CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 3, 4, 6(a), 6(b) **RVDF/22 CRD/07**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-second Session

San José, Costa Rica, 27 April – 1 May 2015

COMMENTS OF GAMBIA

In consideration of the agenda items of the CCRVDF22, the National Codex Committee of The Gambia herby submits The Gambia's| position as follows:

Agenda Item 3: Matters Referred by the Codex Alimentarius Commission and other Codex Committees

The Gambia noted that the CAC37:

- adopted the revision of *the Risk Analysis Principles Applied by the CCRVDF* to include Extrapolation of Maximum Residue Limits (MRLs) of Veterinary Drugs to Additional Species and Use of the Concern Form for the CCRVDF, as proposed by CCRVDF21
- adopted the Risk Management Recommendations (RMRs) for chloramphenicol, malachite green, carbadox, furazolidone, nitrofural, chlorpromazine, stilbenes and olaquindox at step 8; and
- Performance Characteristics for Multi-Residues Methods (MRMs) for Veterinary Drugs (Appendix C of the *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the Use of Veterinary Drugs in Food Producing Animals* (CAC/GL 71-2009)), as recommended by CCRVDF2. at step 5/8
- Approved the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA as proposed by CCRVDF21.
- Approved discontinuation of work on Proposed Draft Maximum Residue Limits for Apramycin (cattle and chicken kidney) as proposed by CCRVDF21.

Codex Strategic Plan(2014-2019) for which all committees are responsible

- The Gambia took note of the four strategic goals and the objectives, activities, expected outcomes and the measureable indicators/outputs as outline in the plan.
- All activities were found to be relevant to the work of the committee
- The Gambia observed that;
- There is need for member states to involve relevant scientific experts when developing country positions;
- Guidance to member states by codex committees on communication of RMD should not be misconstrued as dictating or imposing decisions to members
- Appreciated the challenges in the use of official languages in working groups and made proposals to the secretariat to consider;
- The need to have more technical capacity activities in the margins of the committee sessions. Delegates agreed to forward to the secretariat topics of interest for consideration;
- Appreciated the mechanism in place for timely distribution of documents however, member states were required to provide information in a timely manner;
- The committee to continue holding physical working groups in conjunction with committee meetings where appropriate.

Agenda Item 4 Matters of Interest arising from FAO/WHO and from the 78th Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)

JECFA evaluated and recommended as follow:

- Gentian violet – Gentian violet is structurally related to malachite green.
- JECFA 78th concluded that it was inappropriate to set an ADI for gentian violet as it is genotoxic and carcinogenic. And that MRL could not be recommended.
- JECFA 78th also noted that there was limited information on residues.

The delegates:

- Agreement with JECFA Recommendation of no ADI or MRL
- Compound treated same way as Malachite Green

Recombinant bovine somatotropins – rbST

- Based on a systematic review of the literature published since the last evaluation,
- JECFA reaffirmed its previous decision on the ADI
- ADI "not specified" for somagrebove, sometribove, somavubove and somidobove,

Following are questions forwarded by the CCRVDF21 to JECFA on rbST Matters:

(i) Update the toxicological evaluation

- No new toxicological studies were available. Owing to structural differences between bovine and human somatotrophins, species-specific receptor binding of somatotrophins and lack of bio-activity of rbSTs following oral intake, the National Codex Committee concluded that if any rbST residues are present in milk or tissues, they would pose a negligible risk to human health.

(ii) Update the exposure assessment based on any new occurrence data in food

- The Committee concluded that similar concentrations of total bST were present in milk and tissues of rbST-treated and untreated cows.

Consider new data and information related to the possibility of increased levels of IGF-I in the milk of cows treated with rbSTs

- There is a transient increase in IGF-I concentrations in milk of rbST-treated cows, which fall within the normal physiological range. IGF-I is substantially, if not completely, degraded in the gut and is unlikely to be absorbed from the gut and be bio-available at biologically relevant exposures. Therefore, the contribution of exogenous IGF-I resulting from the ingestion of milk from rbST-treated cows is extremely low in comparison with endogenous production.

Evaluate potential adverse health effects, including the possibility that exposure of human neonates and young children to milk from rbST-treated cows increases health risks (e.g. The development of insulin-dependent diabetes mellitus)

- Exogenous IGF-I from milk makes no significant contribution to circulating levels of IGF-I in humans, and there are no significant differences in the composition of milk from rbST treated cows when compared with the milk from untreated cows. The Committee concluded that there was no additional risk for the development of type 1 diabetes due to the consumption of milk from rbST-treated cows. The National Codex Committee also concluded that the literature did not support a link between exposure to IGF-I in milk from rbST-treated cows and an increased risk of cancer.

Consider new data and information related to the potential effects of rbSTs on the expression of certain viruses in cattle

- There was no new information on the link between rbST use and either potential stimulation of retrovirus expression or prion protein expression in cattle. The Committee considers that the position expressed by the previous Committee remains valid.

(vi) Consider new data and information related to the possible increased use of antimicrobials to treat mastitis in cows and aspects of antimicrobial resistance associated with the use of rbSTs in relation to human health

- The National Codex Committee concluded that there was no evidence to suggest that the use of rbSTs would result in a higher risk to human health due to the possible increased use of antimicrobial agents to treat mastitis or the increased potential for non-compliant antimicrobial residues in milk. The Committee found no specific studies linking the use of rbSTs with the development of antimicrobial resistance. The Committee considers that the previous position remains valid.
- The Gambia recommend acceptance at step 8/ as standard

Agenda Item 4

- JECFA also evaluated
- Zilpaterol hydrochloride
- ADI of 0–0.04 µg/kg body weight on the basis of a LOAEL of 0.76 µg/kg body weight for tremor in humans was established.
- However more data to be evaluated at the next JECFA meeting for the determination of MRLs.
- The Gambia recommended that we await JECFA evaluation.

Other Matters Noted from JECFA

- Dietary exposure to veterinary drug residues
- New methodology on the assessment of exposure being used by JECFA
- Extrapolation of MRLs to minor species
- Guidance was prepared on the criteria/assumptions used by JECFA for interspecies extrapolations, including minimum data required to support such extrapolations among physiologically related species and extrapolation to additional minor species.

Terms to be used

- Extension will be used when sufficient depletion data are available for the minor species to permit the derivation of MRLs for tissues of that species from the depletion curves.
- Extrapolation will be used when insufficient depletion data are available in that species to derive MRLs for tissues from that species.
- MRLs for veterinary drug residues in honey
- A decision-tree for the establishment of MRLs for veterinary drug residues in honey was established for future use.
- Scope of MRLs established by JECFA relating to fish and fish species
- To avoid confusion on the species of fish JECFA defined fish species as:
  - “Fish” will be used when an MRL recommendation applies to multiple species of finfish.
  - “seafood”, “mollusc” will be used for species such as clams, oysters and scallops,
  - And “crustacean” will be used when MRLs are recommended for species such as shrimp, prawn and crayfish.
- FAO/WHO Global Individual Food consumption data Tool (FAO/WHO GIFT)
- Collection and collation of individual food consumption data in ASEAN countries through EU Codex trust fund
- FAO/WHO activities on antimicrobial resistance (AMR).
- Handbook on Risk Communication in food safety which provides guidance on the good risk communication principles and practices and includes hands-on training materials.

<u>Agenda Item 6 (a) Draft MRLs for monepantel, at Step 7</u>

- MRLs were calculated on the basis of the upper limit of the one-sided 95% confidence interval over the 95th percentile of residue concentrations (UTL 95/95).
- Consistent with the shortest withdrawal time assigned in Member States with an approved use, JECFA recommended the following MRLs in sheep tissue (monepantel sulfone, expressed as monepantel),
- New and higher MRL therefore shift back to step 3
  - 500 µg/kg in muscle,
  - 1700 µg/kg in kidney,
  - 7000 µg/kg in liver and
  - 13 000 µg/kg in fat.
- The Gambia recommend acceptance of the proposed higher MRL and acceleration to step 5/8

Agenda Item 6 (b)Proposed draft MRLs for Derquantel, at Step 4

- Based on these new assessments, JECFA proposed the following *revised MRLs* in sheep tissues:
  - 0.3 µg/kg in muscle,
  - 0.4 µg/kg in kidney,
  - 0.8 µg/kg in liver and
  - 7.0 µg/kg in fat.
- Also noted was, the TMDI approach used, as there was insufficient data to calculate an EDI.
- The Gambia accepted the revised MRL and recommend acceleration to step 5/8

Position

The Gambia agrees with the above position as discussed and agreed at both the Colloquium as well as at the National Codex Committee level.