Report of the U.S. Delegate, Codex Committee on Residues of Veterinary Drugs in Foods, 19th Session

The 19th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) was held August 30 - September 3, 2010, in Burlington, Vermont. The session was attended by delegates from 56 Member countries, one Member organization, and Observers from five international organizations. The Committee advanced Maximum Residue Limits (MRLs) for two veterinary drugs to Step 8 for adoption and established seven electronic working groups.

Dr. Kevin Greenlees, Senior Advisor for Science and Policy, at the Food and Drug Administration, Center for Veterinary Medicine, and Dr. Charles Pixley Director of Laboratory Quality Assurance Division, United States Department of Agriculture, Food Safety, and Inspection Service represented the United States. Dr. Steven Vaughn, Director, Office of New Animal Drug Evaluation, Food, and Drug Administration, Center for Veterinary Medicine chaired the Committee for the first time.

The Committee agreed to forward the draft MRLs for narasin in pig tissues and tilmicosin in chicken and turkey tissues for adoption at Step 8. The draft MRLs for narasin in cattle tissues were held at Step 7 to await the FAO/WHO Joint Expert Committee on Food Additives (JECFA) evaluation of the analytical method.

The Committee also forwarded a project document for approval of new work to develop a guidance on performance characteristics for multi-residues methods. On completion of this guidance it would be appended 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*(CAC/GL 71-2009). The Committee also established an electronic Working Group, led by the United Kingdom, to prepare a draft of the appendix and to consider opportunities to facilitate communication with International Atomic Energy Agency (IAEA) on the development of the database on analytical methods and reference standards.

The Committee added a number of veterinary drugs to the Priority List of Veterinary Drugs for Evaluation or Reevaluation by JECFA. The Committee decided to establish two tiers of priority for the veterinary drugs added to the list because there were more compounds than could be addressed by a single JECFA. Tier 1 veterinary drugs will be considered by the next available JECFA; Tier 2 veterinary drugs will be considered by subsequent sessions of the expert committee. The veterinary drugs added to the tier one list were monepantel in sheep tissues, monensin in cattle liver, derquantel in sheep tissues, apramycin in cattle, pig, chicken, and rabbit tissues, amoxicillin in cattle, sheep and pig tissues and cattle and sheep milk, and narasin for the analytical method in cattle tissues. The veterinary drugs added to the tier two list were ractopamine in pig lung, triclabendazole in goat tissues, and ivermectin to re-evaluate the ADI and recommend new MRLs if necessary.

For triclabendazole, the Committee formulated a specific question for JECFA to address which would focus on extrapolating data on sheep and cattle to develop MRLs for goats. In light of this effort to extrapolate data to other species and tissues, the Committee decided to consider a development of a policy on extrapolation of MRLs. The Committee agreed to establish an electronic Working Group, led by Canada, to gather information from national and regional guidelines on extrapolation of MRLs and develop a proposed risk analysis policy of use by the CCRVDF when considering MRL extrapolation.

The Committee agreed to establish a physical Working Group, led by Australia, to meet immediately prior to the next Session to update and develop a new Priority List for Evaluation or Reevaluation by JECFA. The Committee also agreed to establish an electronic Working Group, led by the United States, to update the List of Veterinary Drugs of Potential Interest for Developing Countries and to try to develop dossiers for the veterinary drugs currently on the list.

The Committee considered proposing changes to its terms of reference to allow the Committee to elaborate risk management measures other than MRLs and codes of practice. The Committee proposed to add a new bullet similar to what is included in the terms of reference for the Codex Committee on Pesticide Residues (CCPR) which reads "to consider other matters in relation to the safety of food and feed containing pesticide residues." In order to allow Members time to review the changes, the Committee agreed to circulate the proposed change to the terms of reference for comment and consideration at the next session.

To address the list of compounds that JECFA reviewed and was unable to establish an ADI or MRLs due to specific human health concerns, the Committee established an electronic Working Group, led by the European Union, to provide specific risk management recommendations. The veterinary drugs in this list include carbadox, chloramphenicol, chlorpromazine, malachite green, nitrofurans, nitroimidazoles, olaquindox, and stilbenes (diethylstilbestrol). The risk management recommendations are to be based on the information available through

JECFA reports and monographs and should take into consideration the recommendations made by the 18th CCRVDF regarding malachite green and chloramphenicol.

The Committee agreed to establish an electronic Working Group, led by the United Kingdom, to propose a risk assessment policy for JECFA for those occasions when the Committee would require its advice for setting appropriate limits for veterinary drugs in honey.

The Committee agreed to circulate for comments at Step 3 a revised table on sampling plans for residue control for aquatic animal products and derived edible products of aquatic origin. The Committee also established an electronic Working Group, led by the United States, to consider the comments received and make appropriate revisions to the table.

The 26th Codex Committee on General Principles (CCGP) and the 64th Executive Committee asked that the 19th CCRVDF review and consider revising the Risk Analysis Principles Applied by the CCRVDF and the *Risk Assessment Policy in the setting of Maximum Limits for Residues of Veterinary Drugs in Foods*. To complete this work, the CCRVDF agreed to establish an electronic Working Group, led jointly by France, Japan, and the United States, to revise and update the risk analysis principles and risk assessment policy. Special emphasis is to be given to the section on evaluation of risk management options and to developing risk management and risk communication recommendations for veterinary drugs for which no ADI and/or MRL has been recommended by JECFA. The Committee also established a physical Working Group, jointly led by France, Japan, and the United States, to meet immediately prior to the next Session to discuss the report of the electronic Working Group.