Report of the U.S. Delegate, Codex Committee on Residues of Veterinary Drugs in Foods, 20th Session

The 20th Session of the Codex Committee on Residues of Veterinary Drugs (CCRVDF) was held in San Juan, Puerto Rico, May 7-11, 2012. The Session was attended by 177 delegates from 47 Member Countries and one Member organization and observers from 10 international organizations and FAO and WHO. The United States was represented by Delegate Kevin Greenlees and Alternate Delegate Charles Pixley.

This session was very productive, resulting in resolution of some key issues as well as critical questions for clarification by the Codex Alimentarius Commission (CAC).

The Committee discussed possible changes to the terms of reference for CCRVDF. It agreed that there was no need to include "feed" in the terms of reference, and that possible changes related to risk management matters related to the safety of residues of veterinary drugs in food would be circulated for comment.

The Committee advanced full MRLS for residues of narasin in cattle tissue to the 35th Session of the CAC for adoption at step 8. Similarly, MRLs for amoxicillin residues in cattle, sheep and pig tissues were advanced to the CAC for adoption at step 5/8.

Concerns were raised for the proposed MRLs for residues of apramycin and derquantel. Concern was expressed over the proposed temporary MRL, and only having an MRL in kidney. The Committee agreed to hold MRLs for residues of apramycin in chicken kidney at step 4 until JECFA considers additional data and completes an evaluation of the new information. Similarly, and in response to specific questions by Australia regarding the results of the JECFA evaluation, most notably in the ratio of analytical marker residue to total residues, MRLs for derquantel residues in sheep were held at step 4, and derquantel was added to the priority list for re-evaluation by the JECFA. Questions were also raised regarding the proposed MRLs for monepantel in sheep, particularly regarding the residue following good practices of veterinary drugs across a wide range of international uses. The Committee held this veterinary drug at step 5 while requesting a JECFA evaluation of available residue data. These interactions reflect the active risk management role of CCRVDF in its relationship to its risk assessment body, the JECFA.

The Committee discussed the report of the electronic working group on risk analysis principles for CCRVDF and risk assessment policy for setting maximum limits for residue of veterinary drugs in food and the report of the physical working group that met just prior to the 20th CCRVDF. The Committee agreed to revisions in the risk analysis principles for CCRVDF and risk assessment policy and forwarded the document for adoption by the 35th CAC. However, the "concern form" (similar to a form used by the Codex Committee on Pesticide Residues) that was under discussion was not included, and an electronic working group, led by Brazil and Australia, was created for further discussion on what such a form might look like and how it might be implemented by CCRVDF. A physical working group meeting is planned just prior to the 21st Session.

The Committee considered the report of the electronic Working Group on proposed draft sampling plans for residue control for aquatic animal products and derived edible products of aquatic origin (Table C, Annex B of CAC/GL 71-2009), and the report of an intersession working group, both led by the United States. The Committee agreed to advance the proposed draft Sampling Plan to the 35th Session of the CAC for adoption at Step 5/8.

The Committee considered the reports of the electronic Working Group on the policy for the establishment of MRLs or other limits for honey and the electronic Working Group on guidelines on performance characteristics for multi-residue methods (Appendix to CAC/GL 71-2009). The Committee agreed to continue work on guidances for honey and for multi-residue analytical methods through electronic Working Groups, but with direction to refine and focus the product guidelines. Honey will be chaired by the United Kingdom, and multi-residue analytical methods will be co-chaired by the United Kingdom and Canada. The United States will participate in these electronic working groups. There will also be a physical working group on multi-residue methods prior to the 21st Session.

The Committee agreed to circulate the questions posed by the electronic working group for comment.

The Committee agreed to establish a physical Working Group, led by Canada, to continue the work begun on extrapolation of data for the development of MRLs based on the comments received. The United States will participate in this Working Group.

The Committee discussed additions to the priority list of veterinary drugs for JECFA evaluation as reported by the Priorities working group. The Committee agreed to include gentian violet, lasalocid, phenylpyrazole, emamcetin benzoate, derquantel, monepantel, and apramycin in the priority list.

The Committee was sharply divided over the inclusion of zilpaterol HCl in the priority list, and could not come to consensus. Zilpaterol is a beta-adrenergic agonist drug for use in cattle as a production aid. It is approved for use in the United States and a number of other countries. The addition of this veterinary drug was strongly defended by a number of countries, most notably the United States and Brazil. Zilpaterol's proposed addition to the priority list of veterinary drugs for evaluation by JECFA was strongly opposed by the European Union and a number of other allied countries. A key rationale identified was that there would not likely be consensus and that the Committee should save its resources for veterinary drugs that would be less controversial. The EU delegate stated that the reasons for objection were not based on science, but rather on domestic legislation, consumer preference, and trade. Other countries added concern for animal welfare. The CCRVDF Chair will forward the issue to the CAC along with the proposed addition of zilpaterol to the priority list.

The Committee also discussed ivermectin, which had been proposed for re-evaluation of the ADI at the 19th CCRVDF and was considered in the 75th JECFA. It was agreed to hold ivermectin for discussion at the 21st Session. It was included in part C in the priority list on the basis of an offer by Brazil to provide the results of a search of relevant information to the JECFA in support of the evaluation. Also included in Part C of the priority list for later discussion at the 21st session were flumequine and oxolinic acid.

The Committee agreed to continue the electronic Working Group on the database for needed MRLs (led by the United States) and the physical Working Group on priorities, led by Australia.

The dire financial constraints for funding of JECFA meetings were discussed. CCRVDF members were encouraged by the joint JECFA secretariats and by the CCRVDF chair to make efforts to provide funding to support the expert, scientific risk assessments made possible through the JECFA evaluations.

The Committee discussed in detail the report of the electronic Working Group on risk management recommendations for drugs for which JECFA could not recommend ADI and/or MRLs due to specific human health concerns. Risk management recommendations were drafted for chloramphanicol and malachite green, with language that was very close to that proposed by the United States. Further, the United States asked that an objection be included in the report on the development of risk management language by CCRVDF for veterinary drugs other than those for which the JECFA had completed a risk assessment and for which JECFA had determined that MRLs could not be recommended due to specific human health concerns. The other veterinary drugs identified by the electronic Working Group were referred to a new electronic working group to further develop risk management advice based on the discussion of the Committee. Risk management recommendations for these veterinary drugs, and in general by the CCRVDF is a topic of considerable interest and the United States will be an active participant in the electronic working group.

The United States recognizes the importance of CCRVDF in recommending standards and developing guidelines that protect consumers and while ensuring fair trade practice.

The next meeting of the Committee is scheduled for August 2013, in a location to be named.