10/08/04

EUROPEAN COMMUNITY COMMENTS ON

CX-RVDF 04/15/7

Subject: **REQUEST FOR COMMENTS:** Part II "General Considerations on Analytical Methods for Residues Control" of the Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drugs Residues in Foods (CAC/GL 16-1993)

The European Community supports the general principles of the document considering the quality and applicability of analytical methods to be used in residue control. Nevertheless, the document contains many repetitions and redundancies; it could therefore be considerably shortened without loosing out on details. It would moreover make the document more readable if the definitions explained and used in the document were listed in a glossary or in one list. Definitions for the different types of methods (screening, determinative, confirmatory etc.) should be included in such a list.

Overlaps with document CX/RVDF 04/15/7 *Codex Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods* should also be avoided (see in particular points 1, 2, 3, 38, 39-42) and "*Method Development Considerations*" do, in our view, not fall under the scope of this document (point 16).

The outcome of the discussions of *Joint FAO/WHO Technical Workshop on Residues of Veterinary Drugs without ADI/MRL* (Bangkok, 24 – 26 August 2004) should be considered before redrafting points 6 and 38.

The European Community can support the principle of single laboratory validation (points 15 and 43).

Point 4 and 8: We agree that methods of analysis used in regulatory programmes for control should be fit for purpose. The purpose of individual parts of regulatory programmes differs, in particular with respect to type and detail of information they focus on. The requirements for methods of analysis will therefore depend on the type of the regulatory programme they are employed in (e.g. *System Verification Programmes* or *Targeted Programmes*, see page 7 of CX/RVDF 04/15/7).

Point 5 and 42: We would not completely rule out the use methods for screening which do not provide information on the chemical structure of the residues such as "*plate tests*" linking bacterial growth inhibition patterns to specific antimicrobials. However, here the method determines the result and how it is communicated (e.g. "*growth inhibition observed*"). Therefore these methods have to be described in detail, agreed and to be implemented precisely as documented in order to produce widely acceptable and comparable results. They may also be used alone, but procedures should allow the rebuttal of "positive" test results on reversal of the burden of proof.

Point 11: If particular historical methods are to be accepted, the criteria should be better defined. It is not clear what is required if the "*method performance has been demonstrated through successful use in various laboratories over time*".

Point 27: While the *AOAC Performance Test Program* may be a reliable procedure to validate screening test, an international standard should avoid exclusive reliance on programmes of one provider. We would consider it more appropriate if the required performance of a screening method (e.g. the maximal percentage of false results) could be defined.

Further details are necessary to provide the guidance which allows laboratories to clearly identify what Codex Alimentarius considers acceptable. It should, for example, be indicated what is the *required sensitivity* (point 20), what combined information is necessary to make a statement on sensitivity (point 20 and 26), what would be an appropriate *level of interest* (point 24 and 31) and what would be a *suitable level of performance* (point 22).