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## Japan

### Food and Agricultural Import Regulations and Standards

### Proposed Changes to Maximum Residue Limits in Food

### 2007

**Approved by:**

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**Report Highlights:**

Japan announced a public comment period for proposed changes to the maximum residue limits for the pesticides Cyflumetofen, Dimethomorph, Flufenoxuron, Dinotefuran, the veterinary drugs Difloxacin and Dramectin, and the feed additive Avoparcin.

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

On May 21, 2007 the Japanese Ministry of Health, Labour and Welfare (MHLW) announced proposed changes to the MRLs for Cyflumetofen, Dimethomorph, Flufenoxuron, Dinotefuran, Difloxacin, Dramectin, Avoparcin. The period for sending comments on these proposed changes ends June 4, 2007, 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. After the closing of a the comment periods, the Pharmaceutical Affairs and Food Sanitation Council will meet to discuss any comments received and then a final report will be made based on the conclusions of this session. This report will constitute the final decision.

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

Mailing Address:

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  
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Please also consider copying the U.S. Embassy, Tokyo at [agtokyo@usda.gov](mailto: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 the matters open to public comment:

**Agenda 1. Establishment of Maximum Residue Limits for the Pesticides (Cyflumetofen, Dimethomorph, Flufenoxuron, Dinotefuran) 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

#### <Pesticides>

**Cyflumetofen (acaricide)** The chemical is not permitted for use in Japan. At this time the Ministry of Agriculture, Forestry and Fisheries will newly approve the chemical based on the Agricultural Chemicals Regulation Law. In response to MAFF's action, the MHLW has newly established MRLs for this chemical. For draft MRLs, see Attachment 1-1.

**Dimethomorph (fungicide)** 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 MAFF's action, the MHLW has reviewed the existing MRLs. The existing MRLs for this substance appear either 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.) or in the MRLs List (Item 6, Section A). 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 Attachment 1-2.

**Flufenoxuron (insecticide)** The 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 MAFF's action, the MHLW has reviewed the existing MRLs. The existing MRLs for this substance appear either in the Provisional MRLs List or in the MRLs List. These MRLs have been modified as necessary. Finalized MRLs will be placed in MRLs List, and the MRLs currently placed in Item 7 will be deleted. For draft MRLs, see Attachment 1-3.

#### <Pesticide and veterinary drug >

**Dinotefuran (insecticide)** The chemical is already permitted for use in crops in Japan. MAFF will expand the scope of target crops for which the use of the chemical is permitted. In addition, MAFF will newly approve the use of the chemical as a veterinary drug. In response to MAFF's action, the MHLW has reviewed the existing MRLs. The existing MRLs for this substance appear in the MRLs List only. These MRLs have been modified as necessary. For draft MRLs, see Attachment 1-4.

### Attachment. 1-1

#### **Cyflumetofen (Acaricide)**

*(currently there are no MRLs for this chemical)*

<u>Commodity</u>	<u>Draft MRL (ppm)</u>
Egg plant	5
Water melon	0.5
Melons	1
Unshu orange, pulp	0.5
Citrus natsudaidai , whole	5
Lemon	10
Orange (including navel orange)	10
Grapefruit	10
Lime	10
Other citrus fruits <sup>13</sup>	10
Apple	3
Japanese pear	3

Pear	3
Peach	0.5
Cherry	10
Strawberry	3
Tea	20
Other spices <sup>18</sup>	20

Attachment. 1-2

## Dimethomorph(Fungicide)

Commodity	MRL (draft) ppm	Current MRL ppm
Soybeans, dry	0.2	
Beans, dry <sup>2</sup>	0.3	
Potato	0.1	0.1
Taro		0.1
Sweet potato		0.1
Yam		0.1
Konjac		0.1
Other potatoes <sup>4</sup>		0.1
Japanese radish, leaves (including radish)		2
Turnip, leaves		2
Watercress		2
Chinese cabbage	2.0	1
Cabbage	2.0	1
Brussels sprouts	2.0	2
Kale	20	2
<i>Komatsuna</i> , Japanese mustard spinach	20	2
<i>Kyona</i>	20	2
Qing-geng-cai	20	2
Cauliflower	2.0	2
Broccoli	2.0	2
Other cruciferous vegetables <sup>5</sup>	20	2
Artichoke		2
Chicory		2
Endive		2
<i>Shungiku</i>		2
Lettuce (including cos lettuce and leaf lettuce)	10	0.3
Other composite vegetables <sup>6</sup>		2
Onion	2.0	0.1
Welsh (including leek)	2	2
Garlic	2.0	0.1
<i>Nira</i>		2
Asparagus		2
Multiplying onion		2
Other liliaceous vegetables <sup>7</sup>	2.0	2

\*\*Note: Blank spaces in any of these tables indicate that no MRL for that commodity will be established, and therefore the default tolerance of .01 ppm will apply.

## Dimethomorph(continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Parsley		2
Celery		2
Mitsuba		2
Other umbelliferous vegetables <sup>5</sup>		2
Tomato	3	2
Pimiento (sweet pepper)	1.5	2
Egg plant	1.5	2
Other solanaceous vegetables <sup>6</sup>	1.5	2
Cucumber (including gherkin)	0.7	2
Pumpkin (including squash)	1	2
Oriental pickling melon (vegetable)	0.5	2
Water melon	0.5	0.1
Melons	0.5	0.1
Makurvaun melon	0.5	0.1
Other cucurbitaceous vegetables <sup>10</sup>	0.5	2
Spinach		2
Green soybeans	10	
Other vegetables <sup>12</sup>		2
Loquat		0.1
Peach		0.1
Apricot		5
Japanese plum (including prune)		5
Mume plum		5
Cherry		5
Strawberry		5
Raspberry		5
Blackberry		5
Blueberry		5
Cranberry		5
Huckleberry		5
Other berries <sup>14</sup>		5
Grape	5	5
Kiwifruit		0.1
Date		5
Other fruits <sup>15</sup>	1.5	5
Other oil seeds <sup>16</sup>		0.02
Hop	60	60

## Dimethomorph(continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Other spices <sup>18</sup>	1.5	5
Other herbs <sup>18</sup>	20	2
Cattle, muscle	0.01	0.01
Pig, muscle	0.01	0.01
Other terrestrial mammals <sup>20</sup> , muscle	0.01	0.01
Cattle, fat	0.01	0.01
Pig, fat	0.01	0.01
Other terrestrial mammals, fat	0.01	0.01
Cattle, liver	0.01	0.01
Pig, liver	0.01	0.01
Other terrestrial mammals, liver	0.01	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 <sup>21</sup>	0.01	0.01
Pig, edible offal	0.01	0.01
Other terrestrial mammals, edible offal	0.01	0.01
Milk	0.01	0.01

Attachment. 1-3

Flufenoxuron(Pesticide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)		0.02
Wheat		0.02
Barley		0.02
Rye		0.02
Corn (maize)		0.02
Buckwheat		0.02
Other cereal grains <sup>1</sup>		0.02
Soybeans, dry	0.05	0.02
Beans, dry <sup>2</sup>		0.2
Peas		0.2
Broad beans	0.2	0.2
Peanuts, dry		0.2
Other legumes/pulses <sup>2</sup>		0.2
Potato		0.02
Taro		0.02
Sweet potato		0.02
Yam		0.02
Konjac		0.02
Other potatoes <sup>4</sup>		0.02
Sugar beet	0.5	0.5
Sugarcane		0.02
Japanese radish, roots (including radish)	0.1	0.1
Japanese radish, leaves (including radish)	10	10
Turnip, roots		0.1
Turnip, leaves		10
Horseradish	0.05	0.1
Watercress		10
Chinese cabbage	0.5	0.5
Cabbage	0.5	0.5
Brussels sprouts	0.5	0.5
Kale		10
Komatsuna, Japanese mustard spinach	10	10
Kyona	10	10
Qing-geng-cai	5	10
Cauliflower		10
Broccoli	5	10
Other cruciferous vegetables <sup>5</sup>	5	10

## Flufenoxuron(continued)

Commodity	MRL (draft): ppm	Current MRL ppm
Burdock		0.1
Salsify		0.1
Artichoke		10
Chicory		10
Endive		10
<i>Shungiku</i>	10	10
Lettuce (including cos lettuce and leaf lettuce)	10	10
Other composite vegetables <sup>6</sup>	2	10
Onion		0.02
Welsh (including leek)	10	10
Garlic		0.02
<i>Nira</i>		10
Asparagus	0.5	10
Multiplying onion	10	10
Other alliaceous vegetables <sup>7</sup>		10
Carrot		0.1
Parsnip		0.1
Parsley	10	10
Celery	10	10
<i>Mitsuba</i>	10	10
Other umbelliferous vegetables <sup>8</sup>		10
Tomato	0.5	0.5
Pimiento (sweet pepper)	1	2
Egg plant	2	2
Other solanaceous vegetables <sup>9</sup>	3	2
Cucumber (including gherkin)	2	2
Pumpkin (including squash)	0.2	2
Oriental pickling melon (vegetable)	0.3	2
Watermelon	0.2	0.2
Melons	0.02	0.02
<i>Makurauri</i> melon		0.2
Other cucurbitaceous vegetables <sup>10</sup>	0.5	2
Spinach	10	10
Bamboo shoots		0.1
Okra		2
Ginger		0.1
Peas, immature (with pods)	1	1
Kidney beans, immature (with pods)	1	1
Green soybeans	5	1

## Flufenoxuron (continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Button mushroom		0.02
Shiitake mushroom		0.02
Other mushrooms <sup>11</sup>	0.1	0.1
Other vegetables <sup>12</sup>	10	10
Unshu orange, pulp	0.3	0.3
Citrus <i>natsudaidai</i> , whole	2	2
Lemon	2	2
Orange (including navel orange)	2	2
Grapefruit	2	2
Lime	2	2
Other citrus fruits <sup>13</sup>	2	2
Apple	1	1
Japanese pear	0.5	0.5
Pear	0.5	0.5
Quince		1
Loquat		0.2
Peach	0.1	0.1
Nectarine	0.7	1
Apricot		2
Japanese plum (including prune)		2
Mume plum		2
Cherry	2	2
Strawberry	0.5	0.5
Raspberry		2
Blackberry		2
Blueberry		2
Cranberry		2
Huckleberry		2
Other berries <sup>14</sup>		2
Grape	2	2
Japanese persimmon		1
Banana		1
Kiwifruit		0.2
Papaya		1
Avocado		1
Pineapple		1
Guava		1
Mango		1
Passion fruit		1
Date		2

## Flufenoxuron(continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Other fruits <sup>15</sup>		2
Sunflower seeds		0.02
Sesame seeds		0.02
Safflower seeds		0.02
Cotton seeds	0.03	0.03
Rapeseeds		0.02
Other oil seeds <sup>16</sup>		0.02
Ginkgo nut		0.02
Chestnut		0.02
Pecan		0.02
Almond		0.02
Walnut		0.02
Other nuts <sup>17</sup>		0.02
Tea	15	15
Coffee beans		0.02
Cacao beans		0.02
Hop		0.02
Other spices <sup>18</sup>	10	10
Other herbs <sup>19</sup>	10	10

## Attachment. 1-4

## Dinotefuran(Pesticide)

Commodity	MRL (draft) ppm	Current MRL ppm
Rice (brown rice)	2	1
Soybeans, dry	0.1	0.1
Potato	0.2	0.2
Sugar beet	0.2	0.2
Japanese radish, roots (including radish)	0.5	0.5
Japanese radish, leaves (including radish)	3	3
Turnip, roots	0.5	0.2
Turnip, leaves	5	5
Watercress	5	5
Chinese cabbage	1.4	1.4
Cabbage	2	2
Brussels sprouts	1.4	1.4
Kale	5	5
<i>Komatsuna</i> , Japanese mustard spinach	5	5
<i>Kyona</i>	3	5
Qing-geng-cai	10	5
Cauliflower	2	2
Broccoli	2	2
Other cruciferous vegetables <sup>5</sup>	5	5
Artichoke	5	5
Chicory	5	5
Endive	5	5
<i>Shungiku</i>	20	5
Lettuce (including cos lettuce and leaf lettuce)	5	5
Other composite vegetables <sup>6</sup>	5	5
Welsh (including leek)	5	5
Other liliaceous vegetables <sup>7</sup>	0.7	0.7
Carrot	0.7	0.2
Parsley	5	5
Celery	5	5
<i>Mitsuba</i>	5	5
Other umbelliferous vegetables <sup>8</sup>	5	5
Tomato	2	2
Pimiento (sweet pepper)	3	3
Egg plant	2	2
Other solanaceous vegetables <sup>9</sup>	5	5

## Dinotefuran(continued)

Commodity	MRL (draft) ppm	Current MRL ppm
Cucumber (including gherkin)	2	2
Pumpkin (including squash)	0.5	0.5
Oriental pickling melon (vegetable)	2	2
Water melon	0.5	0.5
Melons	1	1
<i>Makuwauri</i> melon	0.5	0.5
Other cucurbitaceous vegetables <sup>10</sup>	2	2
Spinach	15	5
Okra	2	
Peas, immature (with pods)	5	
Green soybeans	2	2
Other vegetables <sup>12</sup>	5	5
<i>Unshu</i> orange, pulp	2	2
Citrus <i>natsudaidai</i> , whole	1	1
Lemon	3	3
Orange (including navel orange)	3	3
Grapefruit	3	3
Lime	3	3
Other citrus fruits <sup>13</sup>	3	3
Apple	0.5	0.7
Japanese pear	1	1
Pear	1	1
Peach	3	3
Nectarine	2	2
Apricot	5	
Japanese plum (including prune)	0.5	10
Mume plum	5	5
Cherry	10	10
Strawberry	2	2
Grape	10	10
Japanese persimmon	2	2
Mango	1	
Other fruits <sup>15</sup>	0.7	0.7
Cotton seeds	0.4	0.4
Tea	25	25

## Dinotefuran(continued)

Commodity	MRL (draft) ppm	Current MRL ppm
<i>Unshu</i> orange, peel	10	10
Other spices (excluding <i>unshu</i> orange peel) <sup>13</sup>	5	5
Other herbs <sup>12</sup>	5	5
Cattle, muscle	0.05	0.05
Pig, muscle	0.05	0.05
Goat, muscle	0.05	0.05
Horse, muscle	0.05	0.05
Sheep, muscle	0.05	0.05
Cattle, fat	0.05	0.05
Pig, fat	0.05	0.05
Goat, fat	0.05	0.05
Horse, fat	0.05	0.05
Sheep, fat	0.05	0.05
Cattle, liver	0.05	0.05
Pig, liver	0.05	0.05
Goat, liver	0.05	0.05
Horse, liver	0.05	0.05
Sheep, liver	0.05	0.05
Cattle, kidney	0.05	0.05
Pig, kidney	0.05	0.05
Goat, kidney	0.05	0.05
Horse, kidney	0.05	0.05
Sheep, kidney	0.05	0.05
Cattle, edible offal <sup>21</sup>	0.05	0.05
Pig, edible offal	0.05	0.05
Goat, edible offal	0.05	0.05
Horse, edible offal	0.05	0.05
Sheep, edible offal	0.05	0.05
Milk	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 of “MRL (draft)” remain unchanged from the current MRLs. Currently, an MRL of 0.02 ppm is set for some crops, instead of the uniform limit (0.01 ppm) because the determination limit of the applicable analytical method was 0.02 ppm at the time of standards setting. By this review, the uniform limit will be applied to these crops except for (excluding melons and dry soybeans) because the improved method has enabled the determination of flufenoxuron to the level of 0.01 ppm. For melons, the limit will remain unchanged, because it was originally set separately from the concept of uniform limit. For Soybeans, the limit was reviewed with residue data newly obtained.

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 offal, except muscle, fat, liver, and kidney.

## **Agenda 2. Establishment of Standards for the Veterinary Drugs (Veterinary Drugs (Difloxacin and Dramectin) and Feed Additive (Avoparcin) 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**

#### **<Veterinary drugs >**

Difloxacin (synthetic antibacterial) The chemical is permitted for use in Japan. The Ministry of Agriculture, Forestry and Fisheries has reassessed a drug product whose effective ingredient is Difloxacin. 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. [MHLW explained in the May 21 meeting that the reason that so many MRLs for this substance were removed was that they haven't received any test residue results for that commodity from a country where the substance is permitted]

Dramectin (antiparasitic) The chemical is permitted for use in Japan. The Ministry of Agriculture, Forestry and Fisheries has reassessed a drug product whose effective ingredient is Dramectin. 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 these chemicals appear in the Provisional MRLs List (Item 7 of Section A "General Compositional Standard for Food," Part 1 "Food" in the Specifications and Standards for Food, Food Additives, Etc). They 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 Attachment 2-1 for Difloxacin and Attachment 2-2 for Dramectin. [MHLW explained that for some commodities Codex data was used and for some JECFA data was used.]

**<Feed additive and veterinary drug>**

Avoparcin (synthetic antibacterial) The chemical is categorized as feed additive in Japan but categorized as veterinary drug in some countries. Avoparcin is not permitted for use in Japan. MRLs for the substance were established at the introduction of the positive list, based on Australian standards. At this time the MHLW has decided to withdraw the standards for the substance. This is because Australia has withdrawn its standards recently. In addition, there is no information showing that Avoparcin is produced or used in countries other than Japan. The MRLs for the chemical, appearing in the Provisional MRLs List in item 7, will be all deleted. After the revision takes effect, the substance will not be permitted to be included in any food, based on the provision of Item 1 in Section A stipulating that food shall not contain any antimicrobial or synthetic antibacterial. For draft MRLs, see Attachment 2-3. [MHLW explained in the May 21 meeting that the reason the drug was withdrawn in Australia has to do with the development of drug resistance.]

## Attachment 2-1

Diffloxacin (Synthetic Antibacterials)

Commodity	Draft MRL (ppm)	Current MRL (ppm)
Cattle, muscle	0.02	0.4
Pig, muscle		0.02
Terrestrial mammals other than above, muscle		0.4
Cattle, fat	0.02	0.1
Pig, fat		0.02
Terrestrial mammals other than above, fat		0.1
Cattle, liver	0.02	1
Pig, liver		0.02
Terrestrial mammals other than above, liver		1
Cattle, kidney	0.02	0.5
Pig, kidney		0.02
Terrestrial mammals other than above, kidney		0.5
Cattle, edible offal <sup>6</sup>	0.02	0.5
Pig, edible offal		0.02
Terrestrial mammals other than above, edible offal		0.5
Chicken, muscle		0.3
Poultry other than above, muscle		0.3
Chicken, fat		0.4
Poultry other than above, fat		0.4
Chicken, liver		2
Poultry other than above, liver		2
Chicken, kidney		0.6
Poultry other than above, kidney		0.6
Chicken, edible offal		0.6
Poultry other than above, edible offal		0.6
Salmoniformes		0.3
Anguilliformes		0.3
Perciformes		0.3
Fish other than above		0.3
Shelled molluscs		0.3
Crustaceans		0.3
Aquatic animals other than above		0.3

<sup>6</sup> "Edible offal" refers to all edible parts, except muscle, fat, liver, and kidney.

## Attachment 2-3

## Dramectin (antiparasitic)

Commodity	Draft MRL (ppm)	Current MRL (ppm)
Cattle, muscle	0.01	0.01
Pig, muscle	0.01	0.005
Terrestrial mammals other than above, muscle	0.01	0.02
Cattle, fat	0.15	0.15
Pig, fat	0.15	0.15
Terrestrial mammals other than above, fat	0.02	0.1
Cattle, liver	0.1	0.1
Pig, liver	0.1	0.1
Terrestrial mammals other than above, liver	0.02	0.05
Cattle, kidney	0.02	0.02
Pig, kidney	0.02	0.02
Terrestrial mammals other than above, kidney	0.02	0.04
Cattle, edible offal*	0.1	0.02
Pig, edible offal	0.1	0.02
Terrestrial mammals other than above, edible offal	0.02	0.05
Milk	0.015	0.02
Chicken, muscle		0.005
Poultry other than above, muscle		0.005
Chicken, fat		0.005
Poultry other than above, fat		0.005
Chicken, liver		0.005
Poultry other than above, liver		0.005
Chicken, kidney		0.005
Poultry other than above, kidney		0.005
Chicken, edible offal		0.005
Poultry other than above, edible offal		0.005
Chicken, egg		0.005
Poultry other than above, egg		0.005
Salmoniformes		0.005
Anguilliformes		0.005
Perciformes		0.005
Fish other than above		0.005
Shelled molluscs		0.005
Crustaceans		0.005
Aquatic animals other than above		0.005
Honey		0.005

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

## Attachment 2-3

## Avoparcin (synthetic antibacterial)

Commodity	Draft MRL (ppm)	Current MRL (ppm)
Cattle, muscle		0.1
Pig, muscle		0.1
Terrestrial mammals other than above, muscle		0.1
Cattle, fat		0.1
Pig, fat		0.1
Terrestrial mammals other than above, fat		0.1
Cattle, liver		0.1
Pig, liver		0.1
Terrestrial mammals other than above, liver		0.1
Cattle, kidney		0.1
Pig, kidney		0.1
Terrestrial mammals other than above, kidney		0.1
Cattle, edible offal*		0.1
Pig, edible offal		0.1
Terrestrial mammals other than above, edible offal		0.1
Milk		0.01
Chicken, muscle		0.1
Poultry other than above, muscle		0.1
Chicken, fat		0.1
Poultry other than above, fat		0.1
Chicken, liver		0.1
Poultry other than above, liver		0.1
Chicken, kidney		0.1
Poultry other than above, kidney		0.1
Chicken, edible offal		0.1
Poultry other than above, edible offal		0.1

Note : After the revision takes effect, the substance will not be permitted to be included in any food, based on the provision of Item 1 in Section A stipulating that food shall not contain any antimicrobial or synthetic antibacterial.