

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Items 2, 3, 4, 5, 6, 7, 8, 9 and 10

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

26th Session

13-17 a 2023

Portland, Oregon, United States of America

Comments submitted by Nigeria

Agenda Item 2: Matters referred by CAC and/or other subsidiary bodies (CX/RVDF 23/26/2)

Nigeria takes note of matters referred by CAC and other subsidiary bodies as and when available

Agenda Item 3: Matters of interest arising from FAO/WHO including JECFA (CX/RVDF 23/26/3)

Nigeria takes note of the information provided, especially the report of the Joint FAO/WHO experts on food additives (JECFA 94) on the need to evaluate residues of certain veterinary drugs in food and commends JECFA for the information and expert analysis provided.

Agenda Item 4: Matters of interest arising from the Joint FAO/IAEA Centre (CX/RVDF 23/26/4)

Nigeria commends the joint FAO/IAEA in its initiatives and collaboration with African Member States especially in development of laboratory capacity for analysis of veterinary drugs and pesticide residues.

Nigeria also noted the various projects supported by the Joint FAO/IAEA Centre, and also wish to state that going forward we will also want to be part of the Technical Cooperation Projects (TCPs) and Coordinated Research Projects (CRPs) in the areas of control of food hazards, chemical residues and contaminants, laboratory testing, nuclear and isotopic techniques, analytic capabilities in food testing, among others, to participate in the African Food Safety Network (AFoSaN).

Agenda Item 5: Matters of interest arising from WOA, including VICH (CX/RVDF 23/26/5)

Nigeria acknowledges the contribution of WOA and VICH in developing human capacity in Africa, especially in the area of Antimicrobial Resistance (AMR) and Antimicrobial Use (AMU). Also, Nigeria commends WOA strengthening of its collaboration with FAO, UNEP and WHO in AMR, since the establishment of the Quadripartite Joint Secretariat (QJS) on AMR, and the Multi-Partner Trust Fund (MPTF) on AMR in 2019. Nigeria also appreciates the active participation of WOA in the development guidance documents on AMR.

Most Importantly we commend the WOA for the PVS pathway programme aimed at sustainable improvement of a Member's Veterinary Services in compliance with WOA's internationally agreed standards on the quality of Veterinary Services.

Nigeria however notes the VICH Outreach Forum (VOF), and we want to state our intention and consideration to joining the forum to enable us benefit from trainings and use of the VICH guidelines during assessment of veterinary drugs prior to issuance.

Agenda Item 6.1: MRLs for Ivermectin (sheep, pigs and goats – fat, kidney, (REP21/RVDF25 Appendix II liver and muscle) at Step 7 – Comments at Step 6 (in reply to CL 2022/71-RVDF) CX/RVDF 23/26/6

Nigeria recommends the discontinuation of the procedures for the advancement or adoption of MRLs for Ivermectin (sheep, pigs and goats – fat, kidney, (REP21/RVDF25 Appendix II liver and muscle) at Step 7 as JECFA has re-evaluated the MRLs and new recommended MRLs are presented for consideration at CCRVDF26. The MRLs recommended for discontinuation are as follows:

Species	Muscle($\mu\text{g}/\text{kg}$)	Liver ($\mu\text{g}/\text{kg}$)	Kidney ($\mu\text{g}/\text{kg}$)	Fat ($\mu\text{g}/\text{kg}$)
Sheep, pigs and goats	10	15	15	20

Rationale

CCRVD25 recommended to JECFA the reevaluation of the MRLs for Ivermectin for pig, sheep and goat tissues. The results of the evaluation are presented in 6.2.

Agenda Item 6.2: MRLs for Ivermectin (pigs, sheep and goats) and Nicarbazin (chicken) at Step 4 CL 2022/71-RVDF – Comments at Step 3 (in reply to CL 2022/71-RVDF) CX/RVDF 23/26/6

support the adoption of MRLs for Ivermectin in pigs, sheep and goats at Step 5/8 as follows:

Species	Muscle($\mu\text{g}/\text{kg}$)	Liver ($\mu\text{g}/\text{kg}$)	Kidney ($\mu\text{g}/\text{kg}$)	Fat ($\mu\text{g}/\text{kg}$)
Pigs	15	30	20	50
Sheep and Goats	30	60	20	100

Nigeria supports the advancement of MRLs for Nicarbazin in chicken at Step 5 as follows:

Species	Muscle($\mu\text{g}/\text{kg}$)	Liver ($\mu\text{g}/\text{kg}$)	Kidney ($\mu\text{g}/\text{kg}$)	Skin ($\mu\text{g}/\text{kg}$)
Chicken	4000	15000	8000	4000

Rationale

CCRVD25 recommended to JECFA the re-evaluation of the MRLs of Ivermectin as the previous proposals on MRLs were very conservative and some countries had proposed to provide additional scientific data. In the view of the new data, JECFA94 re-evaluated the MRLs for Ivermectin in pig, sheep and goat tissues and the results are proposed for adoption at Step 5/8 to the Commission. JECFA94 assessment established MRLs for Nicarbazin in chicken of 4000 microgram/kg for muscle, 15000 microgram/kg for liver, 8000 microgram/kg for kidney and 4000 microgram/kg for skin, Ivermectin is extensively used as an endectocide, and therefore limits for residues in these commodities need to be established by Codex to protect consumer health and to promote international trade.

Agenda Item 7.1: Extrapolated MRLs for different combinations of compounds/commodities at Step 4 (CX/RVDF 23/26/7) - Comments at Step 3 in reply to CL 2022/75-RVDF CX/RVDF 23/26/7-Add.1

Nigeria commends the chairs of the EWG for the good work undertaken in developing the discussion paper on extrapolation of MRL.

Nigeria recommends that the extrapolated MRLs for the 12 different drugs in the various animal species be advanced to Step 5.

Nigeria notes that the “Approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species” does not allow the extrapolation of the bovine milk MRL for Ivermectin to goat and sheep milk. In view of the criteria not being able to facilitate the elaboration of MRLs for goat and sheep milk,

Nigerian informs Member States that any country that is still interested to have further work done on this matter can send the proposal to the Committee using the standard procedure to enable commissioning of new work.

Rationale

The extrapolation was done in line with the rules set out in the Approach for the extrapolation of maximum residue limits for veterinary drugs to one or more species that was adopted by CAC44. The compounds are commonly used in the African region for the treatment of common diseases in the animals. The availability of MRLs for the compounds will facilitate trade and provide a reference to assure protection of consumer health.

Agenda Item 7.2: Approach for the extrapolation of MRLs for residues of veterinary drugs for offal tissues (CX/RVDF 23/26/7) Comments in reply to CL 2022/76- RVDF CX/RVDF 23/26/7-Add.2

Nigerians commends the chairs of the EWG for the good work undertaken in developing the discussion paper on extrapolation of MRL.

Nigeria supports 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.

Nigerians recommends that Member States can request sponsors to submit datasets for elaboration of MRLs in smooth muscles and that further extrapolation of the established MRLs should be done in smooth muscles.

Rationale

It is noted that the EWG was not able to develop a suitable approach for the extrapolation of MRLs for residues of veterinary drugs in offal tissues. Most offal tissues are smooth muscles which are quite different from skeletal muscles for which MRLs have already been determined. Extrapolation could work if corresponding tissues are used across species. Guidance may be provided by JECFA on how to address the concerns raised about the proposed approach.

Agenda Item 8: Criteria or requirements for the establishment of action levels for unintended or unavoidable carryover from feed to food of animal origin (CX/RVDF 23/26/8) Comments in reply to CL 2022/77- RVDF CX/RVDF 23/26/8-Add.1

Nigeria commends the 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.

Nigeria supports the “general criteria or rules” on the proposed approach 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.

Nigeria further supports the proposed four step procedure for setting the Action Levels for residues of veterinary drugs detected in foods of animal origin (i.e. from non-target animals) determined to be caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed based on the Guidelines on the Application of Risk Assessment for Feed (CXG 80- 2013) and risk assessment approaches.

Nigeria supports the inclusion of an option to use default low levels of carry-over from medicated to un-medicated feed provided that this is supported by data from studies/surveys undertaken in feed mills operating under good manufacturing practice.

Rationale

The proposal to have CCRVDF to request JECFA to conduct an appropriate Human dietary exposure assessment based on the proposed action level will mitigate the risk to human health that could arise from residues of veterinary drugs in food of non-target species caused by unavoidable and unintended veterinary drug carry-over in non-target animal feed.

Animal feed and its ingredients should be obtained and stored under suitable conditions to prevent their contamination by pests or chemical contaminants, physical or microbiological or other undesirable substances during their production, handling, storage and transportation. Animal feed should be in good condition and meet the standards of generally accepted quality. Good agricultural practices (GAP), Good Manufacturing Practices (GMP) and principles of Hazard Analysis Critical Control Points (HACCP) should be followed to control the risks that may appear in food.

Agenda Item 9.1: Matters of interest arising from the Joint CCPR/CCRVDF EWG: Work of the EWG between CCPR53 and CCRVDF25

Nigeria commends the chair and co-chair of the EWG on the work they have done, in which the following recommendations they made:

- 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 ask 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, and
- 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.

Rationale

Some compounds are used as veterinary medicines and as pesticide. Those 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 REP/RVDF25, Appendix VI, Parts II, III, IV and V Comments in reply to CL 2022/72- RVDF CX/RVDF 23/26/11

Nigeria currently has no data/information available to allow the evaluation of some compound/commodity combinations identified in the database on countries' needs for MRLs for veterinary drugs.

However, Nigeria will make available proposals for veterinary drugs that is of interest to the country for inclusion on the priority list for subsequent recommendation to JECFA for evaluation or re-evaluation and we will provide information using the appropriate template.

Nigeria is also interested in supporting the evaluation of Amoxicillin, Norfloxacin, Flumethrin, Imidacloprid and will like to confirm availability of relevant data/information for consideration.

Rationale

Some of the compounds like amoxycillin are routinely used in Africa for the treatment of common diseases in the animals. The availability of MRLs for the compounds would facilitate trade and provide a reference to assure protection of consumer health.

CCRVDF25 agreed to retain Amoxicillin, Ethoxyquin (feed additive use) and Norfloxacin on the Priority List subject to confirmation of the availability of data by CCRVDF26 (2023).