

codex alimentarius commission

FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD HEALTH
ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel.: 3906.57051 Telex: 625825-625853 FAO I Email:codex@fao.org Facsimile: 3906.5705.4593

Agenda Item 3

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

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RISK ANALYSIS: 1) WORKING PRINCIPLES FOR RISK ANALYSIS GOVERNMENT COMMENTS IN REPLY TO CL 1999/16-GP

IASDA (International Alliance of Dietary/Food Supplement Associations)

ENSURING SCIENCE-BASED RISK ANALYSIS PROCEDURES IN FOODS

1. The precautionary principle was introduced in Europe in the early 1970's to provide a tool for decision-making on extraordinary environmental threats. It has since been included in several international environmental agreements. Specifically, the precautionary principle was included in the United Nations Rio Declaration on Development and the Environment. Principle 15 of the declaration sanctioned a precautionary approach where there are threats of "serious or irreversible damage" to the environment. It stated that "lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

2. Due to the multiple precautions already built into food safety regulations, the introduction of such a principle in the food analysis procedure has not been considered necessary. However, the European Union is currently developing guidelines for use of the precautionary principle in food policy. Also, following input from the EU, the Codex Alimentarius Committee on General Principles discussed its inclusion in April 1999 as a potential part of risk management. In response to concerns expressed by many delegations the text was held at Step 3.

3. In the European Union, the description set out in Principle 15 has transformed into an assertion that it should be invoked in food policy "when the scientific bases are insufficient or when there is "some uncertainty" (European Commission, DG XXIV, 1998). This language may at first seem innocuous, but in reality it is the unprecedented establishment of the principle of zero risk in food policy. Politically, this may seem a useful tool for side-stepping difficult decisions related to developments in food science and technology. Scientifically, it threatens to undermine the risk assessment process that has previously been the cornerstone of food safety policy.

4. The zero-risk impetus of the precautionary principle fails to recognise that although science can provide a high level of confidence, it can never provide certainty. Absolute proof of safety is not achievable because it would require the proof of a negative, a proof that risk does not exist. Indeed, it is precisely for this reason that risk assessment, aimed at communicating the extent of risk, has been developed.

5. Many supporters of the precautionary principle in risk management for food policy appear to underestimate the multiple types of precaution already built into risk assessment and risk management.

6. For foods, there are at least seven ways that precaution is built into properly defined and performed risk assessment. Risk assessment procedures include, in the dose-response evaluation, several conservative (i.e., precautionary) assumptions about uncertainty in the data. For each assumption made, an “uncertainty factor” is included in the calculation of a safe level of intake. These specific considerations for which the precautionary assumptions are made and uncertainty factors incorporated include:

- the increased susceptibility of sensitive subgroups (i.e., the large variations in response within the human population),
- extrapolation from animal data to human applications,
- age, gender, and body size differences,
- implications of short-term data for chronic intake,
- extrapolation from a Lowest Observed Adverse Effect Level (LOAEL) to a No Adverse Effect Level (NOAEL),
- incompleteness in the database (absence of any useful type of data), and the
- decreased likelihood of observing adverse effects when there are relatively few test subjects.

7. The right and obligation of risk managers to take precautionary measures, when appropriate, is also built into risk management procedures. Current practice indicates that strong precautionary measures are taken when evidence warrants it.

8. Because of the precautionary procedures and assumptions built into risk assessment and management, a separate and additional precautionary principle in risk assessment would be redundant.

9. The precautionary principle tells policymakers not to proceed unless there is zero risk. Food policy decisions based on this principle would lead to serious curbs to food innovation: new foods that are safe according to traditional risk assessment may be barred from the market if proof of zero risk is not available.

10. If included in risk management, the precautionary principle would invite the use of nonscientific issues to overrule scientific evidence on product safety. Such misuse could stimulate irrational fear of food, or be employed by countries in international standards to disguise unjustified technical barriers to trade.