22/11/02

EUROPEAN COMMUNITY COMMENTS ON

CL 2002/34-RVDF

Subject: **REQUEST FOR COMMENTS:**

A) Recommendations on maximum residue limits from the 58th meeting of JECFA

B) Priority list of veterinary drugs for evaluation or re-evaluation

A) The European Community would like to present the following comments to the recommendation on maximum residue limits for veterinary drugs arising from the 58th meeting of the Joint FAO/WHO Expert Committee on food additives. These comments relate to positions for draft MRLs for ivermectin for bovine milk (at step 5/8), cefuroxime (at step 3), oxytetracycline (at step 8), cypermethrin (at step 3), alphacypermethrin (at step 3), dihydrostreptomycin/streptomycin for milk (at step 3), lincomycin (at step 5/8) and melengestrol acetate (at step 5).

The maximum residue limits proposed for **dihydrostreptomycin/streptomycin** for cattle and sheep milk**, lincomycin** for pig and chicken tissues and **cypermethrin** for sheep provide for appropriate protection of consumer safety and are therefore acceptable.

The proposed maximum residue limits for the following substances can not be supported due reasons provided for each substance(1):

- **Ivermectin:** No information is available on the ratio of marker to total residues in cows milk, which gives an unacceptable uncertainty to the estimation of the theoretical maximum daily intake. Furthermore, there is only limited information concerning residues in milk following different routes of administration and the information requested by the 54th JECFA meeting has not been provided. It is known that from published literature that ivermectin residues in milk are persistent and higher than the MRL proposed for a considerable period of time after administration.

- **Cefuroxime:** The proposed draft MRL for milk do not take into consideration all microbiologically active residues and no reliable estimate can therefore be made of the relevant amount of residues in milk. The parent compound only represents a small part of the total residues with antimicrobial activity, although JECFA assumed, contrary to studies in the dossier (Fergusson and Batten, 1996), that cerfuroxime was the only microbiologically active residue. In addition, data on effects on starter cultures available to JECFA were not taken into account. The MRL proposed for milk has been shown to inhibit the acid production by commercial starter cultures. Finally, a clarification regarding the analytical method is required. It is stated in the JECFA report that the method had been

validated according to existing criteria in the EU for drug registration, contrary to the evaluation in the EU, which had concluded that the same method was insufficiently validated.

- **Alphacypermethrin:** Maximum residue limits for alphacypermetrin should be identical to those proposed for cypermethrin. Alphacypermethrin consists of the two most toxic isomers of cypermethrin and a lower ADI was consequently adopted for alphacypermethrin at the 47th meeting of JECFA. To employ different values for these two substances will lead to problems in residue surveillance and eventually in international trade.

- **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 too high and 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.

- **Melengestrol acetate:** Due to the non-availability of a dossier for this substance in the EU, no definite position can be taken on this substance. It is noted, however, that no analytical method for the monitoring of residues is available and therefore further advancement of this substance is not supported. The substance was evaluated by JECFA partly for use as growth promotor, a use that is prohibited in the European Community.

B) No specific comments can be offered on the priority list of veterinary drugs for evaluation or re-evaluation. It is noted, however, that for a number of substances data requested by JECFA had not been submitted yet.