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Public Comments Accepted on Proposed Changes to Regulations on a Fungicide, Veterinary Drugs, and a New Food Additive

2007

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Report Highlights:

The Japanese Ministry of Health, Labour and Welfare has announced draft changes to the MRLs for Azoxystrobin, Ivermectin and Praziquantel, and the intention to approve Butyraldehyde for use as a flavoring. Comments are being accepted until April 24, 2007.

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

On April 10 the Ministry of Health Labour and Welfare announced the intention to make the following changes: Establishment of Maximum Residue Limits for the pesticide Azoxystrobin and for the veterinary drugs Ivermectin and Praziquantel, and the designation of the Food Additive, Butyraldehyde.

Comments on these proposed changes are being accepted until April 24, 2007. 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, and this will constitute the final decision.

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

All issues, mailing address:

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The comments can be in either English or Japanese. 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.

Details of proposed changes:

1) **Azoxystrobin (fungicide)**

Azoxystrobin is approved as a fungicide under the Japanese Agricultural Chemicals Regulation Law. The Ministry of Agriculture, Forestry and Fisheries will expand the scope of target crops for which the use of the chemical is permitted. In response to MAFF's action, the

MHLW will establish new MRLs for some crops and revise the MRLs, which are specified in the Specifications and Standards for Food, Food Additives, Etc (see Attachment 1). The existing MRLs for this substance appear in the Provisional MRLs List (Item 7, Section A “General Compositional Standards for Food,” Part I “Food” in the Specifications and Standards for Food, Food Additives, Etc.) and the MRLs List (Item 6, Section A). By this activity, the MRLs in the Provisional MRLs List will be modified as necessary and placed in the MRLs List. In addition, some of the MRLs in Item 6 will be modified. The MRLs in Item 7 will be deleted.

Explanatory Notes: Provisional MRLs currently exist but these new MRLs would take their place and be considered permanent after final approval. The new MRLs are higher for some crops (lettuce, spinach, honey, fish) but lower for others (soybeans, cherries, mangoes, papayas). For any spots on the chart where no MRL is listed, the default tolerance of .01 ppm will apply.

Attachment. 1

Azoxystrobin(Fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	0.2	5
Wheat	0.5	0.5
Barley	0.3	0.3
Rye	0.3	0.3
Corn (maize)	0.05	0.1
Buckwheat		0.1
Other cereal grains ¹	0.3	0.3
Soybeans, dry	0.5	0.5
Beans, dry ²	0.5	0.3
Peas	0.5	0.3
Broad beans	0.5	0.3
Peanuts, dry	0.2	0.01
Other legumes/pulses ³	0.5	0.3
Potato	0.05	0.03
Taro	0.03	0.04
Sweet potato	0.03	0.04
Yam	0.03	0.04
Konjac		0.05
Other potatoes ⁴	0.03	0.04
Sugar beet	0.5	0.1
Sugarcane		0.02
Japanese radish, roots (including radish)	0.5	0.3
Japanese radish, leaves (including radish)	50	5
Turnip, roots	0.5	0.3
Turnip, leaves	15	5
Horseradish	0.5	0.4
Watercress	3.0	5
Chinese cabbage	3.0	0.5
Cabbage	3.0	0.5
Brussels sprouts	3.0	5
Kale	5	5
<i>Komatsuna</i> , Japanese mustard spinach	5	5
<i>Kyona</i>	5	5
Qing-geng-cai	5	5
Cauliflower	3.0	5
Broccoli	3.0	5
Other cruciferous vegetables ⁵	30	5

Azoxystrobin(continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Burdock	0.5	0.3
Salsify	0.5	0.4
Artichoke	4.0	5
Chicory	30	5
Endive	30	5
Shungiku	30	5
Lettuce (including cos lettuce and leaf lettuce)	30	5
Other composite vegetables ⁶	50	5
Onion	0.1	0.1
Weish (including leek)	7.5	5
Garlic	0.1	0.1
Nira	5	5
Asparagus	2	5
Multiplying onion	1	5
Other liliaceous vegetables ⁷	50	5
Carrot	0.5	0.1
Parsnip	0.5	0.4
Parsley	50	5
Celery	30	5
Mitsuba	5	5
Other umbelliferous vegetables ⁵	50	5
Tomato	1	1
Pimiento (sweet pepper)	3	2
Egg plant	2	2
Other solanaceous vegetables ⁹	2.0	2
Cucumber (including gherkin)	1	1
Pumpkin (including squash)	1	1
Oriental pickling melon (vegetable)	1	1
Water melon	1	1
Melons	1	1
Makuwazi melon	1	1
Other cucurbitaceous vegetables ¹⁰	1	1
Spinach	30	5
Bamboo shoots		0.05
Okra	3	1
Ginger	0.03	0.04
Peas, immature (with pods)	3.0	2
Kidney beans, immature (with pods)	3.0	2
Green soybeans	3.0	2

Azoxystrobin(continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Button mushroom		0.05
Shiitake mushroom		0.05
Other mushrooms ¹¹		0.05
Other vegetables ¹²	50	5
Unshu orange, pulp	1.0	1
Citrus <i>nataurakital</i> , whole	1.0	1
Lemon	1.0	1
Orange (including navel orange)	1.0	1
Grapefruit	1.0	1
Lime	1.0	1
Other citrus fruits ¹³	1.0	10
Apple	2	2
Japanese pear	2	2
Pear	2	2
Quince		2
Loquat	0.1	0.1
Peach	1.5	1.5
Nectarine	3	1.5
Apricot	1.5	1.5
Japanese plum (including prune)	1.5	1.5
Mume plum	1.5	1.5
Cherry	3	5
Strawberry	3	5
Raspberry	5.0	10
Blackberry	5.0	10
Blueberry	3.0	10
Cranberry	0.5	10
Huckleberry	3.0	10
Other berries ¹⁴	5.0	10
Grape	10	10
Japanese persimmon	1	1
Banana	2.0	2
Kiwifruit		0.1
Papaya	2.0	2
Avocado	1	2
Pineapple		2
Guava	0.3	2
Mango	1	2
Passion fruit	1	2
Date		10

Azoxystrobin(continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Other fruits ¹⁴	3	10
Sunflower seeds		0.05
Sesame seeds		0.05
Safflower seeds	1.0	0.5
Cotton seeds	0.02	0.03
Rapeseeds	1	1
Other oil seeds ¹⁶		0.04
Ginkgo nut	0.02	0.02
Chestnut	0.02	0.02
Pecan	0.02	0.02
Almond	0.02	0.02
Walnut	0.02	0.02
Other nuts ¹⁷	0.5	0.02
Tea	10	10
Coffee beans	0.05	0.02
Cacao beans		0.02
Hop	20	20
Other spices ¹⁸	30	10
Other herbs ¹⁹	50	5
Cattle, muscle	0.01	0.02
Pig, muscle	0.01	0.02
Other terrestrial mammals ²⁰ , muscle	0.01	0.02
Cattle, fat	0.03	0.03
Pig, fat	0.01	0.04
Other terrestrial mammals, fat	0.03	0.03
Cattle, liver	0.3	0.01
Pig, liver	0.3	0.09
Other terrestrial mammals, liver	0.3	0.1
Cattle, kidney	0.07	0.05
Pig, kidney	0.06	0.03
Other terrestrial mammals, kidney	0.07	0.05
Cattle, edible offal ²¹	0.07	0.04
Pig, edible offal	0.01	0.02
Other terrestrial mammals, edible offal	0.07	0.04
Milk	0.01	0.008
Chicken, muscle	0.01	0.05
Other poultry ²² , muscle	0.01	0.05
Chicken, fat	0.01	0.05
Other poultry, fat	0.01	0.05
Chicken, liver	0.01	0.05
Other poultry, liver	0.01	0.05

Azoxystrobin(continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Chicken, kidney	0.01	0.05
Other poultry, kidney	0.01	0.05
Chicken, edible offal	0.01	0.05
Other poultry, edible offal	0.01	0.05
Chicken, eggs	0.01	0.05
Other poultry, eggs	0.01	0.05
Salmoniformes		0.008
Anguilliformes		0.008
Perciformes		0.008
Other fish ²³		0.008
Shelled molluscas		0.008
Crustaceans		0.008
Other aquatic animal ²⁴		0.008
Honey		0.008

Notes:

The uniform limit (0.01 ppm) will be applied to commodities for which revised MRLs are not given. Some limits in the column of "MRL (draft)" remain unchanged from the current MRLs. Currently, an MRL of 0.02 ppm is set for sugarcane and cacao beans, instead of the uniform limit (0.01 ppm) because the determination limit of the applicable analytical method was originally 0.02 ppm. By this revision, the uniform limit will be applied to these crops because the improved method has enabled the determination of azoxystrobin to the level of 0.01 ppm.

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, kele, 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, pimienta (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 offal, except muscle, fat, liver, and kidney.
22. "Other poultry" 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 animals, except fish, shellfish, and crustaceans.

2) Ivermectin and Praziquantel (Veterinary Drug)

Ivermectin and Praziquantel are approved as antiparasitics under the Japanese Pharmaceutical Affairs Law. In response to applications from their makers, the Ministry of Agriculture, Forestry and Fisheries (MAFF) has reassessed drugs whose effective ingredients are Ivermectin and Praziquantel, respectively. This activity is on the basis of the legal requirement stating that approved veterinary drugs must be reassessed every six years. In step with the assessment of these drugs by MAFF, the MHLW has reviewed the existing MRLs for Ivermectin and Praziquantel (see Attachment 2-1 and 2-2).

Separately from the abovementioned application, MAFF has received an application to register a new antiparasitic drug composed of the mixture of Praziquantel and Ivermectin. The MHLW, however, will not set MRLs for the ingredients as the mixture. Instead, the new drug will be controlled by the MRLs for the individual ingredients, given in Attachments 2-1 and 2-2. The MRLs for these drugs 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) will be modified as necessary and placed in the MRLs List (Item 6, Section A). The MRLs in Item 7 will be deleted.

Attachment 2-1 Ivermectin¹ (antiparasitic)

<u>Commodity</u>	<u>Draft MRL (ppm)</u>	<u>Current MRL (ppm)</u>
Cattle, muscle	0.01	0.01
Pig, muscle	0.02	0.02
Sheep, muscle	0.01	0.02
Horse, muscle	0.01	0.01
Terrestrial mammals other than above, muscle	0.02	0.02
Cattle, fat	0.040	0.040
Pig, fat	0.020	0.020
Sheep, fat	0.020	0.020
Horse, fat	0.020	0.020
Terrestrial mammals other than above, fat	0.04	0.04
Cattle, liver	0.10	0.10
Pig, liver	0.015	0.015
Sheep, liver	0.015	0.015
Horse, liver	0.015	0.015
Terrestrial mammals other than above, liver	0.02	0.02
Cattle, kidney	0.01	0.01
Pig, kidney	0.01	0.01
Sheep, kidney	0.01	0.01
Horse, kidney	0.01	0.01
Terrestrial mammals other than above, kidney	0.02	0.02
Cattle, edible offal ²	0.01	0.01
Pig, edible offal	0.01	0.01
Sheep, edible offal	0.015	0.01
Horse, edible offal	0.01	0.01
Terrestrial mammals other than above, edible offal	0.02	0.02
Milk	0.01	0.01
Chicken, muscle	none (default) ³	0.01
Poultry other than above, muscle	none (default)	0.01
Chicken, fat	none (default)	0.02
Poultry other than above, fat	none (default)	0.02
Chicken, liver	none (default)	0.02
Poultry other than above, liver	none (default)	0.02
Chicken, kidney	none (default)	0.02
Poultry other than above, kidney	none (default)	0.02
Chicken, edible offal	none (default)	0.02
Poultry other than above, edible offal	none (default)	0.02

Notes: 1. Calculated as 22,23-dihydroivermectin B1a
2. "Edible offal" refers to all edible parts, except muscle, fat, liver, and kidney
3. For commodities that have no MRL, the Default Tolerance of 0.01 ppm applies

Attachment 2-2 Praziquantel (antiparasitic)

<u>Commodity</u>	<u>Draft MRL (ppm)</u>	<u>Current MRL (ppm)</u>
Cattle, muscle	none (default) ¹	0.02
Pig, muscle	none (default)	0.02
Terrestrial mammals other than above, muscle	0.3	0.05
Cattle, fat	none (default)	0.02
Pig, fat	none (default)	0.02
Terrestrial mammals other than above, fat	0.2	0.03
Cattle, liver	none (default)	0.02
Pig, liver	none (default)	0.02
Terrestrial mammals other than above, liver	4	0.3
Cattle, kidney	none (default)	0.02
Pig, kidney	none (default)	0.02
Terrestrial mammals other than above, kidney	4	0.3
Cattle, edible offal ²	none (default)	0.02
Pig, edible offal	none (default)	0.02
Terrestrial mammals other than above, edible offal	4	0.04
Milk	none (default)	0.02
Chicken, muscle	none (default)	0.02
Poultry other than above, muscle	none (default)	0.02
Chicken, fat	none (default)	0.02
Poultry other than above, fat	none (default)	0.02
Chicken, liver	none (default)	0.02
Poultry other than above, liver	none (default)	0.02
Chicken, kidney	none (default)	0.02
Poultry other than above, kidney	none (default)	0.02
Chicken, edible offal	none (default)	0.02
Poultry other than above, edible offal	none (default)	0.02
Chicken, egg	none (default)	0.02
Poultry other than above, egg	none (default)	0.02
Salmoniformes	none (default)	0.02
Anguilliformes	none (default)	0.02
Perciformes	0.02	0.02
Fish other than above	none (default)	0.02
Shelled molluscas	none (default)	0.02
Crustaceans	none (default)	0.02
Aquatic animals other than above	none (default)	0.02
Honey	none (default)	0.02

Notes:

- 1) For commodities that have no MRL, the Default Tolerance of 0.01 ppm applies
- 2) "edible offal" refers to all edible parts except muscle, fat, liver, and kidney

3) Butyraldehyde (Food Additive)

This activity is to newly designate the flavoring agent butyraldehyde as an authorized food additive. Under Article 10 of the Food Sanitation Law, food additives may be used or marketed only when they are designated by the Minister of Health, Labour and Welfare. Where use standards or specifications are established for additives under Article 11 of the law, those additives may be marketed only when they meet the established standards or specifications. In response to a request from the Minister for opinion, the Subcommittee on Food Additives under the Food Sanitation Committee under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the designation of the substance as food additives. The report from the subcommittee is outlined as below.

Outline

The Minister should designate butyraldehyde under Article 10 of the Food Sanitation Law as a food additive that is unlikely to injure human health. In addition, the Minister should establish compositional specifications and use standards for the substance under Article 11 of the law (see Attachment 3-1).

Attachment 3-1

Butyraldehyde (Butanal)

Standard for use: It must not be used for purposes other than flavoring.

Compositional specifications: Substance name Butyraldehyde

Structural formula:



Molecular formula: C₄H₈O

Mol. Weight: 72.11

Chemical name, CAS number: Butanal [123-72-8]

Content: Butyraldehyde contains not less than 99.0% of butyraldehyde (C₄H₈O).

Description: Butyraldehyde is a colorless and clear liquid, having a characteristic odor.

Identification: Determine the infrared absorption spectrum of Butyraldehyde, as directed in the Liquid Film Method under Infrared Spectrophotometry, and compare it with the Reference Spectrum. Both spectra exhibit absorptions having about the same intensity at the same wave numbers.

Purity:

(1) Refractive index: $n_D^{20} : 1.387-1.387$

(2) Specific gravity: $d_4^{20} : 0.797-0.802$

(3) Acid value: Not more than 5.0 (Flavoring Substance Tests).

Assay: Proceed as directed in the Peak Area Percentage Method in the Gas

Chromatographic Assay under the Flavor Substance Tests. Use operating conditions (2).

Reference Spectrum

