

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Items: 2,3,4,6.1,7,8,10,11

CRD 4

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-fourth Session

Comments Submitted By: Kenya

General Comment

Kenya appreciates the opportunity to provide comments on the following agenda items.

AGENDA ITEM 2: MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER SUBSIDIARY BODIES (CX/RVDF 18/24/2)

General Comment

Kenya takes note of the matters referred by CAC40 and support the recommendations of 73rd Session of the Executive Committee (CCEXEC73) on closer collaboration between CCRVDF and CCPR when considering MRLs for compounds used as both veterinary drugs and pesticides and invited the two Committees to explore innovative ways to foster such collaboration.

AGENDA ITEM 3: MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE 85th MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (CX/RVDF 18/24/3)

General Comment

Kenya appreciates the support by FAO in providing technical support in the area of antimicrobial resistance particularly in the drafting of a National Antimicrobial Policy on prevention and containment of antimicrobial resistance, which was launched during the antibiotic awareness week in November 2017. Kenya looks forward to more efforts being channeled towards a more structured one-health approach in addressing the AMR issues..

Kenya also takes note of the report of the 85th FAO and WHO Expert Committee of Food Additives (JECFA) in the provision of scientific advice to Codex and member countries.

AGENDA ITEM 4: REPORT ON THE OIE ACTIVITIES, INCLUDING THE HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF VETERINARY MEDICINAL PRODUCTS (VICH) CX/RVDF 16/23/4

General Comment

Kenya takes note and appreciates the OIE's close cooperation with Codex, as one of the relevant standard-setting bodies recognized by the SPS Agreement of the WTO.

AGENDA ITEM 6.1: PROPOSED DRAFT MRLs FOR ZILPATEROL HYDROCHLORIDE (CATTLE FAT, KIDNEY, LIVER, MUSCLE) (81st JECFA) AT STEP 4 (REP 17/RVDF App.V)

ZILPATEROL HYDROCHLORIDE (β 2-adrenoceptor agonist)

Specific Comment

Kenya proposes the advancement of Zilpaterol Hydrochloride to step 5 on account of 85th JECFA recommendation.

Rationale: At 81st JECFA meeting on zilpaterol assessment accounted for limited oral bioavailability of only the non-extractable (bound) zilpaterol residues in cattle tissues. The remaining (extractable) zilpaterol residues were considered to be fully bioavailable. At 85th JECFA, as per the new bioavailability data submitted support the approach used in the previous assessment. Following evaluation of these data, the MRLs recommended by JECFA at its eighty-first meeting remain unchanged. JECFA's recommended MRLs for Zilpaterol Hydrochloride in cattle are: 3.3 μ g/kg in kidney, 3.5 μ g/kg in liver and 0.5 μ g/kg in muscle.

AGENDA ITEM 7: DISCUSSION PAPER ON MRLS FOR GROUPS OF FISH SPECIES (CX/RVDF 18/24/7)**Specific Comment**

Kenya commends the good work of the EWG on the discussion paper for groups of fish species. In view of the conclusion of the EWG and the recommendations therein, Kenya supports recommendation 'C' of the EWG which proposes *No grouping, but discuss further guidance on national risk management options as this might seem an effective way forward.*

Rationale: The EWG noted that the absence of MRLs for veterinary drugs in fish species raises challenges for appropriate protection of human health and fair trade practices. So far, there are only five compounds with established MRLs. Of the five substances for which JECFA has made recommendations of MRLs for finfish, two have been for "fish" and three for "salmon" and/or "trout", based on the information provided. For the substances for which recommendations have been for "fish", data have been provided for three or more diverse species of finfish.

Kenya agrees with the EWG submission that lack of MRLs for fish species reduces the variety of drugs available to treat diseases, and thus affects the possibility of maintaining good fish health by veterinary treatments in aquaculture factoring. Therefore, Extrapolating to several fish would contribute to expand the variety of available drugs for fish. Extrapolating MRLs will also reduce the number of studies performed with animals and thus follow the principles of replacement, refinement and reduction principles for animal welfare.

Kenya recognizes that the EWG members had different views on grouping and since it was noted that there were no groupings according to salinity, phylogeny/common physiology and common behavior which have been performed, so grouping according to these parameters needs to be performed before a final grouping can be done. The only approved grouping by fish order so far is performed by VICH. It was also suggested not grouping fish. This due to the fact that the ADI is set independently of the target animal species, and that safety assessments of the drug are done independently of the target animal species.

AGENDA ITEM 8: DISCUSSION PAPER ON EDIBLE OFFAL TISSUES (possible definition and edible offal tissues of interest in international trade) (CX/RVDF 18/24/8)**Specific Comment**

Kenya acknowledge the support accorded by codex Secretariat, CCRVDF secretariat, AUIBAR, University of Nairobi (Dr Florence Mutua), and codex member countries for the invaluable contribution towards the generation of this discussion paper. Kenya further recommends to the CCRVDF24 that the general definition of offal and specific definition of edible offals should be adopted by the committee and forwarded for inclusion into the Glossary of terms and definitions (CXM 5-1993).

Rationale: The 23rd Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF23) agreed to establish an Electronic Working Group (EWG), to prepare a discussion paper in response to the request from 81st JECFA for CCRVDF to "provide a definition of edible offal". The discussion paper aimed at proposing a possible definition of edible offal tissue and specifying edible offal tissues of interest in international trade. It is worth noting that the glossary of terms and definitions (CXM 5-1993) has no definition of offal and or edible offal and groups these tissues with meat.

AGENDA ITEM 10: DISCUSSION PAPER ON THE EVALUATION OF THE RATIONALE FOR THE DECLINE IN NEW COMPOUNDS TO BE INCLUDED IN THE CCRVDF PRIORITY LIST FOR EVALUATION BY JECFA (CX/RVDF 18/24/10)**General Comment**

Kenya commends Health for Animals for the good work done in the discussion paper. Kenya notes that the paper has highlighted the benefits of JECFA evaluation, which are recognised worldwide and also highlights the challenges experienced by the industry during submission of compounds for evaluation. Kenya recommends that the CCRVDF secretariat consider looking into the concerns expressed by the industry with the aim of re-evaluating its processes without compromising the integrity of JECFA as the key risk assessment body.

AGENDA ITEM 11: DATABASE ON COUNTRIES' NEEDS FOR MRLs (CX/RVDF 18/24/11)**General Comment**

Kenya commends the EWG for the work on database on countries needs for MRLs. Kenya supports the recommendations of the EWG to hold an in-session working group to allow discussion of the prioritization approaches presented in the report. Such discussion could help to build consensus on a single top-ten list of veterinary drugs in need of Codex MRLs to be considered by CCRVDF.