

## THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

Voluntary \_ Public

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### Japan

Post: Tokyo

# Japan proposes the revision of MRLs for 6 agricultural chemicals

**Report Categories:** Sanitary/Phytosanitary/Food Safety

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#### **Report Highlights:**

On November 16, 2015, the Ministry of Health, Labor and Welfare (MHLW) of the Government of Japan (GOJ) announced changes to the Maximum Residue Levels (MRLs) for Amisulbrom, Benzofenap, Etofenprox, Isoxaflutole, Pyroquilon. MHLW also proposed the revision of analytical methods for Zinc Sulfate, a food additive.

The Embassy comment period for these proposals is open until Monday, November 30, 2015. MHLW will also notify these MRLs to the WTO, which will allow another opportunity for interested parties to comment on these changes.

#### **General Information:**

On November 16, 2015, the Ministry of Health, Labor and Welfare (MHLW) of the Government of Japan (GOJ) announced changes to the Maximum Residue Levels (MRLs) for Amisulbrom, Benzofenap, Etofenprox, Isoxaflutole, Pyroquilon. MHLW also proposed the revision of analytical methods for Zinc Sulfate, a food additive.

The Embassy comment period for these proposals is open until Monday, November 30, 2015. MHLW will also notify these MRLs to the WTO, which will allow another opportunity for interested parties to comment on these changes.

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

The WTO/SPS notifications 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:

#### Pesticide/Veterinary drug/Feed additive

Mr. Ryouta Nakamura (<u>nakamura-ryouta@mhlw.go.jp</u>) Standards and Evaluation Division, Department of Environmental Health and Food Safety, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare 1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916 Tel: 03-5253-1111, ext. 2487 Fax: 03-3501-4868

#### Food additive

Mr. Takahiro Ikegami (<u>ikegami-takahiro@mhlw.go.jp</u>) Standards and Evaluation Division, Department of Environmental Health and Food Safety, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare 1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916 Tel: 03-5253-1111 (ex. 2459) Fax: 03-3501-4868 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.

MHLW's draft proposal follows:

#### Item 1: Establishment of Standards for Agricultural Chemicals in Food

The Food Sanitation Act authorizes the Minister 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 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<sup>1</sup> for agricultural chemicals in food. Basically, all foods distributed in the Japanese marketplace are subject to regulation of the system.

The MHLW has comprehensively reviewed existing MRLs to modify those that were provisionally set at the introduction of the system. In addition, the MHLW is going to establish MRLs for some commodities. This activity has been targeted at five pesticides (Amisulbrom, Benzofenap, Etofenprox, Isoxaflutole, Pyroquilon).

<sup>1</sup> 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

### (1) Establishment of Maximum Residue Limits for Agricultural Chemicals in Food Amisulbrom (pesticide: herbicide): Permitted for use in Japan.

The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the Ministry of Agriculture, Forestry and Fisheries (MAFF). This action will not strengthen the current regulation for any commodities.

#### Benzofenap (pesticide: insecticide): 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.

#### Etofenprox (pesticide: insecticide): Permitted for use in Japan

The MHLW is going to establish MRLs in some commodities in response to a request for setting MRLs by the Ministry of Agriculture, Forestry and Fisheries (MAFF).

#### Isoxaflutole (pesticide: herbicide): 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).

#### Pyroquilon (pesticide: fungicide): Permitted for use in Japan.

The MHLW is going to establish MRLs in the fish/shellfish in response to the MAFF's request, and modify MRLs in some commodities that were provisionally set at the introduction of the Positive List System. This action will not strengthen the current regulation for any commodities.

#### Amisulbrom

		MRL	MRL		R	eference MRL
Commodity		(draft) ppm	(current) ppm	Registration	Codex ppm	National ppm
Rice (brown rice)	0	0.05	0.05	6		
Soybeans, dry	0	0.3	0.3	6		-
Beans, dry	0	0.2	0.2	5		-
Potato	0	0.05	0.05			
Sugar beet	0	1	1	ş		
Japanese radish, roots (including radish)	0	0.3	0.3	ş		
Japanese radish, leaves (including radish)	0	25	25			
Turnip, roots (including rutabaga)	0	0.5	0.5	-		
Turnip, leaves (including rutabaga)	0	30	30			
Chinese cabbage	0	10	10	ş		
Cabbage	0	3	3	ş		
Kale	0	20	20			
Komatsuna(Japanese mustard spinach)	0	15	15			
Kyona	0	20	20	5		
Qing-geng-cai	0	20	20	6		
Cauliflower	0	2	2	6		
Broccoli	0	2	2			
Other cruciferous vegetables	0	20	20	6		
Lettuce (including cos lettuce and leaf lettuce)	0	20		Request • §		-
Onion	0	0.05	0.05			
Welsh (including leek)	0	3	3	6		
Other liliaceous vegetables	0	0.05		Request		
Tomato	0	2	2	§		
Pimiento (sweet pepper)	0	3	3			
Egg plant	0	1	1	8		
Other solanaceous vegetables	0	5		Request		
Cucumber (including gherkin)	0	0.7	0.7	§		-
Pumpkin (including squash)	0	2	2	3		
Water melon	0	0.05	0.05			
Melons	0	0.05	0.05	¥		
Spinach	0	30	30			
	0	0.7	0.7	9		
Ginger Green soubeans	-	10	10			
Green soybeans	0	0.1	0.1	6		
Unshu orange, pulp Citrus patsudaidai, whole	-	-		6		
Citrus natsudaidai, whole	0	2	2	ě s		
Lemon	0		2			
Orange (including navel orange)	0	2		60		
Grapefruit	0	2	2			
Lime Other sites faite	0	2	2			
Other citrus fruits	0	2	2	-		
Strawberry	0	0.05	0.05	-		
Grape	0	5	5	-		-
Other fruits	0	1	1	6		
Other spices	0	15	15	×		
Other herbs	0	20	20	9		

Note: The residue definition is Amisulbrom 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.

 $\bigcirc\ :\ \mbox{Commodities}$  for which MRLs were maintained or increased

§ : Permitted for use in Japan.

Request : The MRL was modified in response to MAFF request

Benzofenap

	MRL	MRL		R	eference MRL
Commodity	(draft)	(current)	Registration	Codex	National
	ppm	ppm		ppm	ppm
Rice (brown rice)	• 0.05	0.1	§		

Note: The residue definition is Benzofenap 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.

• : Commodities for which MRLs were lowered

§ : Permitted for use in Japan.

#### Etofenprox

	MRL		MRL		Reference MRL		
Commodity	(draft	t)	(current)	Registration	Codex	National	
	ppm		ppm		ppm	ppm	
Rice (brown rice)	0	0.5	0.5	§			
Wheat	0	0.5	0.5	§			
Barley	0	0.5	0.5				
Rye	0	0.5	0.5			1	
Corn (maize, including pop corn and sweet corn		0.3	0.5	§	0.05		
Other cereal grains	0	3		Request			
Soybeans, dry	0	0.2	0.2	§	0.05		
Beans, dry		0.2	0.2	ş	0.05		
Peas		.05	0.05	§			
Broad beans		.05	0.05	§	0.05		
Peanuts, dry		.05	0.05	§			
Other pulses		.05	0.05	§	0.05		
Potato		.05	0.1	§	0.00		
Taro		0.1	0.1	ş	$\vdash$		
Sweet potato		.03	0.1				
Yam		0.1	0.1				
Sugar beet		0.1	0.1	9 §			
Sugarcane		.03	0.5				
			2				
Japanese radish, roots (including radish)	0	2				:	
Japanese radish, leaves (including radish)	0	10	10	§			
Turnip, roots (including rutabaga)	0	2	2				
Turnip, leaves (including rutabaga)	0	10	10				
Chinese cabbage	0	5	5	§			
Cabbage	0	2	2	§			
Brussels sprouts	0	2	2				
Broccoli	0	10		Request			
Other cruciferous vegetables	0	1	1	§			
Lettuce (including cos lettuce and leaf lettuce)	0	2	2	§			
Other composite vegetables	0	2	2	§			
Welsh (including leek)	0	2	2	§			
Multiplying onion (including shallot)	0	2	2				
Mitsuba	0	5	5	§			
Other umbelliferous vegetables	0	2	2	§			
Tomato	0	2	2	§			
Pimiento (sweet pepper)	0	5	5	§			
Egg plant	0	2	2	ş			
Other solanaceous vegetables	0	2	2				
Cucumber (including gherkin)	•	1	2	§		1	
Pumpkin (including squash)	0	1	1	ŝ			
Water melon	0	2	2	§		1	
Melons	0	2	2	§		1	
Makuwauri melon	0	2	2				
Other cucurbitaceous vegetables	0	1	1	§			
Okra	0	3	3	ş			
Ginger	0	2	2	ş			
Peas, immature (with pods)	0	2	2	ş	$\vdash$		
Kidney beans, immature (with pods)	0	2	2	ş	$\vdash$		
Green soybeans	•	-2	5				
Other vegetables	•	10		য Request ∙ §			
Unshu orange, pulp	0	2	2				
	0	2	3	\$ \$			

	Γ	MRL	MRL		R	eference MRL
Commodity		(draft)	(current)	Registration	Codex	National
		ppm	`ppm ´	Ũ	ppm	ppm
Lemon	0	5	5	§		
Orange (including navel orange)	0	5	5	§		
Grapefruit	0	5	5	§		
Lime	0	5	5	ş		
Other citrus fruits	0	5	5	Ş		
Apple	0	2	2	ş	0.6	
Japanese pear	0	2	2	ş	0.6	
Pear	0	2	2	§	0.6	
Peach	0	2	2	ŝ		
Nectarine	0	0.6	0.6		0.6	
Grape	0	4	4		4	
Japanese persimmon	0	2	2	ş		
Mango	0	5	5	§		
Rapeseeds	0	0.01	0.01	-	0.01	
Chestnut	0	2	2	§		
Tea	0	10	10	§		
Other spices	0	20	20	ş		
Other herbs	0	0.7	0.7	§		
Cattle, muscle	0	0.5	0.5			
Pig, muscle	0	0.5	0.5			
Other terrestrial mammals, muscle	0	0.5	0.5			
Cattle, fat	0	7	7		0.5	
Pig, fat	0	7	7		0.5	
Other terrestrial mammals, fat	0	7	7		0.5	
Cattle, liver	0	0.5	0.5		0.05	
Pig, liver	0	0.5	0.5		0.05	
Other terrestrial mammals, liver	0	0.5	0.5		0.05	
Cattle, kidney	0	0.5	0.5		0.05	
Pig, kidney	0	0.5	0.5		0.05	
Other terrestrial mammals, kidney	0	0.5	0.5		0.05	
Cattle, edible offal	0	0.5	0.5		0.05	
Pig, edible offal	0	0.5	0.5		0.05	
Other terrestrial mammals, edible offal	0	0.5	0.5		0.05	
Milk	0	0.5	0.5		0.02	
Chicken, muscle	0	0.01	0.01		0.01	
Other poultry animals, muscle	0	0.01	0.01		0.01	
Chicken, fat	•	0.2	0.5			
Other poultry animals, fat	٠	0.2	0.5			
Chicken, liver	0	0.02	0.02		0.01	
Other poultry animals, liver	0	0.02	0.02		0.01	-
Chicken, kidney	0	0.02	0.02		0.01	
Other poultry animals, kidney	0	0.02	0.02		0.01	
Chicken, edible offal	0	0.02	0.02		0.01	
Other poultry animals, edible offal	0	0.02	0.02		0.01	
Chicken, eggs	•	0.01	0.1		0.01	
Other poultry, eggs	•	0.01	0.1		0.01	
Fish	0	0.8	0.8			
Raisin	0	8	8		8	

Note: The residue definition is Etofenprox 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 lowered
- $\bigcirc\ :\ \mbox{Commodities}$  for which MRLs were maintained or increased
- § : Permitted for use in Japan.

Request : The MRL was modified in response to MAFF request

Isoxaflutole

		MRL	MRL		R	eference MRL
Commodity		(draft)	(current)	Registration	Codex	National
-		ppm	ppm	-	ppm	ppm
Corn (maize, including pop corn and sweet corn	•	0.02	0.02		0.02	
Soybeans, dry	0	0.05		IT		0.05 USA
Other pulses	٠	0.03	0.03		0.01	
Sugarcane	٠	0.01	0.01		0.01	
Cattle, muscle	٠	0.01	0.2		0.01	
Pig, muscle	٠	0.01	0.2		0.01	
Other terrestrial mammals, muscle	٠	0.01	0.2		0.01	
Cattle, fat	٠	0.01	0.2		0.01	
Pig, fat	٠	0.01	0.2		0.01	
Other terrestrial mammals, fat	٠	0.01	0.2		0.01	
Cattle, liver	٠	0.1	0.5		0.1	
Pig, liver	0	0.1	0.1		0.1	
Other terrestrial mammals, liver	0	0.1	0.1		0.1	
Cattle, kidney	0	0.1	0.1		0.1	
Pig, kidney	0	0.1	0.1		0.1	
Other terrestrial mammals, kidney	0	0.1	0.1		0.1	
Cattle, edible offal	0	0.1	0.1		0.1	
Pig, edible offal	0	0.1	0.1		0.1	
Other terrestrial mammals, edible offal	0	0.1	0.1		0.1	
Milk	٠	0.01	0.02		0.01	•
Chicken, muscle	٠	0.01	0.2		0.01	
Other poultry animals, muscle	٠	0.01	0.2		0.01	
Chicken, fat	٠	0.01	0.2		0.01	
Other poultry animals, fat	٠	0.01	0.2		0.01	
Chicken, liver	٠	0.2	0.3		0.2	
Other poultry animals, liver	٠	0.2	0.3		0.2	
Chicken, kidney	0	0.2	0.1		0.2	
Other poultry animals, kidney	0	0.2	0.1		0.2	
Chicken, edible offal	0	0.2	0.1		0.2	
Other poultry animals, edible offal	0	0.2	0.1		0.2	
Chicken, eggs	0	0.01	0.01		0.01	
Other poultry, eggs	0	0.01	0.01		0.01	

Note: The residue definition will be changed to "the sum of Isoxaflutole and its metabolite B [2-cyano-3-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylphenyl)propane-1,3-dione], expressed as Isoxaflutole" for both agricultural and animal products. The current residue definitions are "Isoxaflutole only" for agricultural products, and "Isoxaflutole and its medtabolite B, expressed as Isoxaflutole" for animal products.

\* 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 lowered
- $\bigcirc\ :\ \mbox{Commodities}$  for which MRLs were maintained or increased
- IT : Import tolerance

#### Pyroquilon

	MRL	MRL		R	eference MRL
Commodity	(draft)	(current)	Registration	Codex	National
	ppm	ppm		ppm	ppm
Rice (brown rice)	<ul> <li>0.2</li> </ul>	0.2	ş		
Fish	o 0.2		Request		

Note: The residue definition is Pyroquilon 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.

 $\bigcirc\ :\ \mbox{Commodities}$  for which MRLs were maintained or increased

§ : Permitted for use in Japan.

Request : The MRL was modified in response to MAFF request

Notes:

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

"Beans, dry" including butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Edible offal "refers to all edible parts, except muscle, fat, liver, and kidney "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.

"Other poultry animals" refers to all poultry, except chicken.

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

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

The government of Japan will revise the existing standards for use of zinc sulfate.

#### 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"). In addition, when specifications or standards are established for food additives based on Article 11 of the act and stipulated in the Ministry of Health, Labour and Welfare Notification (Ministry of Health and Welfare Notification No. 370, 1959), those additives shall not be used or marketed unless they meet the standards or specifications.

In response to a request from the Minister, the Committee on Food Additives of the Food Sanitation Council that is established under the Pharmaceutical Affairs and Food Sanitation Council has discussed whether the existing standards for zinc sulfate [CAS: 7446-20-0]\* should be revised.

The committee has concluded that the Minister should revise the standards, based on Article 11 of the act. See Attachment 2-1.

#### Note

Zinc sulfate was designated in 1983 for the purpose of fortifying breast milk substitutes (such as infant formula) with zinc.

The additive is used in Western countries as an essential nutrient for yeast in the fermentation process in beer production.

#### <Additional Information>

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

As of November 16, 2015, the 54 flavorings and 41 of the 45 non-flavoring additives were approved. See Attachment 2-2.

#### Attachment 2-1

#### **Revision of use standards**

#### Zinc Sulfate

#### **Current regulations**

Zink sulfate is permitted for use only in breast milk substitutes.

The use level shall not exceed 6.0 mg/L as zinc in milk formulated in a standard concentration, except when the additive is used in dry milk formulated under the approval of the Minister of Health, Labour and Welfare.

#### Revised regulations

Its use will be expanded to effervescent alcoholic beverages. The allowable maximum level is 0.0010 g/kg of beverage as zinc.

#### Definition of sparkling liquors

Effervescent alcoholic beverages are products specified by the Liquor Tax Act. They include

- ▹ beer,
- ➢ sparkling liquors,
- > other effervescent alcoholic beverages (confined to products containing less than 10 percent alcohol).

Figless of evaluation of for						16 Nov, 2015
		Food Safety	Commission		MHLW	
Substance name	Request for evaluation	Evaluation by expert committee <sup>1</sup>	Notification of result <sup>3</sup>	Discussion by subcommittee <sup>3</sup>	Closing date for comments <sup>4</sup>	Date of designation as food additives
Isobutanol		24 Mar 2004(fin.)	27 May 2004	23 Apr 2004(fin.)	19 Aug 2004	24 Dec 2004
2-Ethyl-3, (5 or 6)- dimethylpyrazine	21 Nov 2003	3 Mar 2004(fin.)	27 May 2004	8 Apr 2004(fin.)	26 Jul 2004	24 Dec 2004
2,3,5,6-Tetramethylpyrazine	1	3 Mar 2004(fin.)	27 May 2004	8 Apr 2004(fin.)	26 Jul 2004	24 Dec 2004
Calcium stearate	4 Mar 2004	20 May 2004(fin.)	29 Jul 2004	24 Jun 2004(fin.)	21 Oct 2004	24 Dec 2004
Propanol	21 Nov 2003	24 Mar 2004 20 May 2004 28 Jul 2004(fin.)	9 Sep 2004	26 Aug 2004(fin.)	14 Dec 2004	24 Feb 2005
Nitrous oxide	20 Oct 2003	17 Dec 2003 5 Oct 2004(fin.)	9 Dec 2004	17 Dec 2004(fin.)	19 Feb 2005	22 Mar 2005
Isopropanol	15 Dec 2003	24 Mar 2004 9 Apr 2004 8 Sep 2004 5 Oct 2004(fin.)	9 Dec 2004	28 Oct 2004(fin.)	4 Mar 2005	28 Apr 2005
Hydroxypropyl cellulse	16 Aug 2004	22 Dec 2004(fin.)	10 Mar 2005	24 Feb 2005(fin.)	14 Jun 2005	19 Aug 2005
Isoamylalcohol 2,3,5-Trimethylpyrazine Amylalcohol	5 Nov 2004	14 Jan 2005(fin.)	17 Mar 2005	24 Feb 2005(fin.)	14 Jun 2005	19 Aug 2005
Natamycin	20 Oct 2003	9 Jan 2004 16 Nov 2004 26 Jan 2005(fin.)	6 May 2005	24 Mar 2005(fin.)	7 Sep 2005	28 Nov 2005
Acetaldehyde	21 Nov 2003	3 Mar 2004 9 Apr 2004 27 Apr 2004 23 Feb 2005 13 Apr 2005(fin.)	21 Jul 2005	23 Jun 2005(fin.)	12 Oct 2005	16 May 2006
2-Ethyl-3-methylpyrazine 5-Methylquinoxaline	7.14 0005	14 Jun 2005(fin.)	18 Aug 2005	28 Jul 2005(fin.)	19 Dec 2005	16 May 2006
Butanol	7 Mar 2005	14 Jun 2005 22 Jul 2005(fin.)	22 Sep 2005	27 Oct 2005 24 Nov 2005(fin.)	26 Apr 2006	12 Sep 2006
Ammonium alginate Potassium alginate Calcium alginate	28 Mar 2005	2 Dec 2005 14 Dec 2005(fin.)	30 Mar 2006	23 Mar 2006(fin.)	5 Sep 2006	26 Dec 2006

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

		Food Safety	Commission		MHLW	
Substance name	Request for evaluation	Evaluation by expect committee <sup>1</sup>			Closing date for comments <sup>4</sup>	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
Acetylated distarch adipate Acetylated distarch phosphate Acetylated oxidized starch Starch sodium octenvlsuccinate Hydroxypropyl starch Hydroxypropyl distarch phosphate Phosphated distarch phosphate Distarch phosphate Distarch phosphate Oxidized starch Starch acetate	26 Nov 2004	23 Mar 2005 17 May 2005 27 Aug 2007 28 Sep 2007(fin.)	29 Nov 2007	28 Nov 2007(fin.) 4 Jul 2008(fin.)	29 May 2008	1 Oct 2008
Magnesium hydroxide	9 Mar 2006	22 Jun 2007 30 Jul 2007 27 Aug 2007(fin.)	1 Nov 2007	24 Oct 2007(fin.)	7 Feb 2008	4 Jul 2008

		Food Safety	Commission		MHLW	
Substance name	Request for evaluation	Evaluation by expert committee <sup>1</sup>	Notification of result <sup>3</sup>	Discussion by subcommittee <sup>3</sup>	Closing date for comments <sup>4</sup>	Date of designation as food additives
Magnesium Monohydrogen Phosphate	28 Mar 2005	31 May 2006 28 Jun 2006 14 Jul 2006 11 Aug 2006 13 Sep 2006 28 Nov 2006 25 Oct 2011 29 Nov 2011 16 Dec 2011(fm)	22 Mar 2012	6 Mar 2012(fin.)	22 Jul 2012	2 Nov 2012
Polyvinylpyrrolidone	20 Jun 2005	13 Sep 2006 13 Oct 2006 28 Nov 2006 19 Dec 2006 26 Jan 2007 18 Dec 2012 22 Jan 2013 22 Feb 2013 27 Mar 2013 25 Apr 2013(fin.)	30 Jul 2013	21 Jun 2013 30 Oct 2013 29 Jan 2014(fin)	Ι	18 Jun 2014
Magnesium silicate(synthetic)	15 Aug 2005	28 Feb 2007 23 Mar 2007 17 Apr 2007 28 Sep 2009 17 Nov 2009(fin.)	21 Jan 2010	25 Dec 2009(fin)	6 Jun 2010	20 Oct 2010
Sodium aluminium silicate	15 Aug 2005	28 Feb 2007 30 May 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013 (under consideration)				
Calcium aluminium silicate	15 Aug 2005	28 Feb 2007 30 May 2012 27 Jul 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013 (under consideration)				
Calcium saccharin	22 May 2006	27 Aug 2007 28 Sep 2007 26 Oct 2007 26 Apr 2011 31 May 2011 28 Jun 2011(fin)	25 Aug 2011	2 Nov 2011 (fin)	12 May 2012	28 Dec 2012

		Food Safety	Commission		MHLW	
Substance name	Request for evaluation	Evaluation by expert committee <sup>1</sup> Notification of result <sup>2</sup>		Discussion by subcommittee <sup>3</sup>		
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
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
Pvrrolidine	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
5-Ethyl-2-methylpyridine	14 Jun 2010	29 Jun 2010(fin)	26 Aug 2010	9 Sep 2010(fin)	3 Jan 2011	15 Mar 2011

		Food Safety	Commission		MHLW	
Substance name	Request for evaluation	Evaluation by expert committee <sup>1</sup> Notification of result <sup>3</sup>		Discussion by subcommittee <sup>3</sup>	Closing date for comments <sup>4</sup>	Date of designation as food additives
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 <i>H</i> - cyclopentapyrazine	12 Aug 2010	31 Aug 2010(fin)	27 Jan 2011	22 Dec 2010(fin)	1 Apr 2011	28 Jun 2011
Pyrazine	12 Aug 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
Annionium isovalerate	28 Nov 2014	-	9 Dec 2014	10 100 2013	21 May 2013	28 501 2015
8-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	I	18 Jun 2014
Carmine	19 Apr 2011	26 Jul 2011 23 Aug 2011 30 May 2012 (under consideration)				
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

		Food Safety	Commission		MHLW	
Substance name	Request for evaluation	Evaluation by expect committee <sup>1</sup>	Notification of result <sup>3</sup>	Discussion by subcommittee <sup>a</sup>	Closing date for comments <sup>4</sup>	Date of designation as food additives
Sodium aluminium phosphate,acidic	19 Apr 2011	30 May 2012 16 May 2013 28 Jun 2013 30 Jul 2013 20 Aug 2013 (under consideration)				
Calcium acetate	19 Apr 2011	24 Apr 2012 15 Nov 2012 18 Dec 2012 22 Jan 2013(fin)	15 Apr 2013	13 Mar 2013	22 Jun 2013	4 Dec 2013
Calcium oxide	19 Apr 2011	24 Apr 2012 15 Nov 2012 18 Dec 2012 22 Jan 2013(fin)	15 Apr 2013	13 Mar 2013	22 Jun 2013	22 Oct 2013
Potassium sulfate	19 Apr 2011	24 Apr 2012 26 Sep 2012 25 Oct 2012(fin.)	21 Jan 2013	6 Dec 2012	11 Mar 2013	15 May 2013
Triethyl citrate	19 Apr 2011	30 May 2012 18 Dec 2012 22 Jan 2013 22 Feb 2013 29 Sep 2014 29 Oct 2014(fin.)	17 Feb 2015	25 Dec 2014	3 Mar 2015	19 May 2015
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