

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

CX 4/60.2

CL 2000/28 - RVDF
September 2000

TO: Codex Contact Points
Interested International Organizations

FROM: Secretary, Codex Alimentarius Commission
FAO, Viale delle Terme di Caracalla, 00100 Italy

SUBJECT: **REQUEST FOR COMMENTS AT STEPS 6 AND 3 ON DRAFT AND
PROPOSED DRAFT MAXIMUM RESIDUE LIMITS FOR VETERINARY
DRUGS (MRLVDS)**

DEADLINE: **30 March 2000**

COMMENTS: **To:** U.S. Codex Office
Food Safety and Inspection Service
US Department of Agriculture
Room 4861 South Building
1400 Independence Ave., SW
Washington, DC, 20250, USA
Fax: +1 202 720 3157
E-mail: uscodex@usda.gov

Copy to: Secretary
Codex Alimentarius Commission
FAO
Viale delle Terme di Caracalla
00100 Rome, Italy
Fax: +39 06 5705 4593
E-mail: codex@fao.org

1. The 54th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) convened in Geneva, Switzerland, from 15 to 24 February 2000. This was the 13th JECFA meeting dealing exclusively with residues of veterinary drugs in foods. The Summary and Conclusions of the 54th JECFA Meeting, including recommendations for maximum residue limits for veterinary drugs in foods, was sent to all Codex Contact Points and Observer organizations in March 2000. The full report of the 54th JECFA Meeting will be published in due course by WHO in the name of both sponsoring organizations, FAO and WHO.

2. At the 47th Session of the Executive Committee of the Codex Alimentarius Commission adopted those proposed draft MRLVDs contained in Appendix V of ALINORM 01/31 at Step 5 and advanced them to Step 6 (ALINORM 01/3, Appendix IV).

3. Governments and interested international organizations are invited to comment on the draft MRLVDs (Part 1) at Step 6 and proposed draft MRLVDs on the basis of recommendations of the 54th JECFA (Part 2) at Step 3. Comments should be sent to the U.S. Codex Office with a copy to the Secretary, Codex Alimentarius Commission. These draft and proposed draft MRLVDs will be considered by the 13th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (October 2001) at Step 7 and 4, respectively.

PART 1. DRAFT MRLVDS AT STEP 6¹

CLENBUTEROL

ADI: 0-0.004 µg/kg body weight (1996)

Residue Definition: Clenbuterol.

Species	Tissue	MRL (µg/kg)	JECFA	CCRVDF	Step
Cattle	Milk	0.05	47	10VI, 11VI, 12V	6

NEOMYCIN

ADI: 0-60 µg/kg body weight (1996)

Residue Definition: Neomycin.

Species	Tissue	MRL (µg/kg)	JECFA	CCRVDF	Step	
Cattle	Liver	15000	1/	52	12V	6(r)
Cattle	Kidney	20000	2/	52	12V	6(r)
Cattle	Milk	500	3/	52	12V	6(a)

The Committee at its 12th Session agreed to seek information on the registration of injectable neomycin products as well as how they were used with respect to Good Practices in the Use of Veterinary Drugs at the national level (CL 2000/11-RVDF, Part 3).

1/ Current Codex MRL: 500 µg/kg.

2/ Current Codex MRL: 10000 µg/kg.

3/ Current Codex MRL: 500 µg/l.

PHOXIM

ADI: 0-4 µg/kg body weight (1999)

Residue Definition: Phoxim

Species	Tissue	MRL (µg/kg)	JECFA	CCRVDF	Step	
Cattle	Muscle	50	T	52	12V	6
Pig	Muscle	50	T	52	12V	6
Sheep	Muscle	50	T	52	12V	6
Goat	Muscle	50	T	52	12V	6
Cattle	Liver	50	T	52	12V	6
Pig	Liver	50	T	52	12V	6
Sheep	Liver	50	T	52	12V	6
Goat	Liver	50	T	52	12V	6
Cattle	Kidney	50	T	52	12V	6
Pig	Kidney	50	T	52	12V	6
Sheep	Kidney	50	T	52	12V	6
Goat	Kidney	50	T	52	12V	6
Cattle	Fat	400	T	52	12V	6
Pig	Fat	400	T	52	12V	6
Sheep	Fat	400	T	52	12V	6
Goat	Fat	400	T	52	12V	6
Cattle	Milk	10	T	52	12V	6

¹ Keys for List of MRLs for Veterinary Drugs

Step: (r), revised MRL; (a), amended MRL.

JECFA: Meeting number of the Joint FAO/WHO Expert Committee on Food Additives where the MRL recommended/considered.

CCRVDF: Session number of the CCRVDF where the MRL was considered and Appendix number of its report where the MRL is contained.

PORCINE SOMATOTROPIN

ADI: Not Specified (1999)

Residue Definition: Not applicable

Species	Tissue	MRL (µg/kg)		JECFA	CCRVDF	Step
Pig	Muscle	not specified	1/	52	12V	6
Pig	Liver	not specified	1/	52	12V	6
Pig	Kidney	not specified	1/	52	12V	6
Pig	Fat	not specified	1/	52	12V	6

The ADI applies only to three specific compounds.

ADI "not specified" means that available data on the toxicity and intake of the veterinary drug indicate a large margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the 52nd JECFA concluded that use of the veterinary drug does not represent a hazard to human health and that there is no need to specify a numerical ADI.

1/ MRL "not specified" means that available data on the identity and concentration of residues of the veterinary drug in animal tissues indicate a wide margin of safety for consumption of residues in food when the drug is used according to good practice in the use of veterinary drugs. For that reason, and for the reasons stated in the individual evaluation, the 52nd JECFA concluded that the presence of drug residues in the named animal product does not present a health concern and that there is no need to specify a numerical MRL.

THIAMPHENICOL

ADI: 0-5 µg/kg body weight (1999)

Residue Definition: Sum of thiamphenicol and thiamphenicol conjugates, measured as thiamphenicol.

Species	Tissue	MRL (µg/kg)		JECFA	CCRVDF	Step
Pig	Muscle	50	T	52	12V	6
Fish	Muscle	50	T	52	12V	6
Pig	Liver	100	T	52	12V	6
Pig	Kidney	500	T	52	12V	6
Pig	Fat	50	T	52	12V	6

PART 2. PROPOSED DRAFT MRLVDS AT STEP 3
(Recommended by the 54th JECFA)

CYHALOTHRIN

ADI: 0-2 µg/kg body weight (2000) temporary
ADI 1/

Residue Definition: Cyhalothrin.

Species	Tissue	MRL (µg/kg)		Step
Cattle	Muscle	20	T	3
Pig	Muscle	20	T	3
Sheep	Muscle	20	T	3
Cattle	Liver	20	T	3
Pig	Liver	20	T	3
Sheep	Liver	20	T 2/	3
Cattle	Kidney	20	T	3
Pig	Kidney	20	T	3
Sheep	Kidney	20	T	3
Cattle	Fat	400	T	3
Pig	Fat	400	T	3
Sheep	Fat	400	T	3
Cattle	Milk	30	T	3

All MRLs are temporary because the ADI is temporary.

1/ Results of appropriate studies to establish a no-observed-effect level (NOEL) for neurobehavioral effects in laboratory animals are required for evaluation in 2002.

2/ Results of the validation of the analytical method to demonstrate a limit of quantification of 0.01 mg/kg (sheep liver) are required for evaluation in 2002.

DICYCLANIL

ADI: 0-7 µg/kg body weight (2000)

Residue Definition: Dicyclanil.

Species	Tissue	MRL (µg/kg)		Step
Sheep	Muscle	200		3
Sheep	Liver	400		3
Sheep	Kidney	400		3
Sheep	Fat	150		3

IVERMECTIN

ADI: 0-1 µg/kg body weight (1992)

Residue Definition: 22,23-Dihydroavermectin B1a (H2B1a).

Species	Tissue	MRL (µg/kg)		Step
Cattle	Milk	10	T 1/	3

1/ Validation data on the analytical method and information on other routes of application to cattle to evaluate the residues in milk are required for evaluation in 2002.

LINCOMYCIN

ADI: 0-30 µg/kg body weight (2000)

Residue Definition: Lincomycin.

Species	Tissue	MRL (µg/kg)		Step
Cattle	Muscle	100	T 1/	3
Pig	Muscle	100		3
Sheep	Muscle	100	T 1/	3
Chicken	Muscle	100	T 1/	3
Cattle	Liver	500	T 1/	3
Pig	Liver	500		3
Sheep	Liver	500	T 1/	3
Chicken	Liver	500	T 1/	3
Cattle	Kidney	1500	T 1/	3
Pig	Kidney	1500		3
Sheep	Kidney	1500	T 1/	3
Chicken	Kidney	1500	T 1/	3
Cattle	Fat	100	T 1/	3
Pig	Fat	100		3
Sheep	Fat	100	T 1/	3
Chicken	Fat	100	T 1/	3
Cattle	Milk	150		3

1/ Data comparable to those provided for tissues of pigs, which show that lincomycin is the major component with significant microbiological activity in tissues of cattle, sheep, and chickens, are required for evaluation in 2002.

MELENGESTROL ACETATE

ADI: 0-0.03 µg/kg body weight (2000)

Residue Definition: Melengestrol acetate.

Species	Tissue	MRL (µg/kg)		Step
Cattle	Liver	2		3
Cattle	Fat	5		3

All MRLs are temporary. A practical analytical method for monitoring residues of melengestrol acetate at the recommended MRL is required for evaluation in 2002.

TRICHLORFON (Metrifonate)

ADI: 0-20 µg/kg body weight (200)

Residue Definition: Trichlorfon

Species	Tissue	MRL (µg/kg)		Step
Cattle	Milk	50		3

MRLs were not recommended by 54th JECFA for muscle, liver, kidney or fat in cattle considering that no detectable residues should be present in tissues from animals treated with trichlorfon when used in accordance with good practice in the use of veterinary drugs. The limit of quantification may be used as guideline maximum residue concentrations in muscle, liver, kidney and fat of cattle (50 µg/kg).