CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item: 7(b) **CRD 2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS
Twentieth Session
San Juan, Puerto Rico, United States of America, 7 –11 May 2012

REPORT OF THE CCRVDF Working Group on revision of the Risk Analysis Principles applied by the CCRVDF and the Risk Assessment Policy for the Setting of MRLs of Veterinary Dugs in Food

1. This Working group met in a face to face meeting on the 6th May 2012 on the afternoon before the 20th Session of the CCRVDF in San Juan (Puerto Rico).

2. This Working group was co-chaired by the France, Japan and the United States of America and with the participation of 25 members and 5 observer organizations, WHO, FAO and the Codex secretariat.

3. The chair reminded that the purpose of this working group is to produce a final document to be presented and discussed at the item 7b on the 20th Session of the CCRVDF. The attached document is the combined results of the work of the electronic Working Group, considering the comments received by e-mail, and of discussion during the current physical working group meeting.

4. The Working Group Co-Chairs noted that some issues are overlapping with:
- the item 5 of the Agenda (CX/RVDF 12/20/5 – "Proposed amendments to the terms of reference of CCRVDF – CL 2010/47-RVDF") ;
- the item 7a of the Agenda (CX/RVDF 12/20/7 – "Proposed amendments to the risk analysis principles applied by the CCRVDF - CL 2010/47-RVDF") ;
- the item 10 of the Agenda (CX/RVDF 12/20/13 – "Risk management recommandations for the veterinary drugs for which no ADI and/or MRL has been recommandaded by JECFA due to specific human health concerns"").

The Co-Chairs further noted that the Codex Secretariat had indicated that both the existing terms of reference, as well as the currently proposed changes to the terms of reference, would provide an adequate framework for the changes being proposed to the risk analysis principles for CCRVDF and that a decision on the language for the terms of reference would not be necessary for the working group to proceed.

As such, the Co-Chairs decided not to discuss terms of reference of the CCRVDF. The terms of reference will be discussed during the plenary session.

5. Annex 1 of the CX/RVDF 12/20/8 has been presented paragraph by paragraph to the floor with the comments received by e-mail. On this basis, all modifications proposed have been discussed in depth. As a result of this work, the Group proposes a final document to the Codex Secretariat (see annex 1).

6. Regarding the proposed revision of the Risk Analysis Principles applied by the Codex committee on residues of veterinary drugs in foods, the Group agrees;

- on the changes on paragraphs 1, 4, 10, 13, 17, 26, 30 and 32 ;

- in the Annex "TEMPLATE FOR INFORMATION REQUIREMENT FOR CONSIDERATION IN THE PRIORITY LIST NECESSARY FOR PRIORITIZATION BY CCRVDF" on changes in the title and in paragraphs 9 and 17;

7. Regarding the proposed revision of the Risk Assesment policy for the setting of maximum limits for residues of veterinary drugs in foods, the Group agrees on the changes on 2b, 2g, 2h, 4 and 5.

8. In annex 1 of this document, the *agreed* modifications listed at points 6 and 7 above are in *italics and underlined.*

9. Some modifications in the proposed revision of the Risk Analysis Principles applied by the Codex committee on residues of veterinary drugs in foods need further consideration by the Committee. These are on 3e, 3f, 11, 19, 21 and 27.

10. The title of the section, Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods needs further consideration by the Committee, as does the proposed FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL/OR REQUEST FOR CLARIFICATION OF CONCERNS.

11. The points listed at points 9 and 10 above are **highlighted in bold grey** in the annex 1 of this document.

12. Details for discussion are :

- **Paragraph 3.** Co-chairs recommended that the specific language on the terms of reference be discussed in the plenary in agenda item 5 and should not be discussed in the working group. A few countries proposed deletion of paragraph 3, suggesting that the terms of reference do not need to be repeated within the risk analysis principles. However, the working group did not reach consensus on this point.

- **Paragraph 11**: As the proposed change is linked with the revision of the risk assessment policy for the setting of maximum limits for residues of veterinary drugs, the working group decided to postpone the discussion regarding paragraph 11 to the decision on this annex and finally was left for discussion in plenary.

- **Paragraph 19.** A member country indicated that the first proposed added sentence may give flexibility and increase efficiency to the risk management options that may be assessed, not only ADIs and MRLs. A change in wording was proposed that "a range of " should be deleted for clarification. It was also discussed that this sentence should be moved to paragraph 17, which is about the ranking of the hazard for risk assessment and risk management priority.Another member country expressed concern regarding the proposed referral of risk management options to JECFA for an evaluation of the science. The working group decided that this sentence should be left for discussion in the plenary. The working group agreed on the deletion of last two added sentences.

- **Paragraph 21.** One member observed that there was a concern regarding the fact that JECFA may recommend temporary MRLs when data are insufficient. This member stated that 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. There was concern expressed by the CODEX and the JECFA secretariat that the proposed provisions about temporary MRLs and temporary ADIs may create confusion. As there were no proposals on the changes in the wording, the point was left for discussion in the plenary.

- **Paragraph 27.** The Working Group discussed the specific bullet points. There were detailed changes in the text that were proposed by two member countries, Some members suggested a need for clarification in the plenary where a written copy may be able to evaluate the wording of the proposed language. The proposed text is provided below

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

- ~~develop~~ **recommend** the MRLs based on the JECFA assessment,

- modif~~y~~**ies** 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 to reconsider the residue evaluation for the veterinary drug in question,

- decline~~s~~ to advance the MRLs based on risk management concerns ***consistent with the Risk Analysis Principles of the Codex Alimentarius or*** *consider~~s~~ and recommend~~s~~ appropriate risk management measures for veterinary drug residues with no ADI/MRL due to* ~~***lack of information or***~~ *specific* ***human*** *health concern, as concluded by JECFA.*

CCRVDF considers the information and recommendations provided by JECFA as well as other ~~***available information***~~ ***legitimate factors*** *in developing these recommended risk management measures. As a result of this consideration, CCRVDF may refer a range of risk management options to JECFA to obtain guidance on the attendant risks and likely risk reductions.*

- **The Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods.** A member country indicated that the change in the title of the document was not necessary and requested that this should be for discussion in the plenary.

- **The WG discussed the "concern form."**

One member of the WG questioned the rationale of developing such a form for CCRVDF. Other members including the WHO secretariat discussed the use of such a form by CCPR.

While there was not agreement that a concern form is necessary among all members of the WG, there was agreement that a concern form could be useful.

Several members of the WG discussed the use of concern form by the CCPR to capture the scientific basis for objections to progressing MRLs through the step process.

One member discussed the potential use of a concern form to articulate and capture concerns that focus the basis of disagreement within CCRVDF, and using the form to serve as a basis to seek consensus and to later assure that issues thought to be resolved are not revisited.

Another member expressed concern that uses of the a concern form could impede, rather than facilitate progression to consensus within the Committee.We did not reach agreement on how the concern form should be used by CCRVDF.

One member proposed a detailed step process for the implementation of the form and solicitation of an evaluation by JECFA. This proposal is provided in the conference room document attached.

Another member proposed a less detailed process that could be captured in the risk analysis principals for CCRVDF in a paragraph or two.

The actual language in the proposed concern form was not discussed by the working group. The working group agreed to refer the text of the concern form to the Committee for discussion.

13. In conclusion, the working group agreed to a number of revisions to the text of the risk analysis principles applied by CCRVDF. The working group also agreed on the usefulness of a concern form by CCRVDF and on the need to discuss how this tool may be used to facilitate the work of the Committee.

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*

Annex 1

1 - Purpose – Scope

1. The purpose of this document is to specify Risk Analysis Principles applied by the Codex Committee on Residues of Veterinary Drugs in Foods. *This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.*

2 - Parties involved

2. The Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius has defined the responsibilities of the various parties involved. The responsibility for providing advice on risk management concerning residues of veterinary drugs lies with the Codex Alimentarius Commission and its subsidiary body, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), while the responsibility for risk assessment lies primarily with the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

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 residue limits (MRLs) for such veterinary drugs;

(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 a veterinary drug, the JECFA recommends no ADI and/or MRL due to specific human health concerns**

4. The CCRVDF shall base its risk management recommendations *in relation to MRLs* to the Codex Alimentarius Commission on JECFA's risk assessments of veterinary drugs.

5. The CCRVDF is primarily responsible for recommending risk management proposals for adoption by the Codex Alimentarius Commission.

6. JECFA is primarily responsible for providing independent scientific advice, the risk assessment, upon which the CCRVDF base their risk management decisions. It assists the CCRVDF by evaluating the available scientific data on the veterinary drug prioritised by the CCRVDF. JECFA also provides advice directly to FAO and WHO and to Member governments.

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.

3 - Risk Management in CCRVDF

8 Risk management should follow a structured approach including:

- preliminary risk management activities;
- evaluation of risk management options; and
- monitoring and review of decisions taken.

9. The decisions should be based on risk assessment, and take into account, where appropriate, other legitimate factors relevant for the health protection of consumers and for fair practices in food trade, in accordance with the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles[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 ;
- Establishment of a preliminary risk profile;
- Ranking of the hazard for risk assessment and risk management priority;
- Commissioning of the risk assessment; and
- ~~*Consideration of the result of the risk assessment.*~~

3.1.1 - Risk Assessment Policy for the Conduct of the Risk Assessment

11. The responsibilities of the CCRVDF and JECFA and their interactions along with core principles and expectations of JECFA evaluations are provided in Risk Assessment Policy for ~~**the Setting of MRLs**~~ **Residues of Veterinary Drugs** in Food, established by the Codex Alimentarius Commission.

3.1.2 - Establishment of Priority List

12. The CCRVDF identifies, with the assistance of Members, the veterinary drugs that may pose a consumer safety problem and/or have a potential adverse impact on international trade. The CCRVDF establishes a priority list for assessment by JECFA.

13. In order to appear on the priority list of veterinary drugs for the establishment of a MRL, the proposed veterinary drug shall meet some or all of the following criteria:

- A Member has proposed the compound for evaluation;
- A Member has established good veterinary practices with regard to the compound;
- The compound has the potential to cause public health and/or international trade problems;
- It is available as a commercial product; and
- There is a commitment that a dossier will be made available.

14. The CCRVDF takes into account the protection of confidential information in accordance with WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) - Section 7: Protection of Undisclosed Information - Article 39, and makes every effort to encourage the willingness of sponsors to provide data for JECFA assessment.

3.1.3 - Establishment of a Preliminary Risk Profile

15. Member(s) request(s) the inclusion of a veterinary drug on the priority list. The available information for evaluating the request shall be provided either directly by the Member(s) or by the sponsor. A preliminary risk profile shall be developed by the Member(s) making the request, using the template presented in the Annex.

16. The CCRVDF considers the preliminary risk profile and makes a decision on whether or not to include the veterinary drug in the priority list.

3.1.4 - Ranking of the Hazard for Risk Assessment and Risk Management Priority

17. The CCRVDF establishes an ad-hoc Working Group open to all its Members and observers, to make recommendations on the veterinary drugs to include into (or to remove from) the priority list of veterinary drugs for the JECFA assessment. *The ~~ad-hoc~~ Working Group also develops and recommends to CCRVDF the questions to be answered by the JECFA Risk Assessment.* The CCRVDF considers these recommendations before agreeing on the priority list, taking into account pending issues such ~~*as temporary Acceptable Daily Intakes (ADIs) and/or MRLs*~~. In its report, the CCRVDF shall specify the reasons for its choice and the criteria used to establish the order of priority.

18. ~~*Prior to development of MRLs for new veterinary drugs not previously evaluated by JECFA, a proposal for this work shall be sent to the Codex Alimentarius Commission with a request for approval as new work*~~ *CCRVDF forwards the agreed priority list of veterinary drugs for the JECFA assessment to the Codex Alimentarius Commission for new work* in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts.

3.1.5 - Commissioning of the Risk Assessment

19. After approval by the Codex Alimentarius Commission of the priority list of veterinary drugs as new work, the CCRVDF forwards it to JECFA with the qualitative preliminary risk profile as well as specific guidance on the CCRVDF risk assessment request. JECFA, WHO and FAO experts then proceed with the assessment of risks related to these veterinary drugs, based on the dossier provided and/or all other available scientific information. **CCRVDF may also refer risk management options, with a view toward obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option.**

~~3.1.6~~ 3.2 - Consideration of the Result of the Risk Assessment

20. When the JECFA risk assessment is completed, a detailed report is prepared for the subsequent session of the CCRVDF for consideration. This report shall clearly indicate the choices made during the risk assessment with respect to scientific uncertainties and the level of confidence in the studies provided.

21. When the data are insufficient, JECFA may recommend temporary MRL on the basis of a temporary ADI using additional safety considerations[2]. If JECFA cannot propose an ADI and/or MRLs due to lack of data, its report should clearly indicate the gaps and a timeframe in which data should be submitted, in order to allow Members to make an appropriate risk management decision.

22. The JECFA assessment reports related to the concerned veterinary drugs should be made available in

sufficient time prior to a CCRVDF meeting to allow for careful consideration by Members. If this is, in exceptional cases, not possible, a provisional report should be made available.

23. JECFA should, if necessary, propose different risk management options. In consequence, JECFA should present, in its report, different risk management options for the CCRVDF to consider. The reporting format should clearly distinguish between the risk assessment and the evaluation of the risk management options

24. The CCRVDF may ask JECFA for any additional explanation.

25. Reasons, discussions and conclusions (or the absence thereof) on risk assessment should be clearly documented, in JECFA reports, for each option reviewed. The risk management decision taken by the CCRVDF (or the absence thereof) should also be fully documented.

~~3.2~~ 3.3 - Evaluation of Risk Management Options

26. The CCRVDF shall proceed with a critical evaluation *of outcomes* of the JECFA *risk assesment including the* proposals on MRLs and may consider other legitimate factors relevant for health protection and fair trade practices in the framework of the risk analysis. According to the 2nd statement of principle, the criteria for the consideration of other factors should be taken into account. These other legitimate factors are those agreed during the 12th session of the CCRVDF[3] and subsequent amendments made by this Committee.

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

- ~~developp~~ **recommend** the MRLs based on the JECFA assessment,

- modif**y** 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 to reconsider the residue evaluation for the veterinary drug in question,

- declines to advance the MRLs based on risk management concerns consistent with the Risk Annalys Principles of the Codex Alimentarius or considers and recommends appropriate risk management measures for veterinary drug residues with no ADI/MRL due to specific human health concern, as concluded by JECFA.

CCRVDF considers the information and recommendations provided by JECFA as well as other legitimate factors in developing these recommended risk management measures. As a result of this consideration, CCRVDF may refer a range of risk management options to JECFA to obtain guidance on the attendant risks and likely risk reductions.

28. Particular attention should be given to availability of analytical methods used for residue detection.

~~3.3.~~ 3.4 - Monitoring and Review of the Decisions Taken

29. Members may ask for the review of decisions taken by the Codex Alimentarius Commission. To this end, veterinary drugs should be proposed for inclusion in the priority list. In particular, review of decisions may be necessary if they pose difficulties in the application of the ~~*Guidelines for the Establishment of a Regulatory Programme for the Control of Veterinary Drug Residues in Foods (CAC/GL 161993)*~~ *Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the use of Veterinary Drugs in Food Producing Animals (CAC/GL71-2009).*

30. The CCRVDF may request JECFA to review any new scientific knowledge and other information relevant to risk assessment and concerning decisions already taken, including the established MRLs. *The CCRVDF should review and update standards or related texts for veterinary drugs in food, as necessary, in the light of new scientific information.*

31. The risk assessment policy for MRL shall be reconsidered based on new issues and experience with the risk analysis of veterinary drugs. To this end, interaction with JECFA is essential. A review may be undertaken of the veterinary drugs appearing on prior JECFA agendas for which no ADI or MRL has been recommended.

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 to Members. The CCRVDF recognises that communication between risk assessors and risk managers is critical to the success of risk analysis activities.

33. In order to ensure the transparency of the assessment process in JECFA, the CCRVDF provides comments on the guidelines related to assessment procedures being drafted or published by JECFA.

ANNEX

TEMPLATE FOR INFORMATION *RECOMMENDED FOR CONSIDERATION IN THE PRIORITY LIST* ~~*NECESSARY FOR PRIORITIZATION*~~ BY CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Administrative information

1. Member(s) submitting the request for inclusion
2. Veterinary drug names
3. Trade names
4. Chemical names *and CAS registry number*
5. Names and addresses of basic producers

Purpose, scope and rationale

6. Identification of the food safety issue (residue hazard)
7. Assessment against the criteria for the inclusion on the priority list

Risk profile elements

8. Justification for use
9. Veterinary use pattern*, including information on approved uses if available*
10. Commodities for which Codex MRLs are required

Risk assessment needs and questions for the risk assessors

~~*11. Identify the feasibility that such an evaluation can be carried out in a reasonable framework*~~

11. Specific request to risk assessors

Available information[4]

12. Countries where the veterinary drugs is registered
13. National/Regional MRLs or any other applicable tolerances
14. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available Timetable
15. Date when data could be submitted to JECFA

[4] When preparing a preliminary risk profile, Member(s) should take into account the updated data requirement, to enable evaluation of a Veterinary drug for the establishment of an ADI and MRLs, published by JECFA

PROPOSED REVISION OF THE

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

Role of JECFA

1 The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an independent scientific expert body convened by both Directors-General of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on veterinary drug residues in food.

2 This annex applies to the work of JECFA in the context of Codex and in particular as it relates to advice requests from the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF).

(a) JECFA provides CCRVDF with science-based risk assessments conducted in accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius and incorporating the four steps of risk assessment. JECFA should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and proposing Maximum Residues Limits (MRLs), *and/or responding to other questions from the CCRVDF.*

(b) JECFA should take into account all available scientific data *and assesment* ~~to establish its~~ *in conducting the* risk assessment. It should use available quantitative information to the greatest extent possible and also qualitative information.

(c) Constraints, uncertainties and assumptions that have an impact on the risk assessment need be clearly communicated by JECFA.

(d) JECFA should provide CCRVDF with information on the applicability, public health consequences and any constraints of the risk assessment to the general population and to particular sub-populations and, as far as possible, should identify potential risks to specific group of populations of potentially enhanced vulnerability (e.g. children).

(e) Risk assessment should be based on realistic exposure scenarios.

(f) When the veterinary drug is used both in veterinary medicine and as a pesticide, a harmonised approach between JECFA and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) should be followed.

(g) MRLs, that are compatible with the ADI, should be ~~*set*~~ *recommended* for ~~*all species*~~ *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* based on appropriate consumption figures. When requested by CCRVDF, extension of MRLs between species will be considered if appropriate data are available.

(h) When scientific data are insufficient to complete an evaluation, JECFA should indicate the data gaps and propose a timeframe in which data should be submitted. JECFA may also recommend guidance according to point 10 of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

Data Protection

3 Considering the importance of intellectual property in the context of data submission for scientific evaluation, JECFA has established procedures to cover the confidentiality of certain data submitted. These procedures enable the sponsor to declare which data is to be considered as confidential. The procedure includes a formal consultation with the sponsor.

Expression of risk assessment results in terms of MRLs

4 MRLs have to be established for *relevant* 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.

5. However, if residue levels in various target tissues are very different, JECFA is requested to consider MRLs for a minimum of two. In this case, the establishment of MRLs for muscle or fat is preferred to enable the ~~control~~ *verification* of the safety of carcasses moving in international trade.

6. When the calculation of MRLs to be compatible with the ADI may be associated with a lengthy withdrawal period, JECFA should clearly describe the situation in its report.

7. JECFA should provide a clear explanation and rationale for its conclusions and recommendations. This is particularly important 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.

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

- Submitted by:

- Date:

- Veterinary drugs concerned:

- Commodity

- MRL (mg/kg)

- Present Step

- Is this a Request for Clarification?

- Is this a new Concern?

- Is this a Continuing Concern?

- Concern (Specific statement of reason for concern to the advancement of the proposed MRL).

- Request for Clarification (Specific statement of clarification requested).

- Proposed solution

- Do you wish this Concern to be Noted in the CCRVDF Report?

- Background materials attached?

RVDF 20/CRD2

codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 7b **CRD**
May 2012

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOOS
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 (CX/RVDF 12/20/8)

Brazil comments

1. In 2010 the CCEXEC recommended to the 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. A "concern form" had been introduced by the CCPR in 2006, which made CCPR's decisions more transparent and helped to advance a number of proposed MRLs.

2. 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.*

3. In 2012 the 27th CCGP asked the advice of the concerned Committees, including the CCRVDF, to the relevance of using concern forms, recognizing that this form may be modified to be applicable.

4. The use of a "concern form" facilitates the progress of Codex standards as it ensures that objections are science-based and have supporting information. It also avoids the delay in advancing MRLs by last minute objections at the session without any legitimate reason taking into account the principles of Codex. Confusion should be avoided between justification of national measures and their validity at the international level.

5. As already recommended by the CCEXEC and CCGP, Brazil strongly supports the adoption of a "concern form" by the CCRVDF as already discussed during the EWG on the *Revision of the Risk Assessment Policy for the setting of Maximum Limits for Residues of Veterinary Drugs in Foods* and proposes the following procedures for its use:

• objections to MRLs must be submitted on the required form before or during the CCRVDF Session; the process would be greatly facilitated if objections were lodged at least one month prior to the session along with all other comments;

• objections described in the "concern form" must have supporting data or scientific information available for a JECFA review. The data or information must be complete and not a summary statement or synopsis;

• the data or information must be made available at the latest within 1 month after the CCRVDF meeting to the appropriate JECFA Secretariat and the Chair of the CCRVDF must be informed of the submission to the JECFA Secretariat;

• the JECFA Secretariat should schedule the objection for a JECFA review before the next CCRVDF meeting;

• if the objector fails to meet the 1 month deadline for submission of the data/information the relevant draft MRL(s) will be advanced according to the normal Step procedure.

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

- Submitted by:

- Date:

- Veterinary drugs concerned:

- Commodity:

- MRL (mg/kg):

- Present Step:

- Is this a Request for Clarification?

- Is this a new Concern?

- Is this a Continuing Concern?

- Concern (Specific statement of reason for concern to the advancement of the proposed MRL):

- Request for Clarification (Specific statement of clarification requested):

- Proposed solution:

- Do you wish this Concern to be Noted in the CCRVDF Report?

- Background materials attached?