



## Report of the United States Delegate, 24th Session, Codex Committee on Residues of Veterinary Drugs in Foods

**April 23-27, 2018**  
**Chicago, Illinois**

The 24<sup>th</sup> Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDf) met in Chicago, IL, April 23-27, 2018. The session was attended by delegates from 69 Member countries, one member organization (the European Union), five 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 Patty Bennett (U.S. Food Safety and Inspection Service), seven governmental advisors and seven nongovernmental advisors. CCRVDf24 was successful in advancing maximum residue limits (MRLs) for several veterinary drugs and forwarding a priority list of drugs for scientific review to the Codex Alimentarius Commission for approval at its 41<sup>st</sup> Session (CAC 41, July 2018), and established two electronic working groups to continue work on edible offal and on MRL extrapolation issues. The United States was disappointed, however, that the Committee did not advance proposed MRLs for the drug zilpaterol hydrochloride as recommended by the Joint Expert Committee on Food Additives (JECFA), despite the absence of any health or scientific concerns.

### Highlights

- The Committee agreed that Codex Risk Management Recommendation (RMR) text allows national authorities to make different risk management decisions to prevent residues of gentian violet in food.
- The Committee agreed that there were no scientific or public health concerns regarding the proposed draft MRLs for zilpaterol hydrochloride; however, the MRLs were blocked from advancing for reasons outside the scope of Codex.
- The Committee agreed to discuss approaches for extrapolating Codex MRLs as part of its risk management functions and to conduct a pilot to explore extrapolating MRLs for 13 veterinary drugs with existing Codex MRLs to additional species.

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

### MEETING SUMMARY

#### Draft RMR for Gentian Violet

The Committee discussed the text for the draft risk management recommendation (RMR) for gentian violet, which had been circulated for comment. Many delegations supported the draft text as written, while the United States and some other delegations suggested deletion or modification of the last sentence, which reads, "This can be accomplished by not using gentian violet in food producing animals." These delegations expressed concern about the last sentence of the draft RMR because it may be interpreted as prescriptive and could limit a national authority's ability to establish appropriate risk management measures specific to their own country. Rather than modify the existing language, the Committee agreed to note in the report that the current RMR text provided sufficient flexibility to allow member countries to choose appropriate risk management approaches to prevent residues of gentian violet in food. The United States and other delegations requested a footnote with similar language or a reference to the report, but this suggestion was not broadly supported by the Committee. CCRVDf24 advanced the proposed text as circulated, including the last sentence, to CAC 41 for final adoption, noting the reservations of the United States, Ecuador, Honduras, and Nicaragua, who remained concerned about potentially overly restrictive interpretation of the risk management recommendation when read independently.

#### Proposed Draft MRLs for Zilpaterol Hydrochloride

The Committee agreed that JECFA had conducted a robust scientific evaluation and that there were no scientific or public health concerns regarding the proposed draft MRLs for zilpaterol hydrochloride. There was extensive support from Member Countries from multiple regions to advance the proposed draft MRLs. However, some delegations, principally from the European region, objected to advancing the MRLs based on concerns outside the mandate of the Committee and Codex, including national legislation, animal welfare, and general opposition to non-therapeutic uses of animal drugs. The World Organization for Animal Health (OIE) spoke in support of its role as the internationally recognized organization for animal health and welfare. The United States noted that the Codex definition for

veterinary drugs in the *Procedural Manual* is not limited to therapeutic uses. The Codex Secretariat referred to the “*Statements of principle concerning the role of science in the Codex decision-making process and the extent to which other factors are taken into account*” in the *Procedural Manual* and highlighted that delegations may abstain from acceptance of a standard without preventing a decision by Codex. Unfortunately, those delegations opposed to advancing the MRLs did not agree to this approach as outlined in the *Procedural Manual*.

The Chair concluded that, while there was consensus on the science, there was no consensus on advancement of the proposed draft MRLs, and he proposed to close the debate for the current session of CCRVDF. As the Committee could not reach consensus to advance the MRLs due to concerns outside the scope of Codex, the proposed draft MRLs for zilpaterol hydrochloride remained at Step 4. Twenty-eight Member Countries objected to the decision to hold the MRLs at Step 4 and placed reservations in the report, including the United States. These delegations expressed strong concerns that Codex procedures were not followed, that no legitimate factors consistent with the *Procedural Manual* had been raised, and that delaying adoption of MRLs with such scientific support would discourage participation in Codex and undermine the legitimacy and fundamental principles of Codex as a science-based standard setting organization. The Codex Secretariat noted that the conclusion of this agenda item would send a strong message that would need to be addressed by the Codex Executive Committee (CCEXEC) and the Codex Alimentarius Commission (CAC) to prevent potential damage to Codex in the future.

#### **Proposed Draft MRLs: Amoxicillin, Ampicillin, Lufenuron, Monopantel and Flumethrin**

The Committee advanced proposed draft MRLs for amoxicillin and ampicillin in finfish, for lufenuron in salmon and trout, and for monopantel in cattle to Step 5/8 for final adoption by CAC41. The Committee revised the proposed draft MRL for flumethrin in honey and advanced it to Step 5, to allow more time for discussion before final adoption.

#### **Extrapolation of MRLs: Groups of Fish Species and Database of Countries’ Needs for MRLs**

The Committee discussed extrapolation of MRLs several times during the meeting. The topic began during the discussion on MRLs for groups of fish species, which concluded that grouping fish species based on many factors might be impractical. The co-chairs of the electronic working group (EWG) on grouping fish species instead proposed a step-wise approach whereby JECFA could recommend MRLs for orders of fish, rather than individual species, and the Committee could consider further extrapolation of the recommended MRLs to finfish or fish in general.

The Committee agreed to establish an EWG, chaired by the European Union (EU), to prepare a discussion paper exploring pragmatic ways for CCRVDF to extrapolate Codex MRLs to more species in its role as risk manager. This discussion paper will look at the proposal for aquatic species, as well as approaches for terrestrial species. The EWG will also conduct a pilot exercise to explore extrapolating MRLs for three veterinary drugs with existing Codex MRLs in at least one species of fish to establish broader MRLs for finfish or fish.

Extrapolation of Codex MRLs was raised again under the discussion on the Database of Countries’ Needs for MRLs. The Committee agreed with recommendations of the in-session working group, led by the United States and Costa Rica, to focus efforts on six compounds which have Codex MRLs in at least one species, but for which MRLs in additional species are needed by Member Countries. Several delegations volunteered to take the lead in gathering available information to develop dossiers and prepare nominations to the Priority List for evaluation at the next CCRVDF. The Committee also identified 10 veterinary drugs with Codex MRLs in one or more ruminant species, which the Committee could consider for extrapolation to additional ruminant species. The Committee agreed to add the 10 veterinary drugs in ruminants to the pilot exercise in the proposed EWG led by the EU. The Committee also agreed to maintain the full database on countries’ needs to serve as a reference for CCRVDF of the priority needs and other compounds still in need of Codex MRLs.

#### **Edible Offal Tissues**

The EWG, led by Kenya, proposed broad definitions for offal and edible offal to the Committee. Many delegations supported including the proposed definitions in the *Glossary of Terms and Definitions for CCRVDF*. The United States also supported inclusion of the broad definitions in the *Glossary*, but encouraged using a case-by-case approach for developing MRLs in additional tissues when warranted and supported by data. Some delegations noted that more specific definitions may be needed to elaborate MRLs in the future and suggested that the Committee should try to harmonize the definitions with the Codex Committee on Pesticide Residues (CCPR), which already had a definition for offal. The Committee agreed to establish a new EWG hosted by Kenya and New Zealand to work with



the CCPR EWG on Classification of Food and Feed “to elaborate a definition for edible offal and for any other animal tissue of relevance, for the purposes of harmonization and elaborating MRLs.”

### **Decline in New Compounds for the Priority List**

The Committee agreed that innovative approaches could be considered for development of MRLs while maintaining the scientific integrity and transparency of the JECFA evaluation and Codex process. The Committee and the JECFA Secretariat supported a potential pilot whereby JECFA could independently evaluate a compound while it was still under evaluation by national authorities for registration. The Committee agreed to develop a discussion paper, to be drafted by Canada with the assistance of Australia, the United States, and the JECFA Secretariat, which would look at the advantages and disadvantages of such a parallel process for a JECFA evaluation. The Committee further agreed to pilot such a parallel approach should a compound become available.

### **Draft Priority List**

The Committee agreed to forward the draft priority list to the CAC41 (2018) for approval. The Committee agreed to separate the draft priority list into two sections. The first section contains proposed compounds for evaluation or re-evaluation by JECFA. This section includes flumethrin (cattle), fosfomycin (chicken and swine), and ivermectin (re-evaluation of MRLs for pigs and sheep/goats). The new second section contains compounds for which CCRVDF will consider extrapolation of Codex MRLs to additional species. This section includes the 13 compounds identified for possible extrapolation to fish in general or to additional ruminant species, as appropriate. The Committee also noted the continuing JECFA evaluations for diflubenzuron, ethion, halquinol, and sisapronil.

### **NEXT SESSION**

The next session of the CCRVDF is tentatively scheduled for April 2020.