CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 7(b) **CX/RVDF 12/20/8**

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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*

(Report of the CCRVDF Electronic 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, led by France, Japan and the United States of America with the assistance of Argentina, Australia, Belgium, Brazil, Canada, the European Union, Finland, Germany, Ghana, Hungary, Ireland, Jamaica, Lesotho, the Netherlands, New Zealand, Norway, Sweden, Switzerland, Thailand, the United Kingdom, and IFAH)

Governments and international organizations wishing to submit comments on the proposed draft revision of the Risk Analysis Principles Applied by the CCRVDF and Risk Assessment Policy for the Setting of MRLVDs (see Annex 1) are invited to do so **no later than 31 March 2012** as follows: U.S. Codex Office, Food safety and Inspection Service, US Department of Agriculture, Room 4861, South Building, 14th Independence Avenue, S.W., Washington DC 20250, USA (Telefax: +1 202 720 3157 ; or ***preferably*** E-mail: CCRVDF-USSEC@fsis.usda.gov , with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Telefax: +39.06.5705.4593; E-mail: Codex@fao.org, ***preferably***).

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in Annex 3 to this document.

1. The Electronic Working group on the Revision of the Risk Analysis Principles Applied by the CCRVDF and Risk Assessment Policy for the Setting of MRLVDs has considered the tasks assigned to it arising from the 19th CCRVDF meeting. At the 19th Session of the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), which met in Burlington, USA – 30th August-3rd September 2010, the Committee agreed to establish an electronic working group, co-chaired by France, Japan and the United States of America, open to all interested Members and observers and working in English only. The Committee assigned to the eWG several tasks (*see* REP11/RVDF – para. 13-15, 18, 101, 110, 141-144), arising from discussions held under Agenda items 2, 8, 9. The terms of reference of the eWG are found in para. 142 of the report. The terms of reference call for the development of an electronic working document pursuant to Activity 2.2 of the Codex Strategic plan;

1. *Revising and updating, as appropriate, the current Risk analysis principles applied by the CCRVDF (p. 101 - Procedural Manual 19th edition, English version) and the Risk assessment policy for the setting of Maximum Limits for Residues of Veterinary Drugs in Foods(MRLVDs) (p.107);*
2. *Special emphasis shall be given to:*
    a. *revising Section 3.2 'Evaluation of risk management options' in order to provide JECFA with specific directions, together with their rationale, on how to generate and submit for consideration by the Committee a range of acceptable values for each MRL to be established;*

b. *Developing risk management and risk communication recommendations for veterinary drugs for which no ADI or MRL have been recommended by JECFA either due to specific human health concerns or a lack of information.*

In addition, the eWG considered the use of a concern form and related procedures for when there are disagreements with a recommended MRL, described in ALINORM 06/29/24 – para. 42 & Appendix X ftp://ftp.fao.org/codex/Alinorm06/al29_24e.pdf (REPORT OF THE THIRTY-EIGHTH SESSION OF THE CODEX COMMITTEE ON PESTICIDE RESIDUES – Fortaleza, Brazil, 3 - 8 April 2006) *(see REP11/RVDF – para.18).*

2. The eWG provided comments through email and through the use of a shared internet site provided through assistance by the United Kingdom.

3. The eWG has provided comments and suggestions that have led to the development of draft documents to address these charges. The Co-Chairs of Electronic Working group on the Revision of the Risk Analysis Principles Applied by the CCRVDF and Risk Assessment Policy for the Setting of MRLVDs have developed a draft revision of the risk analysis principles and risk assessment policy that can serve as the basis for discussion during our physical working group meeting in advance of the 20th CCRVDF. This draft is in Annex 1.

4. The Annex 1 draft takes into account the comments received from the eWG, but the eWG has not had the opportunity to review and comment on this draft. In addition it is recognized that while all comments were considered, the draft does not necessarily reflect the position of all members of the eWG. Accordingly, the co-chairs also provide as background the tabular document we have been using as the basis for our discussions, updated to include all of the comments provided by members of the eWG to the draft proposal provided on August 2, 2011. The table is provided in Annex 2. The co-chairs anticipate that this document will provide background to help move our discussions forward during the physical meeting of the eWG.

5. The table contains:

Column 1	The original text of the Risk Analysis Principles Applied by the CCRVDF and Risk Assessment Policy for the Setting of MRLVDs as provided in the Codex Procedure Manual.
Column 2	Original comments received from the eWG members on the existing text in the Procedural Manual. Comments on the Co-Chairpersons' proposal in the August 2, 2011, email
Column 3	Edits proposed by the Co-Chairpersons in the August 2, 2011, email.

6. Furthermore, the Co-Chairs note that the comments regarding CL 210/47-RVDF and the proposed changes to the Terms of Reference for CCRVDF will provide important context for the discussion during the physical meeting. Members are encouraged to consider the response to CL 210/47-RVDF in addition to the material provided in the current document.

Annex 1

PROPOSED REVISION OF THE

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

(for comments)

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 to the Codex Alimentarius Commission on JECFA's risk assessments of veterinary drugs ~~*in relation to proposed MRLs*~~.

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 *in the integrity of the food chain*;

- 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 *or there is a commitment that such commercial availability is pending*; 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.

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[1] Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors are Taken into Account, Codex Procedural Manual Appendix

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 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.*

3.1.6 - 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 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.

[2] Definition of "Codex maximum limit for residues of veterinary drugs", Codex Procedural Manual

3.2 - Evaluation of Risk Management Options

26. The CCRVDF shall proceed with a critical evaluation of the JECFA 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*~~

- *develops* the MRLs *based on the* JECFAassessment,
- 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 JECFA for reconsideration of the residue evaluation for the veterinary drug in question,
- *decline to advance the MRLs based on risk management concerns* or
- *considers and recommends 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.*

  CCRVDF considers the information and recommendations provided by JECFA as wel as other available relevant information 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 - 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 16-1993)*~~ *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.

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 *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.*

[3] ALINORM 01/31 paragraph 11.

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. *The CCRVDF should review and update standards or related texts for veterinary drugs in food, as necessary, in the light of newly generated scientific data.*

ANNEX

TEMPLATE FOR INFORMATION 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
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
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
12. Specific request to risk assessors

Available information[4]

13. Countries where the veterinary drugs is registered
14. National/Regional MRLs or any other applicable tolerances
15. List of data (pharmacology, toxicology, metabolism, residue depletion, analytical methods) available

Timetable

16. Date when data could be submitted to JECFA
17. *The prospect of completing the work within a reasonable period of time*

[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, *including data used by national/regional authorities to set their standards, if they are* to establish its 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 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 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 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 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.

Expression of risk assessment results in terms of MRLs.

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?

Annex 2

RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Original Text	Comments received from eWG members	Proposal for modification by co-chairpersons as of 2August 2011
	COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011 (COMMENT BY GERMANY) I fully agree with the idea that CCRVDF should consider in future "other matters in relation to the safety of food containing veterinary residues". We have further decided in Burlington that the risk analysis principles should be revised in the sense that risk management recommendation should be developed for veterinary drugs for which no ADI/MRL has been forwarded by JECFA (142. ii second bullet point). I have to regret that I have my doubts about several proposals to amend the text in the sense whether they are covered by the terms of reference of the ewg (e.g. page 5, No.11). When reading the amendments on page 13 (27bis) and page 25 h) and 7, my impression is that the role of JECFA will be weakened. To my understanding this would be a point of fundamental implication which should be discussed frankly and more in general. In consequence I am of the opinion that several amendments are not needed and should be deleted. Furthermore - when looking at the comments- it seems obvious that there is a link to the work of the ewg which which develops risk management options for vet. drugs without ADI/MRL. This should be taken into consideration.	
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.	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY CANADA) "This document also applies to veterinary drug residues in food originating from the presence of residues of veterinary drugs in animal feeds where it can affect food safety." ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY IFAH) We feel that the proposed addition is unnecessary in view of point number 2, which attributes the respective responsibilities to the parties involved. In respect to the comment offered by Canada we feel that this is outside the Codex definition of a veterinary drug and would fall into the category of 'contaminant', thus it would not be a matter for CCRVDF. (COMMENT BY EU) Add the following new paragraph with the footnote:	1-bis This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

Original Text	Comments received from eWG members	Proposal for modification by co-chairpersons as of 2August 2011
	This document also applies to residues of veterinary drugs in food originating from the use of veterinary drugs in feed1 where it can affect food safety. 1 The term "feed" refers to both "feed (feedingstuffs)" and "feed ingredients" as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 054 2004) Rationale: This paragraph was agreed at the 19th session of CCRVDF and is contained in Appendix II of the meeting report REP11/RVDF. There is also an ongoing consultation with CL 2010/47-RVDF (Part C) to include this paragraph in the CCRVDF risk analysis policy. (COMMENT BY JAPAN) It is not necessary to add the new paragraph with the footnote as following EU comment. Rationale: The current Risk Analysis Principles were appropriate to allow the Committee to address animal feeding in the framework of its terms of reference and, therefore, it was not necessary to amend them. （Refer to the paragraph 10 in the REP11/RVDF）	
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).		No modification.
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;	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY CANADA) (e) to consider other matters in relation to the safety of food and feed containing residues of veterinary drugs	*Add points (e) and (f) as follows:* (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

Original Text	Comments received from eWG members	Proposal for modification by co-chairpersons as of 2August 2011
(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.	(COMMENT BY USA) (e) to make recommendations regarding the safety of residues of veterinary drugs in food (COMMENT BY JAPAN) (e) to consider other matters in relation to the safety of food containing veterinary drug residues. (COMMENT BY FRANCE) (f) to develop communication recommendation when after assessment of a veterinary drug, the JECFA recommends no ADI and/or MRL due to specific human health concerns. ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY EU) This paragraph will have to be aligned with the revised terms of reference which are being consulted with CL 2010/47-RVDF (Part C). At this stage, the EU would like to propose adding the term "feed" in the new proposed point e as follows: (e) to consider other matters in relation to the safety of food and feed containing residues of veterinary drugs and make relevant recommendations. (COMMENT BY IFAH) Whilst we do not disagree with the proposed added text, we feel that adding it to the CCRVDF risk analysis principles requires prior approval of the changed mandate of CCRVDF by the Codex Alimentarius Commission. (COMMENT BY JAPAN) It is not necessary to revise the paragraph as following EU comment. Rationale: The current Risk Analysis Principles were appropriate to allow the Committee to address animal feeding in the framework of its terms of reference and, therefore, it was not necessary to amend them. （Refer to the paragraph 10 in the REP11/RVDF） (COMMENT BY USA) The United States suggests deleting paragraph 3 because it is not necessary. It repeats the Committee's Terms of Reference, and if a question were raised about CCRVDF responsibilities for risk analysis or any other topic, it would be settled by a review of the Terms of Reference, which appear elsewhere in the Codex Procedural Manual. Therefore, repeating the text in this document serves no purpose and creates the potential for extra work for the Committee, because any change in the TORs would necessitate a revision of the Risk Analysis document.	communication recommendations when after assessment of a veterinary drug, the JECFA recommends no ADI and/or MRL due to specific human health concerns

Original Text	Comments received from eWG members	Proposal for modification by co-chairpersons as of 2August 2011
4. The CCRVDF shall base its risk management recommendations to the Codex Alimentarius Commission on JECFA's risk assessments of veterinary drugs in relation to proposed MRLs.	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY USA) 4. The CCRVDF shall base its risk management recommendations to the Codex Alimentarius Commission on JECFA's INDEPENDANT SCIENTIFIC ADVICE ON RESIDUES OF VETERINARY DRUGS. ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** *(*COMMENT BY *USA)* The United States has amended paragraph 4 to include an important reference to the *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.* These principles from the Procedural Manual guide all Codex committees on risk management and risk communication and delineate the role of the Codex Alimentarius Commission versus the role of National Governments. As amended the section would read: *The CCRVDF shall base its risk management recommendations to the Codex Alimentarius Commission on JECFA's risk assessments of veterinary drugs in relation to proposed MRLs. CCRVDF will develop the risk management and communication recommendations in accordance with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.*	*No modification.*
5. The CCRVDF is primarily responsible for recommending risk management proposals for adoption by the Codex Alimentarius Commission.		*No modification.*
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.	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY CANADA) Para #6 of the Risk Analysis Principles should be made consistent with para #23 where it states that JECFA should present different risk management options for CCRVDF to consider. (COMMENT BY FRANCE) See alternative proposals for para.23.	*No change in point 6 but consistency is made at new paragraph 23 a*
7. Scientific experts from JECFA are selected in a transparent manner by FAO and WHO under their rules for expert		*No modification.*

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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 Principles28.		
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	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY CANADA) - ~~Consideration of the result of the risk assessment.~~ ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY EU) Add the following to the second indent: - Identification of a food safety problem in the integrity of the food chain and determine if feed may be a source of the food safety problem Rationale: This addition is proposed in Appendix II of the meeting report of the 19th	*Delete last dash point:* - ~~Consideration of the result of the risk assessment.~~

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and risk management priority; - Commissioning of the risk assessment; and - Consideration of the result of the risk assessment.	session of CCRVDF (REP11/RVDF) and is being consulted with CL 2010/47-RVDF (Part C). The EU supports the proposed addition. (COMMENT BY JAPAN) It is not necessary to revise the second indent as following EU comment. Rationale: The current *Risk Analysis Principles* were appropriate to allow the Committee to address animal feeding in the framework of its terms of reference and, therefore, it was not necessary to amend them. （Refer to the paragraph 10 in the REP11/RVDF） *Delete last dash point and amend as follows:* - Ranking of the hazard for risk assessment and risk management priority; and - Commissioning of the risk assessment. - ~~Consideration of the result of the risk assessment.~~ It is necessary to move the print of '; and'.	
3.1.1 - Risk Assessment Policy for the Conduct of the Risk Assessment	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY ARGENTINA) To be inserted: Annex on RISK ASSESSMENT POLICY FOR THE SETTING OF MAXIMUM LIMITS FOR RESIDUES OF VETERINARY DRUGS IN FOODS	*No modification.*
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 in Food, established by the Codex Alimentarius Commission.	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY USA) 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 EVALUATION OF THE SAFETY OF RESIDUES OF VETERINARY DRUGS in Food, established by the Codex Alimentarius Commission. (COMMENT BY CANADA) Provisions should be made in the Risk Assessment Policy for JECFA to explore options of using various data sources including those used by National authorities to set national standards, if they could meet minimal JECFA standard. Criteria may need to be elaborated to define which compounds could qualify for such elaboration. ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY IFAH) IFAH strongly supports the proposed change as we consider it important to allow the	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 **residues of veterinary drugs** in Food, established by the Codex Alimentarius Commission. **Provisions should be made in the Risk Assessment Policy for JECFA to explore options of using various data sources including those used by National authorities to set national standards, if they could meet minimal JECFA standard. Criteria may need to be elaborated to define which compounds could qualify for such elaboration.**

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	review of national assessments. This would facilitate adoption of MRLs for older drugs at Codex. *(*COMMENT BY *USA)* The United States has updated the references in paragraph 11. In addition, we believe that the country comments in paragraph 11 would be more appropriately handled under 3.1.5 – Commissioning of the Risk Assessment (paragraph 19). This section relates to the risk assessment to be performed by JECFA and the communication of instructions from CCRVDF to JECFA regarding the bounds of the risk assessment, which follows Codex procedure. The United States has included 2 new paragraphs in 19 which we believe convey the essential elements of what the eWG wanted to achieve with its comments in paragraph 11. The new section in paragraph 19 as amended would read: ***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 the list 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.* *19 bis JECFA may use various data sources including those used by national authorities to set national standards, if they meet minimal JECFA standards. Criteria may be elaborated to define which compounds could qualify for such elaboration.* *19 bis bis 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.*	
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	***<u>COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011</u>*** (COMMENT BY IFAH) IFAH suggests that the restriction for veterinary drugs to be available as a commercial product as a pre-condition for prioritization should be removed. If the compound from a Sponsor is progressing along a regulatory path, a concurrent review by JECFA would be warranted and would ensure availability of relevant data sets. IFAH supports everything possible to speed up the Codex process for the establishment of MRLs for veterinary products. *(*COMMENT BY *USA)*	*No modification.*

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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	The United States believes in order to increase international harmonization and to keep the Committee at the forefront of developments in veterinary drugs that it is important to allow the Committee to evaluate veterinary drugs prior to their registration in a country. This affords countries the ability, when registration takes place, to harmonize their MRL with that of Codex. For this reason we have amended paragraph 13 to include the reference “or there is a commitment that such commercial availability is pending”. The paragraph as amended would read: *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 or there is a commitment that such commercial availability is pending; and* *- There is a commitment that a dossier will be made available.*	

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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 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.	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY USA) 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 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. ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY JAPAN) 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. **The ad-hoc Working group also develops and recommends to CCRVDF the questions to be answered by the JECFA Risk Assessment.** The additional sentence is not related to the priority list of veterinary drugs. Therefore it is better to move the sentence to the last in this paragraph. *(*COMMENT BY *USA)* The United States has amended paragraph 17 to allow the ad-hoc Working Group to develop and recommend the questions to be answered by the JECFA risk assessment. We have also deleted the reference to temporary ADI's and MRL's as the Codex Committee on General Principles has ruled that Codex does not publish temporary ADI's or MRL's. The paragraph as amended would read: *17. The CCRVDF establishes an ad-hoc Working Group open to all Members and observers, to make recommendations on the veterinary drugs to include into (or remove*	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.

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	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. 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 in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts.	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY USA) 18. Prior to development of A RISK ASSESSMENT 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 in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts. ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY EU) Replace the text of paragraph 18 with the following: CCRVDF forwards the agreed priority list to the Codex Alimentarius Commission for approval as new work. Rationale: The proposed new text reflects the existing procedure for the approval of new substances for CCRVDF agenda. (COMMENT BY USA) The United States has amended paragraph 17 to reflect the role of CCRVDF, which is to request a risk assessment from JECFA. The original text as written leads the reader to believe that the Committee can only request the establishment of MRL's from JECFA. The paragraph as amended would read: 18. Prior to the development of a risk assessment 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 in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts.	18. Prior to development of ~~MRLs~~ **a risk assessment** 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 in accordance with the Procedures for the Elaboration of Codex Standards and Related Texts. 18 . Prior to development of MRLs or other recommendations for new veterinary drug..(unchanged existing §18)
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	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY FRANCE) CCRVDF may also refer a range of risk management options, with a view toward	19-bis. **CCRVDF may also refer a range of risk management options, with a view toward obtaining JECFA's guidance on**

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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.	obtaining JECFA's guidance on the attendant risks and the likely risk reductions associated with each option. ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY EU) In principle, the EU agrees with the new proposed paragraph 19 bis. However, it should be placed after paragraph 17 to become 17 bis because after the approval of the priority list by the CAC it is too late for CCRVDF to formulate additional questions for JECFA. (COMMENT BY IFAH) IFAH supports this addition but strongly encourages the inclusion of additional language such as "however, these risk management options must remain within the scope of the JECFA/CCRVDF authority as an advisory body without infringing the mandate and responsibilities of regulatory authorities (such as "do not use in food-producing animals"), as JECFA/CCRVDF does not have this mandate. (COMMENT BY USA) Please see comments for paragraph 11, which explain the rationale of the United States for the changes to paragraphs 11 and 19..	**the attendant risks and the likely risk reductions associated with each option.**
3.1.6 - 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.		*No modification.*
	ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS (COMMENT BY CANADA) **3.2 - Consideration of the Result of the Risk Assessment** **3.3 - Evaluation of Risk Management Options** **3.4 - Monitoring and Review of the Decisions Taken**	*section 3.1.6 becomes section 3.2,* *section 3.2 becomes section 3.3* *section 3.3 becomes section 3.4*

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21. When the data are insufficient, JECFA may recommend temporary MRL on the basis of a temporary ADI using additional safety considerations29. 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.	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY ARGENTINA) 21. When the data are insufficient, ~~JECFA may recommend temporary MRL on the basis of a temporary ADI using additional safety considerations29~~. 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.	*No modification.*
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.		*No modification.*
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	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY FRANCE) 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~~ 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.	23. JECFA should, if necessary, assess different risk management options when CCRVDF requests JECFA's guidance on the attendant risks and the likely reduction associated with each option.
	ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS (COMMENT BY USA) 23a WHEN REQUESTED BY CCRVDF OR WHEN DEEMED APPROPRIATE BY THE JECFA, AND AS NEEDED BASED ON THE RISK ASSESSMENT, THE REPORT MAY PROVIDE RISK MANAGEMENT RECOMMENDATIONS IN ADDITION TO, OR IN LIEU OF, MRLs TO ADDRESS THE SAFETY OF RESIDUES OF VETERINARY DRUGS	23-bis. When requested by CCRVDF or when deemed appropriate by JECFA, and as needed based on the risk assessment, the report may provide risk management recommendations in addition to, or in lieu of, MRLs to address the safety of residues of veterinary drugs.

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	COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011 (COMMENT BY *USA)* The United States has amended paragraph 23 to reflect the role of JECFA in providing guidance to the Committee on risk and risk reduction and added a new paragraph 23 bis to clarify the reporting obligations of JECFA. As amended the paragraph would read: *23. JECFA should, if necessary, propose and assess different risk management options with a view toward providing guidance on the attendant risks and the likely risk reductions associated with each option. The reporting format should clearly distinguish between risk assessment and the evaluation of the risk management options.* *When requested by CCRVDF or when deemed appropriate by JECFA, and as needed based on the risk assessment, the report may provide risk management recommendations in addition to, or in lieu of, MRL's to address the safety of residues of veterinary drugs.*	
24. The CCRVDF may ask JECFA 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.		*No modification.*
3.2 - Evaluation of Risk Management Options	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY FRANCE) "Where after assessment of a veterinary drug, the JECFA recommends no ADI and/or MRL due to specific human health concerns, risk management and communication recommendations should be developed by CCRVDF"	**3.3 - Evaluation of Risk Management Options** *No other modification (only number of the chapter).*
26. The CCRVDF shall proceed with a critical evaluation of the JECFA 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	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY USA) 26. The CCRVDF shall proceed with a critical evaluation of the JECFA INDEPENDANT SCIENTIFIC ADVICE INCLUDING PROPOSED 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	26. The CCRVDF shall proceed with a critical evaluation of the JECFA **independent scientific advice including proposed** ~~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

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factors should be taken into account. These other legitimate factors are those agreed during the 12th session of the CCRVDF30 and subsequent amendments made by this Committee.	legitimate factors are those agreed during the 12th session of the CCRVDF30 and subsequent amendments made by this Committee. 26a IN ORDER TO FACILITATE THIS EVALUATION, CCRVDF ESTABLISHES A WORKING GROUP, OPEN TO ALL ITS MEMBERS AND OBSERVERS, TO CONSIDER THE JECFA RECOMMENDATIONS AND TO PROVIDE RISK MANAGEMENT RECOMMENDATIONS TO THE CCRVDF. ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY EU) 26. The CCRVDF shall proceed with a critical evaluation of the JECFA assessment…The EU supports this version of paragraph 26 because the term "JECFA assessment" covers all possible JECFA recommendations. *(*COMMENT BY *USA)* The United States has amended paragraph 26 to reflect the independence of JECFA scientific advice and to update the references to the Procedural Manual. As amended the paragraph would read: *26. The CCRVDF shall proceed with a critical evaluation of JECFA's independent scientific advice including proposed MRLs and may consider other legitimate factors relevant for health protection and fair trade practices in the framework of the risk analysis. Taking into account the Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to Which Other Factors Are Taken Into Account including the Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle.*	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 CCRVDF30 and subsequent amendments made by this Committee. 26a. The CCRVDF shall proceed with a critical evaluation of the JECFA assessment…
27. The CCRVDF either recommends the MRLs as proposed by JECFA, modifies them in consideration of other legitimate factors, considers other measures or asks JECFA for reconsideration of the residue evaluation for the veterinary drug in question.	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY JAPAN) <<For veterinary drugs with no ADI/MRL due to lack of information>> 27-bis. The CCRVDF considers and develop temporary MRLs [See note below] for veterinary drugs for which no ADI and/or MRLs are recommended by JECFA due to lack of information, taking into account regional and/or national MRLs and risk assessment data supporting such national/regional MRLs for the substances concerned. To facilitate renew of temporary MRLs to formal Codex MRLs, members are encouraged to provide new or additional data for JECFA re-evaluation of the substances concerned to revise or maintain the MRLs. (Note: The CAC endorsed the position of the 23rd CCGP regarding the adoption of "temporary or interim" MRLs, now in Codex, reference to "temporary" is no more used.	27. The CCRVDF either **develops** ~~recommends~~ the MRLs as **assessed** ~~proposed~~ by JECFA, modifies them in consideration of other legitimate factors, ~~considers other measures, or~~ asks JECFA for reconsideration of the residue evaluation for the veterinary drug in question **or declines to advance the MRLs based on risk management concerns.** **27-bis** **The CCRVDF considers and recommends appropriate risk**

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	So in this e-WG work, we have to consider using other term to explain the status of this type of MRLs. Otherwise we have to elaborate an explanatory note indicating that this type of MRLs are provisional and in an appropriate time frame, they are supposed to be reviewed, taking into account risk assessment made by JECFA using new/additional data. <<For veterinary drugs with no ADI/MRL due to specific health concerns>> 27ter. For veterinary drugs for which no ADI and/or MRLs are recommended by JECFA due to specific health concern, the CCRVDF considers and develops appropriate risk management options to protect health of consumer. Such risk management options include "ban for use", "shall not be contained in any commodity", "setting action limit for control purpose" and/or "restriction to market foods from treated animals".	**management measures for veterinary drug residues with no ADI/MRL due to lack of information or specific health concern, as concluded by JECFA. CCRVDF considers the information and recommendations provided by JECFA as well as all other available relevant information 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.**
	(COMMENT BY THAILAND) 1. Regarding to the question on what subjects or issue to be addressed, generally, we are of the opinion that the section on risk assessment policy should be revised to include guidance or criteria for JECFA to conduct risk assessment of veterinary drugs which have long history of safe use but sufficient data have not been supported by manufacturers. 2. Para 27 of the CCRVDF Rick Analysis Principles, "The CCRVDF either recommends the MRLs as proposed by JECFA, modifies them in consideration of other legitimate factors, considers other measures or asks JECFA for reconsideration of the residue evaluation for the veterinary drug in question." We are of the view that the words "considers other measures" mentioned in para 27 should be further clarified or, if necessary, amended since it is not quite clear in what circumstance CCRVDF can consider other measures and also the term "other legitimate factors" should be adequate to address the situation. ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY IFAH) Again, IFAH is supportive of the proposed change but raises concerns that the proposed text may result in a 'in a never-ending cycle of CCRVDF asking JECFA for opinions, JECFA provides them, CCRVDF reviews and has more questions, … . Good communication between JECFA and CCRVDF is essential. We consider it vital that JECFA should be asked the "correct questions" once, and then CCRVDF should make	

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	the final decision. The policy as redrafted might lend itself to misuse as a delay practice to obstruct advancing of proposed risk management measures. In respect to the comments offered by the colleagues from Japan regarding action limits, IFAH would be in favour of including appropriate language. This would present a major step in facilitating trade, as action would be triggered by objective criteria. *(*COMMENT BY *USA)* The United States has amended paragraph 27 under section 3.2 – Evaluation of Risk Management Options as we believe that it is important to convey in an easily understandable format the range of options available to the Committee when evaluating risk . The amended paragraph 27 would read" *27. The CCRVDF either:* • *Develops the MRLs based on the JECFA assessment,* • *Modifies them in consideration of other legitimate factors relevant to the health protection of consumers and the for the promotion of fair practices in food trade,* • *Asks JECFA for reconsideration of the residue evaluation for the veterinary drug in question,* • *Declines to advance the MRLs based on risk management concerns, or* • *Considers and recommends appropriate risk management measures for veterinary drug residues with no ADI / MRL due to lack of information or specific health concerns, as concluded by JECFA.* 27 bis. CCRVDF considers the information and recommendations provided by JECFA as well as all other available relevant information 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 - Monitoring and Review of the Decisions Taken** 29. Members may ask for the review of decisions taken by the Codex Alimentarius	***<u>COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011</u>*** (COMMENT BY USA) The United States has amended paragraph 29 to update the reference to the 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). The text would read:	*No modification.* **3.4 -** Monitoring and Review of the Decisions Taken

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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 16-1993). 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. 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.	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 Design and Implementation of National Regulatory Food Safety Assurance Programme Associated with the use of Veterinary Drugs in Food Producing Animals (CAC/GL71-2009).	
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, 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	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY JAPAN) 32a. If neither of such risk management options is developed, substances concerned are to be incorporated in a list (to be developed and maintained in Codex data base on veterinary drugs), aimed at facilitating public awareness on the status of the concerned veterinary drugs in Codex and their specific health concerns. This list explains that the substances for which the Codex cannot establish MRLs due to specific health concerns should be regulated adequately to protect health of consumer at National /regional level. (COMMENT BY USA) 32a CCRVDF should, in cooperation with JECFA and the Codex Secretariat, make available to its members a consolidated presentation 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 a form of a consolidated presentation** to Members. The CCRVDF recognises that communication between risk assessors and risk managers is critical to the success of

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to the success of risk analysis activities.	recommendations for residues of veterinary drugs in food. (COMMENT BY ARGENTINA) To be included: section specifically related to risk assessment In current texts, risk assessment is not clearly delimited and is partly mistaken for the definition of the risk assessment policy […] In this sense, it should be mentioned that the risk assessment must also meet the Guiding Principles of Codex for the Application of the Working Principles for Risk Analysis in the framework of the Codex Alimentarius and the provisions laid down in the Decision related to the Statements of Principle Relating to the Role of Food Safety Risk Assessment. ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY USA) The United States has added paragraph 33 bis to reflect the need of the Committee to update standards as new scientific data becomes available. The text as amended would read: 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. The CCRVDF should review and update standards and related texts for veterinary drugs in food, as necessary, in the light of newly generated scientific data.	risk analysis activities. **32-bis**. **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.**
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.	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** ***(COMMENT BY CANADA)*** ***To be included : a new section*** ***CCRVDF Risk Analysis Principles should also include statements such as "standards or related texts for residues of veterinary drugs in foods should be reviewed regularly and updated as necessary to reflect the new scientific knowledge and other information relevant to risk analysis." Alternatively, such a statement could be harmonized to that used by CCPR which does a periodic review of the safety of the pesticide residues in foods.***	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. 33-bis. The CCRVD should review and update standards or related texts for veterinary drugs in food, as necessary, in the light of newly generated scientific data.
	(COMMENT BY ARGENTINA) ***To be included in risk management section:*** ***From : WORKING PRINCIPLES FOR RISK ANALYSIS FOR APPLICATION IN***	No modification.

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	THE FRAMEWORK OF THE CODEX ALIMENTARIUS ***34. In order to avoid unjustified trade barriers, risk management should ensure transparency and consistency in the decision-making process in all cases. Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages. When making a choice among different risk management options, which are equally effective in protecting the health of the consumer, the Commission and its subsidiary bodies should seek and take into consideration the potential impact of such measures on trade among its Member countries and select measures that are no more trade-restrictive than necessary.*** ***35. Risk management should take into account the economic consequences and the feasibility of risk management options. Risk management should also recognize the need for alternative options in the establishment of standards, guidelines and other recommendations, consistent with the protection of consumers' health. In taking these elements into consideration, the Commission and its subsidiary bodies should give particular attention to the circumstances of developing countries.*** ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** ***(COMMENT BY EU)*** ***The new paragraph 33 bis should be placed under section 3.3 (Monitoring and review).*** ***(COMMENT BY JAPAN)*** ***33-bis.*** ***The CCRVDF should review and update standards or related texts for veterinary drugs in food, as necessary, in the light of newly generated scientific data.*** ***'CCRVD' is a misprint for 'CCRVDF'.***	

ANNEX

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

Original Text	**Comments received from eWG members**	**Proposal for modification by co-chairpersons as of 2August 2011**
Administrative information 1. Member(s) submitting the request for inclusion 2. Veterinary drug names 3. Trade names 4. Chemical names 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 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 12. Specific request to risk assessors Available information31 13. Countries where the veterinary drugs is registered 14. National/Regional MRLs or any other applicable tolerances 15. List of data (pharmacology,	***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY JAPAN) 13. Countries where the veterinary drug~~s~~ is registered ‘drugs’ is a misprint for ‘drug’.	*No modification from 1 to 16.*

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toxicology, metabolism, residue depletion, analytical methods) available Timetable 16. Date when data could be submitted to JECFA		
	ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS (COMMENT BY FRANCE) 17. The prospect of completing the work within a reasonable period of time.	**17. The prospect of completing the work within a reasonable period of time.**

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

Original Text	Comments received from eWG members	Proposal for modification by co-chairpersons as of 2August 2011
	ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS (COMMENT BY USA) **RISK ASSESSMENT POLICY FOR THE EVALUATION OF THE SAFETY OF RESIDUES OF VETERINARY DRUGS IN FOODS** The title of the "Risk Assessment Policy for setting the MRLs of Veterinary Drugs in Foods" should be revised to reflect that JECFA should be able to provide, in addition to MRL proposals, a range of other risk management options. (COMMENT BY CANADA) The revised CCRVDF Risk Analysis Principles should include mandate for the Committee to make recommendations other than just adopting the MRLs. This should include amongst others not using a product in food producing animals especially for products with a known human health concerns. […]	**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.		*No change*

Original Text	**Comments received from eWG members**	**Proposal for modification by co-chairpersons as of 2August 2011**
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).	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY USA) (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), proposing Maximum Residues Limits (MRLs) AND RESPONDING TO OTHER QUESTIONS FROM THE 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 to establish its risk assessment. It should use available quantitative information to the greatest extent possible and also qualitative information.	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY CANADA) Texts should be inserted in both the Risk Assessment Policy and CCRVDF Risk Analysis Principles (at various sections) that risk management options other than setting MRLs for veterinary drugs are to be considered and recommended by JEFCA and CCRVDF.	(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 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.		*No modification.*
(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		(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

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vulnerability (e.g. children).		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 for all species based on appropriate consumption figures. When requested by CCRVDF, extension of MRLs between species will be considered if appropriate data are available.		No change
	ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS (COMMENT BY ARGENTINA) To be included: section specifically related to risk assessment In current texts, risk assessment is not clearly delimited and is partly mistaken for the definition of the risk assessment policy […] In this sense, it should be mentioned that the risk assessment must also meet the Guiding Principles of Codex for the Application of the Working Principles for Risk Analysis in the framework of the Codex Alimentarius and the provisions laid down in the Decision related to the Statements of Principle Relating to the Role of Food Safety Risk Assessment.	**New point** **h) When scientific data are insufficient 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	***ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS*** (COMMENT BY CANADA) Under the section of "Expression of risk assessment results in terms of MRLs" other results options should also be included in the situation where no MRLs or ADI could be established because of health concerns or because of data gaps. As well as the expression of results when JECFA recommends withdrawal of MRLs or ADI.	*No change in section on data protection.* ***Expression of risk assessment results in terms of MRLs.*** **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**

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sponsor. Expression of risk assessment results in terms of MRLs 4. MRLs have to be established for 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 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.		**concerns, or when JECFA recommends withdrawal of MRLs or ADI.**

OTHER TEXTS PROPOSED

Original Text	*Comments received from eWG members*	Proposal for modification by co-chairpersons as of 2August 2011
	ORIGINAL COMMENTS RECEIVED FROM THE EWG MEMBERS (COMMENT BY JAPAN) **(CCPR Model)** **FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL/OR REQUEST FOR CLARIFICATION OF CONCERNS** Submitted by: Date:	**FORM FOR EXPRESSING CONCERNS WITH ADVANCEMENT OF AN MRL/OR REQUEST FOR CLARIFICATION OF CONCERNS** **- Submitted by:** **- Date:** **- Veterinary drugs concerned:** **- Commodity**

Original Text	***Comments received from eWG members***	**Proposal for modification by co-chairpersons as of 2August 2011**
	Compounds Commodity MRL (mg/kg) Present Step Is this a Request for Clarification? Is this a 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). Do you wish this Concern to be Noted in the CCRVDF Report? (COMMENT BY BRAZIL**)** **(CCPR Model)** […] Brazil strongly supports the adoption by CCRVDF of the concern form used by CCPR for when there are disagreements with a recommended MRL. **(**COMMENT BY AUSTRALIA) […] CCRVDF will need to agree on policies and procedures relating to use of the concern forms along similar lines to those already agreed to by CCPR (Alinorm 06/29/24 paragraph 42). **(**COMMENT BY USA) Submitted By: Date Veterinary Drug Commodity MRL(s) Present Step Request for Clarification? New Concern? Continuing Concern? Description of the question or concern: Proposed solutions: Should this concern be noted in the CCRVDF report?	**- 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?**

Original Text	***Comments received from eWG members***	**Proposal for modification by co-chairpersons as of 2August 2011**
	Background materials attached?	
Other comments		
	(COMMENT BY AUSTRALIA) 1. Examination of guidance for JECFA on an appropriate portion of the ADI that should be allocated when determining an MRLVD. Some issues that may be considered are: - there is currently no guidance available to JECFA on this issue - whether provision needs to be made for existing and future uses of active constituents when setting MRLs - whether use of 100% of the ADI is appropriate in determining an MRLVD 2. Estimation of dietary exposure is an important issue and needs to be reviewed including - estimates of food intake by consumers - use of TMDI or other methods for estimating residue intake 3. Whether the outcomes of national assessments (e.g MRL, ADI or dietary intake estimates) can be used as a basis for determining Codex MRLs.	
	(COMMENT BY ARGENTINA) Merging the text of Risk Assessment Policy for the Setting of Maximum Limits for Residues of Veterinary Drugs in Foods with the document on Risk Analysis Principles Applied by the CCRVDF into a single text, instead of including it as an annex to the main document, is considered favorable.	
	(COMMENT BY JAPAN) […] suggests that in the course of this e-WG' work, it would be useful for us to refer to the flow-diagram, as presented by Japan in CRD 9 and Add.1 at the last CCRVDF, so as not to miss any important elements need to be incorporated in the CCRVDF- RA documents. ***COMMENTS ON CO-CHAIRPERSONS PROPOSAL OF 2AUGUST2011*** (COMMENT BY EU) In principle, the EU is not against the use of concern forms in CCRVDF. However, there appears to be no real need for them 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 huge amount 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	

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	MRLs, they have ample opportunities to bring them forward with necessary explanations on case-by-case basis.	

Annex 3

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.