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MRL Changes in Cyflufenamid and other 6 chemicals

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Sanitary/Phytosanitary/Food Safety

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Report Highlights:

On March 30, 2010, Government of Japan announced proposed changes to the MRLs for **Cyflufenamid** (fungicide), **Spiromesifen** (insecticide), **Prothioconazole** (fungicide), **Pentoxazone** (herbicide), **1-methylcyclopropene** (plant growth regulators), **Lufenuron** (insecticide) and **Oxibendazole** (veterinary drug). The domestic comment period has closed already however MHLW will 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 March 30, 2010, Government of Japan announced proposed changes to the MRLs for **Cyflufenamid** (fungicide), **Spiromesifen** (insecticide), **Prothioconazole** (fungicide), **Pentoxazone** (herbicide), **1-methylcyclopropene** (plant growth regulators), **Lufenuron** (insecticide) and **Oxibendazole** (veterinary drug). The comment period has closed already, however MHLW will notify these proposed changes to the WTO/SPS committee, which will provide another chance for public comments to be submitted on this subject.

The actual 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 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.

Establishment of Maximum Residue Limits for Agricultural Chemicals in Food

Purpose and Background

The Ministry of Health, Labour and Welfare (MHLW) is responsible for developing the compositional specifications for food.

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the 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 is 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.

This time the MHLW has newly established MRLs (draft) for some food commodities as well as has comprehensively reviewed the current MRLs. This activity is targeted to seven chemicals: **Cyflufenamid** (fungicide), **Spiromesifen** (insecticide), **Prothioconazole** (fungicide), **Pentoxazone** (herbicide), **1-methylcyclopropene** (plant growth regulators), **Lufenuron** (insecticide) and **Oxibendazole** (veterinary drug). 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

Cyflufenamid (fungicide): This chemical is already permitted for use in Japan. 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 1-1.

Spiromesifen (insecticide): This chemical is already permitted for use in Japan. This time the 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 1-2.

Prothioconazole (fungicide): This chemical is not permitted for use in Japan. An application has been filed by a foreign business with the MHLW for the establishment of MRLs for the substance, 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 request by the manufacturer, the MHLW has newly established MRLs (draft) for some crops. Currently, MRLs are not set for any crops. For draft MRLs, see Attachment 1-3.

Pentoxazone (herbicide): This chemical is already permitted for use in Japan. MAFF will expand the scope of target crops for which the use of the chemical is permitted. In response to the MAFF's action, MHLW has newly established MRLs (draft) for some crops. In addition, the MHLW has newly established an MRL (draft) for the "aquatic animals" category. For draft MRLs, see Attachment 1-4.

1-methylcyclopropene (plant growth regulators): 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. For draft MRLs, see Attachment 1-5.

Lufenuron (insecticide): This chemical is already permitted for use in Japan. This time MAFF will expand the scope of target crops for which the use of the chemical is permitted. Also, an application has been filed by a foreign business 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 MAFF's action and the manufacture's

application, the MHLW has newly established MRLs (draft) for some crops and comprehensively reviewed the existing MRLs. For draft MRLs, see Attachment 1-6.

The existing MRLs for **Cyflufenamid** and **Lufenuron** 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.

Oxibendazole (antiparasitics): 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.

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

Cyflufenamid (fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Wheat	0.3	0.5
Barley	0.7	1
Rye	0.7	1
Corn (maize, including pop corn and sweet corn)		1
Buckwheat		1
Other cereal grains ¹	0.7	1
Tomato	0.5	0.5
Pimiento (sweet pepper)	1	1
Egg plant	0.3	0.5
Other solanaceous vegetables ⁹		1
Cucumber (including gherkin)	0.3	0.5
Pumpkin (including squash)	0.3	0.5
Oriental pickling melon (vegetable)	0.2	0.5
Water melon	0.02	0.1
Melons	0.02	0.1
Makuwauri melon		0.1
Other cucurbitaceous vegetables ¹⁰	0.5	0.5
Okra		1
Other vegetables ¹²		0.5

Other citrus fruits ¹³		5
Apple	0.7	1
Japanese pear		1
Pear		1
Quince		1
Loquat		0.1
Peach	0.05	0.1
Nectarine		1
Apricot		5
Japanese plum (including prune)	0.3	5
Mume plum		5
Cherry	5	5
Strawberry	0.7	5
Raspberry		5
Blackberry		5
Blueberry		5
Cranberry		5
Huckleberry		5
Other berries ¹⁴		5
Grape		5
Japanese persimmon	0.5	1
Banana		1
Kiwifruit		0.1
Papaya		1
Avocado		1
Pineapple		1
Guava		1
Mango		1
Passion fruit		1
Date		5
Other fruits ¹⁵		5
Other spices ¹⁸		5
Other herbs ¹⁹		0.5

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

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

Spiromesifen (insecticide)

Commodity	MRL (draft) ppm	Current MRL ppm
Wheat	0.01	0.01
Barley	0.01	0.01
Corn (maize, including pop corn and sweet corn)	0.02	0.02
Other cereal grains ¹	0.01	0.01
Potato	0.02	0.02
Taro	0.02	0.02
Sweet potato	0.02	0.02
Yam	0.02	0.02
Other potatoes ⁴	0.02	0.02
Sugar beet	0.01	0.01
Watercress	12	12
Cabbage	2.0	2.0
Brussels sprouts	2.0	2.0
Kale	12	12
Kyona	12	12
Qing-geng-cai	12	12
Cauliflower	2.0	2.0
Broccoli	2.0	2.0
Other cruciferous vegetables ⁵	12	12
Chicory	12	12
Endive	12	12
Shungiku	12	12
Lettuce (including cos lettuce and leaf lettuce)	12	12
Other composite vegetables ⁶	12	12
Parsley	12	12
Other umbelliferous vegetables ⁸	12	12
Tomato	3	0.7
Pimiento (sweet pepper)	3	0.45
Egg plant	2	0.45
Other solanaceous vegetables ⁹	0.45	0.45
Cucumber (including gherkin)	0.1	0.1
Pumpkin (including squash)	0.1	0.1
Oriental pickling melon (vegetable)	0.1	0.1
Water melon	0.3	0.1

Melons	0.1	0.1
Makuwauri melon	0.1	0.1
Other cucurbitaceous vegetables ¹⁰	0.1	0.1
Spinach	12	12
Ginger	0.02	0.02
Other vegetables ¹²	12	12
Apple	2	2
Japanese pear	2	2
Pear	2	2
Peach	0.2	
Nectarine	1	
Apricot	5	
Japanese plum (including prune)	0.7	
Mume plum	5	
Cherry	5	5
Strawberry	2.0	2.0
Other fruits ¹⁵	0.45	0.45
Cotton seeds	0.5	0.5
Tea (green,black,oolong and wulong tea)	30	30
Tea (black,oolong and wulong tea) (except unfermented tea)	30	30
Other spices ¹⁸	10	10
Other herbs ¹⁹	10	10
Cattle, muscle	0.02	0.05
Other terrestrial mammals ²⁰ , muscle	0.02	0.05
Cattle, fat	0.1	0.05
Other terrestrial mammals, fat	0.1	0.05
Cattle, liver	0.2	0.05
Other terrestrial mammals, liver	0.2	0.05
Cattle, kidney	0.2	0.05
Other terrestrial mammals, kidney	0.2	0.05
Cattle, edible offal ²¹	0.2	0.05
Other terrestrial mammals, edible offal	0.2	0.05
Milk	0.01	0.01

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

The MRLs for spiromesifen are established for the sum of residues of spiromesifen and its metabolite M1 [4-hydroxy-3-(2,4,6-trimethylphenyl)-1-oxyaspiro[4,4]nona-3-en-2-one], calculated as spiromesifen.

Prothioconazole (fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Wheat	0.07	
Barley	0.35	
Soybeans, dry	0.15	
Beans, dry ²	0.9	
Peas	0.9	
Peanuts, dry	0.02	
Other legumes/pulses ³	0.9	
Sugar beet	0.25	
Rapeseeds	0.15	
Cattle, muscle	0.02	
Other terrestrial mammals ²⁰ , muscle	0.02	
Cattle, fat	0.1	
Other terrestrial mammals, fat	0.1	
Cattle, liver	0.2	
Pig, liver	0.05	
Other terrestrial mammals, liver	0.2	
Cattle, kidney	0.2	
Pig, kidney	0.05	
Other terrestrial mammals, kidney	0.2	
Cattle, edible offal ²¹	0.2	
Pig, edible offal	0.05	
Other terrestrial mammals, edible offal	0.2	
Milk	0.02	
Chicken, liver	0.02	
Other poultry animals ²² , liver	0.02	

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

The MRLs for prothioconazole are established for the sum of residues of prothioconazole and its metabolites M17 [2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3-(1H-1,2,4-triazole-1-yl)-2 propanol] and glucronic acid conjugates of prothioconazole and metabolite M17, calculated as prothioconazole on animal products, and for the sum of the residue of prothioconazole and metabolite M17, calculated as prothioconazole on other foods.

Pentoxazone (herbicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.05	0.1
Other cereal grains ¹	0.05	
Fish and shellfish	0.08	

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

1-methylcyclopropene (plant growth regulators)

Commodity	MRL (draft) ppm	Current MRL ppm
Apple	0.01	
Japanese pear	0.01	
Pear	0.01	
Japanese persimmon	0.01	

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

Lufenuron (insecticide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)		0.02
Wheat		0.02
Barley		0.02
Rye		0.02
Corn (maize, including pop corn and sweet corn)	0.05	0.05
Buckwheat		0.02
Other cereal grains ¹		0.02

Soybeans, dry	0.05	0.02
Beans, dry ²		0.02
Peas		0.02
Broad beans		0.02
Peanuts, dry		0.02
Other legumes/pulses ³		0.02
Potato		0.02
Taro		0.02
Sweet potato	0.02	0.05
Yam		0.02
Konjac		0.02
Other potatoes ⁴		0.02
Sugar beet	0.2	0.2
Sugarcane		0.02
Japanese radish, roots (including radish)	0.02	0.05
Japanese radish, leaves (including radish)	3	3
Turnip, roots (including rutabaga)		0.02
Turnip, leaves (including rutabaga)		0.02
Horseradish		0.02
Watercress		0.02
Chinese cabbage	1	1
Cabbage	0.7	1
Brussels sprouts	0.5	1
Kale		0.02
<i>Komatsuna</i> (Japanese mustard spinach)		0.02
<i>Kyona</i>		0.02
Qing-geng-cai		0.02
Cauliflower		0.02
Broccoli	2	0.02
Other cruciferous vegetables ⁵		0.02
Burdock		0.02
Salsify		0.02
Artichoke		0.02
Chicory		0.02
Endive		0.02
<i>Shungiku</i>		0.02
Lettuce (including cos lettuce and leaf lettuce)	1	0.02
Other composite vegetables ⁶		0.02

Onion		0.02
Welsh (including leek)	2	3
Garlic		0.02
<i>Nira</i>		0.02
Asparagus		0.02
Multiplying onion (including shallot)	1	3
Other liliaceous vegetables ⁷		0.02
Carrot		0.02
Parsnip		0.02
Parsley		0.02
Celery		0.02
<i>Mitsuba</i>		0.02
Other umbelliferous vegetables ⁸		0.02
Tomato	0.5	0.5
Pimiento (sweet pepper)	1	1
Egg plant	0.5	0.5
Other solanaceous vegetables ⁹	0.5	0.02
Cucumber (including gherkin)	0.3	0.02
Pumpkin (including squash)		0.02
Oriental pickling melon (vegetable)		0.02
Water melon		0.02
Melons		0.02
<i>Makuwauri</i> melon		0.02
Other cucurbitaceous vegetables ¹⁰		0.02
Spinach		0.02
Bamboo shoots		0.02
Okra		0.02
Ginger		0.02
Peas, immature (with pods)		0.02
Kidney beans, immature (with pods)		0.02
Green soybeans	3	0.02
Button mushroom		0.02
<i>Shiitake</i> mushroom		0.02
Other mushrooms ¹¹		0.02
Other vegetables ¹²		0.02
Unshu orange, pulp	0.02	0.3
Citrus <i>natsudaidai</i> , whole	0.3	0.3
Lemon	0.3	0.3

Orange (including navel orange)	0.3	0.3
Grapefruit	0.3	0.3
Lime	0.3	0.3
Other citrus fruits ¹³	0.3	0.3
Apple	0.7	1
Japanese pear	0.5	0.5
Pear	0.5	0.5
Quince		0.05
Loquat		0.05
Peach		0.02
Nectarine		0.02
Apricot		0.02
Japanese plum (including prune)		0.02
Mume plum		0.02
Cherry		0.02
Strawberry	1	1
Raspberry		0.02
Blackberry		0.02
Blueberry		0.02
Cranberry		0.02
Huckleberry		0.02
Other berries ¹⁴		0.02
Grape	1	1
Japanese persimmon		0.02
Banana		0.02
Kiwifruit		0.02
Papaya		0.02
Avocado		0.02
Pineapple		0.02
Guava		0.02
Mango		0.02
Passion fruit		0.02
Date		0.02
Other fruits ¹⁵		0.02
Sunflower seeds		0.02
Sesame seeds		0.02
Safflower seeds		0.02
Cotton seeds		0.2

Rapeseeds		0.02
Other oil seeds ¹⁶		0.02
Ginkgo nut		0.02
Chestnut		0.02
Pecan		0.02
Almond		0.02
Walnut		0.02
Other nuts ¹⁷		0.02
Tea	10	10
Coffee beans		0.02
Cacao beans		0.02
Hop		0.02
Other spices ¹⁸	3	0.3
Other herbs ¹⁹		0.02
Cattle, muscle	0.1	0.01
Pig, muscle	0.1	0.01
Other terrestrial mammals ²⁰ , muscle	0.1	0.01
Cattle, fat	0.3	1
Pig, fat	0.3	1
Other terrestrial mammals, fat	0.3	1
Cattle, liver	0.02	0.01
Pig, liver	0.02	0.01
Other terrestrial mammals, liver	0.02	0.01
Cattle, kidney	0.01	0.01
Pig, kidney	0.01	0.01
Other terrestrial mammals, kidney	0.01	0.01
Cattle, edible offal ²¹	0.02	0.01
Pig, edible offal	0.02	0.01
Other terrestrial mammals, edible offal	0.02	0.01
Milk	0.05	0.2
Chicken, muscle	0.01	0.01
Other poultry animals ²² , muscle	0.01	0.01
Chicken, fat	0.2	1
Other poultry animals, fat	0.2	1
Chicken, liver	0.03	0.01
Other poultry animals, liver	0.03	0.01
Chicken, kidney	0.02	0.01
Other poultry animals, kidney	0.02	0.01
Chicken, edible offal	0.03	0.01

Other poultry animals, edible offal	0.03	0.01
Chicken, eggs	0.3	0.05
Other poultry, eggs	0.3	0.05

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

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

Oxibendazole (antiparasitics)

Commodity	MRL (draft) ppm	Current MRL ppm
Cattle, muscle		0.03
Pig, muscle		0.1
Other terrestrial mammals ²⁰ , muscle		0.03
Cattle, fat		0.03
Pig, fat		0.5
Other terrestrial mammals, fat		0.03
Cattle, liver		0.03
Pig, liver		0.2
Other terrestrial mammals, liver		0.03
Cattle, kidney		0.03
Pig, kidney		0.1
Other terrestrial mammals, kidney		0.03
Cattle, edible offal ²¹		0.03
Pig, edible offal		0.1
Other terrestrial mammals edible offal		0.03
Milk		0.03
Chicken, muscle		0.03
Other poultry animals ²² , muscle		0.03
Chicken, fat		0.03
Other poultry animals, fat		0.03
Chicken, liver		0.03
Other poultry animals liver		0.03
Chicken, kidney		0.03
Other poultry animals, kidney		0.03

Chicken, edible offal		0.03
Other poultry animals, edible offal		0.03
Chicken, egg		0.03
Other poultry animals, egg		0.03
Salmoniformes		0.03
Anguilliformes		0.03
Perciformes		0.03
Other fish ²³		0.03
Shelled molluscas		0.03
Crustaceans		0.03
Other aquatic animals ²⁴		0.03
Honey		0.03

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

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

Note:

1. "Other cereal grains" refers to all cereal grains, except rice (brown rice), wheat, barley, rye, corn (maize), and buckwheat.
2. "Beans (dry)" includes butter beans, cowbeans (red beans), lentil, lima beans, pedia, sultani, sultapya, and white beans.
3. "Other legumes/pulses" refers to all legumes/pulses, except soybeans (dry), beans (dry), peas, broad beans, peanuts (dry), and spices.
4. "Other potatoes" refers to all potatoes, except potato, taro, sweet potato, yam, and konjac.
5. "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.
6. "Other composite vegetables" refers to all composite vegetables, except burdock, salsify, artichoke, chicory, endive, *shungiku*, lettuce (including cos lettuce and leaf lettuce), and herbs.

7. "Other liliaceous vegetables" refers to all liliaceous vegetables, except onion, welsh (including leek), garlic, *nira*, asparagus, multiplying onion, and herbs.
8. "Other umbelliferous vegetables" refers to all umbelliferous vegetables, except carrot, parsnip, parsley, celery, *mitsuba*, spices, and herbs.
9. "Other solanaceous vegetables" refers to all solanaceous vegetables, except tomato, pimiento (sweet pepper), and egg plant.
10. "Other cucurbitaceous vegetables" refers to all cucurbitaceous vegetables, except cucumber (including gherkin), pumpkin (including squash), oriental pickling melon (vegetable), watermelon, melons, and *makuwauri* melon.
11. "Other mushrooms" refers to all mushrooms, except button mushroom, and *shiitake* mushroom.
12. "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.
13. "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.
14. "Other berries" refers to all berries, except strawberry, raspberry, blackberry, blueberry, cranberry, and huckleberry.
15. "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.
16. "Other oil seeds" refers to all oil seeds, except sunflower seeds, sesame seeds, safflower seeds, cotton seeds, rapeseeds and spices.
17. "Other nuts" refers to all nuts, except ginkgo nut, chestnut, pecan, almond and walnut.

18. "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.
19. "Other herbs" refers to all herbs, except watercress, *nira*, parsley stems and leaves, celery stems and leaves.
20. "Other terrestrial mammals" refers to all terrestrial mammals, except cattle and pig.
21. "Edible offal" refers to all edible parts, except muscle, fat, liver, and kidney.
22. "Other poultry animals" refers to all poultry, except chicken.
23. "Other fish" refers to all fish, except salmoniformes, anguilliformes, and perciformes.
24. "Other aquatic animals" refers to all aquatic animal, except fish, shelled molluscs and crustaceans.