

Report of the U.S. Delegate, 25th Session, Codex Committee on Residues of Veterinary Drugs in Foods

July 12-16,20, 2021

(Virtual)

The 25th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF25) met virtually, July 12-16, and 20, 2021. The session was attended by delegates from 80 Member countries, one member organization (the European Union), 11 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 Louis Bluhm (U.S. Food Safety and Inspection Service), ten governmental advisors and seven nongovernmental advisors. The CCRVDF25 was very productive despite the reduced meeting time and virtual format. The Committee advanced 18 maximum residue limits (MRLs) for four veterinary drugs, forwarded a priority list for approval by the Codex Alimentarius Commission at its next session (CAC44, November 2021), and established three electronic working groups to continue work on important issues to CCRVDF. The United States was disappointed, however, that CCRVDF25 failed to advance MRLs for zilpaterol hydrochloride despite agreement that a robust, independent scientific risk assessment found no food safety concerns with the MRLs recommended by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Highlights

- The Committee advanced six MRLs for three compounds to Step 5/8 or Step 8 for final adoption by CAC44.
- The Committee reiterated that there are no scientific or public health concerns regarding the proposed draft maximum residue limits (MRLs) for zilpaterol hydrochloride; however, the MRLs were blocked once again from advancing for reasons outside the scope of Codex and in conflict with the *Statements of Principle on the Role of Science in Codex Decision-Making and the Extent to which Other Factors Are Taken into Account* (Codex Procedural Manual, 27th Ed., pp. 245-246).
- The Committee adopted an approach for extrapolating Codex MRLs to additional related species and agreed to continue discussion on specific proposals to extrapolate Codex MRLs to ruminant species and finfish.

The following paragraphs summarize key discussions in the Committee in more detail. The official report of the meeting will be posted on the Codex Alimentarius website at <http://www.fao.org/fao-who-codexalimentarius/meetings/it/>

MEETING SUMMARY

Carryover from Feed to Food

The Committee reflected on the scientific advice provided by FAO and WHO in response to questions on the risk of unavoidable carryover of veterinary drugs resulting in unintentional residues in food and noted that such residues were unlikely to pose a risk to consumers but could result in trade issues. The Committee affirmed that the existing Code of Practice on Good Animal Feeding did not require revision but agreed to consider establishment of action levels in appropriate tissues on a case by case basis. An electronic working group chaired by Canada and Australia was established to frame the risk management considerations that would be needed in requesting a recommended action level from the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Proposed Draft MRLs: Flumethrin, Diflubenzuron, Halquinol, and Ivermectin

The Committee advanced the proposed MRL for flumethrin in honey to Step 8 for final adoption by CAC44 (2021). The Committee advanced proposed draft MRLs for diflubenzuron in salmon and halquinol in swine to Step 5/8 for final adoption by CAC44 (2021). The EU, Norway, Switzerland, and Egypt recorded reservations to advancing the halquinol MRLs. The Committee advanced the proposed draft MRLs for ivermectin in sheep, pig, and goats to Step 5 (interim adoption by CAC44, allowing for further consideration at the next CCRVDF session), while requesting a re-evaluation by JECFA to consider additional data and established Good Veterinary Practice (GVP) from the EU which had not been provided to JECFA88 and may support higher MRLs.

Proposed Draft MRLs for Zilpaterol Hydrochloride

Consistent with the conclusions of the previous session (CCRVDF24, 2018), the Committee once again agreed that JECFA had conducted a robust scientific evaluation and that there were no outstanding scientific or public health concerns regarding the proposed draft MRLs for zilpaterol hydrochloride. A few members (notably, the Russian Federation and Kazakhstan) raised hypothetical concerns but did not offer any evidence or data to support those concerns. There was extensive support from members to advance the proposed draft MRLs for final adoption at Step 5/8, recognizing that all procedures have been followed and that no new data have been presented over the three years since the Committee's last meeting. Many members from the Coordinating Committee for Latin America and the Caribbean (CCLAC) and the Coordinating Committee for Africa (CCAFRICA) expressed their strong support for advancing science-based standards, even in cases where zilpaterol was not approved in their countries. Japan and the Republic of Korea also joined the United States in supporting the MRLs. However, some members (notably, the European Union) continued to object to advancing the MRLs based on concerns outside the mandate of the Committee and Codex, primarily for reasons of national legislation which did not allow use of zilpaterol hydrochloride, beta-agonists, or veterinary drugs for non-therapeutic purposes.

The United States noted that objections due to national legislation and those not relevant to the Codex mandate should not be taken into account in the determination of consensus as 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* explicitly excludes other factors that are

not relevant worldwide. Members objecting to the MRLs were reminded that paragraph 4 of the *Statements of Principle* allows members to abstain from acceptance of a standard without preventing a decision by Codex by placing a reservation, as many of the same members chose to do for an earlier MRL discussion. The EU and others objecting to the MRLs refused to place a reservation. With no consensus to either advance or hold the proposed draft MRLs for zilpaterol, the Chairperson noted that all efforts to reach consensus had been exhausted and that he would request CCEXEC81 and CAC44 to provide a recommendation on the way forward.

Extrapolation of MRLs to Additional Species

The Committee discussed the proposed approach for extrapolation of existing Codex MRLs to other related species and agreed to forward the approach outlined in Conference Room Document 3 (CRD3), with some modifications, for adoption as an Annex to the *Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods (Procedural Manual, 27th Ed., pp. 146 ff)*. During the discussion, the United States proposed limited modifications to the proposed approach to ensure that Codex MRLs are extrapolated in a deliberate manner by the Committee to address risks to consumers where they exist. Although these proposals were not accepted, the United States supported the adoption of the extrapolation criteria as they may serve as a useful tool for the Committee and allow development of additional Codex MRLs for related species where data are unlikely to be available for a JECFA evaluation. The final text on extrapolation is contained in Appendix III of the official Committee report (REP21/RVDF).

As part of the effort to develop the extrapolation approach, twelve veterinary drugs were recommended for extrapolation to ruminants or finfish as a pilot. There was insufficient time to consider the proposed extrapolated MRLs so the Committee agreed to circulate the proposals for comment and to establish an electronic working group chaired by the EU, Costa Rica, and Uganda to further consider the proposed extrapolated MRLs prior to the next CCRVDF session. The electronic working group was also tasked with exploring criteria which would allow extrapolation of Codex MRLs to edible offal tissues.

Expanding Options for Standards Development

The Committee continued discussion on a number of topics intended to increase the availability of Codex veterinary drug MRLs and the efficiency of their development. All of these efforts received broad support from members including the United States.

The Committee agreed to a definition of “edible offal,” based on the recommendations of an EWG chaired by Kenya and New Zealand, as follows: “those parts of an animal, apart from the skeletal muscle, fat, and attached skin, that are considered fit for human consumption.” The Committee also recommended that the Codex Committee on Pesticide Residues (CCPR) adopt this as a common definition for both committees. CCRVDF25 reestablished an electronic working group chaired by Kenya and New Zealand to continue collaboration and harmonization with the CCPR electronic working group on the Classification of Food and Feed.

The Committee considered a discussion paper prepared by Canada on the parallel review of a veterinary drug by JECFA while it was still under evaluation by a member with the intention of shortening the time between a national approval and establishment of Codex MRLs. The Committee agreed that no changes to the *Procedural Manual* were required to allow for parallel review and agreed to keep the approach as an option for future evaluations by JECFA.

The Committee agreed to maintain the Database on Countries' Needs for MRLs as a reference document for future CCRVDF sessions. The Database will continue to be updated by the United States and Costa Rica as progress is made on establishment of MRLs for veterinary drugs identified as high priority by members.

The Committee agreed to forward the Priority List to the CAC44 (2021) for approval. The Priority List contains imidacloprid for evaluation of MRLs in finfish; ivermectin for re-evaluation of MRLs in pigs, sheep, and goats; nicarbazin for re-evaluation of MRLs in chickens; and ivermectin in goat and sheep milk for consideration by CCRVDF for extrapolation. The Committee also noted the continuing JECFA evaluation for selamectin.

Next Session

The next session of the CCRVDF is tentatively scheduled for 2023.