

การปรับปรุงแก้ไขมาตรฐานสารเคมีตกค้างและสารปรุงแต่งอาหาร
The 235th Materials for Promotion of Food Import Facilitation

กระทรวงสาธารณสุข แรงงานและสวัสดิการญี่ปุ่น พิจารณาปรับปรุงแก้ไขมาตรฐานสารเคมีตกค้างทางการเกษตร และสารปรุงแต่งอาหาร (Food Additives) ตามพระราชบัญญัติสุขอนามัยอาหารญี่ปุ่น สรุปสาระสำคัญ ดังนี้

(๑) ปรับปรุงแก้ไขมาตรฐานสารเคมีทางการเกษตร จำนวน ๖ รายการ

๑	ชื่อสารเคมี	Oxazosulfyl
	ประเภทสารเคมี	Pesticide : Insecticide
	การใช้ในประเทศญี่ปุ่น	ไม่อนุญาตให้ใช้ในประเทศญี่ปุ่น
	การปรับปรุงแก้ไข	กระทรวงสาธารณสุขญี่ปุ่นปรับปรุงมาตรฐานสำหรับอาหารบางรายการ เนื่องจากกระทรวงเกษตรญี่ปุ่นกำลังจะอนุญาตการใช้สารกำจัดแมลงดังกล่าวในอาหารบางรายการ เช่น ข้าว ผลิตภัณฑ์เนื้อสัตว์ ผลิตภัณฑ์ประมง ผลการปรับปรุงแก้ไขได้เพิ่มความเข้มงวดต่ออาหารรายการใดๆ
๒	ชื่อสารเคมี	Cartap, Thiocyclam and Bensultap
	ประเภทสารเคมี	Pesticide : Insecticide
	การใช้ในประเทศญี่ปุ่น	อนุญาตการใช้ในประเทศญี่ปุ่น
	การปรับปรุงแก้ไข	สารกำจัดแมลง ๓ รายการดังกล่าว มีปฏิกิริยาทางเคมีเหมือนกัน จึงกำหนดมาตรฐานการตกค้างครอบคลุมทั้ง ๓ รายการรวมทั้งเมตาบอไลต์ กระทรวงสาธารณสุขญี่ปุ่นพิจารณาปรับปรุงมาตรฐานที่บังคับใช้มาตั้งแต่ปี ๒๕๔๙ เพิ่มความเข้มงวดต่ออาหารเกือบทุกรายการ
๓	ชื่อสารเคมี	Fenhexamid
	ประเภทสารเคมี	Pesticide : Fungicide
	การใช้ในประเทศญี่ปุ่น	อนุญาตการใช้ในประเทศญี่ปุ่น
	การปรับปรุงแก้ไข	ปรับปรุงมาตรฐานการตกค้างสำหรับผลกีวี่โดยอ้างอิงมาตรฐาน CODEX พร้อมกับการพิจารณาปรับปรุงมาตรฐานอาหารรายการอื่นๆในโอกาสเดียวกัน เพิ่มความเข้มงวดต่อผลแตงกวา
๔	ชื่อสารเคมี	Prohydrojasmon
	ประเภทสารเคมี	Pesticide : Plant growth regulator / repellent
	การใช้ในประเทศญี่ปุ่น	อนุญาตการใช้ในประเทศญี่ปุ่น
	การปรับปรุงแก้ไข	กำหนดมาตรฐานใหม่สำหรับมะเขือเทศ ปรับปรุงมาตรฐานส้มแมนดารินให้ครอบคลุมการทดสอบที่ครอบคลุมเปลือกส้ม

ร่างมาตรฐานและรายละเอียดที่ปรากฏในเอกสารแนบท้าย อาจได้รับการปรับปรุงแก้ไขอีก ก่อนหรือหลังการประกาศใช้ ขอความร่วมมือตรวจสอบข้อมูลที่เป็นปัจจุบัน (Update) ก่อนอ้างอิงใช้งาน

๕	ชื่อสารเคมี	Flometoquin
	ประเภทสารเคมี	Pesticide : Insecticide
	การใช้ในประเทศญี่ปุ่น	อนุญาตการใช้ในประเทศญี่ปุ่น
	การปรับปรุงแก้ไข	กำหนดมาตรฐานใหม่สำหรับหน่อไม้ฝรั่ง (0.07 ppm) มะม่วง (0.05 ppm) ดอกกะหล่ำ ฯลฯ และ แก้ไขมาตรฐานสำหรับมะเขือเทศ (1 ppm→2 ppm)
๖	ชื่อสารเคมี	Tildipirosin
	ประเภทสารเคมี	Veterinary drugs : Antibiotic
	การใช้ในประเทศญี่ปุ่น	ไม่อนุญาตให้ใช้ในประเทศญี่ปุ่น
	การปรับปรุงแก้ไข	ปรับปรุงมาตรฐาน ลดความเข้มงวดในการใช้ยาปฏิชีวนะดังกล่าว สำหรับผลิตภัณฑ์เนื้อโคและเนื้อสุกรตามที่สหภาพยุโรปนำเสนอข้อมูลทางวิชาการ ห้ามการตกค้างในอาหารรายการอื่น ๆ ที่ไม่ปรากฏในตารางแนบท้าย

(๒) ขึ้นทะเบียนและปรับปรุงมาตรฐานการใช้สารปรุงแต่งอาหาร Food Additives

กระทรวงสาธารณสุขญี่ปุ่นกำลังจะขึ้นทะเบียน อนุญาตการใช้สารปรุงแต่ง/วัตถุเจือปนอาหาร จำนวน ๒ รายการ เช่นเดียวกับสหรัฐอเมริกาและสหภาพยุโรป ได้แก่ Dipotassium L-Tartrate และ Metatartaric Acid โดยอนุญาตการใช้เฉพาะการผลิตเหล้าองุ่น เพื่อชะลอ/ป้องกันการเน่าตัวของกรดเกลือ กำจัดกรดในกระบวนการผลิตเหล้าองุ่น

ในโอกาสเดียวกันนี้ กระทรวงสาธารณสุขญี่ปุ่นพิจารณาปรับปรุงมาตรฐานที่กำหนดสำหรับการใช้สารปรุงแต่ง Calcium Carbonate ซึ่งได้รับการขึ้นทะเบียน อนุญาตการใช้ในประเทศญี่ปุ่นมาตั้งแต่ปี ๒๕๐๐ เพิ่มเติม โดยกำหนดมาตรฐาน Calcium Carbonate (Double Salt) ขึ้นใหม่ สำหรับการใช้กำจัดกรดในกระบวนการผลิตเหล้าองุ่น เช่นเดียวกับมาตรฐานที่ใช้ในสหรัฐอเมริกาและสหภาพยุโรป

หน่วยงานที่เกี่ยวข้องในประเทศไทย สามารถติดต่อ ขอความร่วมมือกระทรวงสาธารณสุขญี่ปุ่น พิจารณาแก้ไขปรับปรุงมาตรฐานที่บังคับใช้แล้ว ให้สอดคล้องกับมาตรฐานของประเทศไทยได้ โดยรวบรวม นำเสนอข้อมูลทางวิชาการสนับสนุน ประกอบการพิจารณาของกระทรวงสาธารณสุขญี่ปุ่นได้เสมอ (Based on Application)

หากสามารถนำส่งข้อมูล ภายในวันที่ ๑๕ กันยายน ๒๕๖๓ กระทรวงสาธารณสุข อาจพิจารณาปรับปรุงแก้ไขร่างมาตรฐานใหม่อีก ก่อนรวบรวมแจ้ง WTO/SPS ในโอกาสต่อไป

ร่างมาตรฐานและรายละเอียดที่ปรากฏในเอกสารแนบท้าย อาจได้รับการปรับปรุงแก้ไขอีก ก่อนหรือหลังการประกาศใช้ ขอความร่วมมือตรวจสอบข้อมูลที่เป็นปัจจุบัน (Update) ก่อนอ้างอิงใช้งาน

**Item to be explained(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 13, Paragraph 1 of the act is not permitted to be marketed in Japan unless it complies with the established standards

On May 29, 2006, Japan introduced the Positive List System¹ for agricultural and veterinary chemicals in food. All foods distributed in the Japanese marketplace are subject to regulation of the system.

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

**Pesticides : Oxazosulfyl, Cartap, Thiocyclam and Bensultap, Fenhexamid,
Prohydrojasmon, Flometoquin**
Veterinary drugs : Tildipirosin

<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 Tuesday, September 15, 2020. 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>

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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

Oxazosulfyl (pesticides: Insecticide): Not permitted for use in Japan. The MHLW is going to establish MRL in a certain commodity in response to a request for setting it by the Ministry of Agriculture, Forestry and Fisheries (MAFF) with the intention to newly register this substance as a pesticide. This action will not strengthen the current regulation for any commodities.

Cartap, Thiocyclam and Bensultap (pesticides: Insecticide): Permitted for use in Japan. The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the MAFF with the intention to expand its use pattern. In addition, the MHLW is going to modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System.

Fenhexamid (pesticides: Fungicide): Permitted for use in Japan. The MHLW is going to establish MRL in one commodity 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).

Prohydrojasmon (pesticides: Plant growth regulator/repellent): Permitted for use in Japan. The MHLW is going to establish MRL in one commodity in response to a request for setting it by the MAFF with the intention to expand its use pattern. This action will not strengthen the current regulation for any commodities.

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

Tildipirosin (veterinary drugs: antibiotic): Not permitted for use in Japan as a veterinary drug. 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.

Oxazosulfyl

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	0.01		Request		1
Cattle, muscle	0.01		Request		1
Pig, muscle	0.01		Request		1
Other terrestrial mammals, muscle	0.01		Request		1
Cattle, fat	○ 0.2		Request		1
Pig, fat	○ 0.2		Request		1
Other terrestrial mammals, fat	○ 0.2		Request		1
Cattle, liver	○ 0.06		Request		1
Pig, liver	○ 0.06		Request		1
Other terrestrial mammals, liver	○ 0.06		Request		1
Cattle, kidney	0.01		Request		1
Pig, kidney	0.01		Request		1
Other terrestrial mammals, kidney	0.01		Request		1
Cattle, edible offal	○ 0.06		Request		1
Pig, edible offal	○ 0.06		Request		1
Other terrestrial mammals, edible offal	○ 0.06		Request		1
Milk	0.01		Request		1
Chicken, muscle	0.01		Request		1
Other poultry, muscle	0.01		Request		1
Chicken, fat	○ 0.02		Request		1
Other poultry, fat	○ 0.02		Request		1
Chicken, liver	○ 0.05		Request		1
Other poultry, liver	○ 0.05		Request		1
Chicken, kidney	○ 0.05		Request		1
Other poultry, kidney	○ 0.05		Request		1
Chicken, edible offal	○ 0.05		Request		1
Other poultry, edible offal	○ 0.05		Request		1
Chicken eggs	0.01		Request		1
Other poultry, eggs	0.01		Request		1
Fish	○ 0.05		Request		1

The residue definition is Oxazosulfyl 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 increased.

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

Cartap, Thiocyclam and Bensultap

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Rice (brown rice)	○ 0.3	0.2	§		1
Wheat	●	0.2			1
Barley	●	0.2			1
Rye	●	0.2			1
Corn (maize, including pop corn and sweet corn)	● 0.1	0.2	§		1
Buckwheat	●	0.2			1
Other cereal grains	0.2	0.2	§		1
Potato	0.1	0.1	§		1
Taro	0.1	0.1	§		1
Sweet potato	● 0.05	0.1	§		1
Japanese yam (including Chinese yam)	●	0.1			1
Konjac	●	0.1			1
Other potatoes	●	0.1			1
Sugar beet	○ 0.2		Request		1
Japanese radish, roots (including radish)	● 0.5	3	§		1
Japanese radish, leaves (including radish)	3	3	§		1
Turnip, roots (including rutabaga)	●	3			1
Turnip, leaves (including rutabaga)	●	3			1
Horseradish	●	3			1
Watercress	●	3			1
Chinese cabbage	● 2	3	§		1
Cabbage	● 0.7	3	§		1
Brussels sprouts	●	3			1
Kale	●	3			1
Komatsuna (Japanese mustard spinach)	●	3			1
Kyona	●	3			1
Qing-geng-cai	● 2	3	§		1
Cauliflower	●	3			1
Broccoli	● 2	3	§		1
Other cruciferous vegetables	● 1	3	§		1
Burdock	●	3			1
Salsify	●	3			1
Artichoke	●	3			1
Chicory	●	3			1
Endive	●	3			1
Shungiku	● 0.8	3	§		1
Lettuce (including cos lettuce and leaf lettuce)	● 2	3	§		1
Other composite vegetables	● 0.5	3	§		1
Onion	● 0.2	3	§		1
Welsh (including leek)	○ 5	3	§ • Request		1
Garlic	●	3			1
Nira	● 1	3	§		1
Asparagus	● 0.7	3	§		1
Multiplying onion (including shallot)	● 0.7	3	§		1
Other liliaceous vegetables	●	3			1
Carrot	●	3			1
Parsnip	●	3			1
Parsley	●	3			1
Celery	○ 15	3	Request		1
Mitsuba	●	3			1
Other umbelliferous vegetables	●	3			1

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Tomato	●	3			
Pimiento (sweet pepper)	●	3			
Egg plant	●	3			
Other solanaceous vegetables	●	3			
Cucumber (including gherkin)	●	3			
Pumpkin (including squash)	●	3			
Oriental pickling melon (vegetable)	●	3			
Water melon	●	3			
Melons	●	3			
Makuwauri melon	●	3			
Other cucurbitaceous vegetables	●	3			
Spinach	3	3	§		
Bamboo shoots	●	3			
Okra	●	3			
Ginger	● 0.2	3	§		
Peas, immature (with pods)	3	3	§		
Kidney beans, immature (with pods)	● 2	3	§		
Green soybeans	●	3			
Button mushroom	●	3			
Shiitake mushroom	●	3			
Other mushrooms	●	3			
Other vegetables	● 1	3	§		
Unshu orange, pulp	●	3			
Citrus natsudaiddai, whole	●	3			
Lemon	●	3			
Orange (including navel orange)	●	3			
Grapefruit	●	3			
Lime	●	3			
Other citrus fruits	●	3			
Apple	●	3			
Japanese pear	●	3			
Pear	●	3			
Quince	●	3			
Loquat	3	3	§		
Loquat (whole commodity after removal of stems)	0.4	3	§		
Peach	●	3			
Nectarine	●	3			
Apricot	●	3			
Japanese plum (including prune)	●	3			
Mume plum	●	3			
Cherry	●	3			
Strawberry	●	3			
Raspberry	●	3			
Blackberry	●	3			
Blueberry	●	3			
Cranberry	●	3			
Huckleberry	●	3			
Other berries	●	3			
Grape	● 2	3	§		
Japanese persimmon	● 0.4	3	§		
Banana	●	3			

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Kiwifruit		3	§		
Kiwifruit (whole commodity)	6		§		
Papaya	●	3			
Avocado	●	3			
Pineapple	●	3			
Guava	●	3			
Mango	●	3			
Passion fruit	●	3			
Date	●	3			
Other fruits	●	3			
Sunflower seeds	●	3			
Sesame seeds	●	3			
Safflower seeds	●	3			
Cotton seeds	●	3			
Rapeseeds	●	3			
Other oil seeds	●	3			
Ginkgo nut	●	3			
Chestnut	● 0.03	3	§		
Pecan	●	3			
Almond	●	3			
Walnut	●	3			
Other nuts	●	3			
Tea	30	30	§		
Hop	10	10	§		
Other spices	●	3			
Other herbs	● 1	3	§		

The residue definition will be sum of Cartap hydrochloride, Cartap, Thiocyclam hydrogen oxalate, Thiocyclam, Bensultap, metabolite A[*N,N*-dimethyl-1,2-dithiolan-4-amine] and Metabolites that are hydrolyzed and oxidized into metabolite A under basic conditions, expressed as Cartap hydrochloride .
Current residue definition is sum of Cartap and Thiocyclam, expressed as Cartap hydrochloride.

* 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 a food category to which MRL applies is not set.

* 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.

○ : Commodities for which MRLs are to be increased.

§ : Permitted for use in Japan.

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

Fenhexamid

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Beans, dry	0.05	0.05	\$		
Watercress	30	30			30 ¹ USA
Other cruciferous vegetables	30	30			30 ¹ USA
Chicory	30	30			30 ¹ USA
Endive	30	30			30 ¹ USA
Shungiku	30	30			30 ¹ USA
Lettuce (including cos lettuce and leaf lettuce)	30	30		30	
Other composite vegetables	30	30			30 ¹ USA
Onion	0.05	0.05	\$		
Parsley	30	30			30 ¹ USA
Tomato	2	2	\$	2	
Pimiento (sweet pepper)	2	2		2	
Egg plant	2	2	\$	2	
Other solanaceous vegetables	2	2		2	
Cucumber (including gherkin)	● 1	2	\$	1	
Pumpkin (including squash)	1	1		1	
Other vegetables	30	30			30 ¹ USA
Unshu orange, pulp	/	0.5	\$		
Unshu orange (whole commodity)	5	/	\$		
Citrus natsudaidai, whole	5	5	\$		
Lemon	5	5	\$		
Orange (including navel orange)	5	5	\$		
Grapefruit	5	5	\$		
Lime	5	5	\$		
Other citrus fruits	5	5	\$		
Apple	2	2	\$		
Peach	/	0.7	\$		
Peach (whole commodity after removal of stems and stones but the residue calculated and expressed on the whole commodity without stems)	10	/	\$	10	
Nectarine	10	10		10	
Apricot	10	10		10	
Japanese plum (including prune)	1	1	\$	1	
Mume plum	6	6			
Cherry	10	10	\$	7	
Strawberry	10	10	\$	10	
Raspberry	15	15		15	
Blackberry	15	15		15	
Blueberry	5	5		5	
Huckleberry	5	5		5	
Other berries	15	15		15	
Grape	20	20	\$	15	
Kiwifruit (whole commodity)	○ 15		IT	15	
Other fruits	3	3			
Almond	0.02	0.02		0.02	
Other nuts	0.02	0.02			0.02 ¹ USA
Hop	100	100	\$		
Other spices	20	20	\$		
Other herbs	30	30			30 ¹ USA
Cattle, muscle	0.05	0.05			
Pig, muscle	0.05	0.05			
Other terrestrial mammals, muscle	0.05	0.05			
Cattle, fat	0.05	0.05		0.05	

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Pig, fat	0.05	0.05		0.05	↓
Other terrestrial mammals, fat	0.05	0.05		0.05	↓
Cattle, liver	0.05	0.05		0.05	↓
Pig, liver	0.05	0.05		0.05	↓
Other terrestrial mammals, liver	0.05	0.05		0.05	↓
Cattle, kidney	0.05	0.05		0.05	↓
Pig, kidney	0.05	0.05		0.05	↓
Other terrestrial mammals, kidney	0.05	0.05		0.05	↓
Cattle, edible offal	0.05	0.05		0.05	↓
Pig, edible offal	0.05	0.05		0.05	↓
Other terrestrial mammals, edible offal	0.05	0.05		0.05	↓
Milk	0.01	0.01		0.01	↓
Raisin※1				25	↓

The residue definition is Fenhexamid 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 a food category to which MRL applies is not set.

* 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.

○ : Commodities for which MRLs are to be increased.

§ : Permitted for use in Japan.

IT: Import tolerance application

※1) For processed foods "Raisin", the MRL of this raw commodity (Grape) will be applied, taking into account of its processing factor. JMPR estimated this processing factor as following: 1.86 for Raisin.

Prohydrojasmon

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Tomato	○ 0.3		Request		↓
Unshu orange, pulp	↗	0.01	§		↓
Unshu orange (whole commodity)	0.02	↘	§		↓
Citrus natsudaidai, whole	0.01	0.01	§		↓
Lemon	0.01	0.01	§		↓
Orange (including navel orange)	0.01	0.01	§		↓
Grapefruit	0.01	0.01	§		↓
Lime	0.01	0.01	§		↓
Other citrus fruits	0.01	0.01	§		↓
Apple	0.01	0.01	§		↓
Grape	0.01	0.01	§		↓
Other spices	0.03	0.03	§		↓

The residue definition will be Prohydrojasmon 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 a food category to which MRL applies is not set.

* 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 increased.

§ : Permitted for use in Japan.

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

Flometoquin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Japanese radish, roots (including radish)	0.1	0.1	§		1
Japanese radish, leaves (including radish)	5	5	§		1
Chinese cabbage	2	2	§		1
Cabbage	0.5	0.5	§		1
Cauliflower	○ 6		Request		1
Broccoli	○ 6		Request		1
Onion	0.05	0.05	§		1
Welsh (including leek)	1	1	§		1
Nira	○ 6		Request		1
Asparagus	○ 0.7		Request		1
Multiplying onion (including shallot)	○ 2		Request		1
Tomato	○ 2	1	§ · Request		1
Pimiento (sweet pepper)	2	2	§		1
Egg plant	1	1	§		1
Water melon	/	0.05	§		1
Water melon (whole commodity after removal of stems)	0.7	/	§		1
Spinach	2	2	§		1
Unshu orange, pulp	/	0.05	§		1
Unshu orange (whole commodity)	0.7	/	§		1
Citrus natsudaikai, whole	1	1	§		1
Lemon	1	1	§		1
Orange (including navel orange)	1	1	§		1
Grapefruit	1	1	§		1
Lime	1	1	§		1
Other citrus fruits	1	1	§		1
Strawberry	2	2	§		1
Mango	○ 0.5		Request		1
Tea	5	5	§		1
Other spices	3	3	§		1
Other herbs	○ 2		Request		1

The residue definition is Flometoquin 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 a food category to which MRL applies is not set.

* 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 increased.

§ : Permitted for use in Japan.

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

Tildipirosin

Commodity	MRL (draft) ppm	MRL (current) ppm	Registration	Reference MRL	
				Codex ppm	National ppm
Cattle, muscle	○ 0.4		IT		0.4 ¹ EU
Pig, muscle	○ 1	0.6	IT		1.2 ¹ EU
Cattle, fat	○ 0.2		IT		0.2 ¹ EU
Pig, fat	○ 0.8	0.6	IT		0.8 ¹ EU
Cattle, liver	○ 2		IT		2 ¹ EU
Pig, liver		5	IT		5 ¹ EU
Cattle, kidney	○ 3		IT		3 ¹ EU
Pig, kidney		10	IT		10 ¹ EU
Cattle, edible offal	○ 3		IT		¹
Pig, edible offal		10	IT		¹

The residue definition is Tildipirosin only.

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

○ : Commodities for which MRLs are to be increased.

IT : Import tolerance application

Notes:

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

“Beans, dry” includes butter beans, cowbeans (red beans), lentil, lima beans, pedia, 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, pimienta (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 spices (limited to roots and rhizome)” includes asafoetida roots, turmeric root, galangal rhizome and licorice root.

“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” refers to all poultry, except chicken.

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

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

Item 2

Designation of Food Additives and Establishment of Specifications and Standards (Dipotassium L-tartrate, Metatartaric acid, and Calcium carbonate (double salt))

The government of Japan is taking necessary steps to designate two substances (Dipotassium L-tartrate and Metatartaric acid) as food additives and establish compositional specifications and use standards for the substances and Calcium carbonate (double salt).

Summary

Japan prohibits the sale etc. of food additives which are not designated by the Minister of Health, Labour and Welfare (“the Minister”) under Article 12 of the Food Sanitation Act (Act No. 233 of 1947; “the Act”). In addition, when specifications or standards for food additives are stipulated in the Specifications and Standards for Foods, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959) pursuant to Article 13 of the Act, the sale etc. of those additives are prohibited unless they meet the specifications or the standards.

1. Dipotassium L-tartrate

On August 25, 2020, the Committee on Food Additives of the Food Sanitation Council established under the Pharmaceutical Affairs and Food Sanitation Council (“the Committee”) deliberated on Dipotassium L-tartrate and concluded that it is appropriate for this substance to be designated as a food additive that is unlikely cause harm to human health pursuant to Article 12 of the Act. The Committee also concluded that it is appropriate for compositional specifications and use standards to be established for the additive pursuant to Article 13 of the Act. See Attachment 2a for the details.

Notes

Dipotassium L-tartrate is known as a deacidification agent (or a tartar generation inhibitor). Dipotassium L-tartrate added in wine before the completion of a finished product combines with excess acids to forcibly generate tartar (the main component is potassium hydrogen L-tartrate). By filtration of the resulting tartar, the acids are removed.

The European Union permits deacidification treatment in wine production within the range in which the maximum reduction of total acid does not exceed 1 g/L (tartaric acid basis) in wine. The United States allows the domestic distribution of dipotassium L-tartrate-treated wine products imported from EU countries, although the additive is not contained in the “materials authorized for the treatment of wine and juice” (27 CFR 24.246).

2. Metatartaric acid

On August 25, 2020, the Committee deliberated on Metatartaric acid and concluded that it is appropriate for this substance to be designated as a food additive that is unlikely cause harm to human health pursuant to Article 12 of the Act. The Committee also concluded that it is appropriate for compositional specifications and use standards to be established for the additive pursuant to Article 13 of the Act. See Attachment 2b for the details.

Notes

Metatartaric acid is a crystallization inhibitor. It delays the formation and precipitation of tartaric salts to prevent the generation of lees in wine.

The EU permits the use of Metatartaric acid in the wine production at a level not exceeding 100 mg/L. The United States allows the domestic distribution of dipotassium L-tartrate treated wine products imported from EU countries, although the additive is not contained in the “materials authorized for the treatment of wine and juice” (27 CFR 24.246). Australia and New Zealand permit the use of the additive in wine under GMP (the Good Manufacture Practice) compliance.

3. Calcium carbonate (double salt)

On August 25, 2020, the Committee deliberated on Calcium carbonate (double salt) and concluded that it is appropriate for compositional specifications and use standards to be established for this substance pursuant to Article 13 of the Act, separately from the specifications for Calcium carbonate. See Attachment 2c for the details.

Notes

Calcium carbonate (double salt) consists of not less than 98.0% of calcium carbonate (CaCO_3) and it is produced by a method through which the resulting product possibly

contains the calcium double salt of L-tartaric and L-malic acids. When used in grape juice used for wine production or wine, Calcium carbonate crystalizes organic acids, such as malic acid, with the aid of the calcium double salt of L-tartaric and L-malic acids as seed crystals, to precipitate and remove these acids.

The EU and the United States permit the use of calcium carbonate (double salt) in wine. Japan designated Calcium carbonate as a food additive in 1957.

Dipotassium L-Tartrate

L-酒石酸カリウム

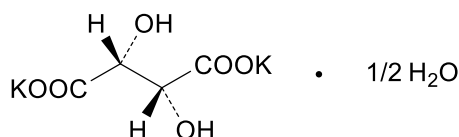
Standards for Use (draft)

Permitted for use in grape juice used for wine production and grape wine only.

Compositional Specifications (draft)

Substance Name Dipotassium L-Tartrate

Structural Formula



Molecular Formula $C_4H_4K_2O_6 \cdot 1/2 H_2O$

Molecular Weight 235.28

Chemical Name [CAS number]

Dipotassium (2*R*,3*R*)-2,3-dihydroxybutanedioate hemihydrate [6100-19-2]

Content Dipotassium L-Tartrate, when dried, contains not less than 99.0% of dipotassium L-tartrate ($C_4H_4K_2O_6 = 226.27$).

Description Dipotassium L-Tartrate occurs as colorless to white crystals or fine granular powder.

Identification

(1) A solution of Dipotassium L-Tartrate (1 in 10) is dextrorotatory.

(2) Dipotassium L-Tartrate responds to responds to test (1) for Calcium Salt and to all tests for Tartrate in the Qualitative Tests.

Specific Rotation $[\alpha]_D^{20}$: +27.2 to +29.7° (5 g, water, 50 mL, on the dried basis).

pH 7.0–9.0 (0.5 g, water 50 mL).

Purity

(1) Lead Not more than 5 µg/g as Pb (0.80 g, Method 3, Control Solution: Lead Standard Solution 4.0 mL, Flame Method).

(2) Arsenic Not more than 3 µg/g as As (0.50 g, Method 1, Standard Color: Arsenic

Standard Solution 3.0 mL, Apparatus B).

(3) Oxalate Not more than 100 µg/g as C₂H₂O₄ (on the dried basis).

Test Solution Weigh accurately an amount equivalent to about 0.1 g of Dipotassium L-Tartrate on the dried basis, and add sulfuric acid TS (0.01 mol/L) to dissolve it and to make exactly 20 mL.

Control Solution Weigh accurately an amount equivalent to about 10 mg of oxalic acid dihydrate on the dried basis, and add sulfuric acid TS (0.01 mol/L) to dissolve it and to make exactly 100 mL. To exactly 0.5 mL of this solution, add sulfuric acid TS (0.01 mol/L) to make exactly 200 mL.

Procedure Analyze 10-µL portions of the test solution and the control solution by liquid chromatography using the operating conditions given below. Measure the peak area of oxalic acid for each of the test and control solutions by the automatic integration method. The peak area for the test solution is not larger than that for the control solution.

Operating Conditions

Detector: Ultraviolet spectrophotometer (wavelength: 210 nm).

Column: A stainless steel tube (6–8 mm internal diameter and 30 cm length). If necessary, two connected columns may be used.

Column packing material: 8-µm H-form cation-exchange resin for liquid chromatography.

Guard column: Use a column with the same internal diameter that is packed with the same packing material as for the column above.

Column temperature: 50°C.

Eluent: Sulfuric acid TS (0.01 mol/L).

Flow rate: 0.6 mL/min.

Loss on Drying Not more than 4.0% (150°C, 4 hours).

Assay Weigh accurately about 0.2 g of Dipotassium L-Tartrate, previously dried, add 3 mL of formic acid, and dissolve it by warming. Add 50 mL of acetic acid for nonaqueous titration, and titrate with 0.1 mol/L perchloric acid. Usually a potentiometer is used to confirm the endpoint. When crystal violet–acetic acid TS (1 mL) is used as the indicator, the endpoint is when the color of the solution changes from purple through blue to green. Separately, perform a blank test to make any necessary correction.

Each mL of 0.1 mol/L perchloric acid = 11.31 mg of C₄H₄K₂O₆

Reagents, Solutions, and Other Reference Materials

Sulfuric Acid TS (0.01 mol/L) Add water to 10 mL of sulfuric acid TS (1 mol/L) to make 1000 mL.

Metatartaric Acid

メタ酒石酸

Standards for Use (draft)

Permitted for use in grape wine only. Shall be used at not more than 0.10 g/kg in grape wine.

Compositional Specifications (draft)

Substance Name Metatartaric Acid

Chemical Name [CAS number]

Metatartaric Acid [39469-81-3]

Definition Metatartaric Acid is a polydisperse mixture of molecules with various chain lengths and branches. It is obtained by heating L-tartaric acid under atmospheric or vacuum pressure and partially esterifying the resulting fused substance.

Content Metatartaric Acid contains the equivalent of 99.5–113% of L-tartaric acid ($C_4H_6O_6 = 150.09$).

Description Metatartaric Acid occurs as deliquescent, white to yellowish white crystals or powder. It has a slight odor like caramel.

Identification Metatartaric Acid responds to all tests for Tartrate in the Qualitative Tests.

pH 1.4–2.2 (1.0 g, water 100 mL).

Purity

(1) Clarity of solution Almost clear (1.0 g, water 10 mL).

Almost clear (1.0 g, ethanol (95) 30 mL).

(2) Degree of esterification Not less than 32%.

Calculate the esterification value of Metatartaric Acid by the formula:

$$\text{Degree of esterification (\%)} = \frac{(20 - b)}{(a + 20 - b)} \times 100$$

Determine a and b according to the procedure given in the Assay.

a = volume (mL) of 1 mol/L sodium hydroxide consumed,

b = volume (mL) of 0.5 mol/L sulfuric acid consumed.

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

(4) Arsenic Not more than 3 µg/g as As (0.50 g, Method 1, Standard Color: Arsenic

Standard Solution 3.0 mL, Apparatus B).

Assay Weigh quickly and accurately about 2 g of Metatartaric Acid, and dissolve it in water to make exactly 100 mL. Transfer exactly 50 mL of this solution into a flask, and immediately titrate with 1 mol/L sodium hydroxide (indicator: 10 drops of bromothymol blue TS). The endpoint is when the color of the solution changes to bluish green. Refer to the amount of the sodium hydroxide consumed as a mL. Add 20 mL of 1 mol/L sodium hydroxide to the flask, stopper, allow to stand for 2 hours, and immediately titrate with 0.5 mol/L sulfuric acid. The endpoint is when the color of the solution changes to bluish green. Refer to the amount of the sulfuric acid consumed as b mL. Calculate the content of metatartaric acid by the formula:

$$\text{Content (\%)} \text{ of metatartaric acid (as L-tartaric acid } \text{C}_4\text{H}_6\text{O}_6) = \frac{(a + 20 - b) \times 15.01}{\text{Weight (g) of the sample}}$$

Storage Standards Store in a hermetic container, protected from moisture.

Calcium Carbonate (Double Salt)

炭酸カルシウム (複塩)

Standards for Use (draft)

Permitted for use in grape juice used for wine production and grape wine only.

Compositional Specifications (draft)

Substance Name Calcium Carbonate (double salt)

Molecular Formula CaCO_3

Molecular Weight 100.09

Chemical Name [CAS number]

Calcium carbonate [471-34-1, Calcium carbonate]

Definition Calcium Carbonate (double salt) consists mainly of calcium carbonate and it is produced by a method through which the resulting product possibly contains the calcium double salt of L-tartaric and L-malic acids.

Content Calcium Carbonate, when calculated on the dried basis, contains 98.0–102.0% of calcium carbonate (CaCO_3).

Description Calcium Carbonate occurs as a fine white powder. It is odorless.

Identification To 1 g of Calcium Carbonate, add 10 mL of water and 7 mL of diluted acetic acid (1 in 4). It effervesces and dissolves. When boiled and neutralized with ammonia TS, this solution responds to all tests for Calcium Salt in the Qualitative Tests.

Purity

(1) Hydrochloric acid-insoluble substances Not more than 0.20%.

Weigh 5.0 g of Calcium Carbonate, add 10 mL of water, then gradually add 12 mL of hydrochloric acid dropwise while stirring, and add water to make 200 mL. Filter through a filter paper for quantitative analysis (5C), and wash the residue on the filter paper with boiling water until the washings are free of chloride. Heat gradually the residue together with the filter paper to carbonization, incinerate at 450–550°C for 3 hours or more, and weigh.

(2) Free alkali Weigh 3.0 g of Calcium Carbonate, add 30 mL of freshly boiled and cooled water, shake for 3 minutes, and filter the solution. To 20 mL of the filtrate, add 2 drops of phenolphthalein TS. A pink color develops, and it disappears when 0.20 mL of 0.1 mol/L hydrochloric acid is added.

(3) Lead Not more than 3 µg/g as Pb (2.0 g, Method 5, Control Solution: Lead Standard Solution 6.0 mL, Flame Method).

Sample Solution To the specified amount of Calcium Carbonate, add 20 mL of diluted hydrochloric acid (1 in 4), and boil gently for 15 minutes with a watch glass covering it. Allow to cool, add 30 mL of water, and use the resulting solution as the sample solution. If the sample does not dissolve completely, evaporate it to dryness, and add 20 mL of diluted hydrochloric acid (1 in 4) to the residue. Boil gently for 5 minutes with a watch glass covering it, allow to cool, and add 30 mL of water.

In Method 5 of the Lead Limit Test, use 50 mL of a solution of diammonium hydrogen citrate (1 in 2) and 1 mL of bromothymol blue TS as the indicator instead of thymol blue TS, and then add ammonia solution until the color of the solution changes from yellow to yellow-green.

(4) Alkali metals and magnesium Not more than 1%.

Weigh 1.0 g of Calcium Carbonate, dissolve it by gradually adding 30 mL of diluted hydrochloric acid (1 in 10), and let the carbon dioxide out by boiling. Cool, neutralize with ammonia TS, add 60 mL of a solution of ammonium oxalate monohydrate (1 in 25), and heat on a water bath for 1 hour. After cooling, add water to make 100 mL, and stir thoroughly. Centrifuge it, and filter the supernatant. Measure 50 mL of the filtrate, add 0.5 mL of sulfuric acid, evaporate to dryness, ignite to constant weight at 600°C, and weigh.

(5) Barium Not more than 0.030% as Ba.

Test Solution Weigh 1.0 g of Calcium Carbonate, dissolve it in 8 mL of diluted hydrochloric acid (1 in 4), and add water to make 20 mL.

Procedure Add 2 g of sodium acetate trihydrate, 1 mL of diluted acetic acid (1 in 20), and 0.5 mL of potassium chromate solution (1 in 20) to the test solution, and allow to stand for 15 minutes. The solution is not more turbid than a control solution prepared as follows: To 0.30 mL of Barium Standard Solution, add water to make 20 mL, and then treat in the same manner as for the test solution.

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

Test Solution Weigh the specified amount of Calcium Carbonate, moisten with 1 mL of water, and dissolve it in 4 mL of diluted hydrochloric acid (1 in 4).

Loss on Drying Not more than 2.0% (200°C, 4 hours).

Assay Weigh accurately about 2 g of Calcium Carbonate, and add gradually exactly 50 mL of 1 mol/L hydrochloric acid. Heat the container containing the solution in a water bath for about 10 minutes. After cooling, titrate the excess hydrochloric acid with 1mol/L sodium hydroxide (indicator: 4–5 drops of methyl red TS). The endpoint is when red color of the solution changes to yellow. Calculate on the dried basis.

Each mL of 1 mol/L hydrochloric acid = 50.04 mg of CaCO₃