

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
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Agenda Item 3a)

CX/GP 01/3

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON GENERAL PRINCIPLES

Sixteenth Session

Paris, France, 23 - 27 April 2001

### WORKING PRINCIPLES FOR RISK ANALYSIS: THE APPLICATION OF PRECAUTION IN RISK MANAGEMENT

#### I - BACKGROUND

The 15<sup>th</sup> Session of the Committee on General Principles considered the Application of Precaution in Risk Management in the Proposed Draft Working Principles for Risk Analysis (para. 34-35), in the framework of the section on Risk Management. The Committee discussed the proposals put forward in the comments and in the course of the session in order to provide recommendations on the use of precaution in risk management but recognized that no consensus existed at this stage. The Committee agreed that the alternative texts would be circulated for comments, as part of the Proposed Draft Working Principles for Risk Analysis and that a drafting group coordinated by the French Secretariat would work by electronic mail in order to prepare a revised text for consideration by the next session. The Committee noted that the French Secretariat would ensure prompt distribution of material to all members and observers, including replies to the Circular Letter sent at Step 3.

The relevant sections of the Proposed Draft Working Principles were circulated for comments by CL 2000/12-GP (April 2000). The French Secretariat prepared a revised text and a list of the main issues to be solved on the basis of the comments received, either formally at Step 3 or informally in the Working Group. The revised text is hereby circulated for additional comments at Step 3 and consideration by the 16<sup>th</sup> Session of the Committee. A Working Group will be held on 21 April 2001 to consider the Application of Precaution in Risk Management and discuss the proposed text in order to facilitate the discussion, as agreed by the Committee at its 15<sup>th</sup> Session.

Governments and international organizations wishing to submit comments on the above document should do so in writing to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, with a copy to the Codex Contact Point for France, SGCI/CODEX, Carré Austerlitz, 2 Boulevard Diderot 75703 Paris Cedex 12, Fax. 33 (0)1 4487 16 04, Email: [sgci-codex-fr@sgci.finances.gouv.fr](mailto:sgci-codex-fr@sgci.finances.gouv.fr) **before 15 March 2001.**

**Note:** The comments submitted at Step 3 in reply to the CL will be published in a separate document (CX/GP 01/3-Add.1)

## II - PROPOSAL FOR REDRAFTING PARAGRAPHS 34 AND 35

34. "When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food <sup>[1]</sup>, and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and their extent, it may be appropriate for [risk managers/members governments] to apply precaution <sup>[2]</sup> through interim measures to protect the health of consumers, without awaiting additional scientific data and a full risk assessment.

However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly [within a reasonable time frame/until a more complete risk assessment is performed]."

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[1] It is recognized that hazard identification is a crucial step in this process.

[2] Some Members refer to this concept as the "precautionary principle".

35. In such situations the following considerations should be taken into account :

- 1) Examination of the full range of management options should be undertaken with all the stakeholders. This should include an assessment of the potential advantages and disadvantages of the alternative measures, including, where appropriate, flexibility and cost, effectiveness considerations.
- 2) There should be a transparent explanation of the need for the measures and the procedures followed to establish them.
- 3) The decisions/measures taken are proportional to the potential extent of the health risk and based on the available scientific data.
- 4) The decisions/measures taken are consistent with those taken in similar circumstances, based on all the available pertinent information, including available scientific information.  
The measures taken are the least trade restrictive to achieve protection of the health of consumers.
- 5) The decisions/measures are subject to an on-going, transparent review process involving interested stakeholders.
- 6) Information should continue to be gathered to strengthen the scientific evidence. The original decisions should be reviewed and decisions taken to retain, modify, strengthen or rescind any measures as appropriate in the light of such information.

### III - DISCUSSION

#### **Paragraph 34**

Following the submission of comments in the framework of the Working Group, a revised version was drafted (see section II). This takes into account the discussions at the 15<sup>th</sup> Session of the Codex Committee on General Principles and the elements of consensus in the above mentioned comments. However a number of questions remain to be discussed.

➤ The first issue is whether both footnotes should be retained:

- *Footnote 1 : [It is recognized that hazard identification is a crucial step in this process]*

All comments recognize that hazard identification is an essential step. However it appears useful to clarify further this requirement.

The Procedural Manual defines Hazard Identification as “The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.”

What elements should be identified at the hazard identification stage : clarifying the nature of the hazard, evidence/probability of occurrence of adverse health effects ?

The reply to this question should be considered in the wider framework of the factors that trigger the use of the precautionary principle/approach (the extent of scientific data, other objective elements..)

- *Footnote 2: [ Some Members refer to this concept as the "precautionary principle".]*

Some comments request that this reference be deleted.

In view of the positions which have already been expressed, should it be deleted or not ?

➤ The second issue concerns two terms which were retained in square brackets:

- *[Risk managers/member governments]*

It remains to be decided whether the precautionary principle/approach is relevant in Codex work.

This question is controversial.

Some comments point out that the concept is not relevant for Codex work, since it should work on the basis of scientific evidence. In this context, if scientific evidence is insufficient, Codex should refrain from developing standards. The decisions related to the implementation of the precautionary principle/approach would therefore be relevant only for member governments.

- *[within a reasonable time frame]*

When and how should a decision taken on the basis of the precautionary principle/approach be revised ?

On the basis of the comments, two alternative drafts could be proposed. The first refers to the proposal from Malaysia for “a reasonable time frame”. The second links the review to “a more complete risk assessment”

#### **Paragraph 35**

This paragraph was amended at two levels, in reply to the comments received.

1) The presentation of the paragraph was reorganized in order to improve the clarity and logic of the text.

2) Some amendments were introduced in each individual point (underlined in the text). This was intended to address several concurring comments on a consensus basis.