NEOMYCIN

First draft prepared by
Dr. Dieter Arnold
Federal Institute for Health Protection
of Consumers and Veterinary Medicine
Berlin, Germany

ADDENDUM

to the Neomycin residue monograph prepared by the 43rd meeting of the Committee and published in FAO Food and Nutrition Paper 41/7, Rome 1995

No new residue depletion studies were submitted by the sponsor. Therefore, no new residue monograph was prepared. However, in view of the final ADI established by the Committee at the present meeting certain residue data were re-evaluated before final MRLs were established. These selected studies support the oral use of neomycin sulfate in certain food animals.

In a series of recently conducted residue depletion studies in cattle, swine, sheep, and goats, respectively, neomycin sulfate equivalent to 15.4 mg of neomycin base per kg of body weight was given to the animals as a single daily dose over fourteen days. No measurable residues of neomycin were found in any of the samples of liver, muscle and fat taken at any time after the last administration of the drug to the animals. The limit of quantification was 0.5 mg/kg in these studies. Kidney was considered to be the target tissue in these species and parent neomycin was established as the marker residue. The range of concentrations of neomycin found in the kidneys of cattle, swine, sheep and goats at one day withdrawal time was from below the limit of detection up to about 4.2 mg/kg.

However, when a separate similar depletion study was conducted in young calves (three days old at the beginning of the study), the depletion of the residues from kidney was slow in these young animals. Twenty-eight days after the administration of the last dose 3.9-6.8 mg of neomycin per kg of tissue were still found in the kidneys of the four animals slaughtered at this sampling time.

In a study conducted in 1967 where 15 female calves of an average body weight of 170 kg had been given oral doses of neomycin sulfate equivalent to 7.7 mg of neomycin base per kilogramm of body weight per day on five consecutive days measurable concentrations of neomycin residues were also found in the livers of some animals (e.g., 2.75 mg/kg at 3 days withdrawal, 1.01 mg/kg at 7 days withdrawal, 0.62 mg/kg at 17 days withdrawal and 1.7 mg/kg at 24 days withdrawal). However, such findings have not been confirmed in the contemporary studies. The Committee concluded that the establishment of MRLs in edible tissues should be based on the results obtained in the well designed and well documented contemporary studies.

Maximum Residue Limits

The Committee, at its 43rd Meeting, had recommended temporary MRLs because the ADI was temporary. These MRLs were: kidney 5 mg/kg, and muscle, liver and fat 0.5 mg/kg expressed as parent drug for cattle, sheep, goats, pigs, turkeys, ducks and chickens. The temporary MRLs recommended for chicken eggs and cow's milk were 0.5 mg/kg and 0.5 mg/l respectively, expressed as the parent drug.

The Committee concluded that it was unnecessary to change these MRLs with the exception of the MRLs for kidney. In the case of kidney the Committee recognized that in order to enable the establishment of practical withdrawal times for all target animal species it was necessary to double the MRLs for kidney from 5 mg/kg to 10 mg/kg.

The following final MRLs were recommended for cattle, sheep, goats, pigs, turkeys, ducks and chickens: kidney 10 mg/kg, and muscle, liver and fat 0.5 mg/kg expressed as parent drug. The final MRLs

recommended for chicken eggs and cow's milk are 0.5 mg/kg and 0.5 mg/l respectively, expressed as the parent drug.

From the above MRL values, the calculated theoretical maximum daily intake of neomycin residues is 1525 micrograms, based on a daily food intake of 300 g of muscle, 100 g of liver, 50 g each of kidney and fat, 100 g of eggs and 1.5 l of milk (see the Report of the 34th Session of JECFA). This is considerably less than the maximum ADI of 3600 micrograms of neomycin for a 60-kg person.