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Japan Proposes New Standards for Canthaxanthin and Seven Pesticides

Report Categories:
Sanitary/Phytosanitary/Food Safety
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Report Highlights:
On October 7, 2014, the Government of Japan (GOJ) announced proposed standards of use for Canthaxanthin (a food additive) and changes to the Maximum Residue Levels (MRLs) for seven agricultural chemicals: Ethiprole, Epoxiconazole, Spiromesifen, Tebufloquin, Propiconazole, Benthiavalicarb-isopropyl, and Penthiopyrad. This foreign embassies' comment period for these changes will close on October 24, 2014. After that, there will be a domestic public comment period and a WTO notification by the Ministry of Health, Labor, and Welfare (MHLW), which will provide other opportunities to submit public comments on this subject.

General Information:
On October 7, 2014, the GOJ announced proposed standards of use for Canthaxanthin (a food additive) and changes to the MRLs for seven agricultural chemicals: Ethiprole, Epoxiconazole, Spiromesifen, Tebufloquin, Propiconazole, Benthiavalicarb-isopropyl, and Penthiopyrad. This foreign embassies' comment period for these changes will close on October 24, 2014, after which, there will be a domestic public comment period and a WTO notification by MHLW, which will provide other opportunities to submit public comments on this subject.

Any parties interested in submitting comments to MHLW should do so as soon as possible. In the case of MRL changes, if you are requesting that Japan adopt the same limits as U.S. MRLs, the request should be accompanied by data supporting U.S. MRLs, such as a risk assessment and residue data. The information MHLW requires would include toxicity data for target chemicals, residue trial data that support the MRLs, and target food commodities. Please be advised that the Limit of Quantitation (LOQ) and the Limit of Detection (LOD) cannot be used as reference data to set up Japanese MRLs. For Japan's MRLs and the details of the information MHLW needs, please visit the following GOJ websites:

Pesticides: http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/01.pdf
Feed additives: http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/02.pdf
Veterinary drugs: http://www.mhlw.go.jp/english/topics/foodsafety/residue/dl/03.pdf

After the domestic comment period closes, MHLW will then notify these proposed changes to the WTO/SPS committee which will provide another opportunity to submit public comments on this subject. The actual WTO/SPS notification can be found at the site below:

http://www.wto.org/english/tratop_e/sps_e/work_and_doc_e.htm

After the WTO comment period closes, a final report will be released based on the conclusions reached by a session of the Pharmaceutical Affairs and Food Sanitation Council scheduled to be held at a later date. The Council's report will constitute the final decision.

Comments to the GOJ can be made either in Japanese or English and can be sent to the below points of contact:

Standards and Evaluation Division,
Department of Food Safety,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916
Tel: 03-5253-1111 Fax: 03-3501-4868

For pesticides/veterinary drugs,
Mr. F. Ichinose (ichinose-fumimasa@mhlw.go.jp)

Tel: ex. 2487

For food additives,
Mr. T. Ikegami (ikegami-takahiro@mhlw.go.jp)
Tel: ex. 2459

Post requests that the U.S. Embassy-Tokyo also be copied on any comments at agtokyo@usda.gov to allow them to be considered as part of the official U.S. Government comments to the WTO.

(Below is a copy of MHLW's announcement)

Item 1. Establishment of Maximum Residue Limits for Agricultural Chemicals in Food

MHLW is going to amend existing residue standards for agricultural chemicals in foods.

Summary

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labor and Welfare is authorized to establish residue standards (MRLs) for pesticides, feed additives, and veterinary drugs (hereafter referred to as just "agricultural chemicals") that may remain in foods. Any food for which standards are established pursuant to the provisions is not permitted to be marketed in Japan unless it complies with the established standards.

On May 29, 2006, the MHLW introduced the positive list system for agricultural chemicals in food.* Basically, all foods distributed in the Japanese marketplace are subject to regulation based on the system.

This time, MHLW has comprehensively reviewed existing MRLs to modify those that were provisionally set at the introduction of the system. Additionally, MHLW has revised MRLs (draft) for some commodities. This action targets seven pesticides: Benthiavalicarb-isopropyl, Epoxiconazole, Ethiprole, Penthiopyrad, Propiconazole, Spiromesifen, and Tebufloquin. Details are included below.

**Note: The positive list system was established based on the 2003 amendment of the Food Sanitation Law. The system aims to prohibit the distribution of any food in the Japanese marketplace if it contains agricultural chemicals at amounts exceeding a certain level (0.01 ppm) specified under the Law.*

Outline

Epoxiconazole (fungicide): Application in Japan is not permitted.
The MHLW has newly established MRLs for some commodities. The action has been to respond to a request from abroad 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). In addition, the MHLW has modified some MRLs that were provisionally set at the introduction of the Positive List System.

Propiconazole (fungicide): Application in Japan is permitted.

MRLs have been newly set for some food commodities. This action has been based on the decision of the Ministry of Agriculture, Forestry and Fisheries (MAFF) to expand the scope of the use of this pesticide in response to an application from a business. MHLW has also established MRLs for some additional commodities. This action is in response to a request from abroad 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). Additionally, MHLW has modified some MRLs that were provisionally set at the introduction of the Positive List System.

Ethiprole (insecticide), Spiromesifen (insecticide), Tebufloquin, (fungicide), Benthiavalicarb-isopropyl (fungicide) , and Penthiopyrad (insecticide):
Application in Japan is permitted.
MHLW has decided to retain or raise current MRLs for these chemicals. There are no commodities for which MRLs will be lowered by this action at this time; therefore, MHLW will not notify the WTO-SPS Committee for these five substances.

Epoxiconazole

					Reference MRL		
	MRL		**MRL**				
Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Wheat	●	0.2	0.5	IT		0.2	EU
Barley	○	1	0.5	IT		1	EU
Rye	○	0.2		IT		0.2	EU
Other cereal grains	○	1		IT		1	EU
Soybeans, dry	○	0.05		IT		0.05	Brazil
Peanuts, dry	○	0.05		IT		0.05	Brazil
Sugarcane	○	0.03		IT		0.03	Brazil
Banana	●	0.5	1	IT		0.5	EU
Avocado	●		0.5				
Coffee beans	○	0.05		IT		0.05	EU
Cattle, muscle	○	0.01	0.01			0.01	EU
Pig, muscle	○	0.01	0.01			0.01	EU
Other terrestrial mammals, muscle	○	0.01	0.01			0.01	EU
Cattle, fat	○	0.01	0.01			0.01	EU
Pig, fat	○	0.01	0.01			0.01	EU
Other terrestrial mammals, fat	○	0.01	0.01			0.01	EU
Cattle, liver	○	0.2	0.05			0.2	EU
Pig, liver	○	0.2	0.05			0.2	EU
Other terrestrial mammals, liver	○	0.2	0.05			0.2	EU
Cattle, kidney	●	0.02	0.05			0.02	EU

Pig, kidney	●	0.02	0.05			0.02	EU
Other terrestrial mammals, kidney	●	0.02	0.05			0.02	EU
Cattle, edible offal	○	0.2	0.05			0.02	EU
Pig, edible offal	○	0.2	0.05			0.02	EU
Other terrestrial mammals, edible offal	○	0.2	0.05			0.02	EU
Milk	●	0.002	0.01			0.002	EU
Chicken, muscle	●	0.01	0.02			0.01	EU
Other poultry, muscle	●	0.01	0.02			0.01	EU
Chicken, fat	●	0.01	0.05			0.01	EU
Other poultry, fat	●	0.01	0.05			0.01	EU
Chicken, liver	●	0.01	0.02			0.01	EU
Other poultry, liver	●	0.01	0.02			0.01	EU
Chicken, kidney	●	0.01	0.02			0.01	EU
Other poultry, kidney	●	0.01	0.02			0.01	EU
Chicken, edible offal	●	0.01	0.02			0.01	EU
Other poultry, edible offal	●	0.01	0.02			0.01	EU
Chicken eggs	○	0.01	0.01			0.02	EU
Other poultry, eggs	○	0.01	0.01			0.02	EU

Note: The residue definition is epoxiconazole 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 were lowered

○ : Commodities for which MRLs were increased

IT : Import tolerance

Propiconazole

					Reference MRL		
	MRL		**MRL**				
Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Rice (brown rice)	○	0.1	0.1				
Wheat	○	1	1.0	§	0.02	0.3	USA
Barley	○	1	1.0	§	0.2		
Rye	○	0.3	0.05	IT	0.02	0.3	USA
Corn (maize, including pop corn and sweet corn)	○	1	1.0	§	0.05		
Buckwheat	○	1	1.0				
Other cereal grains	○	4	0.05	IT	0.02	3.5	USA

Soybeans, dry	○	2	0.05	IT		2.0	USA
Beans, dry	○	0.05	0.05				
Peas	○	0.05	0.05				
Broad beans	○	0.05	0.05				
Peanuts, dry	○	0.2	0.05	IT		0.2	USA
Other pulses	○	0.05	0.05				
Potato	○	0.05	0.05				
Taro	●		0.05				
Sweet potato	○	0.05	0.05				
Yam	●		0.05				
Konjac	●		0.05				
Other potatoes	●		0.05				
Sugar beet	○	0.3	0.05	IT	0.02	0.3	USA
Sugarcane	○	0.05	0.05		0.02		
Japanese radish, roots (including radish)	○	0.05	0.05				
Japanese radish, leaves (including radish)	●		0.05				
Turnip, roots (including rutabaga)	○	0.05	0.05				
Turnip, leaves (including rutabaga)	●		0.05				
Horseradish	○	0.05	0.05				
Watercress	●		0.05				
Chinese cabbage	○	0.05	0.05				
Cabbage	○	0.05	0.05				
Brussels sprouts	○	0.05	0.05				
Kale	○	0.05	0.05				
Komatsuna(Japanese mustard spinach)	●		0.05				
Kyona	●		0.05				
Qing-geng-cai	○	0.05	0.05				
Cauliflower	○	0.05	0.05				
Broccoli	○	0.05	0.05				
Other cruciferous vegetables	○	0.05	0.05				
Burdock	●		0.05				
Salsify	●		0.05				
Artichoke	●		0.05				
Chicory	○	0.05	0.05				
Endive	○	0.05	0.05				
Shungiku	●		0.05				
Lettuce (including cos lettuce and leaf lettuce)	●		0.05				
Other composite vegetables	○	5	0.05			5.0	USA

Onion	○	0.2	0.05	IT		0.2	USA
Welsh (including leek)	○	0.1	0.05	IT		0.1	EU
Garlic	○	0.05	0.05				
Nira	●		0.05				
Asparagus	○	0.05	0.05				
Multiplying onion (including shallot)	●		0.05				
					Reference MRL		
	MRL		**MRL**				
Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Other liliaceous vegetables	○	0.2	0.05			0.2	USA
Carrot	○	0.3	0.05	IT		0.25	USA
Parsnip	●		0.05				
Parsley	○	13	0.05	IT		13	USA
Celery	○	5	5.0			5.0	USA
Mitsuba	●		0.05				
Other umbelliferous vegetables	○	5	0.05			5.0	USA
Tomato	○	0.05	0.05				
Pimiento (sweet pepper)	○	0.1	0.1				
Egg plant	○	0.05	0.05				
Other solanaceous vegetables	●		0.05				
Cucumber (including gherkin)	○	0.05	0.05				
Pumpkin (including squash)	○	0.05	0.05				
Oriental pickling melon (vegetable)	●		0.05				
Water melon	○	0.05	0.05				
Melons	○	0.05	0.05				
Makuwauri melon	●		0.05				
Other cucurbitaceous vegetables	○	0.05	0.05				
Spinach	○	0.05	0.05				
Bamboo shoots	●		0.05				
Okra	●		0.05				
Ginger	●		0.05				
Peas, immature (with pods)	○	0.05	0.05				
Kidney beans, immature (with pods)	○	0.05	0.05				
Green soybeans	●	0.07	1		0.07		
Button mushroom	○	0.1	0.1				
Shiitake mushroom	●		0.05				
Other mushrooms	●		0.05				

Other vegetables	○	5	0.05			5.0	USA
Unshu orange, pulp	○	0.05	0.05				
Citrus natsudaidai, whole	○	0.05	0.05				
Lemon	○	0.05	0.05				
Orange (including navel orange)	○	0.05	0.05				
Grapefruit	○	0.05	0.05				
Lime	○	0.05	0.05				
Other citrus fruits	○	0.05	0.05				
Apple	○	0.05	0.05				
Japanese pear	○	0.05	0.05				
Pear	○	0.05	0.05				
Quince	○	0.05	0.05				
Loquat	●		0.05				
Peach	○	1	1.0				
Nectarine	○	1	1.0				
Apricot	○	1	1.0				
Japanese plum (including prune)	○	1	1.0				
Mume plum	○	1	1.0				
Cherry	○	1	1.0				
Strawberry	○	1	0.05	IT		1.3	USA
Raspberry	○	0.05	0.05				
Blackberry	○	0.05	0.05				
Blueberry	○	1	1			1.3	USA
					Reference MRL		
	MRL		**MRL**				
Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Cranberry	○	1	0.05	IT	0.3	1.0	USA
Huckleberry	●		1				
Other berries	○	1	0.05			1.3	USA
Grape	○	0.5	0.5				
Japanese persimmon	●		0.1				
Banana	○	0.1	0.1		0.1		
Kiwifruit	○	0.05	0.05				
Avocado	○	0.05	0.05				
Pineapple	○	0.1	0.1		0.02		
Guava	●		0.05				
Mango	○	0.05	0.05				
Passion fruit	○	0.05	0.05				
Date	○	0.05	0.05				
Other fruits	●		0.1				

Sunflower seeds	○	0.05	0.05				
Sesame seeds	○	0.05	0.05				
Safflower seeds	●		0.05				
Cotton seeds	○	0.05	0.05				
Rapeseeds	○	0.07	0.05		0.07		
Other oil seeds	○	0.05	0.05				
Ginkgo nut	●		0.1				
Chestnut	●		0.1				
Pecan	○	0.05	0.05		0.02		
Almond	○	0.05	0.05				
Walnut	○	0.05	0.05				
Other nuts	○	0.05	0.05				
Tea	○	0.1	0.1				
Coffee beans	○	0.1	0.1		0.02		
Hop	○	0.1	0.1				
Other spices	●		0.1				
Other herbs	●		0.05				
Cattle, muscle	●	0.01	0.05		0.01		
Pig, muscle	●	0.01	0.05		0.01		
Other terrestrial mammals, muscle	●	0.01	0.05		0.01		
Cattle, fat	●	0.01	0.08		0.01		
Pig, fat	●	0.01	0.08		0.01		
Other terrestrial mammals, fat	●	0.01	0.08		0.01		
Cattle, liver	●	0.01	0.05		0.01		
Pig, liver	●	0.01	0.05		0.01		
Other terrestrial mammals, liver	●	0.01	0.05		0.01		
Cattle, kidney	●	0.01	0.05		0.01		
Pig, kidney	●	0.01	0.05		0.01		
Other terrestrial mammals, kidney	●	0.01	0.05		0.01		
Cattle, edible offal	●	0.01	0.05		0.01		
Pig, edible offal	●	0.01	0.05		0.01		
Other terrestrial mammals, edible offal	●	0.01	0.05		0.01		
Milk	○	0.01	0.01		0.01		
Chicken, muscle	●	0.01	0.05		0.01		
Other poultry, muscle	●	0.01	0.05		0.01		
Chicken, fat	●	0.01	0.08		0.01		
Other poultry, fat	●	0.01	0.08		0.01		
					Reference MRL		
	MRL		**MRL**				

Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Chicken, liver	●	0.01	0.1		0.01		
Other poultry, liver	●	0.01	0.1		0.01		
Chicken, kidney	●	0.01	0.1		0.01		
Other poultry, kidney	●	0.01	0.1		0.01		
Chicken, edible offal	●	0.01	0.08		0.01		
Other poultry, edible offal	●	0.01	0.08		0.01		
Chicken eggs	●	0.01	0.05		0.01		
Other poultry, eggs	●	0.01	0.05		0.01		

Note: The residue definition is propiconazole 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 were lowered
○ : Commodities for which MRLs were increased
§ : Permitted for use in Japan.
IT : Import tolerance

Ethiprole

					Reference MRL		
	MRL		**MRL**				
Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Rice (brown rice)	○	0.2	0.2	§			
Soybeans, dry	○	0.2	0.2	§			
Green soybeans	○	0.5	0.5	§			
Unshu orange, pulp	○	0.1	0.1	§			
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	○	1	1	§			
Japanese persimmon	○	0.2	0.2	§			
Mango	○	0.5		Request			
Tea	○	10	10	§			
Other spices	○	3	3	§			
Fish	○	0.09	0.09				

Note: The residue definition is ethiprole 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 were increased

§ : Permitted for use in Japan.

Request : The MRL was modified in response to MAFF request

Spiromesifen

					Reference MRL		
	MRL		**MRL**				
Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Wheat	○	0.01	0.01			0.03	USA
Barley	○	0.01	0.01			0.03	USA
Corn (maize, including pop corn and sweet corn)	○	0.02	0.02			0.02	USA
Other cereal grains	○	0.01	0.01			0.03	USA
Beans, dry	○	0.02	0.02			0.02	USA
Peas	○	0.2	0.2			0.20	USA
Broad beans	○	0.02	0.02			0.02	USA
Other pulses	○	0.2	0.2			0.20	USA
Potato	○	0.02	0.02			0.02	USA
Taro	○	0.02	0.02			0.02	USA
Sweet potato	○	0.02	0.02			0.02	USA
Yam	○	0.02	0.02			0.02	USA
Other potatoes	○	0.02	0.02			0.02	USA
Sugar beet	○	0.01	0.01			0.03	USA
Watercress	○	12	12			12	USA
Cabbage	○	2	2			2.0	USA
Brussels sprouts	○	2	2			2.0	USA
Kale	○	12	12			12	USA
Kyona	○	12	12			12	USA
Qing-geng-cai	○	12	12			12	USA
Cauliflower	○	2	2			2.0	USA
Broccoli	○	2	2			2.0	USA
Other cruciferous vegetables	○	12	12			12	USA
Chicory	○	12	12			12	USA
Endive	○	12	12			12	USA
Shungiku	○	12	12			12	USA
Lettuce (including cos	○	12	12			12	USA

lettuce and leaf lettuce)							
Other composite vegetables	○	12	12			12	USA
Onion	○	0.09	0.09			0.09	USA
Welsh (including leek)	○	0.09	0.09			0.09	USA
Garlic	○	0.09	0.09			0.09	USA
Nira	○	0.09	0.09			0.09	USA
Multiplying onion (including shallot)	○	0.09	0.09			0.09	USA
Other liliaceous vegetables	○	0.09	0.09			0.09	USA
Parsley	○	12	12			12	USA
Celery	○	6	6			6.0	USA
Other umbelliferous vegetables	○	12	12			12	USA
Tomato	○	3	3	§			
Pimiento (sweet pepper)	○	3	3	§			
Egg plant	○	2	2	§			
Other solanaceous vegetables	○	5	5	§			
Cucumber (including gherkin)	○	0.1	0.1			0.10	USA
Pumpkin (including squash)	○	0.1	0.1			0.10	USA
Oriental pickling melon (vegetable)	○	0.1	0.1			0.10	USA
Water melon	○	0.3	0.3	§			
Melons	○	0.1	0.1				
Makuwauri melon	○	0.1	0.1				
Other cucurbitaceous vegetables	○	0.1	0.1			0.10	USA
Spinach	○	12	12			12	USA
Ginger	○	0.02	0.02			0.02	USA
Kidney beans, immature (with pods)	○	1	1			1	EU

					Reference MRL		
	MRL		**MRL**				
Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Other vegetables	○	12	12			12	USA
Unshu orange, pulp	○	0.2		Request			
Citrus natsudaidai,	○	2		Request			

whole							
Lemon	○	2		Request			
Orange (including navel orange)	○	2		Request			
Grapefruit	○	2		Request			
Lime	○	2		Request			
Other citrus fruits	○	2		Request			
Apple	○	2	2	§			
Japanese pear	○	2	2	§			
Pear	○	2	2	§			
Peach	○	0.2	0.2	§			
Nectarine	○	1	1	§			
Apricot	○	5	5	§			
Japanese plum (including prune)	○	0.7	0.7	§			
Mume plum	○	5	5	§			
Cherry	○	5	5	§			
Strawberry	○	2	2			2.0	USA
Blueberry	○	2	2			2.0	USA
Cranberry	○	2	2			2.0	USA
Other berries	○	2	2			2.0	USA
Grape	○	10	10	§			
Other fruits	○	0.5	0.5				
Cotton seeds	○	0.5	0.5			0.50	USA
Tea	○	30	30	§			
Other spices	○	10	10	§			
Other herbs	○	45	45			45	USA
Cattle, muscle	○	0.02	0.02			0.02	USA
Other terrestrial mammals, muscle	○	0.02	0.02			0.02	USA
Cattle, fat	○	0.1	0.1			0.10	USA
Other terrestrial mammals, fat	○	0.1	0.1			0.10	USA
Cattle, liver	○	0.2	0.2			0.20	USA
Other terrestrial mammals, liver	○	0.2	0.2			0.20	USA
Cattle, kidney	○	0.2	0.2			0.20	USA
Other terrestrial mammals, kidney	○	0.2	0.2			0.20	USA
Cattle, edible offal	○	0.2	0.2			0.20	USA
Other terrestrial mammals, edible offal	○	0.2	0.2			0.20	USA
Milk	○	0.01	0.01			0.01	USA
Fish	○	0.06	0.06				

Note:Residue definition
For crops and fish/shellfish, the sum of spiromesifen and metabolite M1 (4-hydroxy-3-mesityl-1-oxaspiro[4.4]non-3-en-2-one), expressed as spiromesifen. For terrestrial animal products (meat eggs, and dairy products), the sum of spiromesifen, and metabolites M1 and M2 (4-hydroxy-3-(4-hydroxymethyl-2,6-dimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one) and the conjugate of M2, each expressed as spiromesifen.
* 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 were increased
§ : Permitted for use in Japan.
Request : The MRL was modified in response to MAFF request

Tebufloquin

					Reference MRL		
	MRL		**MRL**				
Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Rice (brown rice)	○	0.5	0.5	§			
Soybeans, dry	○	0.2		Request			
Chinese cabbage	○	0.1		Request			
Welsh (including leek)	○	0.2		Request			
Tomato	○	1		Request			
Tea	○	15		Request			
Fish	○	0.09	0.09				

Note:Residue definition
The sum of tebufloquin and metabolite M1 (6-tert-butyl-8-fluoro-2,3-dimethyl-4(1H)-quinolinone), expressed as tebufloquin.
* 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 were increased
§ : Permitted for use in Japan.
Request : The MRL was modified in response to MAFF request

Benthiavalicarb-isopropyl

				Reference MRL
	MRL	**MRL**		

Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Soybeans, dry	○	0.05	0.05	§			
Potato	○	0.02	0.02	§			
Chinese cabbage	○	2	2	§			
Cabbage	○	0.05	0.05	§			
Broccoli	○	1		Request			
Onion	○	0.02	0.02	§			
Welsh (including leek)	○	0.7	0.7	§			
Asparagus	○	0.3	0.3	§			
Other liliaceous vegetables	○	0.05	0.05	§			
Tomato	○	2	2	§			
Egg plant	○	2	2	§			
Other solanaceous vegetables	○	2		IT		2	Korea
Cucumber (including gherkin)	○	0.5	0.5	§			
Pumpkin (including squash)	○	0.3	0.3	§			
Water melon	○	0.05	0.05	§			
Melons	○	0.05	0.05	§			
Strawberry	○	2		Request			
Grape	○	2	2	§			
Other fruits	○	1		Request			

Note: The residue definition is benthiavalicarb-isopropyl 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 were increased

§ : Permitted for use in Japan.

Request : The MRL was modified in response to MAFF request

IT : Import tolerance

Penthiopyrad

				Reference MRL		
	MRL	**MRL**				
Commodity	**(draft)**	**(current)**	**Registration**	Codex	National	
	ppm	**ppm**		ppm	ppm	
Wheat	○ 0.2	0.2		0.1	0.15	USA

Barley	○	0.2	0.2		0.2	0.15	USA
Rye	○	0.2	0.2		0.1	0.15	USA
Corn (maize, including pop corn and sweet corn)	○	0.02	0.02		0.02		
Buckwheat	○	0.2	0.2			0.15	USA
Other cereal grains	○	0.8	0.8		0.8	0.8	USA
Soybeans, dry	○	0.4	0.4		0.3	0.40	USA
Beans, dry	○	0.4	0.4		0.3	0.40	USA
Peas	○	0.4	0.4		0.3	0.40	USA
Broad beans	○	0.4	0.4		0.3	0.40	USA
Peanuts, dry	○	0.05	0.04		0.05		
Other pulses	○	0.4	0.4		0.3	0.40	USA
Potato	○	0.06	0.06		0.05	0.06	USA
Taro	○	0.06	0.06			0.06	USA
Sweet potato	○	0.06	0.06			0.06	USA
Yam	○	0.06	0.06			0.06	USA
Other potatoes	○	0.06	0.06			0.06	USA
Sugar beet	○	0.5			0.5		
Japanese radish, leaves (including radish)	○	30	30		30		
Turnip, leaves (including rutabaga)	○	50	50		50		
Watercress	○	30	30		30		
Chinese cabbage	○	30	30	§	30		
Cabbage	○	5	5	§	4	5.0	USA
Brussels sprouts	○	5	5			5.0	USA
Kale	○	50	50		30	50	USA
Komatsuna(Japanese mustard spinach)	○	50	50		30	50	USA
Kyona	○	50	50		30	50	USA
Qing-geng-cai	○	50	50		30	50	USA
Cauliflower	○	5	5		5	5.0	USA
Broccoli	○	10	5	Request	5		
Other cruciferous vegetables	○	50	50		30	50	USA
Chicory	○	30	30		30		
Endive	○	30	30		30	30	USA
Shungiku	○	30	30		30	30	USA
Lettuce (including cos lettuce and leaf lettuce)	○	30	30	§	30	30	USA
Other composite vegetables	○	30	30		30	30	USA
Onion	○	0.7	0.7	§	0.7		
Welsh (including leek)	○	4	4	§	4		
Nira	○	20		Request			

Asparagus	○	0.3	0.3	§			
Other liliaceous vegetables	○	4	4		4		
Carrot	○	0.6	0.6	§	0.6		
Parsley	○	30	30			30	USA
Celery	○	30	30		15	30	USA
Other umbelliferous vegetables	○	30	30			30	USA
Tomato	○	3	3	§	2	3.0	USA
Pimiento (sweet pepper)	○	3	3	§	2	3.0	USA
Egg plant	○	3	3	§	2	3.0	USA
Other solanaceous vegetables	○	30	30	§	30		
Cucumber (including gherkin)	○	0.5	0.5	§	0.5		
Pumpkin (including squash)	○	0.5	0.5	§	0.5		

					Reference MRL		
	MRL		**MRL**				
Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Oriental pickling melon (vegetable)	○	0.5	0.5		0.5		
Water melon	○	0.05	0.05	§			
Melons	○	0.05	0.05	§			
Other cucurbitaceous vegetables	○	30	30	§	30		
Spinach	○	30	30		30	30	USA
Okra	○	2	2	§	2		
Ginger	○	0.06	0.06			0.06	USA
Peas, immature (with pods)	○	4	4	§	3	4.0	USA
Kidney beans, immature (with pods)	○	4	4	§	3	4.0	USA
Green soybeans	○	4	4	§		4.0	USA
Shiitake mushroom	○	2	2		2		
Other mushrooms	○	2	2		2		
Other vegetables	○	30	30	§	30		
Unshu orange, pulp	○	0.5	0.5	§			
Citrus natsudaidai, whole	○	2		Request			
Lemon	○	3		Request			
Orange (including navel orange)	○	3		Request			
Grapefruit	○	3		Request			
Lime	○	3		Request			
Other citrus fruits	○	3		Request			
Apple	○	2	2	§	0.4		
Japanese pear	○	3	3	§	0.4		
Pear	○	3	3	§	0.4		
Quince	○	0.5	0.5		0.4	0.50	USA

Peach	○	0.2	0.2	§			
Nectarine	○	4	4	§	4		
Apricot	○	10	4	Request	4		
Japanese plum (including prune)	○	4	4	§	4		
Mume plum	○	10	4	Request	4		
Cherry	○	5	5	§	4		
Strawberry	○	3	3	§	3	3.0	USA
Blueberry	○	3	3			3.0	USA
Cranberry	○	3	3			3.0	USA
Other berries	○	3	3			3.0	USA
Grape	○	10	10	§			
Japanese persimmon	○	3	3	§			
Other fruits	○	3	3		2	3.0	USA
Sunflower seeds	○	2	2			1.5	USA
Cotton seeds	○	2	2		0.5	1.5	USA
Rapeseeds	○	2	2		0.5	1.5	USA
Ginkgo nut	○	0.05	0.05		0.05		
Chestnut	○	0.06	0.06		0.05	0.06	USA
Pecan	○	0.06	0.06		0.05	0.06	USA
Almond	○	0.06	0.06		0.05	0.06	USA
Walnut	○	0.06	0.06		0.05	0.06	USA
Other nuts	○	0.06	0.06		0.05	0.06	USA
Other spices	○	15	15	§			
Other herbs	○	50	50	§	30	50	USA
Cattle, muscle	○	0.04			0.04		
Pig, muscle	○	0.04			0.04		
Other terrestrial mammals, muscle	○	0.04			0.04		

					Reference MRL		
	MRL		**MRL**				
Commodity	**(draft)**		**(current)**	**Registration**	Codex	National	
	ppm		**ppm**		ppm	ppm	
Cattle, fat	○	0.05			0.05		
Pig, fat	○	0.05			0.05		
Other terrestrial mammals, fat	○	0.05			0.05		
Cattle, liver	○	0.08			0.08		
Pig, liver	○	0.08			0.08		
Other terrestrial mammals, liver	○	0.08			0.08		
Cattle, kidney	○	0.08			0.08		
Pig, kidney	○	0.08			0.08		
Other terrestrial mammals, kidney	○	0.08			0.08		
Cattle, edible offal	○	0.08			0.08		

Pig, edible offal	○	0.08			0.08		
Other terrestrial mammals, edible offal	○	0.08			0.08		
Milk	○	0.04			0.04		
Chicken, muscle	○	0.03			0.03		
Other poultry, muscle	○	0.03			0.03		
Chicken, fat	○	0.03			0.03		
Other poultry, fat	○	0.03			0.03		
Chicken, liver	○	0.03			0.03		
Other poultry, liver	○	0.03			0.03		
Chicken, kidney	○	0.03			0.03		
Other poultry, kidney	○	0.03			0.03		
Chicken, edible offal	○	0.03			0.03		
Other poultry, edible offal	○	0.03			0.03		
Chicken eggs	○	0.03			0.03		
Other poultry, eggs	○	0.03			0.03		
Wheat germ	○	0.2			0.2		
Wheat bran	○	0.2			0.2		
Corn flour	○	0.05			0.05		
Corn oil (except edible corn oil that meets the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	○	0.2			0.15		
Peanut oils, (limited to refined peanut oil and peanut salad oil that meet the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	○	0.5			0.5		
Rapeseed oils, (limited to refined rapeseed oil and rapeseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	○	1			1		
Rapeseed oils, crude (except refined rapeseed oil and rapeseed salad oil that meet the JAS for Edible Vegetable Fats and Oils, and other edible oils that meet standards equivalent to or stricter than JAS)	○	1			1		

Note:Residue definition

For crops, pentipyrad only. For terrestrial animal products (meat eggs, and dairy products), the sum

of pentipyrad and metabolite PAM (1-methyl-3-trifluoromethyl-1H-pyrazol-4-carboxamide), expressed as pentipyrad.
* 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 were increased
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Request : The MRL was modified in response to MAFF request

Item 2. Designation of Food Additives

The GOJ will designate Canthaxanthin as an authorized food additive.

Summary
Under Article 10 of the Food Sanitation Act, food additives shall not be used or marketed without authorization by the Minister of Health, Labour and Welfare (hereinafter referred as "the Minister"). Additionally, when specifications or standards are established for food additives based on Article 11 of the act and stipulated in the MHLW Notification (Ministry of Health and Welfare Notification No. 370, 1959), those additives shall not be used or marketed unless they meet the listed standards or specifications.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council has discussed the suitability of the designation of Canthaxanthin [CAS: 514－78－3]* as a food additive.

The committee concluded that the Minister should designate Canthaxanthin as a food additive unlikely to harm human health, based on Article 10 of the Act, and establish compositional specifications, based on Article 11 of the Act. See Attachments 2-1.

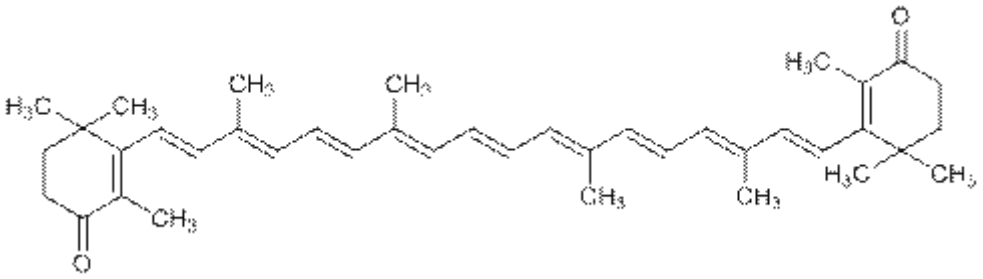
** Note:*
Canthaxanthin is categorized as a coloring agent in the Codex standards. There is a maximum use limit set at 35 mg/kg on fish paste products (surimi). Also use limits are set for some other food products (e.g., 200 mg/kg of jams, jellies, and marmalades).
In the United States, the substance is permitted up to 30 mg in one pound (0.45 kg) of solid and semi-solid commodities and in one pint (0.47 L) of liquid commodities.

<Additional Information>
Progress in the designation procedure for 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 October 10, 2014, 51 of the 54 flavorings and 39 of the 45 non-flavoring additives were already

approved. Please see Attachment 2-2.

Attachment 2-1
Canthaxanthin
カンタキサンチン



Standards for use
Only permitted for use in fish pastes products (*kamaboko* only) up to 0.035 g per kg of each product.

Compositional specifications
Substance name Canthaxanthin
Molecular formula $C_{40}H_{52}O_2$
Molecular weight 564.84
Chemical name [CAS number] b,b-Carotene-4,4'-dione ［514－78－3］
Content Canthaxanthin contains not less than 96.0% of canthaxanthin ($C_{40}H_{52}O_2$).
Description Canthaxanthin occurs as dark-purple crystals or crystalline powder.
Identification (1) A solution of Canthaxanthin in acetone (1 in 25,000) develops an orange color. To 5 ml of this solution, add 1 ml of sodium nitrite solution (1 in 20) and 1 ml of 0.5 mol/L sulfuric acid. The solution is immediately decolored.
(2) A solution of Canthaxanthin in cyclohexane (1 in 400,000) exhibits an absorption maximum at a wavelength of 470 nm.
Purity
(1) Lead Not more than 2.0 mg/g as Pb.
Test Solution Weigh 2.0 g of Canthaxanthin in a platinum, quartz, or porcelain crucible or a quartz beaker. Heat gradually, and stop heating before the sample starts to carbonize. Add 1 ml of sulfuric acid, and heat by increasing the temperature gradually until the sample is carbonized and white fumes are no longer evolved. If necessary, add sulfuric acid again, and heat until the sample is almost carbonized. Loosely lid the crucible if necessary, heat in an electric furnace by increasing the temperature gradually, and incinerate at 450–600°C. If any carbonized matter still remains, crush the residue with a glass rod, moisten with 1 ml of diluted sulfuric acid (1 in 4) and 1 ml of nitric acid, and heat until white fumes are

no longer evolved. Then, ignite in the electric furnace to complete incineration. To the residue, add 10 ml of diluted sulfuric acid (1 in 4), and evaporate on a water bath to dryness. To the residue, add a small amount of diluted nitric acid (1 in 100), and dissolve it while heating. After cooling, add diluted nitric acid (1 in 100) again to make exactly 10 ml. When incineration is done at 500°C or below, a heat-resistant glass beaker can be used.

Control Solution Add water to exactly measured 1 ml of Lead Standard Stock Solution to make exactly 100 ml. To exactly measured 4 ml of this solution, add diluted nitric acid (1 in 100) to make exactly 10 ml.

Procedure Proceed as directed under Method 1 in the Lead Limit Test.

(2) Arsenic Not more than4.0 mg/g as As_2O_3 (0.50 g, Method 3, Apparatus B).

(3) Subsidiary Colors Not more than 5%.

Test Solution Weigh 0.020 g of Canthaxanthin, and dissolve in 25 ml of dichloromethane.

Procedure Perform thin-layer chromatography. Use a thin-layer plate coated with silica gel for thin-layer chromatography and dried at 110°C for 1 hour. Apply 400 ml of the test solution in an about 3 mm-wide strip on the original line on the thin-layer plate. Develop using a 95:5 mixture of dichloromethane and diethyl ether as the developing solvent and using no control solution. Stop the development when the solvent front has ascended to a point about 15 cm above the original line, and air-dry the plate. Scrap the darkest colored part—which contains the main constituent—off the plate, and transfer in a centrifuging tube. Add exactly 40 ml of dichloromethane, and shake for 10 minutes, and centrifuge. Measure exactly 10 ml of the supernatant, and add dichloromethane to make exactly 50 ml. Refer to this solution as solution A. Similarly, scrap off the other colored part into a centrifuging tube, add exactly 20 ml of dichloromethane, shake for 10 minutes, and centrifuge. Refer to the resulting supernatant as solution B. Measure the absorbances of solutions A and B (A_A, and A_B) at a wavelength of 485 nm against dichloromethane. Determine the amount of the subsidiary colors by the following formula.

Note: The above procedure should be conducted while avoiding light exposure.

$$\text{Amount}\,(\%) = \frac{A_B}{A_A \times 10 + A_B} \times 100$$

Loss on Drying Not more than 0.10%.

Assay Weigh accurately about 0.05 g of Canthaxanthin, dissolve in 10 ml of chloroform, and add cyclohexane to make exactly 50 ml. Measure exactly 5 ml of this solution, and add cyclohexane to make exactly 100 ml. To 5 ml of the second solution, exactly measured, add cyclohexane to make exactly 100 ml. Measure the absorbance (A) of the resulting solution at the maximum at about 470 nm.

$$\text{Canthaxanthin}\ (C_{40}H_{52}O_2)(\%) = \frac{200}{\text{Weight (g) of the sample}} \times \frac{A}{2{,}200} \times 100$$

Storage standards Store in a hermetic container, protected from light, under inert gas.

Reagents and Solutions

Dichloromethane CH_2Cl_2 [K8161]