

Comments on "Proposed Draft Working Principles for Risk Analysis for Food Safety"

1. Comments on "Summary of possible options"

1) The committee may wish to consider the following questions:

"whether work should proceed on the development of risk analysis principles intended for government;"

[Japan's Position]

- Positive.

[Rationale]

- Article 5 of the SPS Agreement requires WTO members to ensure their SPS measures to be based on a risk assessment taking into account risk assessment techniques developed by the relevant international organizations. Japan believes the Codex should be the most appropriate entity to develop the risk assessment techniques relating to sanitary measures to protect human life or health as "the relevant international organization."
- At the 20th CCGP meeting, the Representative of WTO stated that risk assessment guidance for governments had already been developed by IPPC and OIE and that it would be helpful if Codex could provide risk analysis guidance in the area of food safety to governments. Such guidance would also facilitate the judgment as to whether a country had properly conducted risk assessments as required by the SPS Agreement before applying a risk management measure. (see para. 42 in ALINORM 04/27/33A)
- Codex recommendation on risk analysis can serve as common basis for member states to conduct their own risk analysis.

"whether the format of the document as basic principles should retained;"

[Japan's Position]

- Positive

[Rationale]

- Recommendation on risk analysis is required to accommodate any risk analysis applied to various situations. Accordingly, this recommendation should be flexible enough for member countries to apply in various situations. Detailed methodologies can be elaborated by appropriate Codex committees when targeted situations are specified.
- It is easier to reach consensus by sticking to basic principles than by exploring possibility of detailed methodology.

"whether the principles applicable within Codex can be used as a basis for discussion with the required changes to make them applicable to governments, or if another approach is preferable such as:"

- ***referring only to the recommendations of FAO/WHO expert Consultations***
- ***additional guidance from FAO/WHO concerning general risk analysis principles for government.***
- To reach consensus promptly, it would be most effective to start our discussion with "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius", which we have already agreed on,

and make necessary revision.

- Essence of the recommendations of FAO/WHO expert Consultations have been already incorporated in “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius” when adopted.

2) If principles intended for governments are to be developed, the Committee may consider including only a reference to the sections that are already included in the adopted Working Principles, and retaining the sections that are specifically intended to governments.

[Japan's Position]

- Negative

[Rationale]

- Stand-alone document would be better since it can serve as handy reference for the food safety officials in member countries.

3) As it may be difficult to reach consensus on some aspects of risk management, the Committee may consider:

- **whether this document should include the section on risk management or separate it in a first stage in order to concentrate on the areas where consensus appears more likely and to advance them to further steps;**
- **if the section on risk management is retained, whether it should include the section on precaution in risk management, with the understanding that a general reference to precaution in risk analysis is retained in paragraph 9;**

[Japan's Position]

- Risk management section is necessary within this principle. However to facilitate elaboration of this recommendation, we should first focus on “SCOPE”, “RISK ANALYSIS- GENERAL ASPECTS”, “RISK ASSESSMENT” and “RISK COMMUNICATION” and later proceed to “RISK MANAGEMENT”.

- **replacing the section on risk management with a reference to the recommendations of the FAO/WHO Expert Consultation on Risk Management and Food Safety.**

[Japan's Position]

- Considering the fact that we established “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius” on the basis of the recommendations of the FAO/WHO Expert Consultation on Risk Management and Food Safety, we should follow the same path. “RISK MANAGEMENT” section of this principle should be established based on “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius” by modifying, adding or deleting necessary revision as guidance for member countries.

4) Should the Committee decide to proceed with the consideration of the document, the text attached as Annex 2 may be used as a basis for discussion.

[Japan's Position]

- Positive

[Rationale]

- The text attached as Annex 2 was made on the basis of “Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius” we have already agreed to.

2. Comments on ANNEX 2

1) Para. 1

The phrase “in light of the purpose of Codex Alimentarius Commission” should be added, as well as a footnote:

The purpose of the Principles is to provide a framework for the conduct of risk analysis applied to food safety issues, as guidance to governments in light of the purpose of Codex Alimentarius Commission¹.

(In footnote)

¹ Reference to Article 1 a), Statutes of the Codex Alimentarius Commission, Procedural Manual ; Thirteenth Edition

[Rationale]

The phrase “in light of the purpose of Codex Alimentarius Commission” should be added, so that the purpose of Codex is upheld in guidance to governments.

2) para.18

The phrase “ecological and environmental conditions” should be deleted.

[Rationale]

- It is commented that the phrase “ecological and environmental conditions” indicates the conditions that may develop pathogens such as biotoxins. However, the phrase “ecological and environmental conditions” might imply wider range of meanings and could lead misunderstanding.
- It is not necessary to note the phrase “ecological and environmental conditions” because while dealing with development of pathogens, these conditions could be regarded as relevant factors to and included with production, transport, storage and handling practices.