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-Add. 1**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

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

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

AUSTRALIA

1. The USA should be commended on preparing an excellent paper that deals with numerous issues that are critical to the continuing success of both CCRVDF and JECFA. Australia strongly supports the paper in principle and the recommendations in paragraph 17.

BRAZIL

2. Brazil supports the progress of the discussions of the subjects in the document, through the establishment of a Working Group.

CUBA

3. We agree with the recognition of the advances of the Committee in the recommendation of maximum residue limits of veterinary drugs in foods, but we also recognize that the progress made in the development of food safety standards in this area has deteriorated in the last CCRVDF sessions. The actions proposed in this document are aimed at responding more to needs and capabilities in developing countries.

4. We agree with this matter, as well as the rest of the comments made by the Committee.

NEW ZEALAND

General Comments

5. New Zealand agrees that the paper prepared by the US raises a number of issues that need to be addressed by the CCRVDF if this Committee is to better serve all of its members' interests in the future. The slow progress in the work of the Committee has been of concern to New Zealand, as has been the lack of recognition by many members of the standards promulgated. New Zealand is of the opinion that this Committee needs to focus better its efforts on the primary mandate of Codex, namely protecting consumers' health and facilitating international food trade.

Introduction

6. The paper replaces various Codex defined terms such as "maximum limit for residues of a veterinary drug" (MRLVD) and "code of practice" with the ambiguous paraphrase "food safety standards". New Zealand considers that by doing so, a degree of specificity is lost, and this new term does not accurately depict the full range of factors considered in the promulgation of the standards, such as the MRLVDs, let alone the various codes of practice.

7. The definition of a Codex MRLVD takes into account various aspects of food technology and analytical considerations, as well as toxicological aspects. It acknowledges that MRLs can be reduced to reflect the level that is actually needed under good animal husbandry practices. Most acceptable daily intakes (ADIs) dealt with by the Committee have been calculated based on what should be without appreciable risk even after long term exposure. This, along with the lack of a direct correlation of a residue exceeding any one MRLVD with a potential intake exceeding the associated ADI, means that single or intermittent residues exceeding any MRL thus derived does not in itself constitute a risk to human health. New Zealand recommends any future paper use the specific terms, rather than attempt to represent any of them by the use of a non-defined and potentially misunderstood term.

Priority Compound Issue, and Proposed Actions

8. The paper briefly discusses how the process can be better adapted to facilitate the needs of developing countries, which may be using veterinary drugs for which the available data does not meet the current standards stated in guidelines currently used by JECFA. New Zealand considers that there are perhaps two common situations where problems arise. Firstly, the toxicological databases of some older drugs may no longer fully meet today's standards, and/or secondly, there may not be species-specific residue metabolism databases for some of the uses registered in member countries. This is especially so for new or novel minor uses in "minor species". The lack of application of a risk-based framework to such situations is restricting various countries from promoting MRLs that they feel are necessary for trade – especially for many older compounds and/or novel uses.

9. With respect to the first point, New Zealand suggests that a more flexible approach in allocating an additional uncertainty factor when deriving an ADI could deal with situations where the toxicological database is no longer up to current standards, especially where the drug has long term historical use.

10. With respect to the second point above, New Zealand reminds the Committee that this was the subject of a discussion paper on minor species and minor uses that was presented to the Twelfth Session of CCRVDF (CX/RVDF 00/14-Add 1). Given the non-species specificity of the model diet used by JECFA, as well as the likely minor component any novel use would contribute to dietary exposure, it is unlikely that the extension of most MRLVDs to cover minor species or novel uses would lead to higher exposures than the TMDI estimations calculated by JECFA, in practical situations.

11. Furthermore, it is relevant to note that most toxicological studies are conducted using just the parent drug, and/or a single metabolite, and thus do not directly relate to any specific ratio of metabolites found in any one food species. Accordingly, New Zealand believes, with few exceptions, that the extrapolation of MRLVDs to cover trade in product from minor species or novel uses could be done much more commonly without compromising food safety. For example, humans will consume only a given amount of meat or milk per day, regardless of from which species the food is derived, so the potential intake of the residue will be the same, regardless of the animal treated. Therefore, MRLs should usually be extended across several species, unless there is a specific reason not to do so.

Intellectual Property Issue

12. New Zealand does not support any attempt to restrict the ability of countries to determine which commodities are allocated residue limits, regardless of which commercial company's data has been used in the estimation of the ADI. The outputs of this Committee relate to facilitating the trade of safe food between members, and not the protection of the commercial interests of chemical companies. Countries must retain the right to have the use practices and resulting residues that they have assessed as necessary and safe within their sovereignties to be considered and recognised by the other member nations of the FAO and WHO.

Conclusion

13. New Zealand supports the continued discussion of these issues and would consider being a part of any body set up to further progress them.

EUROPEAN COMMUNITY

14. The European Community would like to thank the United States of America for the preparation of this discussion paper.

General Comments

15. This discussion paper has been prepared by the United States after concerns raised by the delegations from Chile and Costa Rica as to delays in the progress of the work by the Committee in the establishment of maximum residue limits.

16. First, it has to be acknowledged that the progress of the work of the Committee and that of the scientific expert Committee JECFA is dependent on the submission of sufficient scientific documentation by sponsors for the various substances used in veterinary medicinal products. Secondly, it is the responsibility of all nations to propose substances for evaluation in agreement with sponsors.

17. The United States propose to create a drafting group in the CCRVDF to address this problem. However, the conclusions of the Codex Alimentarius Commission in July 2001 already have put emphasis on the increased participation of developing countries, the strengthening of the scientific support and improved efficiency in the medium term action plan (ALINORM 01/41 para. 59 and 64).

18. In view of the planning meeting to be organised by the Chairperson of CAC in November 2001 on this issue, it seems premature to create such a drafting group. The European Community therefore proposes not to support the creation of a drafting group at this stage.