codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item 2 **CX/GP 07/24/2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON GENERAL PRINCIPLES
Twenty-fourth Session
Paris, France, 2- 6 April 2007

MATTERS REFERRED TO THE COMMITTEE

MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION AND OTHER CODEX COMMITTEES

A. MATTERS REFERRED BY THE CODEX ALIMENTARIUS COMMISSION

1. Decisions of the 29th Session of the Commission on the work of the Committee[1]

Rules of Procedure[2]

The proposed amendments were adopted by the Commission and entered into force following their approval by the Directors-General of FAO and WHO.

Proposals to amend other Sections of the Procedural Manual[3]

The proposed amendments to the *Guide to the Consideration of Standards at Step 8 of the Procedure of the Elaboration of Codex Standards including Consideration of any Statement Relating to Economic Impact* and the *Consequential Amendments to the Guidelines on the Conduct of Meetings of Codex Committee and Ad hoc Intergovernmental Task Forces* were adopted and Comments made by Malaysia and India were referred back to the CCGP (see A2.)

Terms of Reference of the Committee on Food Additives and the Committee on Contaminants in Foods[4]

The Commission adopted the terms of reference and consequential amendments to the Procedural Manual.

Criteria for Prioritization Process of Compounds for Evaluation by JMPR[5]

The Commission adopted the Criteria.

The Use of Analytical Results: Sampling Plans, Relationship between the Analytical Results, the Measurement Uncertainty, Recovery Factors and Provisions in Codex Standards[6]

The Commission adopted the text.

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[1] ALINORM 06/29/41, paras. 16-35, Appendix III.
[2] ALINORM 06/29/41, paras. 16-21
[3] ALINORM 06/29/41, paras. 22-23
[4] ALINORM 06/29/41, paras. 26-29
[5] ALINORM 06/29/41, paras. 30-32
[6] ALINORM 06/29/41, paras. 33-34

2. Matters referred by the 29th Session of the Commission

Amendments to the General Principles of the Codex Alimentarius[7]

In view of the substantial issues raised by several delegations, the Commission agreed to return the proposed amendment to the CCGP, taking into account the comments presented at the 29th Session of the Commission (see Agenda Item 7).

Guide to the Consideration of Standards at Step 8 of the Procedure of the Elaboration of Codex Standards including Consideration of any Statement Relating to Economic Impact[8]

At the 29th Session of the Commission the Delegation of Malaysia, while supporting the amendments to the Elaboration Procedure Part 3 and 4, expressed the view that six paragraphs in the *Guide to the Consideration of Standards at Step 8*, proposed for deletion, should be reinserted in order to ensure that Codex work was not affected by the adoption of insufficiently considered amendments, and to allow delegations sufficient time to consider these amendments. The Delegation of India pointed out that the following provisions of the *Guide* should be reinserted in the Elaboration Procedure at Step 8: paragraph 2 on the timing of the Circular Letter in order to ensure timely availability of comments; and paragraph 6 allowing Members to draw the attention of the Commission to any matter which had not, in that Member's opinion, been satisfactorily resolved at an earlier step. These proposals were supported by several delegations, who stressed the importance of the issue of economic impact, especially for developing countries.

After some discussion, the Commission agreed to adopt the amendments as proposed and to refer the proposals made by India in its written comments (CAC29-LIM 12 re-distributed at this session) and Malaysia to the CCGP in order to consider whether the reinsertion of the paragraphs deleted in the *Guide* was needed in the Elaboration Procedure.

Codex General Standard for Contaminants and Toxins in Foods (GSCTF)[9]

The Commission **agreed** to the recommendation of the CCFAC to include a specific reference to the GSCTF in the sections on contaminants of Codex commodity standards and decided to request the CCGP to finalize the standard wording for the contaminants section, based on the text proposed by the CCFAC, for inclusion in the Procedural Manual as follows:

> "The products covered by this Standard shall comply with the Maximum Levels of the Codex General Standard for Contaminants and Toxins in Foods (CODEX/STAN 193-1995) and the maximum residue limits for pesticides and veterinary drugs established by the CAC"[10]

3. Matters referred by the 28th Session of the Commission

Terms of reference of the Coordinating Committees

While discussing the review of the Regional Coordinating Committees, the Commission noted that the Coordinating Committee for Latin America and the Caribbean (CCLAC) had proposed to amend its mandate to include an additional bullet point "To promote the adoption of regional positions on strategic subjects". The Commission had after some discussion referred the proposed amendment to the terms of reference of the CCLAC and its possible extension to the other Coordinating Committees to the Committee on General Principles for further consideration[11] .

The CCGP at its 23rd Session discussed the issue in detail and decided to recommend to the CCLAC to practice the adoption of regional positions as appropriate while keeping their terms of reference

[7] ALINORM 06/29/41, paras. 24-25
[8] ALINORM 06/29/41, paras. 22-23; CAC29-LIM 12
[9] ALINORM 06/29/41, para. 194
[10] ALINORM 06/29/12, para. 119
[11] ALINORM 05/28/41, para. 130

unchanged. The CCLAC was invited to report on their experience to the 24th Session of the CCGP. All other Coordinating Committees were invited to discuss the possible inclusion of the sentence proposed by the CCLAC into their terms of reference and its possible implications and report their views to the CCGP. The 24th Session of the CCGP would consider this matter again in the light of the feedback from all Coordinating Committees.[12]

The Regional Coordinating Committees at their sessions held in 2006/2007 expressed their views on the matter. Three of the Coordinating Committees (CCNASWP, CCEURO and CCAFRICA) generally agreed that the current terms of reference should be unchanged because they were considered broad enough. They also agreed that the terms of reference of all Coordinating Committees should be kept harmonised. Within CCASIA and CCNEA there were diverging opinions on this issue. CCLAC supported the proposed amendment. The excerpts of the discussions at the Coordinating Committees are included in Appendix 1.

B. MATTERS REFERRED BY OTHER COMMITTEES

1. Committee on Pesticide Residues (CCPR)

Draft Risk Analysis Principles Applied by the Committee on Pesticide Residues[13]

The CCPR agreed to forward the Draft Risk Analysis Principles to the 24th Session of the Committee on General Principles for endorsement and to Step 8 for adoption by the 30th Session of the Codex Alimentarius Commission (2007) (see Appendix 3).

2. Committee on Residues of Veterinary Drugs in Food (CCRVDF)

Status of the proposed draft Risk Management Methodologies, including Risk Assessment Policies in the Codex Committee on Residues of Veterinary Drugs in Foods[14]

The CCRVDF agreed to forward the renamed Risk Analysis Principles applied by the CCRVDF and the Risk Assessment Policy for the Setting of MRLs in Food to the Codex Alimentarius Commission, through the Codex Committee on General Principles, for adoption and inclusion in the Codex Procedural Manual (see Appendices 4 and 5).

3. Committee on Food Import and Export Inspection and Certification Systems

Proposed draft Revised Code of Ethics for International Trade in Foods (see Agenda Item 4)

4. Committee on Methods of Analysis and Sampling (CCMAS)

Proposed Amendment to the Principles for the Establishment or Selection of Codex Sampling Procedures[15]

The CCMAS proposes to amend the Principles for the Establishment or Selection of Codex Sampling Procedures as indicated in Appendix 2.

5. 58th Session of the Executive Committee of the Codex Alimentarius Commission

Review of observer status with the Codex Alimentarius Commission[16]

The Executive Committee was of the opinion that current and future policy and rules on how to deal with the issue of double representation should be applied to existing and prospective observers equally. In this context the Executive Committee discussed the issue of how to review the status of existing observers, provided for in section 6 of the Principles. In particular it was noted that a number of observers had been

[12] ALINORM 06/29/33, paras. 6-18
[13] ALINORM 06/29/24, para. 159 and Appendix V
[14] ALINORM 06/29/31, para. 111 and appendices VIII and IX
[15] ALINORM 07/30/23, para. 114 and Appendix V
[16] ALINORM 06/29/3A, paras. 106-108

admitted before the adoption of the first version of the Principles by the Commission. The question was raised whether the first paragraph of section 6 of the Principles was to be interpreted to the effect that those observers were virtually "un-reviewable" because the paragraph made reference to the "criteria that applied at the time it was granted observer status". The clarification of the scope of this paragraph would allow the Secretariat to fully implement the provisions of section 4 of the Principles.

The Legal Adviser of WHO explained that the Principles gave three possible reasons for terminating observer status of an organization: (1) because it no longer meets the criteria that applied at the time it was granted observer status; (2) because of reasons of exceptional nature; (3) because of not having shown sufficient interest in participation. Concerning the first reason mentioned, he expressed the view that the term "criteria" could be interpreted as being used as a general term and could refer to those rules that applied generally, including rules or criteria used by the parent organizations at that time.

The Executive Committee recommended that the Committee on General Principles be invited to clarify the intent and scope of section 6, paragraph 1 of the "Principles Concerning the Participation of International Non-Governmental Organizations in the Work of The Codex Alimentarius Commission" at its next session, with input from the legal services of WHO and FAO.

6. FAO/WHO Coordinating Committee for Latin America and the Caribbean

Risk Analysis Principles for application by Governments[17](see Agenda Item 3)

The CCLAC committed itself to continue discussing this matter with the goal of finding a common position and agreed that, if such document was moved forward in the Step Procedure and if the concept of "precaution" was to be included, this should be phrased in such a way as to make it clear that "precaution" was a qualified exception
to be applied in a limited way, under strict criteria and timeframes and should not go beyond what was contained in the WTO/SPS Agreement while the terminology used must be aligned with those of the aforesaid Agreement and relevant Codex texts.

Code of Ethics for International Trade in Foods[18] (see Agenda Item 4)

The CCLAC reiterated its position that no further work was needed on the Code as the Principles contained therein were already addressed in the relevant WTO Agreements and Codex texts and thus supported recommendation 2 of CCFICS regarding the use of relevant Codex texts and technical assistance to establish or strengthen national food export/import control systems in those Codex Members which such systems were not sufficient.

7. FAO/WHO Coordinating Committee for Europe

Risk Analysis Principles for application by Governments[19] (see Agenda Item 3)

The CCEURO congratulated the Working Group on Working Principles for Risk Analysis for Food Safety for Application by Governments for its achievement and fully supported the progress of the document in the Codex procedure.

Code of Ethics for International Trade in Foods[20] (see Agenda Item 4)

The CCEURO:

- Agreed that the Code should concentrate on the ethical aspects of international trade and not reiterate what other Codex texts and the WTO agreements already stated;
- Agreed that the scope should be focused on the protection of consumers in countries which do not have yet the means of checking well the quality and the safety of the imported food; and therefore
- Fully supported the following principle:
  "A country should not export or re-export food to a country if this food is generally recognised dangerous, unfit for human consumption, adulterated or misleading to the consumer."

[17] ALINORM 07/30/36, paragraphs 110-111

[18] ALINORM 07/30/36, paragraph 113

[19] ALINORM 07/30/19, paragraph 63

[20] ALINORM 07/30/19, paragraph 68

Appendix 1

VIEWS EXPRESSED WITHIN THE COORDINATING COMMITTEES ON THE PROPOSED AMENDMENT TO TERMS OF REFERENCE BY THE CCLAC

Coordinating Committee for North America and the South West Pacific, 9th Session (Apia, Samoa, 10-13 October 2006)[21]:

> "26. The Coordinating Committee discussed the possible inclusion of the sentence: "To promote the adoption of regional positions on strategic subjects", proposed by the Coordinating Committee for Latin America and the Caribbean (CCLAC) into its own terms of reference and its possible implications.
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> 27. Some delegations expressed their view that the current Terms of Reference were sufficiently broad to allow Coordinating Committees to formulate regional positions among members, where necessary, and that it seemed not necessary to amend them. Although one delegation supported the inclusion of the proposed CCLAC phrase, most delegations did not support its inclusion and further suggested that all Coordinating Committees should have the same Terms of Reference. The Coordinating Committee generally agreed that the current Terms of Reference should be kept unchanged.
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> 28. The Coordinating Committee noted the view of a delegation that the inclusion of the proposed sentence should be considered further since the Coordinating Committee should be more proactive to represent the views of the region on strategic issues."

Coordinating Committee for Latin America and the Caribbean, 15th Session (Mar del Plata, Argentina, 13-17 November 2006)[22]:

> "8. The Committee reiterated the need to include the proposed phrase in the terms of reference of the CCLAC. The possibility of expressing needs as currently set out in the terms of reference differed from the intention of establishing common positions. The Committee suggested that each Coordinating Committee should take a decision as to whether this would be a useful role. It also considered that the notion that all or none of the Coordinating Committees should change their terms of reference lacked legal or logical foundation. The Committee endorsed this amendment to its terms of reference and recommended that the member countries should advocate such a position in the relevant fora."

Coordinating Committee for Asia, 15th Session (Seoul, Korea, 21-24 November 2006) [23]:

> "25. The Committee recalled that the Coordinating Committee for Latin America and the Caribbean had proposed to add in its terms of reference an additional item "to promote the adoption of regional positions on strategic subjects", and that the Committee on General Principles had invited all other Coordinating Committees to discuss this proposal and its implications in order to reconsider whether this new item could be included in the terms of reference of all coordinating committees, which were identical.
>
> 26. The Delegation of India supported the amendment from the CCLAC and proposed some additional amendments to the terms of reference of the Committee. Several other delegations expressed the view that the meaning of "strategic subjects" was not clearly defined and would be difficult to interpret. Some delegations pointed out that it would be difficult to reach a common position as there were different views among member countries in the region and questioned the purpose of this amendment. The Committee therefore recognized that there was no consensus to include in its terms of reference the amendment proposed by the CCLAC."

[21] ALINORM 07/30/32, paragraphs 26-28.
[22] ALINORM 07/30/36, paragraph 8.
[23] ALINORM 07/30/15, paragraphs 25-26.

Coordinating Committee for Europe, 25th Session (Vilnius, Lithuania, 15-18 January 2007)[24]:

> "30. The Chairperson invited the Coordinating Committee to address two questions: (i) whether it is desirable to keep the terms of reference of all Coordinating Committees harmonised, and (ii) what reasons would justify an amendment to the current terms of reference for CCLAC, and eventually for CCEURO, to refer to "promoting the adoption of regional positions on strategic subjects".
>
> 31. The Delegation of Germany, speaking on behalf of the Member States of the European Union, stated that the terms of reference of the Coordinating Committees should be kept harmonised and that if a change was to be made in the terms of reference of one coordinating committee then the same change should be made to the terms of reference of the other committees. The Delegation further stated that the promotion of the adoption of regional positions was already covered by the current terms of reference and there was no need to amend them. This view was supported by the Delegation of Switzerland.
>
> 32. The Coordinating Committee also noted the views and comments of other delegations that if regional positions were adopted on many issues being discussed by the Commission, the Commission might lose the important advantage of diversity of opinions; that seeking consensus and reaching compromise might become even more challenging than ever if regional positions originating from different coordinating committees were systematically presented to the Commission and such situation might imply a substantive change in Codex decision-making process; and that it should be evaluated whether, if one coordinating committee changed its terms of reference (TOR) to include a new function, there were legal implications for other coordinating committees who considered their TOR to be broad enough to include such a function and who therefore did not change their TOR.
>
> 33. The Coordinating Committee agreed that there was no need to change the TORs of coordinating committees as proposed by CCLAC since in its view the current terms of reference were broad enough to cover the envisaged functions, and that the terms of reference of all coordinating committees should remain harmonised."

Coordinating Committee for Africa, 17th Session (Rabat, Morocco, 23-26 January 2006)[25]:

> "17. The Coordinating Committee recalled that the matter had been referred to the Committee from the Committee on General Principles for its view, subsequent to the proposal from the Coordinating Committee for Latin America and the Caribbean (CCLAC) to amend its terms of reference.
>
> 18. Many delegations that spoke were not in favour of amending the terms of reference of CCLAC and other Coordinating Committees, since i) the current terms of reference were broad enough to allow Coordinating Committees to adopt regional positions and thus there was no need to amend the terms of reference, ii) the proposed amendment might turn the Codex Commission into a Commission comprising "regional blocs" instead of "sovereign states", iii) it was difficult to distinguish between what constituted "strategic subjects" and what did not, and iv) the regional positions, once adopted by a Coordinating Committee, might be taken as legally binding on all countries of the region. These delegations further noted that the terms of reference of all Coordinating Committees should remain harmonized to keep aligned the roles and functions of these committees within the Commission.
>
> 19. Some delegations stated that the discussions in Coordinating Committees should be sensitive to economic issues involving food trade faced by countries of the region, and should take into account the concerns of those countries, including the request to develop a new Codex text, to be voiced and heard in the Commission.

[24] ALINORM 07/30/19, paragraphs 30-33.
[25] ALINORM 07/30/28, paragraph 17-21.

20. Some other delegations stated that the intent of the proposal made by CCLAC required further clarification and that the Commission should defer any amendment to the terms of reference of Coordinating Committees until more experience was gained by CCLAC.

21. The Coordinating Committee agreed to advise the Committee on General Principles that the terms of reference of all Coordinating Committees should remain unchanged since there were no imperative reasons that justify the proposed amendment."

Coordinating Committee for the Near East, 4th Session (Amman, Jordan, 26 February – 1 March)[26]:

"17. The Coordinating Committee recalled that the matter had been referred to the Committee from the Committee on General Principles for its view, subsequent to the proposal from the Coordinating Committee for Latin America and the Caribbean (CCLAC) to amend its terms of reference.

18. The Delegation of Jordan stated that there was no apparent need and justification for amending the terms of reference of CCLAC and other Coordinating Committees, since the current terms of reference were broad enough to allow Coordinating Committees to adopt regional positions if they so wished. The delegation also indicated that it was important to keep consistent and harmonised the terms of reference of all Coordinating Committees. This position was supported by the Delegations of Egypt and Oman.

19. The Delegation of Tunisia stated that the Terms of Reference of all Coordinating Committees should stay the same and it was in favour of the amendment proposed by CCLAC and that the amendment, if adopted, should be applied to all Coordinating Committees. The Delegation of Lebanon expressed the view that if CCLAC promoted the adoption of regional positions on strategic subjects, then the Coordinating Committee for the Near East should be able to do the same.

20. The Coordinating Committee noted that CCLAC already started to promote the adoption of regional positions. Clarification was therefore sought as to whether the proposed amendment was indeed necessary. The Committee noted that legal advice from the Legal Offices of FAO and WHO would be available when CCGP would discuss this matter at its forthcoming session."

[26] ALINORM 07/30/40, paras. 17-20.

PROPOSED AMENDMENT TO THE PRINCIPLES FOR THE ESTABLISHMENT OR SELECTION OF CODEX SAMPLING PROCEDURES

PURPOSE OF CODEX METHODS OF SAMPLING

Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard. The sampling methods are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.

METHODS OF SAMPLING

Types of Sampling Plans and Procedures

(a) Sampling Plans for Commodity Defects:

Such plans~~These~~ are normally applied to visual defects (e.g. loss of colour, ~~mis-graded for~~ misgrading of size, etc.) and extraneous matter. They are~~will~~ normally ~~be~~ attributes plans, and plans such as those included in Section 3.1 and 4.2 of the ~~FAO/WHO Codex Alimentarius Sampling Plans for Prepackaged Foods (AQL 6.5)~~ *General Guidelines on Sampling (CAC/GL 50-2004)* (hereinafter referred to as "General Guidelines") may be applied.

(b) Sampling Plans for Net Contents:

~~These~~ Such plans are ~~sampling plans~~those which apply to pre-packaged foods generally and are intended to serve to check compliance of lots or consignments with provisions for net contents. Plans such as those included in Section 3.3 and 4.4 of the General Guidelines may be applied.

(c) Sampling Plans for Compositional Criteria:

Such plans are normally applied to analytically determined compositional criteria (e.g., loss on drying in white sugar, etc.). They are predominantly based on variable procedures with unknown standard deviation. Plans such as those included in Section 4.3 of the General Guidelines may be applied.

(d) Specific Sampling Plans for Health-related Properties:

Such plans are ~~generally~~ normally applied to heterogeneous conditions, e.g., in the assessment of microbiological spoilage, microbial by-products or sporadically occurring chemical contaminants.

General Instructions for the Selection of Methods of Sampling

~~(a) Official methods of sampling as elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such methods, when attracted to Codex standards, may be revised using Codex recommended sampling terms (to be elaborated).~~
(a) Sampling methods described in the General Guidelines or official methods of sampling elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such official methods may be written using the General Guidelines when attracted to Codex standards.

(b) When selecting appropriate sampling plans, Table 1 in the General Guidelines may be utilized.

(~~b~~c) The appropriate Codex Commodity Committee should indicate, before it elaborates any sampling plan, or before any plan is endorsed by the Codex Committee on Methods of Analysis and Sampling, the following:

(i) the basis on which the criteria in the Codex Commodity standards have been drawn up (e.g. whether on the basis that every item in a lot, or a specified high proportion, shall comply with the provision in the standard or whether the average of a set of samples extracted from a lot must comply and, if so, whether a minimum or maximum tolerance, as appropriate, is to be given);

(ii) whether there is to be any differentiation in the relative importance of the criteria in the standards and, if so, what is the appropriate statistical parameter each criterion should attract, and hence, the basis for judgement when a lot is in conformity with a standard.

(~~c~~d) Instructions on the procedure for the taking of samples should indicate the following:

(i) the measures necessary in order to ensure that the sample taken is representative of the consignment or of the lot;

(ii) the size and the number of individual items forming the sample taken from the lot or consignment;

(iii) the administrative measures for taking and handling the sample.

(~~d~~e) The sampling protocol may include the following information:

(i) the statistical criteria to be used for acceptance or rejection of the lot on the basis of the sample;

(ii) the procedures to be adopted in cases of dispute.

GENERAL CONSIDERATIONS

(a) The Codex Committee on Methods of Analysis and Sampling should maintain closest possible relations with all interested organizations working on methods of analysis and sampling.

(b) The Codex Committee on Methods of Analysis and Sampling should organize its work in such a manner as to keep under constant review all methods of analysis and sampling published in the Codex Alimentarius.

(c) In the Codex methods of analysis, provision should be made for variations in reagent concentrations and specifications from country to country.

(d) Codex methods of analysis which have been derived from scientific journals, theses, or publications, either not readily available or available in languages other than the official languages of FAO and WHO, or which for other reasons should be printed in the Codex Alimentarius *in extenso*, should follow the standard layout for methods of analysis as adopted by the Codex Committee on Methods of Analysis and Sampling.

(e) Methods of analysis which have already been printed as official methods of analysis in other available publications and which are adopted as Codex methods need only be quoted by reference in the Codex Alimentarius.

DRAFT RISK ANALYSIS PRINCIPLES APPLIED BY THE CODEX COMMITTEE ON PESTICIDE RESIDUES

Advanced for adoption at Step 8

SCOPE

1. This document addresses the respective applications of risk analysis principles by the Codex Committee on Pesticide Residues (CCPR) as the risk management body and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) as the risk assessment body and facilitates the uniform application of the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[27]. This document should be read in conjunction with the Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius.

ROLES OF CCPR AND JMPR IN RISK ANALYSIS

INTERACTION BETWEEN CCPR AND JMPR

2. In addressing pesticide residue issues in Codex, providing advice on risk management is the responsibility of the Codex Alimentarius Commission (CAC) and CCPR while conducting risk assessment is the responsibility of JMPR.

3. CCPR and JMPR recognize that an adequate communication between risk assessors and risk managers is an essential requirement for successfully performing their risk analysis activities.

4. CCPR and JMPR should continue to develop procedures to enhance communication between the two bodies.

5. CCPR and JMPR should ensure that their respective contributions to the risk analysis process result in outputs that are scientifically based, fully transparent, thoroughly documented and available in a timely manner to members[28].

6. JMPR, in consultation with CCPR, should continue to explore developing minimum data requirements necessary for JMPR to perform risk assessments.

7. These requirements should be used by CCPR as a fundamental criterion as described in the Annex in preparing its Priority List for JMPR. The JMPR Secretariat should consider whether these minimum data requirement have been met when preparing the provisional agenda for meetings of JMPR.

ROLE OF CCPR

8. CCPR is primarily responsible for recommending risk management proposals for adoption by the CAC.[29]

9. CCPR shall base its risk management recommendations, such as MRLs, to the CAC following JMPR's risk assessments of the respective pesticides, and considering, where appropriate, other legitimate factors such as relevant to the health protection of consumers and for the promotion of fair practices in food trade.

10. In cases where JMPR has performed a risk assessment and CCPR or the CAC determines that additional scientific guidance is necessary, CCPR or CAC may make a specific request to JMPR to provide further scientific guidance necessary for a risk management decision.

[27] ALINORM 03/26/6

[28] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

[29] Reports of CCPR sessions are available from the Codex Alimentarius web site: www.codexalimentarius.net.

11. CCPR's risk management recommendations to the CAC shall take into account the relevant uncertainties) as described by JMPR.

12. CCPR shall consider maximum residue levels (MRLs) only for those pesticides for which JMPR has completed a full safety evaluation.

13. CCPR shall base its recommendations on the GEMS/Food diets used to identify consumption patterns on a global scale when recommending MRLs in food. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but available consumption data provided by members.

14. When establishing its standards, CCPR shall clearly state when it applies any considerations based on other legitimate factors in addition to JMPR's risk assessment and recommended maximum residue levels and specify its reasons for doing so.

15. CCPR shall consider the following when preparing its priority list of compounds for JMPR evaluation:

- CCPR's Terms of Reference;
- JMPR's Terms of Reference;
- The Codex Alimentarius Commission's Medium-Term Plan of Work;
- The Criteria for the Establishment of Work Priorities;
- The Criteria for Inclusion of Compounds on the Priority List;
- The Criteria for Selecting Food Commodities for which Codex MRLs or EMRLs should be Established;
- The Criteria for Evaluation of New Chemicals;
- The Criteria for Prioritization Process of Compounds for Evaluation by JMPR
- A commitment to provide the necessary data for the evaluation in time.

16. When referring substances to JMPR, the CCPR shall provide background information and clearly specify the reasons for the request when chemicals are nominated for evaluation.

17. When referring substances to JMPR, the CCPR may also refer a range of risk management options, with a view toward obtaining JMPR's guidance on the attendant risks and the likely risk reductions associated with each option.

18. CCPR shall request JMPR to review any methods and guidelines being considered by CCPR for assessing maximum limits for pesticides.

ROLE OF JMPR

19. The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) consists of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. It is an independent scientific expert body convened by both Director Generals of FAO and WHO according to the rules of both organizations, charged with the task to provide scientific advice on pesticide residues.

This guidance document applies to the work of JMPR in the context of Codex and in particular as it relates to advice requests from CCPR.

20. JMPR is primarily responsible for performing the risk assessments upon which CCPR and ultimately the CAC base their risk management decisions[30]. JMPR also proposes MRLs based on Good Agricultural Practices (GAPs)/ registered uses or in specific cases, such as EMRLs, based on monitoring data.

21. JMPR provides CCPR with science-based risk assessments that include the four components of risk assessment as defined by CAC and safety assessments that can serve as the basis for CCPR's risk-management discussions. JMPR should continue to use its risk assessment process for establishing Acceptable Daily Intakes (ADIs) and Acute Reference Doses (ARfDs) where appropriate.

22. JMPR should identify and communicate to CCPR in its assessments any information on the applicability and any constraints of the risk assessment to the general population and to particular sub-populations and will as far as possible identify potential risks to populations of potentially enhanced vulnerability (e.g. children).

23. JMPR is responsible for evaluating exposure to pesticides. JMPR should strive to base its exposure assessment and hence the dietary risk assessments on global data, including that from developing countries. In addition to GEMS/Food data, monitoring data and exposure studies may be used. The GEMS/Food diets are used to assess the risk of chronic exposure. The acute exposure calculations are not based on those diets, but on the available high percentile consumption data as provided by members.

24. JMPR should communicate to CCPR the magnitude and source of uncertainties in its risk assessments. When communicating this information, JMPR should provide CCPR a description of the methodology and procedures by which JMPR estimated any uncertainty in its risk assessment.

25. JMPR should communicate to CCPR the basis for all assumptions used in its risk assessments.

[30] JMPR reports and evaluation monographs are available from the FAO web site: www.fao.org/ag/agp/agpp/Pesticid/Default.htm

ANNEX: LIST OF RISK MANAGEMENT POLICIES USED BY CCPR

1. This part of the document addresses the risk management policy that is used by the Codex Committee on Pesticides Residues (CCPR) when discussing the risk assessments, the exposure to pesticides and the proposals for MRLs which are the outcomes of the Joint FAO/WHO Meeting on Pesticides Residues (JMPR).

ESTABLISHMENT OF MRLs/EMRLs

Procedure for Proposing Pesticides for Codex Priority Lists

2. CCPR has developed a policy document in relation to establishing a priority list of pesticides for evaluation or re-evaluation by JMPR[31].

3. Before a pesticide can be considered for the Priority List, it must:

- be available for use as a commercial product; and
- not have been already accepted for consideration.

4. To meet the criteria for inclusion in the priority list, the use of the pesticide must: give rise to residues in or on a food or feed commodity moving in international trade, the presence of which is (or may be) a matter of public health concern and thus create (or have the potential to create) problems in international trade.

5. When prioritising new chemicals for evaluation by the JMPR, the Committee shall consider the following criteria:

- if the chemical has a reduced acute and/or chronic toxicity to humans compared with other chemicals in its classification;
- the data nominated;
- the date that data will be submitted; and
- where possible, allocating new chemicals to be evaluated on at least a 50:50 basis with periodic re-evaluation chemicals to be evaluated.

6. When prioritising chemicals for periodic re-evaluation by the JMPR, the Committee shall consider the following criteria:

- chemicals that have not been reviewed toxicologically for more than 15 years and/or not having a significant review of maximum residue limits;
- the year the chemical is listed in the list for Candidate Chemicals for Periodic Re-evaluation – not yet scheduled;
- the date that data will be submitted and the availability of data;
- if the intake and/or toxicity profile indicate some level of public health concern;
- whether the CCPR has been advised by a national government that the chemical has been responsible for trade disruption;
- if there is a closely related chemical that is a candidate for periodic re-evaluation that can be evaluated concurrently; and

[31] Draft Revised Criteria for Prioritization Process of Compounds for Evaluation by JMPR; ALINORM 05/28/24, Appendix XV.

- allocating periodic re-evaluation chemicals to be evaluated on a maximum ratio of 50:50 with new chemicals to be evaluated.

7. Once the JMPR has reviewed a chemical, three scenarios may occur:

- the data confirm the existing Codex MRL, it remains in place, or

- a new MRL is recommended or an amendment of an existing MRL. The new or amended proposal enters at Step 3 of the Codex procedure. The existing MRL remains in place for no more than four years or

- insufficient data have been submitted to confirm or amend an existing Codex MRL. The Codex MRL is recommended for withdrawal. However, the manufacturer or countries may provide a commitment to the JMPR and CCPR to provide the necessary data for review within four years. The existing Codex MRL is maintained for a period of no more than four years pending the review of the additional data. A second period of four years is not granted.

MRLs for Commodities of Animal Origin

8. Farm animal metabolism studies are required whenever a pesticide is applied directly to livestock, to animal premises or housing, or when significant residues remain in crops or commodities used in animal feed, in forage crops, or in plant parts that could be used in animal feeds. The results of farm animal feeding studies and residues in animal feed serve also as a primary source of information for estimating maximum residue levels in animal products.

9. If no adequate studies are available, no MRLs will be established for commodities of animal origin. MRLs for feeds (and the primary crops) should not be established in the absence of animal transfer data. Where the exposure of livestock to pesticides through feeds leads to residues at the limit of quantitation, MRLs at the LOQ must be established for animal commodities. MRLs should be established for all mammalian species where pesticides on feeds are concerned and for specific species (e.g cattle, sheep) where direct treatments of pesticides are concerned.

10. Where the recommended maximum residue limits for animal commodities resulting from direct treatment of the animal, regardless of whether they are recommended by JMPR or JECFA and from residues in animal feed do not agree, the higher recommendation will prevail.

MRLs for Processed or Ready-to-eat Foods or Feeds

11. CCPR agreed not to establish MRLs for processed foods and feeds unless separate higher MRLs are necessary for specific processed commodities. However, this policy is under discussion at the moment.

MRLs for spices

12. CCPR agreed that MRLs for spices can be established on the basis of monitoring data in accordance with the guidelines established by JMPR.

MRLs for fat-soluble pesticides

13 If a pesticide is detertmined as “fat soluble” after consideration of the following factors, it is indicated with the text “The residues are fat soluble” in the residue definition:

- When available, it is the partitioning of the residue (as defined) in muscle versus fat in the metabolism studies and livestock feeding studies that determines the designation of a residue as being “fat soluble”.

- In the absence of useful information on the distribution of residues in muscle and fat, residues with logPow>3 are likely to be “fat soluble”

14. For fat soluble pesticides, two MRLs are recommended if data permit: one for whole milk and one for milk fat. For enforcement purposes, a comparison can be made either of the residue in milk fat with the MRL for milk fat or of the residue in whole milk with the MRL for milk.

Establishment of MRLs

15. The CCPR is entrusted with the elaboration of Maximum Residue Limits (MRLs) of pesticide residues in food and feed. The JMPR is using the WHO Guidelines for predicting dietery intake of pesticides residues (revised)(1997)[32]. The JMPR is recommending MRLs establishing Supervised Trial Median Residues (STMRs) for new and periodic review compounds for dietary intake purposes. In cases the intake exceeds the Acceptable Daily Intake (ADI) in one or more of the regional diets, the JMPR, when recommending MRLs, flags this situation indicating the type of data which may be useful to further refine the dietary intake estimate.

16. When the ADI is exceeded in one or more regional diets, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level. If further refinement is not possible then MRLs (and CXLs) are withdrawn until the remaining MRLs and CXLs give no longer rise to intake concerns. This procedure should be reviewed at regular interval.

17. The JMPR is currently routinely establishing acute reference doses (ARfDs), where appropriate, and indicates cases where an ARfD is not necessary. The 1999 JMPR for the first time calculated the short-term dietary intake estimates following an approach using the International and National Estimates of Short-term Intake (IESTI, NESTI). The procedure allows for estimating the short-term risk for relevant subgroups of the population, like children. The JMPR flags cases when the IESTI for a given commodity exceeds the acute RfD.

18. When the ARfD is exceeded for a given commodity, then the MRLs will not advance to Step 8 pending further refinement of the intake at the international level.

19. When a Draft MRL has been returned to Step 6 three times, the CCPR should ask JMPR to examine residue data from other appropriate GAPs and to recommend MRLs which cause no dietary intake concerns if possible.

20. If further refinement is not possible then MRLs (and CXLs) are withdrawn. More sophisticated methodologies such as probabilistic approaches are under investigation at the moment.

21. The estimate of the short-term dietary intake requires substantial food consumption data that currently are only sparsely available. Governments are urged to generate relevant consumption data and to submit these data to the WHO.

Utilization of Steps 5/8 for elaboration of MRLs

22. Preconditions for utilization of Step 5/8 Procedure

- New MRL circulated at Step 3
- JMPR report available electronically by early February
- No intake concerns identified by JMPR

23. Steps 5/8 Procedure

- If the preconditions listed above are met.
- If a delegation has a concern with advancing a given MRL, a concern form should be completed detailing the concern along with a description of the data that will be submitted to substantiate the concern preferably along with responses to the CL, or at the latest, one month after the CCPR session.

[32] Programme of Food Safety and Food Aid; WHO/FSF/FOS/97.7

- If the JMPR Secretariat or the CCPR can address that concern at the upcoming CCPR session, and the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 5/8.
- If the concern cannot be addressed at the meeting, the MRL will be advanced to Step 5 at the CCPR session and the concern will be addressed by the JMPR as soon as possible but the rest of the MRLs should be advanced to Step 5/8.
- The result of the consideration of the concern by the JMPR will be considered at the next CCPR session. If the JMPR position remains unchanged, the CCPR will decide if the MRL will be advanced to Step 8.

Establishment of EMRLs

24. The Extraneous Maximum Residue Limit (EMRL) refers to a pesticide residue or a contaminant arising from environmental sources (including former agricultural uses) other than the use of the pesticide or contaminant substance directly or indirectly on the commodity. It is the maximum concentration of a pesticide residue that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food, agricultural commodity or animal feed.

25. Chemicals for which EMRLs are most likely to be needed are persistent in the environment for a relatively long period after uses haven been discontinued and are expected to occur in foods or feeds at levels of sufficient concern to warrant monitoring.

26. All relevant and geographically representative monitoring data (including nil-residue results) are required to make reasonable estimates to cover international trade. JMPR has developed a standard format for reporting pesticide residues monitoring data[33].

27. The JMPR compares data distribution in terms of the likely percentages of violations that might occur if a given EMRL is proposed to the CCPR.

28. Because residues gradually decrease, CCPR evaluates every 5 years, if possible, the existing EMRLs, based on the reassessments of the JMPR.

29. The CCPR generally agreed at the 30th Session on the potential elements for inclusion in a set of criteria for estimation of EMRLS while it also agreed not to initiate a full exercise of criteria elaboration.

Periodic Review Procedure

30. The Committee agreed on the Periodic Review Procedure, which was endorsed by the CAC and attached to the list of MRLs prepared for each session of the CCPR. Those Codex MRLs confirmed by JMPR under the Periodic Review shall be distributed to members and interested organizations for comments.

Deleting Codex MRLs

31. Every year new compounds are introduced. These compounds are often new pesticides which are safer than existing ones. Old compounds are then no longer supported/produced by industry and existing Codex MRLs (CXLs) can be deleted.

32. If information is delivered between two sessions of CCPR, that a certain compound is no longer supported, this information will be shared during the first coming session (t=0). The proposal will be to delete the existing CXLs at the following session (t=0+1 year).

33. It may happen that compounds are no longer supported in Codex, but are supported in some selected countries. If there is no international trade in commodities where the active compounds may have been used, CCPR will not establish MRLs.

[33] Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed; FAO Plant Production and Protection Paper, 170, 2002, ISBN 92-5-104759-6

MRLs AND METHODS OF ANALYSIS

34. JMPR needs data and information for their evaluations. Among these are methods of analysis. Methods should include specialized methods used in supervised trials and enforcement methods.

35. If no methods of analysis are available for enforcing MRLs for a specific compounds, no MRLs will be established by CCPR.

Appendix 4

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

(for inclusion in the Codex Procedural Manual)

1. PURPOSE – SCOPE

1. The purpose of this document is to specify Risk Analysis Principlesapplied by the Codex Committee on Residues of Veterinary Drugs in Foods.

2. PARTIES INVOLVED

2. The *Working Principles for Risk Analysis for application in the framework of the Codex Alimentarius*[34] 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 (CAC) and its subsidiary body, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRDVF), 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 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 MRLs for such veterinary drugs;

(c) to develop codes of practice as may be required;

(d) to consider whether available methods of sampling and analysis for the determination of veterinary drug residues in foods.

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

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

6. JECFA is primarily responsible for providing independent scientific advice, the risk assessment, upon which CCRVDF base their risk management decisions. It assists the CCRVDF by evaluating the available scientific data on the veterinary drug prioritised by 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.

[34] Codex Procedural Manual, 15th Edition page 101 (English version).

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*[35].

3.1 Preliminary risk management activities

10. This first phase of risk management covers:

- Establishment of risk assessment policy for the conduct of the risk assessments;
- Identification of a food safety problem;
- Establishment of a preliminary risk profile;
- Ranking of the hazard for risk assessment and risk management priority;
- Commissioning of the risk assessment; and
- Consideration of the result of the risk assessment.

3.1.1 RISK ASSESSMENT POLICY FOR THE CONDUCT OF THE RISK ASSESSMENT

11. The responsibilities of 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 IDENTIFICATION OF A FOOD SAFETY PROBLEM (ESTABLISHMENT OF THE PRIORITY LIST)

12. 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. 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 maximum residue limit (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 rules 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.

[35] Codex Procedural Manual, 15th Edition page 159 (English version)

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.

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.[36]

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 the 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

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[37]. 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. The JECFA should, if necessary, propose different risk management options. In consequence, JECFA should present, in its report, different risk management options for 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 CCRVDF (or the absence thereof) should also be fully documented.

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[38] and subsequent amendments made by this Committee.

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.

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

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36 Codex Procedural Manual, 15th Edition pages 19-30 (English version).

37 Codex Procedural Manual, 15th Edition page 45 (English version).

38 See Report of the 12th session of the CCRVDF ALINORM 01/31 para 11.

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 Program for the Control of Veterinary Drug Residues in Foods.*

30. 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*[39], 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.

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.

[39] Codex Procedural Manual, 15th Edition page 161 (English version).

ANNEX

TEMPLATE FOR INFORMATION NECESSARY FOR PRIORITIZATION BY CCRVDF

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[40]

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 methodos) available

TIMETABLE

16. Date when data could be submitted to JECFA

[40] 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 DRAFT
RISK ASSESSMENT POLICY FOR THE SETTING OF MRLS IN FOOD

(for inclusion in the Codex Procedural Manual)

Role of JECFA

1. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an independent scientific expert body convened by both Director Generals 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 CCRVDF

(a) JECFA provides CCRVDF with science-based risk assessments conducted in accordance with the *Statements of principles relating to the role of food safety risk assessment*[41] and incorporating the four steps of risk assessment. JECFA should continue to use its risk assessment process for establishing ADIs and proposing MRLs.

(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.

(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 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.

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.

[41] Codex Procedural Manual 15th Edition page 161 (English version).