

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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Agenda Item 3, 4, 8(a), 8(b), 8(c)

RVDF/22 CRD/10

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 KENYA

AGENDA 3: MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES.

General Comment :

Kenya took note that the CAC37 adopted some matters related to CCVRF and recommends that committee take note of the matters adopted and implement where applicable.

CODEX STRATEGIC PLAN 2014-2019

2014-2019 Strategic Plan Activities for which “all committees” are responsible.

Comment:

Kenya went through the four strategic goals and the objectives, activities, expected outcomes and the measurable indicators/outputs as outline in the plan.

All activities were found to be relevant to the work of the committee in addition to the following comments:

Kenya recommendations are as follows:

1. There is need for codex member countries to involve relevant scientific experts when developing country positions;

2. Guidance from codex committees on communication of Risk Management Decisions should not be misconstrued as dictating or imposing decisions to members;

Goal 3: Facilitate the effective participation of all Codex Members.

Activity 3.1.5: To the extent possible, promote the use of the official languages of the Commission in committees and working groups.

3. The challenges regarding Goal 3 activity 3.1.5, in the use of official languages in working groups :**Codex committee should facilitate use of the codex official languages presented in the working group.**

4. More technical capacity activities should be undertaken on the margins of the committee sessions. Codex members are advised to forward topics of interest to the CCRVDF secretariat for consideration and members should participate in physical working groups in conjunction with Codex committee meetings where appropriate.

AGENDA 4: MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE 78TH MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA)

Para 4 Bullet one of the JECFA 78th Meeting : Comment on Gentine Violet ADI:

Kenya went through the outcome of JECFA 78th session meeting which concluded that it was inappropriate to set an ADI for Gentian Violet because it is genotoxic and carcinogenic. In addition to that JECFA could not recommend MRLs, as it was not considered appropriate to establish an ADI. There was also limited information on residues. It was also observed by JECFA that Gentian Violet is structurally related to malachite green and concluded that Gentine Violet should be considered carcinogenic acting by a genotoxic mode of action.

COMMENT

Therefore, Kenya concurs with JECFA 78th session recommendations of no ADI and MRLs for Gentian Violet and should be treated the same way as Malachite Green. However, we recommend further studies to

be conducted by JECFA on residues of Gentian Violet in food. For this case Kenya reserve its comments on this Gentine Violet usage.

Para 4 Bullet two of the JECFA 78th Meeting COMMENT ON rbST

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 “not specified” for somagrebove, sometribove, somavubove and somidobove. ***It was noted that “The Committee at its fortieth meeting established an ADI and MRLs “not specified” for these four rbSTs. The term “not specified” was used because of the lack of bioactivity following oral intake of rbSTs and IGF-I and the low concentrations and non-toxic nature of the residues of these compounds. The ADI and MRLs “not specified” were reaffirmed by the Committee at its fiftieth meeting”.***

We 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. We observed that there are no specific studies linking the use of rbSTs with the development of antimicrobial resistance. The Committee considers that the previous position remains valid.

Kenya having reviewed the report based on the questions forwarded to JECFA 78th Session by CCRVDF 21, we recommend to the committee to consider adoption of rbST at step 8.

Para 4 bullet 3: Zilpaterolhydrochloride

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. Kenya took note that the 78th session committee was not able to recommend MRLs for zilpaterol due to insufficient data.

The following data are needed to establish MRLs: (i) results from studies investigating marker residue in liver and kidney;(ii) results from studies determining marker residue to total residue ratio in liver and kidney;(iii) results from depletion studies to enable the derivation of MRLs compatible with the ADI.

All such studies should use sufficiently sensitive validated analytical methods capable of measuring zilpaterol and its major metabolites in edible tissues of cattle.

COMMENT

We note that there is need for more data in order to determine the MRL for zilpaterol hydrochloride and propose that the codex committee await JECFA evaluation based on availability of data submitted by codex member countries.

Para 5 :Dietary exposure to veterinary drug residues

General comment

Kenya note that JECFA has adopted a new methodology on the assessment of exposure to veterinary drugs residues. The two new methods for estimating dietary exposure are the global estimate of acute dietary exposure (GEADE) and the global estimate of chronic dietary exposure (GECDE). Both methods differ from the EDI by having the capacity to estimate specific dietary exposure for additional population groups (children aged 12 months and older and infants younger than 12 months) and by using more realistic global consumption amounts as inputs into the calculations.

COMMENT

We agree with JECFA that the new approach should continue to be used in parallel with the model diet approach until more experience has been obtained in the interpretation of the results with the new approach.

Para 6 :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.

COMMENT

Kenya recommends that JECFA continues to undertake studies in minor species {*Codex definition of minor species: minor animal species can be defined as those which are not included in the following list of major animal species: - cattle and sheep(meat), :-Cattle(milk),:-pigs,:-Chicken(including eggs)*}

MRLs for veterinary drug residues in honey.

Kenya noted that a decision-tree for the establishment of MRLs for veterinary drug residues in honey was established for future use. This was based on consideration of three potential situations envisaged and discussed by JECFA: (i) the establishment of an MRL for honey for substances with an ADI, typically established by JECFA or JMPR, MRL for honey for substances for which an ADI has not previously been established by JECFA or JMPR; and (iii) the establishment of an MRL for honey for substances that are not approved for use in food animals and/or a Codex MRL in a food-producing animals or food commodity; (ii) the establishment of an MRL for honey for substances for which an ADI has not previously been established by JECFA or JMPR; and (iii) the establishment of an MRL for honey for substances that are not approved for use in food animals.

COMMENT

Kenya recommends that member states continue to provide national monitoring data on contaminants (**for example extraneous and pesticide residues MRLs**) and residues of veterinary drugs in honey production

Scope of MRLs established by JECFA relating to fish and fish species.

Kenya appreciates the clarification made on the definition of fish and fish species by JECFA as stated in this document on “ fish, seafood and crustacean” and therefore **We would like the committee on fish and fishery products to take note on the definitions and amend the fish and fishery codex standards appropriately.**

AGENDA 8 (a) DRAFT PRIORITY LIST OF VETERINARY DRUGS REQUIRING EVALUATION OR RE-EVALUATION BY JECFA (Report of the EWG on Priority)**General comments**

We appreciate the comments submitted **Algeria, Chile, Costa Rica, Norway, Republic of Korea and the United States of America on the CL2014/3-RVDF**

SPECIFIC COMMENT:

Kenya appreciates and takes note of the work done by the electronic working group on draft priority list of veterinary drugs requiring evaluation or re-evaluation by JECFA. We therefore agree with the recommendation of the EWG that CCRVDF forward the Priority List (Annex 1) to the 38th Session of the Codex Alimentarius Commission for approval

AGENDA 8(b) ALTERNATIVE APPROACH TO MOVE COMPOUNDS FROM THE DATABASE ON COUNTRIES' NEED FOR MRLS TO THE JECFA PRIORITY LIST**COMMENT**

Kenya appreciate and take note of the recommendations by the electronic working group on alternative approach to move compounds from the database on countries' need for MRLs to the JECFA Priority List. We further agree with the recommendations of the EWG and also support the implementation of the full global survey and the CCRVDF committee works closely with OIE secretariat as they undertake the survey.

AGENDA 8 (c) DATABASE ON COUNTRIES' NEED FOR MRLS**COMMENT:**

We took note of the database and observed that only four African countries submitted their needs for MRLs to the database compared to the previous list, which had three.

Kenya encourages CODEX member states to be more proactive and submit their needs for MRLs to the database.