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FAIRS Subject Report

WTO Notification G/SPS/N/JPN/186

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Report Highlights:
Japan has proposed establishment of maximum residue limits (MRL) for the veterinary drug difloxacin in foods. Japan notified the WTO on June 29, 2007.

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

Executive Summary
On June 29, 2007 the Japanese Ministry of Health, Labour and Welfare (MHLW) announced establishment of the MRLs for Difloxacin to the WTO/SPS committee. The notification is open for comment within 60 days of circulation by the WTO Secretariat.

Establishment of Standards for the Veterinary Drugs (Difloxacin) 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]

Attachment 2-1

Difloxacin (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	0.8
Pig, kidney		0.02
Terrestrial mammals other than above, kidney		0.8
Cattle, edible offal*	0.02	0.8
Pig, edible offal		0.02
Terrestrial mammals other than above, edible offal		0.8
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

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