



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS**  
**Twenty-first Session**  
**Minneapolis, Minnesota, United States of America, 26 – 30 August 2013**

**PROPOSED “CONCERN FORM” FOR THE CCRVDF (FORMAT AND POLICY FOR ITS USE)**

Comments submitted by:

Argentina, Brazil, Costa Rica, Cuba, Kenya, Nigeria, United States of America and African Union (AU)

**ARGENTINA, BRAZIL, COSTA RICA, CUBA AND UNITED STATES OF AMERICA**

1. **The Executive Committee of the Codex Alimentarius Commission – CCEXEC**, during its 64<sup>th</sup> Session, noted with particular interest that to facilitate decision taking relating to scientific issues, a Concern Form had been introduced by the CCPR in 2006. **If a delegation has a concern with advancing a given MRL, this form should be completed one month after the CCPR session, detailing the concern along with a description of the data that will be submitted to substantiate it. JMPR evaluates it and gives its opinion on substantiation of this concern.** The introduction of a Concern Form has made CCPR decisions more transparent and has helped to advance a number of proposed MRLs. (ALINORM 10/33/3A, para. 81)
2. **In 2010 the CCEXEC recommended to CCRVDF to consider using a Concern Form as is used by the CCPR to adhere to the statements of principle concerning the role of science and to encourage data owners through the respective regulatory authorities to submit data.** (ALINORM 10/33/3A, para. 87)
3. As the use of the Concern Form was described in the relevant risk analysis principles applied by CCPR, the CCRVDF in 2010 agreed that a similar approach should be taken for veterinary drugs residues. It was, therefore, agreed that consideration of the concern form would be integrated into the work on the revision of the *Risk Analysis Principles applied by the CCRVDF*. (REP11/RVDF, para. 18)
4. **Codex needs to base its decisions on sound science**, in view of the status of Codex as a reference body under the WTO SPS Agreement, and should not base its decisions on factors outside its mandate. Some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide; therefore, these factors are considered outside the mandate of Codex and should not influence the risk management.
5. Although there is a smaller number of MRLs under consideration at the agenda of CCRVDF when compared to CCPR, **factors outside the mandate of Codex which are not related to protecting the health of consumers still hold and have held CCRVDF standards at step 8 of the Codex Procedure and unnecessarily have delayed their advancement during the whole Step Process, jeopardizing the role of Codex.**
6. The Concern Form is an important tool that will assist in making CCRVDF decisions more transparent and will help advance the proposed draft MRLs, ensuring that concerns raised at CCRVDF are science-based, clearly articulated and (where appropriate) have supporting scientific information for JECFA to evaluate. It also avoids that objections based on reasons that are not legitimate factors according to the Principles of Codex delay the advance of standards by the CCRVDF.
7. For the reasons mentioned **the Codex members listed above strongly support the adoption of the proposed Concern Form by CCRVDF and the inclusion of its policy procedure into the *Risk Analysis Principles Applied by the CCRVDF* in the Codex Procedural Manual.**

**KENYA**

We appreciate the work done by eWG to come up with the draft of the 'concern form' for the CCRVDF that is found to be very useful for food safety purposes.

However, we noted the scope, procedure and format of the Concern Form and agreed with the recommendations of the eWG on the Proposed "*Concern Form*" For The CCRVDF (*Format And Policy Procedure For Its Use*) and should be added to the *Risk Analysis Principles Applied by the CCRVDF* in the Codex Procedural Manual

**NIGERIA**

Nigeria is of the opinion that the point of entry of concern forms identified as step 3 and step 5 differs from that indicated in the procedural manual (step 1-8) and therefore requests for further clarification..

**Comments on Format**

We suggest that a foot note should be inserted to indicate those who can make requests and at what level such request can be made.

**AFRICAN UNION (AU)**

African Experts noted the scope, procedure and format of the Concern Form and agreed with the recommendations of the eWG on the Proposed "*Concern Form*" For The CCRVDF (*Format And Policy Procedure For Its Use*).

AU recommends that further work be done on the concern form to make it more explicit.