THE ROLE OF "SCIENCE" AND "OTHER FACTORS" IN RISK ANALYSIS
(see Resolution on ‘Risk Analysis and the role of Other Factors’ Doc Food-16-00)

Current Situation

As consumer organizations within the EU and the US seek to participate more actively in food safety policymaking at both national and international levels, it is essential to have a common understanding of the “rules”- that is, principles for sound decision-making on food safety.

Developing and then adhering to credible, agreed decision-making rules is essential to make the processes open and transparent and to boost consumer acceptance of the soundness of safety decisions.

Within the Codex system, discussion has been under way for some years on what is called “Risk Analysis.” As used in Codex, the term “Risk Analysis” refers to a set of principles defining how food-related risks are to be assessed and managed. When fully implemented, the Risk Analysis framework should provide clear understanding of how risks are to be assessed and managed, and of the role risk communication plays in the process.

As a foundation for its Risk-Analysis framework, Codex has adopted four “Statements of Principle” that define the basis for Codex decisions in very broad terms. The statements include the principles that Codex decisions should be based on a thorough review of all relevant scientific evidence, and that “other legitimate factors relevant to the protection of consumer health or the promotion of fair practices in food trade” may also be part of the basis for decisions.

Everyone agrees that sound science is an essential basis for food safety decisions. There is also general recognition that some “other factors,” such as economic costs and benefits, good agricultural, manufacturing and veterinary practices, practicalities of measurement and enforcement, and national trade interests also should be legitimately considered when establishing food safety policies. However, the devil is in the details, and to date Codex has reached no consensus on which “other factors” are legitimate, or on where in the food safety process they are appropriately considered. It has been especially difficult to reach agreement on when factors should be applied to decisions only at the national level, and when they should be part of the basis for “harmonized” international safety standards that aim to facilitate trade.
The perspectives of the US and the EU have on this debate have tended to diverge. One prominent debate concerns the extent to which ethical/social considerations, and factors like environmental sustainability and animal welfare, which affect consumer preferences but are not strictly speaking based on science, should be given weight in food safety decisions. The US has argued that if scientific data suggest that something is safe, consumer objections to it based on perceptions that it is, say, unethical, should not be allowed to create trade barriers. The member governments of the EU have been more inclined to argue for giving such factors some weight in policy making. Another disputed issue is the application of the Precautionary Principle; no transatlantic consensus exists on how to define it, or on whether, when and how to invoke the Precautionary Principle in making food safety decisions.

**A Consumer Perspective:**

Consumers International has prepared two papers on “Other Legitimate Factors,” for the April 1999 and September 1998 meetings of the Codex Committee on general principles. Highlights of the consumer perspective articulated there include:

- Some industry and government participants in Codex have stressed that the only legitimate basis for food safety decisions is “science,” and that “other factors” are “political” in nature and should not be considered. Although Codex rejected this view when it adopted the Four Statements of Principle, it still must be vigorously defended against. The plain fact is that science can tell us what the risks are, but deciding how much risk is acceptable and how to manage risks are social choices, and require a participatory political process for balancing values—not merely “science.”

- Many non-scientific “other factors” are considered now in Codex and in other food safety decision-making processes, but they are often neither transparent nor openly debated and weighted.

Some of the “science” used in decisions includes non-transparent “other factors.” For example, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), which provides risk assessments for Codex committees, also recommends “Maximum Residue Levels” (MRL). An MRL is a decision on the acceptable level of health risk, which is a social value judgment, not “science.” JMPR also generally must decide what weight to give to scientific uncertainty and to what is not known, as well as to the existing evidence. It is not unusual for expert bodies like the JMPR to dismiss uncertainties as unimportant, and to conclude that lack of evidence of harm equates with proof of safety. This also is very much a value judgment, not a scientific one.

- Balancing risks and benefits, and decisions on whether a precautionary approach is required, are examples of risk management decisions that must be made in an open, transparent manner, with participation by consumers and other affected interests. Such decisions should not be made by risk assessors meeting in closed sessions, as JMPR and other expert bodies typically do.

- Factors that affect consumer preference, including ethical and religious concerns, desire to promote more sustainable food production practices, and many other things

that consumers value, may affect consumer health only indirectly, if at all. But they are definitely related to “promoting a fair practices in food trade,” and as such they are clearly legitimate “other factors” that the decision-making process must recognize.

- Consumers have a right to know the essential nature of the foods they are buying, and they have the right to choose what to buy, based on any and all factors that concern them. To protect these rights, food labeling needs to be used more widely to provide consumers with information they have clearly demanded about foods. For example, all genetically modified foods should be required to be labeled as such.

To improve openness and transparency, and thereby the soundness and credibility of decisions, Codex and other food safety authorities need to develop, communicate and then follow clear principles defining where in the process these “other legitimate factors” are properly considered. The effort now under way to do so within Codex is laudable, but it is proceeding very slowly, and achieving consensus has been difficult.

The TACD urges the US and EU governments to commit themselves to completing a policy on "other legitimate factors" besides "science", and making risk analysis a high priority within their Codex work, and to acknowledge that "other legitimate factors" have an essential role to play and are already implicit in risk decisions even if they are currently not openly acknowledged. Every effort must be made to reach consensus on these difficult but very important issues to improve the quality and transparency of decisions and to enhance consumer choice and protection.