



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS



WORLD
HEALTH
ORGANIZATION

FAO/WHO Training Manual

Training Programme for Developing Food Standards within
a Risk Analysis Framework

Food and Agriculture Organization of the United Nations
World Health Organization

Finalized 2006

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This training manual utilized FAO, WHO and Codex materials and was developed by FAO consultant, Dr Simon Brooke-Taylor under the Developing Food Standards within a Risk Analysis Framework supported by the Standard and Trade Development Facility (STDF) project. The material was used in the training course workshop organized under the project for the benefit of Asian countries, in Bangkok, Thailand, in December 2005

Training course Programme

Introduction to the training course on developing food standards within a risk analysis framework.....	1
Introduction of case study resource materials	1
Module 1 - Discussion of pre-training course questionnaires.....	3
Module 2 - Introduction to risk analysis, international trends and its relevance in establishing food standards.	4
Module 3 - Risk Analysis and its components.....	6
3A. Introduction	6
3B. Risk Analysis - an overview.....	6
3C. Risk Assessment.....	8
Hazard Identification and Characterisation.....	8
Chemical Hazards	8
Substances intentionally added to food -	8
Substances unintentionally present in food -	9
Microbial Hazards	9
Summary of Hazard Characterisation Terms	10
Exposure Assessment	10
Chemical Hazards.....	10
Microbial Hazards	11
Risk characterization	11
Chemical Hazards.....	11
Microbial hazards.....	12
3D. Risk Management	13
General principles of food safety risk management	14
3E. Risk Communication	16
3F. Group Discussions	18
3G Question and Answer Session.....	18
Module 4 - Risk management and developing a food standard (theory sessions with practical case studies and working groups).....	19
4A. Identifying the need for a food regulatory measure	19
Contents.....	19
Facilitator introduction	19
The legal framework and criteria for assessing standards and determining acceptable level of risk.....	19
Overarching requirements for an effective food control system	19
Organizational Structures for National Food Control Systems.....	19
Food Regulatory Measures.....	22
Identifying risks and defining acceptable levels of risk.....	23
Developing a risk assessment policy	23
Defining appropriate levels of protection for food standards	24
Categorizing and evaluating the risks: likelihood and consequences	25
Group Exercise 4A	27
4B. Involving the Community and Consulting Effectively - Preliminary Consultation	28
Contents.....	28
Facilitator introduction	28
Why Consult?.....	28
Identifying stakeholders	28
How to consult (information, time lines and resources).....	29
How to consult?	30

Group Exercise 4B	31
4C. Considering issues: scientific, regulatory, international obligations.....	32
Contents.....	32
Facilitator introduction	32
What does the science say	32
Sources of the risk assessment.....	32
Understanding the risk assessment output (i.e. the risk characterisation)	32
Developing a risk management strategy.....	33
What are the international obligations	36
Is there a Codex or other relevant international standard?	36
Does the science support this standard.....	36
Can the international standard be accepted	36
Is there a need for a national/regional risk assessment.....	36
Group Exercise 4C.....	37
4D. Developing options and assessing regulatory impact/ competition policy aspects..	38
Contents.....	38
What are the regulatory options	38
Codex example.....	38
Regulatory impact assessment.....	38
Content of a Regulatory Impact Assessment.....	39
Group Exercise 4D.....	40
4E. Drafting a Standard	41
Contents.....	41
Facilitator introduction	41
Preparation of drafting instructions	41
The parts of a standard.....	41
4F. Notifying stakeholders about the proposed standard and undertaking further consultation	42
Contents.....	42
Facilitator introduction	42
Why consult on a draft standard?	42
Elements of effective risk communication	42
Group Exercise 4F	43
4G. Analysing issues and revising standards	44
Facilitator introduction	44
4H. Final decision making (legislative process or other political consideration).....	45
Facilitator Introduction.....	45
Publication in government gazette.....	45
Implementation	45
Group discussions.....	45
Final Round Up - Programme Close	46
Appendices	47
1. Codex Risk Analysis Definitions	48
2. WTO SPS & TBT Agreements.....	49
3. Extract from the WTO Agreement on Technical Barriers to Trade.....	52
4. Useful Resources and Links	53
5. Pre-training questionnaire	56

Introduction to the training course on developing food standards within a risk analysis framework

Introduction of presenters
Format for training course
Start / Finish times
Meals
Housekeeping etc.

Introduction of case study resource materials

During the training course, students will be asked to undertake an number of class exercises. Three comprehensive risk assessments prepared by FAO/WHO, for aspartame (a food additive), fumonosins (a contaminant found in corn) and *Vibrio parahaemolyticus* in Oysters, have been included in the training package as resource materials for these case studies. In addition as range of other relevant resource documents are included in the package.

This material should be drawn to the students attention at this stage of the training course to enable them to familiarise themselves with the content in advance of the exercises.

Suggested Programme

	Mon	Tues	Wed	Thus	Fri
	Delegates arrival and registration	Discussion of pre-training course questionnaires (cont)	Module 4 - Risk management and Standard Setting 5.A. Identifying the need for a food regulatory measure Includes Group Exercise	4C cont Includes Group Exercise ----- 4D. Developing options and assessing regulatory impact/competition policy aspects	4G. Analysing issues and revising standards 4H. Final decision making (legislative process or other political consideration)
		Morning Break	Morning Break	Morning Break	Morning Break
		Module 2 - Introduction to risk analysis, international trends and its relevance in establishing food standards.	4A cont ----- 4B. Involving the Community and Consulting Effectively - Preliminary Consultation	4D cont Includes Group Exercise	Module 6 - Round up & training course close
	Lunch	Lunch	Lunch	Lunch	Lunch
	training course Opening Introduction of presenters Housekeeping issues	Module 3 - Introduction to Risk Analysis	4B cont Includes Group Exercise	4E. Drafting a Standard Includes Group Exercise	
	Afternoon Break	Afternoon Break	Afternoon Break	Afternoon Break	
	Module 1- Discussion of pre-training course questionnaires	Module 3 cont . Includes introduction and group discussion of Codex RA principles and FAO case studies	5C. Considering issues: scientific, regulatory, international obligations	4F. Notifying stakeholders about the proposed standard and undertaking further consultation Includes Group Exercise	

Module 1 - Discussion of pre-training course questionnaires

Prior to the commencement of the training course, all participating delegations should be invited to complete a questionnaire (Appendix 5) to identify/ assess the current state of risk based standards setting in their country.

Introduction of module by facilitator followed by individual presentations by delegates about their respective national food regulatory system (5 minutes each).

Discussion of benefits / limitations

Questions to ask:

How transparent is the system?

How timely/responsive is the system?

Does the system have regard to international standards?

Are standards mandatory or voluntary?

Module 2 - Introduction to risk analysis, international trends and its relevance in establishing food standards.

Food Standards & International Trends

- The importance of food standards for public health protection and trade facilitation
- The international context
 - WTO
 - SPS & TBT
 - Codex
 - FAO/WHO

Food Standards

- Protect consumers from chronic or acute, chemical and biological hazards that may make food injurious to the health
 - Microbiological hazards;
 - Pesticide residues;
 - Use & Misuse of food additives;
 - Chemical contaminants, including biological toxins;
 - Adulteration.
- Facilitate Trade
 - Expanding world economy
 - Trade liberalisation
 - Build trust and confidence of consumers at home and overseas, and importers in the integrity of national food systems;
 - Create and sustain demand for food

WTO

- SPS & TBT agreements
 - SPS - measures to protect human, animal and plant life and health.
 - Benchmark for food = Codex Alimentarius
 - TBT - technical regulations on traditional quality factors, fraudulent practices, packaging, labelling etc.
 - Benchmark = International Standards (including Codex)

Codex

- A part of FAO/WHO Food Standards programme
- Develops international food standards
 - Protect public health
 - Promote fair trade in food
- Each country has copy of procedural manual
- The Commission
 - all member countries
 - meets annually
 - ultimate decision making body
- Committees
 - Commodity specific, or
 - Horizontal
- Process for development of standards
 - Includes consultation stages at:
 - Proposal
 - Draft standard
 - Final standard

FAO/WHO

FAO's Food Quality and Standards Division is concerned with the maintenance and improvement of the quality and safety of foods at the international, regional, and national levels. It promotes the establishment and operation of national regulatory frameworks compatible with international requirements, in particular those of the Codex Alimentarius Commission. It also provides technical advice for capacity-building of food control systems and programmes at national and local levels to ensure food quality and safety throughout the food chain. It provides scientific assessments of food safety and related guidance to the Codex Alimentarius Commission and to countries. This includes the assessment of food additives, chemical and microbiological contaminants, naturally occurring toxicants, residues of veterinary drugs and foods derived from modern biotechnology.

The WHO Department of Food Safety, Zoonoses and Foodborne Diseases (FOS) strives to reduce the serious negative impact of foodborne diseases worldwide. FOS works with other WHO departments, Regional Offices and WHO collaborating centres as well as other international and national agencies. In particular, WHO works closely with the Food and Agriculture Organization of the United Nations (FAO) to address food safety issues along the entire food production chain--from production to consumption--using new methods of risk analysis. These methods provide efficient, science-based tools to improve food safety, thereby benefiting both public health and economic development. FOS endeavours to help all WHO Member States, both developing and developed, through the approaches outlined in the WHO Global Strategy for Food Safety.

Module 3 - Risk Analysis and its components

3A. Introduction

- The introduction of the WTO agreement on Sanitary and Phytosanitary Measures has placed increased emphasis on the importance of sound science in the development of food regulatory measures. Risk analysis provides an integrated mechanism to organise data, enable estimation of human risks and development of consistent generic outcomes across the food supply.
- This module provides background information about the process of risk analysis and its component parts, risk assessment, risk management and risk communication. The module provides illustrations of the use of risk analysis within the Codex system.

3B. Risk Analysis - an overview

- *Risk Analysis: A process consisting of three components: risk assessment, risk management and risk communication.*
- *Risk: A function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food.*
- Risk analysis is a structured, systematic process that examines the potential adverse health effect consequential to a hazard or condition of a food and develops options for mitigating that risk. It includes interactive communication among all interested parties involved in the process.
- Risk Analysis is often represented by the following diagram:



Risk analysis achieves consistency across a variety of scientific disciplines by introducing the concept of risk as a means of establishing an appropriate priority or level of protection for a food regulatory measure. As a result, risk analysis has become the cornerstone in developing food control measures.

Why undertake risk analysis?

- To identify methods to address food safety more effectively
- To introduce appropriate food control measures

3C. Risk Assessment

Risk Assessment: The scientific evaluation of known or potential adverse health effects resulting from human exposure to foodborne hazards. The process consists of the following steps:

- (i) hazard identification,*
- (ii) hazard characterization,*
- (iii) exposure assessment, and*
- (iv) risk characterization.*

The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties.

Hazard: A biological, chemical, or physical agent in or property of food that may have an adverse health effect.

Hazard Identification: The identification of known or potential health effects associated with a particular agent.

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data is obtainable.

Exposure Assessment: The qualitative and/or quantitative evaluation of the degree of intake likely to occur.

Risk Characterisation: Integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties.

The four component parts of risk assessment may take different forms depending upon whether the hazard is a chemical intentionally added to food (e.g. a food additives), a chemical contaminant, a pesticide or veterinary drug, a microbial hazard (e.g. a pathogenic micro-organism or a microbial toxin).

Hazard Identification and Characterisation

Chemical Hazards

Substances intentionally added to food -

i.e. Food Additives and Processing Aids, Pesticide Residues, Veterinary Drug Residues

The Hazard Identification and Characterisation of substances which are intentionally added to food generally takes the form of a toxicological evaluation of animal studies, undertaken by the manufacturers, which have been designed to reveal adverse effects associated with high level of exposure to the substance. These studies may also be supported by human clinical trails designed to confirm the safety of the substance in intended use. Epidemiological data may also be available for substances with a long history of use. The aim of the toxicological evaluation is to understand the mechanisms of

toxicity (if any) of the substance and determine a level of exposure at which no adverse effects are seen, called the no-observed-effect level (NOEL). The NOEL is then used, together with various safety factors, to define an **Acceptable Daily Intake (ADI)** for the substance or residue. The ADI is a quantitative hazard characterisation expressed as the amount of the substance, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (notionally "zero" risk).

Occasionally, it will be determined that total exposure to the substance at any level which it is likely to be encountered in food does not represent a hazard to health. In this case, a risk characterisation of "**ADI not specified**" may be preferred, meaning that the total daily intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food, does not represent a hazard to health.

Substances unintentionally present in food -

i.e. **Contaminants(e.g. Heavy metals, industrial chemicals) and natural toxicants(e.g. Mycotoxins).**

The toxicological evaluation of contaminants and natural toxicants is generally carried out using a mixture of animal studies and human epidemiological data. Where a threshold for adverse effects can be identified, a NOEL will be determined and from this a quantitative hazard characterisation similar to the ADI established. In the case of substances that have no intended function in the food, the word "tolerable" is used in place of "acceptable" and "provisional" is added to indicate the tentative nature of the outcome. For substances such as cadmium that may or are known to accumulate in the body, a weekly value, the provisional tolerable weekly intake (PTWI), is used, whereas for substances such as tin or arsenic, which do not accumulate a provisional maximum tolerable daily intake (PMTDI) is established.

It is not always possible to establish a threshold from the data available. In these cases (e.g. aflatoxins which are genotoxic carcinogens), a recommendation is made that the level of the contaminant in food should be reduced to as low as reasonably achievable (ALARA). The ALARA level, which may be viewed as the irreducible level for a contaminant, is defined as that concentration of a substance that cannot be eliminated from a food without involving the discarding of that food altogether or severely compromising the ultimate availability of major food supplies.

Microbial Hazards

For microbial hazards, the purpose of hazard identification is to identify the microorganisms or the microbial toxins of concern with food. Hazards can be identified from relevant data sources.

Hazard characterisation will predominately be a qualitative or quantitative description of the severity and duration of adverse effects that may result from the ingestion of a microorganism or its toxin in food. A dose-response assessment is generally performed if the data are obtainable.

Relevant data may be obtained from clinical studies, epidemiological studies and surveillance, laboratory animal studies, investigations of the characteristics of microorganisms, the interaction between microorganisms and their environment through the food chain from primary production up to and including consumption, and studies on analogous microorganisms and situations.

Summary of Hazard Characterisation Terms

Hazard	Hazard Characterisation
Chemical Hazards	
<i>Food Additive</i> <i>Pesticide Residues</i> <i>Veterinary Drug Residues</i>	Acceptable Daily Intake (ADI) the amount of the substance, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk (notionally "zero" risk). "ADI not specified" - the total daily intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background in food, does not represent a hazard to health
<i>Contaminants</i> <i>Heavy metals</i> <i>Mycotoxins</i>	Provisional Tolerable Weekly Intake PTWI Provisional Maximum Tolerable Daily Intake PMTDI the amount of the substance, expressed on a body weight basis, that can be tolerated weekly or daily over a lifetime without appreciable health risk (notionally "zero" risk). "ALARA" as low as reasonably achievable - no threshold for adverse effects would be determined
Microbial Hazards	A qualitative or quantitative description of the severity and duration of adverse effects that may result from the ingestion of a microorganism or its toxin in food. A dose-response assessment is generally performed if the data are obtainable.

Exposure Assessment

Chemical Hazards

Estimates of dietary intakes of food additives, residues of pesticides and veterinary drugs and contaminants require information on the consumption of relevant foods and the concentrations of the chemical of interest in those foods. In general, three approaches are available in exposure assessment: (1) total diet studies; (2) selective studies of individual foods, and; (3) duplicate portion studies.

Guidelines for the study of dietary intakes of chemical contaminants are available from WHO (GEMS/Food, 1985). In recent years, direct monitoring of human tissues and body fluids has been increasingly used to assess exposure. For example, the determination of levels of organochlorine compounds in breast milk, which are mainly derived from the diet, has provided an integrated assessment of human exposure to these substances (GEMS/Food, in press).

Dietary intake determinations can be relatively straight-forward for additives, pesticides and veterinary drugs as the relevant foods and their use levels are specified by their approved conditions of use. However, the actual levels of additives and residues of pesticides and veterinary drugs present in foods are often well below the maximum levels permitted. In regard to residues of pesticides and veterinary drugs, levels on or in food are often totally absent because only a portion of the crop/animal population is usually treated.

Data on the levels of food additives in foodstuffs can be obtained from the manufacturers. The dietary intake of contaminants requires information on their distribution in foods that can only be obtained by analysing representative samples of foods with sufficiently sensitive and reliable analytical methods.

The theoretical total dietary intake of additives, pesticides and veterinary drugs must be below their corresponding ADIs. Frequently, the actual intake is well below the ADI. Therefore, models may be used to demonstrate that the level of exposure to a hazard will not exceed the acceptable risk threshold (e.g. the ADI or PTWI) but should not be used to demonstrate the opposite.

GEMS/Food currently maintains a database of regional diets as well as a composite "global" diet. Daily dietary intakes of nearly 250 individual primary and semi-processed food commodities are available. The African, Asian, East Mediterranean, European and Latin American regional diets are based on selected national data from FAO Food Balance Sheets. Consumption data derived using this approach provide no information on extreme consumers.

No information is available in GEMS/Food on the intake of food additives although intakes in developed countries are anticipated to be greater than in developing countries because of the higher portion of processed foods in the diet.

Microbial Hazards

The exposure assessment of a microbial hazard gives an estimate of either the number of pathogenic bacteria or the level of bacterial toxin consumed in food. While levels of chemical agents in food may change slightly due to processing, populations of bacterial pathogens are dynamic and may increase or decrease dramatically in food matrices. Changes in populations of bacteria are affected by complex interactions of factors such as:

- (i) ecology of the bacterial pathogen of concern;
- (ii) processing, packaging and storing of food;
- (iii) preparation steps, such as cooking, which may inactivate bacterial agents; and,
- (iv) cultural factors relating to consumers.

Risk characterization

Chemical Hazards

The outcome of the risk characterization is an estimate of the likelihood of adverse health effects occurring in human populations as a consequence of exposure to the hazard. The risk characterization takes into account the results of the hazard identification, hazard characterization, and exposure assessment.

For hazards for which a threshold can be established, the risk is notionally maintained at zero by ensuring that exposure does not exceed the numerical ADI or PTWI/PMTDI. For hazards for which a threshold cannot be set, a population risk is determined from the product of exposure and potency.

The risk characterization should describe the uncertainties involved in each step of the risk assessment process. Uncertainty in risk characterization may arise from the extrapolation of findings in animal studies to humans both in terms of the relevance of the findings to humans at a biochemical level (for example, an effect seen in one animal species may not have a parallel in humans) and at a metabolic level (for example, that the sensitivity of the animal model may be substantially greater or less than human sensitivity to the same substance). Potential variations between most sensitive animal models and humans are generally addressed by the application of safety factors between the NOEL and the ADI or PTWI/PMTDI. The validity of these assumptions will generally be tested during human clinical trials.

Microbial hazards

Characterizing the risk associated with biological pathogens will depend on the considerations and information described in the hazard identification, hazard characterization and exposure assessment steps. A risk characterization will result in a qualitative or quantitative estimate of the potential for adverse effects from a particular bacterial agent on a specific population.

It has not yet been determined whether a quantitative risk assessment approach is possible and appropriate for characterization of risk associated with foodborne bacterial pathogens. Thus, by default, the qualitative approach to characterizing risk may be the only current alternative.

The qualitative risk assessment process depends on experience with a specific food, a knowledge of ecology of bacterial pathogens, epidemiological data, and expert judgement regarding hazards associated with the manner in which the food is produced, processed, stored, and prepared for consumption.

3D. Risk Management

Risk Management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

The Risk Management framework comprises four components:

- A. Risk evaluation
 - i. Identification of a food safety problem.
 - ii. Establishment of a risk profile.
 - iii. Ranking of the hazard for risk assessment and risk management priority.
 - iv. Establishment of risk assessment policy for conduct of risk assessment.
 - v. Commissioning of risk assessment.
 - vi. Consideration of risk assessment result.
- B. Risk management option assessment
 - i. Identification of available management options.
 - ii. Selection of preferred management option, including consideration of an appropriate safety standard.
 - iii. Final management decision.
- C. Implementation of management decision
- D. Monitoring and review
 - i. Assessment of effectiveness of measures taken.
 - ii. Review risk management and/or assessment as necessary.

The outcome of the risk evaluation process should be combined with the evaluation of available risk management options in order to reach a decision on management of the risk. In arriving at this decision, human health protection should be the primary consideration, with other factors (e.g. economic costs, benefits, technical feasibility, risk perceptions, etc.) being considered as appropriate. Implementation of the management decision should be followed by monitoring both the effectiveness of the control measure and its impact on risk to the exposed consumer population, to ensure that the food safety objective is being met.

It is important that all interested parties (or stakeholders) who are likely to be affected by risk management decisions have an opportunity for input into the risk management process. These groups may include (but should not be limited to) consumer organizations, representatives of the food industry and trade, education and research institutions, and regulatory bodies.

A consultative process can be implemented in many ways, ranging from public meetings to opportunities to comment on public documents. Inputs from interested parties can be introduced and considered at every stage of the risk management policy formulation process, including evaluation and review.

General principles of food safety risk management

Principle 1: 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. In certain circumstances, not all of these elements will be included in risk management activities (e.g. standard setting by Codex, with implementation of control measures by national governments).

Principle 2: Protection of human health should be the primary consideration 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 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 3: Risk management decisions and practices should be transparent.

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: Determination of risk assessment policy should be included as a specific component of risk management.

Risk assessment policy sets the guidelines for value judgements and policy choices which may need to be applied at specific decision points in the risk assessment process, and preferably should be determined in advance of risk assessment, in collaboration with risk assessors.

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 recognised that risk analysis is an iterative process, and interactions between risk managers and risk assessors are essential for practical application.

Principle 6: Risk management decisions should take into account the uncertainty in the output of the risk assessment.

The risk estimate should, wherever possible, include a numerical expression of uncertainty, and this must be conveyed to risk managers in a readily understandable form so that the full implications of the range of uncertainty can be included in decision-making. For example, if the risk estimate is highly uncertain the risk management decision might be more conservative.

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.

3E. Risk Communication

Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

Risk communication, as an integral part of risk analysis, is a necessary and critical tool to appropriately define issues and to develop, understand and arrive at the best risk management decisions.

The fundamental goal of risk communication is to provide meaningful, relevant and accurate information, in clear and understandable terms targeted to a specific audience. It may not resolve all differences between parties, but may lead to a better understanding of those differences. It may also lead to more widely understood and accepted risk management decisions. Effective risk communication should have goals that build and maintain trust and confidence. It should facilitate a higher degree of consensus and support by all interested parties for the risk management option(s) being proposed.

The goals of risk communication

1. Promote awareness and understanding of the specific issues under consideration during the risk analysis process, by all participants;
2. Promote consistency and transparency in arriving at and implementing risk management decisions;
3. Provide a sound basis for understanding the risk management decisions proposed or implemented;
4. Improve the overall effectiveness and efficiency of the risk analysis process;
5. Contribute to the development and delivery of effective information and education programmes, when they are selected as risk management options;
6. Foster public trust and confidence in the safety of the food supply;
7. Strengthen the working relationships and mutual respect among all participants;
8. Promote the appropriate involvement of all interested parties in the risk communication process; and,
9. Exchange information on the knowledge, attitudes, values, practices and perceptions of interested parties concerning risks associated with food and related topics.

Before a formal risk assessment is initiated, appropriate information must be obtained from interested parties to prepare a "risk profile". This describes the food safety problem and its context, and identifies those elements of the hazard or risk which are relevant to various risk management decisions. This often involves a range of preliminary risk evaluation activities, which rely on effective risk communication (e.g., ranking for international standard setting or putting a food safety problem in an appropriate national or international context). Risk characterization is the primary means by which food safety risk assessment findings are communicated to risk managers and other interested parties. Numerical estimates in the characterization, therefore, should be supported by qualitative information about the nature of the risk and about the weight of evidence that defines and supports it. There are inherent difficulties in communicating the quantitative aspects of a risk assessment. They include ensuring that the scientific uncertainties inherent in the risk

characterization are clearly explained and that scientific terminology and technical jargon do not render the presentation of risk less understandable to the target audience. Communications among risk assessors, risk managers and other interested parties should use language and concepts that are suitable for the intended audience.

Risk communication facilitates the identification and weighting of policy and decision alternatives by risk managers in the risk analysis process. Interactive communication among all interested parties tends to assure transparency, facilitate consistency and improve the risk management process. To the extent that it is practical and reasonable, interested parties should be involved in identifying management options, developing the criteria for selecting those options and providing input to the implementation and evaluation strategy. When a final risk management decision has been reached, it is important that the basis for the decision be clearly communicated to all interested parties.

During the selection of risk management options, the risk manager may often need to consider factors in addition to science in the evaluation of a risk. This is particularly important at the national government level. Interactive communications are essential to identify social, economic, religious, ethical, and other concerns, so that these can be openly considered and addressed.

Preparation of risk messages for dissemination is an important part of the risk communication process. It is also a deliberate and specialized undertaking and should be treated as such. Good risk communication and proper risk messages will not always decrease conflict and mistrust, but inadequate risk communication and poorly developed messages will almost certainly increase both.

3F. Group Discussions

- Introduction and discussion of Codex principles for the use of risk analysis in standards setting
- Introduction of the 3 FAO/WHO risk assessments, for aspartame, fumonosins in corn and vibrio in oysters, to be used as case studies for practical risk management (Module 5)

3G. Question and Answer Session

Module 4 - Risk management and developing a food standard (theory sessions with practical case studies and working groups)

4A. Identifying the need for a food regulatory measure

Contents

- The legal framework and criteria for assessing standards and determining acceptable level of risk
- Developing a risk profile
- Identifying risks
- Developing a risk assessment policy and identifying acceptable levels of risk
- Categorizing and evaluating the risks: likelihood and consequences

Facilitator introduction

The legal framework and criteria for assessing standards and determining acceptable level of risk

Overarching requirements for an effective food control system

- A national strategy for food control with defined objectives;
- Appropriate food legislation to achieve the objectives defined by the national strategy, including development and implementation of food standards;
- Food regulatory measures, including regulations, standards and codes of practice, that are harmonised with international requirements and maintained and updated periodically;
- Effective food surveillance and control systems;
- Systems for improving food safety and quality along the food chain i.e. HACCP-based food control programmes;
- Training programmes for food handlers and processors, food inspectors, and analysts;
- Enhanced inputs into research, foodborne disease surveillance, and data collection, as well as creating increased scientific capacity within the system; and
- Consumer education and other community outreach initiatives.

Organizational Structures for National Food Control Systems

Given the wide scope of food control systems, there are at least three types of organizational arrangements that may be encountered at the national level. These are:

- Multiple Agency System - A system based on multiple agencies responsible for food control. Typically, under such arrangements the food control responsibilities are shared between Government Ministries such as Health, Agriculture, Commerce, Environment, Trade and Industry, and Tourism, and the roles and responsibilities of each of these agencies are specified but quite different.
- Single Agency System; A system that consolidates all responsibility for

protecting public health and food safety into a single food control agency with clearly defined terms of reference has considerable merit.

- Integrated System -A system based on an integrated National Food Control Agency addressing the entire food chain from farm-to-table, and having the mandate to allocate resources to high priority areas and to address important sources of risk.

Whichever system is in place, then relevant agency/agencies should be empowered in legislation to develop food standards that can be implemented under food legislation. Where multiple agencies are involved, it is important that the roles and responsibilities of the different agencies are elaborated in legislation or through high-level inter-agency agreements.

The enabling legislation should set out the process to be followed in the development of standards, including the use of science based risk analysis and community/stakeholder consultation. The principles that underlie the desired level of food safety protection or the acceptable level of risk may also be elaborated in legislation. Particularly, the objectives that the agency may have regard to in developing standards and the priority order in which these criteria are to be considered. Example of such matters might include:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices;
- the prevention of misleading or deceptive conduct;
- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food.

Examples from the Codex Alimentarius procedural manual:

STATUTES OF THE CODEX ALIMENTARIUS COMMISSION

Article 1

The Codex Alimentarius Commission shall, subject to Article 5 below, be responsible for making proposals to, and shall be consulted by, the Directors-General of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) on all matters pertaining to the implementation of the Joint FAO/WHO Food Standards Programme, the purpose of which is:

- (a) protecting the health of the consumers and ensuring fair practices in the food trade;*
- (b) promoting coordination of all food standards work undertaken by international governmental and non governmental organizations;*
- (c) determining priorities and initiating and guiding the preparation of draft standards through and with the aid of appropriate organizations;*
- (d) finalizing standards elaborated under (c) above and, after acceptance by governments, publishing them in a Codex Alimentarius either as regional or world wide standards, together with international standards already finalized by other bodies under (b) above, wherever this is practicable;*
- (e) amending published standards, after appropriate survey in the light of developments.*

GENERAL PRINCIPLES OF THE CODEX ALIMENTARIUS

PURPOSE OF THE CODEX ALIMENTARIUS

1. The Codex Alimentarius is a collection of internationally adopted food standards presented in a uniform manner. These food standards aim at protecting consumers' health and ensuring fair practices in the food trade. The Codex Alimentarius also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures intended to assist in achieving the purposes of the Codex Alimentarius. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

SCOPE OF THE CODEX ALIMENTARIUS

2. The Codex Alimentarius includes standards for all the principle foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the extent necessary to achieve the purposes of the Codex Alimentarius as defined. The Codex Alimentarius includes provisions in respect of food hygiene, food additives, pesticide residues, contaminants, labelling and presentation, methods of analysis and sampling. It also includes provisions of an advisory nature in the form of codes of practice, guidelines and other recommended measures.

NATURE OF CODEX STANDARDS

3. Codex standards contain requirements for food aimed at ensuring for the consumer a sound, wholesome food product free from adulteration, correctly labelled and presented. A Codex standard for any food or foods should be drawn up in accordance with the Format for Codex Commodity Standards and contain, as appropriate, the criteria listed therein.

Food Regulatory Measures

Food regulatory measures may take a number of formats:

- standards
- codes of practice
- guidelines

Different issues will warrant different types of measure.

Food regulatory measures may be mandatory or voluntary. Compliance with mandatory food regulatory measures is generally effected through the overarching national food legislation. Compliance with voluntary food regulatory measures can be promoted through industry organisations or market demand and may involve the implementation of HACCP and /or quality assurance auditing and quality endorsement or quality symbol programs.

Compliance with **Food standards** can be voluntary but is normally mandatory. Food standards may apply generally or be specific to individual foods. Food standards can deal with such matters as:

- the labelling and composition of food (including the use of food additives),
- maximum levels of contaminants and pesticide residues,
- maximum levels of pathogenic bacteria,
- food preparation or packaging.

A feature of food standards is that compliance can generally be determined by inspection of analysis of the food.

Compliance with **Codes of practice** may be mandatory or voluntary. Codes of practices generally address the processing and handling of food. Compliance with a Code of Practice may not be easily assessed by examination of the food but is generally assessed through auditing. A HACCP programme is an example of a Code of Practice type of food regulatory measure employed to ensure the safety of food and protect consumer health.

Compliance with **Guidelines** are generally voluntary. Guidelines can address matters relating to foods themselves or the method of production and processing.

A common feature of food standards and other mandatory food regulatory measures, irrespective of the food control model, is that they must be recognised in legislation and carry legal sanctions if not complied with. In order to achieve this there should be a mechanism for standards to be adopted as secondary legislation (e.g. regulations) under appropriate food laws. Adoption of food standards may be achieved through reference to the Parliament, by Ministerial decree or may be delegated by Government to the food control agency. In the latter case, a detailed (statutory) process is often prescribed in legislation that sets out the process(es) that the food control agency is to undertake in developing standard. The process is likely to detail the administrative and consultative steps to be taken and identify objectives (such as protecting the health of the consumers and ensuring fair practices in the food trade;) and acceptable levels of risk against which standards are to be assessed.

Food regulatory measures, including standards, may be established for a variety of scientific and socio-economic reasons such as:

- protecting consumer health and safety
- ensuring food safety
- ensuring food quality
- promoting fair trade
- protecting national interests
- promoting international trade
- harmonisation with international standards

Identifying risks and defining acceptable levels of risk

Examples of reasons to consider a new food regulatory measure include:

- outbreak of food-borne illness
 - microbiological, or
 - chemical
- a potential new chemical hazard
 - a contaminant analysed in food
 - a pesticide or agricultural chemical residue
 - a new chemical registered
 - a residue found in imported food
 - a new food additive registered
- alignment with Codex / trading partners' standards
- to support consumer confidence in food supply

Developing a risk assessment policy

Risk assessment policy sets the guidelines for value judgements and policy choices which may need to be applied at specific decision points in the risk assessment process, and preferably should be determined, in collaboration with risk assessors, in advance of risk assessment. The guidelines should be documented so as to ensure consistency and transparency and protect the scientific integrity of the risk assessment. Examples of risk assessment policy setting activities are:

- establishing the population(s) at risk,
- establishing criteria for ranking of hazards,
- establishing acceptable levels of risk for different hazards and guidelines for application of safety factors.

Once the risk assessment policy has been established, a functional separation of risk management and risk assessment should be applied to ensure the scientific integrity of the risk assessment process and reduce any conflict of interest between risk assessment and risk management. In applying this separation, however, it is recognised that risk analysis is an iterative process, and, in practice, interactions between risk managers and risk

assessors are essential. In some organisations or situations, the risk assessors and risk managers may be the same people. In these cases functional separation of tasks and documentation of the distinct risk assessment and management decision making stages should be employed to demonstrate the separation.

In the risk assessment of chemical substances such as food additives and pesticide residues, the concept of the acceptable daily intake (ADI) illustrates a components of risk assessment policy which is generally accepted by Codex and by regulators world wide. The ADI is the amount of the substance, expressed on a body weight basis, that may be consumed over an entire lifetime without "appreciable risk" to the consumer. The ADI is established by applying various safety factors to a level of consumption that does not result in any observed adverse effect in appropriate toxicological and/or epidemiological studies of suitable duration in humans or animals. The safety factors applied will be generally greater where animal studies only are available and smaller where a comprehensive human data base and/or a good understanding of the underlying biochemical and metabolic mechanisms of toxicity allows a higher level of certainty. Provided that technologically appropriate use of the additive (in accordance with Good Manufacturing Practice) or the pesticide (in accordance with Good Agricultural Practice) will not exceed the ADI when estimates of dietary exposure are made, the risks to consumers from the substance are considered to be negligible, and therefore acceptable. Where the technologically appropriate level of use result in consumption in excess of the ADI, the risks from use of the substance as proposed will generally be considered to be greater than the acceptable level of risk and require further risk management strategies will be required to reduce . The use of the ADI in this way represents a value judgement that the acceptable level of risk from the chemical substance is a "negligible risk" when consumed below the ADI. The actual methods by which exposure estimates are calculated reflect another risk assessment policy criteria.

Defining appropriate levels of protection for food standards

Protection of human health should be the primary consideration in risk management decisions.

Decisions on acceptable levels of risk and appropriate levels of food safety protection should be determined primarily by human health considerations, and arbitrary or unjustified differences in the risk levels should be avoided. Consideration of other factors (e.g. economic costs, benefits, technical feasibility, and societal preferences) may be appropriately considered during the risk management stage, particularly in the determination of measures to be taken. These considerations should not be arbitrary and should be made explicit.

A government may establish its levels of protection for food standards by any means available under its law, including by referendum. Ultimately, the chosen appropriate level of protection is a societal value judgement. The World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) expressly affirms the right of each government to choose its own levels of food safety protection, including a "zero risk" level if it so chooses.

The WTO SPS Agreement defines the appropriate level of protection as follows:

Appropriate level of sanitary or phytosanitary protection - The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory. NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

The SPS Agreement requires that the hazard be scientifically supported as a genuine risk to human health but imposes no requirement to establish a scientific basis for the chosen level of protection applied to control that hazard. Accordingly, countries can establish any level of protection they consider appropriate and develop food safety measures accordingly to eliminate or manage food safety hazards. While food safety measures must be based objectively on scientific or technical knowledge about controlling food safety hazards, a country's chosen level of protection is a societal choice of what is deemed appropriate. An appropriate level of protection may be objective or subjective in its tolerance for particular hazards.

The SPS Agreement (Article 4) and the WTO Agreement on Technical Barriers to Trade (TBT Agreement, Article 2.7) both establish a concept of equivalence of food safety measures. Equivalence is based upon an inter-relationship between food safety measures, regulatory objectives, and the levels of protection. The agreements require member countries to ensure their measures are objective, science-based and consistent. They should also conform with international standards, where they exist, unless they are considered to be an ineffective or inappropriate means for the fulfilment of a country's legitimate policy objectives (TBT) or insufficient to achieve what the country determines to be an appropriate level of sanitary or phytosanitary protection (SPS). Because measures can take many forms, member countries are encouraged to accept as equivalent, measures and regulations of other members, provided they are satisfied these alternative measures and regulations meet their appropriate level of protection.

Effectively, the inclusion of the concept of equivalence within the WTO agreements, raises the expectation that countries will be able to elaborate the levels of food safety protection (and therefore the acceptable level of risk) within their own food safety measures, where these differ from Codex standards. National standards in compliance with Codex standards are deemed to represent an acceptable level of protection and cannot be challenged in the WTO. Consequently, ensuring that national standards are either harmonized with or less prescriptive than Codex standards represents the most effective way for countries to ensure that their chosen level of protection does not exceed that considered appropriate from an international perspective. Nonetheless, countries will generally wish to assure themselves of the veracity of Codex standards before adopting them and be in a position to justify them in the context of national or social benefits.

Countries may choose to set that are less prescriptive than Codex standards especially where the risk management strategies embodied within them are considered too prescriptive or trade restrictive at a national level, having regard to the national food safety objectives.

Categorizing and evaluating the risks: likelihood and consequences

The risks inherent in a failure of food safety management may be defined in terms of:

- Health risks
 - food-borne illness outbreaks,
- Economic risks
 - damage or lose reputation for quality production
 - damage or lose access to export markets
 - loss of markets for domestic producers

- Social risks
 - consumers mislead about products
 - consumers lose confidence in producers
 - consumers lose confidence in Government/regulators
 - consumers ability to make ethical choices
 - halal
 - vegetarian

Risks can be characterised in terms of the probability that they will occur on a scale from likely to rare and in terms of the likely consequences if/when the risks are realised from benign to catastrophic.

Some risks may be assessed as extremely likely to occur but essentially benign and therefore not warranting the development of a food standard - many compositional and quality aspect of food may fall into this category. Other risks may be highly infrequent but if they do occur likely to have catastrophic outcomes such as death or permanent disability of consumers, or substantial loss of trade contracts and markets and justify the development of substantial regulatory measures.

Example of risk prioritisation as implemented by the Codex Committee on Food Additives and Contaminants (CCFAC) through the preamble to the General Standard for Contaminants and Natural Toxins in Food

1.4.2 Procedure for preliminary discussion about contaminants in the CCFAC Suggestions for new contaminants or new contaminant/commodity combinations to be discussed in the CCFAC and to be included in the GSC may be raised by delegates or by the secretariat. An initial discussion may be held based on oral contributions, but preferably on the basis of a note containing relevant and adequate information. For a satisfactory preliminary review the following information is essential:

1. *Identification of the contaminant and concise information about the background of the problem.*
2. *Indications about the availability of toxicological information and analytical and intake data, including references.*
3. *Indications about (potential) health problems.*
4. *Indications about existing and expected barriers to international trade.*
5. *Information about technological possibilities and economic aspects related to the management of the contaminant problem in food.*
6. *Preferably a proposal for action by the CCFAC.*

Group Exercise 4A

Participant in the course divide into groups of (approx) six. As far a possible, groups should be representative of a various countries and skills.

1. Group exercise - using one of the FAO Case studies, at a national level:
 1. Identify the associated risks (health, economic social, scientific, ethical),
 2. propose appropriate levels of protection for these risks, taking into account benefits arising from production of and/or access to the foods concerned.
2. Groups report back to plenary followed by discussion led by the presenter.

4B. Involving the Community and Consulting Effectively - Preliminary Consultation

Contents

- Why consult?
- Identifying stakeholders?
- How to consult (information, timelines and resources)

Facilitator introduction

Why Consult?

Risk communication is "an interactive exchange of information and opinions concerning risk and risk related factors among risk assessors, risk managers, consumers and other interested parties"

Effective community consultation as a part of risk communication achieves a number of outcomes including:

- Promoting awareness and understanding of the issues under consideration and the risk management decisions by stakeholders;
- Promoting consistency and transparency in risk management decisions;
- Improving the overall effectiveness and efficiency of the risk analysis process;
- Fostering public trust and confidence in the safety of the food supply;
- Promoting the appropriate involvement of all interested parties in the risk communication process; and,

Communication strategies will differ for different issues and different target audiences. This is most apparent when dealing with issues where specific groups have differing views of a risk. These differences in perception, which may be due to economic, social or cultural differences, should be recognized and respected. It is the outcome, i.e. effectively managed risk, which is most important. Differing methods of reaching the outcome should be considered.

Identifying stakeholders

There are a range of potential stakeholders in the development of a new standard. The actual stakeholders who will need to be involved in the development of a standard will depend upon the issues raised and the related risks. Potential stakeholders include:

- Government
 - Trade Ministry
 - Primary Production (Agriculture & Fisheries) Ministries
 - Health Ministry
 - Science and Technology Ministry
 - Industry Ministry
 - Regional/Local Government
 - Food inspectors (National, regional and/or local level)

- Industry
 - Primary production
 - Food processing
 - Food retail
 - Food service
 - Food safety /HACCP auditors
- Consumers
 - General population
 - at-risk groups
 - special interest groups
 - ethical religious groups
- Public Health Professionals
 - hospitals / medical specialists
 - academics
- Trading Partners
 - WTO notification
 - bilateral partners

How to consult (information, time lines and resources)

Depending on the nature of the identified risk(s) and to whom the communication is to be directed preliminary consultation may contain a range of information. The objectives of the consultation will determine the precise information provided. The aim of the consultation is to both inform the stakeholders and to solicit the provision of data and scientific opinion about the risks and the potential management solutions which can be used during the subsequent consideration of issues. In some cases, a food safety risk assessment will already have been undertaken at this stage (e.g. through Codex by JECFA, JMPR or JEMRA as appropriate, or by other/developed countries) and considerable information about the risks can be provided to the stakeholders at this stage. In other cases, potential risks may have been identified sufficiently to enable initiation of a standards development process but the risks may not be fully characterised. In this case, the information provided will be less detailed but the consultation may place greater emphasis on the collection of data or scientific opinion.

Examples of the information provided in a preliminary consultation might include:

- The nature of the risks and benefits
 - Health, economic, social, scientific and ethical
 - The urgency of the situation.
 - Whether the risk is becoming greater or smaller (trends).
 - The nature and size of the population at risk.
 - Potential benefits associated with each risk.
 - Who benefits and in what ways.

- How risks and benefits will be balanced in the assessment process.
- A request for relevant data (scientific, economic, social) to be used in the assessment of the risk(s)
- Uncertainties in risk assessment
 - The methods to be used to assess the risk.
 - The background to the regulatory policy and its assumptions
- Risk management options
 - The potential action(s) that may be taken to control or manage the risk(s).

In addition, consultation may take the form of an open request for data and comment or may direct stakeholders to respond to a set of questions or issues designed to focus their responses to those matters or issues considered important or relevant. The latter option is likely to result in submissions which are more straightforward and easier to evaluate within the context of the subsequent consideration of issues, however, if not well designed, it also has the potential to limit or direct consideration away from critical issues.

How to consult?

Consultation about the development of a standard may take a number of forms, depending upon the nature of the issues, the urgency of the situation and economic, social and cultural circumstances. Consultations can take the form of:

1. Presentation and discussion by a panel or committee comprised of relevant experts and stakeholder representatives. Panels may be standing bodies which, for example consider all food standards matters, or may be appointed for a specific issue or consultation. This option can provide rapid responses but may reduce the acceptance of the outcomes by the broad community or limit the provision of supporting data or scientific opinion to the subsequent assessment.

Panels or committees require locations for meeting and secretarial support.

Participants, especially representatives of community groups and academia, may also expect their travel expenses to be covered and may require per diem or honorarium payments.

Compared to widespread consultation, panels can provide very rapid response and be resource light due to the focussed nature of the consultation and the opportunity for issues to be discussed and resolved at a meeting.

2. Targeted consultation may be an effective means of consultation where very rapid turnaround is required or for highly specific or technical issues. Where the issues concerned are highly specific to a sector of the community or technically highly complex such that it is unlikely that the broad community will understand them, targeted consultation, in which information is provided to and comment sought only from representative organisations and appropriate experts may be effective. Relevant organisations might include industry associations, consumer organisations and professional bodies.

A typical targeted consultation would include the preparation of an issues paper which is circulated to relevant bodies or individuals. Those consulted are then given a period of time in which to respond. This period of time should be sufficient to enable representative bodies to consult with their members.

Targeted consultation may provide rapid input from stakeholders and be relatively light in terms of time and resource demand. However, as the consulted bodies are effectively free to comment on any aspect of the matter undergoing consultation,

the extent and detail of submissions may be an unknown factor and may be, in the subsequent assessment stage, resource intensive. This can be limited to some extent by identifying specific questions in the issues paper to which stakeholders are invited to address in their submissions.

3. Advertising and obtaining direct public comment. A typical open public consultation would commence with the preparation of an issues paper setting out the information discussed previously. In this type of consultation, the invitation to receive the issues paper and make submissions is notified to all stakeholders, through advertisements in newspapers, posting on public websites, and email notification to registered users. Those who wish to consult given a period of time in which to respond. This period of time should be sufficient to enable representative bodies to consult with their members.

The method provides for the widest possible stakeholder input and, thereby, potentially the greatest provision of data and scientific opinion and the highest level of understanding and acceptance of the outcomes. Due to the need to ensure that all potential stakeholders are given adequate time to respond to the notification, this method of consultation may be comparatively slow compared to other options discussed. The option is also potentially resource intensive in terms of the need to prepare an issues paper and the need to address and respond to, in the subsequent assessment stage, all of the issues raised in stakeholder submissions. As with targeted consultations, this can be limited to some extent by identifying specific questions in the issues paper to which stakeholders are invited to address in their submissions.

Group Exercise 4B

Participant in the course divide into groups of (approx) six. As far a possible, groups should be representative of a various countries and skills.

- Within a national context, prepare a communication/consultation plan relevant to one of the FAO case studies.
- Presentation by each groups to the class.
- Discussion of plans led by the presenter.

4C. Considering issues: scientific, regulatory, international obligations

Contents

- What does the science say
 - source(s) of the risk assessment
 - understanding the risk assessment output (i.e. the risk characterisation)
 - developing a risk management strategy

- What are the international obligations
 - is there a Codex or other relevant international standard?
 - does the science support this standard
 - can the international standard be accepted
 - is there a need for a national/regional risk assessment

Facilitator introduction

What does the science say

Sources of the risk assessment

The risk assessment may be carried out at the national level or may be sourced from an appropriate external body. Significant resources are needed to conduct an effective risk assessment. The commitment of the necessary resources becomes an important element of the decision to commission a risk assessment or use an existing risk assessment. In many cases, the cost in terms of time and money for national governments to undertake their own risk assessments is prohibitive.

The FAO/WHO food standards programme, through Codex and the various expert committees (JECFA, JMPR and JEMRA), conducts systematic risk assessments of food risks and provides this advice for use by member countries in the form of publicly available monographs and other documents. In addition, a number of national regulatory bodies, e.g. the US FDA and Health Canada, or regional bodies, e.g. EFSA and FSANZ, routinely undertake their own risk assessments which are then made publicly available, often via the Internet.

The use of externally prepared risk assessments may still require the collection of national data on intake and occurrence of the chemical, which will incur costs. Costs can be covered from various sources, but this should not bias the objective outcome. Sources for funding for national data collection to support risk assessment, may include manufacturers, government agencies, international organizations, research institutes and universities.

Understanding the risk assessment output (i.e. the risk characterisation)

The risk characterisation is the final stage of the risk assessment. The outcome of the risk characterization is an estimate of the likelihood of adverse health effects in human populations as a consequence of the estimated exposure to the hazard. At the risk characterization step, the uncertainties involved in each step of the risk assessment process should be described. Uncertainty in risk characterization will reflect the uncertainties in the preceding steps of the risk assessment. The extrapolation of results of animal studies to the human situation may produce two types of uncertainties: (i) uncertainties with respect to the relevance of the experimental findings to the humans, for

example adverse effects in animal studies may arise due to metabolism not found in humans; and, (ii) uncertainties with respect to specific human sensitivity for effects of a chemical that cannot be studied in experimental animals. In practice, these uncertainties are dealt with by expert judgement and by additional studies, preferably in humans, which may be performed during both the pre- and post-marketing phases.

The risk characterisation should provide risk managers with, wherever possible, a numerical expression of uncertainty inherent in the risk assessment, and should be in a readily understandable form so that the full implications of the range of uncertainty can be included in risk management decision-making process.

In the case of biological risks, such as foodborne pathogens, the qualitative risk assessment process depends on experience with a specific food, a knowledge of ecology of bacterial pathogens, epidemiological data, and expert judgement regarding hazards associated with the manner in which the food is produced, processed, stored, and prepared for consumption. In these circumstances, it is often not possible to provide a qualitative risk assessment and therefore, the risk characterisation may, of necessity, be a qualitative estimate of the potential for adverse effects from the particular bacterial agent on a specific population.

Risk managers should examine the risk characterisation in the context of their risk assessment policy and their risk management strategy (see below)

Developing a risk management strategy

Protection of human health should be the primary consideration in risk management decisions. As previously discussed, 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 factors (e.g. economic costs, benefits, technical feasibility, and societal preferences) are appropriate in a risk management context, particularly in the determination of measures to be taken. These considerations should not be arbitrary and should be explicit in the risk management strategy.

The risk management strategy should aim to describe the way in which food safety risk and other factors will be balanced in determining an appropriate risk management measure, elaborate the conditions under which a food standard or other regulatory measure will be established and objective criteria that will be used to determine the appropriate type of standard. The risk management strategy should have regard to the availability of administrative and technical capability and resources necessary to enforce the identified regulatory measure identified.

The risk management team should use the risk management strategy to identify suitable standards and other regulatory mechanisms to address the risks identified in the risk characterisation prepared by the risk assessors. It is likely that there will be more than one possible option to address the identified risks. The risk managers at this stage should rank the options from a food safety perspective and may indicate a preferred option, however, this should not be finalised until the regulatory impact assessment has been completed. The strategy should not at this stage attempt to compare the social impacts of the various regulatory options.

Example:

The Codex Committee on Food Additives and Contaminants (CCFAC) is currently developing a General Standard for Contaminants and Toxins in Food (CODEX STAN 193-1995). The preamble to the standard elaborated by CCFAC contains a detailed risk management strategy for contaminants and toxins in food, in particular addressing when and how contaminants and natural toxins will be included in the standard:

Principles for establishing maximum levels in foods and feeds

Maximum levels shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They shall be set in such a way that the consumer is adequately protected. At the same time the technological possibilities to comply with maximum levels shall be taken into account. The principles of Good Manufacturing Practice, Good Veterinary Practice and Good Agricultural Practice shall be used. Maximum levels shall be based on sound scientific principles leading to levels which are acceptable worldwide, so that international trade in these foods is facilitated. Maximum levels shall be clearly defined with respect to status and intended use.

Establishment of maximum levels for contaminants

The establishment of maximum levels of contaminants in foods involves several principles, some of which have already been mentioned. Briefly stated, the following criteria will help in maintaining a consistent policy in this matter:

- MLs shall be set only for those contaminants that present both a significant risk to public health and a known or expected problem in international trade.

- MLs shall be set only for those foods that are significant for the total exposure of the consumer to the contaminant.

- MLs shall be set as low as reasonably achievable. Providing it is acceptable from the toxicological point of view, MLs shall be set at a level which is (slightly) higher than the normal range of variation in levels in foods that are produced with current adequate technological methods, in order to avoid undue disruptions of food production and trade. Where possible, MLs shall be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation, unless a higher ML can be shown to be acceptable from a public health point of view and appreciable economic aspects are at stake.

- Proposals for MLs in products shall be based on data from at least various countries and sources, encompassing the main production areas/processes of those products, as far as they are engaged in international trade. When there is evidence that contamination patterns are sufficiently understood and will be comparable on a global scale, more limited data may be enough.

- MLs may be set for product groups when sufficient information is available about the contamination pattern for the whole group, or when there are other arguments that extrapolation is appropriate.

- Numerical values for MLs shall preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs.

- MLs shall apply to representative samples per lot. If necessary, appropriate methods of sampling shall be specified.

- MLs should not be lower than a level which can be analysed with methods of analysis that can be readily applied in normal product control laboratories, unless public health considerations necessitate a lower detection limit which can only be controlled by means of a more elaborate method of analysis. In all cases, however, a validated method of analysis should be available with which a ML can be controlled.

- The contaminant as it should be analysed and to which the ML applies should be clearly defined. The definition may include important metabolites when this is appropriate from an analytical or toxicological point of view. It may also be aimed at indicator substances which are chosen from a group of related contaminants. - The product as it should be analysed and to which the ML applies, should be clearly defined. In general, MLs are set on primary products. MLs shall in general preferably be expressed as a level of the contaminant related to the product as it is, on a fresh weight basis. In some cases, however, there may be valid arguments to prefer expression on a dry weight basis. Preferably the product shall be defined as it moves in trade, with provisions where necessary for the removal of inedible parts that might disturb the preparation of the sample and the analysis. The product definitions used by the CCPR and contained in the Classification of foods and feeds may serve as guidance on this subject; other product definitions should only be used for specified reasons. For contaminant purposes, however, analysis and consequently MLs will preferably be on the basis of the edible part of the product.

For fat soluble contaminants which may accumulate in animal products, provisions should be applied regarding the application of the ML to products with various fat content (comparable to the provisions for fat soluble pesticides).

- Guidance is desirable regarding the possible application of MLs established for primary products to processed products and multi-ingredient products. When products are concentrated, dried or diluted, use of the concentration or dilution factor is generally appropriate in order to be able to obtain a primary judgement of the contaminant levels in these processed products. The maximum contaminant concentration in a multi-ingredient food can likewise be calculated from the composition of the food. Information regarding the behaviour of the contaminant during processing (e.g. washing, peeling, extraction, cooking, drying etc.) is however desirable to give more adequate guidance here. When contaminant levels are consistently different in processed products related to the primary products from which they are derived, and sufficient information is available about the contamination pattern, it may be appropriate to establish separate maximum levels for these processed products. This also applies when contamination may occur during processing. In general however, maximum levels should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient foods by using appropriate factors. When these factors are sufficiently known, they should be added to the data base about the contaminant and mentioned in connection to the maximum level in a product.

- MLs shall preferably not be set higher than is acceptable in a primary (theoretical maximum intake and risk estimation) approach of their acceptability from a public health point of view. When this poses problems in relation to other criteria for establishing MLs, further evaluations are necessary regarding the possibilities to reduce the contaminant levels, e.g. by improving GAP and/or GMP conditions. When this does not bring a satisfactory solution, further refined risk assessment and contaminant risk management evaluations will have to be made in order to try to reach agreement about an acceptable ML.

What are the international obligations

Is there a Codex or other relevant international standard?

The risk management team should identify relevant international standards that have been developed to address the identified risks.

For food safety, the WTO SPS Agreement recognizes, as the international reference, the standards, guidelines and recommendations established by the Codex Alimentarius Commission. Codex standards address food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practices.

Likewise, international standards established by the International Office of Epizootics (OIE) and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention (IPPC) have been recognized in the SPS Agreement as providing references with regard to animal and plant life or health.

In addition to complying with Codex standards a country might also wish to have regard to the standards developed by regional trading groups and by major trading partners.

Does the science support this standard

The risk management team should compare the options developed to meet their risk management policy, in the light of the risk assessment, with the identified international standards. This process should address not only the text of the standard but also the capability of the national enforcement systems to implement the standard and the intended/expected outcomes of the standard in terms of its food safety objectives.

Can the international standard be accepted

Within the context of the SPS agreement, Codex standards and related texts are deemed necessary to protect human health. As long as a country employs these standards, its measures are presumed to be consistent with the provisions of the SPS Agreement. Harmonization with Codex eliminates the necessity of a country having to provide other countries with justifiable reasons as to why the measures they are applying are necessary in order to protect human health. There is therefore strong encouragement for countries to adopt Codex standards.

In considering whether a Codex standard can be accepted, the risk managers should consider the extent to which it can be expected to deliver outcomes that meet its predetermined appropriate levels of protection and food safety objectives.

Is there a need for a national/regional risk assessment

Codex and other international/regional standards are by design intended to address food safety risks to the international or regional population as a whole. Risk managers may conclude that, taking into account national or sub-national factors, that the international standard does not meet its own food safety objectives and will not provide an adequate level of protection for its own community. Reasons for such a decision might include traditional food production, preparation or handling procedures, unique dietary patterns or climatic conditions that enhance the risks and were not taken into account in the risk analysis underpinning the international/regional standard. In these cases, a supplementary risk assessment may be justified. National standards may set higher or lower levels of food safety protection than is present in a Codex Standard.

Where a decision is taken to develop a national standard that is not consistent with the international standard, because it imposes a higher level of food safety protection, a national/local risk assessment will be necessary to justify these measures.

Group Exercise 4C

Participants in the course divide into groups of (approx) six. As far a possible, groups should be representative of a various countries and skills.

For one of the FAO risk assessment case studies

- identify the risk assessment key elements and conclusions
- identify the relevant international/Codex standard (if any)
- each group reports back to the class
- discussion led by facilitator

4D. Developing options and assessing regulatory impact/ competition policy aspects

Contents

- What are the regulatory options
- Regulatory impact assessment

What are the regulatory options

On completion of the assessment of the scientific, regulatory and international issues risk managers will have developed a range of options that may be employed to address the identified risks. These options may include:

- do nothing (do not make a regulatory measure)
- make a voluntary measure
e.g. a guideline or a code of practice.
- make a standard
 - what sort of standard?
 - consider the options including any international standards

Standards may be generic or commodity based. The elements of a standard may include identification of the hazard (i.e. the chemical or biological agent), the food or foods affected, conditions of production, processing, storage, handling or preparation, quantitative limits and or reference to Good Manufacturing Practice, Good Agricultural Practice or Good Veterinary Practice.

Codex example

Within the Codex General Standard for Food Additives (GSFA), the Codex Committee on Food Additives and Contaminants (CCFAC), has employed different approaches to classify food additives and processing aids based on their risk characterisation.

- Additives which are designated "ADI not specified" are considered safe for use under all circumstances and are listed to be permitted to a maximum level consistent with GMP for foods except in a limited list of foods where additives are in general considered unnecessary,
- Additives with a numerical ADI are listed by food and generally have numerical ADIs. The listing of an additive in a specific food category and the maximum level of use are subject to an assessment that the maximum level is technologically justified and the ADI will not be exceeded,
- Additives which have undergone a risk assessment (including evaluation by JECFA and allocation of an ADI) are not listed in the standard,
- Processing aids are not included in the GSFA but are listed in an inventory which is not a part of the general standard, for the information of member states.

Regulatory impact assessment

A Regulatory Impact Assessment (RIA) is a tool to assist decision-making. It is a method of systematically and consistently examining potential impacts arising from government action and communicating the information to decision-makers. Both the analysis and communication aspects are important. Completion of a RIA help provide the risk managers and the regulatory authorities with an assurance that new or amended regulatory

proposals are subject to proper analysis and scrutiny as to their necessity, efficiency, and net impact on community welfare. This will enhance the government's ability to make well-based decisions.

Content of a Regulatory Impact Assessment

The RIA should contain the following information:

- a statement of the nature and magnitude of the problem and the need for regulatory action;
- a summary of the risk assessment policy and the acceptable levels of risk
- a summary of the risk assessment outcomes, the consultation undertaken and of the consideration of relevant issues by risk managers;
- a list of potential regulatory measures identified to address the risks, including relevant international standards.
- for each of the options identified, the RIA should contain a statement of the benefits and costs for each stakeholder group (i.e. government, industry groups and consumers), including administrative, compliance, and economic benefits and costs. Where possible these should be quantified. Non-quantifiable benefits and costs should also be included and identified appropriately; and
- identification of the preferred regulatory option(s)

A typical assessment of costs and benefits might include:

Government:

- Relative costs of inspection and enforcement;
- Reduced health service costs arising from a safer food supply;
- Political costs/benefits of a safe food supply.

Industry

- Direct costs of compliance;
 - introduction of HACCP/quality management systems,
 - changes to process.,
 - changes to packaging/labelling.
- Benefits;
 - increased access to export markets,
 - increased sales.

Consumers

- better access to safe food and better food choices;
- Increased cost of food (passed on from food manufacturers);
- Reduced incidence of food-borne illness.

The regulatory impact assessment should be drafted so as to provide a systematic and logical basis for the adoption of the preferred regulatory option.

Group Exercise 4D

Participants in the course divide into groups of (approx) six. As far a possible, groups should be representative of a various countries and skills.

For one of the case studies, within a national context

- identify the regulatory options
- prepare a RIA that addresses the options and supports the preferred option
- Each group presents its options and RIA to the class.
- Discussion of plans led by the facilitator.

4E. Drafting a Standard

Contents

- Preparation of drafting instructions
- The parts of a standard

Facilitator introduction

The application of the risk management strategy to the risk characterisation, arising from the risk assessment, together with the regulatory impact assessment will enable risk managers to identify the regulatory option that most closely meets the national objectives in terms of protection of public safety and justifies a decision to adopt an international standard or develop a national variant.

Preparation of drafting instructions

In order to enable the preparation of a draft standard which meets the chosen option, risk manager should prepare drafting instructions which include identification of:

- the appropriate legislation under which the standard(s) will be implemented and enforced;
- the aims and objectives of the proposed standard(s);
- the criteria that are to be addressed in the standard (these criteria might include the identity of the hazard, maximum levels, foods concerned, process/production criteria relevant to the enforcement of the standard etc.)
- any other relevant information to be included in the standard.

Drafting of the standard may be undertaken by general administrative staff or by legally qualified personnel, depending upon national administrative arrangement. At a national level, a standard is a piece of legislation and should be consistent with and enforceable under appropriate implementing food legislation. For this reason legal council familiar with national food law(s) should be involved in preparing of clearing the draft standard.

Where a decision is taken to adopt a standard consistent with the Codex standard, this may be implemented by:

- a reference in national legislation to the Codex standard text,
- reproduction of the Codex text in national legislation,
- drafting a standard in a format appropriate to national legislation which implements the relevant elements of the Codex standard.

The parts of a standard

Introduction to the Format for Codex Commodity Standards (Codex Procedural Manual) and the relationship between commodity standards and general standards.

4F. Notifying stakeholders about the proposed standard and undertaking further consultation

Contents

- Why consult on a draft standard?
- Elements of effective risk communication

Facilitator introduction

Why consult on a draft standard?

Reasons for stakeholder notification and consultation have been discussed previously. Consultation on a draft standard provides

- stakeholder awareness and understanding of the issues under consideration and the risk management decisions;
- consistency and transparency in the risk management decision;
- a mechanism to ensure the overall effectiveness of the proposed regulatory option
- public trust and confidence in the safety of the food supply;
- an appropriate mechanism for involvement of all interested parties in the standards setting process.

Elements of effective risk communication

Depending on what is to be communicated and to whom, risk communication messages may contain information on the following:

The nature of the risk

- A description of the hazard
- magnitude and severity of the hazard
- the urgency of the situation
- the methods used to assess the risks
- a summary of the risk characterisation (including the uncertainties)

The risk management

- the other factors considered
 - trade
 - economic
 - social
 - ethical/religious

The proposed risk management actions

- Risk management options considered
- The justification for choosing a preferred risk management option

The Regulatory Impact Assessment (RIA).

All of the key messages for this round of community consultation will have been identified and documented during the standard development process. The task for risk managers at this stage is to present the information in a way that can be understood by stakeholders,.

Group Exercise 4F

Participants in the course divide into groups of (approx) six. As far a possible, groups should be representative of a various countries and skills.

- For one of the FAO risk assessment case studies;
 - identify affected stakeholders,
 - predict their likely responses to the preferred regulatory option
 - prepare a list of key items to be included in feedback to consumers,
 - report back and class discussion.

4G. Analysing issues and revising standards

Facilitator introduction

An important element in community consultation on a draft food standard is to receive comments and address them in an open and transparent manner.

Community submissions are likely to include both generic comments on the policy and assumptions that underpin the use of risk analysis in food standards setting and comments that are specific to the hazards being addressed and the risk analysis itself. The resource requirements for consultation on a draft standard are essentially similar to those discussed previously for consultation on the issues.

Once the standard has been developed and implemented, the focus of risk management moves to monitoring and review. There are a number of ways in which standards can be reviewed such as:

- central reporting of routine surveillance
- central reporting of food-borne illness
- specific surveys
 - food specific
 - consumer specific

A key factor in the review of standards is the development of objective measures against which a standard can be measured.

Examples:

- Percentage of failing foods in surveys
- Incidence of food borne illness

4H. Final decision making (legislative process or other political consideration)

Facilitator Introduction

Standards should be adopted into legislation by appropriate political means . The FAO/WHO publication Assuring Food Safety and Quality: Guidelines for strengthening National Food Control Systems.

Publication in government gazette

Once adopted standards should be published in the government gazette or other such legal instrument

Implementation

Standards should be implemented according to the urgency determined during the risk analysis:

- Food standards which address matters of urgent public health and safety concern, or relax regulations or permit new ingredients may commence upon gazetteer.
- For standards that introduce mandatory changes to food formulations or labelling it is appropriate to allow the food industry and importers reasonable time (1-2 years in some cases) to implement the changes in their product.

Group discussions

- setting objective measures for review of standards
- surveys - what, where how?
 - introduction to total diet surveys,
 - GEMS food

Final Round Up - Programme Close

Summary of:

- Risk Analysis
- The steps of Risk Management
- Resources and links

Appendices

1. Codex Risk Analysis Definitions
2. WTO SPS Agreement
3. Useful resources and Links
4. Pre-training course questionnaire

1. Codex Risk Analysis Definitions¹

Risk Analysis: A process consisting of three components: risk assessment, risk management and risk communication.

Risk: A function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food.

Risk Assessment: The scientific evaluation of known or potential adverse health effects resulting from human exposure to food-borne hazards. The process consists of the following steps:

- (i) hazard identification,*
- (ii) hazard characterization,*
- (iii) exposure assessment, and*
- (iv) risk characterization.*

The definition includes quantitative risk assessment, which emphasizes reliance on numerical expressions of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties.

Hazard: A biological, chemical, or physical agent in or property of food that may have an adverse health effect.

Hazard Identification: The identification of known or potential health effects associated with a particular agent.

Hazard Characterization: The qualitative and/or quantitative evaluation of the nature of the adverse effects associated with biological, chemical, and physical agents which may be present in food. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data is obtainable.

Exposure Assessment: The qualitative and/or quantitative evaluation of the degree of intake likely to occur.

Risk Characterisation: Integration of hazard identification, hazard characterization and exposure assessment into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties.

Risk Management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

Risk Communication: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

¹ From Codex Alimentarius Procedural Manual 14th Edition

2. WTO SPS & TBT Agreements

Extracts from the WTO AGREEMENT ON THE APPLICATION OF SANITARY AND PHYTOSANITARY MEASURES

Article 5

Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection

1. Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
2. In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.
3. In assessing the risk to animal or plant life or health and determining the measure to be applied for achieving the appropriate level of sanitary or phytosanitary protection from such risk, Members shall take into account as relevant economic factors: the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease; the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks.
4. Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects.
5. With the objective of achieving consistency in the application of the concept of appropriate level of sanitary or phytosanitary protection against risks to human life or health, or to animal and plant life or health, each Member shall avoid arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade. Members shall cooperate in the Committee, in accordance with paragraphs 1, 2 and 3 of Article 12, to develop guidelines to further the practical implementation of this provision. In developing the guidelines, the Committee shall take into account all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves.
6. Without prejudice to paragraph 2 of Article 3, when establishing or maintaining sanitary or phytosanitary measures to achieve the appropriate level of sanitary or phytosanitary protection, Members shall ensure that such measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility.

ANNEX A

DEFINITIONS⁴

1. Sanitary or phytosanitary measure - Any measure applied:

- (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- (b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

2. Harmonization - The establishment, recognition and application of common sanitary and phytosanitary measures by different Members.

3. International standards, guidelines and recommendations

- (a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
- (b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
- (c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and (d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

4. Risk assessment - The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

5. Appropriate level of sanitary or phytosanitary protection - The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

NOTE: Many Members otherwise refer to this concept as the "acceptable level of risk".

Extract from the WTO AGREEMENT ON TECHNICAL BARRIERS TO TRADE
TECHNICAL REGULATIONS AND STANDARDS

Article 2

Preparation, Adoption and Application of Technical Regulations by Central Government Bodies

With respect to their central government bodies:

2.1 Members shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country.

2.2 Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.

2.3 Technical regulations shall not be maintained if the circumstances or objectives giving rise to their adoption no longer exist or if the changed circumstances or objectives can be addressed in a less trade-restrictive manner.

2.4 Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.

2.5 A Member preparing, adopting or applying a technical regulation which may have a significant effect on trade of other Members shall, upon the request of another Member, explain the justification for that technical regulation in terms of the provisions of paragraphs 2 to 4. Whenever a technical regulation is prepared, adopted or applied for one of the legitimate objectives explicitly mentioned in paragraph 2, and is in accordance with relevant international standards, it shall be reputedly presumed not to create an unnecessary obstacle to international trade.

2.6 With a view to harmonizing technical regulations on as wide a basis as possible, Members shall play a full part, within the limits of their resources, in the preparation by appropriate international standardizing bodies of international standards for products for which they either have adopted, or expect to adopt, technical regulations.

2.7 Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own, provided they are satisfied that these regulations adequately fulfil the objectives of their own regulations.

2.8 Wherever appropriate, Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.

3. Useful Resources and Links

<i>Resource/Organisation</i>	<i>URL</i>
1. International Organisations	
FAO Food Quality and Standards (ESN) <i>THE FAO FOOD AND NUTRITION DIVISION AIMS TO:</i> <i>Create sustainable improvements in nutrition, especially among nutritionally vulnerable households and population groups;</i> <i>Raise awareness of the benefits of combating hunger and reducing malnutrition;</i> <i>Assist countries in identifying people who are food insecure and vulnerable to nutritional problems;</i> <i>Promote food safety and prevent food borne diseases;</i> <i>Focus on consumer protection and fair practices in food trade.</i>	http://www.fao.org/es/ESN/index_en.stm
Codex Alimentarius - procedural manual (includes risk analysis definitions) - General Standard For Food Additives (GSFA) on-line	http://www.codexalimentarius.net http://www.codexalimentarius.net/web/procedural_manual.jsp http://www.codexalimentarius.net/gsfaonline
JECFA - Joint FAO/WHO Expert Committee on Food Additives Provides independent scientific expert advice to the Codex Alimentarius Commission and its specialist Committees	http://www.codexalimentarius.net/web/jecfa.jsp
JMPR - Joint FAO/WHO Meetings on Pesticide Residues Provides independent scientific expert advice to the Codex Alimentarius Commission and its specialist Committees	http://www.codexalimentarius.net/web/jmpr.jsp
JEMRA - Joint FAO/WHO Meeting on Microbiological Risk Assessment Provides independent scientific expert advice to the Codex Alimentarius Commission and its specialist Committees	http://www.codexalimentarius.net/web/jemra.jsp
WHO - World Health Organisation Food Safety	http://www.who.int/foodsafety/en/
WTO - The World Trade Organisation SPS agreement TBT agreement	http://www.wto.org/english/tratop_e/sps_e/sps_e.htm http://www.wto.org/english/tratop_e/tbt_e/tbt_e.htm
2. Portals and Reference Documents	

Resource/Organisation	URL
International Portal on Food Safety, Animal & Plant Health	http://www.ipfsaph.org/
Application of Risk Analysis to Food Standards Issues, a Joint FAO/WHO Expert Consultation, Geneva, Switzerland, 13-17 March 1995	http://www.who.int/entity/foodsafety/publications/micro/march1995/en/index.html
Risk Management and Food Safety, a Joint FAO/WHO Consultation, Rome, Italy, 27 - 31 Jan 1997	http://www.who.int/entity/foodsafety/publications/micro/jan1997/en/index.html
The Application of Risk Communication to Food Standards and Safety Matters, a Joint FAO/WHO Expert Consultation. Rome, Italy, 2-6 February 1998 FAO Food and Nutrition Papers - 70	http://www.who.int/entity/foodsafety/publications/micro/feb1998/en/index.html
Risk assessment of Campylobacter spp. in broiler chickens and vibrio spp. in seafood FAO Food and Nutrition Papers - 75	
Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts	ftp://ftp.fao.org/docrep/fao/006/y4302e/y4302e00.pdf
GEMS Food	http://www.who.int/foodsafety/chem/gems/en/index.html
Risk assessment of microbiological hazards in foods. Report of a Joint FAO/WHO Expert consultation Geneva, Switzerland 15-19 March 1999	
3. Regional and national organisations	
US FDA - Center for Food Safety and Applied Nutrition	http://www.cfsan.fda.gov/
European Union - Food Safety Portal EU food safety and food legislation links. A comprehensive guide to European Food Law	http://europa.eu.int/pol/food/index_en.htm
European Food Safety Agency	http://efsa.eu.int/
Food Standards Australia New Zealand	http://www.foodstandards.gov.au
Health Canada - Food and Nutrition	http://www.hc-sc.gc.ca/fn-an/index_e.html
Canadian Food Inspection Agency	http://www.inspection.gc.ca/
Ministry of Health, Labour and Welfare - Japan	http://www.mhlw.go.jp/
Food Standards Agency UK	http://www.food.gov.uk/
New Zealand Food Safety Authority	http://www.nzfsa.govt.nz/

<i>Resource/Organisation</i>	<i>URL</i>
4. Other risk analysis references	
Joint Institute for Food Safety and Applied Nutrition - Food Safety Clearing House (USA)	http://www.foodrisk.org/index.cfm
Australian Food Safety Centre of Excellence	http://www.foodsafetycentre.com.au/
5. Case Study Specific resources	
Vibrio parahaemolyticus	http://www.cdc.gov/ncidod/dbmd/diseaseinfo/vibrioparahaemolyticus_g.htm

5. Pre-training questionnaire

All participating delegations should be invited to complete the questionnaire prior to the commencement of the training course, to identify/ assess the current state of risk based standards setting in their country.

A2-3: Template for Collection of Information on Food Standards

The following template can be used to collect information about mandatory and voluntary standards covering food products, additives, contaminants, processing and packaging, labelling, health and hygiene, weights and measures, imports and exports, etc.

Country:				
Date:				
Title of relevant standard	Description of coverage/scope	Legally binding (yes/no) If yes, indicate date enacted	Date of amendments (if any)	Responsible agency

Country:				
Date:				
Title of relevant standard	Description of coverage/scope	Legally binding (yes/no) If yes, indicate date enacted	Date of amendments (if any)	Responsible agency