ANNEX 4

ACCEPTABLE DAILY INTAKES, OTHER TOXICOLOGICAL INFORMATION, AND INFORMATION ON SPECIFICATIONS

Antimicrobial agents

Cefuroxime

Acceptable daily intake: The temporary ADI established at the fifty-eighth meeting of the Committee (WHO TRS 911, 2002) was withdrawn.

Residue definition: The temporary MRL for cows' milk was withdrawn.

Chloramphenicol

Acceptable daily intake: The Committee concluded that it is not appropriate to establish an ADI for chloramphenicol.

Residue definition: The Committee concluded that:

There was no evidence supporting the hypothesis that chloramphenicol is synthesized naturally in detectable amounts in soil. Although this possibility is highly unlikely, data generated with modern analytical methods would be required to confirm this;

There was evidence that low concentrations of chloramphenicol found in food monitoring programmes in the year 2002 could not originate from residues of chloramphenicol persisting in the environment after historical veterinary uses of the drug in food-producing animals. However, owing to the high variability of the half-life of chloramphenicol under different environmental conditions, such a mechanism might occasionally cause low-level contamination in food;

Valid analytical methods are available to monitor low levels of chloramphenicol in foods. However, confirmatory methods require sophisticated and expensive equipment.

Flumequine

Acceptable daily intake: The Committee re-established an ADI of 0–30 μg/kg bw.

Residue definition: Flumequine

Recommended maximum residue limits (MRLs)

Species	Fat (μg/kg)	Kidney (μg/kg)	Liver (μg/kg)	Muscle (μg/kg)
Cattle	1000	3000	500	500
Black tiger shrimp (*P. monodon*)	—	—	—	500[a]
Chickens	1000	3000	500	500
Pigs	1000	3000	500	500
Sheep	1000	3000	500	500
Trout	—	—	—	500[b]

[a] The MRL is temporary; the following information is requested by 2006: (1) A detailed description of a regulatory method, including its performance characteristics and validation data; (2) Information on the approved dose for treatment of black tiger shrimp and the results of residue studies conducted at the recommended dose.

[b] Muscle including normal proportions of skin.

Lincomycin

Acceptable daily intake: 0–30 μg/kg bw (established at the fifty-fourth meeting of the Committee (WHO TRS 900, 2001))

Residue definition: The MRLs that were recommended by the fifty-fourth (WHO TRS 900, 2001) and fifty-eighth (WHO TRS 911, 2002) meetings of the Committee were not reconsidered and were maintained.

MRLs for cattle tissues were considered but not recommended by the Committee at its present meeting.

Pirlimycin

Acceptable daily intake: The Committee established an ADI of 0–8 μg/kg bw

Residue definition: Pirlimycin

Recommended maximum residue limits (MRLs)[a]

Species	Fat (μg/kg)	Kidney (μg/kg)	Liver (μg/kg)	Milk (μg/kg)	Muscle (μg/kg)
Cattle	100	400	1000	100	100

[a] For the maximum residue limits for pirlimycin, the Committee noted that the analytical method submitted by the sponsor had been validated suitably, however, the mass spectrometry interface used was no longer commercially available and therefore the method would not comply with all Codex requirements for a Regulatory Analytical Method. Since the Committee received information that verification of this method using different equipment was in progress, it recommended that CCRVDF should propose the MRL for adoption by the Codex Alimentarius Commission only if this work has been completed and made available to the Working Group Methods of Analysis and Sampling in the CCRVDF.

Insecticides

Cyhalothrin

Acceptable daily intake: The Committee established an ADI of 0–5 μg/kg bw

Residue definition: Cyhalothrin

Recommended maximum residue limits (MRLs)

Species	Fat (μg/kg)	Kidney (μg/kg)	Liver (μg/kg)	Milk (μg/kg)	Muscle (μg/kg)
Cattle	400	20	20	30	20
Pigs	400	20	20	—	20
Sheep	400	20	50	—	20

Cypermethrin and α-cypermethrin

Acceptable daily intake: The Committee established a group ADI of 0–20 μg/kg bw for cypermethrin and α-cypermethrin

Residue definition: Total of cypermethrin residues (resulting from the use of cypermethrin or α-cypermethrin as veterinary drugs)

Recommended maximum residue limits (MRLs)

Species	Fat (μg/kg)	Kidney (μg/kg)	Liver (μg/kg)	Milk (μg/kg)	Muscle (μg/kg)
Cattle	1000	50	50	100	50
Sheep	1000	50	50	100	50

Doramectin

Acceptable daily intake: 0–1 μg/kg bw (established at the fifty-eighth meeting of the Committee (WHO TRS 911, 2002))

Residue definition: Doramectin

Recommended maximum residue limit (MRL)

Species	Milk (μg/kg)
Cattle	15[a]

[a] The Committee noted that (1) on the basis of the MRL of 15 μg/kg for doramectin in whole milk from cows, the milk-discard times would be approximately 240 h, according to studies using the pour-on treatment. Milk discard times would be approximately 480 h after treatment with doramectin the dose formulated for injection; (2) in milk containing 4% milk fat, the residues in milk fat would be equivalent to 375 μg/kg (15 μg/kg ÷ 0.04 = 375 μg/kg). This is higher than the MRL of 150 μg/kg in fat tissue; (3) the discard time necessary to accommodate the recommended MRL in milk is unlikely to be consistent with good veterinary practice.

Phoxim

Acceptable daily intake: 0–4 μg/kg bw (established at the fifty-second meeting of the Committee (WHO TRS 893, 2000))

Residue definition: The MRLs for sheep, pigs and goats that were recommended by the Committee at its fifty-eighth meeting (WHO TRS 911, 2002) were not reconsidered and were maintained.

The temporary MRLs for cattle that were recommended by the Committee at its fifty-second (WHO TRS 893, 2000) and fifty-eighth (WHO TRS 911, 2002) meetings were withdrawn.

Production aids

Melengestrol acetate

Acceptable daily intake: 0–0.03 μg/kg bw (established at the fifty-fourth meeting of the Committee (WHO TRS 900, 2001)

Residue definition: Melengestrol acetate

Recommended maximum residue limits (MRLs)

Species	Fat (μg/kg)	Liver (μg/kg)
Cattle	8	5

Ractopamine

Acceptable daily intake: The Committee established an ADI of 0–1 μg/kg bw

Residue definition: Ractopamine

Recommended maximum residue limits (MRLs)

Species	Fat (μg/kg)	Kidney (μg/kg)	Liver (μg/kg)	Muscle (μg/kg)
Cattle	10	90	40	10
Pigs	10	90	40	10