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## Japan

### Food and Agricultural Import Regulations and Standards

#### MRL Change to Veterinary Drug - Tilmicosin

## 2007

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**Report Highlights:**

On November 30, 2007, MHLW announced proposed changes to the MRL of a veterinary drug, Tilmicosin. MHLW will notify these changes to the WTO SPS committee after finalizing the proposed change.

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Includes PSD Changes: No  
Includes Trade Matrix: No  
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**Executive Summary**

On November 30, 2007, MHLW announced proposed changes to the MRL of a veterinary drug, Tilmicosin. MHLW will notify these changes to the WTO SPS committee after finalizing the proposed change.

**Purpose**

The period for comments directly to MHLW closed December 14, 2007, however MHLW intends to notify these proposed changes to the WTO/SPS committee, which would be the last chance for public comments to be submitted on this subject. Then after the closing of the comment period in the WTO, a report to the Minister of Health, Labour, and Welfare 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 that you would like to be considered for inclusion in the official U.S. Government comments to the MHLW, please send those as soon as possible to the Agriculture Section of the U.S. Embassy in Tokyo, at [agtokyo@usda.gov](mailto:agtokyo@usda.gov).

For comments directly to MHLW, please send those to following contacts.

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Pharmaceutical and Food Safety Bureau,  
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**Establishment of Standards for the Veterinary Drug Tilmicosin in Food*****Purpose and Background***

The Ministry of Health, Labour and Welfare is going to develop the compositional specification for food.

Under the provisions of Article 11, Paragraph 1 of the Food Sanitation Law, the Minister of Health, Labour, and Welfare is authorized to 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 (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 reviewed MRLs for a veterinary drug which had been provisionally established at the time of the introduction of the new system. This activity is targeted to Tilmicosin. 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 the activity***

Tilmicosin (antimicrobial): The chemical is permitted for use in Japan. The Ministry of Agriculture, Forestry and Fisheries (MAFF) has reassessed a drug product whose effective ingredient is Tilmicosin. This is on the basis of the legal requirement stating that veterinary drugs, must be reassessed two years after approval. In response to MAFF's action, the MHLW has reviewed some existing MRLs for the substance.

The existing MRLs for the chemical appear either in the MRLs List (the Item 6, Section A "General Compositional Standard for Food," Part 1 "Food" in the Specifications and Standards for Food, Food Additives, Etc.) or in the Provisional MRLs List (Item 7, Section A), according to food commodities. The finalized MRLs will be placed on the MRLs List in Item 6, and the MRLs placed in Item 7 will be deleted. For draft MRLs, see Attachment 2 for Tilmicosin.

## Attachment 2

Tilmicosin (Antimicrobial)

Commodity	Draft MRL (ppm)	Current MRL (ppm)
Cattle, muscle	0.1	0.1
Pig, muscle	0.1	0.1
Sheep, muscle	0.1	0.1
Terrestrial mammals other than above, muscle	0.05	0.05
Cattle, fat	0.1	0.1
Pig, fat	0.1	0.1
Sheep, fat	0.1	0.1
Terrestrial mammals other than above, fat	0.05	0.05
Cattle, liver	1	1
Pig, liver	1.5	1.5
Sheep, liver	1	1
Terrestrial mammals other than above, liver	0.6	1
Cattle, kidney	0.3	0.3
Pig, kidney	1	1
Sheep, kidney	0.3	0.3
Terrestrial mammals other than above, kidney	1	1
Cattle, edible offal <sup>2</sup>	0.5	1
Pig, edible offal	1	1
Sheep, edible offal	0.3	0.3
Terrestrial mammals other than above, edible offal	1	1
Milk	0.05	0.05
Chicken, muscle	0.07	0.08
Poultry other than above, muscle	0.07	0.08
Chicken, fat	0.07	0.08
Poultry other than above, fat	0.07	0.08
Chicken, liver	1	1
Poultry other than above, liver	0.5	1
Chicken, kidney	0.25	0.3
Poultry other than above, kidney	0.25	0.3
Chicken, edible offal	1	0.3
Poultry other than above, edible offal	0.25	0.3
Salmoniformes		0.05
Anguilliformes		0.05
Perciformes		0.05
Fish other than above		0.05

Shelled molluscas		0.05
Crustaceans		0.05
Aquatic animals other than above		0.05

Note: The MRLs shaded in the above table were established in Ministry of Health, Labour and Welfare Notification No. 499, 2005 (enforced on May 29, 2006).

After the revision of MRLs takes effect, Tilmicosin shall not be included in the commodities for which no MRL is given.

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