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## UNIT 6 RISK MANAGEMENT

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### 6.0 OBJECTIVES

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After studying this unit, we shall be able to:

- describe what is risk management;
- define key terms related to risk management;
- identify general principles of food safety risk management;
- identify steps involved as per generic risk management framework; and
- describe role of food chain professional in risk management.

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### 6.1 INTRODUCTION

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Food safety is a priority for consumers. They want safe food which will keep them healthy. It is the responsibility of food safety authorities to meet consumers' expectations and to guarantee them a high level of health protection, by adopting the necessary measures. The significant world-wide increase in food-borne illness that has been recognized in recent years, especially arising from enteric organisms, suggests the need for more effective control using internationally agreed risk management methods.

#### 6.1.1 What is Risk Management?

It is primarily one of the three aspects of risk analysis, the others being risk assessment and risk communication. The Codex has adopted the following definition: risk management is the process of weighing up the various possible policies, taking account of the evaluation of risks and other factors involved in the health protection of consumers and the promotion of fair trade practices, and taking decisions accordingly, i.e. choosing and implementing the appropriate prevention and monitoring measures. The management of food-

related risk therefore involves balancing the recommendations formulated by the experts commissioned to scientifically evaluate the risks, and the resources of all types that social and commercial groups and manufacturers can set aside for dealing with these risks.

### 6.1.2 Perspectives on Risk

Food safety risks can be viewed as a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food. The “scientific” view is the primary one for decision-making, but risk managers also apply other legitimate factors in identifying the most appropriate risk management option in managing the risk.

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## 6.2 DEFINITIONS OF KEY RISK MANAGEMENT TERMS

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**Risk assessment policy:** Documented guidelines on the choice of options and associated judgments for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

Risk assessment policy setting is a risk management responsibility, which should be carried out in full collaboration with risk assessors, and which serves to protect the scientific integrity of the risk assessment. The guidelines should be documented so as to ensure consistency and transparency. Examples of risk assessment policy setting are establishing the population(s) at risk, establishing criteria for ranking of hazards, and guidelines for application of safety factors.

**Risk profile:** A description of the food safety problem and its context.

Risk profiling is the process of describing a food safety problem and its context, in order to identify those elements of the hazard or risk which are relevant to various risk management decisions. The risk profile would include identifying aspects of hazards relevant to prioritizing and setting the risk assessment policy and aspects of the risk relevant to the choice of safety standards and management options.

A typical risk profile might include the following: a brief description of the situation, product or commodity involved; the human health and economic concerns; potential consequences; consumer perception of the risks; the distribution of risks and benefits of risk assessment.

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## 6.3 GENERAL PRINCIPLES OF FOOD SAFETY RISK MANAGEMENT

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The general principles applied in the food safety risk management by the Codex are briefly presented below:

**Principle 1: Protection of human health should be the primary objective in risk management decisions**

Decisions on acceptable levels of risk should be determined primarily by human health considerations, and arbitrary or unjustified differences in the risk levels should be avoided. Consideration of other additional factors (e.g. economic costs, benefits, technical feasibility, and societal preferences) may be

appropriate in some risk management contexts, particularly in the determination of measures to be taken. These considerations should not be arbitrary and should be made explicit.

**Principle 2: Risk management should follow a structured approach**

The elements of a structured approach to risk management are: Risk Evaluation, Risk Management Option Assessment, Implementation of Management Decision, and Monitoring and Review.

However, in a practical context, it may not be necessary to include all the elements. For example, risk management decisions at the national level are likely to use all of the elements of risk management, whereas the risk management activities of Codex do not generally include implementation, monitoring and review.

**Principle 3: Risk management decisions and practices should be transparent, consistent and fully documented**

Risk management should include the identification and systematic documentation of all elements of the risk management process including decision-making, so that the rationale is transparent to all interested parties.

**Principle 4: Risk management should take into account the whole food chain**

Risk management should address each of the segments in the food chain as individual continuums, when considering means for controlling the public health risks associated with food (both domestic and imported products). This should typically include primary production, product design and processing, transport, storage, distribution, marketing, preparation and consumption.

**Principle 5: Risk management should ensure the scientific integrity of the risk assessment process by maintaining the functional separation of risk management and risk assessment**

Functional separation of risk management and risk assessment serves to ensure the scientific integrity of the risk assessment process and reduce any conflict of interest between risk assessment and risk management. However, it is recognized that risk analysis is an on-going, two-way interactive process, and risk managers should ensure effective interaction with risk assessors for practical application.

**Principle 6: Risk managers should take account of risks resulting from regional differences in hazards in the food chain and regional differences in available risk management options**

The risk managers should consider the full implications of the range of uncertainty and variability conveyed by the risk assessors in decision-making. For example, if the risk estimate is highly uncertain the risk management decision might be more strict.

**Principle 7: Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process**

On-going reciprocal communication among all interested parties is an integral part of the risk management process. Risk communication is more than the dissemination of information, and a major function is the process by which

information and opinion essential to effective risk management is incorporated into the decision.

**Principle 8: Risk management should be a continuing process that takes into account all newly generated data in the evaluation and review of risk management decisions**

Subsequent to the application of a risk management decision, periodic evaluation of the decision should be made to determine its effectiveness in meeting food safety objectives. Monitoring and other activities will likely be necessary to carry out the review effectively.

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**Check Your Progress Exercise 1**



**Note:** a) Use the space below for your answers.  
b) Check your answers with those given at the end of the unit.

- 1) Define the following:
  - Risk assessment policy
  - Risk profile

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- 2) Why risk management should follow a structured approach?

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- 3) How functional separation between risk manager and risk assessors is important?

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- 4) Enumerate various general principles of food safety risk management?

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## 6.4 A GENERAL RISK MANAGEMENT FRAMEWORK

A generic process for carrying out risk management is presented in Fig. 6.1. A generic RMF for food safety risk management must be functional in both strategic, long term situations (e.g. development of international and national standards when sufficient time is available) and in the short term work of national food safety authorities (e.g. responding rapidly to a disease outbreak). In all cases, it is necessary to strive to obtain the best scientific information available. In the former situation, risk managers will usually have access to extensive scientific information in the form of risk assessment reports. In the latter situation, risk managers are not likely to have access to a complete risk assessment and therefore will need to rely on whatever scientific information on risks is readily available (such as human health surveys / monitoring and food-borne disease outbreak data) as a basis for preliminary decisions on control measures.

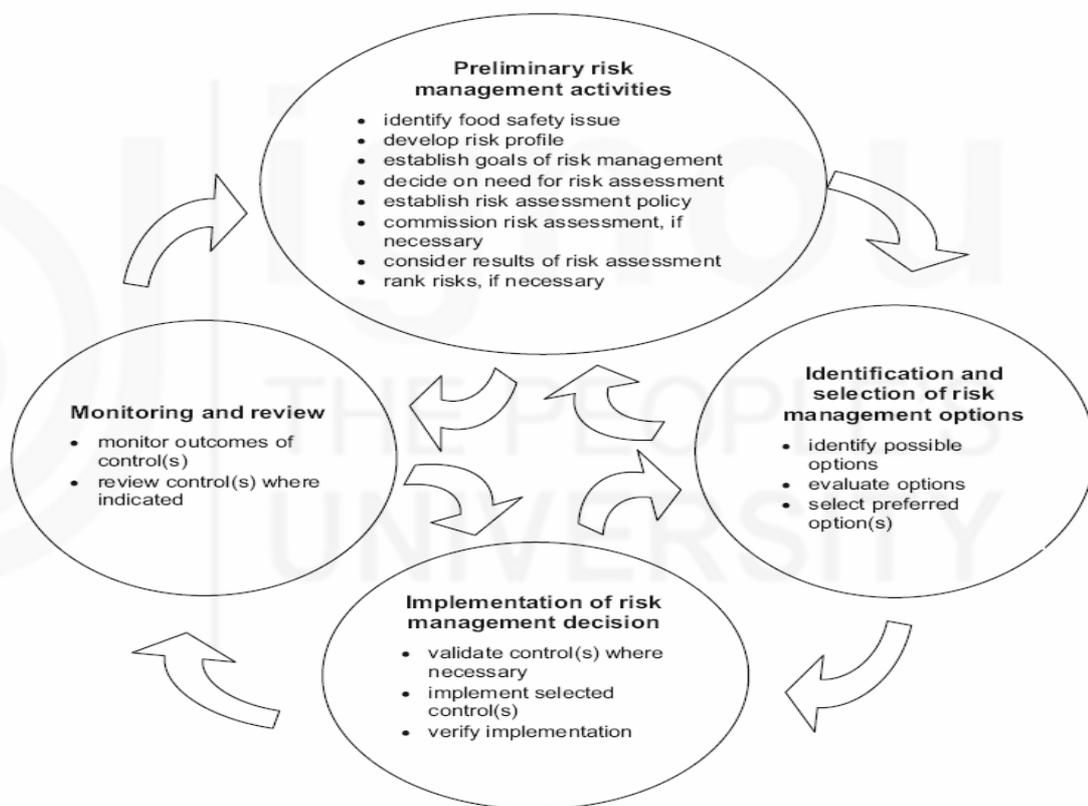


Fig. 6.1: Generic framework of risk management

### 6.4.1 Preliminary Risk Management Activities

#### Step 1: Identify and describe the food safety issue

At the start of this process, the food safety issue should be clearly identified and communicated from the risk managers to risk assessors, as well as affected consumers and industry. Food safety issue identification may be performed by the risk manager or be the result of collaboration between different interested parties. Examples of identifying food safety issue are given in Examples of Step 1.

## Examples of Step 1: Identifying a food safety issue

- ***Methylmercury in fish*** was first identified as a food-borne hazard in the 1950s when an outbreak of severe neurological (nervous system) disease occurred in babies whose mothers ate fish from Minamata Bay in Japan, which had been polluted by mercury from local industry. More recently, an epidemiological study (scientific study of cause / occurrence of a disease) in the Faeroe Islands, where the diet is rich in seafood, provided evidence that the amount of mercury in fish and whale meat in the absence of heavy pollution is still high enough in some circumstances to pose risks to the foetus.
- ***Listeria monocytogenes*** has long been recognized as an important food-borne pathogen. Several recent outbreaks of listeriosis (disease caused by *Listeria monocytogenes* infection) in the United States, traced back to ready-to-eat meat products, have elevated public and regulatory concerns and made assessing and managing *Listeria monocytogenes* risks a high priority for both government and industry in the United States.
- ***The agent of BSE (Bovine Spongiform Encephalopathy, popularly called the mad cow disease)*** in meat from cattle was recognized as a food-borne risk to human health (as opposed to a disease of cattle only) in the United Kingdom in the 1990s. Since then, the World Organization for Animal Health (OIE) has been developing relevant risk-based standards taking into account the BSE disease status of cattle in the exporting country.

Within Codex, a food safety issue may be raised by a member government, or by an intergovernmental or observer organization. Food safety issues may be identified on the basis of information arising from a variety of sources, such as:

- surveys of the prevalence and concentration of hazards in the food chain or the environment,
- human disease surveillance data,
- epidemiological or clinical studies,
- laboratory studies,
- scientific, technological or medical advances,
- lack of compliance with standards,
- recommendations of experts, public input, etc.

## Step 2: Develop a risk profile

The risk profile is a description of a food safety problem and its context that presents in a concise form, the current state of knowledge related to a food safety issue, describes potential risk management options, if any, that have been identified to date and the food safety policy context that will influence further possible actions. Examples of information that may be included are given next to below. A risk profile should present, to the extent possible, information on the following.

- 1) Hazard-food commodity combination(s) of concern.
- 2) Description of the public health problem.
- 3) Food production, processing, distribution and consumption.
- 4) Other risk profile elements such as the extent of international trade of the food commodity; existence of regional/international trade agreements.

- 5) Risk assessment needs and questions for the risk assessors.
- 6) Major knowledge gaps.

### **Examples of information that may be included in a risk profile**

- Initial statement of the food safety issue.
- Description of the hazard and food(s) involved.
- How and where the hazard enters the food supply.
- Which foods expose consumers to the hazard and how much of those foods are consumed by various populations.
- Frequency, distribution and levels of occurrence of the hazard in foods.
- Identification of possible risks from the available scientific literature.
- Nature of values at risk (human health, economic, cultural, etc.).
- Distribution of the risk (who produces, benefits from, and/or bears the risk).
- Characteristics of the commodity/hazard that might affect the availability and feasibility of risk management options.
- Current risk management practices relevant to the issue, including any regulatory standards in place.
- Public perceptions of the possible risks.
- Information about possible risk management (control) measures.
- Preliminary indication of questions that a risk assessment could (and could not) be expected to answer.
- Preliminary identification of important scientific data gaps that may prevent or limit a risk assessment.
- Implications of risk management in terms of international agreements (e.g. SPS Agreement).

### **Step 3: Establish broad risk management goals**

Following development of the risk profile, risk managers need to decide on the broader risk management goals. This is likely to occur in conjunction with a decision on whether or not a risk assessment is feasible or necessary. Some generic risk management goals that may require a risk assessment to resolve a food safety issue are shown below.

### **Examples of generic risk management goals that may require a risk assessment to resolve a food safety issue**

- Developing specific regulatory standards or other risk management measures that can be expected to reduce risks associated with a specific food-hazard combination to an agreed acceptable level (e.g. for an emerging microbiological hazard).
- Developing specific regulatory standards or other risk management measures for a veterinary drug that leaves residues in foods to ensure that exposure to the residue is limited to levels that do not exceed the acceptable daily intake.
- Ranking risks associated with different hazard-food combinations to establish priorities for risk management (e.g. *Listeria monocytogenes* in different food categories).

- Analysing the economic costs and benefits (risk reduction impacts) of different risk management options for a particular food safety issue, so as to choose the most suitable controls.
- Estimating “benchmark” levels of risk for certain priority hazards so that progress toward specific public-health goals can be measured (e.g. a 50 per cent reduction in food-borne disease caused by enteric pathogens over a 10-year period).
- Demonstrating that no significant increase in risk to consumers is associated with the introduction of a new food production method or food processing technology.
- Demonstrating that no significant increase in risk to consumers is associated with the use by an exporting country of a control system or process to manage a risk, that is different from the control system or process used in an importing country (i.e. demonstrating equivalence); e.g. different pasteurization regimes.

#### **Step 4: Decide whether a risk assessment is necessary**

Deciding whether a risk assessment is necessary is a joint decision for risk managers and risk assessors and may be part of establishing broader risk management goals. A risk assessment is likely to be especially desirable when the nature and magnitude of the risk are not well characterized, when a risk brings multiple societal values into conflict or is a pressing public concern, or when risk management has major trade implications. A risk assessment also can guide research by facilitating the ranking of risks of most importance.

Practical issues that impact on the decision as to whether a risk assessment is needed are time and resources available; how urgently a risk management response is needed; consistency with responses to other similar issues; and availability of scientific information. If the risk profile indicates that food-borne risks are significant and immediate, the regulator may decide to impose interim regulatory control measures while a risk assessment is undertaken. On the other hand, some issues can be resolved simply and rapidly without need for a risk assessment. In some situations, a specific regulatory response will be deemed unnecessary because of the limited nature of possible risks. Examples of Step 4 offers some examples of cases in which a risk assessment is or is not likely to be needed.

#### **Examples of Deciding whether a risk assessment is needed**

- Shreds of metal are detected in canned peaches from a particular cannery. The source is identified as fragile blades on a newly installed slicer. The machine is repaired; a metal detector is installed. *Problem solved by Good Hygienic Practice (GHP); no risk assessment needed.*
- National food safety authorities are trying to decide whether to ban the use of certain antibiotics in animal feeds to help mitigate antimicrobial resistance (reduce chances of development of resistance in the disease causing micro-organisms against the antibiotics used for treatment). The economic stakes are high, with human health impacts quite uncertain. *Risk assessment is necessary to help determine the risk contribution, in terms of development of antimicrobial resistance, of food-animal related uses of antimicrobials compared to that from use in human medicine.*

- *Listeria monocytogenes* produces a serious food-borne illness with a very high fatality rate. The pathogen can contaminate dozens of foods belonging to more than 20 different food categories. To set risk management priorities, the United States government carries out integrated risk assessments for *Listeria monocytogenes* in 23 food categories, yielding a clear priority ranking. *Food safety issue managed based on a risk assessment.*

### **Step 5: Establish a risk assessment policy**

Risk assessment policy setting is a risk management responsibility, which should be carried out in full collaboration with risk assessors. The risk assessment policy could be of a generic nature or specific to risk assessment, and should be documented to ensure consistency, clarity and transparency. A risk assessment policy underpins a clear understanding of the scope of the risk assessment and the manner in which it will be conducted. It often defines the parts of the food system, the populations, geographic areas and the time period to be covered. An example of establishing a risk assessment policy is given below.

### **Example of establishing a risk assessment policy**

In the United States in 1996, Congress, acting as risk managers, established a new policy directing risk assessments by the United States Environmental Protection Agency (EPA) for pesticide residues in the diet. Legislation now requires the EPA to ensure that pesticide residue limits protect the most sensitive populations (infants and children); to apply an additional uncertainty factor when the evidence is insufficient to be reasonably certain that the standard uncertainty factors would ensure safety; and to consider the cumulative effects of multiple residues that share a common mechanism of toxic action, as well as exposures from water and home pesticide use, when defining tolerable exposure from food.

A risk assessment policy may include:

- criteria for ranking risks (where, for example, the assessment covers different risks posed by the same contaminant, or risks posed by the contaminant in different foods),
- procedures for applying uncertainty factors,
- guidance as to the appropriate level of protection, and
- the scope of the risk assessment.

### **Step 6: Commissioning the risk assessment**

Once a decision is made that a risk assessment is required, risk managers must arrange to get the risk assessment done. In general, risk managers must assemble an appropriate team of experts to carry out the task, and then interact with the risk assessors extensively enough to instruct them clearly on the work to be performed, while maintaining a “functional separation” between risk assessment and risk management activities. Responsibilities of risk managers in commissioning and supporting a risk assessment are as given below.

### **Responsibilities of risk managers in commissioning and supporting a risk assessment**

- Ensure that all aspects of the commissioning and conduct of the risk assessment are documented and transparent.

- Clearly communicate the purposes and scope of the risk assessment, the risk assessment policy, and the form of the desired outputs, to the risk assessors.
- Provide sufficient resources and set a realistic timetable.
- Maintain “functional separation” between risk assessment and risk management to the extent practicable.
- Ensure that the risk assessment team has an appropriate balance of expertise and is free from conflicts of interests and undue biases.
- Facilitate effective and iterative communication with the risk assessors during the entire process.

Functional separation means separating out the tasks that are carried out as part of risk and may not necessarily mean establishment of different bodies and personnel for risk management and risk assessment. In practice, “functional separation” means that risk managers and risk assessors have different jobs to do, and they each need to do their own jobs. Risk managers must avoid the temptation to “guide” the risk assessment so that it supports a preferred risk management decision, and risk assessors must assemble and assess the evidence objectively, without being influenced by risk management concerns such as economic benefits of an activity, costs of reducing exposure or consumer perceptions of risks.

**Step 7: Consider the results of the risk assessment**

The risk assessment should clearly and fully answer the questions asked by the risk managers as far as possible given the availability of data and where appropriate, identify and quantify sources of uncertainties in risk estimates. In judging the risk assessment complete, risk managers need to:

- be fully informed about the strengths and weaknesses of the risk assessment and its outputs.
- be sufficiently familiar with the risk assessment techniques used, so that they can explain it adequately to external stakeholders.
- understand the nature, sources and extent of uncertainties and variability in risk estimates.
- be aware of and acknowledge all important assumptions made during the risk assessment and their impact on the results.

**Step 8: Rank food safety issues and set priorities for risk management**

The primary criterion for ranking is generally the perceived relative level of risk, each issue presents to consumers, so that risk management resources can be optimally applied to reduce overall food-borne public health risks. The risk ranking exercise with *Listeria* in food in the United States (see Section 6.4.1 Step 3) illustrates a case in which the relative risk per food category was totally different from the absolute risk.

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**Check Your Progress Exercise 2**



- Note:** a) Use the space below for your answers.  
 b) Check your answers with those given at the end of the unit.

1) What are the sources to be used for identification of food safety issue?

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- 2) Give examples of information to be included in risk profile?
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- 3) What are different aspects to be covered under risk assessment policy?
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- 4) State various responsibilities of risk managers in commissioning and supporting risk assessment?
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### 6.4.2 Selection of Risk Management Options

The second major phase of the generic risk management framework (presented above in Fig. 6.1) involves the identification, evaluation and selection of risk management options. Although this step ordinarily cannot be fully undertaken until a risk assessment has been completed, as a practical matter, it begins very early in a risk analysis, and is reviewed as information about the risk grows more complete and quantitative.

#### Step 1: Identify available risk management options

The risk manager needs to ensure that risk management options are identified and the acceptable one(s) selected for subsequent implementation by relevant interested parties. In this, risk managers need to consider the suitability of risk management options to reduce the risk posed by a food safety issue to an appropriate level and any practical issues regarding the implementation of the selected risk management options that need to be managed. Examples of potential risk management options (used either alone or in combination) available for Codex or countries, as appropriate are listed below.

Elaboration of standards and related texts **i.e. codes of practices<sup>2</sup>**.

### **Countries**

- Establish regulatory requirements;
- Develop (or encourage the development of) specific documents and guides e.g. Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP), HACCP;
- Adopt or adapt Codex standards and related texts to the national situation;
- Define an Food safety objective for a particular food safety issue, leaving flexibility to industry to select appropriate control measures to meet it;
- Establish control measures specifying relevant requirements for industry that do not have the means to establish appropriate measures themselves or who adopt appropriate control measures at specific stages of the food / feed (where the presence of hazards in feed may affect the safety of foods derived from an animal), chain where they are of critical importance to the performance of the overall chain;
- Establish requirements for inspection and audit procedures, certification or approval procedures;
- Require import certificates for certain products; and
- Create awareness and develop educational and training programmes to communicate that:
  - prevention of contamination and/or introduction of hazards should be addressed at all relevant stages in the food/feed chain;
  - rapid withdrawal/recall of food/feed procedures are in place, including appropriate traceability/product tracing for effectiveness; and
  - properly labelling includes information that instructs the consumer regarding safe handling practices and where appropriate, briefly informs the consumer of the food safety issue.

Examples of generic options for managing food-related risks (whether the hazards involved are chemical or microbiological) are illustrated given below.

### **Examples of generic approaches to identifying risk management options**

- Eliminate potential for risks (e.g. ban sales of an imported food with a history of high levels of microbial contamination, prohibit use of a carcinogenic food additive).
- Identify those points between production and consumption where food safety measures could be implemented to:

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<sup>2</sup> When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as code of practice, provided that such a text would be supported by the available scientific evidence, Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, Codex Alimentarius Commission, Procedural Manual, 17 Edition (website: [www.codexalimentarius.net](http://www.codexalimentarius.net)).