REPORT OF THE U.S. DELEGATE TO THE
26TH SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

February 13 to 17, 2023
Portland, Oregon, United States of America

The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its 26th Session (CCRVDF26) in Portland, Oregon, from 13 to 17 February 2023 and was attended by approximately 150 delegates from 50 countries, one Member Organization (the European Union/EU), seven Observer Organizations, and representatives of the United Nations Food and Agriculture Organization (FAO) and World Health Organization (WHO). Brandi Robinson of the U.S. Food and Drug Administration chaired the session. The United States was represented by Delegate Jonathan Greene (U.S. Food and Drug Administration), Alternate Delegate Louis Bluhm (U.S. Department of Agriculture, Food Safety and Inspection Service), seven governmental advisors, and three nongovernmental advisors. CCRVDF26 was the first time the Committee met in person since 2018.

HIGHLIGHTS

The Committee advanced 57 maximum residue limits (MRLs) for 13 veterinary drugs to Step 5/8 for final adoption. This included the first use of recently adopted criteria to allow extrapolation of MRLs among related species. CCRVDF26 also held productive discussions on the following topics:

- Extrapolation of MRLs among related species and to edible offal tissues within species
- Establishment of action levels for residues of veterinary drugs in edible tissues of animal origin caused by unavoidable and unintended carryover of veterinary drugs in animal feed
- Coordination between CCRVDF and the Codex Committee on Pesticide Residues (CCPR)

Based on the outcomes of these discussions, CCRVDF decided to continue three existing Electronic Working Groups (EWGs) and assigned new work to them. The EWG on edible offal completed its work at CCRVDF26, having completed its task of developing a definition for edible offal that was agreed upon by CCRVDF and CCPR and adopted by the Codex Alimentarius Commission (CAC). Finally, CCRVDF26 forwarded a priority list for approval by the 46th Session of CAC (CAC46, November 2023).

The following paragraphs discuss the conclusions of the Committee In more detail. The full official report of the session will be posted when final at https://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=CCRVDF&session=26.

MEETING SUMMARY

Maximum Residue Limits for Ivermectin and Nicarbazin

Draft MRLs for ivermectin in fat, kidney, liver, and muscle of sheep, pigs, and goats were circulated at Step 3 for comment and discussed at Step 4 by the Committee. These draft MRLs resulted from a reevaluation by the 94th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA94, 2022). The Committee advanced the draft MRLs to Step 5/8 for final adoption by CAC46. Another set of MRLs for ivermectin in sheep, pigs, and goats was circulated at Step 6 for comment. However, as the Committee agreed to advance the updated MRLs, it decided to discontinue the work on the set of ivermectin MRLs at Step 6.

The EU, North Macedonia, Switzerland, and the United Kingdom expressed reservations about the ivermectin MRLs in sheep and goat kidney and liver and in pig fat, kidney, liver, and muscle because these MRLs remained below those established in the EU.

Draft MRLs for nicarbazin in chicken kidney, liver, muscle, and skin with fat were circulated at Step 3 for comment and discussed at Step 4 by the Committee. These MRLs were the result of a reevaluation by JECFA94 (2022). The Committee advanced these MRLs to Step 5/8 for final adoption.

The proposed MRLs for ivermectin and nicarbazin are as follows:

Veterinary Drug	Species	Fat* (µg/kg)	Kidney(µg/kg)	Liver(µg/kg)	Muscle (µg/kg)
Ivermectin	Pigs	50	20	30	15
Ivermectin	Sheep and Goats	100	20	60	30
Nicarbazin	Chickens	4000	8000	15000	4000

*Skin with fat for chickens

Extrapolated Maximum Residue Limits for Different Combinations of Compounds and Commodities

Draft MRLs from one or more ruminant species and one or more fish species were extrapolated to all other ruminant species and all other finfish, respectively, as part of the work of an EWG on extrapolation. The draft MRLs were circulated for comment at Step 3 and discussed by the Committee at Step 4. The Committee advanced the MRLs to Step 5/8 for final adoption.

The proposed extrapolated MRLs are as follows:

Veterinary Drug	Species Group	Fat (µg/kg)	Kidney (µg/kg)	Liver (µg/kg)	Muscle (µg/kg)	Milk (µg/kg)
Amoxicillin	All Other Ruminants	50	50	50	50	4
Benzylpenicillin	All Other Ruminants	NA	50	50	50	4
Cyhalothrin in	All Other Ruminants	400	20	20	20	30
Cypermethrin	All Other Ruminants	1000	50	50	50	-
Deltamethrin	All Other Ruminants	500	50	50	30	-
Levamisole	All Other Ruminants	10	10	100	10	-
Moxidectin	All Other Ruminants	500	50	100	20	-
Spectinomycin	All Other Ruminants	2000	5000	2000	500	200
Tetracyclines	All Other Ruminants	-	1200	600	200	100
Tilmicosin	All Other Ruminants	100	300	1000	100	-
Deltamethrin	All Fin Fish	-	-	-	-	30
Flumequine	All Fin Fish	-	-	-	-	500

The EU, North Macedonia, Switzerland, and the United Kingdom expressed reservations about the MRLs for tetracyclines in ruminant kidney, liver, and muscle; deltamethrin in ruminant fat, kidney, liver, and muscle; spectinomycin in ruminant fat, liver, and muscle; and tilmicosin in ruminant fat and muscle. In their opinion, with these MRLs, the acceptable daily intake (ADI) would be exceeded if the EU Theoretical Maximum Daily Intake (TMDI) model were used instead of the risk assessment procedures used by JECFA.

Extrapolation of Maximum Residue Limits Between Species and to Edible Offal Tissues

The Extrapolation EWG determined that some of the MRLs proposed for extrapolation did not meet the criteria established in Annex C of the *Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods*, in the Codex *Procedural Manual*. Even though the Committee

agreed to not extrapolate these MRLs, the Committee did decide to explore ways to enhance the current criteria's potential for extrapolation across species, such as between ruminants and camels as well as between milk of different species, when justified.

The Extrapolation EWG also discussed how MRLs could be extrapolated to edible offal tissues other than liver and kidney within a species (*i.e.,* other edible offal). However, the EWG could not develop a suitable approach. The Committee discussed what information and data might help CCRVDF create a set of criteria or procedures for extrapolating MRLs to other edible offal tissues within a species. The Committee determined that veterinary drug residue distribution data in edible tissues, including other edible offal, and consumption data on other edible offal might enable CCRVDF to develop extrapolation criteria or procedures for other edible offal tissues. The JECFA Secretariat encouraged members to submit consumption data to the FAO/WHO Global Individual Food Consumption Data Tool (GIFT) and FAO/WHO Chronic Individual Food Consumption (CIFOCOss) databases. The Committee determined that members could submit tissue residue distribution data for compounds to the Extrapolation EWG. The type of distribution data submitted should not be limited to veterinary drugs, as understanding how classes of compounds distribute within the animal body is an important aspect.

The Committee decided to continue the Extrapolation EWG and tasked it with the following:

- Continue to evaluate possibilities for extrapolation of MRLs for veterinary drugs as recommended by the Committee.
- Summarize available information on the distribution of compounds in different edible offal tissues to evaluate the possibility of extrapolating MRLs to edible offal tissues other than liver and kidney.
- Examine opportunities to enhance the current criteria's potential for extrapolation across species, such as between ruminants and camels as well as between milk of different species, where justified.

Establishment of action levels for residues of veterinary drugs in edible tissues caused by unavoidable and unintended carryover of veterinary drugs in animal feed

At CCRVDF25 (2021), the Committee recognized that unintended and unavoidable carryover of veterinary drugs could occur in animal feed despite following Good Manufacturing Practices (GMPs) and Good Veterinary Practices (GVPs). In some situations, when unintended and unavoidable carryover occurs, residues of veterinary drugs become present in the edible tissues of non-target species. CCRVDF25 (2021) established an EWG tasked with exploring the possibility of developing criteria for establishing action levels in edible tissue of animal origin for residues of veterinary drugs caused by unintended and unavoidable carryover of veterinary drugs in feed.

The EWG proposed a procedure to the Committee. However, several delegations, including the United States, expressed the view that, although this was an important issue, discussions on formalizing the process should be deferred to a later session, to allow certain aspects of the procedure to be considered in more detail. The Committee agreed that a decision on formalizing the procedures would not be made at CCRVDF26. The Committee discussed this topic at great length and made significant progress; however, several aspects of the procedure remained undecided by the Committee. Recognizing that the work was incomplete, the Committee agreed to continue the EWG on action levels to develop further the criteria and procedures for establishing action levels, using the revised document and discussions at

CCRVDF26 as the basis. The EWG will also revisit the nicarbazin pilot case and consider other veterinary drugs.

During the discussions on action levels, the EU intervened stating that, at first, the development of action levels should exclude veterinary drugs that are antibacterial agents until guidance is provided on how to address risks in relation to antimicrobial resistance (AMR). In response the United States pointed out that the Codex definition of a veterinary drug did not exclude veterinary drugs that are antibacterial agents. The United States also noted that the *Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods* provides the framework to establish risk management tools for residues of veterinary drugs in foods, including residues from veterinary drugs that exhibit antimicrobial activity. Finally, the United States noted that the procedures would be limited to veterinary drugs that had been evaluated by JECFA. Because JECFA evaluates whether residues of veterinary drugs in foods cause an increase in bacterial resistance within the human intestinal microbiome and the action levels will be examined in relation to the JECFA-recommended health-based guidance value, the United States concluded that risks in relation to AMR were considered within the proposed procedure.

Coordination between CCRVDF and the Codex Committee on Pesticide Residues (CCPR) on issues affecting both committees

CCRVDF25 (2021) noted that collaboration between CCRVDF and CCPR could be improved on issues that affect both committees. The 52nd Session of CCPR (CCPR52, 2021) also encouraged greater cooperation on cross-cutting issues. The 81st Session of the Executive Committee (CCEXEC81, 2021) recommended a Joint CCRVDF-CCPR EWG to accomplish this work. The 44th Session of the CAC (CAC44, 2021) agreed to establish a Joint CCRVDF-CCPR EWG, chaired by the United States, to identify and prioritize areas of further collaboration between the two Committees.

The United States, as Chair of the Joint CCRVDF-CCPR EWG, presented the EWG recommendations to CCRVDF26. The Committee agreed to:

- Ask JECFA and JMPR to continue working toward harmonizing their risk assessment methodologies and explore ways in which data can be shared between the two expert committees.
- Recommend that, when a call for compounds for the priority list is issued, CCRVDF ask whether the compound is a dual-use compound and whether the data could be shared with JMPR, and request CCPR consider doing the same.
- Develop a list of compounds with dual use as a pesticide and veterinary drug for which no or only one Codex MRL has been established. Member countries will provide the information to populate this list.
- Identify dual-use compounds that have different Codex MRLs for similar edible commodities of animal origin and recommend, on a case-by-case basis, a harmonized MRL(s) for the compound(s) and affected commodity(ies). The higher of the two divergent MRL values might be recommended.

The Committee agreed that the Joint CCRVDF-CCPR EWG should continue its work, including the new work described above. The Committee also decided that Brazil would co-chair the Joint CCRVDF-CCPR EWG with the United States.

In addition to the Joint CCRVDF-CCPR EWG, the Committee discussed previous work by another EWG on edible offal, which was tasked with developing a definition for edible offal in coordination with CCPR. The Committee affirmed that the Edible Offal EWG had completed its work and developed a definition for edible offal that was accepted by CCRVDF and CCPR and adopted by the CAC. Although not part of its original task, the EWG also noted that clarification was needed on definitions and/or food descriptors and when to use them for "fat," "fat with skin," "fat/skin," and "skin." The Committee agreed that this work was needed and added the work to the terms of reference for the Joint CCRVDF-CCPR EWG.

Priority List of Veterinary Drugs for Evaluation or Reevaluation by JECFA

The Committee agreed to forward a priority list of veterinary drugs to the CAC46 (2023) for approval.

NEXT SESSION

The 27th Session of the CCRVDF is tentatively scheduled for 2024.