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MRL Changes in Spirotetramat Butamifos Milbemectin and Imidocarb

Report Categories:

Sanitary/Phytosanitary/Food Safety

Approved By:

Jeffrey Nawn

Prepared By:

Suguru Sato

Report Highlights:

On December 8, 2009, Government of Japan announced proposed changes to the MRLs for Spirotetramat, Butamifos, Milbemectin, and Imidocarb. The comment period will close on December 22, 2009. 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 to this subject.

General Information:

On December 8, 2009, Government of Japan announced proposed changes to the MRLs for Spirotetramat, Butamifos, Milbemectin, and Imidocarb. The comment period will close on December

22, 2009. Comments should be directed to MHLW as soon as possible. MHLW will also notify these proposed changes to the WTO/SPS committee, which will provide for another opportunity for public comments to be submitted. 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, which is slated to be held at a later date; this will constitute the final decision.

The comments can be either Japanese or English.

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

Standards and Evaluation Division,
Department of Food Safety,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare
1-2-2, Chiyoda-ku, Kasumigaseki, Tokyo, 100-8916
Tel: 03-5253-1111
Fax: 03-3501-4868

Pesticide

Mr. K. OGI (ogi-katsuhiro@mhlw.go.jp)
Ms. N. SARUTA (saruta-noriko@mhlw.go.jp)
Ms. A. NAKATA (nakata-ayumi@mhlw.go.jp)
Mr. H. WATANABE (watanabe-hidemi@mhlw.go.jp)
Ms. K. MIYOSHI (miyoshi-kanako@mhlw.go.jp)
Tel. ex. 2487

Veterinary drug

Mr. K. URAGAMI (uragami-kenji@mhlw.go.jp)
Mr. H. DEGUCHI (deguchi-haruyuki@mhlw.go.jp)
Mr. Y. ISHII (ishii-yasuhiroaa@mhlw.go.jp)
Tel. ex. 2489

Please also consider copying the U.S. Embassy, Tokyo at agtokyo@usda.gov on your comments in order for them to be considered as part of the official U.S. Government comments to the WTO.

Establishment of Maximum Residue Limits for Agricultural Chemicals in Food

Purpose and Background

The Ministry of Health, Labour and Welfare (MHLW) is going to develop the compositional specification 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.

MHLW is currently proposing newly established MRLs (draft) for some food commodities, and has comprehensively reviewed the current MRLs. This activity is targeted to four chemicals:

Spirotetramat (insecticide), **Butamifos** (herbicide), **Milbemectin** (insecticide), and **Imidocarb** (antiparasitics). 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

Spirotetramat (insecticide): This chemical is not currently 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 1-1.

Butamifos (herbicide): This chemical is already permitted for use in Japan. The 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.

Milbemectin (insecticide): This chemical is already permitted for use in Japan. 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 1-3.

The existing MRLs for **Butamifos** and **Milbemectin** appear in either of the MRLs List (the Item 6, Section A “General Compositional Standards for Food,” Part I “Food” of the Specifications and Standards for Food, Food Additives, Etc.) or 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.

Imidocarb (antiparasitics): This chemical is not currently 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 1-4.

The existing MRLs for **Imidocarb** 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.

Attachment 1-1

Spirotetramat (insecticide)

Commodity	MRL (draft) ppm	Current MRL ppm
Potato	0.8	
Taro	0.6	
Sweet potato	0.6	
Yam	0.6	
Other potatoes ⁴	0.6	
Japanese radish, leaves (including radish)	7	

Turnip, leaves (including rutabaga)	7	
Watercress	7	
Chinese cabbage	7	
Cabbage	0.3	
Brussels sprouts	1	
Kale	7	
<i>Komatsuna</i> (Japanese mustard spinach)	7	
Qing-geng-cai	7	
Cauliflower	1	
Broccoli	1	
Other cruciferous vegetables ⁵	7	
Chicory	7	
Endive	7	
<i>Shungiku</i>	7	
Lettuce (including cos lettuce and leaf lettuce)	3	
Other composite vegetables ⁶	7	
Onion	0.5	
Parsley	5	
Celery	5	
Other umbelliferous vegetables ⁸	5	
Tomato	1	
Pimiento (sweet pepper)	1	
Egg plant	1	
Other solanaceous vegetables ⁹	7	
Cucumber (including gherkin)	0.2	
Pumpkin (including squash)	0.2	
Oriental pickling melon (vegetable)	0.2	
Water melon	0.03	
Melons	0.03	
<i>Makuwauri</i> melon	0.03	
Other cucurbitaceous vegetables ¹⁰	7	

Spirotetramat (Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Spinach	7	

Okra	1	
Ginger	0.6	
Other vegetables ¹²	7	
Citrus <i>natsudaidai</i> , whole	1	
Lemon	1	
Orange (including navel orange)	1	
Grapefruit	1	
Lime	1	
Other citrus fruits ¹³	1	
Apple	0.7	
Japanese pear	0.7	
Pear	0.7	
Quince	0.7	
Loquat	0.7	
Nectarine	3	
Apricot	3	
Japanese plum (including prune)	3	
Mume plum	3	
Cherry	3	
Grape	2	
Mango	0.3	
Other fruits ¹⁵	1	
Cotton seeds	1	
Ginkgo nut	0.5	
Chestnut	0.5	
Pecan	0.5	
Almond	0.5	
Walnut	0.5	
Other nuts ¹⁷	0.5	
Hop	15	
Other herbs ¹⁹	7	

Spirotetramat (Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
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Cattle, muscle	0.02	
Pig, muscle	0.02	
Other terrestrial mammals ²⁰ , muscle	0.02	
Cattle, fat	0.02	
Pig, fat	0.02	
Other terrestrial mammals, fat	0.02	
Cattle, liver	0.02	
Pig, liver	0.02	
Other terrestrial mammals, liver	0.02	
Cattle, kidney	0.02	
Pig, kidney	0.02	
Other terrestrial mammals, kidney	0.02	
Cattle, edible offal ²¹	0.02	
Pig, edible offal	0.02	
Other terrestrial mammals, edible offal	0.02	
Potato flakes	1.6	
Pepper, dried	15	
Plum, dried	5	
Raisin	4	

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.

MRLs for spirotetramat are established for the sum of residues of spirotetramat and its metabolite M1 [*cis*-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one], calculated as spirotetramat.

Attachment 1-2

Butamifos (herbicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.05	0.05
Beans, dry ²		0.05
Peas		0.05
Broad beans		0.05
Peanuts, dry	0.02	0.05

Other legumes/pulses ³		0.05
Potato	0.2	0.2
Taro	0.02	0.05
Sweet potato	0.01	0.2
Yam	0.05	0.05
Konjac	0.02	0.05
Other potatoes ⁴		0.2
Japanese radish, roots (including radish)		0.05
Japanese radish, leaves (including radish)		0.05
Turnip, roots (including rutabaga)		0.05
Turnip, leaves (including rutabaga)		0.05
Horseradish		0.05
Watercress		0.05
Chinese cabbage	0.01	0.05
Cabbage	0.02	0.05
Brussels sprouts		0.05
Kale		0.05
<i>Komatsuna</i> (Japanese mustard spinach)		0.05
<i>Kyona</i>		0.05
Qing-geng-cai		0.05
Cauliflower		0.05
Broccoli	0.02	0.05
Other cruciferous vegetables ⁵	0.02	0.05
Burdock		0.05
Salsify		0.05
Artichoke		0.05
Chicory		0.05
Endive		0.05
<i>Shungiku</i>		0.05
Lettuce (including cos lettuce and leaf lettuce)	0.01	0.05
Other composite vegetables ⁶		0.05

Butamifos(Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Onion	0.02	0.05

Welsh (including leek)	0.03	0.05
Garlic	0.01	0.05
<i>Nira</i>	0.05	0.05
Asparagus	0.05	0.05
Multiplying onion (including shallot)	0.05	0.05
Other liliaceous vegetables ⁷	0.05	0.05
Carrot	0.03	0.05
Parsnip		0.05
Parsley	0.02	0.05
Celery		0.05
<i>Mitsuba</i>		0.05
Other umbelliferous vegetables ⁸	0.05	0.05
Tomato	0.02	0.05
Pimiento (sweet pepper)	0.05	0.05
Egg plant	0.02	0.05
Other solanaceous vegetables ⁹	0.05	0.05
Cucumber (including gherkin)	0.02	0.05
Pumpkin (including squash)	0.01	0.05
Oriental pickling melon (vegetable)		0.05
Water melon	0.01	0.05
Melons	0.05	0.05
<i>Makuwauri</i> melon		0.05
Other cucurbitaceous vegetables ¹⁰	0.02	0.05
Spinach		0.05
Bamboo shoots		0.05
Okra		0.05
Ginger		0.05
Other vegetables ¹²	0.02	0.05
<i>Unshu</i> orange, pulp		0.05
Citrus <i>natsudaidai</i> , whole		0.05
Lemon		0.05
Orange (including navel orange)		0.05
Grapefruit		0.05
Lime		0.05
Other citrus fruits ¹³		0.05
Loquat		0.05

Butamifos(Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Peach		0.05
Apricot		0.05
Japanese plum (including prune)		0.05
Mume plum		0.05
Cherry		0.05
Strawberry	0.05	0.05
Raspberry		0.05
Blackberry		0.05
Blueberry		0.05
Cranberry		0.05
Huckleberry		0.05
Other berries ¹⁴		0.05
Grape		0.05
Kiwifruit		0.05
Date		0.05
Other fruits ¹⁵		0.05
Other spices ¹⁸		0.05
Other herbs ¹⁹	0.05	0.05
Fish and shellfish	0.03	

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.
Attachment 1-3

Milbemectin(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)		0.02

Buckwheat		0.02
Other cereal grains ¹		0.02
Soybeans, dry	0.1	0.02
Beans, dry ²	0.2	0.2
Peas		0.2
Broad beans		0.2
Peanuts, dry		0.2
Other legumes/pulses ³		0.2
Potato		0.1
Taro		0.1
Sweet potato	0.05	0.1
Yam	0.1	0.1
Konjac		0.1
Other potatoes ⁴		0.1
Sugar beet		0.02
Sugarcane		0.02
Japanese radish, roots (including radish)		0.02
Japanese radish, leaves (including radish)		5
Turnip, roots (including rutabaga)		0.02
Turnip, leaves (including rutabaga)		5
Horseradish		0.02
Watercress		5
Chinese cabbage		0.02
Cabbage		0.02
Brussels sprouts		5
Kale		5
<i>Komatsuna</i> (Japanese mustard spinach)		5
<i>Kyona</i>		5
Qing-geng-cai		5
Cauliflower		5
Broccoli		5
Other cruciferous vegetables ⁵		5

Milbemectin (Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
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Burdock		0.02
Salsify		0.02
Artichoke		5
Chicory		5
Endive		5
<i>Shungiku</i>		5
Lettuce (including cos lettuce and leaf lettuce)		5
Other composite vegetables ⁶	2	5
Onion		0.02
Welsh (including leek)		5
Garlic		0.02
<i>Nira</i>		5
Asparagus	0.3	5
Multiplying onion (including shallot)		5
Other liliaceous vegetables ⁷		5
Carrot		0.02
Parsnip		0.02
Parsley	0.7	5
Celery	0.5	5
<i>Mitsuba</i>	1	5
Other umbelliferous vegetables ⁸		5
Tomato	0.2	0.2
Pimiento (sweet pepper)	0.2	0.02
Egg plant	0.2	0.2
Other solanaceous vegetables ⁹	0.2	0.2
Cucumber (including gherkin)	0.2	0.2
Pumpkin (including squash)		0.2
Oriental pickling melon (vegetable)		0.2
Water melon	0.2	0.2
Melons	0.2	0.2
<i>Makuwauri</i> melon		0.2
Other cucurbitaceous vegetables ¹⁰		0.2
Spinach		5
Bamboo shoots		0.02
Okra		0.02
Ginger		0.02
Peas, immature (with pods)	0.3	0.02
Kidney beans, immature (with pods)	0.3	0.02

Green soybeans	0.2	0.02
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Milbemectin (Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Button mushroom		0.02
<i>Shiitake</i> mushroom		0.02
Other mushrooms ¹¹		0.02
Other vegetables ¹²	3	5
<i>Unshu</i> orange, pulp	0.2	0.2
Citrus <i>natsudaidai</i> , whole	0.2	0.2
Lemon	0.2	0.2
Orange (including navel orange)	0.2	0.2
Grapefruit	0.2	0.2
Lime	0.2	0.2
Other citrus fruits ¹³	0.2	0.5
Apple	0.2	0.2
Japanese pear	0.2	0.2
Pear	0.2	0.2
Quince		0.2
Loquat		0.2
Peach	0.2	0.2
Nectarine	0.2	0.2
Apricot		0.5
Japanese plum (including prune)		0.5
Mume plum		0.5
Cherry	0.3	0.5
Strawberry	0.2	0.5
Raspberry		0.5
Blackberry		0.5
Blueberry		0.5
Cranberry		0.5
Huckleberry		0.5
Other berries ¹⁴		0.5
Grape	0.2	0.5
Japanese persimmon		0.2

Banana	0.1	0.2
Kiwifruit		0.2
Papaya		0.2
Avocado		0.2
Pineapple		0.2
Guava		0.2
Mango		0.2
Passion fruit		0.2
Date		0.5

Milbemectin (Continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Other fruits ¹⁵		0.5
Sunflower seeds		0.02
Sesame seeds		0.02
Safflower seeds		0.02
Cotton seeds		0.02
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 (green,black,oolong and wulong tea)	0.7	2
Coffee beans		0.02
Cacao beans		0.02
Hop		0.02
Other spices ¹⁸	0.7	5
Other herbs ¹⁹	5	5

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.

MRLs for milbemectin are established for the sum of residues of milbemectin

A3[(10E,14E,16E,22Z)-(1R,4S,5'S,6R,6'R,8R,13R,20R,21R,24S)-21,24-dihydroxy-5',6',11,13,22-pentamethyl-3,7,19-trioxatetracyclo[15.6.1.1^{4,8}.0^{20,24}]]pentacosa-10,14,16,22-

tetraene-6-spiro-2'-tetrahydropyran-2-one] and milbemectin A4[(10*E*,14*E*,16*E*,22*Z*)-(1*R*,4*S*,5'*S*,6*R*,6'*R*,8*R*,13*R*,20*R*,21*R*,24*S*)-6'-ethyl-21,24-dihydroxy-5',11,13,22-tetramethyl-3,7,19-trioxatetracyclo[15.6.1.1^{4,8}.0^{20,24}]]pentacos-10,14,16,22-tetraene-6-spiro-2'-tetrahydropyran-2-one].

Attachment 1-4

Imidocarb (antiparasitics)

Commodity	MRL (draft) ppm	Current MRL ppm
Cattle,muscle	0.3	0.3
Cattle,fat	0.05	0.05
Cattle,liver	1.5	1.5
Cattle,kidney	2	2
Cattle,edible offal ²¹	2	5
Milk	0.05	0.05

The uniform limit (0.01 ppm) is applied to commodities for which draft MRLs are not given.

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, pegia, 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, and 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.