12/09/01

FURTHER
EUROPEAN COMMUNITY COMMENTS ON

Codex Circular Letter CL 2000/28-RVDF : Request for comments at steps 6 and 3 on draft and proposed draft MRLs for veterinary drugs

Following the previously transmitted European Community comments on Codex Circular Letter CL 2000/28-RVDF (20/04/2001), the Committee for Veterinary Medicinal Products has now provided further comments in relation to outstanding items. These comments relate to positions still to be addressed (dicyclanil, clenbuterol and ivermectin) and more detailed justifications for some of the positions (thiamphenicol, trichlorfon (metrifonate) and cyhalothrin for porcine tissues) taken by the European Community (ANNEX I).

Part 1. Draft MRLs at step 6.

- **Thiamphenicol**[1]**:** The European Community does not give support to the proposed draft Codex MRLs for thiamphenicol due to severe lack of reliable data for the determination of ADI and the ratio of marker to total residues. Very similar deficiencies were found in the dossier put forward by the JECFA and in that submitted to the European Community, on the basis of which it was not possible to establish definitive MRLs.

- **Clenbuterol (bovine milk) :** The European Community can accept the draft Codex MRLs as the value is in accordance with European Council Regulation (EEC) N° 2377/90.

Part 2. Proposed draft MRLs at step 3

- **Trichlorfon** (metrifonate) (1): The European Community does not give the support for the proposed draft Codex MRLs for trichlorfon (metrifonate) for the following reasons: Severe safety concerns are expressed in view of the substance being clearly fetotoxic, teratogenic and mutagenic. There is also convincing data on congenital effects in humans. The proposed ADI is furthermore based on a totally inappropriate study on acute effects in a diseased human sub-population (patients with Alzheimer disease).

- **Cyhalothrin** (1): The European Community does not give the support for the proposed Codex MRLs for cyhalothrin for porcine tissues at present, as the ratio of marker to total residues can not be determined due to a lack of adequate studies.

[1] The European Community position is based on the following decision taken at the 24th session of the Codex Alimentarius : « When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commisison should not proceed to elaborate a standard… » (Alinorm 01/41 – para. 70)

- **Dicyclanil :** The European Community cannot give support to the proposed draft Codex MRLs for dicyclanil, as the use of dicyclanil itself as a marker gives an estimated total maximum daily intake far above the ADI (330%).

- **Ivermectin** [(1)]**:** The European Community cannot give the support for the draft Codex MRL for ivermectin for milk at present, as no information is available on the ratio of marker to total residues, which gives an unacceptable uncertainty to the estimation of the theoretical maximum daily intake.