



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:

Brazil, Chile, Costa Rica, European Union and Philippines

BRAZIL

General comments

Brazil co-chaired the EWG on Concern Form with Australia and appreciates the opportunity to acknowledge the work done by all members during the EWG and the overall improvement of the scope, format and policy procedure of the proposed Concern Form since its very first version, reflecting the contributions received.

Brazil strongly supports the immediate 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.

The Concern Form is a tool of utmost importance 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.

CHILE

General Comments

We consider that it can be a useful tool when facing conflicting issues. It would be appropriate, on one side, to focus the issue on relevant Codex Alimentarius matters. On the other side, it leaves evidence about the motives of the opposition to advance it, so they can be reviewed when future discussions arise during further steps of the draft development.

In summary, Chile supports the use of the concern form, but only to apply it on those cases when the request for MRLs is conflicting; the main objective of this would be that the country with concerns about the MRLs can present evidences of them. Also, it is proposed not to make it a mandatory step, but to emphasize that the use of the concern form should be done with previous Committee approval, after the country has been able to present their concerns.

COSTA RICA

In this case, we totally agree with the Concern Form, who's work has been progressing under Brazil coordination, and it is already implemented by the Pesticides Committee; the Concern Form will give more transparency and clarity when formulating our concerns about an issue or a drug.

EUROPEAN UNION

The European Union and its Member states (EUMS) would like to thank Australia and Brazil for leading the work on concern forms.

The EUMS would like re-iterate their position already expressed in the eWG that there is no need for concern forms at CCRVDF because of the low number of MRLs that CCRVDF has to deal with at any one time. The situation is completely different at CCPR which has each time hundreds of MRLs on its agenda

because of the high number of pesticide/commodity combinations. To speed up the process, CCPR had to introduce the procedure with concern forms. At CCRVDF, when countries have concerns about proposed MRLs, they can bring them forward with necessary explanations on a case-by-case basis. There is thus no need to create an additional layer of procedures for CCRVDF by introducing the concept of concern forms.

Not only are concern forms redundant for CCRVDF but a new procedure with concern forms could lead to an overall distortion of the role of CCRVDF and slow down the advancement of MRLs. That is because a new specific procedure for expressing scientific concerns on JECFA assessments would encourage countries to express such concerns. That is not the task of CCRVDF. Instead, CCRVDF's task is to consider JECFA recommendations from a risk management point of view. As a result of that consideration CCRVDF can sometimes request clarification from JECFA or even ask JECFA to review its risk assessment but that is not a task *per se* for CCRVDF.

If, despite the above issues, CCRVDF will choose to go ahead with concern forms then the procedure should match with the existing procedures, i.e. it should not overlap, duplicate or contradict them. Creating a specific and independent procedure for concern forms would only create confusion and complicate the work of CCRVDF. To avoid that, the EUMS would like to make the following specific comments on Annex 1 of document CX/RVDF 13/21/9:

Modify paragraph 1 as follows:

"A concern form, as already used by the Codex Committee on Pesticide Residues - CCPR since 2006, is intended to be a tool for Member States to put forward concerns and requests for clarification, accompanied where appropriate with scientific data and information, to the attention of JECFA concerning its risk assessment. It is important because it will assist in making CCRVDF decisions more transparent ~~and can help to advance the proposed draft MRLs.~~"

Rationale: Creation of a new procedure with concern forms would not help to advance the proposed MRLs. On the contrary, it could encourage member countries to challenge JECFA risk assessments thus slowing down the advancement of MRLs.

Modify paragraph 2 as follows:

~~"The use of a concern form will facilitate the progress of Codex standards as it ensures that concerns raised at CCRVDF are clearly articulated and, where appropriate, have supporting scientific information for JECFA to evaluate. It provides formality and transparency to the way scientific concerns are expressed to the Committee and will ensure that the concerns are accurately captured and efficiently addressed, allowing the standards (MRLs) to move forward as supported by the science."~~

Rationale: The use of concern forms would not facilitate the progress of Codex standards or allow MRLs to move forward. Instead, as commented above, a new procedure with concern forms could actually slow down the advancement of MRLs. The use of concern forms would not make addressing scientific concerns more efficient compared to the existing procedures.

Modify paragraph 3 as follows:

"The concern form is intended to be used when the draft proposed or proposed MRLs are circulated for comments at Step 3 or Step 6 of the Step Procedure. It should be submitted directly to CCRVDF Secretariat prior to its session, **together with other comments on the draft proposed or proposed MRLs**, in order to be circulated among CCRVDF members. ~~Earlier submission of the concern form to CCRVDF might allow JECFA to prepare clarification in response to some concerns during the plenary session, would facilitate the discussion and lead to more rapid consensus."~~

Rationale: In addition to scientific concerns or requests for clarification to JECFA, for which concern forms would be used, member countries may have other types of comments related to risk management. JECFA has no opportunity to respond to concern forms because there is no JECFA meeting after the submission of concern forms and before the CCRVDF session.

Modify the 2nd bullet point of paragraph 5 as follows:

"Where appropriate, C concerns described in the concern form **should** ~~must~~ have sound supporting data or scientific based information that should be made available for a JECFA review. Scientific data should be complete and not a summary statement or synopsis;"

Rationale: As stated in the 3rd bullet point, concern forms do not need to have supporting data or scientific information if they are used for submitting requests for clarification to JECFA.

Modify the 2nd bullet point of paragraph 5 as follows:

"Concerns or rRequests for clarification related to interpretation of the existing supporting data (e.g. review of the ADI) can be submitted without the need for any additional data."

Rationale: There can also be concerns about the interpretation of the existing data without a need for any additional data.

Delete the 4th bullet point of paragraph 5:

~~When necessary, concern supporting data should be made available to the appropriate JECFA Secretariat within one month after the CCRVDF Session for which the concern form was provided, and the Chair and members of the CCRVDF should be informed of the submission to the JECFA Secretariat;~~

Rationale: The concern or request for clarification has to be put on the JECFA priority list and the commitment for providing data, if necessary, with an appropriate deadline is agreed in that context. There is thus no need for setting other deadlines for the data submission.

Modify the 6th bullet point of paragraph 5 as follows:

"The JECFA Secretariat should schedule the concern for a JECFA review ~~by an appropriate mechanism~~ to allow JECFA to respond by the next CCRVDF Session;"

Rationale: The meaning of "an appropriate mechanism" is not clear and it is redundant.

Delete the 7th bullet point of paragraph 5:

~~If the data/information is not provided to the JECFA Secretariat by the one month deadline for submission or the JECFA recommended MRLs remain unchanged, the relevant draft MRLs will follow the normal Step procedure, consistent with the decisions of the most recent CCRVDF Session;~~

Rationale: Referring to comments made on the 4th bullet point, there is a well-defined procedure in place for setting up the JECFA priority list, including possible submission of data with deadlines. No additional and redundant procedures should be created.

Modify the 8th bullet point of paragraph 5 as follows:

~~"If necessary, a physical Working Group should be conveyed immediately before the CCRVDF Session in order to discuss and organize t~~The concern forms received **should be discussed and organised in the working group on JECFA priorities and be further considered by CCRVDF on the basis of recommendations of the working group.**"

Rationale: Referring to earlier comments, there is a well-defined procedure in place for setting up the JECFA priority list. No additional and redundant procedures should be created.

Replace the heading of the format with the following:

"Format for putting forward concerns of requests for clarification to the attention of JECFA concerning its risk assessment"

Rationale: The suggested new heading reflects the fact that concern forms would be used for expressing concerns or requests for clarification concerning JECFA assessments. There may be other types of comments or concerns as regards the draft or proposed draft MRLs and in those cases concern forms would not be used.

Delete the following bullet point from the format:

~~–Proposed solution (consistent with Codex Principles)~~

Rationale: There is no need to propose any solutions. If CCRVDF decides to submit the concern or request for clarification to JECFA, then, according to the suggested procedure, the relevant MRLs will not advance pending JECFA's response and its consideration by the subsequent session of CCRVDF.

PHILIPPINES

The Philippines gives value to the proposed "Concern Form" because of its usefulness and benefits for all members of CCRVDF.

Further, the Philippines would like to propose for the following:

Item	Document Text	Proposal
Procedure: Bullet No 4	When necessary, concern supporting data should be made available to the appropriate JECFA Secretariat within one month after the CCRVDF Session for which the concern form was provided, and the Chair and members of the CCRVDF should be informed of the submission to the JECFA Secretariat.	When necessary, concern supporting data should be made available to the appropriate JECFA Secretariat <i>within one month when requires, at the end of study period</i> after the CCRVDF Session for which the concern form was <i>is</i> provided; and the Chair and members of the CCRVDF should be informed of the submission to the JECFA Secretariat.
Procedure: Bullet No 8	If necessary, a Physical Working Group should be conveyed immediately before the CCRVDF Session in order to discuss and organize the concern forms received	Requesting for clarification of this statement and give example of "necessary"
Procedure: Additional Bullet (Bullet 9)		The Committee after one year adoption of the "Concern Form" should validate its effectiveness.
Format of Concern Form Bullet 7 and 8	<ul style="list-style-type: none"> - Is this a Request for Clarification? - Is this a new concern - Concern (Specific statement of) 	Re-order bullet 7 and 8 <ul style="list-style-type: none"> - Is this a new concern? - Is this a request for Clarification? - Concern (Specific...)
Bullet 11	- Types of data or analysis that will be submitted to JECFA concerning (ie toxicology, residue, microbiology, diet)	Type of data or analysis that will be submitted <u>or requested</u> to JECFA concerning (ie toxicology, residue, microbiology, diet)