

Shoku-An No. 1130001

November 30, 2006

Director Notice*

Department of Food Safety

Pharmaceutical and Food Safety Bureau

Ministry of Health, Labour and Welfare

Partial Revision of Specifications and Standards for Food, Food Additives, Etc.

The Minister of Health, Labour and Welfare has issued the Notification to Partially Revise the Specifications and Standards for Food, Food Additives, Etc. (Ministry of Health, Labour and Welfare Notification No. 645, 2006) Based on the notification, the specifications and standards (Ministry of Health and Welfare Notification No. 370, 1959) have been revised.

1. Outline of revision

The Minister of Health, Labour and Welfare has revised specifications and standards as given below, based on the provision of Paragraph 1 Article 11 of the Food Sanitation Law.

i) Analytical method of nitrofurans

The reaction ratio of derivatization reagent to sample solution has been changed in the analytical method, specified in Item 5, Section A *General Compositional Standards for Food*, Part I *Food* of Notification No. 370..

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ii) Analytical method of malachite green

A clean-up method has been added, and the operating condition of mobile phase has been changed in the analytical method, specified in Item 5, Section A, Part I of Notification No. 370..

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iii) MRLs for enrofloxacin and tulathromycin

MRLs for the veterinary drugs enrofloxacin and tulathromycin have been established (see Attachment). The analytical methods for enrofloxacin and tulathromycin are announced in Director Notice Syoku-An No. 1130004.

* This document is rearranged from the original Director Notice (Syoku-An No.1130001, November 30, 2006). This rearrangement aims to help English readers understand the notice.

2. Date of enforcement

i) Analytical methods of nitrofurans and malachite green
November 30, 2006

ii) MRLs for enrofloxacin
November 30, 2006

The revision of MRLs for the food categories below will take effect on May 30, 2007.

“Other terrestrial mammals, muscle,” “Other terrestrial mammals, fat,” “Other terrestrial mammals, liver,” “Other terrestrial mammals, kidney,” “Other terrestrial mammals, edible offal,” “Other poultry, muscle,” “Other poultry, fat,” “Other poultry, liver,” “Other poultry, kidney,” “Other poultry, edible offal,” “Salmoniformes,” “Anguilliformes,” “Perciformes,” “Other fish,” “Shelled molluscas,” “Crustaceans,” and “Other aquatic animals.”

iii) MRLs for tulathromycin
November 30, 2006

3. Other matters

i) Analytical method of malachite green

- a. The test procedure should be performed promptly because reversible oxidation and reduction may occur between malachite green and its metabolite leucomalachite green.
- b. In the acetonitril–water/hexane distribution or the acetonitrile/water/dichloromethane distribution, when the solvents are emulsified, they should be centrifuged to separate both phases completely.
- c. The acetonitrile/dichloromethane layer should be sufficiently dehydrated to prevent the water from getting into the strongly acidic cation exchanger cartridge column when the layer is poured into the column.,
- d. When eel sample is applied, correction of recovery rate should be conducted by the internal standard method using a stable isotope labeled standard or the standard addition method.

ii) MRLs for enrofloxacin

MRLs for enrofloxacin are established for the sum of residues of enrofloxacin and its metabolite ciprofloxacin.

(Attachment)

Enrofloxacin (synthetic antimicrobial agent)

Commodity	Current MRL (ppm)	Revised MRL ⁶ (ppm)	DOE
Cattle, muscle	0.01	0.05	○
Pig, muscle	0.01	0.05	○
Other terrestrial mammals ¹ , muscle	0.1	0.05	●
Cattle, fat	0.01	0.05	○
Pig, fat	0.01	0.05	○
Other terrestrial mammals, fat	0.1	0.05	●
Cattle, liver	0.01	0.1	○
Pig, liver	0.01	0.1	○
Other terrestrial mammals, liver	0.3	0.1	●
Cattle, kidney	0.01	0.1	○
Pig, kidney	0.01	0.1	○
Other terrestrial mammals, kidney	0.2	0.1	●
Cattle, edible offal ²	0.01	0.05	○
Pig, edible offal	0.01	0.05	○
Other terrestrial mammals, edible offal	0.2	0.05	●
milk	0.02	0.05	○
Chicken, muscle	0.01	0.05	○
Other poultry ³ , muscle	0.1	0.05	●
Chicken, fat	0.01	0.05	○
Other poultry, fat	0.1	0.05	●
Chicken, liver	0.01	0.1	○
Other poultry, liver	0.2	0.1	●
Chicken, kidney	0.01	0.1	○
Other poultry, kidney	0.3	0.1	●
Chicken, edible offal	0.01	0.1	○
Other poultry, edible offal	0.2	0.1	●
Salmoniformes	0.1		●
Anguilliformes	0.1		●
Perciformes	0.1		●
Other fish ⁴	0.1		●
Shelled molluscas	0.1		●
Crustaceans	0.1		●
Other aquatic animal ⁵	0.1		●

Tulathromycin (antibiotics)

Commodity	Current MRL (ppm)	Revised MRL (ppm)	DOE
Cattle, muscle	0.1	0.3	○
Pig, muscle	0.1	2	○
Cattle, fat	0.1	0.2	○
Pig, fat	0.1	0.3	○
Cattle, liver	4	5	○
Pig, liver	3	4	○
Cattle, kidney	3	3	○
Pig, kidney	9	9	○
Cattle, edible offal ¹	3	3	○
Pig, edible offal ¹	3	5	○

Notes:

- 1 "Other terrestrial mammals" refer to all terrestrial mammals except cattle and pig.
- 2 "Edible offal" refer to all edible parts except the muscle, fat, liver, and kidney.
- 3 "Other poultry" refer to all poultry except chicken.
- 4 "Other fish" refer to all fish except salmoniformes, anguilliformes, and perciformes.
- 5 "Other aquatic animal" refer to all aquatic animals except fish, shelled molluscas, and crustaceans.
- 6 Each limit in this column is expressed as the sum of residues of enrofloxacin and its metabolite ciprofloxacin.

DOE : Date of enforcement

○ : November 30, 2006

● : May 30, 2007

None of enrofloxacin and tulathromycin shall be detected in any of the commodities for which MRLs are not given in the MRLs List (item 6 (1), Section A, Part I of Notification No. 370).