codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 10 **CX/RVDF 03/9**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Fourteenth Session

Washington, D.C., USA, 4 - 7 March 2003

DISCUSSION PAPER ON RESIDUES ISSUES FOR THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

(prepared by the United States of America)

Governments and international organizations wishing to submit comments on the following subject matter are invited to do so **no later than 3 February 2003** as follows: U.S. Codex Office, Food Safety and Inspection Service, US Department of Agriculture, Room 4861, South Building, 14th and Independence Avenue, S.W., Washington, DC 20250, USA (Fax No: +1.202.720.3157; e-mail: uscodex@usda.gov), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org).

INTRODUCTION

1. At the 12th Session of the CCRVDF, the delegations of Chile and Costa Rica expressed their concern at the delays in the progress in the work of the Committee especially regarding the importance of Codex MRLs for regulatory authorities to establish science-based legislation and inspection systems to protect the health of consumers. They proposed that the Committee should consider new measures that would facilitate progress in the decision-making process[1]. Other Codex Committees have expressed concerns regarding trade vulnerabilities resulting from delays in establishing MRLs. In response, the United States introduced a discussion paper on this issue at the 13th Session.

2. In introducing the paper, the United States focused on four process and procedure related matters - the prioritization of compounds of interest to developing countries for JECFA evaluation, adherence to process related matters used by the CCRVDF in the advancement of MRLs, intellectual property issues and coordination of work with expert bodies (i.e., JECFA) and other Codex Committees.

3. The 13th Session of the Committee noted that the establishment and advancement of scientifically based MRLs for purposes of health protection was delayed, in part, by the lack of data and/or industry sponsors (and that more government input was required); an examination of the procedures, including terms of reference, might be required; that the ongoing FAO/WHO review of the procedures used by expert committees might further assist the Committee; and that the ongoing work in the Committee might be further expedited by taking account of the Criteria for the Establishment of Work Priorities as set out in the Codex Alimentarius Procedural Manual.

[1] ALINORM 01/31, paragraphs 143-144.

4. In concluding its discussion, the Committee agreed that developing country concerns needed to be addressed, especially with regard to elaborating MRLs for compounds still being used in these countries. The Codex Alimentarius Commission Draft Medium-Term Plan for 2003-2007 includes strategic objectives, among others, on the extension of coverage of MRLs for pesticides and veterinary drugs to include products of particular interest to developing member countries, giving priorities to compounds most likely to impact on the health of consumers; and review of MRLs for pesticides and veterinary drugs considering new information on safety and good agricultural/veterinary practices, including those from developing countries[2].

5. The Committee requested the United States to prepare a revised discussion paper for the 14th Session of CCRVDF, taking into account the Medium Term Plan of the CAC that emphasizes consideration of the interests and needs of developing countries. Further, the document should focus on ways and means to improve the operation of the Committee without duplicating the Committee's related effort to elaborate its policy on risk management methodologies and risk assessment policies. Finally, the paper should outline a clear plan of action on what issues need to be further examined to improve the efficiency of elaborating MRLs by the Committee.

PROPOSALS FOR CCRVDF CONSIDERATION

6. While acknowledging the notable improvement on the outcomes of the 13th Session of the CCRVDF regarding advancement of MRLs compared to some of its previous sessions, the United States believes that the basic substance of the issues raised at the 13th Session still remain. The following discussion points will attempt to elaborate some specific actions for the Committee's consideration (as requested by the 13th Session of the Committee), independent of the Committee's work on risk management methodologies, including risk assessment policy.

7. The Codex Procedural Manual[3] elaborates the *Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to Which Other Factors are Taken Into Account.* Acknowledging the importance of all four of the principles in elaborating Codex standards, with regard to this discussion paper, the fourth principle is noted in particular. It states "When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standards without necessarily preventing the decision by Codex". Ideally, unanimous decisions by the Committee ought to be realized, but this is not always the situation and many Committees have relied on consensus for many decisions. The CCRVDF has retained the existing status of recommended MRLs on many occasions when consensus, rather than unanimous agreement has been reached. This dilemma has delayed some substances from being advanced to the Commission for final adoption. As a result, member governments and sponsors of veterinary medicines become disenchanted with making the commitment to provide dossiers for the Committee and developing countries' needs are not met.

8. We encourage the member governments participating in the Committee, to rigorously abide to the statement of principle, in particular, concerning the role of science in the decision making process for advancing recommended MRLs to the Commission with the full intent and the spirit of the statements of principle. We are very much aware of the sensitive nature of agreeing on a necessary level of protection of public health and the recent decision by the 24th Commission that a standard should not be developed when there is insufficient scientific information. Nevertheless, we believe CCRVDF must remain cognizant of the primary objectives of Codex of facilitating trade as well as meeting the public health needs of all member governments for their food safety programmes. Strict adherence to the fourth statement of principle will serve the Committee well to keep the focus and attention on its primary responsibilities and improve the efficiency of its decision-making.

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2 ALINORM 03/31, paragraph 81-84.

3 Joint FAO/WHO Food Standards Programme, Codex Alimentarius Commission Procedural Manual, Twelfth Edition, page 165, Rome, 2001

9. We acknowledge the current priority work sponsored by FAO and WHO on its comprehensive evaluation on relevant functions and activities of Codex Alimentarius and commend the significant effort put forth. We suggest an additional effort, with the concurrence of the Codex Secretariat, that CCRVDF conduct an assessment of specific needs of member governments, with particular attention to developing countries and those in transition, regarding priorities and other process related issues (including guidance documents and related texts) to meet member government food safety needs regarding veterinary drugs. We foresee that this work will be beneficial in identifying additional specifics for the Committee to consider for further improvement in the Committee's productivity. We acknowledge that to optimize the results of an assessment of needs will require a carefully planned questionnaire. Outcomes from this assessment of needs would be provided to the Committee and its ad hoc working groups on Priorities and Methods of Analysis and Sampling, as may be appropriate.

10. To the ad hoc Working group on Priorities, we suggest that there is need to: 1) review CCRVDF procedures for recommending substances to be evaluated by JECFA, taking into account, in particular, food safety needs of developing countries and those in transition, and; 2) propose guidance or recommendations that would improve the willingness of member governments or other sponsors to provide data for JECFA evaluation. Examples include, but are not limited to, intellectual property concerns and guidance or incentives for sponsors of drugs with a long history of use. We note that the current priority considerations for recommending a substance for JECFA evaluation considers 1) that use of the drug has the potential to cause public health and/or trade problems; 2) that the drug is available as a commercial product, and; 3) that commitment that a dossier will be available. While these are indeed important, at the present time, there is no specific consideration for a developing country's need for a food safety evaluation of a veterinary medicine. It is conceivable that with MRLs for substances of particular interest and need by developing countries, the market for these drugs may expand as well as encouraging their prudent use in food producing animals.

11. We bring to the attention of the Committee that the uncertainties of how JECFA might evaluate and respond to concerns on the adequacy of available data regarding antimicrobial effects on the human intestinal microflora and a potential request for new studies on such effects was responsible, in part, for the sponsor of two new substances scheduled for review at the 60th JECFA to withdraw the substances for safety evaluation. At the time of the drafting of the principles developed by JECFA for the evaluation of drugs with a long history of use, the needs regarding assessment of microbiological effects on the human intestinal microflora were not specifically considered[4]. Therefore, we recommend that CCRVDF request JECFA to reevaluate and update its procedures for the evaluation of drugs with a long history of use with specific attention to data requirements for antimicrobial drugs

12. To address intellectual property concerns by sponsors of pesticides, the Joint Meeting on Pesticide Residues (JMPR) has developed the following statement to be used with all JMPR reports: "The summaries and evaluations contained in this book are, in most cases, based on unpublished proprietary data submitted for the purpose of the JMPR assessment. A registration authority should not grant a registration on the basis of an evaluation unless it has first received an authorisation for such use from the owner who submitted the data for JMPR review or has received the data on which the summaries are based, either from the owner of the data or from a second party that has obtained permission from the owner of the data for this purpose."[5] The CCRVDF ought to consider making a similar recommendation to the JECFA joint secretariats to be placed on JECFA reports. In addition, the CCRVDF should request JECFA to address a specific procedural issue regarding intellectual property concerns by original sponsors of a veterinary drug. In particular, JECFA should consider that where a previously evaluated veterinary drug is to be evaluated for a new use by any sponsor, the original sponsor should be made aware of the additional request.

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4 See reports of the 40th and 43rd Sessions of JECFA, WHO Technical Report Series Nos. 832 (Geneva 1993) and 855 (Geneva 1995).

5 See for example, Report of the 2001 Joint FAO/WHO Meeting on Pesticide Residues, FAO, 2002.

13. As indicated above, the Codex Committee on Pesticide Residues (CCPR) at its 34th Session devoted considerable discussion on the development of recommended MRLs and establishing them as Codex standards[6]. A CCPR discussion paper addressing trade vulnerabilities arising from the current Codex MRL process and the review of the working procedures of the JMPR were discussed jointly. In addressing the eight options in the trade vulnerability discussion paper, CCPR agreed that the feasibility and the procedures for the establishment of Codex Interim MRLs on the basis of using national government MRLs as interim, time-limited Codex MRLs pending JMPR review, should be explored further by the CCPR and the Codex Alimentarius Commission. A working group was established to prepare a paper for the 35th Session of CCPR on a pilot project for the examination of National MRLs as interim Codex MRLs for safer replacement pesticides. The Committee ought to keep apprised of this work and consider other appropriate alternatives to expedite establishment of veterinary drug MRLs (e.g., for substances of public health needs for developing countries). Where mutual benefits may occur, CCRVDF should harmonize its procedures with CCPR for recommending MRLs. Therefore, we propose that CCRVDF establish a working group to further facilitate harmonization of procedures with CCPR and to expedite the establishment of MRLs for veterinary drugs consistent with the 1999 report of the joint JECFA-JMPR meeting on harmonization of MRLs.

14. While the initiative for the CCPR effort has been the need to alleviate trade vulnerabilities with regard to inability to use a safer pesticide that does not have a Codex MRL, CCRVDF has its specific needs related to protection of public health. We are aware that food animal practices and pest management systems for food animals in tropical and sub-tropical climates and environments are different than those in temperate climates and, therefore, require different treatments, practices and veterinary medicines. Without safety evaluations (e.g., MRLs) of those veterinary medicines commonly used in developing country or region-specific veterinary practice, consumers in these countries may be at greater risk when no MRLs or methods are available to regulate or monitor the safe use of those veterinary medicines.

15. The scheduling of meetings of CCRVDF and JECFA, in accord with the Codex Secretariat and the joint secretariats for JECFA, needs to be addressed. It should be noted that typically, recent JMPR meetings are convened in September of the year preceding the subsequent March/April meeting of CCPR (approximately six months between meetings). Likewise, meetings of JECFA for the Codex Committee on Food Additives and Contaminants (CCFAC) are typically held in June of the year preceding the subsequent March/April CCFAC (approximately nine months between meetings). At the present time, the JECFA meeting for residues of veterinary drugs is being held in February 2003, preceding the CCRVDF meeting in March 2003. The scheduling between meetings was better when CCRVDF Sessions were held in October following a JECFA meeting in the previous February. To give an example of the impact of timing of the meetings, it should be noted that the 14th Session of CCRVDF will consider MRLs recommended at the 58th meeting of JECFA held in February 2002 for the first time. The 60th JECFA meeting will have been convened before the 14th Session of CCRVDF has considered recommendations of the 58th JECFA. We should note that it is an all too common discussion point at the CCRVDF sessions that member governments have not had sufficient time to evaluate the MRL recommendations in the summary reports published immediately following the JECFA meetings when the WHO Technical Report Series monographs on the JECFA recommendations have not been published. CCRVDF should consider requesting the Codex Secretariat for assistance with improved coordination of meetings.

15. We believe that affirmative action on these recommendations and others that may be proposed by member governments, provide specific initiatives and a plan of action to further enable CCRVDF to better fulfill its terms of reference:

- To determine priorities for the consideration for residues of veterinary drugs in foods;
- To recommend maximum levels of such substances;
- To develop codes of practice as may be required;

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6 ALINORM 03/24, paragraphs 181-200.

- To consider methods of sampling and analysis for the determination of veterinary drug residues in foods.

16. Finally, we propose that any specific actions and recommendations that CCRVDF may agree to regarding the issues noted above, as an outcome to this discussion paper, should become an agenda item at subsequent CCRVDF Sessions to draw attention to actions taken and progress made by CCRVDF and JECFA, as appropriate.