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Voluntary - Public

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### MRL Changes in Amisulbrom and other 6 chemicals

#### Report Categories:

Sanitary/Phytosanitary/Food Safety

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#### Report Highlights:

On February 3, 2010, Government of Japan announced proposed changes to the MRLs for Amisulbrom, Iprobenfos, Tolyfluanid, Pyrifluquinazon, Fluacrypyrim, Cefquinome and Olaquinox. The comment period will close on February 17, 2010. After the domestic comment period closes, MHLW will then notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject.

#### General Information:

On February 3, 2010, Government of Japan announced proposed changes to the MRLs for Amisulbrom, Iprobenfos, Tolyfluanid, Pyrifluquinazon, Fluacrypyrim, Cefquinome and Olaquinox. The period for sending comments on these changes ends February 17, 2010. Please note that GOJ proposed to drop some

MRLs. For instance, Olaquinox shall not be detected in any food in the proposed regulation. If you have comments it is best to send directly to MHLW as soon as possible. However, MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject. Then after the closing of a the comment period in the WTO, a final report 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; this will constitute the final decision.

The comments to MHLW can be either Japanese or English.

If you have comments, please send them directly to the Japanese Government at:

Please also consider copying the U.S. Embassy, Tokyo at [agtokyo@usda.gov](mailto:agtokyo@usda.gov) on your comments.

#### MHLW contact information

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### **Establishment of Maximum Residue Limits for Agricultural Chemicals in Food**

#### Background

The Ministry of Health, Labour and Welfare (MHLW) develops the compositional specification for food.

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, MHLW is authorized to establish residue standards (maximum residue limits: 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 are not permitted to be marketed in Japan unless such food 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.

MHLW periodically establishes new MRLs (draft) for food commodities, as well as has comprehensively reviews the existing MRLs. The most recent activity is targeted at seven chemicals: **Amisulbrom** (fungicide), **Iprobenfos** (fungicide), **Tolyfluanid** (fungicide), **Pyriproxyfen** (insecticide), **Fluacrypyrim** (insecticide), **Cefquinome** (veterinary drug) and **Olaquinox** (feed additives and veterinary drugs). Details are given 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 of revision

**Amisulbrom** (fungicide): This chemical is already permitted for use in Japan. Ministry of Agriculture, Forestry and Fisheries (MAFF) will expand the scope of target crops for which the use of the chemical is permitted. In response to the MAFF’s action, the MHLW has newly established MRLs (draft) for some crops and has comprehensively reviewed the existing MRLs. For draft MRLs, see Attachment 1-1.

**Iprobenfos** (fungicide): This chemical is already permitted for use in Japan. MHLW has reviewed the MRLs that had been provisionally established at the time of the introduction of the new system. Also, the MHLW has newly established a MRL (draft) for the “aquatic animals” category. For draft MRLs, see Attachment 1-2.

**Tolyfluanid** (fungicide): This chemical is not permitted for use in Japan. An application has been filed by the Korean Government with the MHLW for the establishment of MRLs for the chemical, based on the Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals Used outside Japan, published on 5 February 2004. In response to the application, the MHLW has newly established MRLs (draft) for some crops and comprehensively reviewed the existing MRLs. For

draft MRLs, see Attachment 1-3.

**Pyriproxyfen** (insecticide): This chemical is not permitted for use in Japan. This time MAFF has decided to approve the chemical based on the Agricultural Chemicals Regulation Law. In response to the MAFF's action, the MHLW has newly established MRLs (draft) for some crops. Currently, MRLs are not set for any crops. For draft MRLs, see Attachment 1-4.

**Fluacrypyrim** (insecticide): This chemical is already permitted for use in Japan. The MHLW has reviewed the MRLs which had been provisionally established at the time of the introduction of the new system. For draft MRLs, see Attachment 1-5.

The existing MRLs for **Iprobenfos**, **Tolyfluanid** and **Fluacrypyrim** appear in Provisional MRLs List (Item 7, Section A), according to food commodities. These MRLs have been modified as necessary. Finalized MRLs will be placed on the MRLs List in Item 6, and the MRLs currently placed in Item 7 will be deleted.

**Cefquinome** (antimicrobial): This chemical is permitted for use in Japan. The MHLW has comprehensively reviewed MRLs that had been provisionally established at the time of the introduction of the new system. For draft MRLs, see Attachment 1-6.

**Olaquinox** (synthetic antibacterial drug): This chemical is not permitted for use in Japan. The MHLW has comprehensively reviewed MRLs that had been provisionally established at the time of the introduction of the new system. For draft MRLs, see Attachment 1-7. Olaquinox's MRLs are planned to be deleted due to carcinogenicity.

The existing MRLs for **Cefquinome** appear in Provisional MRLs List (Item 7, Section A), according to food commodities. These MRLs have been modified as necessary. Finalized MRLs will be placed on the MRLs List in Item 6, and the MRLs currently placed in Item 7 will be deleted.

And the existing MRLs for **Olaquinox** appear in Provisional MRLs List (Item 7, Section A), according to food commodities. These MRLs have been modified as necessary. The substance will be placed in Item 5, which specifies substances that shall not be included in food. The MRLs currently placed in Item 7 will be deleted.

Attachment 1-1

Amisulbrom(fungicide)

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Commodity	MRL (draft) ppm	Current MRL ppm
Soybeans, dry	0.3	0.3
Beans, dry <sup>1</sup>	0.2	
Potato	0.05	0.05
Sugar beet	1	
Japanese radish, roots (including radish)	0.3	
Japanese radish, leaves (including radish)	25	
Chinese cabbage	10	
Cabbage	3	
Kale	20	
<i>Komatsuna</i> (Japanese mustard spinach)	15	
<i>Kyona</i>	20	
Qing-geng-cai	20	
Broccoli	2	
Other cruciferous vegetables <sup>2</sup>	20	
Lettuce (including cos lettuce and leaf lettuce)	10	
Tomato	2	2
Pimiento (sweet pepper)	3	
Egg plant	1	
Cucumber (including gherkin)	0.7	0.7
Melons	0.05	0.05
Spinach	30	
Green soybeans	10	
<i>Unshu</i> orange, pulp	0.1	
Citrus <i>natsudaidai</i> , whole	2	
Lemon	2	
Orange (including navel orange)	2	
Grapefruit	2	
Lime	2	
Other citrus fruits <sup>5</sup>	2	
Strawberry	0.05	
Grape	5	3
Other spices <sup>8</sup>	15	
Other herbs <sup>9</sup>	20	

The uniform limit (0.01 ppm) is applied to commodities not in this list.

Attachment 1-2  
Iprobenfos(fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
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Rice (brown rice)	0.2	0.2
Fish and shellfish	0.3	

The uniform limit (0.01 ppm) is applied to commodities not in this list.

#### Attachment 1-3

##### Tolylfluand(fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Lettuce (including cos lettuce and leaf lettuce)	15	15
Welsh (including leek)	2	2
Tomato	3	3
Pimiento (sweet pepper)	2	2
Other solanaceous vegetables <sup>3</sup>	1	
Cucumber (including gherkin)	1	1
Other vegetables <sup>4</sup>	0.05	
Apple	5	5
Japanese pear	5	5
Pear	5	5
Quince	5	5
Loquat	5	5
Strawberry	5	5
Raspberry	5	5
Blackberry	5	5
Blueberry		20
Cranberry		20
Huckleberry		20
Other berries <sup>6</sup>	0.5	5
Grape	3	3
Other fruits <sup>7</sup>		0.5
Hop	50	50
Other spices <sup>8</sup>		0.5
Pepper, dried	20	

The uniform limit (0.01 ppm) is applied to commodities for which no numerical level is given in draft MRL.

The uniform limit is also applied to all other commodities not in this list.

#### Attachment 1-4

##### Pyrifluquinazon(insecticide)

Commodity	MRL (draft) ppm	Current MRL ppm
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Potato	0.2	
Cabbage	0.5	
Lettuce (including cos lettuce and leaf lettuce)	10	
Tomato	1	
Pimiento (sweet pepper)	1	
Egg plant	0.3	
Cucumber (including gherkin)	0.2	
<i>Unshu</i> orange, pulp	0.2	
Citrus <i>natsudaikai</i> , whole	1	
Lemon	1	
Orange (including navel orange)	1	
Grapefruit	1	
Lime	1	
Other citrus fruits <sup>5</sup>	1	
Apple	0.5	
Japanese pear	1	
Pear	1	
Peach	0.2	
Nectarine	0.7	
Strawberry	2	
Grape	3	
Japanese persimmon	0.5	
Tea (green,black,oolong and wulong tea)	20	
Other spices <sup>8</sup>	5	

The uniform limit (0.01 ppm) is applied to commodities not in this list.

The MRLs for pyrifluquinazon are established for the sum of residues of pyrifluquinazon and its metabolite B [1, 2, 3, 4-tetrahydro-3-[(3-pyridylmethyl)amino]-6-[1, 2, 2, 2-tetrafluoro-1-(trifluoromethyl)ethyl]quinazoline-2-one], calculated as pyrifluquinazon.

#### Fluacrypyrim(insecticide)

Commodity	MRL (draft) ppm	Current MRL ppm
<i>Unshu</i> orange, pulp	0.05	0.1
Citrus <i>natsudaikai</i> , whole	0.5	0.5
Lemon	0.5	0.5
Orange (including navel orange)	0.5	0.5
Grapefruit	0.5	0.5
Lime	0.5	0.5
Other citrus fruits <sup>5</sup>	0.5	0.5
Apple	2	2
Japanese pear	2	2

Pear	2	2
Quince		2
Nectarine		2
Japanese persimmon		2
Banana		2
Papaya		2
Avocado		2
Pineapple		2
Guava		2
Mango		2
Passion fruit		2
Other spices <sup>8</sup>	5	0.5

The uniform limit (0.01 ppm) is applied to commodities for which no numerical level is given in draft MRL.

The uniform limit is also applied to all other commodities not in this list.

#### Attachment 1-6

##### Cefquinome (antimicrobial)

Commodity	MRL (draft) ppm	Current MRL ppm
Cattle, muscle	0.02	0.04
Pig, muscle	0.05	0.05
Other terrestrial mammals <sup>10</sup> , muscle	0.05	0.05
Cattle, fat	0.02	0.04
Pig, fat	0.05	0.05
Other terrestrial mammals, fat	0.05	0.05
Cattle, liver	0.02	0.04
Pig, liver	0.1	0.1
Other terrestrial mammals, liver	0.1	0.1
Cattle, kidney	0.02	0.04
Pig, kidney	0.2	0.2
Other terrestrial mammals, kidney	0.2	0.2
Cattle, edible offal <sup>11</sup>	0.02	0.04
Pig, edible offal	0.2	0.1
Other terrestrial mammals edible offal	0.2	0.1
Milk	0.02	0.02

Cefquinome will not be permitted to remain in any food not in this list.

#### Attachment 1-7

##### Olaquinox (synthetic antibacterial drug)

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Commodity	MRL (draft) ppm	Current MRL ppm
Pig, muscle		0.3
Pig, fat		0.3
Pig, liver		0.3
Pig, kidney		0.3
Pig, edible offal <sup>11</sup>		0.3
Chicken, muscle		0.3
Other poultry animals <sup>12</sup> , muscle		0.3
Chicken, fat		0.3
Other poultry animals, fat		0.3
Chicken, liver		0.3
Other poultry animals liver		0.3
Chicken, kidney		0.3
Other poultry animals, kidney		0.3
Chicken, edible offal		0.3
Other poultry animals, edible offal		0.3

Olaquinox shall not be included in food.

The metabolite 3-methylquinoxaline-2-carboxylic acid is the marker compound for residues of Olaquinox.

Note:

1. “Beans (dry)” includes butter beans, cowbeans (red beans), lentil, lima beans, pegia, sultani, sultapya, and white beans.
2. “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.
3. “Other solanaceous vegetables” refers to all solanaceous vegetables, except tomato, pimienta (sweet pepper), and egg plant.
4. “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.
5. “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.

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

7. “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.

8. “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.

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

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

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

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