

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD  
HEALTH  
ORGANIZATION



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Agenda Item 6 (d)

CX/RVDF 06/16/7  
March 2006

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

### Sixteenth Session

*Cancun, Quintana Roo, Mexico, 8 -12 May 2006*

### DRAFT AND PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY DRUGS (at Step 6 and Step 3 of the Procedure)

Governments and international organizations wishing to submit comments at Step 3 and Step 6 on the draft and proposed draft Maximum Residues Limits for Veterinary Drugs arising from the 66<sup>th</sup> JECFA Meeting are invited to do so **no later than 15 April 2006** 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](mailto:uscodex@usda.gov), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: [Codex@fao.org](mailto:Codex@fao.org)).

### BACKGROUND

1. The 66<sup>th</sup> Meeting Joint FAO/WHO Expert Committee on Food Additives (JECFA) was convened in Rome, Italy from 22 to 28 February 2006 to evaluate residues of certain veterinary drugs in foods. The full reports of the meeting will be published in the WHO Technical Report Series. 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*.
2. Annex 1 of the document presents the recommendations of the 66<sup>th</sup> JECFA Meeting on Maximum Residues Limits (MRLs) for veterinary drugs. These recommendations will be considered by the 16<sup>th</sup> Session of the Codex Committee on Residues of Veterinary Drugs in Foods (May 2006).
3. Governments and international organizations wishing to submit comments at Step 3 and Step 6 on the draft and proposed draft Maximum residues limits for Veterinary Drugs arising from the 66<sup>th</sup> JECFA Meeting are invited to do so **no later than 15 April 2006**.

## ANNEX 1

**RECOMMENDATIONS ON MAXIMUM RESIDUE LIMITS (MRLs) FOR VETERINARY DRUGS ARISING FROM THE 66<sup>TH</sup> MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES**

**COLISTIN** (antimicrobial agent)

**Acceptable Daily Intake:** The Committee established an ADI of 0–7 µg/kg body weight (66<sup>th</sup> JECFA, 2006).

**Residue Definition:** Sum of colistin A and colistin B

Species	Tissue	Current MRL (µg/kg)	MRLs(µg/kg) recommended by 66 <sup>th</sup> JECFA	Step	JECFA	ALINORM
Cattle	Muscle		150	3	66	
Cattle	Liver		150	3	66	
Cattle	Kidney		200	3	66	
Cattle	Fat		150	3	66	
Cattle	Milk		50	3	66	
Sheep	Muscle		150	3	66	
Sheep	Liver		150	3	66	
Sheep	Kidney		200	3	66	
Sheep	Fat		150	3	66	
Sheep	Milk		50	3	66	
Goat	Muscle		150	3	66	
Goat	Liver		150	3	66	
Goat	Kidney		200	3	66	
Goat	Fat		150	3	66	
Pig	Muscle		150	3	66	
Pig	Liver		150	3	66	
Pig	Kidney		200	3	66	
Pig	Fat		150 <sup>a</sup>	3	66	
Chicken	Muscle		150	3	66	
Chicken	Liver		150	3	66	
Chicken	Kidney		200	3	66	
Chicken	Fat		150 <sup>a</sup>	3	66	
Chicken	Eggs		300	3	66	
Turkey	Muscle		150	3	66	
Turkey	Liver		150	3	66	
Turkey	Kidney		200	3	66	
Turkey	Fat		150 <sup>a</sup>	3	66	
Rabbits	Muscle		150	3	66	
Rabbits	Liver		150	3	66	
Rabbits	Kidney		200	3	66	
Rabbits	Fat		150	3	66	

<sup>a</sup> The MRL includes skin + fat.

**Keys for List of Maximum Residue Limits for Veterinary Drugs:**

- Step - indicate current step;
- JECFA - meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the MRL was recommended / considered;
- ALINORM - indicates Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

**ERYTHROMYCIN** (antimicrobial agent)

**Acceptable Daily Intake:** The Committee established an ADI of 0–0.7 µg/kg body weight. (66<sup>th</sup> JECFA, 2006).

**Residue Definition:** Erythromycin A

Species	Tissue	Current MRL (µg/kg)	MRLs(µg/kg) recommended by 66 <sup>th</sup> JECFA	Step	JECFA	ALINORM
Chicken	Muscle		100	3	66	
Chicken	Liver		100	3	66	
Chicken	Kidney		100	3	66	
Chicken	Fat		100 <sup>a</sup>	3	66	
Chicken	Eggs		50	3	66	
Turkey	Muscle		100	3	66	
Turkey	Liver		100	3	66	
Turkey	Kidney		100	3	66	
Turkey	Fat		100 <sup>a</sup>	3	66	

<sup>a</sup> The MRL includes skin + fat.

**FLUMEQUINE** (antimicrobial agent)

**Acceptable Daily Intake:** The Committee established an ADI of 0–30 µg/kg body weight (62<sup>nd</sup> JECFA 2004).

**Residue Definition:** Flumequine

Species	Tissue	Current draft MRL (µg/kg) <sup>1</sup>	MRLs(µg/kg) recommended by 66 <sup>th</sup> JECFA	Step	JECFA	ALINORM
Black tiger shrimp ( <i>P. monodon</i> )	Muscle	500 T	500 T <sup>a</sup>	3	62, 66	15V
Shrimp	Muscle		500 T <sup>a,b</sup>	3	66	

<sup>a</sup> The MRL is temporary, muscle including normal proportions of skin. The following information is requested by the end of 2008: (1) Information on the approved dose for the treatment of diseases in shrimp and the results of residue depletion studies conducted at the recommended dose.

<sup>b</sup> The assignment of the temporary MRL applies to all freshwater and marine shrimp.

<sup>1</sup> The 28<sup>th</sup> Session of the Codex Alimentarius Commission adopted the MRL for flumequine in muscle of Black tiger shrimp (*P. monodon*) to Step 5 and advanced it to Step 6 as proposed by the 16<sup>th</sup> Session of the Codex Committee on Residues of Veterinary Drugs in Foods (ALINORM 05/28/41, para. 71 and Appendix VI).

**MELENGESTROL ACETATE** (production aid)

**Acceptable Daily Intake:** The Committee established an ADI of 0-0.03 µg/kg body weight (54<sup>th</sup> JECFA, 2000).

**Residue Definition:** Melengestrol acetate

Species	Tissue	Current draft MRL (µg/kg) <sup>2</sup>	MRLs(µg/kg) recommended by 66 <sup>th</sup> JECFA	Step	JECFA	ALINORM
Cattle	Muscle		1	6	66	
Cattle	Liver	2 T	10	6	54, 58, 66	13V, 14 IV
Cattle	Kidney		2	6	66	
Cattle	Fat	5 T	18	6	54, 58, 66	13V, 14 IV

**RACTOPAMINE** (production aid)

**Acceptable Daily Intake:** The Committee established an ADI of 0–1 µg/kg body weight (62<sup>nd</sup> JECFA, 2004).

**Residue Definition:** Ractopamine

Species	Tissue	Current proposed draft MRL (µg/kg) <sup>3</sup>	MRLs(µg/kg) recommended by 66 <sup>th</sup> JECFA	Step	JECFA	ALINORM
Cattle	Muscle	10	10	3	62, 66	15 VI
Cattle	Liver	40	40	3	62, 66	15 VI
Cattle	Kidney	90	90	3	62, 66	15 VI
Cattle	Fat	10	10	3	62, 66	15 VI
Pig	Muscle	10	10	3	62, 66	15 VI
Pig	Liver	40	40	3	62, 66	15 VI
Pig	Kidney	90	90	3	62, 66	15 VI
Pig	Fat	10	10 <sup>a</sup>	3	62, 66	15 VI

<sup>a</sup> The MRL includes skin + fat.

<sup>2</sup> The 14<sup>th</sup> Session of the Codex Committee on Residues of Veterinary Drugs in Foods agreed to retain the MRLs for melengestrol acetate at Step 6 and requested JECFA re-evaluation (ALINORM 03/31A, para. 63). The 15<sup>th</sup> Session of the Committee noted that the recalculated MRL for melengestrol acetate would be circulated for comments at Step 6 for consideration at its 16<sup>th</sup> Session (ALINORM 05/28/31, para. 62).

<sup>3</sup> The 15<sup>th</sup> Session of the Codex Committee on Residues of Veterinary Drugs in Foods retained the MRLs for ractopamine at Step 4, with the understanding that after detailed examination of the report of the 62<sup>nd</sup> JECFA, due consideration would be given to the advancement of the MRLs to Step 5 and 8 at its next session (ALINORM 05/28/31, para. 91). The Committee also included ractopamine in the priority list if veterinary drugs proposed for evaluation or re-evaluation of JECFA for recalculation of the MRLs and TMDI taking into account the decision regarding the rounding practice (ALINORM 05/28/31, Appendix IX).

**TRICLABENDAZOLE** (anthelmintic)

**Acceptable Daily Intake:** The Committee established an ADI of 0–30 µg/kg body weight (40<sup>th</sup> JECFA, 1992).

**Residue Definition:** Keto-triclabendazole

Species	Tissue	Current MRL (µg/kg) <sup>4</sup>	MRLs(µg/kg) recommended by 66 <sup>th</sup> JECFA	Step	JECFA	ALINORM
Cattle	Muscle	200	150	3	40, 66	
Cattle	Liver	300	200	3	40, 66	
Cattle	Kidney	300	100	3	40, 66	
Cattle	Fat	100	100	3	40, 66	
Sheep	Muscle	100	150	3	40, 66	
Sheep	Liver	100	200	3	40, 66	
Sheep	Kidney	100	100	3	40, 66	
Sheep	Fat	100	100	3	40, 66	
Goat	Muscle		150	3	66	
Goat	Liver		200	3	66	
Goat	Kidney		100	3	66	
Goat	Fat		100	3	66	

<sup>4</sup> The current MRLs for triclabendazole were adopted by the 21<sup>st</sup> Session of the Codex Alimentarius Commission in 1997.