codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00153 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

Agenda Item 5 **CX/GP 10/26/5-Part 1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX ALIMENTARIUS COMMITTEE ON GENERAL PRINCIPLES
Twenty-sixth Session
Paris, France, 12 -16 April 2010

REVIEW OF THE RISK ANALYSIS POLICIES OF CODEX COMMITTEES

COMMENTS IN REPLY TO CL 2010/01-GP
(Australia, Chile, Costa Rica, European Union, Kenya, CRN)

AUSTRALIA

Australia would like to thank the Secretariat for preparing the comprehensive review of the risk analysis policies of Codex Committees presented in the circular letter. Australia strongly supports the review of risk analysis policies of Codex Committees to enhance the consistency of risk analysis policies and communication across committees. As a general comment regarding format we would also encourage consistency in the use of numbering for Sections and paragraphs.

Australia would like to offer the following comments in respect of the individual committees risk analysis policies.

In relation to CCFA & CCCF:

The principles that are applied to the Codex Committee on Food Additives and Contaminants (CCFAC) were revised at the first meeting of the CCFA and CCCF respectively. With regard to CCFA, the principles were revised to address food additives, and for the CCCF, food contaminants. However, the general text within the *Risk Analysis Principles* document has not been revised substantially by the CCFA.

The suggestions within CL 2010/1-GP for renaming the title of: *Section 2* closely aligns with 'risk analysis'; *Section 3*, aligns with 'risk management'; and *Section 4* aligns with 'risk assessment' appear sound. Although, Australia recommends that these sections would need re-ordering and revision.

For the suggested 'risk communication' section, it is not clear on the intention of this section. Australia believes that this section would largely contain information on how the CCFA prioritises and communicates with JECFA and the community at large.

Australia supports the approach that is suggested for the CCFA and CCCF.

In relation to CCPR

Australia notes that at its 40th Session, the Codex Committee on Pesticide Residues (CCPR) agreed to recommend the revision of the *Risk Analysis Principles applied by the Codex Committee on Pesticide Residues* to the Commission (ALINORM 08/31/24, paras. 129-134) we note that this revision has not been completed. In regard to specific elements suggested in the Secretariat paper these should be refered to the CCPR to consider in its review.

In relation to CCRVDF

Australia supports the comments and proposals relating to the CCRVDF risk analysis policies, in particular we strongly support the proposal to include a more general section on risk communication, incorporating existing provisions including those under 3.1.6.

With regard to the proposal that Paragraph 18 is unnecessary as it refers to the approval of new work, we would support its deletion because, in our view, the inclusion of this paragraph seems to conflict with the process for the establishment of the Priority List for evaluations by JECFA which is approved by the Commission as new work as a whole rather than as individual pieces of new work.

In relation to CCNFSDU:

Since the *Nutritional Risk Analysis Principles and Guidelines for Application to the Work of the CCNFSDU* (Nutritional Risk Analysis Principles and Guidelines) were adopted by the Commission in 2009, FAO and WHO advised the CCNFSDU at its 31st session, 2009 of the proposed establishment of the Joint FAO/WHO Expert Meetings on Nutrition (JEMNU).

Specifically, FAO and WHO advised that:

> *"JEMNU is to replace the current ad hoc expert consultation arrangement of provision of scientific advice on food and nutrition to Codex and Member States, while keeping flexibility and a low administrative burden"*. And further, *"the JEMNU process will entail a series of consultations that will develop and refine scientific questions and analyse the outcome of systematic reviews addressing them"*.

It is anticipated that JEMNU would perform the role of risk assessor to CCNFSDU most of the time. Australia considers that the CCGP review of Codex risk analysis policies provides an opportunity, once the establishment of JEMNU is confirmed, to revise the Nutritional Risk Analysis Principles and Guidelines to make reference to the JEMNU and to consider in more detail how the Committee might interact with the new body. In particular, the issue of risk communication could be further elaborated.

Australia further agrees that Section 6 – Selection of a Risk Assessor by CCNFSDU could be deleted and the two paragraphs distributed within the previous text as suggested by CCGP with consequent renumbering of all relevant paragraphs. The following changes to the text, with minor editorial amendment, could be considered:

A Insert Paragraph 33 into Section 1 as new paragraph 4.

4. Consistent with their important role in providing scientific advice to the Codex Alimentarius Commission and its subsidiary bodies, the CCNFSDU acknowledges FAO and WHO as ~~the~~ **its** primary source of nutritional risk assessment advice ~~to Codex Alimentarius~~. This acknowledgment however, does not preclude the possible consideration of recommendations arising from other internationally recognised expert bodies, as approved by the Commission.

B Insert Paragraph 34 into Section 5 as new paragraph 19. Also delete paragraph 31 as it would become redundant with this change.

19. All **CCNFSDU** requests for risk assessment advice should be accompanied by terms of reference and where appropriate, risk assessment policy to provide guidance to the risk assessor. ~~These parameters should be established by CCNFSDU.~~

~~31. Nutritional risk assessment policy should be articulated as appropriate for the selected risk assessor prior to the conduct of the nutritional risk assessment.~~

In relation to CCFH:

Australia supports the comments referring to CCFH matters, particularly, the suggested changes to the Annex on the process of work management in the Committee, namely within the section on *Obtaining Scientific Advice*, deleting the section on the interaction between risk assessors and risk managers. This area was covered in the main document on Principles and Procedures, and at the 41st Session of the CCFH, the group focussed on ensuring that the main document was included in the scope to obtain advice from other sources, including JEMRA.

The CCFH has anticipated that there will be potential replication and duplication between the Annex and the main document, and the committee expected that there would be some revision of the Annex based on these grounds.

CHILE

We agree with the Secretariat's report, particularly with the recommendation that the committees draft their documents according to the structure of the Working Principles for Risk Analysis approved by the Commission and produced at this Committee on General principles. This applies to new documents and to all the documents that have already been drafted, but that have to be adapted or reordered according to the above-mentioned format and structure.

Reordering will contribute to the consistency review process by the Committee on General Principles. In this way, repetitions in the same document can be avoided, as was remarked in the Secretariat's report.

The structure mentioned in the document should include the four aspects: risk assessment policy, risk assessment, risk management and risk communication.

The scope of the document will depend on whether the recommendations of the respective Committee refer to the Codex, in which case the document "Working Principles for Risk Analysis for Application in the Framework of the Codex" would be the basis; or whether the text focuses on recommendations to the governments, in which case the basis would be the document "Working Principles for Risk Analysis for Food Safety for Application by Governments".

For the specific case of documents from the different Committees, so diligently analyzed by the Secretariat, the recommendations could be endorsed in each case. As a result, the Secretariat's work would facilitate the Committee on General Principles' work.

COSTA RICA

Additives and Contaminants:

Costa Rica considers that risk analysis should be conducted separately for contaminants and additives. There should be two separate documents, as each substance has very different effects and different exposure factors are taken into account to establish the maximum limits of each.

In reference to the submitted proposals, Costa Rica agrees with the proposal to amend the titles:

"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".

Costa Rica also supports the insertion of a section on risk communication.

Pesticide Residues:

Concerning Pesticide Residues, as it is said in the document, in 1998 the Commission approved 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". To do so, the CCPR set up an electronic working party that completed the revision and merged the three documents into one. This document will be submitted to the Committee's consideration at the next session in April. However, the new document does not reorder the sections according to the three components of risk analysis, as indicated by the Committee on General Principles. Costa Rica considers that the recommendations in this document on the principles applied by the CCPR should have been communicated to the CCPR before concluding the revision for incorporation into the final document that will be reviewed at the next session.

Nutrition and Foods for Special Dietary Uses:

Costa Rica agrees with the proposals to amend the form of the document "Nutritional Risk Analysis Principles for Application to the Work of the Codex Committee on Nutrition and Foods for Special Dietary Use".

However, Costa Rica would like the topic of risk communication to be expanded, to take into account the specificities of nutritional risk assessment.

Residues of Veterinary Drugs:

Concerning the "Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods" and the "Risk Assessment Policy for Setting of MRLs for Residues of Veterinary Drugs in Foods", Costa Rica considers that the functions of each committee are very different in terms of scope of action and responsibility. The functions of the CCRVDF and JEFCA interconnect; their respective functions have to be more strongly emphasized for greater clarity.

1. For the above reason, it is essential to "reorder" all the provisions of both documents, to ensure they have a logical sequence and that users can find the entire context of risk analysis in a single document. The term "incorporate" can change many things that have already been clearly defined. The soundest approach would be to ensure that the scientific part of the process is not interfered with.
2. If one considers both terms, it is important to point out that, "this may not involve significant amendments of the recommendations themselves but rather a reordering of existing paragraphs."

Costa Rica agrees that reordering the documents would be logical, and helpful for reader comprehension.

The provisions for prioritization could be included in a single section, in addition to examining the possibility of including new provisions so that, in general, this topic does not become too great a constraint for developing countries such as Costa Rica.

EUROPEAN UNION

The European Union and its Member States (EUMS) would like to thank the Codex Secretariat for the thorough review of the consistency of the risk analysis policies of Codex Committees presented in CL 2010/1 GP.

The EUMSs take note that CCGP developed the current *Working Principles on Risk Analysis for Application in the Framework of Codex Alimentarius*. Thereafter, other Codex Committees developed their own specific texts on risk analysis principles. These specific texts were submitted to CCGP for review and endorsement before their adoption by the CAC and insertion in the Procedural Manual. At that stage, CCGP did not identify any glaring inconsistencies between the specific texts and the provisions of the *Working Principles*.

The EUMS are of the view that the current review should build on the results of previous endorsements and be limited in its scope to discussing whether the consideration of Committee specific texts on risk analysis principles show any inconsistencies or defects that were not identified before and need to be remedied.

Review of the structure and scope of the specific texts

The matters covered by the *Working Principles* are addressed in the five specific texts. The main difference is essentially about the order in which the material is arranged in each specific text:

- Three specific texts (CCRVDF, CCFH, CCNFSDU) follow the risk analysis process in which the risk assessment step is sandwiched between activities by risk managers. More emphasis is put on "preliminary risk management activities", which only feature modestly, in a short footnote, in the *Working Principles*, and specific sections have been developed to this effect;

- In two other specific texts (CCFA/CCCF, CCPR) the essential elements of risk analysis are covered but they are contained in sections explaining the roles of respective players: risk assessment/Joint Expert Body (JEB), risk management/Codex Committee.

In one specific text (CCNFSDU), due allowance had to be made for the specificity of the area of work and the lack of a permanent JEB, by further developing sections on 'introduction and scope', on 'risk assessment' policy and by extending the list of definitions given in *Working Principles*.

None of the specific texts deals with risk communication in its entirety. Instead, they focus on the 'iterative interaction' between risk managers and risk assessors. This is acceptable, keeping in mind the purpose of the texts.

Specific texts contain sections on procedural issues, for example on priority setting, which fall outside the scope of risk analysis principles but give useful guidance for the Committees in their work.

These differences in the scope and/or in the structure do not make any of the specific texts inconsistent with the *Working Principles* or result in any substantial gaps in the matters covered. A reshuffling of sections to achieve a uniform structure would be of limited practical value.

Considering that the Committee specific texts are broadly consistent with the *Working Principles*, the EUMS question the need to revise the specific texts only for the sake of aligning their structure with the *Working Principles*. Such work would consume the already limited resources of Codex Committees which could otherwise be devoted to the core Codex activity, i.e. standards development, thereby potentially delaying the achievement of Strategic Goal 3: "Strengthening Codex work-management capabilities" of the CAC Strategic Plan 2008-2013.

At the same time, the EUMS note that CCPR is currently in the process of reviewing its risk analysis principles. It would therefore be appropriate to recommend that CCPR takes into account in that work the specific recommendations in CL 2010/1 GP under the section "Pesticide Residues".

Review of the consistency in terminology

The word “evaluation” is present 24 times in the specific documents, in contexts where using the word “assessment” would be mandated by the *Working Principles*.

Although the *Working Principles* have been adopted by the CAC as far back as 2001, this obsolete usage is not limited to the documents under review and is still prevalent in many documents circulated on behalf of these Committees and their JEB (for example CX/PR 10/42/14-Rev – section A 1st line; CX/FA 10/42/1 – title of the Agenda Item 9, etc…).

The Committee could correct the mistake in the current texts and invite other Committees to give proper currency to the language adopted by the CAC.

KENYA

Background information

As a general remark in 25th session of CCGP, it was 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 was tasked to 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

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.

In this regard, Kenya would like to submit the following general comment.

General comment

- *There is need of consistency with working principles and consideration for additional aspects that are specific to the committee.*
- *Each committee, that is food additives, contaminants in food, pesticide residues in food, veterinary residues in food, Nutrition and food hygiene, needs to review the order of their presentation to enhance communication among relevant codex committees. In this case the word ‘presentation’ refers to format of the principles of risk analysis according to the three components of risk analysis*.

COUNCIL FOR RESPONSIBLE NUTRITION (CRN)

Introduction

The Codex Alimentarius Commission Strategic Plan 2008-2013 includes a Goal (2.1) for the CCGP to review by 2011 the consistency of the Risk Analysis Principles elaborated by the relevant Codex Committees. Accordingly, the Provisional Agenda for the CCGP 26 Session on 12-16 April 2010 includes Agenda Item 5: Review of the Risk Analysis Policies of Codex Committees.

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) completed its development of Nutritional Risk Analysis Principles in 2008, and this document was adopted by the Commission in 2009. These CCNFSDU principles of risk analysis are briefly discussed in CX5/15 in CL 2010/1-GP. This comment by CRN addresses the CCNFSDU Risk Analysis Principles with the objective of improving the scientific accuracy and completeness of the CCGP work to fulfill its mandate to review the consistency of Risk Analysis Principles elaborated by the relevant Codex Committees after discussion under Agenda Item 5 in the 2010 meeting of the CCGP.

Comments

When the Nutritional Risk Analysis Principles were discussed in the meeting of the CCNFSDU that promoted them to Step 10 for consideration by the Commission, there was some debate about the use and meaning of the term "hazard." The issue was whether "hazard" should be used to refer to an "agent" or "substance in food" or to the "adverse effect" that would serve as the basis for limiting the amount of a nutrient to be permitted.

There is wide acceptance by authoritative scientific bodies to use the term "hazard" to refer to the adverse **effect** of significant concern. For example, the U.S. Institute of Medicine (IOM) uses "hazard" to mean the critical adverse effect selected as the basis of the Tolerable Upper Intake Level (UL) for a nutrient. This usage is also adopted by the European Commission Scientific Committee on Food (SCF), the U.K. Expert Group on Vitamins and Minerals (EVM) and the Food and Agriculture Organization and World Health Organization (FAO/WHO) definition of the UL. These usages by the IOM, SCF, EVM, and FAO/WHO are cited and quoted below.

In contrast to these uses by authoritative scientific bodies, the Codex Procedural Manual, 17th Edition, includes different and perhaps ambiguous uses of the term "hazard." Specifically in the Procedural Manual, the primary use of the term "hazard" is to refer to a chemical or physical **agent**:

- Referring to residues of veterinary drugs in foods, it describes the "hazard" as relating to the time and amount of the residue. Thus, in this usage, the "hazard" is not the agent but an effect that is dependent on the identity and amount of the agent.
- It further elaborates, "A biological, chemical or physical **agent** in, or condition of, food with the potential to cause an adverse health effect." In this usage, "hazard" seems primarily defined as an agent, and not an effect of an agent. On the other hand, the phrase "or condition of" in the same sentence could be interpreted as relating the term "hazard" to either the agent or to the potential of the food containing that agent to produce an adverse effect.

Recommendation

Noting that,

- The Procedural Manual uses a definition for "hazard" that is different from those in the authoritative scientific documents on nutrient risk assessment being cited as the basis in the draft Risk Analysis guideline, and
- The Procedure Manual will be seen as the final authority on the definition of terms used in Codex guidelines.

It is recommend that,

- Accompanying the definition of the term "nutrient-related hazard" in the draft Risk Analysis guideline, a footnote should be inserted that acknowledges that the scientific references cited in the guideline use the term "hazard" as relating to an effect, whereas the Procedural Manual uses the term to refer to an agent. A suggested draft for the footnote follows:

FOOTNOTE: The reference documents and the section on risk assessment use the term *hazard* in a manner that differs from the Procedural Manual, but if these differences are recognized they should not produce any conflict in application of the guideline.

References

The references for the quoted contents of scientific documents and Procedural Manual are below.

1) Food and Nutrition Board, Institute of Medicine. Dietary reference intakes: a risk assessment model for establishing upper intake levels for nutrients. Washington, DC: National Academy Press; 1998.

Excerpt from page 8:

Steps in the Risk Assessment Process
The organization of risk assessment is based on a model proposed by the NRC (1983, 1994); that model is widely used in public health and regulatory decision making. The steps of risk assessment as applied to nutrients are as follows (see also Figure 1):
• Step 1. *Hazard identification* involves the collection, organization, and evaluation of all information pertaining to the adverse effects of a given nutrient. It concludes with a summary of the evidence concerning the capacity of the nutrient to cause one or more types of toxicity in humans."

The statement in the first step in "hazard identification" describes the evaluation of all information pertaining to adverse effects of a nutrient. Thus, this first publication on the UL method clearly refers to hazard as an effect, not an agent or substance. In this method, the agent is the nutrient, and the adverse effect is the hazard.

In summary, the UL method uses the term "hazard" to refer to an effect, but not to the agent producing the effect.

2) Scientific Committee on Food, Scientific Panel on Dietetic Products, Nutrition and Allergies. Tolerable upper intake levels for vitamins and minerals. European Food Safety Authority; 2006.

Excerpt from page 10:

The process of the risk assessment may be divided into a number of steps (FAO/WHO, 1995; FNB, 1997, 1998, 2000):
Step 1. Hazard identification - identification of known or potential adverse health effects of a given nutrient. It involves the collection, organisation and evaluation of all information pertaining to the adverse effects of a given nutrient. It concludes with a summary of the evidence concerning the capacity of the nutrient to cause one or more types of adverse effect in humans.

This usage of the term "hazard" by this European Commission body is identical to that in the IOM document cited above.

3) Expert Group on Vitamins and Minerals. Safe upper levels for vitamins and minerals. London (UK): Food Standards Agency; 2003.

Excerpt from EVM report:

Approach taken by EVM
The EVM is concerned solely with risk assessment, which comprises:
• hazard identification;
• hazard characterisation (including dose-response assessment);
• exposure assessment; and
• risk characterisation.

The available database is reviewed and hazards (adverse effects) identified and characterised.

Thus, the EVM explicitly relates the term "hazard" to adverse effects.

4) FAO/WHO. A model for establishing upper levels of intake for nutrients and related substances. Geneva: FAO/WHO Technical Workshop on Nutrient Risk Assessment; 2006.

Excerpt from **"**Food [modification of IPCS, 2004a: 'hazard']"

hazard: inherent property of a nutrient or related substance to cause adverse health effects depending upon the level of intake

As quoted above, the FAO/WHO Nutrient Risk Assessment report clearly defines "hazard" as a property of a nutrient or related substances, not as the nutrient itself.

5) Procedural Manual, 17th Edition, Codex Alimentarius Commission

Excerpt from page 43:

Codex maximum limit for residues of veterinary drugs (MRLVD) is the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or µg/kg on a fresh weight basis) that is recommended by the Codex Alimentarius Commission to be legally permitted or recognized as acceptable in or on a food. It is based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects.

Excerpt from page 44:

DEFINITIONS OF RISK ANALYSIS TERMS RELATED TO FOOD SAFETY ***Hazard***: A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect. ***Risk***: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. ***Risk Analysis***: A process consisting of three components: risk assessment, risk management and risk communication. ***Risk Assessment***: A scientifically based process consisting of the following