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FOOD AND AGRICULTURE
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Agenda Item 5 (b)

CX/RVDF 09/18/5
December 2008

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Eighteenth Session
11-15 May 2009¹

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS (at Step 3 of the Procedure)

Governments and international organizations wishing to submit comments at Step 3 on the proposed draft Maximum Residues Limits for Veterinary Drugs arising from the 70th JECFA Meeting are invited to do so **no later than 31 March 2009** as follows: U.S. Codex Office, Food safety and Inspection Service, US Department of Agriculture, Room 4861, South Building, 14th Independence Avenue, S.W., Washington DC 20250, USA (Telefax: +1 202 720 3157 ; or *preferably* E-mail: uscodex@usda.gov, with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org, *preferably*).

BACKGROUND

1. The 70th Meeting Joint FAO/WHO Expert Committee on Food Additives (JECFA) was convened in Geneva, Switzerland, from 21 to 29 October 2008 to evaluate residues of certain veterinary drugs in foods. The full reports of the meeting will be published in the WHO Technical Report Series². Toxicological monographs summarising the data that were considered by the Committee will be published in *WHO Food Additives Series*; residue monographs summarising the data that were considered by the Committee will be published in *FAO JECFA Monographs*. Recommendations on the other veterinary drugs i.e. malachite green and melengestrol acetate (at step 7), as well as other considerations and recommendations are provided in the document CX/RVDF 09/18/3 (Agenda Item Matters from FAO/WHO and from the 70th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA))".

2. Annex 1 of the document presents the recommendations of the 70th JECFA Meeting on numerical Maximum Residues Limits (MRLs) for the veterinary drugs avilamycin, dexamethasone, monensin, narasin, tilmicosin, triclabendazole and tylosin.

¹ Exact venue to be communicated.

² Summary and conclusions of the 70th JECFA meeting are available on FAO and WHO websites as follows: <http://www.fao.org/ag/agn/agns/files/JECFA70summaryreportEfinal.pdf> and <http://www.who.int/entity/ipcs/food/jecfa/summaries/summary70.pdf>

3. Governments and international organizations wishing to submit comments at Step 3 on the proposed draft Maximum Residues Limits for Veterinary Drugs recommended by the 70th JECFA Meeting (*see* Annex 1) are invited to do so **no later than 31 March 2009.**

ANNEX 1

**PROPOSED DRAFT MAXIMUM RESIDUE LIMITS (MRLs) FOR VETERINARY DRUGS
(AT STEP 3)**

Recommendations on arising from the 70th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

AVILAMYCIN (antimicrobial agent)

Acceptable Daily Intake: 0–2 mg/kg body weight on the basis of a NOAEL of 150 mg avilamycin activity/kg body weight per day and a safety factor of 100 and rounding to one significant figure (70th JECFA, 2008).

Residue Definition: Dichloroisoeverninic acid (DIA).

Species	Tissue	MRLs(µg/kg) recommended by the 70 th JECFA	Step	JECFA
Pigs	Muscle	200	3	70
Pigs	Liver	300	3	70
Pigs	Kidney	200	3	70
Pigs	Skin/Fat	200	3	70
Chicken	Muscle	200	3	70
Chicken	Liver	300	3	70
Chicken	Kidney	200	3	70
Chicken	Skin/Fat	200	3	70
Turkey	Muscle	200	3	70
Turkey	Liver	300	3	70
Turkey	Kidney	200	3	70
Turkey	Skin/Fat	200	3	70
Rabbits	Muscle	200	3	70
Rabbits	Liver	300	3	70
Rabbits	Kidney	200	3	70
Rabbits	Skin/Fat	200	3	70

DEXAMETHASONE (glucocorticosteroid)

Acceptable Daily Intake: 0–0.015 µg/kg body weight (42nd JECFA, 1995).

Residue Definition: Dexamethasone.

Species	Tissue	MRLs(µg/kg) recommended by the 70 th JECFA	Step	JECFA
Cattle	Muscle	1.0	3	70
Cattle	Liver	2.0	3	70
Cattle	Kidney	1.0	3	70
Cattle	Milk	0.3	3	70
Pigs	Muscle	1.0	3	70
Pigs	Liver	2.0	3	70
Pigs	Kidney	1.0	3	70
Horses	Muscle	1.0	3	70
Horses	Liver	2.0	3	70
Horses	Kidney	1.0	3	70

MONENSIN (antimicrobial agent and production aid)

Acceptable Daily Intake: 0–10 µg/kg body weight on the basis of a NOAEL of 1.14 mg/kg body weight per day and a safety factor of 100 and rounding to one significant figure. (70th JECFA, 2008).

Residue Definition: Monensin.

Species	Tissue	MRLs(µg/kg) recommended by the 70 th JECFA	Step	JECFA
Cattle	Muscle	10	3	70
Cattle	Liver	10	3	70
Cattle	Kidney	10	3	70
Cattle	Fat	100	3	70
Cattle	Milk	2	3	70
Sheep	Muscle	10	3	70
Sheep	Liver	10	3	70
Sheep	Kidney	10	3	70
Sheep	Fat	100	3	70
Goats	Muscle	10	3	70
Goats	Liver	10	3	70
Goats	Kidney	10	3	70
Goats	Fat	100	3	70
Chicken	Muscle	10	3	70
Chicken	Liver	10	3	70
Chicken	Kidney	10	3	70
Chicken	Fat	100	3	70
Turkey	Muscle	10	3	70
Turkey	Liver	10	3	70
Turkey	Kidney	10	3	70
Turkey	Fat	100	3	70
Quail	Muscle	10	3	70
Quail	Liver	10	3	70
Quail	Kidney	10	3	70
Quail	Fat	100	3	70

NARASIN (antimicrobial agent and production aid)

Acceptable Daily Intake: 0–5 µg/kg body weight on the basis of a NOAEL of 0.5 mg/kg body weight per day and a safety factor of 100 (70th JECFA, 2008).

Residue Definition: Narasin A.

Species	Tissue	MRLs(µg/kg) recommended by the 70 th JECFA	Step	JECFA
Cattle	Muscle	15 T ^a	3	70
Cattle	Liver	50 T ^a	3	70
Cattle	Kidney	15 T ^a	3	70
Cattle	Fat	50 T ^a	3	70
Chicken	Muscle	15	3	70
Chicken	Liver	50	3	70
Chicken	Kidney	15	3	70
Chicken	Fat	50	3	70

Species	Tissue	MRLs($\mu\text{g}/\text{kg}$) recommended by the 70 th JECFA	Step	JECFA
Pigs	Muscle	15	3	70
Pigs	Liver	50	3	70
Pigs	Kidney	15	3	70
Pigs	Fat	50	3	70

^a The MRL is temporary. Before re-evaluation of narasin with the aim of recommending MRLs in tissues of cattle, the Committee would require a detailed description of a regulatory method, including its performance characteristics and validation data. This information is required by the end of 2010.

TILMICOSIN (antimicrobial agent)

Acceptable Daily Intake: 0–40 $\mu\text{g}/\text{kg}$ body weight (47th JECFA, 1998).

Residue Definition: Tilmicosin.

Species	Tissue	MRLs($\mu\text{g}/\text{kg}$) recommended by the 70 th JECFA	Step	JECFA
Chicken	Muscle	150	3	70
Chicken	Liver	2400	3	70
Chicken	Kidney	600	3	70
Chicken	Skin/Fat	250	3	70
Turkey	Muscle	100	3	70
Turkey	Liver	1400	3	70
Turkey	Kidney	1200	3	70
Turkey	Skin/Fat	250	3	70

TRICLABENDAZOLE (anthelmintic)

Acceptable Daily Intake: 0–3 $\mu\text{g}/\text{kg}$ body weight (40th JECFA, 1993).

Residue Definition: Ketotriclabendazole.

Species	Tissue	Current MRL ($\mu\text{g}/\text{kg}$)	JECFA	MRLs($\mu\text{g}/\text{kg}$) recommended by the 70 th JECFA	Step	JECFA	
Cattle	Muscle	200	22 nd CAC (1997)	40	250	3	70
Cattle	Liver	300	22 nd CAC (1997)	40	850	3	70
Cattle	Kidney	300	22 nd CAC (1997)	40	400	3	70
Cattle	Fat	100	22 nd CAC (1997)	40	100	3	70
Sheep	Muscle	100	22 nd CAC (1997)	40	200	3	70
Sheep	Liver	100	22 nd CAC (1997)	40	300	3	70
Sheep	Kidney	100	22 nd CAC (1997)	40	200	3	70
Sheep	Fat	100	22 nd CAC (1997)	40	100	3	70

TYLOSIN (antimicrobial agent)

Acceptable Daily Intake: 0–30 µg/kg body weight based on a microbiological end-point derived from in vitro MIC susceptibility testing and faecal binding data (MIC_{calc} = 1.698) (70th JECFA, 2008).

Residue Definition: Tylosin A.

Species	Tissue	MRLs(µg/kg) recommended by the 70 th JECFA	Step	JECFA
Cattle	Muscle	100	3	70
Cattle	Liver	100	3	70
Cattle	Kidney	100	3	70
Cattle	Fat	100	3	70
Cattle	Milk	100	3	70
Pigs	Muscle	100	3	70
Pigs	Liver	100	3	70
Pigs	Kidney	100	3	70
Pigs	Fat	100	3	70
Chicken	Muscle	100	3	70
Chicken	Liver	100	3	70
Chicken	Kidney	100	3	70
Chicken	Skin/Fat	100	3	70
Chicken	Eggs	300	3	70