The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines Evaluation Unit

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

SPIRAMYCIN (1)

SUMMARY REPORT

1. Spiramycin is an antibiotic of the macrolides group expressed by certain strains of *Ambofaciens streptomyces*. The solubility in water of spiramycin has been improved by the development of an adipate ("fatty") form, and the stability in food by a coated form.

2. The Working Party on the Safety of Residues of the Committee for Veterinary Medicinal Products evaluated all the available data concerning the toxicology, metabolism and pharmacokinetics of the residues of this antibiotic in the human gut flora and in the fermenting agents used in the dairy industry.

3. Evaluation of the safety of the residues of this antibiotic has also been undertaken by the 38th Joint WHO/FAO Expert Committee on Food Additives (JECFA). Members of the Residues Working Party of the CVMP who are also members of JECFA have been able to give this working party the benefit of their experience. JECFA agreed on this methodological approach to evaluate the safety of the residues of spiramycin. Therefore the Working Party accepted the following provisional Acceptable Daily Intake (ADI) and Maximum Residues Limits (MRLs) which have been established :

   - Provisional Acceptable Daily Intake = 50 µg/kg
   - Maximum Residue Limits :

     50 µg/kg muscle (bovine, pigs)
     300 µg/kg liver (bovine, pigs)
     200 µg/kg kidney (bovine, pigs)
     150 µg/kg milk (bovine)

4. The results of the following studies are required for the adoption of a final ADI and of final MRLs :

   · *in vivo* studies concerning the effects of spiramycin on the human gut flora;
   · a radio-labelled study carried out in order to determine the importance of spiramycin and of its metabolites with regard to residues in bovine, porcine and poultry tissues;
   · a pharmacokinetic study of the residues of spiramycin in bovine and porcine fat and in edible poultry tissues.

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