CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 2 **CX/RVDF 10/19/2**

July 2010

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Nineteenth Session

Burlington, Vermont, United States of America, 30 August – 3 September 2010

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES AND TASK FORCES

MATTERS ARISING FROM THE 32ND AND 33RD SESSION OF THE CODEX ALIMENTARIUS COMMISSION

A. Matters for information

Standards and Related Texts adopted at Steps 8 and 5/8[1]

1. The 32nd Session of the Commission adopted the Maximum Residue Limits (MRLs) for Veterinary Drugs (melengestrol acetate in cattle tissues; avilamycin in pigs, chicken, turkey and rabbit tissues; dexamethasone in cattle, pig and horse tissues; monensin in cattle, sheep, goat, chicken, turkey and quail tissues; narasin in chicken tissues; triclabendazole in cattle and sheep tissues; and tylosin in cattle, pig and chicken tissues) and the Guidelines for the Design and Implementation of National Regulatory Food Safety Assurance Programmes Associated with the Use of Veterinary Drugs in Food Producing Animals (CAC/GL 71-2009), as proposed by the 18th Session of the CCRVDF.

Standards and Related Texts adopted at Steps 5[2]

2. The 32nd Session of the Commission adopted the proposed draft MRLs for narasin (in cattle and pig tissues) and tilmicosin (in chicken and turkey tissues) at Step 5 and advanced them to Step 6.

3. The Committee will consider the above draft MRLs under Agenda Item 4.

Revocation of Standards and Related Texts[3]

4. The 32nd Session of the Commission agreed to revoke from the Codex Alimentarius the following texts as proposed by the 18th Session of CCRVDF: temporary MRLs for tilmicosin in sheep milk; *Guidelines for the Establishment of a Regulatory Programme for Control of Veterinary Drug Residues in Foods* (CAC/GL 16-1993); and *Code of Practice for Control of the Use of Veterinary Drugs* (CAC/RCP 38-1993).

Approval of new work for the elaboration of new standards and related texts[4]

5. The 32nd Session of the Commission approved the Priority List of Veterinary Drugs for Evaluation or Re-evaluation by JECFA, as proposed by the 18th Session of the CCRVDF.

Discontinuation of work[5]

6. The 32nd Session of the Commission approved the discontinuation of draft MRLs for triclabendazole in goat tissues, as proposed by the 18th Session of the CCRVDF.

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[1] ALINORM 09/32/REP, paras 23 and 57-63 and Appendix III
[2] ALINORM 09/32/REP, paras 81 and 88 and Appendix IV
[3] ALINORM 09/32/REP, para. 89 and Appendix V
[4] ALINORM 09/32/REP, para. 113 and Appendix VI
[5] ALINORM 08/31/REP, para. 122 and Appendix VII

***Draft MRLs for Ractopamine*[6]**

7. The 32nd and 33rd Session of the Commission had an extensive discussion of the draft MRLs for ractopamine that were held at Step 8. The 33rd Session of the Commission agreed to defer this discussion until its 34th Session and to hold the draft MRLs for ractopamine at Step 8.

***Draft MRLs for Bovine Somatotropin*[7]**

8. The 32nd and 33rd Session of the Commission noted that no request had been received to change the status of the draft MRLs for bovine somatotropin.

***Future Work on Animal Feeding*[8]**

9. The 33rd Session of the Commission agreed to establish a Codex *ad hoc* Intergovernmental Codex Task Force on Animal Feeding to work on: (i) development of guidelines, intended for governments, on how to apply the existing Codex risk assessment methodologies to the various types of hazards related to contaminants/residues in feed ingredients, including feed additives used in feedingstuffs for food producing animals; and (ii) development of a prioritized list of hazards in feed and feed ingredients for governmental use. The Commission further agreed that work on criteria for the global identification and notification of emergency situations affecting animal feed be referred to FAO and WHO.

***Antimicrobial Resistance*[9]**

10. The 33rd Session of the Commission adopted the proposed draft *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance* (Ref. ALINORM 10/33/42 Appendix II) at Step 5 and advanced them to Step 6. The draft Guidelines will be considered by the 4th Session of the Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance, to be held in Muju, Republic of Korea on 18-22 October 2010.

B. Matters for action

***Proposed Review of Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods*[10]**

11. The report of the electronic working group on future work on animal feeding, established by the 32nd Session of the Commission[11], was presented at the 33rd Session of the Commission. The report included, among others, a review of existing Codex risk analysis principles as to their applicability to animal feed, which identified some gaps in their applicability to animal feed and proposed revision to address these gaps.

12. The Commission agreed to refer the proposed reviews to the relevant committees, i.e. CCGP, CCFA, CCCF, CCPR, CCRVDF and CCFICS for review. The Commission further agreed to request the CCGP to ensure consistency of the risk analysis texts after they have been reviewed by the relevant committees.

13. The Committee **is invited** to consider the proposed review of the *Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods* (attached as Annex 1 to this document) for further consideration by the CCGP.

MATTERS ARISING FROM THE 63RD AND 64TH SESSION OF THE EXECUTIVE COMMITTEE

A. Matters for information

***Critical Review for the Elaboration of Codex Standards and Related Texts – Monitoring of Standard Development*[12]**

The 63rd Session of the Executive Committee noted some comments on the difficulties related to the work of the CCRVDF but agreed that this was not for discussion at this stage.

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[6] ALINORM 09/32/REP paras 66-79 and ALINORM 10/33/REP paras 49-60
[7] ALINORM 09/32/REP para. 65 and ALINORM 10/33/REP para. 61
[8] ALINORM 10/33/REP, paras 95-112
[9] ALINORM 10/33/REP, para. 66 and Appendix IV
[10] ALINORM 10/33/REP paras 95-97 and 100-101
[11] ALINORM 09/32/REP, paras 170-176
[12] ALINORM 10/33/3 paras 15-17

Study on the Speed of the Codex Standard-Setting Process[13]

14. The 64th Session of the Executive Committee noted that though the CCRVDF used similar good practices as the other committees, the advancement of some items was difficult, one of the factors being national legislation. The Executive Committee recommended to the CCRVDF: to consider using a concern form as is used by the CCPR (Ref. ALINORM 10/33/3A paras 81-82); to adhere to the statements of principle concerning the role of science especially statement 4; and to encourage data owners through the respective regulatory authorities to submit data.

MATTERS ARISING FROM OTHER COMMITTEES AND TASK FORCES

A. Matters for action

Committee on General Principles (CCGP)

Review of the Risk Analysis Policies of Codex Committees[14]

15. The 26th Session of the CCGP agreed that risk analysis policies developed by Codex committees were generally consistent with the *Working Principles for Risk Analysis*, which complied with the mandate given to the Committee under Activity 2.1. The Committee also agreed to forward the review presented in CL 2010/1-GP to the committees concerned for their consideration and review of their risk analysis policies, which would initiate Activity 2.2 of the Strategic Plan.

16. The Committee **is invited** to consider the review of its analysis policies, which is included in CL 2010/1-CG. Relevant excerpts of CL 2001/1-GP are attached as Annex 2 to this document.

Proposal for Revision of the Definition of "Hazard" in the Procedural Manual[15]

17. The 26th Session of the CCGP could not reach a conclusion on a proposal to revise the definition of "hazard" in the Procedural Manual by adding the following footnote: "*This definition of hazard as an agent differs from the definition as an effect in many of the authoritative scientific references cited by several Codex committees in their documents on risk analysis. This difference should not be interpreted as producing any conflict in the interpretation or application of the Working Principles of Risk Analysis.*"

18. The Committee **is invited** to consider the above proposal and provide its advice to the next Session of the CCGP.

[13] ALINORM 10/33/3A paras 83-88
[14] ALINORM 10/33/33 paras 47-55
[15] ALINORM 10/33/33 paras 56-58

Annex 1

Proposal

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

Proposed changes in ***Italics and bold***

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.

a) This document also applies to veterinary drugs in food originating from residues of veterinary drugs in feed[16] of animal origin where it can impact food safety.

2. PARTIES INVOLVED

1. 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).

2. 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.

3. 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.

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

5. 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.

6. 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

7. Risk management should follow a structured approach including:

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

[16] 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)

8. 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*[17].

3.1 Preliminary risk management activities

9. 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 and determine if feed may be a source of the food safety problem;***
- Establishment of a preliminary risk profile;
- Ranking of the hazard for risk assessment and risk management priority;
- Commissioning of the risk assessment; and
- Consideration of the result of the risk assessment.

3.1.1 Risk Assessment Policy for the Conduct of the Risk Assessment

10. 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.

3.1.2 Establishment of Priority List

11. 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.

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

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

13. 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

14. 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.

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

[17] 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

16. 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.

17. 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*.

3.1.5 Commissioning of the Risk Assessment

18. 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.

3.1.6 Consideration of the Result of the Risk Assessment

19. 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.

20. When the data are insufficient, JECFA may recommend temporary MRL on the basis of a temporary ADI using additional safety considerations[18]. 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.

21. 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.

22. 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.

23. The CCRVDF may ask JECFA any additional explanation.

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

3.2 Evaluation of Risk Management Options

25. 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[19] and subsequent amendments made by this Committee.

26. 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.

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

[18] Definition of “Codex maximum limit for residues of veterinary drugs”, Codex Procedural Manual
[19] ALINORM 01/31 paragraph 11

3.3 Monitoring and Review of the Decisions Taken

28. 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).

29. 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.

30. 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

31. 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 to the success of risk analysis activities.

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

ANNEX

TEMPLATE FOR INFORMATION 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[20]

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.

[20] 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

Annex 2

REVIEW OF THE RISK ANALYSIS POLICIES OF CODEX COMMITTEES

(excerpts from CL 2010/1-GP)

Background

The review of the risk analysis policies of Codex Committees is included in the Strategic Plan of the Codex Alimentarius Commission under Goal 2. Promoting Widest and Consistent Application of Scientific Principles and Risk Analysis, as follows:

- Activity 2.1 Review the consistency of risk analysis principles elaborated by the relevant Codex Committees (completion by 2011)
- Activity 2.2 Review risk analysis principles developed by relevant Codex Committees (completion by 2013)
- Activity 2.3 Enhance communication among relevant Codex subsidiary bodies and the FAO/WHO scientific expert bodies (ongoing)

The 61st Session of the Executive Committee (2008) considered the implementation of the Strategic Plan 2008-2013. While noting that the Committees on Nutrition and Foods for Special Dietary Uses and on Food Hygiene had not completed their work for development of risk analysis policy documents in their respective areas, it recommended that the 25th Session of the Committee on General Principles (April 2009) initiate Activity 2.1 and agree on a timeline to complete the review. Activity 2.2 would be started once Activity 2.1 was completed. (ALINORM 08/31/3A, para. 131). The 31st Session of the Commission (2008) endorsed this recommendation (ALINORM 08/31/REP, para. 133).

The 25th Session of the Committee on General Principles (2009) had a general discussion on the approach to the review and the main aspects to be taken into account. The Committee agreed to confirm its objective of completing the review by 2011 as initially scheduled and noted that subject to adoption by the Commission, the risk analysis policy developed by the Committee on Nutrition and Foods for Special Dietary Uses would also be considered. This document was subsequently adopted by the 32nd Session of the Commission in 2009.

At the time the document on risk analysis policies and procedures applied by the Committee on Food Hygiene (CCFH) was still under development. It was finalised by the last session of the CCFH and is presented for endorsement to the present session (ALINORM 10/33/13, Appendix VII).

The Committee on General Principles is invited to discuss the main aspects to be taken into account in the review to provide general recommendations, and to consider the documents developed by each relevant committee. The present document includes some general considerations on the overall approach to the review and specific sections on each of the documents developed in the areas of additives and contaminants, pesticide residues, veterinary drug residues, nutrition, and food hygiene, which can be used by the Committee as a basis for further comments and discussion.

General considerations

Several sets of principles for risk analysis already exist, all of which were developed after the *Working Principles* were adopted. All Committees concerned have developed their risk analysis policies and some of them are still discussing new issues or reviewing their approaches to risk management, which may result in new developments or updates in the near future.

However, this should not prevent the Committee from initiating the review of the current principles for risk analysis in the relevant areas, while recognising that some of the texts under consideration may be amended and reconsidered. The Committee on General Principles may also make some general recommendations to the Committees that are still revising or developing risk analysis policies in order to ensure consistency with the *Working Principles.*

As a general remark, it may be noted that the format of the principles for risk analysis developed by Codex committees does not always follow the structure of the Working Principles and the components of risk

analysis, but rather a description of the respective responsibilities and tasks carried out by the Committee concerned and the expert committees providing scientific advice.

The Committee on General Principles may consider a general recommendation to the committees concerned to review their documents in order to follow the structure of the Working Principles and to proceed according to the components of risk analysis. In several cases there would be no need for substantial amendments but rather for reordering the text.

At the last session of the Committee, it was noted the differences in the documents might be due to the nature of the specific risks considered and that the review should take into account these specificities (such as chemical and microbiological risks as regards food safety, and the application of risk analysis to nutrition issues). However there are also substantial differences in the structure of the risk analysis principles developed to address chemical risks related to additives, contaminants, veterinary drugs and pesticide residues, between them or as compared with the *Working Principles.*

Another general remark is that in several documents on risk analysis, the section on risk assessment policy is missing as a separate section, although several elements of such policy may appear throughout the text. At the last session of the Committee on General Principles, it was pointed out that the establishment of risk assessment policies was essential to the risk analysis process and that several elements should be considered when reviewing risk analysis policies.

While the *Working Principles* address only the components of risk analysis, it may be noted that elements of procedure are also included in various sections of specific documents, which may lead to repetition of texts appearing elsewhere in the Manual, such as the Elaboration Procedure or Criteria for New Work. A general recommendation might be to concentrate only on the risk analysis process and to avoid repeating elements of procedure in risk analysis documents, although that may not always be easy in practice, especially when considering new work related to the prioritisation process.

At the last session, the Committee briefly discussed the provisions presented in the annexes to the risk policy documents, such as data requirements and criteria for prioritisation and it was agreed that they would be taken into account in the review of risk analysis principles. These texts have been considered according to their relevance to risk analysis principles and policies for each specific food safety area.

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Residues of Veterinary Drugs

The *Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods* mainly describe the risk management applied by the Committee, in addition to some general considerations, while the *Risk Assessment Policy for the Setting of MRLs for Residues of Veterinary Drugs in Foods* include recommendations concerning the responsibilities of JECFA.

The Committee might consider a recommendation to incorporate and reorder all provisions of both texts into a single document which would follow the structure of the *Working Principles.* This may not involve significant amendments of the recommendations themselves but rather a reordering of existing paragraphs.

A general section on risk analysis could include some of the paragraphs in current *Section 2. Parties involved*, while paragraph 2 could be included in the Scope. As in the case of pesticide residues, consideration could be given to the application of paragraph 9 of the *Working Principles* on the separation between risk assessment and risk management to MRL setting for veterinary drugs.

The section on risk assessment could incorporate most sections currently presented in the *Risk Assessment Policy for the Setting of MRLs for Residues of Veterinary Drugs in Foods* which describe the role of JECFA. Although section 3.1.1 *Risk Assessment Policy for the Conduct of the Risk Assessment* refers to this document, its contents appear to be more relevant for risk assessment than risk assessment policy. This section could also include paragraphs 7, 20 and 21.

As in the case of pesticide residues, the provisions relating to the prioritisation could be included under a single section, including the information currently presented in the template.

Although the title of Section 3.1.4 refers to Ranking of the Hazard, its content is more related to procedures and the decision process followed in the Committee. Paragraph 18 may not be necessary as it refers to the approval of new work, which is described under the elaboration procedure in the Manual.

Section 4 refers to risk communication in the context of risk management, while paragraph 32 mentions the risk analysis process as a whole. Consideration may be given to the inclusion of a more general section on risk communication, incorporating some provisions put forward in other paragraphs, for example 3.1.6 *Consideration of the Result of Risk Assessment.*