

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Items 3, 4, 5, 6, 7, 8, 9, 10

CRD17

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

26th Session

13-17 February 2023

Portland, Oregon, United States of America

*Comments submitted by Uganda*

#### **Agenda Item 3: Matters of interest arising from FAO/WHO including JECFA**

Uganda takes note of the information provided in CX/RVDF 23/26/3 and especially the report from JECFA 94.

#### **Agenda Item 4: Matters of interest arising from the Joint FAO/IAEA**

The Joint FAO/IAEA division is commended for its initiatives and collaboration with Uganda and other African member states in development of laboratory capacity for analysis of veterinary drug and pesticide residues.

Uganda encourages other African countries who have not yet benefited from these programs to apply and benefit from the available projects.

#### **Agenda Item 5: Matters of interest arising from WOA, including VICH**

The WOA, including VICH division is commended for its initiatives and collaboration in the development of the human capacity in the African Region.

Uganda takes note of the information provided in CX/RVDF 23/26/5. As a member of the VICH Outreach Forum (VOF), Uganda has benefited from the trainings, breakout sessions and in-meeting open discussions, and refers to the VICH guidelines relevant to Codex work during assessment of veterinary medicinal products prior to issuance of marketing authorizations.

#### **Agenda Item 6: MRLs for veterinary drugs in foods**

##### Agenda Item 6.1: MRLs for Ivermectin (sheep, pigs and goats – fat, kidney, liver and muscle) at Step 7

Uganda commends the outcome of the evaluation done by JECFA and is in support of the new evaluation results.

Uganda recommends the withdraw and advancement or adoption of MRLs for Ivermectin (sheep, pigs and goats – fat, kidney, at Step 7.

##### **Justification:**

During the CCRVDF25 session, it was recommended that JECFA re-evaluate the MRLs for Ivermectin for pig, sheep and goat tissues. JECFA has re-evaluated the MRLs and the new recommended MRLs are to be presented for consideration at CCRVDF26

##### Agenda item 6.2: MRLs for Ivermectin (pigs, sheep and goats) and Nicarbazin (chicken) at Step 4

Uganda commends the outcome of the evaluation done by JECFA and is in support of the new evaluation results.

Uganda is in support of the advancement of MRLs for Ivermectin (pigs, sheep and goats) and Nicarbazin (chicken), to Step 5.

##### **Justification:**

During the CCRVDF25 session, it was recommended that JECFA re-evaluate the MRLs for Ivermectin for pig, sheep and goat tissues and Nicarbazin (chicken). JECFA has re-evaluated the MRLs and the new recommended MRLs are to be presented for consideration at CCRVDF26.

**Agenda Item 7: Extrapolation of MRLs for veterinary drugs in foods to one or more species**Agenda item 7.1: Extrapolated MRLs for different combinations of compounds/commodities at Step 4

Uganda appreciates the work done by the chairs of the EWG for the good work undertaken in developing the discussion paper on extrapolation of MRL and JECFA.

Uganda is in support of the proposed extrapolated MRLs for different drugs/compounds in the different animal species by JECFA and recommended for the advancement of the extrapolated MRLs for different drugs/compounds in the different animal species to the next step.

**Justification:**

The extrapolation was done in line with the rules spelt out in the Approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species that was adopted by CAC44.

Agenda item 7.2: Approach for the extrapolation of MRLs for residues of veterinary drugs for offal tissues

Uganda thanks the Chair and Co-chairs of the EWG for the work undertaken in developing the discussion paper on extrapolation of MRLs. Uganda recommends the following:

Uganda is in support of the proposal by the EWG, that further discussions should be held during CCRVDF26 on how to generate MRLs in edible offal tissues other than kidney and liver.

**Justification:**

- a) The Electronic Working Group (EWG) was not able to develop a suitable approach for the extrapolation of MRLs for residues of veterinary drugs in offal tissues. The specific concerns that were raised on the suggested pragmatic approach to extrapolate the lowest MRL established in liver or kidney to all offal tissues are all technically acceptable.
- b) Secondly recommends that more guidance may be provided by JECFA on how to address the concerns raised about the proposed approach.

Uganda has reservations extrapolation of bovine milk MRL for Ivermectin to goat and sheep milk

**Justification:**

The "Approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species" does not allow the extrapolation of bovine milk MRL for Ivermectin to goat and sheep milk.

According to information in the report of the EWG, bovine milk MRL did not meet the "specific criteria for extrapolation" to goats and sheep as indicated because of the following:

- a) MRL for milk has only been established in 1 species and the M:T is not 1.
- b) In addition, some uncertainty was also expressed with regards to whether Ivermectin B1a can be considered to be the same as the parent compound.

Uganda recommends that CCRVDF26 may request the sponsors to generate data packages and information required for evaluation of Ivermectin in goat and sheep milk by JECFA.

Uganda is in support of the recommendation by the EWG on the proposal to seek advice from JECFA on whether the appropriate M:T value for residues of Deltamethrin in bovine milk is 1.

**Agenda item 8: Criteria and procedures for the establishment of action levels for unintended and unavoidable carryover of veterinary drugs from feed to food of animal origin**

Uganda thanks the Chair and Co -chairs of the EWG for the work undertaken in developing EWG for developing the criteria and procedures for the establishment of action levels for residues of veterinary drugs in foods linked to the unintended and unavoidable carryover of veterinary drugs from non-target feed to food of animal origin. .

Uganda is in supports the "general criteria or requirements" for establishing action levels for veterinary drug residues in food products from non-target animals linked to the unintended and unavoidable carry-over of veterinary drugs in non-target animal feed. Therefore recommending adoption of the procedure by CCRVDF26

**Justification:**

The EWG put into consideration all relevant factors such as authorized veterinary drugs, feed production mechanisms, established Codex MRLs, availability of analytical methods etc.

Uganda further supports the proposed four step procedure for setting the Action Levels for residues of veterinary drugs detected in foods of non-target animals determined to be caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed thus recommending its adoption by CCRVDF26..

**Justification:**

This is because it is based on the already established Codex Guidelines on the Application of Risk Assessment for Feed (CXG 80-2013) and risk assessment approaches.

Uganda recommends adoption of Option 2 i.e. the highest residue levels in feed determined by feed mills is used to estimate the veterinary drug carry-over level in non-target feed for non-target animal.

**Justification:**

When calculating Transfer Factors (TFs) it may be assumed that metabolism of the drug takes places in the different tissues and the level of residues in the tissue or commodity of interest is low.

The proposed roles and responsibilities for CCRVDF and JECFA are very appropriate since each committee has the requisite expertise.

Uganda is in support of proposed action level of 0.220 mg/kg for Nicarbazin in Chicken Eggs to be adopted by CCRVDF26.

**Justification:**

The human dietary exposure to Nicarbazin residues was assessed using the JECFA TMDI (Theoretical Maximum Daily Intake) which is a conservative approach

**Agenda Item 9: Coordination of work between CCPR and CCRVDF****Agenda item 9.1: Matters of interest arising from the Joint CCPR/CCRVDF Working Group CX/RVDF 23/26/9**

Uganda thanks the Chair and Co -chairs of the joint EWG for the work undertaken in developing harmonised discussion paper between CCPR and CCRVDF.

Uganda is in support of the recommendations that were proposed by the joint CCPR/CCRVDF EWG that included but limited to:

- a) CCPR and CCRVDF to continue working towards harmonizing their risk assessment methodologies, including ways to establish single, harmonized acceptable daily intake values and MRLs for dual-use compounds.
- b) JECFA/JMPR to request sponsors to consent to data sharing upon submission of the data packages
- c) The current joint EWG to identify and prioritize issues affecting both committees and recommend ways to address the issues and to inform CAC accordingly
- d) Development of a database of dual-use compounds that can be shared between committees to facilitate the development of a single, harmonized MRL
- e) Creation of Joint EWG that will identify dual-use compounds that have different MRLs for the same edible commodity of animal origin and recommend a single, harmonized MRL(s) for the compound(s) and affected commodity(ies) to be transmitted to CCPR and CCRVDF

**Justification:**

Some compounds are used as veterinary medicines and well as pesticides. These compounds can have different MRLs for the same edible commodity of animal origin.

To solve that issue, CCEXEC (CCEXEC81, 2021) recommended that CCRVDF and CCPR make use of a joint Electronic Working Group (EWG) to further advance the work on cross-sectional issues to facilitate the establishment of single/harmonized MRLs for edible animal tissues for compounds with dual use.

**Agenda item 10: Priority list of veterinary drugs for evaluation or re-evaluation by JECFA**

Uganda commends the work done by JECFA on the list of Veterinary drugs for inclusion in the Priority List for evaluation/re-evaluation.

Uganda is unable to propose any compound to be included in the Priority List

**Justification:**

Uganda is still building capacity to generate the relevant data/information required for submission to JECFA.

Uganda has reservations on the Veterinary drugs (Amoxicillin, Ethoxyquin and Norfloxaci) for which data availability should be confirmed at CCRVDF26.

**Justification:**

Uganda is Unable to support evaluation of the compounds (Amoxicillin, Ethoxyquin and Norfloxaci) due to lack of capacity to generate the relevant data

Uganda has reservations on the proposed Veterinary drugs (Ethion, Flumethrin and Fosfomycin) for which additional data / information is necessary to complete the JECFA evaluation

**Justification:**

Uganda is Unable to support evaluation of the compounds due to lack of capacity to generate the relevant data.

Uganda cannot confirm availability of information on Selamectin in reference to good veterinary practice (GVP).

**Justification:**

Uganda still building capacity to generate the relevant data/information required.