

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
HEALTH
ORGANIZATION



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Agenda Item 3

CX/GP 00/3-Add.5

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON GENERAL PRINCIPLES

Fifteenth Session, Paris, France, 10 - 14 April 2000

RISK ANALYSIS: 1) WORKING PRINCIPLES FOR RISK ANALYSIS

GOVERNMENT COMMENTS IN REPLY TO CL 1999/16-GP

COMMENTS OF THE UNITED STATES

The United States appreciates this opportunity to comment on **CL1999/16 – GP** specifically on the request for comments on “a definition of the precautionary principle or a statement of a precautionary approach and the conditions under which it would be applied.” The United States is also providing comment on the “working principles for risk analysis”, as presented in **CX/GP 00/3**.

PRECAUTION

The United States endorses the General Recommendations of the FAO Conference on International Trade in Food Beyond 2000, Melbourne, Australia, 11- 15 October 1999. Specific to this response, the U.S. calls attention to the following General Recommendation:

The Conference called upon all parties to recognize that precaution has been and should remain an essential element of risk analysis in the formulation of national and international standards and agreed that the Codex Alimentarius Commission was the appropriate forum to discuss this issue.

Terms referring to “precaution” or similar concepts have been used in a number of international discussions or agreements, with considerable variation between definitions and application. The United States believes that the concept of “precaution” cannot be reduced to a single formulation applicable to all contexts. Terms referring to “precaution” should be used in a specific context only after full discussion and agreement on a definition and scope of application for that specific context. Therefore, the United States believes that any reference in Codex should be to “the use of precaution in the formulation of food safety standards”.

Precaution: Inherent Throughout the U.S. Food Safety System

The U.S. national food safety system has evolved during the past 100 years into its current science-based regime, which offers a very high level of consumer protection and confidence. Precaution has been an inherent part of our food safety system at the federal, state and local levels, and in the three separate branches of government -- executive, legislative and judicial -- each working together to form

complementary and interdependent legal authorities and responsibilities for protecting Americans' health and safety. U.S. food safety laws, regulations and policies have precautionary approaches embedded in them.

The principal federal agencies responsible for providing consumer protection are the Food and Drug Administration, Department of Health and Human Services; the Food Safety and Inspection Service, Department of Agriculture; and the Environmental Protection Agency. These and other agencies with a food safety mission -- such as the Centers for Disease Control and Prevention -- are accountable to all three branches of government and to the public. Food safety agencies exercise precaution not in any single manner but in various ways during the science-based risk assessment and management processes. Precaution is used in identifying the hazard, analyzing the risk, and deciding the most appropriate protective measure. Agencies responsible for enforcement also use precaution when determining whether to allow a product to be sold or used in the United States.

Precaution is also inherent in the legal responsibilities of producers, distributors, importers and others in the food sector, who are legally required to provide only safe and wholesome food. These food sellers are held legally responsible even in the absence of actual knowledge of a product's hazard. Government enforcement of food safety laws and regulations can result in criminal punishment and/or seizure of product, injunctions against the producer, and other penalties. Private liability laws reinforce incentives for industry to make every effort to ensure that only safe food is marketed.

The U.S. food safety system is further strengthened by its use of experts in and outside of government and by its transparent regulatory process. U.S. agencies' highly qualified science and public health experts work cooperatively to ensure the safety of U.S. food. In addition, outside experts are regularly consulted on a wide array of cutting-edge issues. Statutory requirements to ensure regulations are developed in a fully transparent and interactive manner, with the public providing valuable guidance on actual and perceived concerns about food safety which are factored into a precautionary regulatory approach.

Precaution is also inherent in the u.s. Food safety system as it addresses emerging problems, food safety incidents and technological advances. In a continuing effort to ensure safe food, u.s. Agencies are strengthening their coordination to achieve a seamless national food safety system from farm to table. With precaution already being exercised within each agency's regulatory regime and throughout the u.s. System, precaution will remain an inherent element of the u.s. Science-based approach to this seamless system.

Precaution in Codex

Codex must consider the diversity of socio-economic conditions among nations when discussing the application of precaution at the international level. The United States believes that there are aspects of precaution that, while appropriate at the national or community level, would not be appropriate at an international level?

Codex should carefully delineate between what is appropriate for Codex to consider and what lies within the jurisdiction of member countries, especially with respect to risk management. If the uncertainty that a proposed risk management option (i.e., Codex standard or related text) would achieve the appropriate level of risk reduction is unacceptably high, then Codex should reject the option and delay further elaboration of the standard until the uncertainty can be resolved. To do otherwise is to contradict the Codex Alimentarius Commission's stated principle that its standards and related texts will be based on "sound scientific analysis and evidence" (Codex Alimentarius Procedural Manual, 10th ed. p. 146, 1997). However, under the WTO/SPS Agreement, member countries may take provisional food safety measures in such situations.

WORKING PRINCIPLES FOR RISK ANALYSIS

The following are the United States comments on the Proposed Draft Working Principles for Risk Analysis at Step 3, as reported in **CX/GP 00/3**:

SCOPE

3: This statement of Scope has raised a new and, as far as the United States is aware, undefined concept of “a thorough risk analysis”. Lacking criteria to distinguish a thorough analysis from a non-thorough one, the United States believes that these words should be struck and the statement reworded to read:

The Objective of the Working Principles is to ensure that Codex standards and related texts intended to protect the health of consumers are based on risk analysis.

RISK ANALYSIS – GENERAL ASPECTS

1: Add the term science-based, to read as follows.

“The risk analysis process used in Codex should be science-based, consistent, open and transparent and”

Additionally, the term “consistent” is somewhat vague, inviting the question, consistent with what? The U.S. recognizes that it could also refer to consistent in its application for similar entities (e.g., pesticides, food additives). Clarity is needed here.

5: The United States endorses the General Recommendations of the FAO Conference on International Trade in Food Beyond 2000, Melbourne, Australia, 11- 15 October 1999. Specific to this response, the U.S. calls attention to the following General Recommendation:

The Conference called upon all parties to recognize that precaution has been and should remain an essential element of risk analysis in the formulation of national and international standards and agreed that the Codex Alimentarius Commission was the appropriate forum to discuss this issue

Therefore, the United States believes that the current wording of this principle should be replaced with the following:

“Precaution is an essential element of risk analysis.”

Accordingly, the US also recommends the deletion of Principle 38.

RISK ASSESSMENT

11, 12, 13: The United States is concerned that there is considerable redundancy or lack of clarity in these three principles, considered as a group. Also, the current order of the principles is confusing; “hazard identification” (**13**) should precede “risk characterization” (**12**). Therefore, the US suggests that principle 13 be renumbered to 12 and that the former 12 be reworded as new 13, to read:

At the risk characterization step, the cumulative uncertainty derived from each step in the risk assessment process should be described. The constraints that are likely to influence the quality of the risk estimate should be identified.

RISK ASSESSMENT POLICY

At the 14th Session of CCGP, it was agreed that working principles on the application of risk assessment policies needed to be developed at least to a common level of understanding before it would be possible to develop an appropriate definition (ALINORM 99/33A, para. 14). The United States is not certain that the current working principles for risk assessment policy achieve the necessary level of development for a definition. Therefore, the U.S. recommends that a new working principle be considered, as follows:

“X. Risk assessment policy contains documented guidelines for scientific judgments and policy choices to be applied at appropriate decision points in risk assessment.”

RISK MANAGEMENT

26: The United States agrees that the primary focus of risk management should be the protection of public health. However, the Working Principles should also recognize that Codex’s mission is to protect consumer health **and** promote fair practices in food trade. Further, to be consistent with the text of the Report of the Joint FAO/WHO Expert Consultation on Risk Management, the U.S. suggests that additional sentences be added to this principle, to read:

" Consideration should also be given to account for their feasibility and the principle of minimizing negative trade effects. These considerations should not be arbitrary and should be made explicit."

27: To emphasize that Risk Management flows from Risk Assessment, the U.S. suggests that the phrase “that is grounded on science-based risk assessments” be added to the first sentence of 27, to read as follows.

“Risk management should follow a structured approach that is grounded on science-based risk assessments”.

30: Risk management options should be evaluated in light of overall risk reduction and not just in terms of a reduction of the health hazard considered. Negative effects with respect to other risks should be considered. Accordingly, the United States suggests that the first sentence of this principle be re-written, to read:

“ Risk management options should be evaluated in terms of overall reduction of risk.”

As part of a structured approach to Risk Management, Codex should also recognize its role in facilitating fair trade in food. We also believe it would be helpful for the working principles to acknowledge this role by adding a second sentence to this principle, to read as follows:

“When deciding among risk management options that are equivalent with respect to consumer health protection and are feasible, Codex should choose the option that minimizes negative trade effects.”

Finally, we do not fully understand the final sentence in this principle.

38: See Principle 5 above. While the United States supports the deletion of this principle (38), it finds the "**alternative wording**" proposed to be preferable to that in paragraph 38. The United States, recognizing that the hazard identification step is crucial, recommends that a criteria-based, structured process, such as weight-of-the-evidence, be developed to insure that a potential, and not hypothetical, hazard has been identified. If a purported hazard fails to meet the hazard identification criteria, further risk analysis is inappropriate.