



## **Report of the U.S. Delegate, 21st Session, Codex Committee on Residues of Veterinary Drugs in Foods**

The 21<sup>st</sup> session of the [Codex Committee on Residues of Veterinary Drugs in Foods](http://www.codexalimentarius.org/download/report/802/REP14_RVe.pdf) (CCRVDF) met in Minneapolis, Minnesota, August 26-30, 2013. The Session was attended by 200 delegates from 61 Member countries, one member organization (the European Union), Observers from 11 international organizations, and representatives of the United Nations Food and Agriculture Organization (FAO) and World Health Organization. The United States was represented by Delegate Kevin Greenlees (U.S. Food and Drug Administration), Alternate Delegate Charles Pixley (U.S. Food Safety and Inspection Service), eight governmental advisors and five nongovernmental advisors. A full report of the meeting is posted at [http://www.codexalimentarius.org/download/report/802/REP14\\_RVe.pdf](http://www.codexalimentarius.org/download/report/802/REP14_RVe.pdf).

The session was opened by Brian Ronholm, Deputy Under Secretary for Food Safety, U.S. Department of Agriculture.

The Committee agreed to hold the draft Maximum Residue Limits (MRLs) for monepantel in sheep at Step 7 and the draft MRLs for derquantel at Step 4 pending the results of a Joint Expert Committee on Food Additives (JECFA) evaluation.

The Committee was informed that the sponsor of the drug apramycin would not be providing the information identified during the 20<sup>th</sup> session of CCRVDF as necessary for establishment of MRLs. Upon consideration, the Committee decided to remove apramycin from the priority list and to recommend that the Codex Alimentarius Commission discontinue work on the proposed draft MRLs.

The Committee discussed the current terms of reference for CCRVDF and whether there should be a change to the language to recognize risk management activities by the Committee more explicitly. The Committee decided that no changes to the current terms of reference were necessary and agreed to discontinue work on the terms of reference.

The Committee discussed risk management recommendations for certain veterinary drugs for which no Acceptable Daily Intake (ADI) and/or MRL had been recommended by JECFA due to specific human health concerns. The Committee discussed specific risk management recommendations to competent national authorities for chloramphenicol, malachite green, carbadox, two nitrofurans, chlorpromazine, stilbenes, olaquinox, and four nitroimidazoles. Risk management language was recommended to the Commission for adoption at Step 5/8 for all of the compounds except for the four nitroimidazoles which were held at Step 4 to allow an evaluation and recommendation from JECFA prior to the next session of CCRVDF. The United States noted that there were significant data gaps identified for other compounds in addition to the

nitroimidazoles. One compound, metronidazole, had not actually been evaluated by the JECFA while another, chlorpromazine, had been evaluated 22 years ago with very little data available to JECFA. The United States expressed a reservation to advancing risk management language to Step 5/8 due to its concern that the risk management recommendations might intrude on the risk management role of competent national authorities, fail to recognize the impact of data gaps on risk management and poorly communicate risk management advice to national authorities. The Delegation of Brazil also expressed a reservation to the risk management recommendations for nitrofurural, chlorpromazine, and olaquinox, noting the need for a careful case-by-case approach and concerns about recommendations based on lack of information or on assumptions. Brazil also expressed concern about the need for a clear distinction between the role of Codex and the role of national competent authorities as risk managers.

The Committee agreed that the risk management recommendations should be included in the database for MRLs of veterinary drugs on the Codex website, with a link provided to the JECFA database of summaries for the evaluation of each compound.

The Committee agreed to forward the proposed draft guidelines on performance characteristics for multi-residue methods as Appendix C to CAC/GL 71-2009 (N01-2011) to the Commission for adoption at Step 5/8.

The Committee discussed the risk analysis policy on extrapolation of MRLs of veterinary drugs to additional species and tissues. The Committee identified additional questions to be considered by JECFA and agreed to forward the proposed changes to the Risk Analysis Principles for CCRVDF to the Commission through the Committee on General Principles.

The Committee considered the format and policy procedures for the use of a concern form. The concern form is intended to improve communication between the Committee and JECFA. Following extensive discussion, the Committee agreed in principle to the use of a concern form, established a template, and agreed to recommend amendments to the Risk Analysis Principles Applied by the CCRVDF to the Commission through the Committee on General Principles. The Delegation of the European Union expressed its reservation on the use of a concern form by CCRVDF.

The Committee discussed the database on needs for MRLs for developing countries. The United States agreed to continue to manage the database, and the Committee agreed to use a Circular Letter (CL) to reach a wider audience in requesting additional information. The United States proposed an additional approach that would start with identification of the needs for treatment of animal diseases, identification of drugs to treat these diseases, and identification of known health and/or trade problems, and further proposed requesting FAO and WHO to provide advice on this information. An electronic Working Group could then be formed to consider the data gaps and



alternative approaches to fill those gaps to allow an assessment of the veterinary drugs by JECFA. The Committee agreed to this approach and to the formation of an electronic Working Group chaired by the United States and Costa Rica.

The Committee considered a discussion paper on guidelines for the establishment of MRLs or other limits for honey. Following a discussion, the Committee agreed that detailed guidance on setting MRLs in honey was not currently required. The Committee agreed to pose questions to JECFA on the use of monitoring data as the basis for MRLs for honey, an approach similar to that currently used for spices by the Joint Meeting on Pesticide Residues and the Committee on Pesticide Residues (JMPR).

The Committee discussed current challenges, problems and solutions. The CCRVDF Chair announced his intention to draft a discussion paper regarding the issues and concerns that impact the ability of the CCRVDF to perform its work efficiently and that this paper would be available at the next session of the Committee.

The use of physical working groups prior to the 21<sup>st</sup> CCRVDF meeting was considered to be a particularly valuable tool that contributed to the work accomplished in the current meeting.

The 22<sup>nd</sup> Session of CCRVDF is scheduled for April 13 - 17, 2015. While a location for the next session of CCRVDF has yet to be determined, Costa Rica offered to co-host the meeting.