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

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

TRICLABENDAZOLE

SUMMARY REPORT (2)

1. Triclabendazole had previously been scientifically assessed according to the requirements of Council Regulation (EEC) 2377/90. The measures taken according to this assessment had been published in Commission Regulation (EEC) 895/93.

2. Following provisional MRLs for the sum of extractable residues that may be oxidised to Keto-triclabendazole were established :

   0.15 mg/kg muscle, liver, kidney
   0.05 mg/kg fat,

   applicable to the species bovine and ovine. A time period terminating on 1 July 1995 was applied to the provisional MRLs.

3. The CVMP is aware of the differences in the interpretation made by JECFA of the toxicological data. The JECFA report concludes that the reported increase in mortality and lower body weights of pups in the F2 generation of the 15 ppm group (0.75 mg/kg bw/day) of the two-generation rat study were not treatment-related and an ADI of 0-0.003 mg/kg bw/day was proposed based on a chronic mouse study. The CVMP considered that the possibility of these effects being treatment-related had not been disproved. However, given the fact that further data on the total residues in edible tissues in sheep might still lead JECFA or the CVMP to reconsider the MRLs assigned to these target tissues, the CVMP agreed to recommend the MRLs set out in paragraph 5 as provisional.

4. Dossiers addressing the questions raised by the previous scientific evaluation of this compound by the CVMP are announced by industry and it became evident that scientific studies relating to this matter are currently in progress.

5. According to Article 4 of Council Regulation (EEC) 2377/90, to allow for the completion of the studies in progress, the time period applying for the provisional MRLs is extended until 1 July 1997. The submission of the further information becoming available from the ongoing studies is required before 1 July 1996.

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