

10/03/2003

**EUROPEAN COMMUNITY**  
**COMMENTS ON**

**CODEX CIRCULAR LETTER CL 2001/49 – RVDF**

**Report of the 13<sup>th</sup> session of the Codex Committee on Residues of  
Veterinary Drugs in Foods (Alinorm 03/31) - Request for comments**

**Matters for Adoption by the 25<sup>th</sup> Session of the Codex Alimentarius  
Commission at Step 8, Step 5/8 or Step 5 under the accelerated  
Procedure**

**Part A i and ii (Appendix II and III):**

The European Community would like to make the following comments regarding acceptance of MRLs proposed at step 8 (appendix II) and 5/8 (appendix III), respectively:

In accordance with the scientific assessment performed, the MRLs proposed for the following substances can be accepted from the point of view of adequate protection of human health: abamectin, carazolol, clenbuterol, eprinomectin and phoxim. Nevertheless, the maximum residue limits legally permitted in the European Union may differ to those proposed as Codex standards at step 8.

The MRLs for cyhalothrin proposed for step 5/8 can not be supported, as the 14<sup>th</sup> session of CCRVDF proposed to return cyhalothrin to step 6, pending further reconsideration by JECFA.

The MRLs for chlortetracycline/oxytetracycline/tetracycline and cyfluthrin and the proposal not specify MRLs for porcine somatotropin are not acceptable.

Specific reasons for the position taken by the European Community regarding these substances are provided below.

**Chlortetracycline/oxytetracycline/tetracycline**

The maximum residue limits proposed for cattle, pigs, sheep, poultry, giant prawns and fish are not supported. The ADI adopted by JECFA is not acceptable as it does not sufficiently take into consideration the uncertainties with the method employed to derive the ADI. A safety factor is necessary as the microbiological model study has not been validated and it is further assumed that no variation in the human population is possible as regards the selection of resistant Enterobacteriaceae strains for tetracyclines. The 4-epimer is also microbiologically active and it is considered necessary to include this substance in the marker residue.

### Cyfluthrin

The toxicological study in the rat used to determine the ADI cannot be recognised as hematological parameters were changed in all dose groups. Another recent study on pharmacological and neurotoxicological effects of cyfluthrin has also showed toxic effects on locomotor activity in lower doses. There is thus concern that the MRLs proposed could have a negative impact on human health.

### Porcine somatotropin

Porcine somatotropin is the porcine analogue to BST, which is prohibited for use in the European Union. The use of porcine somatotropin as growth promotor coupled with the risk of remaining residues at the injection site and the uncertainties with respect to hormonal effects due to secondary increased production of IGF-1 in tissues of treated pigs may present a risk to human health. The position of the European Community is based on the decision taken at the 24<sup>th</sup> session of the Codex Alimentarius Commission: “ When there is evidence that a human health risk exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard..” (ALINORM 01/41 – para. 81).

### **Part A iii:**

As regards the amendments to the glossary of terms, these are only acceptable if a reintroduction of the reference to the average fat content of 4% for milk is made. This was originally proposed to enable a direct and clear comparison of MRLs between the veterinary residues and the pesticide sector.