

codex alimentarius commission



FOOD AND AGRICULTURE
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Interested International Organizations

FROM: Secretariat, Codex Alimentarius Commission
Joint FAO/WHO Food Standards Programme
FAO, 00153 Rome, Italy

SUBJECT: **Review of the Risk Analysis Policies of Codex Committees**

DEADLINE: **31 March 2010**

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Following the decision of the Committee on General Principles at its 25th Session (2009), the Secretariat prepared a review of the Risk Analysis Policies of Codex Committee, for consideration by the 26th Session of the Committee (Paris, France, 12-16 April 2010). 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.

Governments and international organizations wishing to provide comments should do so in writing, preferably by email, to the above addresses, **before 31 March 2010.**

REVIEW OF THE RISK ANALYSIS POLICIES OF CODEX COMMITTEES

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.

Additives and Contaminants

The *Risk Analysis Principles Applied by the Codex Committee on Food Additives and the Codex Committee on Contaminants in Foods* do not follow the format of the Working Principles, insofar as the requirements are not presented as risk assessment, risk management and risk communication. However, as they follow the respective role and activities of the Committees (CCFA and CCCF) and JECFA, it would appear relatively easy to retain current provisions in the main text, changing only the title of some of the sections

Section 2. CCFA/CCCF and JECFA could be described as “risk analysis”, *Section 3. CCFA/CCCF* as “risk management”; and *Section 4. JECFA* as “risk assessment”. Although no specific section exist on risk assessment policy, it may be noted that paragraph 19 of the general *Working Principles* has been applied in practice in order to establish maximum levels for contaminants, by the Committee on Food Additives and Contaminants and subsequently by the Committee on Contaminants in Foods. This possibility is currently mentioned under paragraph 22 both for additives and contaminants, but might be more specific for contaminants. Some consideration could also be given to the insertion of a section on risk communication that could include the current provisions related to the interaction between risk assessors and risk managers.

As these principles were developed when the Committee on Food Additives and Contaminants was still in existence as a single committee, they were amended accordingly when two separate committees were established. In view of possible differences or specificities regarding additives and contaminants, it might also be useful to consider whether two separate sets of principles could be developed for additives and for contaminants. However, if many of the provisions are common and the differences are few and clearly identified, this may not be essential to clarify the process.

In the *Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups*, although the title refers to the Committee, many sections describe the process followed by JECFA, especially Sections 2, 3 and 4, and therefore could be considered for incorporation into the main Risk Analysis Principles under “risk assessment”. Section 5 might be considered under risk assessment policy.

Pesticide Residues

The 24th Session of the Committee on General Principles (2007) considered the *Draft Risk Analysis Principles Applied by the Codex Committee on Pesticide Residues*, and several comments were made in the discussion, especially as regards the need to ensure consistency between the documents describing risk analysis policies throughout Codex, and the discrepancies between the documents under consideration for pesticide residues, veterinary drugs, additives and contaminants.

The Committee did not consider substantial changes and agreed that, following the adoption of the text, all adopted risk analysis policies should be reviewed by the Committee, especially as regards their consistency with the general *Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius*. The Committee endorsed the above document and also recommended that the Committee on Pesticide Residues review the *MRL Periodic Review Procedure* in the light of more recent documents related to the MRL setting process and consider the publication of this procedure in the Procedural Manual (ALINORM 07/30/33, para. 27-34 and 159). The 31st Session of the Commission subsequently adopted the document (ALINORM 07/30/REP para. 30-34).

The proposal for new work from the 40th Session of the Committee on Pesticide Residues on the revision of the *Risk Analysis Principles applied by the Codex Committee on Pesticide Residues*, which would incorporate the *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR* and the *MRL Periodic Review Procedure* was approved by the Commission in 2008.

The 41st Session of the CCPR (2009) considered a first version of the document and agreed that it would be revised for consideration at its next session. The Committee acknowledged that the revision should be finalized by 2010 as the Committee on General Principles would review the consistency of risk analysis principles elaborated by relevant subsidiary bodies of the Commission in 2011 (ALINORM 09/31/24, paras 184-185). The 42nd Session of the CCPR (2010) will consider the revised version presented in CX/PR 10/42/12.

As indicated above, several issues were raised in the Committee on Pesticide Residues, the Committee on General Principles and the Commission on these risk analysis principles. They are currently under revision and will be considered further by that Committee. The present review will not consider the new draft under discussion as this is the responsibility of the CCPR, but concentrates on the issue of consistency with the general *Working Principles* as specified the Strategic Plan. The recommendations that the Committee may wish to make in this regard could also be considered by the CCPR to provide further orientation in the revision of the current *Risk Analysis Principles*.

As regards the general issue of consistency, the structure of the principles applied to pesticide residues does not follow the general *Working Principles* and as mentioned in the general considerations, the Committee may consider a general recommendation to reorder the document according to the three components of risk analysis. However, this may not be sufficient as the provisions for inclusion in each section need further consideration, especially to take into account the recommendations that appear in the Annex or in other documents addressing the process of MRL setting.

A general section on risk analysis for pesticides could be added to address the specificities of MRL setting for pesticides, such as the application of paragraph 9 of the *Working Principles* referring to the separation between risk assessment and risk management, as in the case of pesticide residues, MRLs are initially proposed by JMPR.

While discussing the general approach at the last session of the Committee on General Principles, it was pointed out that different approaches existed to MRL setting (based on GAPs or on ADIs). A general description of the approach taken for pesticides (based on GAPs) could be included in a general section on risk analysis.

In the first section of the Principles, *Interaction between CCPR and JMPR*, paragraph 2 could be included in the scope while some other paragraphs (3 and 4) could be placed under a new “risk communication” section, or possibly in a general section on risk analysis (paragraph 5).

The sections on risk assessment and risk management could incorporate most of the provisions currently presented under the “Role of JMPR” and “Role of CCPR” respectively.

As in the case of other risk analysis principles, there is no section on risk assessment policy and its inclusion would also be useful to describe the specificities of MRL setting. For example, paragraph 17 of the CCPR Risk Analysis Principles is related to paragraph 16 of the *Working Principles* on the possibility of asking risk assessors to evaluate the potential changes in risk resulting from different risk management options. This section could also incorporate paragraphs 15 and 16 which address the selection of substances for evaluation by JMPR.

The Committee, when endorsing the Risk Analysis Principles, recommended that the Committee on Pesticide Residues review the MRL *Periodic Review Procedure* in the light of more recent documents related to the MRL setting process. The use of this procedure is currently under discussion in the CCPR and how it will be revised or further used is not for discussion in the present review. However, the CCGP may recommend that whatever the future content and form of the section, it should be integrated into the risk analysis principles and included in the Procedural Manual.

Annex and Criteria

Several recommendations presented in the sub-sections of the *Annex : List of Risk Management Policies Used by CCPR* may be relevant for inclusion under “risk assessment policy” or “risk management”: Procedure for Proposing Pesticides for Codex Priority List, MRLs for Commodities of Animal Origin, MRLs for ready-to-eat foods or feeds, MRLs for spices and MRLs for fat-soluble pesticides, and could be reintegrated into the main text of the Risk Analysis Principles.

As the *Procedure for Proposing Pesticides for Codex Priority List* and the *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR* both address prioritisation, consideration could be given to grouping all the provisions on prioritisation in a single section in the Risk Analysis Principles, or in an annex, as may be the case.

The four sections on the establishment of specific types of MRLs could be considered for integration into the “risk assessment policy”, while some provisions related to the studies considered by JMPR could be part of risk assessment.

The *Establishment of MRL* section could be integrated into the main text according to the relevance of each paragraph to risk management or risk assessment, in view of its importance to describe the process. Paragraph 17 refers to the establishment of the ARfD and approach followed by JMPR and could be included under Risk Assessment.

Under *Utilization of Steps 5/8 for elaboration of MRLs*, the process described is not related to risk analysis as such but to the procedure for decision in the Committee and consideration might be given to deleting it from the Risk Analysis Principles and including it in another section of the Manual.

The section on the Establishment of EMRLs includes both elements of risk assessment and risk management. It could be deleted as a separate section and EMRL setting would be addressed according to the risk assessment and risk management components of the process, to be included in the relevant sections. Paragraph 29 is a record of a discussion held in the Committee, not an element of risk analysis and therefore could be deleted in its present form, or rewritten as a statement concerning the criteria for EMRLs.

As the section on *Deleting Codex MRLs* is related to the provisions described in the *Procedure for Proposing Pesticides for Codex Priority Lists*, especially paragraph 7 (third indent) and the risk management decisions of the Committee, these provisions could also be integrated into the Risk Analysis Principles.

As regards *MRLs and Methods of Analysis*, paragraph 34, which refers to JMPR, might be considered under “risk assessment”. Paragraph 35 might be transferred to the risk management section or alternatively the Committee might review the need for its inclusion, as it is not systematically applied.

The *Criteria for the Prioritization Process of Compounds for Evaluation by JMPR* also include section 2.2 *Periodic Re-Evaluation* and it might be useful to group all provisions on the periodic review in a single section instead of retaining the separate document on the *MRL Periodic Review Procedure*, the review of which was earlier recommended.

In section 2.3 *Evaluations* of the *Criteria*, some recommendations relate to the interaction between risk assessors and risk managers, not only to the criteria for prioritisation in the Committee, and may be considered for inclusion in the main text of the document.

As a result of the above, the main points proposed for consideration are the reordering of the current sections according to the three components of risk analysis; the reconsideration of current provisions as to their relevance for each section; the inclusion of a general section on risk analysis and a section on risk assessment policy; and the integration of the relevant recommendations provisions from the Annex and the Criteria into the main text of the *Risk Analysis Principles*.

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*.

Nutrition and Foods for Special Dietary Uses

When the *Working Principles* were developed, they were mainly intended to address risk analysis in the context of chemical and microbiological hazards and to ensure food safety. As the Principles are of general application, they were taken into account in the development of the *Nutritional Risk Analysis Principles for Application to the Work of the CCNFSDU*. However, due to the nature of the subject and the addition of health aspects in addition to food safety, it was necessary to introduce several new concepts and definitions that were specifically required to develop the concept of risk analysis as applied to nutrition. For this reason, a comparison with the *Working Principles* may not be as relevant as in the case of risk analysis principles addressing chemical or microbiological hazards, and only a few remarks are presented below.

The *Nutritional Risk Analysis Principles* generally follow the structure of the *Working Principles* as regards the description of risk assessment and risk management. There are no specific provisions regarding risk communication, only a reference to the corresponding section in the *Working Principles*, and this section might be further developed to take into account the specificities of nutrition risk assessment, if needed.

As regards the order of the sections, the last section *Selection of Risk Assessor by CCNFSDU* includes only two paragraphs which might also be transferred to other sections. Paragraph 33 could be inserted at the beginning of the document, possibly under Section 1 which identifies the risk manager and could also refer to the risk assessor.

Paragraph 34 refers to the request for risk assessment formulated by the CCNFSDU and could be transferred to the section on *Nutritional Problem Formulation* or in *Nutritional Risk Management*, rather than including it at the end of the document.

Food Hygiene

The last session of the Committee on Food Hygiene (2009) completed its risk analysis policies and the *Proposed Draft Risk Analysis Principles and Procedures Applied by the Codex Committee on Food Hygiene* are submitted to the Committee for endorsement under Agenda Item 2. The Committee may wish to take into account the consistency with the Working Principles while discussing the endorsement of the document. However, as it is not yet adopted in its final form, it will be for the Committee to decide whether it should also be considered in detail in the present review.

Taking into account the specificities of microbiological risk analysis, it appears that the main part of the document clearly describes the various components of risk analysis as applied in the area of food hygiene, including preliminary risk management activities and the establishment of a risk profile, and the steps of risk assessment applied by JEMRA.

As regards the Annex, the Committee may recall that a similar document was considered by the 23rd Session of the Committee (2006) (CX/GP 06/23/2 Part II) where some amendments were proposed and referred back to the CCFH (ALINORM 06/29/33, para. 45-57). One of the recommendations made at the time was that the Committee on Food Hygiene consider the development of a document explaining its policies in the application of risk analysis, as the document proposed included both elements related to decision making and interaction between risk assessors and risk managers.

The Annex includes detailed provisions on the process of work management in the Committee, which are not directly related to the risk analysis process. The Committee may wish to consider as a general issue whether such an Annex should be included in a document on risk analysis policies and whether this is consistent with the *Working Principles*. In other documents on risk analysis policies, there may be a few references to procedure or process issues, as mentioned in the relevant sections above, but in the CCFH document, these issues are discussed in considerable detail.

The section on the *Process for Considering Proposals for New Work* describes how the relevant working group may be convened and operate. The Committee may consider whether this is really necessary as all Committees can always convene working groups according to their needs, provided they follow the *Guidelines on Physical Working Groups*, and the few specificities pertaining to the organisation of each committee may not require specific provisions in the Procedural Manual.

In the *Proposals for New Work* section, it is specified that a risk profile should be developed in addition to the usual requirements for new work. This requirement is already mentioned in paragraph 2 of section II of the main document and may not need to be repeated in the Annex. Paragraph 6 and 7 of the Annex may not be needed as the critical review already specifies that the type of Codex standard or related text proposed, the food safety problem to be addressed, and the relationship with existing Codex standards should be specified in the project documents.

As regards the section on *Obtaining Scientific Advice*, since the main document describes the interaction between risk assessors and risk managers in Section V and VI, it is not clear why there is a need to include another section on the request for scientific advice to JEMRA in an Annex. In order to ensure consistency with the Working Principles, all provisions related to the three components of risk analysis should preferably be included in the same document. The Committee may therefore consider deleting this section and incorporating any relevant provisions therein into the main text. When the CCGP considered a similar document in 2006, as mentioned above, it recommended that such provisions be included in the risk analysis policies document paper to be developed. As this document has been finalised, relations between CCFH and JEMRA may not need to be considered both in the main document and in the Annex.