codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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**Agenda Item 11** **CX/RVDF 01/11**
**July 2001**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**

**Thirteenth Session, 4-7 December 2001**
**Charleston, South Carolina, USA**

# DISCUSSION PAPER ON RESIDUE 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 1 October 2001** 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).

**Secretariat Note:** The United States has requested the consideration of this item in accordance with Rule V.3 of the Codex Alimentarius Procedural Manual that *Any Member of the Commission may request the Dircectors-General of FAO or WHO to include specific items in the Provisional Agenda.*

## Background

1. At the 12th Session (March 2000) of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), the delegations of Chile and Costa Rica expressed their concern at the delays in the progress in the work of the Committee, especially in view of the improtance of Codex MRLs for regulatory authorities, in order to establish science based legislation and inspcection systems to protect the health of consumers. They proposed that the Committee should consider mechanisms which would facilitate progress in the decision process.

2. Although the importance of this question was recognized, due to time constraints the Committee was unable to consider it further. Therefore, the Committee agreed to discuss it further at its next session.[1]

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

**Introduction**

3. Two of the four *Terms of Reference* for the Committee are to recommend maximum residue limits (food safety standards) for residues of veterinary drugs in foods, in accord with the Codex principles of risk analysis, and to determine priorities of veterinary medicinal products for consideration of residue limits in foods[2]. In general, CCRVDF has had a relatively successful history in accomplishing these two important roles of the Committee through recommendations of approximately 300 maximum residue limits (MRL). Further, the Committee has developed codes of practice, recommended methods for determining compliance with the MRLs and other relevant matters within the terms of reference and the agreed medium-term plan of work. There have been, however, some substances that have sharply divided the Committee in its risk management responsibilities and contributed recently to more limited progress in recommending maximum residue limits to the Codex Alimentarius Commission for adoption as Codex standards. As well, support for developing new food standard recommendations is a matter of growing concern. We believe the Committee needs to review its current situation on how it is fulfilling its terms of reference and meeting the needs of all Member Governments.

4. Briefly, the development of draft food safety standards involves the CCRVDF as risk managers and the FAO/WHO Joint Expert Committee on Food Additives (JECFA) as risk assessors. In fulfilling these two independent responsibilities, the CCRVDF and JECFA work in a collaborative manner. The CCRVDF will continue to elaborate its appropriate role of risk management responsibilities and relevant interaction with that of the JECFA and its scientific risk assessment responsibilities within the Codex framework at the current Session[3]. The Committee has actively engaged itself, as risk managers, in developing and applying the Codex risk analysis principles and methodologies appropriate to the Committee's specific terms of reference within the framework of the current medium-term action plan. Through its *ad hoc* Working Group on Priorities, CCRVDF has provided a list of recommended substances that meet the Committee's criteria for priority consideration by the Joint Secretaries to JECFA. The Committee has also considered the development of quality criteria for data used in risk assessment. In accord with this initiative and to facilitate transparency in its food safety assessment procedures, the FAO and WHO Joint Secretaries to JECFA have provided the Committee a written report on the risk assessment procedures elaborated and applied by JECFA in their safety assessment of compounds of priority to CCRVDF[4].

**Codex Committee Comments**

5. While acknowledging the successes, it is becoming more evident that progress in developing and advancing food safety standards for residues of veterinary drugs in food has deteriorated in the most recent meetings of CCRVDF. Likewise, support for developing food safety standards is declining. In support of this concern, delegations and observers of this Committee[5] as well as the Codex Coordinating Committee for North America and the Southwest Pacific[6] (CCNASWP), for example, have expressed specific concern to this matter. In particular, attention is drawn to the comments from Costa Rica and Chile at the 12th Session of the Committee on their growing frustration at the delays in the progress in the work of CCRVDF, especially considering the importance of Codex MRLs for regulatory authorities in order to establish science-based residue control programmes at the national and international levels to protect the health of consumers. From the perspective of the Sixth Session of CCNASWP, trade vulnerabilities may result from the lengthy process for developing relevant Codex MRLs for pesticides and veterinary drugs. Such slowness, they noted, because of potential trade considerations, could also prevent some growers from using new and safer compounds approved for use at the national level. CCNASWP suggested that the Codex Medium-Term Plan for 2003-2007 bring particular attention to this matter.

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[2] Codex Alimentarius Commission, Procedural Manual, Eleventh edition, pp. 112-113

[3] *Discussion Paper on Risk Analysis Principles and Methodologies in the Codex Committee on Residues of Veterinary Drugs in Foods* (CX/RVDF 01/9, Agenda Item 9).

[4] *JECFA Procedures for Recommending MRLs of Residues of Veterinary Drugs in Food*, FAO, Rome, 1999

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

[6] See ALINORM 01/32, Paragraphs 71-73.

6. This paper attempts to focus the Committee's attention to this important matter by highlighting some relevant issues we believe contribute to the current concerns regarding productivity and provides some specific actions for the Committee's consideration. There may be many other relevant issues not mentioned in the comments below and we welcome additional interventions from Member Governments on this matter.

**Priority Compound Issue**

7. Information from the U.S. delegation members, the Food and Drug Administration, the animal health industry and other non-government organizations suggests that the current shortage of priority compounds scheduled for review by JECFA is due in part to a lack of sufficient information for many compounds to substantiate that they meet the existing criteria for consideration by the *ad hoc* Working Group on Priorities. For other compounds with a long history of use there may be insufficient, contemporary scientific information or studies (in major or minor animal species) to meet data requirements. For example, some of the substances requested by Egypt, Costa Rica and Tanzania at the Committee's 12th Session may fit into this category. It is brought to the attention of the Committee that at the 12th Session of CCRVDF there was much discussion in the working group and plenary session by Committee delegates on efforts to develop workable mechanisms to provide dossiers for approximately 14 substances for which safety evaluations have been published elsewhere[7]. To date proposed action plans as follow-up have not been successful, but additional options are being pursued[8]. It is important to note that lack of commitments to provide complete dossiers on compounds of interest creates the real potential for an insufficient agenda to warrant a meeting of JECFA for residues of veterinary drugs in food. Such a scenario would further contribute to a decline in the Committee's development of food safety standards.

8. Through the 12 Sessions of the Committee the large majority of substances for which requests were made for developing draft standards and commitments to provide necessary scientific data have been supported by a relatively small number of Member Governments from developed countries. While recognizing that draft MRLs for these substances does provide benefit to developing countries, these substances may not always have been among the highest priorities of developing countries nor may some of the countries have the ability to fully implement certain Codex standards, guidelines and recommendations. The draft Codex Medium-Term Plan for 2003-2007[9] highlights the importance of being more responsive to developing country needs and capabilities. Therefore, the time for the CCRVDF to re-assess how it might proceed with developing food standards of high priority to developing country public health and national needs is now (see footnote 8, page 3).

9. In addition to the matter of meeting developing country needs using existing priority criteria and the need to examine whether additional or alternative criteria may be warranted, other considerations exist. Examples of issues to be considered in this assessment include the costs involved with developing the necessary dossiers and whether this might serve as an obstacle to compound sponsorship by developing countries. CCRVDF needs to consider alternative funding mechanisms or procedures that could accomplish this important initiative. In addition, CCRVDF ought to evaluate what impact such an initiative will have on the worldwide reputation and recognition of Codex as the pre-eminent body for development of science-based food standards (see also footnote 8, page 3).

**Committee Process Issue**

10. Another consideration CCRVDF Member Governments may need to provide more vigilance to "process" related matters. In particular attention must be given to improved adherence to appropriate basic principles adopted by Codex. An important consideration is renewed commitment to the spirit and intent of the *Statements of Principle* concerning the role of science in the Codex decision-making process and the extent to which other factors relevant to food safety are taken into account. We believe this should be a matter of great interest to all

[7] See ALINORM 01/31, paragraphs 126-132.
[8] See page 5 for some suggested actions to be considered by CCRVDF
[9] January 18, 2001Chairman'sDraft Action Plan for 2003-2007

Member Governments. In this regard, while noting the importance of all four of the principles to facilitate the advancement of draft standards, particular attention ought to be given to the fourth principle which 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 standard without necessarily preventing the decision by Codex".

**Intellectual Property Issue**

11. Data sponsors have expressed an interest in having the Committee address the potentially difficult matter of intellectual property issues as a means to promote the willingness of sponsors to provide dossiers compounds of priority to the Committee for JECFA evaluations. CCRVDF needs to formulate some incentives, in accord with acceptable Codex procedures, to encourage the resource commitment of data sponsors to compile the necessary dossiers for JECFA. One particular matter of interest, for example, is the opportunity to seek additional application of an ADI to new uses of a substance in accord with good practice in the use of veterinary medicines. The *ad hoc* Working Group on Priorities may wish to address the matter and provide the Committee with some appropriate options.

12. Without data sponsors, the scientific information necessary for recommending MRLs by JECFA is limited. Addressing intellectual property issues may encourage data sponsors, Member Governments, Committee observer status members and others to provide the relevant scientific dossiers for compounds of priority interest to CCRVDF. While recognizing that this may be seen as a matter of concern between data sponsors and JECFA, comments from the Committee may be welcomed. It may be appropriate for the *ad hoc* Working Group on Priorities to consider this matter to provide risk management options to the Committee.

**Coordination of Work Issue**

13. Another matter of consideration for CCRVDF is greater emphasis on co-ordination of meetings and publications relevant to the Committee's work. While a recurring theme, additional emphasis ought to be taken to reinforce initiatives to expedite and accelerate the process for adoption of standards for residues of veterinary drugs in food. Examples include more timely co-ordination of CCRVDF and JECFA meetings as well as more timely availability of the subsequent JECFA report for CCRVDF and its Member Governments[10]. Earlier availability of the JECFA reports will provide more time for Member Governments to adequately assess these scientific reports and to develop their risk management options as well as further highlighting the transparency of the risk analysis process. Early collaborative discussions among Member Governments and responses to Codex circular letters should improve harmonisation efforts by the Committee in advancing draft food safety recommendations.

14. As noted above, improved liaison and communication among Member Governments and with the FAO/WHO Joint Food Standards Programme prior to sessions of the Committee should be stressed. This could be accomplished through any of the several available communication media accessible by Member Governments and would be particularly useful for addressing issues and substances that may have more potentially difficult trade implications.

**Proposed Actions**

15. The importance of the Committee's responsibility to develop draft standards for residues of veterinary drugs in food has encouraged this attempt to draw attention of the Committee to several factors that may contribute to the current level of productivity. Objectively addressing the measures indicated above, and any other

[10] The complete draft summary report of the 56th JECFA meeting on mycotoxins held in February 2001 was posted the FAO and WHO web sites in early March 2001. This indicates a concerted effort by the JECFA Joint Secretaries to be more responsive to Codex Committee needs and should be encouraged for posting JECFA reports for meetings devoted to residues of veterinary drugs in food in a similar manner.

recommended improvements, to facilitate the development and advancement of MRLs may be welcomed as constructive progress by Codex and Member Governments, improve Committee interest among Member Governments and help the Committee to meet its medium-term work plan.

16. It is not the intent of the U.S. delegation that this document criticize our accomplishments, rather, it is to encourage Member Governments that more attention be given to important Committee work and to facilitate greater liaison and harmonization among Member Governments. Together we can seek potential solutions to resolve these and other important issues before the Committee.

17. As a way forward, we respectfully encourage and recommend to the Committee, in collaboration and concurrence with the FAO/WHO Joint Food Standards Programme, to establish a drafting group or other appropriate body, to draft a set of proposals addressing the matters of high interest noted above, as well as those issues of other Member Governments, for consideration at the next session of the Committee. The United States would be willing to lead such an initiative encouraging a broad spectrum of Member Governments to collaborate in this effort. We believe it would be particularly valuable to have sufficient representation of Member Governments from developing countries to draft, in collaboration with the FAO/WHO Joint Food Standards Programme, options or mechanisms to supplement developing country resources that could strengthen their capability to meet their National food safety needs regarding residues of veterinary drugs in food. The *ad hoc* Working Group on Priorities should consider drafting recommendations for the Committee regarding options for placing substances of high interest to Member Governments from developing countries onto the Committee's priority list for developing food safety standards. In addition the *ad hoc* Working Group on Priorities should draft some recommendations for the Committee to support and address intellectual property issues. The group should also explore mechanisms to better co-ordinate Committee and JECFA meetings and publications. Finally, we encourage the Committee to consider this a regular agenda item at its forthcoming meetings, to monitor progress on initiatives undertaken by the Committee.

18. Other Member Governments may have additional comments or points of view on this document or related issues and these are welcomed.