



Report of the U.S. Delegate, 23rd Session, Codex Committee on Residues of Veterinary Drugs in Foods

The 23rd Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF23) met in Houston, TX, October 17-21, 2016. The session was attended by delegates from 62 Member countries, one member organization (the European Union), eight observer organizations, and representatives of the United Nations Food and Agriculture Organization (FAO) and World Health Organization (WHO). The United States was represented by Delegate Brandi Robinson (U.S. Food and Drug Administration), Alternate Delegate Charles Pixley (U.S. Food Safety and Inspection Service), eleven governmental advisors and eight nongovernmental advisors.

CCRVDF23 was very productive and successful as the Committee advanced maximum residue limits (MRLs) for several veterinary drugs, forwarded a full priority list for approval by the Codex Alimentarius Commission at its next session (CAC40, July 2017), and established additional electronic working groups to continue work on issues of importance to Codex members.

The following paragraphs summarize the discussions in the Committee. The official report of the meeting is posted on the [Codex Alimentarius website](#).

MEETING SUMMARY

- Matters of Interest Arising from FAO/WHO and from the 81st Joint FAO/WHO Expert Committee on Food Additives (JECFA, November 2015)(Agenda Item 3)
The Committee noted and discussed many of the items presented under this agenda item. The Committee noted the JECFA requests for additional data for diflubenzuron and sisapronil.

--MRLs for Generic Fish Species

In response to a request from CCRVDF22, JECFA considered the possibility of extending species-specific fish MRLs to larger fish species groupings. The JECFA requested feedback from the CCRVDF on the criteria that should be used in considering generic fish species groupings. The Committee established an electronic working group (EWG) hosted by Norway and co-hosted by Japan to develop a discussion paper on establishing MRLs for groups of fish.

--MRLs in Offal Tissues

The 81st JECFA noted that there many definitions of offal developed by regulators and organizations and requested further guidance from CCRVDF on a defined list of offal tissues with a view to setting MRLs in those tissues. The Committee agreed to establish an EWG hosted by Kenya to prepare a discussion paper proposing a definition for offal and identifying offal tissues in international trade.

- Proposed Draft Risk Management Recommendation (RMR) for Gentian Violet (Agenda Item 5)
The Committee discussed the two options for proposed draft RMR language for gentian violet which had been circulated for comment at Step 3. Many delegations supported the Option 1 language which included the sentence, "This can be accomplished by not using gentian violet in food producing animals." Many delegations also supported the Option 2 language which removed this last sentence from the draft RMR because it may be interpreted to limit a national authority's ability to establish appropriate risk management measures specific to their own populations. The Chair offered a third option in an effort to find a compromise between the two options. The United States and other delegations offered support for the compromise language, but it was not broadly supported by the Committee. The CCRVDF23 advanced the Option 1 language, with inclusion of the last sentence, to Step 5, for further review and a final decision at the next session, and noted the reservation of the United States to the final sentence of the draft RMR.
- Proposed Draft MRLs (Agenda Items 6.1 and 6.2)
The Committee discussed the proposed draft MRLs for lasalocid sodium which had been held at Step 4 to allow JECFA to review two concern forms that were raised at CCRVDF22. The European Union reiterated their concerns regarding the JECFA evaluation. The Committee noted that the 81st JECFA had considered and responded to the concern forms provided by the European Union and Canada and reconfirmed the MRLs recommended by the 78th



JECFA. In view of the recommendation of JECFA, the Committee agreed to advance the proposed draft MRLs to Step 5/8 for final adoption by CAC40.

The Committee advanced proposed draft MRLs for ivermectin in cattle tissues and teflubenzuron in salmon to Step 5/8. The United States had nominated the re-evaluation of ivermectin at the last session of CCRVDF (CCRVDF22, April 27-May 1, 2015).

The Committee agreed to hold the proposed draft MRLs for zilpaterol hydrochloride at Step 4 to allow for JECFA evaluation of supplemental data. The supplemental data for zilpaterol hydrochloride had been offered by the pharmaceutical sponsor to address some limitations of the data previously submitted to the 81st JECFA. The United States supported the Chair's proposal to hold the proposed draft MRLs to allow JECFA to provide the best possible risk assessment and other delegations supported or did not object to the proposal. Some delegations, notably the EU, stated their opposition to establishment of MRLs based on their domestic policies toward use of this class of drugs.

- **Unintended Presence of Residues in Food Due to Carry-over of Drug Residues in Feed (Agenda Item 7.1)**
The Committee discussed the recommendations from a physical working group meeting co-chaired by the United States and Canada held just prior to CCRVDF23. The Committee agreed to forward a request to FAO/WHO for scientific advice on whether the presence of residues of veterinary drugs at a level associated with unavoidable carryover in feed poses a risk to human health, what risk management recommendations could be considered to address trade issues while protecting human health, and whether there are additional measures that could be incorporated into the Code of Practice on Good Animal Feeding to minimize unavoidable carryover. CCRVDF requested FAO and WHO for scientific advice on these general questions, using lasalocid sodium in eggs as a working example because data are available. The Committee agreed to defer further discussion of the carryover issue until FAO/WHO are able to provide a response to the scientific advice request.
- **Rating System to Establish Priority for CCRVDF Work (Agenda Item 7.2)**
The Committee discussed the possibility of adopting a rating system to prioritize the work of the CCRVDF based on the discussion paper prepared by France as host of the EWG formed to review the issue. The Committee agreed to discontinue work on the rating system, noting that the CCRVDF current workload did not warrant the need for a new rating tool at this time.
- **Global Survey (Agenda Item 8)**
The Committee noted the summarized results of the Global Survey conducted by an EWG co-hosted by Costa Rica and the United States. The Committee agreed with the EWG report recommendation to continue to develop and maintain the "Database on Countries' Needs for MRLs" by circular letter. The Committee also agreed to establish a new EWG co-hosted by Costa Rica and the United States to further consider the results of the global survey and to identify a smaller list of high priority veterinary drugs in need of MRLs and their respective information gaps which are preventing an evaluation by JECFA.
- **Draft Priority List (Agenda Item 9)**
The Committee agreed to forward the draft priority list of veterinary drugs for evaluation or re-evaluation by the JECFA to the CAC40 for approval. The draft priority list contains requests for amoxicillin in fin fish, ampicillin in fin fish, bismuth sub-nitrate in cattle milk, ethion in cattle tissues, flumethrin in honey, halquinol in swine tissues, lufenuron in fin fish, and monepantel in cattle tissues. The United States nominated halquinol for evaluation and supported the nomination of ampicillin by offering access to the amoxicillin toxicology data package previously submitted to the JECFA. The Committee also noted the continuing JECFA evaluations for diflubenzuron in salmon, sisapronil in cattle tissues, and zilpaterol hydrochloride in cattle tissues.

With respect to ethion, Argentina had proposed a pilot project for JECFA to conduct the evaluation using "non-traditional data sources" (scientific literature, previous work by the Joint Meeting on Pesticide Residues), along with additional data to be supplied by Argentina and Uruguay. The Committee requested JECFA to proceed with the evaluation based on available data and, if not possible to complete the evaluation, to identify data gaps and provide advice on moving the work forward.

The Committee agreed to gather future nominations to the Priority List through a circular letter. The Committee also established a Priority List physical working group, which will meet prior to the next session and be led by Australia.



Next Session

The next session of the CCRVDF is tentatively scheduled for April 2018.