weigh 10.0 g of sample.

For honey, weigh 10.0 g of sample and dissolve the sample with 10 g of water.

Add 50 mL of acetone to the sample, homogenize, centrifuge at 3,000 rpm for 5 minutes, and collect the supernatant. Add 30 mL of acetone to the residue, homogenize, and centrifuge

as described above. Collect the supernatant, combine the resulting supernatants, and add acetone to make exactly 100 mL. Take exactly a 10 mL aliquot of the solution, add 3 mL of water and 130 μL of formic acid for except fat, 1 mL of water and 110 μL of formic acid for fat.

b. Clean-up

Add 10 mL each of methanol and acetone/formic acid/water (10:0.13:3, v/v/v) for except fat, add 10 mL each of methanol and acetone/formic acid/water (10:0.11:1, v/v/v) for fat, to a sulfonate-modified methacrylate copolymer cartridge (1,000 mg) sequentially, and discard the effluents. Transfer the solution obtained in "a. Extraction" to the cartridge, and discard the effluent. Add 20 mL each of formic acid/methanol (1:99, v/v), methanol and acetone to the cartridge sequentially, and discard the effluent. Elute with 15 mL of acetone/ammonia solution (19:1, v/v), concentrate the eluate to about 1 mL at below 40ºC. Add 0.1 vol% formic acid/0.1 vol% formic acid-acetonitrile solution (3:2, v/v) to make exactly 5 mL, and use this solution as the test solution.

5. Measurement

a. Calibration curve

Prepare chlorpromazine standard solutions (0.1 vol% formic acid/0.1 vol% formic acid-acetonitrile solution (3:2, v/v)) of several concentrations. Inject each standard solution to LC-MS/MS, and make a calibration curve by peak-height or peak-area method. When the test solution is prepared following “4. Procedure”, the sample containing 0.0001 mg/kg of chlorpromazine gives the test solution of 0.00002 mg/L in concentration.

b. Quantification

Inject the test solution to LC-MS/MS, and calculate the concentration of chlorpromazine from the calibration curve made in "a. Calibration curve".

c. Confirmation

Confirm using LC-MS/MS.

d. Measurement conditions

(Example)

Column: Octadecylsilanized silica gel, 2.1 mm in inside diameter, 150 mm in length and 3 μm in particle diameter

Column temperature: 40°C

Mobile phase: 0.1 vol% formic acid/0.1 vol% formic acid-acetonitrile solution (3:2, v/v)

Ionization mode: ESI (+)

Major monitoring ions (*m/z*): Precursor ion 319, product ion 86, 58

Injection volume: 5 µL
Expected retention time: 4 min

6. Limit of Quantification

0.0001 mg/kg

Item 3. Designation of A Food Additive, and Establishment and Revision of Specifications for Food Additives

The government of Japan will designate Dimethyl dicarbonate as a food additive; establish the compositional specifications for two existing food additives (Isomaltodextranase and Japanese persimmon color); and revise the existing compositional specifications for Enju extract and *dl*-α-Tocopherol.

Summary

The Food Sanitation Act (Act No. 233 of 1947; hereinafter referred to as "the Act"), in Article 10, prohibits the use and the sale of the food additives the Minister of Health, Labour and Welfare (hereinafter referred to as "the Minister") does not designate. In addition, when specifications or standards for food additives are stipulated in the Ministry of Health and Welfare Notification (Notification No. 370, 1959) pursuant to Article 11 of the Act, those additives shall not be used or sold unless they meet the standards or the specifications.

1. Dimethyl dicarbonate

On February 27, 2019, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council (hereinafter referred to as "the Committee") deliberated on Dimethyl dicarbonate, and concluded that the Minister should designate Dimethyl dicarbonate as a food additive that is unlikely to harm human health pursuant to Article 10 of the Act and should establish the specifications and the standards for the additive pursuant to Article 11 of the Act (See Attachment 3-1 for the details).

Situations in other countries

Dimethyl dicarbonate is used as a sterilizing agent. It is listed in the General Standard for Food Additives (GSFA) and permitted for use in beverages as preservatives unless it is not detected in final products. It is also included in the list of processing aids that was prepared by the Codex Alimentarius Commission as a microbial controlling agent. In 1990, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated this additive as allowed to be used to pasteurize beverages with a concentration of not more than 250 mg/kg if it meets Good Manufacturing Practice.

The United States permitted the use of Dimethyl dicarbonate to inactivate wine yeasts in 1988 and expanded the scope of use to other beverages thereafter.

The European Union (EU) permitted the use of this additive in nonalcoholic

beverages (flavored beverages, concentrated tea beverages, and nonalcoholic wines) as preservatives in 1995 and expanded the scope of use to other beverages thereafter. The European Food Safety Authority (EFSA) has evaluated Dimethyl dicarbonate as allowed to be used with a concentration of not more than 250 mg/L as a preservative.

Australia and New Zealand permitted the use in nonalcoholic beverages in 1996 and in wines in 2004 as preservatives. In 2011, they determined to reclassify Dimethyl dicarbonate as processing aids, which had been classified as preservatives.

2. Isomaltodextranase, Japanese persimmon color, Enju extract, and *dl*-α-Tocopherol

On February 27, 2019, the Committee deliberated on Isomaltodextranase, Japanese persimmon color, Enju extract, and *dl*-α-Tocopherol. The Committee concluded that the Minister should establish the specifications for Isomaltodextranase and Japanese persimmon color, and revise the specifications of Enju extract and *dl*-α-Tocopherol pursuant to Article 11 of the Act (See Attachment 3-2 for the details).

Additional Information

Progress in the designation procedure of food additives (54 flavorings and 42 non-flavoring additives) that have been proven safe by JECFA and that are widely used in countries other than Japan.

As of March 13, 2019, all flavorings and 41 non-flavoring additives are designated (See Attachment 3-3 for the details).

Of four aluminum-containing additives (Calcium aluminum silicate, Sodium aluminum phosphate (acidic), Sodium aluminum silicate, Carmine), the Ministry of Health, Labour and Welfare (MHLW) has discontinued procedures for the designation of the additives excluding Carmine. This is because the MHLW has determined that there will be no need to these substances, based on the results of survey the MHLW conducted in the light of the global trend of reduction of aluminum intake.

Dimethyl Dicarbonate

二炭酸ジメチル

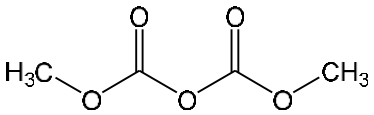
Standards for use (draft)

Dimethyl Dicarbonate is permitted for use in fruit wines and nonalcoholic beverages (excluding mineral waters). It shall be used at not more than 0.25 g/kg in fruit wines (excluding grape wine) and nonalcoholic beverages and at not more than 0.20 /kg in grape wine.

Compositional Specifications (draft)

Substance name Dimethyl Dicarbonate

Structural formula



Molecular formula $C_4H_6O_5$

Molecular weight 134.09

Chemical name [CAS number]
Dimethyl dicarbonate [4525-33-1]

Content Dimethyl Dicarbonate contains not less than 99.8% of dimethyl dicarbonate ($C_4H_6O_5$).

Description Dimethyl Dicarbonate is a colorless liquid.

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

Purity

(1) Lead Not more than 1 μg/g as Pb (Electrothermal Method).

Test Solution Weigh accurately about 1.5 g of Dimethyl Dicarbonate into a container made of polyethylene, quartz, or hard-glass, and add 0.75 mL of nitric acid (for trace metals determination). Stopper loosely, heat up gradually with stirring or occasional shaking, heat at 90℃ for 30 minutes, and cool. Add dropwise 0.85 mL of hydrogen peroxide, heat at 95℃ for 5–

10 minutes with stirring or occasional shaking, and cool. Add dropwise hydrogen peroxide, heat in the same manner, and cool. Transfer this solution into a 25-mL volumetric flask, wash the container with a small amount of water, combine the washings with the solution, and add water to make 25 mL.

Standard Solutions Prepare four standard solutions with different concentrations. Transfer exactly 1, 2.5, 5, 10 mL of Lead Standard Solution into four separate 100-mL volumetric flasks, and to them, add a diluted solution (3 in 100) of nitric acid (for trace metals determination) to make exactly 100 mL.

Procedure Measure exactly a constant portion of the test solution and the standard solutions, and to each, add a quarter volume of a solution of magnesium nitrate hexahydrate (1 in 50), prepared before use. Analyze 25 µL portions of these solutions as directed in Lead Limit Test (Atomic Absorption Spectrophotometry) using the operating conditions given below. Determine the concentration (ng/mL) of lead in the test solution from the calibration curve prepared using the standard solutions. Calculate the amount of lead in the sample by the formula given below. Perform a blank test using the blank test solution prepared with water instead of Dimethyl Dicarbonate in the same manner as for the test solution, and make any necessary correction.

$$\text{Amount (µg/g) of lead} = \frac{\text{Concentration (ng/mL)} \times 25}{\text{Weight (g) of the sample} \times 1000}$$

Operating Conditions

Light source: Lead hollow cathode lamp.

Wavelength: 283.3 nm.

Temperature for drying: A constant temperature of 200–250℃.

Temperature for incineration: A constant temperature of 700–750℃.

Temperature for atomization: A constant temperature of 1800–2000℃.

(2) Dimethyl carbonate Not more than 0.2%.

The procedure given here should be operated as quickly as possible, protected from moisture.

Test Solution Weigh accurately about 5 g of Dimethyl Dicarbonate, add 0.5 mL of the internal standard solution, and add *tert*-butyl methyl ether to make exactly 5 mL.

Standard Solution Weigh accurately about 10 mg of dimethyl carbonate, add exactly 0.5 mL of the internal standard solution, and add *tert*-butyl methyl ether to make exactly 5 mL.

Internal Standard Solution Dissolve 50 mg of 3-pentanone in *tert*-butyl methyl ether to make exactly 5 mL.

Procedure Analyze 0.5-µL portions of the test solution and the standard solution by gas chromatography using the operating conditions given below. Determine the peak area ratios (Q_T and Q_S) of dimethyl carbonate to 3-pentanone for the test solution and the standard solution, respectively. Determine the amount of dimethyl carbonate by the formula:

$$\text{Amount (\%) of dimethyl carbonate } (C_3H_6O_3) = \frac{\text{Weight (mg) of dimethyl carbonate}}{\text{Weight (g) of the sample} \times 1000} \times \frac{Q_T}{Q_S} \times 100$$

Operating conditions

Detector: Flame ionization detector.

Column: A fused silica tube (0.53 mm internal diameter and 60 m length) coated with a 1.5 µm thick layer of dimethylpolysiloxane for gas chromatography.

Column temperature: Maintain the temperature at 45℃ for 7.5 minutes, raise at 10℃/minute to 75℃, then raise at 25℃/minute to 125 ℃, and maintain the temperature at 125℃ for 2 minutes. Raise at 30℃/minute to 260 ℃, and maintain the temperature at 260℃ for 4.5 minutes.

Detector temperature: 300 C.

Injection method: Cold on-column injection method.

Carrier gas: Helium.

Flow rate: Adjust so that the peak of 3-pentanone appears in 4–8 minutes of injection.

Assay The procedure given here should be operated as quickly as possible, protected from moisture.

Weigh accurately 2 g of Dimethyl Dicarbonate, add 100 mL of acetone (dehydrated), and mix. To this solution, add exactly 20 mL of dibutylamine–toluene TS (1 mol/L), stir, and immediately titrate the excess dibutylamine with 1 mol/L hydrochloric acid. Use a potentiometer to confirm the endpoint. Perform a blank test in the same manner, and determine the content of dimethyl dicarbonate by the formula:

$$\text{Content (\%) of dimethyl dicarbonate } (C_4H_6O_5) = \frac{(a - b) \times 0.1341}{\text{Weight (g) of the sample}} \times 100$$

a = volume (mL) of 1 mol/L hydrochloric acid consumed in the blank test.

b = volume (mL) of 1 mol/L hydrochloric acid consumed in the test.

Storing Standard Store in a hermetic container at 20–30 C.°

Reagents, Solutions, and Other Reference Materials

Acetone (dehydrated) CH_3COCH_3 [67-64-1] A colorless, clear liquid.

Content Not less than 99.5% of acetone (CH_3COCH_3).

Specific gravity d_{20}^{20}: 0.788–0.792.

Water Not more than 0.001%.

Assay Analyze 0.2-µL portions of acetone by gas chromatography. Measure the peak area of each peak, excluding the peak of the solvent, to determine the percentage of the main peak by the peak area percentage method.

Operating conditions

Detector: Flame ionization detector.

Column: A fused silica tube (0.53 mm internal diameter and 30 m length) coated with a 5.0 µm thick layer of dimethylpolysiloxane for gas chromatography.

Column temperature: Maintain the temperature at 40℃ for 5 minutes, raise at

5°C/minute to 90°C, and maintain the temperature at 90°C for 2 minutes.
Injection port temperature: 150°C.
Detector temperature: 150°C.
Carrier gas: Helium.
Flow rate: 5 mL/min.

***tert*-Butyl Methyl Ether** $C_5H_{12}O$ [1634-04-4] A colorless liquid.

Content Not less than 99.5% of *tert*-butyl methyl ether ($C_5H_{12}O$).

Specific gravity d_{20}^{20}: 0.738–0.744.

Water Not more than 0.08%.

Assay Analyze 0.2-µL portions of *tert*-butyl methyl ether by gas chromatography. Measure the peak area of each peak, excluding the peak of the solvent, to determine the percentage of the main peak by the peak area percentage method.

Operating conditions

Detector: Flame ionization detector.

Column: A fused silica tube (0.53 mm internal diameter and 15 m length) coated with a 5.0 µm thick layer of a mixture of 5% phenyl/95% methylpolysiloxane for gas chromatography.

Column temperature: Maintain the temperature at 40°C for 10 minutes, raise at 20°C/minute to 260°C, and maintain the temperature at 260°C for 4 minutes.

Injection port temperature: 200°C.

Detector temperature: 260°C.

Carrier gas: Helium or Nitrogen.

Flow rate: A constant rate of about 4 mL/min.

Injection method: Split.

Split ratio: 1 : 50.

Dibutylamine $C_8H_{19}N$ [111-92-2] A colorless, clear liquid.

Content Not less than 99.0% of dibutylamine ($C_8H_{19}N$).

Specific gravity d_{20}^{20}: 0.756–0.764.

Water Not more than 0.3%.

Assay Analyze 0.2-µL portions of dibutylamine by gas chromatography. Measure the peak area of each peak, excluding the peak of the solvent, to determine the percentage of the main peak by the peak area percentage method.

Operating conditions

Detector: Flame ionization detector.

Column: A fused silica tube (0.32 mm internal diameter and 25 m length) coated with a 1.2 µm thick layer of polyethylene glycol for gas chromatography.

Column temperature: Maintain the temperature at 60°C for 2 minutes, raise at 5°C/minute to 100°C, and maintain the temperature at 100°C for 20 minutes.

Injection port temperature: A constant temperature of 150–170°C.

Detector temperature: 200°C.

Carrier gas: Nitrogen.

Flow rate: Adjust so that the peak of dibutylamine appears in about 20 minutes of injection.

Injection method: Split.

Split ratio: 1 : 80.

Dibutylamine–Toluene TS (1 mol/L) Dissolve 129.3 g of dibutylamine in toluene to make 1000 mL. Prepare before use.

Dimethyl Carbonate $C_3H_6O_3$ [616-38-6] A colorless to slightly light yellow liquid.

Content Not less than 98.0% of dimethyl carbonate ($C_3H_6O_3$).

Refractive index n_D^{20}: 1.365–1.372.

Water Not more than 0.2%.

Assay Analyze 0.2-μL portions of dimethyl carbonate by gas chromatography. Measure the peak area of each peak, excluding the peak of the solvent, to determine the percentage of the main peak by the peak area percentage method.

Operating conditions

Detector: Flame ionization detector.

Column: A fused silica tube (0.32 mm internal diameter and 15 m length) coated with a 5.0 μm thick layer of dimethylpolysiloxane for gas chromatography.

Column temperature: Maintain the temperature at 50℃ for 10 minutes, raise at 20℃/minute to 250℃, and maintain the temperature at 250 ℃ for 5 minutes.

Injection port temperature: 200°C.

Detector temperature: 260℃.

Carrier gas: Helium.

Flow rate: A constant rate of about 1.5 mL/min.

Injection method: Split.

Split ratio: 1 : 200.

Nitric Acid (for trace metal determination) HNO_3 [K8451, for trace metal determination] [7697-37-2] Use a reagent with a nitric acid concentration of 69–70%, unless otherwise specified.

3-Pentanone $C_5H_{10}O$ [96-22-0] A colorless to light yellow liquid.

Content Not less than 98.0% of 3-pentanone ($C_5H_{10}O$).

Refractive index n_D^{20}: 1.390 –1.396.

Water Not more than 0.2%.

Assay Analyze 0.2-μL portions of 3-pentanone by gas chromatography. Measure the peak area of each peak, excluding the peak of the solvent, to determine the percentage of the main peak by the peak area percentage method.

Operating conditions

Detector: Flame ionization detector.

Column: A fused silica tube (0.32 mm internal diameter and 15 m length) coated with a 5.0 µm thick layer of a mixture of 5% phenyl/95% methylpolysiloxane for gas chromatography.

Column temperature: Maintain the temperature at 70 ℃ for 10 minutes, raise at 20℃/minute to 250 ℃, and maintain the temperature at 250 ℃ for 6 minutes.

Injection port temperature: 250°C.

Detector temperature: 260 ℃.

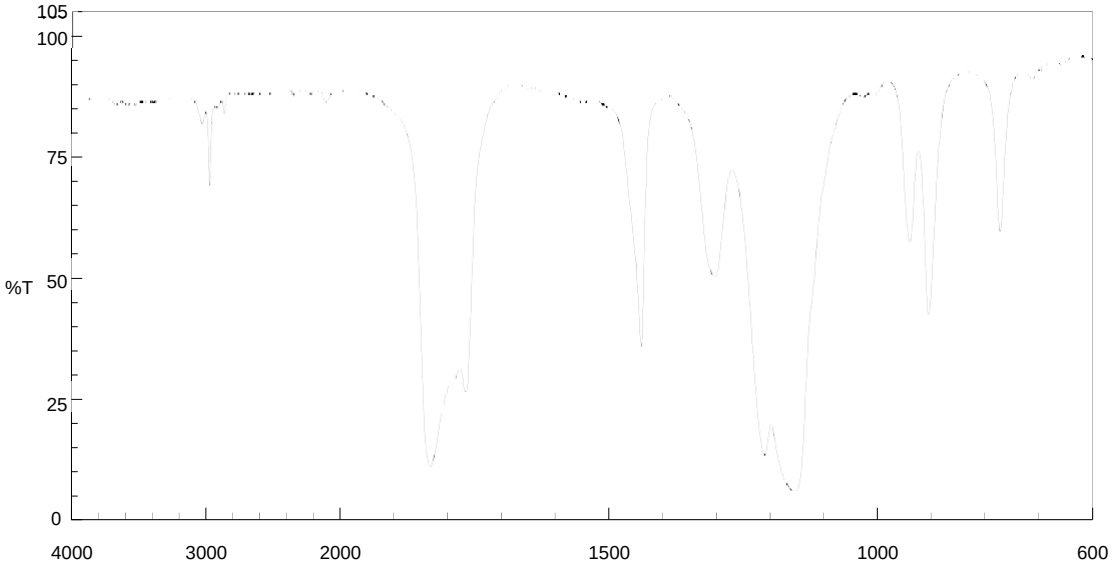
Carrier gas: Helium.

Flow rate: A constant rate of about 1.5 mL/min.

Injection method: Split.

Split ratio: 1 : 300.

Infrared Reference Spectrum



Isomaltodextranase

イソマルトデキストラナーゼ

Compositional Specifications (draft)

Definition Isomaltodextranase includes enzymes that degrade dextran. It is derived from the culture of bacteria (limited to the genus *Arthrobacter*). It may contain foods used exclusively for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its activity. It may also contain food additives used for bulking, powdering, diluting, stabilizing, or preserving it or for adjusting its pH or activity.

Description Isomaltodextranase occurs as white to dark brown granules, powder, or paste, or as a colorless to dark brown liquid. It is odorless or has a characteristic odor.

Identification Isomaltodextranase complies with the Isomaltodextranase Activity Test.

Purity

(1) Lead Not more than 5 μg/g as Pb (0.80 g, Method 1, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).

If the residue does not dissolve in 5 mL of diluted nitric acid (1 in 100) in the preparation of the test solution, conduct the test using Method 3.

(2) Arsenic Not more than 3 μg/g as As (0.50 g, Method 5, Standard Color: Arsenic Standard Solution 3.0 mL, Apparatus B).

Microbial Limits Proceed as directed under the Microbial Limit Tests.

Total plate count: Not more than 50,000 per gram.

Escherichia coli: Negative per test.

Salmonella: Negative per test.

Sample Fluid Prepare as directed in Method 3 for total plate count.

Pre-enrichment Culture Prepare as directed in Method 3 for the *Escherichia coli* test and Method 2 for the *Salmonella* test.

The requirement of total plate count can be disregarded if unsterilized Isomaltodextranase is used for captive consumption in the manufacture of food that will be sterilized or pasteurized before the completion of the final product.

Isomaltodextranase Activity Test Perform the test using the method given below. If the activity test cannot be performed by the given method, appropriate replacement of the sample dilution factor, buffer solution, and temperature for reaction is acceptable where this is scientifically justifiable.

Method 1

Sample Solution Weigh 1.0 g of Isomaltodextranase, add water or acetate buffer (0.05

mol/L) at pH 4.5 to dissolve it or disperse it uniformly, and make 10 mL. As necessary, prepare a 10-fold, 100-fold, or 1000-fold dilution by adding water or the same buffer to the resulting solution.

Substrate Solution Weigh 1.25 g of dextran (molecular weight: 150,000), and dissolve it in acetate buffer (0.05 mol/L) at pH 4.5 to make 100 mL.

Test Solution To 5 mL of the substrate solution, equilibrated at 40°C, add 0.2 mL of the sample solution, and mix. Incubate the mixture at 40°C for 20 minutes. Transfer 1 mL of this solution into a test tube containing 2 mL of Somogyi copper TS. Cover the mouth of the test tube with a glass bead, heat in a water bath for 10 minutes, and cool to room temperature. Add 2 mL of Nelson TS, mix, allow to stand for 30 minutes, and add 5 mL of water.

Control Solution To 5 mL of the substrate solution, equilibrated at 40°C, add 0.2 mL of the sample solution and mix. Transfer 1 mL of this solution into a test tube containing 2 mL of Somogyi copper TS, and mix immediately. Cover the mouth of the test tube with a glass bead, heat in a water bath for 10 minutes, and cool to room temperature. Add 2 mL of Nelson TS, mix, allow to stand for 30 minutes, and add 5 mL of water.

Procedure Measure the absorbance of the test solution and the control solution at a wavelength of 520 nm. The absorbance value of the test solution is higher than that of the control solution. If the test solution and the control solution are turbid, centrifuge them, and use the supernatants.

Method 2

Sample Solution Weigh 1.0 g of Isomaltodextranase, add water or acetate buffer (0.05 mol/L) at pH 4.5 to dissolve it or disperse it uniformly, and make 10 mL. As necessary, prepare a 10-fold, 100-fold, 1000-fold, or 10,000-fold dilution by adding water or the same buffer to the resulting solution.

Substrate Solution Weigh 1.25 g of dextran (molecular weight: 150,000), and dissolve it in acetate buffer (0.05 mol/L) at pH 4.5 to make 50 mL.

Test Solution Add 500 µL of the sample solution to 500 µL of the substrate solution and mix. Incubate the mixture at 40°C for 4 hours, heat in a water bath for 10 minutes, and cool to room temperature.

Standard Solution Dissolve 0.13 g of isomaltose in10 mL of water.

Control Solution Add 500 µL of the sample solution to 500 µL of the substrate solution, and mix. Heat immediately in a water bath for 10 minutes and cool.

Procedure Analyze 2-µL portions of the test solution, standard solution, and control solution by thin-layer chromatography using a 6 : 4 : 1 mixture of 1-butanol/pyridine/water as the developing solvent. Use a thin-layer plate coated with silica gel for thin-layer chromatography as the solid support and then dried at 110°C for 1 hour. Stop the development when the solvent front has ascended to a point about 15 cm above the original line, and air-dry the plate. Spray with 15% sulfuric acid–methanol TS, heat at 100°C for 10 minutes, and examine. One of the spots from the test solution has the same R_f value as

that from the standard solution and is darker in color than the spot with the same R_f value from the control solution.

Reagents, Solutions, and Other Reference Materials

Dextran (molecular weight: 150,000) $(C_6H_{10}O_5)_n$ Use a product suitable for the corresponding enzyme activity tests.

Isomaltose $C_{12}H_{22}O_{11}$ Use a product suitable for the corresponding enzyme activity tests.

Japanese Persimmon Color

カキ色素

Compositional Specifications

(draft) Definition

Japanese Persimmon Color is obtained from the fruits of the *Diospyros kaki* Thunb. It is produced from fermented and roasted fruits through extraction with hydrous ethanol or an alkaline solution and neutralization. It may contain dextrin or lactose.

Color value The Color Value ($E_{1cm}^{10\%}$) of Japanese Persimmon Color is not less than 20 and is in the range of 90-110% of the labeled value.

Description Japanese Persimmon Color occurs as red-brown to dark brown lumps, powder, paste, or liquid. It has a slight characteristic odor.

Identification

(1) Weigh an amount of Japanese Persimmon Color equivalent to 2.5 g of Japanese persimmon color with a Color Value 20, and dissolve it in 100 mL of citrate buffer (pH 7.0). The resulting solution is red-brown to dark brown.

(2) To 5 mL of the solution prepared in Identification (1), add 2–3 drops of hydrochloric acid and allow to stand. A red-brown to dark brown precipitate is produced.

(3) To 5 mL of the solution prepared in Identification (1), add 2 mL of iron(III) chloride hexahydrate solution (1 in 50). A gray to dark brown precipitate is produced.

(4) Weigh an amount of Japanese Persimmon Color equivalent to 1 g of Japanese persimmon color with a Color Value 20, and dissolve it in 100 mL of sodium hydroxide solution (1 in 250). To 5 mL of this solution, add 10 mL of diluted hydrochloric acid (9 in 1000) and 0.1 mL of zinc chloride TS (pH 3.0), and stir. Stopper it, and warm at 50°C for 20 minutes. If necessary, centrifuge at 3000 rpm for 10 minutes. A yellow-brown to dark brown precipitate is produced.

Purity

(1) Lead Not more than 2 μg/g as Pb (2.0 g, Method 1, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).

(2) Arsenic Not more than 3 μg/g as As (0.50 g, Method 3, Standard Color: Arsenic Standard Solution 3.0 mL, Apparatus B).

Color value determination Proceed as directed under Color Value Determination, according to the following operating conditions:

Operating Conditions

Solvent: Citrate buffer (pH 7.0).

Wavelength: 500 nm.

Enju Extract

Japanese Pagoda Tree Extract

エンジュ抽出物

The compositional specifications for Enju extract will be revised as follows:

Revised regulation	Current regulation
Identification (3) Dissolve 20 mg of Enju Extract in 100 mL of ethanol (95) and add 2 mL of ethanol (95) to make 20 mL. The solution exhibits absorption maxima at wavelengths of approximately 257 nm and 361 nm.	**Identification** (3) Dissolve 10 mg of Enju Extract in 100 mL of ethanol (95). The solution exhibits absorption maxima at wavelengths of approximately 257 nm and 361 nm.

dl-α-Tocopherol

dl-α-トコフェロール

The compositional specifications of *dl*-α-Tocopherol will be revised as follows:

Revised regulations	Current regulations
Description *dl*-α-Tocopherol is a light yellow to red-brown, clear, viscous liquid. It is odorless.	**Description** *dl*-α-Tocopherol is a light yellow to yellow-brown, viscous liquid. It is odorless.

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

15 March. 2019

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

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

Substance name	Request for evaluation	Food Safety Commission		MHLW		
		Evaluation by expert committee[1]	Notification of result[2]	Discussion by subcommittee[3]	Closing date for comments[4]	Date of designation as food additives
Acetylated distarch adipate Acetylated distarch phosphate Acetylated oxidized starch Starch sodium octenylsuccinate Hydroxypropyl starch Hydroxypropyl distarch phosphate Phosphated distarch phosphate Monostarch phosphate Distarch phosphate Oxidized starch Starch acetate	26 Nov 2004	23 Mar 2005 17 May 2005 27 Aug 2007 28 Sep 2007(fin.)	29 Nov 2007	28 Nov 2007(fin.) 29 May 2008 4 Jul 2008(fin.)	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	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	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 Cancelled on 8 Jan 2019	28 Feb 2007 30 May 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013				
Calcium aluminium silicate	15 Aug 2005 Cancelled on 8 Jan 2019	28 Feb 2007 30 May 2012 27 Jul 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013				
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 Cancelled on 8 Jan 2019	30 May 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013				
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. Withdrawal of 10 food additives that are no longer distributed in Japan from the List of Existing Food Additives (revision of the List of Existing Food Additives prescribed in the Food Sanitation Act)

Summary

The Ministry of Health, Labour and Welfare (hereinafter referred to as "the MHLW") will withdraw 10 food additives (attachment) from the List of the Existing Food Additives.[1]

Currently these 10 food additives have been found to be no longer distributed in Japan and are supposed to be withdrawn from the List. Consequently, the use of these additives will be prohibited on and after February 27, 2020, at the latest. These 10 food additives are found in MHLW Notification No.45 that was issued on February 28, 2019, for public comments.

Background

According to Article 2-3 of the Supplementary Provisions of Act No.101 of 1995 (the Act to Partially Revise the Food Sanitation Act and Nutrition Improvement Act), the MHLW is responsible for its risk management decision to withdraw food additives from the List of the Existing Food Additives in the MHLW Notification No.120 of 1996, when it is determined that food additives concerned, or preparations or foods containing them are no longer marketed. Such decision is made by taking into account thoroughly the actual situation of the sale, manufacturing, import, processing, use, storage, and display of the substances.

In the decision for the 10 food additives, the MHLW took into consideration outcome of the survey carried out from 2017 through 2018 addressing substances whose distribution was unknown.

The survey examined the situation on sale, manufacturing, import, processing, use, storage, and display of the said substances in the Japanese market. Through a careful analysis of the survey result, the MHLW concluded that they were no longer distributed

[1] "Existing food additives" refer to non-synthetic food additives that were marketed or used on the date of the amendment of the Food Sanitation Act (May 24, 1995) and that appear in the List of Existing Food Additives.

in the domestic market.

Criteria of judgement for withdrawal of the 10 substances are as follows: the substances whose distribution had not been confirmed in Japan.

Action to be taken

Following the issuance of the Notification No.45 on February 2019, The MHLW will proceed with the process including 6-month public comment.

Timeline of the process

1. February 28, 2019: Publish the Notification No.45 listing food additives to be withdrawn

◆ Comment period (6-month and includes the WTO comment period)
Those who claim to modify the list should submit an application to the MHLW with documents which prove actual distribution of the additives concerned, or preparations or food containing them in the Japanese market.

2. August 27, 2019: Due date for comment submission

3. In another six month period, the List of the Existing Food Additives will be revised to formally withdraw these additives. The revised list will come into force on February 27, 2020, at the latest. Thereafter, the use of them as food additives is prohibited.

Attachment-1

List of Existing Food Additives to Be Withdrawn
(As of February 2019)

No.	Substance Name	No. (in the List of Existing Food Additives)
1	Itaconic acid（イタコン酸）	29
2	Fish scale foil(魚鱗箔) A substance that is obtained by extraction from the epithelium of fish	87
3	Kooroo colour [Matsudai colour](クーロー色素) A substance that is obtained by extraction from the roots of *somemono-imo* (*Dioscorea matsudai* HAYATA)	114
4	Spice extracts(香辛料抽出物) Substances that are obtained by extraction or steam-distillation from chervil	122
5	Bone carbon black (骨炭色素) A substance that is obtained by carbonizing bones and consists mainly of carbon	135
6	Sesami straw ash extarct(ゴマ柄灰抽出物) A substance that is obtained by extraction from the ashes of sesami stems or leaves	137
7	Shea nut colour（シアナット色素） A substance that is obtained by extraction from the fruits or seed coats of shea	149
8	Ferritin(フェリチン)	263
9	Hego-ginkgo leaf extract(ヘゴ・イチョウ抽出物) A substance that is obtained by extraction from the leaves of ginkgo and hego (*Cyathea boninsimensis* COPEL)	287
10	Levan(レバン) A substance that is obtained from the culture fluid of *Bacillus subtilis* bacteria and consists mainly of polysaccharides	359