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Japan

FAIRS Subject Report

Japan Proposes MRL Changes

2007

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Report Highlights:

On June 20, 2007, Japan proposed changes to the maximum residue limits (MRL) for the pesticides Uniconazole P, Tolfenpyrad, and Fenbuconazole and the establishment of standards for the veterinary drug Ceftiofur in food.

Includes PSD Changes: No
Includes Trade Matrix: No
Trade Report
Tokyo [JA1]
[JA]

The Japanese Ministry of Health Labour and Welfare (MHLW) announced in June proposed changes to the maximum residue limits (MRL) for the pesticides Uniconazole P, Tolfenpyrad, and Fenbuconazole and the establishment of standards for the veterinary drug Ceftiofur in food. The period for comments directly to MHLW closed at July 4, 2007, however MHLW will notify these proposed changes to the WTO/SPS committee, which would be the last chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a report to the Minister of Health, Labour, and Welfare will be made based on the conclusions of a session of the Pharmaceutical Affairs and Food Sanitation Council slated to be held at a later date, and this will constitute the final decision.

If you would like to comment on these proposals, please send a message to the Agriculture Section of the U.S. Embassy in Tokyo, at agtokyo@usda.gov.

Agenda 1. Establishment of Maximum Residue Limits for the Pesticides (Uniconazole P, Tolfenpyrad, and Fenbuconazole) in Food

Purpose

This activity is to develop specifications and standards for foods. Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare may establish residue standards (maximum residue limits: MRLs) for pesticides, feed additives, and veterinary drugs (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 unless such food complies with the established standards.

On May 29, 2006, the Ministry of Health, Labour and Welfare 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.

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 certain levels specified under the Law.

Outline of the activity

The chemicals—Uniconazole P (plant growth regulator), Tolfenpyrad (acaricide), and Fenbuconazole (fungicide)—are already permitted for use in Japan. The Ministry of Agriculture, Forestry and Fisheries has decided to expand the scope of target crops for which the use of these chemicals is permitted. In response to MAFF's action, the MHLW has reviewed the existing MRLs for them. The MRLs appear either in the MRLs List (Item 6, Section A "General Compositional Standards for Food," Part I "Food" in the Specifications and Standards for Food, Food Additives, Etc.) or the Provisional MRLs List (Item 7, Section A), according to crops. These MRLs have been modified as necessary. Finalized MRLs will be placed in the MRLs List in Item 6, and the MRLs currently placed in Item 7 will be deleted. For draft MRLs, see Attachments 1-1, 1-2, and 1-3.

Attachment 1-1

Uniconazole P(Plant growth Regulator)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.1	0.1
Sugar beet	0.1	0.1
Chinese cabbage		0.1
Cabbage	0.1	0.1
Brussels sprouts	0.1	0.1
Lettuce (including cos lettuce and leaf lettuce)	0.05	
Onion	0.05	
Apricot		0.1
Japanese plum (including prune)		0.1
Mume plum		0.1
Cherry		0.1
Strawberry	0.1	0.1
Raspberry		0.1
Blackberry		0.1
Blueberry		0.1
Cranberry		0.1
Huckleberry		0.1
Other berries ³		0.1
Grape		0.1
Avocado	0.5	0.02
Date		0.1
Other fruits ⁴		0.1
Other spices ⁵		0.1

Attachment. 1-2

Tolfenpyrad(Acaricide)

Commodity	MRL (draft) ppm	Current MRL ppm
Japanese radish, roots (including radish)	0.2	0.2
Japanese radish, leaves (including radish)	10	10
Turnip, roots	1	1
Turnip, leaves	25	25
Chinese cabbage	0.5	0.5
Cabbage	0.3	0.3
Broccoli	1	1
Lettuce (including cos lettuce and leaf lettuce)	10	5
Welsh (including leek)	5	5
Tomato	2	2
Pimiento (sweet pepper)	3	
Egg plant	2	2
Cucumber (including gherkin)	1	1
Water melon	0.05	0.05
Other cucurbitaceous vegetables ¹		2
Peas, immature (with pods)	2	
<i>Unshu</i> orange, pulp	0.1	0.1
Citrus <i>natsudaidai</i> , whole	3	3
Lemon	3	3
Orange (including navel orange)	3	3
Grapefruit	3	3
Lime	3	3
Other citrus fruits ²	3	3
Japanese pear	2	2
Pear	2	2
Peach	0.2	0.2
Nectarine	5	
Tea	20	15
Other spices ⁵	15	3

Attachment 1-3

Fenbuconazole(Fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Wheat	0.1	0.1
Barley	0.2	0.2
Rye	0.1	0.1
Peanuts, dry	0.1	
Cucumber (including gherkin)	0.2	0.2
Pumpkin (including squash)	0.05	0.05
Water melon		0.2
Melons	0.2	0.2
Makusauri melon	0.2	0.2
Unshu orange, pulp	1.0	
Citrus natsudaikai, whole	1.0	
Lemon	1.0	
Orange (including navel orange)	1.0	
Grapefruit	1.0	0.5
Lime	1.0	
Other citrus fruits ⁴	1.0	
Apple	1	1
Japanese pear	0.7	1
Pear	0.7	1
Quince	0.1	0.1
Loquat	0.1	0.1
Peach	0.5	0.5
Nectarine	1.0	1
Apricot	0.5	0.5
Japanese plum (including prune)	1.0	5
Mume plum	2	5
Cherry	1	1
Strawberry		5
Raspberry		5
Blackberry		5
Blueberry	0.3	5
Cranberry	0.5	5
Huckleberry	0.3	5
Other berries ⁵	0.3	5
Grape	3	3
Japanese persimmon		1
Banana	0.05	0.05
Kiwifruit		0.2
Papaya		1
Avocado		1
Pineapple		1
Guava		1
Mango		1

Note:

Fenbuconazole(Fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Passion fruit		1
Date		5
Other fruits ^a		5
Sunflower seeds	0.05	0.05
Rapeseeds	0.05	0.05
Pecan	0.05	0.05
Almond	0.05	
Tea	10	5
Other spices ^v	1.0	5
Cattle, muscle	0.05	0.05
Pig, muscle	0.01	0.01
Other terrestrial mammals ⁷ , muscle	0.01	0.01
Cattle, fat	0.05	0.05
Pig, fat		0.01
Other terrestrial mammals, fat		0.01
Cattle, liver	0.05	0.05
Pig, liver	0.01	0.01
Other terrestrial mammals, liver	0.05	0.01
Cattle, kidney	0.05	0.05
Pig, kidney	0.01	0.01
Other terrestrial mammals, kidney	0.05	0.01
Cattle, edible offal ^y	0.05	0.05
Pig, edible offal	0.01	0.01
Other terrestrial mammals, edible offal	0.05	0.01
Milk	0.05	0.05
Chicken, muscle	0.05	0.05
Other poultry ² , muscle	0.05	0.05
Chicken, fat	0.05	0.05
Other poultry, fat	0.05	0.05
Chicken, liver	0.05	0.05
Other poultry, liver	0.05	0.05
Chicken, kidney	0.05	0.05
Other poultry, kidney	0.05	0.05
Chicken, edible offal	0.05	0.05
Other poultry, edible offal	0.05	0.05
Chicken, eggs	0.05	0.05
Other poultry, eggs	0.05	0.05

Note:

The uniform limit (0.01 ppm) will be applied to commodities for which draft MRLs are not given. Some limits in the column "MRL (draft)" remain unchanged from the current MRLs.

1. "Other cucurbitaceous vegetables" refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and makuwauri melon.
2. "Other citrus fruits" refers to all citrus fruits, except unshu orange (pulp), citrus natsudaikai (pulp), citrus natsudaikai (peel), citrus natsudaikai (whole), lemon, orange (including navel orange), grapefruit, lime, and spices.
3. "Other berries" refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.
4. "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.
5. "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.
6. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.
7. "Edible offal" refers to all edible offals, except muscle, fat, liver, and kidney.
8. "Other poultry" refers to all poultry, except chicken.

Agenda 2. Establishment of Standards for the Veterinary Drug (Ceftiofur) in Food

Purpose

This activity is to develop specifications and standards for foods. Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare may 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 is not permitted to be marketed unless such food complies with the established standards.

On May 29, 2006 the Ministry of Health, Labour and Welfare 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.

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 market place if it contains agricultural chemicals at amounts exceeding certain levels specified under the Law.

Outline of the activity

Ceftiofur (antimicrobial) The chemical is permitted for use in Japan. The Ministry of Agriculture, Forestry and Fisheries has reassessed a drug product whose effective ingredient is Ceftiofur. This is on the basis of the legal requirement stating that veterinary drugs, once approved, must be reassessed every six years. In response to MAFF's assessment, the MHLW has reviewed the existing MRLs for the substance.

The MRLs for the chemical currently appearing in the Provisional MRLs List (Item 7, Section A "General Compositional Standard for Food," Part 1 "Food" in the Specifications and Standards for Food, Food Additives, Etc) have been modified as necessary. The finalized MRLs will be placed in the MRLs List (Item 6, Section A), and the MRLs placed in Item 7 will be deleted. For draft MRLs, see Attachment 2.

Attachment 2

Ceftiofur (Antimicrobial)

Commodity	Draft MRL ¹ (ppm)	Current MRL ² (ppm)
Cattle, muscle	1.0	1.0
Pig, muscle	1.0	1.0
Terrestrial mammals other than above, muscle	1	1
Cattle, fat	2.0	2.0
Pig, fat	2.0	2.0
Terrestrial mammals other than above, fat	1	2
Cattle, liver	2.0	2.0
Pig, liver	2.0	2.0
Terrestrial mammals other than above, liver	2	2
Cattle, kidney	6.0	6.0
Pig, kidney	6.0	6.0
Terrestrial mammals other than above, kidney	15	6
Cattle, edible offal ²	2	2
Pig, edible offal	2	2
Terrestrial mammals other than above, edible offal	2	2
Milk	0.1	0.1

Note: The MRLs shaded in the above table were established in Ministry of Health, Labour and Welfare Notification No. 499, 2005 (enforced on May 29, 2006).

1. Calculated as Desfuroyceftiofur.

2. "Edible offal" refers to all edible parts, except muscle, fat, liver, and kidney.