codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 9(a) **CX/RVDF 00/9**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
Twelfth Session
Washington, D.C., 28 - 31 March 2000

METHODS OF ANALYSIS FOR VETERINARY DRUGS

REVIEW OF PERFORMANCE-BASED CRITERIA FOR METHODS OF ANALYSIS AND SAMPLING FOR VETERINARY DRUGS RESIDUES IN FOODS

(Prepared by Canada and the United States of America)

1. The 11th Session of the CCRVDF requested Australia to prepare a revised version of a discussion paper submitted for circulation prior to that Meeting. The delegations of Canada, France, Mexico, the Netherlands, New Zealand and the representatives of OIE and WVA agreed to assist Australia in this effort.

2. Subsequent to the 11th Session of the CCRVDF, an International Workshop on Principles and Practices of Method Validation was held in the Hungarian Academy of Sciences, Budapest, Hungary, November 4-6, 1999. The Workshop was jointly sponsored by AOAC International, the FAO, IAEA and the International Union of Pure and Applied Chemistry (IUPAC). A guideline document on single laboratory method validation was discussed at the Workshop and is now being circulated by the IUPAC Project Coordinators to interested parties, such as the attendees at the Workshop, IUPAC contact scientists, AOAC International, for comment. It is intended that this document, if adopted by IUPAC, shall provide a harmonized guideline on the issue of validation of methods within a single laboratory.

3. In addition, following the Workshop in Budapest, a joint FAO/IAEA Consultation was held in Miskolc, Hungary, November 8-12, 1999, to develop a practical approach to validation of a method within a single laboratory. The document containing the "practical guidelines" has been distributed to a number of national regulatory authorities in the short time available prior to the 12th Session of the CCRVDF and is also intended to be distributed to other interested Codex Committees, particularly the CCPR.

4. The Workshop and the Consultation, as well as the IUPAC Project to develop a harmonized guideline, are all intended to build on the recommendations of the Joint FAO/IAEA Expert Consultation on Validation of Analytical for Food Control (Vienna, 1997)[1].

5. The CCRVDF may consider that it would be premature to develop a guidance document on method validation requirements for the CCRVDF until the documents on single laboratory method validation are finalized by the International Union of Pure and Applied Chemistry and AOAC International. These documents could then be used to support the recommendations of the Vienna Consultation and to elaborate a specific guidance for the Working Group to apply in reviewing methods.

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1 Food and Nutrition Paper 68, FAO (1998)

The CCRVDF may wish to request Australia and the other interested delegations to continue work on such a document for consideration at the next Session.

6. In anticipation of the outcome of this work, the Committee may wish to continue to collect information on methods that are currently being used for regulatory purposes in member states, to review the available validation information on these methods and to make this information available to all interested members. Information on any such methods which is made available will be considered by the Working Group to review and recommend methods for, respectively, anthementics; antimicrobials; antiprotozoals, insecticides, trypanocides; and growth promoters, beta-adrenoceptor blockers, and tranquillizers.

7. The Committee also should note that the practice within the CCPR is to list methods which are demonstrated to have been used in regulatory monitoring or in the development of regulatory submissions when such methods have demonstrated performance criteria which are fit for the intended purpose, such as monitoring for compliance with an MRL. Such methods do not necessarily meet the criteria for a reference method in that they have not been subjected to a collaborative trial. However, they may meet the requirement that a suitable method be known to be available to support a proposed MRL.