CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Items 2, 3, 4, 7.1, 8 **CRD 5**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-third Session

Houston, Texas, United States of America, 17 – 21 October 2016

COMMENTS OF THE AFRICAN UNION

AGENDA ITEM 2: Matters Referred by the Codex Alimentarius Commission and other subsidiary bodies (CX/RVDF 16/23/2)

Comment: African Union (**AU**) takes note of the matters referred by:

1. **CAC 38 with regard to**:

- Amendments to the Procedural Manual;
- Standards and Related Texts adopted at Steps 8 and 5/8;
- Draft MRLs for Bovine Somatotropins;
- Approval of new work for the elaboration of new standards and related texts; and
- Approval of discontinued work.

2. **CAC39 with regard to**:

- Consistency of the Risk Analysis Texts across the Relevant Committees; and
- Codex Work on Antimicrobial Resistance.

AGENDA ITEM 3: MATTERS OF INTEREST ARISING FROM FAO/WHO AND FROM THE 81ST MEETING OF THE JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES (JECFA) (CX/RVDF 16/23/3)

Comment: AU takes note of the following activities conducted since the last session of 22nd session of CCRVDF:

- FAO and WHO Expert Committee of Food Additives (JECFA) in the provision of scientific advice to Codex and member countries; and
- Other activities of interest to CCRVDF.

1. ***Information from the Joint FAO/WHO Expert Committee on Food Additives (JECFA)***

Since the last session of the CCRVDF, two JECFA meetings (i.e. JECFA 80th and 81st) have been convened. JECFA 81st recommended Maximum Residues Limits (MRLs) for the following veterinary drugs: ivermectin, teflubenzuron and zilpaterol hydrochloride. Furthermore JECFA 81st evaluated three other veterinary drugs, Diflubenzuron, Lasalocid sodium and Sisapronil. JECFA was unable to recommend MRLs for diflubenzuron and Sisapronil but re-affirmed the MRL for Lasalocid Sodium.

2. ***General Considerations by JECFA 81st***

a. *Chronic dietary exposure assessment*

JECFA agreed to continue using the new *Global Estimate for Chronic Dietary Exposure* (GECDE) approach in parallel with the *Estimated Dietary Intake* (EDI) model to assess more accurately the chronic dietary exposure to veterinary drug residues. This is in order to gain experience and to continue improving the new methodology.

Moreover, JECFA 81st identified two additional important issues concerned with the methodologies applied by JECFA and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) to estimate chronic dietary exposures that merit general consideration.

This has necessitated the establishment of a Working Group of Experts to address these issues and a call for expression of interest for national institutions to contribute.

b. *MRLs for generic fish species*

CCRVDF22 required JECFA 81st to respond to the following questions:

1. Extrapolation of MRLs in fish species; and

2. For emamectin benzoate, provide an assessment as to whether there are any issues preventing extrapolation of the proposed MRLs to a general finfish MRLs or a more appropriate sub-grouping.

In response to the first question, JECFA concluded that in order to properly address the issue of extrapolation of MRLs to fish species, JECFA requires (in addition to the information identified by JECFA 78th) further information on adequate groupings of fish species so that representative species can be identified from which MRLs may be extrapolated to other similar species.

In response to the second question, JECFA concluded that in order to consider a request to extrapolate the MRLs recommended for salmon and trout to additional fish species, JECFA81st would require information on such approved uses, data to demonstrate pharmacokinetic and depletion behaviour of emamectin in a non-salmonid species and information to demonstrate that the method validated for the analysis of the high lipid content tissue of salmon and trout is applicable to non-salmonid species, preferably a species with low lipid content.

c. *Acute reference dose (ARfD) for veterinary drugs*

Following a recommendation of JECFA 75th, a working group to elaborate guidance on the establishment of ARfDs for veterinary drugs was formed. This guidance is posted on the WHO website for public comments, prior to its full implementation by JECFA.

d. *Processing of food containing residues of veterinary drugs*

During the evaluation of diflubenzuron by JECFA 81st, the possibility of its thermal degradation to 4-chloroaniline (PCA), a metabolite of substantial toxicological concern, was discussed. As this reaction can occur at temperatures achievable during home cooking (>100 °C), the possibility for the degradation of diflubenzuron to PCA has to be taken into account in the risk assessment of the residues of diflubenzuron. In the evaluation of residues of pesticides by JMPR, the effect of processing, including cooking in the home, on the amount and nature of the residues ingested by consumers is routinely considered. JECFA therefore considered whether this should also be undertaken routinely in its assessment of residues of veterinary drugs.

JECFA therefore concluded that it would not routinely assess, or seek to address, the effects of processing foods on residues of veterinary drugs. However, if there is evidence, or some other reason to suspect, that processing of foods containing residues of specific veterinary drugs could have toxicological implications, such as for diflubenzuron, the effect of processing should be taken into consideration in the assessment of that compound.

e. *Coordination of the agendas of JECFA and JMPR*

JMPR evaluates residues of pesticides in food, whereas JECFA (veterinary drug residues) evaluates residues of veterinary drugs in food. In general, although there are many assessment principles in common – and these are being harmonized to the extent possible – the groups tend to operate largely independently. There are some substances that are used both as pesticides and as veterinary drugs such as teflubenzuron. As such, JECFA 81st recommended that where dual-use substances are to be evaluated by both JMPR and JECFA, CCPR and CCRVDF coordinate the prioritization of such substances for evaluation by the respective experts.

f. *Update and revision of Principles and methods for the risk assessment of chemicals in food (EHC 240)*

The JECFA discussed whether processing data should be sought for all residues of veterinary drugs. It was agreed that this would not be practical, but that the issue should be dealt with on a case-by-case basis, where there was some reason for possible concern. Some minor amendment of *Environmental Health Criteria monograph- 240* (EHC 240) might be necessary to reflect this.

g. *Update on JECFA databases*

The FAO JECFA databases (one for food additives, one for flavouring agents and one for residues of veterinary drugs) were developed in early 2000 and were based on outdated underlying software. The FAO Secretariat has therefore carried out a project to modernize these three databases. The new databases do also allow for improved interconnectivity with other databases, such as the Codex database of adopted MRLs of residues of veterinary drugs and the WHO summaries of JECFA evaluations.

h. *Guidance for the evaluation of veterinary drug residues in food by JECFA*

The FAO/WHO JECFA Secretariat has revised the guidance documents for JECFA monographers and reviewers evaluating residues of veterinary drugs. While these guidance documents are intended primarily for JECFA Experts who prepare residue and toxicological monographs for JECFA, they will also be useful to manufacturers who submit dossiers to JECFA and other parties interested in understanding the process followed in the evaluation of residues of veterinary drugs in food by JECFA. The revised FAO JECFA guidance is divided in three modules that are available on the FAO web site. *(Module I: http://www.fao.org/3/a-bl002e.pdf Module II: http://www.fao.org/3/a-bl003e.pdf Module III: http://www.fao.org/3/a-bl004e.pdf)*

3. ***Global Food Consumption Databases and ongoing activities to support countries to generate and to use data for risk analysis purposes***

Reliable information on food consumption, collected at individual level, is needed to estimate dietary exposure to chemicals and biological agents in the general population and in vulnerable population groups. To address the issue of insufficient access to such data, FAO and WHO have continued the work on the two following tools (initiated in 2014), to develop global food consumption databases:

- CIFOCOs (FAO/WHO Chronic Individual Food Consumption Data summary statistics).
- FAO/WHO GIFT (FAO/WHO Global Individual Food consumption data Tool).

As part of the ongoing efforts to build national capacity and to populate these databases, a study to improve and harmonize food consumption data in ASEAN countries will be conducted over 2 years starting in May 2016.

4. ***FAO/WHO Activities on Antimicrobial Resistance (AMR)***

FAO

To support the implementation of the FAO Resolution on AMR and contribute appropriately to the AMR Global Action Plan, FAO has developed a plan of action, which defines its role and approach to supporting the food and agriculture sectors on the issue of AMR. This revolves around the four pillars of: (i) Awareness; (ii) Evidence; (iii) Governance; and (iv) Practices; and focuses on a cross-cutting approach to ensure involvement of the relevant food and agriculture entities as well as the legislative and standard setting bodies.

WHO

Since the adoption of the WHO Global Action Plan (GAP) on AMR in 2015, the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) is playing an active role in the implementation of GAP and in 2015 developed a five-year strategic framework to support the GAP. Five thematic working groups were established to operationalize this framework with the ultimate aim to minimize the public health impact of AMR associated with the use of antimicrobials in the food chain.

AGENDA ITEM 3: ACTIVITIES OF THE JOINT FAO/IAEA DIVISION OF NUCLEAR TECHNIQUES IN FOOD AND AGRICULTURE RELEVANT TO CODEX WORK1 (CX/RVDF 16/23/3 Add.1)

Comment: **AU** notes the IAEA activities in the following areas:

1. Coordinated Research Projects

2. Residues Of Veterinary Drugs And Related Contaminants In Foods

3. Laboratory Networks

4. Database Of Analytical Methods For Veterinary Drug Residues

AU commends the IAEA in its initiatives and collaboration with African countries especially in development of human and physical capacity. **AU and its member states** wish to participate and benefit from these programs.

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

Comment: AU appreciates the OIE's close cooperation with Codex, as one of the relevant standard-setting bodies recognized by the SPS Agreement of the WTO.

The key focus of the OIE's work relevant to CCRVDF has been on antimicrobial resistance, in close cooperation with FAO and WHO, and in providing support to the VICH initiative.

AU notes the OIE activities in the following areas:

- Cooperation between the OIE and the Codex Alimentarius Commission
- Capacity building Activities

- The OIE PVS Pathway
- OIE laboratory twinning approach
- Antimicrobial resistance

AGENDA ITEM 7.1: DISCUSSION PAPER ON UNINTENDED PRESENCE OF RESIDUES OF VETERINARY DRUGS IN FOOD COMMODITIES RESULTING FROM THE CARRY-OVER OF DRUG RESIDUES INTO FEED (CX/RVDF 16/23/7)

Comment: AU appreciates and congratulates the EWG for the good work on the discussion paper on unintended presence of residues of veterinary drugs in food commodities resulting from the carry-over of drug residues into feed.

AU advises its member states that the *Code of Practice on Good Animal Feeding (CAC/RCP54-2004)* highlights the need to have procedures in place to avoid cross-contamination. Also following Good Feed Manufacturing Practices and developing Hazard Analysis Critical Control Point (HAACP) plans would greatly reduce the risk of unintentional carryover.

African member states are also advised to take note of the following;

- The *Code of Practice on Good Animal Feeding* highlights the need to have procedures in place to avoid cross-contamination between batches of feed and feed ingredients, such as flushing, sequencing, and physical clean-out.
- The Code further notes, “In cases where the food safety risk associated with cross-contamination is high and the use of proper flushing and cleaning methods is deemed insufficient, consideration should be given to the use of completely separate production lines, transfer, storage and delivery equipment.”
- The Code also notes “Chemical fertilizers, pesticides and other materials not intended for use in feed and feed ingredients should be stored separately from feed and feed ingredients to avoid the potential for manufacturing errors and contamination of feed and feed ingredients.”
- The code therefore provides an overarching principle that could cover the carryover residue management.
- Following Good Feed Manufacturing Practices and developing Hazard Analysis Critical Control Point (HAACP) plans would greatly reduce the risk of unintentional carryover.
- A numerical standard setting could be considered if sufficiently justified and will be based on the rationale provided in the priority setting discussion.
- A name for the numerical standard needs further discussion to achieve consensus.
- There is no agreement on when a standard in food is set for residues resulting from unintentional carryover of drug residues in feed, whether a standard also needs to be established for feed.

This paper therefore requires further discussion in the physical working group and at the CCRVDF plenary to clarify various issues arising from the EWG.

AGENDA ITEM 8: GLOBAL SURVEY TO PROVIDE INFORMATION TO THE CCRVDF TO MOVE COMPOUNDS FROM THE DATABASE ON COUNTRIES’ NEEDS FOR MRLS TO THE JECFA PRIORITY LIST AND DATABASE ON COUNTRIES’ NEEDS FOR MRLS (CX/RVDF 16/23/9)

Comment: AU appreciates and commends the efforts of the EWG and the co-chairs for providing guidance and leadership in conducting the survey.

AU supports the following recommendations of the EWG that:

- The Committee continues to develop and maintain the database of the Database of Countries Needs for MRLs by circular letter; and
- That CCRVDF23 establish a EWG to consider the results of the global survey in order to identify priority veterinary drugs and identify information gaps for a successful and comprehensive assessment JECFA, and recommend approaches to obtain the required information.

AU observes that, unfortunately, Animal Trypanosomosis, which is a major disease of livestock in Africa and the drugs (*Diminazene Aceturate and Isometamedium Chloride*) used in controlling it, were not captured in the survey despite being submitted.

AU member countries are called to note the following:

- The preliminary examination of the results of the survey supplemented and expanded the information available through the database on the needs of the countries; and

- The survey only provided information on topics of disease between species and regions, suggesting the possibility of pooling resources to address common needs and leverage data across a wider network of constituents.

In summary the global survey proposes to divide the needed Maximum Residue Limits for veterinary medicinal into two groups:

1. Veterinary drugs with MRLs in some species and which have previously been evaluated by JECFA and that might require studies in other species for which there are no MRLs; and

2. Veterinary drugs that have no MRLs in any species, which would require a full dossier for JECFA.