EUROPEAN COMMUNITY POSITION

Follow-up of 12th CCRVDF meeting

Scientific justifications for certain positions of the European Community.

The 12th meeting of CCRVDF in March 2000, where the European Community objected to draft MRLs for a number of substances, requested the European Community to provide scientific justifications for its positions. These justifications are now provided for cyfluthrin, deltamethrin, eprinomectin and flumequine.

The communication from the Committee for Veterinary Medicinal Products is enclosed (ANNEX I).

<u>Cyfluthrin</u>: The study in rats chosen for the determination of the No-Effect-Level (NOEL) cannot be recognised, as changes in haematological parameters were seen at all dose levels. Furthermore, recent data on pharmacological and neurotoxicological effects of cyfluhtrin (barbiturate sleeping time in mice and locomotor activity) have revealed effects at lower doses than the NOEL proposed by JECFA. Nevertheless, given that the proposed Codex MRLs are at step 4, the European Community does not oppose the advancement at this stage, but presents concerns regarding the evaluation of this substance and requests a re-evaluation. The European Community would object the advancement of the proposed MRLs to step 8, unless their comments would have been considered and satisfactorily addressed.

Deltamethrin: The European Community has concerns that the estimated daily intake from veterinary drug residues and pesticidal residues would result in the ADI being exceeded with the proposed Codex MRLs (114%). Nevertheless, the European Community does not oppose the advancement of the process at this stage, but presents concerns regarding the evaluation of this substance and requests a reevaluation and a reduction of the MRLs proposed. The European Community would object to the advancement of the proposed MRLs to step 8, unless their comments would have been considered and satisfactorily addressed.

Eprinomectin: Having reconsidered the assessment made by JECFA, it can be concluded that the MRLs proposed by Codex do not differ significantly from those adopted by the European Community in accordance with Council Regulation (EEC) No 2377/90 and do not pose any risks with respect to consumer safety. The European Community can accept the draft Codex MRLs for eprinomectin.

Flumequine: The European Community expresses its concerns relating to the ADI and the MRLs proposed by JECFA. The toxicological ADI chosen is substantially higher than the microbiological ADI established in the European Community, which is based on data on the most sensitive predominant micro-organism (*E. coli*). Furthermore, taking into account the different ratios of marker to total residues, the European ADI would be exceeded to a varying degree in different species. The only exception in this respect is the species trout. Therefore, the European Community continues not to support the draft

Codex MRLs for flumequine, with the exception of that proposed for trout, which is acceptable.