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 7b **CRD 9**

Original language only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twentieth Session

San Juan, Puerto Rico, 7-11 May 2012

PROPOSED REVISION OF *RISK ANALYSIS PRINCIPLES APPLIED BY THE CCRVDF* AND THE *RISK ASSESSMENT POLICY FOR THE SETTING OF MAXIMUM LIMITS FOR RESIDUES OF VETERINARY DRUGS IN FOODS*

Comments of Egypt, European Union, Ghana and Nigeria

EGYPT

Egypt is in agreement with the EWG providing that the CCRVDF should review and update standards or related type for veterinary drugs in food, as necessary in the light of newly generated scientific data .

JECFA should provide a clear explanation and rationale for its conclusions and recommendations especially when no ADI can be established and / or no MRLs can be recommended due to data gaps or because of specific public health concerns or when JECFA recommends withdrawal of MRLs or ADI.

EUROPEAN UNION

The European Union and its Member States (EUMS) would like to thank France, Japan and the United States for leading the work on revising the risk analysis principles of CCRVDF.

The EUMS can largely agree with the proposed revisions with the following specific comments.

Risk Analysis Principles

Paragraph 3:

Delete the paragraph.

Rationale: There is no need to repeat the terms of reference of CCRVDF in the risk analysis principles.

Paragraph 21

According to this paragraph, JECFA may recommend temporary MRLs when data are insufficient. This provision should be further studied in view of paragraph 10 of the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius* which says that when data are insufficient or incomplete, no standard (i.e. an MRL in this case) should be developed but elaboration of a related text, such as a code of practice, should be considered. This means that temporary JECFA MRLs may be of a limited value for CCRVDF because CCRVDF would not be able to use them as a basis to recommend MRLs.

Paragraph 26

Modify the fist sentence as follows:

"The CCRVDF shall proceed with a critical evaluation of the JECFA **risk assessment, including** the proposals for MRL, and may…"

Rationale: The evaluation of CCRVDF should not be limited only to the MRLs but should cover the entire JECFA risk assessment.

Paragraph 32

The EUMS have concerns about the two new sentences at the end of the paragraph. They suggest that CCRVDF should make publicly available and communicate to national authorities information on veterinary drugs under consideration by CCRVDF, including JECFA concerns, and risk management recommendations of CCRVDF. Considerations of CCRVDF are already published in the reports of CCRVDF sessions and JECFA reports are publicly available as well. Therefore, there seems to be no need for an additional tool to make them publicly available. The second sentence

suggests that CCRVDF should communicate risk management recommendations directly to national authorities. The EUMS are of the view that any such risk management recommendations should be formally adopted via the formal Codex step procedure and published as Codex standards/guidelines.

Paragraph 33

Move the new sentence at the end of the paragraph to become the first paragraph under section 3.3.

Rationale: This sentence is about review of existing standards and therefore it better fits under section 3.3.

Annex

Add the following in point 4 under Administrative information:

Chemical names **and CAS registry number**

Risk Assessment Policy

Paragraph 2(g)

Replace the term "all species" with the following:

"target animal tissues (e.g. muscle, fat, or fat and skin, kidney, liver), and specific food commodities (e.g. eggs, milk, honey) originating from the target animals species to which a veterinary drug can be administered according to good veterinary practice"

Concern form

In principle, the EUMS are not against the use of concern forms in CCRVDF. However, there appears to be no real need for such forms because of the low number of MRLs that CCRVDF has to deal with at any one time. The situation is different in CCPR which has each time a large number of MRLs on its agenda because of the high number of pesticide/commodity combinations. To speed up the process, CCPR had to introduce the concept of concern forms. In CCRVDF, when countries have problems with proposed MRLs, they have ample opportunities to bring them forward with necessary explanations on a case-by-case basis.

GHANA

Section 2 – Parties involved, paragraph 3f

Specific Comments

Ghana proposes that paragraph 3f be rephrased as to read as follows : ''to develop risk management and ***risk*** communication recommendations when after assessment by JECFA, no ADI and/or MRL is established, due to specific human health concerns''

Rationale

There is the need to place emphases on the fact that the ''communication'' referred to is a ''risk communication'' and also to clarify that the risk assessment body is JECFA

Section 3.1 - Preliminary risk management activities, Paragraph 10 Bullet 6

Specific comments

Ghana does not support the deletion of bullet 6 and recommends that the sentence in bullet 6 i.e. ***''Consideration of the result of the risk assessment''*** be reinstated.

Rationale

The deletion of the last sentence does not make it consistent with the provisions in section 3.1 of the document ''PREVISION OF RISK ANALYSIS PRINCIPLES APPLIED BY CCRVDF'' (REP11/RVDF Appendix II).

Section 3.2 Evaluation of Risk Management Options, paragraph 27

Ghana recommends that paragraph 27 should be rephrased to reflect decision points. We therefore propose the following :

27. The CCRVDF ~~*either : recommends*~~ ***may***

- ***recommend*** ~~*develops*~~ the MRLs *based on the* JECFA assessment
- ***modify*** ~~modifies~~ them in consideration of other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade''

- ~~*considers other measures* or~~ ~~asks~~ ***request*** JECFA for reconsideration of the residue evaluation for the veterinary drug in question''
- ***consider*** ~~considers~~ and ~~recommends~~ **recommend** appropriate risk management measures for veterinary drug residues with on ADI/MRL due to lack of information or specific health concern, as concluded by JECFA

Rationale

Bullet 1

''***Develop***'' was changed to ''***recommend***'' to ensure consistency with the second Terms of Reference for the CCRVDF (20th Edition of the Procedural Manual) which states :

*''To **recommend** maximum levels of such substances''*

NIGERIA

Nigeria commends the e-Working Group led by France, Japan and the United State of America.

Under 2 – Parties involved

Under paragraph 7: Scientific experts from JECFA are selected in a transparent manner by FAO and WHO under their rules for expert committees on the basis of the competence, expertise, experience in the evaluation of compounds used as veterinary drugs and their independence with regard to the interests involved, taking into account geographical representation ~~where possible.~~

Justification

The term "where possible" can be used as an excuse for exclusion of some regions from participation in JECFA work.

Under 3.1- Preliminary risk management activities

Under paragraph 10 –bullet 2 to read: Identification of a food safety problem in ~~the integrity of~~ the food chain; and,

Justification

For the purpose of clarity

Under 3.2 – Evaluation of Risk Management options

Nigeria considers paragraph 27 adequate except for the amendments proposed as follows:

27. The CCRVDF ***may*** ~~either~~: ~~recommends~~

- ***recommend*** ~~*develops*~~ *the MRLs based on the JECFA assessment,*
- ***modify*** ~~*modifies*~~ *them in consideration of other legitimate factors relevant to the health protection of consumers and for the promotion of fair practices in food trade,*
- ~~*considers other measures or asks*~~ ***requests*** *JECFA* ~~*for reconsideration*~~ *to reconsider the residue evaluation for the veterinary drug in question,*
- *decline to advance the MRLs based on risk management concerns or*,
- ***consider*** *and* ***recommend*** *appropriate risk management measures for veterinary drug residues with no ADI/MRL due to lack of information or specific health concern, as concluded by JECFA*.