REPORT OF THE UNITED STATES DELEGATE TO THE 27TH SESSION OF THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

October 21 to 25, 2024

Omaha, Nebraska, United States of America

BACKGROUND SUMMARY

The Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) held its 27th Session (CCRVDF27) in Omaha, Nebraska, from October 21 to 25, 2024, and was attended by approximately 148 delegates from 46 countries, one Member Organization (European Union; EU), 5 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 Jonathan Greene (U.S. Food and Drug Administration, Center for Veterinary Medicine), Alternate Delegate Louis Bluhm (U.S. Department of Agriculture, Food Safety and Inspection Service), five governmental advisors, and three nongovernmental advisors.

HIGHLIGHTS

The United States was successful in achieving its major goals for the session. The 27th Session of CCRVDF agreed to the following:

- Advance the MRLs for clopidol in chicken kidney, liver, muscle, and skin/fat, and the MRLs for imidacloprid in fillet of finfish, to Step 5/8 for final adoption.
- Advance the MRLs for fumagillin dicyclohexylamine (DCH) in fish fillet and honey to Step 5, which would allow additional consideration following the concerns expressed by the United States, Canada, and Australia.
- Amend the existing MRL extrapolation criteria to allow for extrapolation in cases where the marker residue was a homolog that constituted a major part of the parent substance.
- Include an additional criterion in the existing extrapolation criteria for milk MRLs.
- Include a new set of MRL extrapolation criteria for camelid species.
- Advance the extrapolated MRLs for lufenuron in fillet of finfish, emamectin benzoate in fillet of finfish, and ivermectin in milk of all other ruminants to Step 5/8 for final adoption.
- Develop a complimentary approach consisting of action levels and a Codex Guideline to address residues of veterinary drugs in foods caused by unavoidable and unintentional carryover of veterinary drugs in animal feed.
- Support the work of the Joint Electronic Working Group (EWG) between the Codex Committee on Pesticide Residues (CCPR) and CCRVDF, and endorse exploring the feasibility of a virtual session of the Joint EWG and a virtual Joint Session of CCPR and CCRVDF.

- Forward a priority list of veterinary drugs for evaluation by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), extrapolation by CCRVDF, or establishment of action levels by CCRVDF to the 47th Session of the Codex Alimentarius Commission (CAC47).

A more detailed summary of CCRVDF27 is provided below. The official report of CCRVDF27 is posted on the Codex website at the following link: https://www.fao.org/fao-who-codexalimentarius/meetings/detail/de/?meeting=CCRVDF&session=27.

NEXT SESSION OF CCRVDF

The 28th Session of CCRVDF is tentatively scheduled for March 2026 in the United States of America.

MEETING SUMMARY

MAXIMUM RESIDUE LIMITS FOR CLOPIDOL, IMIDACLOPRID AND FUMAGILLIN DICYCLOHEXYLAMINE (DCH)
To Be Presented for Adoption at Next CAC? Yes Have the United States' Objectives Been Met? Yes Is it anticipated that this item will or should be raised at the CAC? Yes
United States Objective The U.S. objective was to support the MRL recommendations for clopidol in chicken kidney, liver, muscle, and skin/fat, and for imidacloprid in finfish fillet, made by the 98th meeting of JECFA (JECFA98, 2024). The U.S. objective also was to express concern with and not support the MRL recommendations for fumagillin DCH in fish fillet and honey because of an incomplete food safety risk assessment.
Outcome/Conclusion The Committee agreed to advance the MRLs for clopidol in chicken kidney, liver, muscle and skin/fat and for imidacloprid in fillet of finfish to Step 5/8 for final adoption. The United States expressed concerns about the MRLs recommended by JECFA98 for fumagillin DCH because the risk assessment lacked certain data that are needed for a food safety risk assessment, such as complete toxicology, metabolism, and residue depletion data. Canada also expressed concern over the lack of complete data. In addition, the United States, Canada, and Australia expressed concern about the proposed marker residue (DCH) in honey because it did not appear to be a suitable marker residue as it is not unique to the use of fumagillin DCH as a veterinary drug and could lead to incorrect compliance conclusions about honey. Because of these concerns, the Committee advanced the MRLs for fumagillin DCH in fish fillet and honey to Step 5, which would allow additional consideration and discussion following the concerns expressed by the United States, Canada, and Australia.
Other Comments Upon review of the JECFA98 report, the United States noted that the risk assessment leading to the recommended MRLs for fumagillin DCH in fish fillet and honey lacked several studies that are needed for an adequate food safety risk assessment for residues of veterinary drugs in foods. JECFA acknowledged the missing data and made assumptions and applied safety factors to account for the missing data. However, the United States disagreed with the assumptions and application of additional safety factors because it is not standard accepted practice to do so when conducting a risk assessment for residues of veterinary drugs in foods. Therefore, the United States expressed concerns and did not support advancement to Step 5/8. The United States committed to submitting a concern form within one month of CCRVDF.

EXTRAPOLATION OF MRLS FOR VETERINARY DRUGS IN FOODS TO ONE OR MORE SPECIES AND/OR COMMODITY
To Be Presented for Adoption at Next CAC? Yes Have the United States' Objectives Been Met? Yes Is it anticipated that this item will or should be raised at the CAC? Yes
United States Objective The U.S. objective was to support enhancements and additions to the existing MRL extrapolation criteria that produce science-based food safety standards and to support the proposed extrapolated MRLs for lufenuron in fillet of finfish and emamectin benzoate in fillet and muscle of finish. For other edible offal, the U.S. objective was to support further work on ways to extrapolate existing MRLs to other edible offal tissues that consider both consumer safety and the ability to achieve compliance.
Outcome/Conclusion The Committee enhanced the MRL extrapolation criteria by allowing for the possibility of extrapolation in cases where the marker residue is a homolog that constitutes a major part of the parent substance, and by allowing for extrapolation to milk of other ruminants if the dietary exposure from commodities with existing MRLs is very low relative to the Codex Health-Based Guidance Value. In addition, the Committee developed new MRL extrapolation criteria to enable extrapolation of existing MRLs to tissues of camelid species. The Committee agreed to advance the extrapolated MRLs for lufenuron in fillet of finfish, emamectin benzoate in fillet and muscle of finish, and ivermectin in milk of all other ruminants to Step 5/8 for final adoption. Regarding extrapolation of MRLs to other edible offal tissues, the Committee agreed to begin work on an extrapolation approach that considers both consumer safety and the ability to comply with the extrapolated MRL value. The Committee also agreed to re-establish the electronic working group (EWG) on extrapolation and tasked it with considering an approach to extrapolate MRLs to other edible offal tissues, considering any nominations for extrapolation under Part V of the priority list, and considering proposals to enhance the existing MRL extrapolation criteria.

RESIDUES OF VETERINARY DRUGS IN FOODS CAUSED BY UNAVOIDABLE AND UNINTENTIONAL CARRYOVER OF VETERINARY DRUGS IN ANIMAL FEED

To Be Presented for Adoption at Next CAC? No
Have the United States' Objectives Been Met? Yes
Is it anticipated that this item will or should be raised at the CAC? Yes

United States Objective

The U.S. objective was to ensure that fixed action levels were not the only approach considered for addressing residues of veterinary drugs in foods caused by unavoidable and unintentional carryover of veterinary drugs in animal feed, and to provide alternative risk-based approaches.

Outcome/Conclusion

The Committee finalized a document that describes how to derive action levels for residues of veterinary drugs in foods caused by unavoidable and unintentional carryover of veterinary drugs in animal feed. The Committee agreed to define an action level as follows:

Action level: *A concentration of residue resulting from unintended and unavoidable carry-over in a feed of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) in a non-target animal that is recommended by the Codex Alimentarius Commission to be recognized as acceptable in or on a food, above which action should be taken.*

Recognizing that there are limited data to derive action levels and that small exceedances of the action levels likely are not a food safety concern, the Committee also agreed to propose new work to develop a Codex guideline containing guidance to competent authorities on actions that may be taken when residues of veterinary drugs in food are below or above action levels or there are no action levels established.

The action levels and guideline document are envisioned by the Committee to be a complementary approach for addressing residues of veterinary drugs in foods caused by unavoidable and unintentional carryover of veterinary drugs in animal feed.

The Committee agreed to re-establish the EWG on carryover chaired by Canada and co-Chaired by Australia and the United States to do the following:

- develop the draft Codex Guideline containing guidance for actions that competent authorities could take upon detection of residues of veterinary drugs in food of animal origin caused by unavoidable and unintentional carryover of veterinary drugs in animal feed
- develop action levels as approved on the priority list

Other Comments

The United States worked diligently to persuade the Committee that developing only fixed action levels would likely result in compliance issues because the data on carryover are limited to non-existent and not representative of carryover that occurs globally. In addition, the United States successfully argued that, because of the limited data, exceedance of fixed action levels is likely to occur even when Good Manufacturing Practices are followed, and these small exceedances that are reflective of the variable nature of carryover are unlikely to be a food

safety concern. Therefore, developing only fixed action levels to address carryover would likely result in the rejection of good quality food product and contribute to food waste.

The United States provided alternative approaches to address carryover, including one that very closely resembles the complementary approach agreed to by the Committee. The result will be a complementary approach that enables risk managers to make rapid decisions to accept food when the action level is not exceeded and that provides risk managers with guidance on how to make a risk-based food safety decision when there are slight exceedances of the action levels or when no action levels have been established.

COORDINATION OF WORK BETWEEN CCPR AND CCRVDF
To Be Presented for Adoption at Next CAC? No Have the United States' Objectives Been Met? Yes Is it anticipated that this item will or should be raised at the CAC? Yes
United States Objective The U.S. objective was to support the continued work of the Joint EWG between CCPR and CCRVDF (chaired by the United States) and to endorse the proposal to schedule a virtual session of the Joint EWG that precedes a possible virtual Joint Session of CCPR and CCRVDF to address the current terms of reference assigned to the Joint EWG.
Outcome/Conclusion The Committee indicated their continued support of the Joint EWG and endorsed exploring the feasibility of scheduling a virtual session of the Joint EWG that precedes a possible virtual Joint Session of CCPR and CCRVDF.
Other Comments The United States, as Chair of the Joint EWG, introduced the topic and provided a status update on the work of the Joint EWG, which also was provided to the 55th Session of CCPR (2024). The Chair informed the committee of the challenges faced by the Joint EWG. Although there was good representation in terms of registered members, there was limited participation on the substantial issues of MRL harmonization and food descriptor harmonization. In addition, some of the limited comments began to diverge from the direction provided by 26th Session of CCRVDF (2023) and 54th Session of CCPR (2023). Also, the Chairs of the Joint EWG expressed that operating within the online forum only and then presenting recommendations to each committee separately is hindering progress in combination with the limited participation. The challenges have prevented the Chairs from making recommendations to both committees on the topics of MRL harmonization and food descriptor harmonization. To address these challenges, the Chairs of the Joint EWG recommended convening a virtual session of the Joint EWG followed by the possibility of a virtual Joint Session of CCRVDF and CCPR. Some members expressed that limited participation within the Joint EWG might be due to difficulties with accessing and using the online forum in which the EWG operates. The Codex Secretariat acknowledged that the online forum might not be perfect, but that, because it handles a large amount of Codex work, it might not be easy to find a quick solution. The Codex Secretariat welcomed feedback on the topic and encouraged members to provide specific examples of challenges they face and solutions for improving work in the virtual space.

PRIORITY LIST OF VETERINARY DRUGS FOR EVALUATION BY JECFA, EXPTRAPOLATION BY CCRVDF, OR ESTABLISHMENT OF ACTION LEVELS BY CCRVDF
To Be Presented for Adoption at Next CAC? Yes, for approval Have the United States' Objectives Been Met? Yes Is it anticipated that this item will or should be raised at the CAC? Yes
United States Objective The U.S. objective was to support inclusion of veterinary drugs on the priority list where there is a commitment to provide the necessary data and information.
Outcome/Conclusion The Committee agreed to include compounds on parts I, V, and VI of the priority list for evaluation by JECFA, extrapolation by CCRVDF, or establishment of action levels by CCRVDF and to forward these parts to CAC47 (2024) for approval.