CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7b **CX/RVDF 12/20/8 Add. 1**
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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 THE *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 Australia, Brazil, Chile, Costa Rica, Kenya, Norway, Philippines, Thailand, Consumers International and IACFO

AUSTRALIA

General Comments

Throughout the document, the term 'should' is used in many instances where it may be more appropriate to use the term 'must'. This occurs not only in the original text but also in the proposed changes.

Specific Comments

Section 3.1 – Preliminary risk management activities, Para 10

The proposed addition "in the integrity of the food chain" is not necessary in the second dashed point.

The word "and" needs to be moved to the previous dashed point as the final point has now been deleted.

Section 3.1.5 – Commissioning of the Risk Assessment, Para 19

Last sentence in italics in paragraph 19 is not required.

Section 3.1.6 - Consideration of the Result of the Risk Assessment, Para 24

Add the word 'for' after JECFA. So the para would read:

"The CCRVDF may ask JECFA **for** any additional explanation."

Section 3.2 – Evaluation of Risk Management Options, Para 27, 1st point

A space needs to be inserted between the words "JECFA" and "assessment"

Section 3.2 – Evaluation of Risk Management Options, Para 27 4th point

An 's' should be added to 'decline' so that it reads

- *decline**s** to advance the MRLs based on risk management concerns*

An 'l' should be added to 'well' in the 5th point so that it reads

- *CCRVDF considers the information and recommendations provided by JECFA as wel**l** as other ...*

PROPOSED REVISION OF THE RISK ASSESSMENT POLICY FOR THE SETTING OF MAXIMUM LIMITS FOR RESIDUES OF VETERINARY DRUGS IN FOODS

General Comments

Throughout the document, the term 'should' is used in many instances where it may be more appropriate to use the term 'must'. This occurs not only in the original text but also in the proposed changes.

Specific Comments

Para 2(b)

Replace 'if they are to establish its' in the second line, with 'in conducting'

(b) JECFA should take into account all available scientific data, *including data used by*

national/regional authorities to set their standards, ~~if they are~~ ~~to establish its~~ **in conducting the** risk assessment. It should use available quantitative information to the greatest extent possible and also qualitative information.

Para 2(h)

Delete the second part of the first sentence as shown below

h) When scientific data are insufficient JECFA should indicate the data gaps~~ and propose a time frame in which data should be submitted~~.

Form for Expressing Concerns with Advancement of an MRL or Request for Clarification of Concerns

The use of the concern form has been agreed. However, the actual policy and procedures for its use have not yet been developed or agreed by CCRVDF although CCPR has these in place.

BRAZIL

General comments

Brazil congratulates France, Japan and the United States for providing the Report of the electronic Working Group on Revision of the *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* and would like to thank for the opportunity to submit its comments.

Specific comments

Annex 1

3.1 - Preliminary risk management activities

10. This first phase of risk management covers:

- Establishment of risk assessment policy for the conduct of the risk assessments;

- Identification of a food safety problem ***~~in the integrity of the food chain;~~***

Rationale: maintain as the original version, no need to detail.

3.1.5 - Commissioning of the Risk Assessment

19. … . ***CCRVDF may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.*** …

Rationale: Brazil asks for clarification of the need to introduce this sentence. In paragraph 23 it is already stated that JECFA, in its assessment reports, should present different risk management options for the CCRVDF to consider. Once JECFA does the Risk Analysis and not Risk Management, would the JECFA recommended MRLs go back to JECFA with a range of risk management options??? How long would it take to in fact recommend MRLs by CCRVDF???

3.2 - Evaluation of Risk Management Options

26. The CCRVDF shall proceed with a critical evaluation of the **results of JECFA's risk assessment** ~~proposals on MRLs~~ and may consider other legitimate factors relevant for health protection and fair trade practices in the framework of the risk analysis. …

Rationale: the result of JECFA's work may be not to propose MRLs.

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

…

- ~~*decline to advance the MRLs based on risk management concerns*~~

Rationale: delete the 4th bullet. Concerns about establishing MRLs should be stated in previous moments, already when discussing the priority list and during the process, and should be addressed by member countries by using the concern form.

4 - Risk Communication in the Context of Risk Management

32. In accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, the CCRVDF, in cooperation with JECFA *and the Codex Secretariat*, shall ensure that the risk analysis process is fully transparent and thoroughly documented and that results are made available in a timely manner *in the form of a consolidated presentation* to Members. The CCRVDF recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities. *Risk communication to inform national/regional risk managers on veterinary drugs under consideration by CCRVDF, including those for which no ADI/MRL has been recommended by JECFA, should be made*

publically available. The communication should include the risk management recommendation(s) of CCRVDF. ~~and the basis for the recommendation(s), typically, but not necessarily limited to, the key findings/concerns of the JECFA.~~

Rationale: delete the end of this sentence, since this part of the document is addressing Risk Communication and not how CCRVDF should proceed with Risk Management.

ANNEX

TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Administrative information

16. Date when data could be submitted to JECFA

17. The prospect of completing the work within a reasonable period of time

Rationale: Brazil asks for clarification of the need to introduce item 17, once item 16 already asks for the date when data could be submitted. Which and whose work is to be completed within a reasonable period of time?

CHILE

General Comments

Chile supports the adoption of the proposed modifications.

Rationale

Chile considers that the proposed modifications help to clarify and demarcate the elements of the Risk Analysis Principles applied by the CCRVDF and the Risk Assessment Policy for the setting of Maximum Residue Limits (MRLs) for residues of veterinary drugs in foods, enhancing the transparency of the process.

COSTA RICA

Costa Rica appreciates the opportunity to present the following comments:

In general, the working group agreed with the changes made to comments in paragraph 9 about the importance of risk management being based on the risk assessment.

In paragraph 19, where the following was added: "CCRVDF may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option. JECFA may use various data sources including those used by national/regional authorities to set national/regional standards, if they meet minimal JECFA standards. Criteria may be developed to define which compounds could qualify for such elaboration."

It was concluded that this addition should be considered in a broader debate in the CCRVDF group because it could lead to confusion, and it must be very clear that the guidelines used by the team of experts should prevail so as not to create any doubts regarding the evaluation team's conclusions. Also, we should be very

careful—in some very specific instances JECFA, if it deems it appropriate, could use some information sources or conclusions from national or regional entities.

In paragraph 27, where it says "se rehúsa a promover el LMR debido a preocupaciones en la gestión de riesgo," we suggest saying "se declina de promover..." For example: [This comment only applies to the Spanish version]

- Se ~~rehúsa a~~ **declina de** promover el LMR debido a preocupaciones en la gestión de riesgo". [This comment only applies to the Spanish version].

In paragraph 32, in the third from last line, it says, "pero no necesariamente con respecto a los hallazgos...." It should say "pero no necesariamente limitada a los hallazgos y/o preocupaciones del JECFA." For example: [This comment only applies to the Spanish version].

- pero no necesariamente **limitada** ~~con respecto~~ **a los** hallazgos **y/o preocupaciones del JECFA.** [This comment only applies to the Spanish version].

Regarding the Risk Assessment Policy for the setting of maximum residue limits (MRLs) for veterinary drugs in foods:

In paragraph 2, subparagraph h), instead of "lagunas de información" change to "carencias de información." For example:

- …~~lagunas~~ **carencias** de información

Furthermore, we support the form submitted for expressing concerns regarding the advance of an MRL or requesting clarification regarding any other concerns.

On page 10, in the section "Form for expressing concerns about the advancement of an MRL or requesting clarification regarding concerns," we suggest changing where it says "problematic veterinary drugs" by deleting the term "problematic" and leaving just "veterinary drugs." For example:

- ~~problematic~~ veterinary drugs

KENYA

Issues and observations

i. Under ''RESPONSIBILITIES OF CCRVDF'' item ''f'' is not very understandable.

ii. Under '' Preliminary Risk Management Activities'' the deletion of the last sentence does not make it to conform with the document '' AMENDMENT ON RISK ANALYSIS PRINCIPLES APPLIED BY CCRVDF''

iii. The rendition of paragraph 27 of this document doesn't indicate that these are decision options open to the CCRVDF when deciding on JECFA recommendations after risk assessment.

Comments

To make this section clearer, recast item ''f'' as follows :

'' to develop RM and RC recommendations when after assessment by JECFA, no ADI and/or MRL is established, due to specific human health concerns''

ii. The deleted item '' Consideration of the result of the Risk Assessment'' should also be reinstated.

iii. The paragraph should be modified as follows :

- rewrite opening phrase as ''CCRVDF may : ''
- change ''modifies'' to ''modify'' in the first bullet
- change ''asks'' to ''request'' in the second bullet
- change ''considers'' to ''consider'' in the third bullet and
- ''recommends'' to ''recommend'' in the fourth bullet

NORWAY

Specific comments

2 – Parties involved

Paragraph 3: We suggest deleting the paragraph.

Reason: Paragraph 3 repeats the TOR and it is not necessary to include the Terms of reference of CCRVDF in the Risk analysis document as both the TOR and the Risk Analysis document are included in the Procedural Manual. Discussions on the amendments of the Terms of Reference will be held under agenda item 5.

3.1.2 – Establishment of the priority list

Paragraph 13, 4th bullet point: Replace the word "it" in the beginning of the sentence, by "the compound": ~~It~~ **The compound** is available as a commercial product…

Reason: To make it more clear and avoid misunderstanding.

3.1.5 – Commissioning of the risk Assessment

Paragraph 19: We might suggest deleting or amending the last sentence "Criteria may be developed to define which compounds could qualify for such elaboration."

Reason: The committee could benefit from a bit more clarity or explanation of the need for criteria as this might seem unnecessary, and might have a limiting effect.

3.2 – Evaluation of Risk Management Options

We agree with the modification made by the co-chairpersons in the document RVDF 12/20/8, page 24, para 27 and support this text, as it is better than the one in the main body of the document (page 6).

PHILIPPINES

General Comments:

Philippines would like to extend its gratitude for the members of E-Working Group for their effort to revise "The 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." Equally important, Philippines supports the continued advancement of the document that is realistic and applicable to all member countries.

Specific Comments:

Paragraph No 3.

According to its mandate, the responsibilities of the CCRVDF regarding veterinary drug residues in food are:

a) To determine priorities for the consideration of residues of veterinary drugs in foods;

b) To recommend maximum levels of such substances;

c) To develop codes of practice as may be required;

d) To consider methods of sampling and analysis for the determination of veterinary drug residues in foods;

e) ***To consider other matters in relation to the safety of food containing residues of veterinary drugs and make relevant recommendations;***

f) ***To develop risk management and communication recommendations when after assessment of veterinary drug, the JECFA recommends no ADI and/or MRL due to specific human health concerns.***

Philippine Position:

1. The existing CCRVDF Terms of Reference from "Items a to d" do not need to be changed;
2. The addition of Item "e" "to consider other matters in relation to the safety of food containing residues of veterinary drugs and make relevant recommendations" can be studied at the next session, for this

will add flexibility to the current function of the Committee and would thereby accommodate future matters not currently identified but may concern residues of veterinary drugs in foods;

3. Further, considering that CCRVDF is responsible for residues of veterinary drugs in foods as it affect human health, the Philippines is not supporting the inclusion of "feeds" as part of CCRVDF Terms of Reference given that veterinary drugs is intentionally added in feeds as one of its components and not residues. Residues are already in the foods; and
4. For Item "f", the Philippines proposes for the possibility of considering the concept later on under Item "e", but with consideration of readiness of member country in developing and adopting risk management.

THAILAND

We have comments as follows;

Section 3.1 Preliminary Risk Management activities

- **Para 10**, the sentence should be modified as follow ;

"- Identification of a food safety problem *in ~~the integrity of~~* ***relation to*** *the food chain;*"

The word "integrity" may not be clear. It should be replaced with "relation to".

- **Para 13 -** bullet 4, the sentence should be modified as follows;

"It is available as a commercial products or there is a commitment that such commercial availability is pending ***and it should be a commercial product by the deadline of data submission for evaluation of toxicological and/or residue studies by the JECFA****."*

We are of the opinion that it should be a complete commercial product prior to evaluation for safety of the product by JECFA.

Section 3.1.5 Commissioning of the Risk Assessment

- **Para 19**, We propose to delete the sentence " …JECFA may use various data sources including those used by national/regional authorities to set national/regional standards, if they meet minimal JECFA standards." therefore the text is read as follows:

"*CCRVDF may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option. ~~JECFA may use various data sources including those used by national/regional authorities to set national/regional standards, if they meet minimal JECFA standards.~~ Criteria may be developed to define which compounds could qualify for such elaboration.*"

Generally, the context under para 19 addressed the role of CCRVDF as a risk manager and the word "minimal JECFA standard" is not clear. Moreover, we believed that JECFA already has procedure to follow in conducting risk assessment.

CONSUMERS INTERNATIONAL

General comments:

CI for the most part agrees with the suggested changes in the current document and believes they correctly describe the appropriate risk management roles of the CCRVDF.

CI recommends in comments below some additional language that we hope will be included in the final document clarifying that the purpose of risk management in Codex is the protection of consumer health and that Codex has provisions for addressing cases where scientific information is lacking. Finally, CI asks that risk communication about antimicrobial veterinary drugs by CCRVDF include communication about antimicrobial resistance and the management of antimicrobial resistance. Given this is the primary Codex body that discusses risks related to veterinary drug use, CI feels it is important that communication around antimicrobial resistance be included in CCRVDF risk analysis.

Specific comments:

Annex 1 PROPOSED REVISION OF THE RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Paragraph 3. CI supports additional bullets.

Paragraph 4. CI supports removal of stricken through text.

New Paragraph before current paragraph 9. CI recommends the following paragraph clearly stating that the purpose of risk management in CCRVDF is the protection of the health of consumers be added before the current paragraph 9. This is directly from the procedural manual and is highly relevant to the discussion around drugs for which there is no ADI/MRL as these are the drugs that create such a risk to consumers that no MRL can be recommended.

Recommended text for new paragraph before paragraph 9:

CCRVDF decisions and recommendations on risk management should have as their primary objective the protection of the health of consumers.

New paragraph after the current paragraph 9. CI recommends that a new paragraph be added after the current paragraph 9 that explains the role of CCRVDF when scientific evidence is incomplete or insufficient. This is directly relevant to the discussion in the CCRVDF for drugs for which no ADI/MRL can be set because some of the drugs on the list have not been evaluated because of a lack of data. It is also unlikely that information will be forthcoming on some of the older drugs known to create health risks.

Recommended text adapted from Codex Procedural Manual for new paragraph after paragraph 9:

When there is evidence that a risk to human health exists from a residue of veterinary drugs in food but scientific data are insufficient or incomplete, CCRVDF should not recommend an MRL but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.

Paragraph 10. CI does not support the proposed new language.

Paragraph 13. Given the considerable resource constraints of CCRVDF and JECFA, CI does not support working on drugs that are not yet available as a commercial product.

Paragraph 16. CI recommends including at this point language directing CCRVDF to consider taking risk management steps other than setting a standard at the stage of risk profile when there is evidence of a human health risk but insufficient scientific evidence available to go forward with a risk assessment.

Recommended text to be placed at end of paragraph: **If there is evidence that residues of a veterinary drug create a specific human health risk but there is not sufficient information for an evaluation by JECFA, CCRVDF should consider taking other risk management steps such as elaborating a related text.**

Paragraph 27. CI supports the suggested changes in paragraph 27 but notes the changes should be edited for clarity by adding conjunctions such as "and" and "or."

Paragraph 32. CI supports the additional text included in this paragraph but recommends that the new paragraph be split in two with a new paragraph starting with "Risk communication to inform national/regional risk managers on veterinary drugs ..."

In addition, CI recommends the following language be included at the end of the new paragraph:

When risk management recommendations are made about veterinary drugs that are antimicrobial agents, the recommendation should state that the drug is an antimicrobial with the potential to contribute to antimicrobial resistance in food that may require further risk management as described in Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CAC/GL 77- 2011.

ANNEX – TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

CI recommends a new numbered item be added under the heading “Risk profile elements” after numbered item 10 that requests information on antimicrobial class.

Recommended language:

11. Antimicrobial class

IACFO

IACFO supports the Working Group's proposed revisions, including the responsibilities in line (e) and (f) as stated below.

Annex 1

2 – Parties involved

[…]

3. According to its mandate, the responsibilities of the CCRVDF regarding veterinary drug residues in food are:

[…]

(e) to consider other matters in relation to the safety of food containing residues of veterinary drugs and make relevant recommendations.

(f) to develop risk management and communication recommendations when after assessment of a veterinary drug, the JECFA recommends no ADI and/or MRL due to specific human health concerns.

Rationale: The inclusion of responsibility (e) provides CCRVDF with the ability to take into consideration other significant matters related to veterinary drug use. The inclusion of responsibility (f) will provide member countries with the best guidance on the use of these veterinary drugs based on the best available research. Risk management and communication recommendations on this issue will aid countries in making decisions that are the most protection of public health.

3.1.5 – Commissioning of the Risk Assessment

19. […] CCRVDF may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option. JECFA may use various data sources including those used by national/regional authorities to set national/regional standards, if they meet minimal JECFA standards. Criteria may be developed to define which compounds could qualify for such elaboration.

Rationale: IACFO supports the new language as stated above. There is a broad range of practices globally in the use of veterinary drugs – in some countries there are few legal restrictions, while other countries require consultations with veterinarians. Therefore, it is within the scope of Committee to consider and give a range of recommendations on the appropriate risk management measures concerning the use of veterinary drugs in food-producing animals. Additionally, requiring data sources to meet JECFA standards is essential for promoting the use of high-quality data and research to make the best possible recommendations. If veterinary drugs are not well managed, human health is at risk by means of drug residue exposure in the food supply and the rise and spread of antibiotic resistant pathogens in food and the environment.

4 – Risk Communication in the Context of Risk Management

IACFO supports the new language added to paragraph 32.

Rationale: The interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties is imperative. Risk communication should be considered at all stages of developing a management strategy. In making this information publicly available and the rationale transparent, risk managers must be prepared to announce results and to provide the rationale for their decisions and the implications of the results to all interested parties. This is especially important for communicating the key findings and concerns effectively with risk managers about veterinary drugs for which no ADI/MRL has been recommended by JECFA.

FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL/OR REQUEST FOR CLARIFICATION OF CONCERNS

IACFO recommends that additional information concerning the drug's producers be provided when completing the form.

-*Submitted by:*

-*Date:*

-*Veterinary drugs concerned:*

-***Names and locations of the drug's producers:***

[…]

Rationale: Asking for this additional information will provide background on which companies and countries are most invested in this drug's trade and revenue. Transparency related to production and trade interests should be part of the form.