codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 7 **CX/RVDF 09/18/7 Add.1**
April 2009

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Eighteenth Session

Natal, Brazil, 11-15 May 2009

DISCUSSION PAPER ON CONSIDERATION OF METHODS OF ANALYSIS AND SAMPLING IN CCRVDF

(Report of the electronic Working Group on Methods of Analysis and Sampling)

Comments Submitted by:

Argentina, Egypt, European Community, Iran, Kenya, United States of America and Uruguay

ARGENTINA

After reviewing the Procedural Manual, and by virtue of the inherent competencies of the work of Codex performed by each Technical Committee and each Scientific Committee, Argentina believes that JECFA is the body responsible for performing risk assessments related to residues of veterinary drugs and for developing recommendations on reference methods of analysis for each veterinary drug.

In view of this, Argentina supports the establishment of a Working Group to evaluate the methods of analysis provided by JECFA, in the frame of the MRLs established for residues of veterinary drugs, in order to be considered according to the performance criteria and other issues inherent to risk management.

In terms of the Performance Criteria for Analytical Methods, Argentina believes it is important to mention that in the 30th Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS), held March 9 to 13, 2009, the document on Guidelines on Establishing Methods Criteria for the Identification of Relevant Analytical Methods was approved, which will ultimately be endorsed by the 32nd Session of the Codex Alimentarius Commission next July.

In this regard, Argentina considers that the criteria addressed in the document pertaining to the Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals should be consistent with the ones approved in the CCMAS.

In addition, at the above mentioned session, the Guidelines on Analytical Terminology were updated and approved. These guidelines contain the definitions that will be included in the Codex Procedural Manual. Therefore, it would be appropriate for the CCRVDF to adopt the terminology that has already been defined by the CCMAS in order to unify criteria and maintain only one glossary.

Also, Argentina wishes to highlight how important it is for the approved methods to be transformed into performance criteria. By doing this, any validated method that meets the criteria for one specific substance may be used for the determination of residues in a manner consistent with the detection of residues of veterinary drugs in food.

In regard to the performance criteria for multi-residue analytical methods, Argentina considers that it is appropriate to address this issue, as long as it is used in relation to the chemical GROUP or FAMILY of the substances. Its use must be stated as an option within the existing methods, and its application should not be subordinated to the application of certain specific technologies.

Finally, in reference to the Compendium of Validated Methods of Analysis, Argentina believes that this work should be discontinued, and that the compilation gathered so far should be used as a bibliographical reference valid as of the date of publication.

EGYPT

Article: Need for analytical methods:

Item 5: deleting the sentence (to develop codes of practice as may be required) as it is not clear and unmeaning.

Item 6: No need to mention that work carried out by the council of Europe should be taken into account as the committee has already liaised closely with the methods of analysis and sampling (CCMAS).

Item 11: To stick to validation of methods of analysis by a minimum of three labs and not six labs.

Article: Analytical methods linked to the Codex Alimentarius Step Process:

Item 12: Full agreement with the advice that methods should be available before CCRVDF advances MRLs to step 8.

Item 14: For sure that a specific problem could arise by reliance on costly methods which were beyond the accessibility of many developing countries.

Item 20: As suitable validation data exists, recommended methods for all veterinary medicines and not for a number only as mentioned in the paper.

Item 24: No need to mention that developing countries might wish to assess their method needs in order to include this in the exercise; instead, methods must be unified for all countries including developing ones.

Article : Use and value of the compendium of analytical methods.

Item 37: It is more preferred to fix a number of years for the application of methods and not to be changed continuously by advancement of new technology or new legislation, to avoid confusion in following obsolete methods.

Item 40: It is mentioned that compendium analytical methods should not be accepted, even that it was mentioned in conclusion and recommendations that the current version of the compendium should be mentioned as a resource for 5 years then withdrawn . Better to omit previously mentioned notification in item 40.

Finally it was a marvelous effort carried by the EWG in preparing this valuable comprehensive paper.

EUROPEAN COMMUNITY

Recommendations a and b

It is appropriate that CCRVDF, when considering MRL recommendations of JECFA, verifies that the analytical method provided to JECFA fulfils the appropriate performance criteria in paragraphs 201-226 of Appendix VI of ALINORM 08/31/31. However, CCRVDF should not recommend any such method for monitoring purposes as there are often other more efficient methods available, especially for screening purposes.

Recommendation c

CCRVDF should ensure that the performance criteria for analytical methods are kept up to date. The ECMS therefore agree with the recommendation to consider developing performance criteria for multi-residue analytical methods. In that context, also issues in relation to method validation could be considered.

Recommendations d and e

It has become evident over the years that CCRVDF is not in a position to establish a list of recommended analytical methods for residues for which Codex MRLs have been established and to keep such a list updated taking into account technological developments in laboratory techniques. Therefore, the ECMS are in favour of suspension of further work on the compendium and its eventual withdrawal.

IRAN

The Islamic Republic of Iran believes that methods of analysis and sampling for veterinary medicines should be compiled and be available for analysts. Because analysts need official and validated methods for drug analysis. It can be carry out by co-operation of related technical committees of ISO (International Organization for Standardization) and a working group of CCRVDF. These methods should be published as International Standards. ISO has valuable experiences in developing standards and also validation of analytical test methods.

The compendium provides a useful resource to developing international standards in this area.

KENYA

We have read this paper which was prepared the United Kingdom and Canada, with input from Australia, Belgium, Germany, the Netherlands, Norway, Japan, Sweden, and IFAH and proposes that the current version of the compendium should be maintained as a resource of initial analytical methods and analytical contacts for the benefit of scientists working on veterinary drug residue surveillance programmes, this is because the compendium may continue to provide a useful initial resource to analysts working in this area especially for some developing countries, provided it can meet the performance criteria set out in codex standard.

UNITED STATES OF AMERICA

The United States supports recommendations a, c, d, and e from the report of the electronic Working Group on Methods of Analysis and Sampling. However, the United States would like to further discuss recommendation b, "For the purposes of trade, analytical methods should not be considered as set or unalterable, but that any analytical method may be used PROVIDED it can meet the performance criteria set out in Appendix VI (paragraphs 201-226) of ALINORM 08/31/31."

The performance criteria as provided in Appendix VI of ALINORM 08/31/31 are listed for fortified tissue. In cases where the marker residue is readily extracted from matrix and not transformed, the method can probably be changed if performance criteria are met and the procedure is tested with incurred residues (although it is recommended that the new procedure be bridged to the original procedure used to measure the residues for MRL determination). But for bound residues, the reference extraction procedure (validated using radiolabeled incurred residues) should be followed in order to avoid false negative results. Similarly, in "total residue" methods (where multiple metabolites are converted to a single moiety), a spiked sample with parent compound and/or one metabolite does not replicate what happens in an incurred sample. So the reference method, validated with incurred radiolabeled residues, should be followed at least until the final chemical transformation. In both of these cases fortified samples cannot replicate the results obtained with the original procedure using incurred residues.

URUGUAY

Issue No. 1

The future of the compendium of analytical methods

Uruguay agrees with the recommendations stated in document CX/RVDF 09/18/07 (paragraph 41 (e), page 6).

It is emphasized that the task of periodically maintaining and updating the compendium is considered very important because it is a significant starting point for analysts working in residue programmes, even if some of the methods are not validated according to the criteria established by Codex and have not attained a complete recommended status.

Issue No. 2

The link between analytical methods and advancing Codex Maximum Residue Limits (MRLs) to Step 8

Uruguay agrees with the statement in paragraph 15, on page 3 of the document, regarding the advancement of the MRL to Step 8.

Uruguay also agrees with the statement in paragraph 41 (b) with regard to the idea that methods are not static and that, for the purposes of trade, any method may be used that meets the performance criteria set out in Appendix VI (paragraphs 201 – 226) of ALINORM 08/31/31.

Issue No. 3

The criteria necessary for analytical methods to be assessed and considered suitable

Uruguay agrees with the statement in paragraph 41 (c) of document CX/RVDF 09/18/07, emphasizing that most of the analyses performed in our Residue Programme are multi-residue analytical methods (Sulfa compounds, Avermectins, Benzimidazoles, Stilbenes, Carbamates, Nitrofurans, metabolites, etc.).

There is a gap in these cases. Therefore, it is necessary to establish performance criteria for multi-residue analytical methods, just as it was done for single drug methods.