

RISK MANAGEMENT AND FOOD SAFETY

**Report of a Joint FAO/WHO Consultation
Rome, Italy, 27 to 31 January 1997**



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CONTENTS

CONTENTS	iii
LIST OF ACRONYMS	v
1. INTRODUCTION	1
2. BACKGROUND	2
Scope of the consultation	2
3. THE GOAL OF FOOD RISK MANAGEMENT	3
4. INTERNATIONAL TRADE	3
“Safe and wholesome”	3
5. DEFINITIONS OF KEY RISK MANAGEMENT TERMS	4
6. RISK MANAGEMENT FRAMEWORK	5
A. Risk evaluation	5
B. Risk management option assessment	5
C. Implementation of management decision	5
D. Monitoring and review	5
7. GENERAL PRINCIPLES OF FOOD SAFETY RISK MANAGEMENT	6
8. CURRENT RISK MANAGEMENT PRACTICES IN THE CODEX ALIMENTARIUS COMMISSION, ITS SUBSIDIARY BODIES, AND ADVISORY EXPERT COMMITTEES	7
The Joint FAO/WHO Expert Committee on Food Additives and the Joint FAO/WHO Meeting on Pesticide Residues (JECFA and JMPR)	7
Codex Alimentarius Commission (CAC)	9
Codex Committee on Food Additives and Contaminants (CCFAC)	10
Codex Committee for Residues of Veterinary Drugs in Foods (CCRVDF)	11
Codex Committee on Pesticide Residues (CCPR)	12
Codex Committee on Food Hygiene (CCFH)	13
Codex Committee on General Principles (CCGP)	15

Codex Committee on Food Labelling (CCFL).....	15
Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)	15
The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU).....	16
Codex Committee on Methods of Analysis and Sampling (CCMAS).....	16
Codex Committee on Meat Hygiene (CCMH).....	16
9. RECOMMENDATIONS	17
10. REFERENCES.....	19
Annexes	
STRUCTURE OF RISK ANALYSIS (Diagram).....	20
LIST OF PARTICIPANTS	21
CONCLUSIONS AND RECOMMENDATIONS OF THE 1995 CONSULTATION	24

LIST OF ACRONYMS

ADI	Acceptable Daily Intake
ALARA	As Low as Reasonably Achievable
Acute RfD	Acute Reference Doses
CAC	Codex Alimentarius Commission
CCFAC	Codex Committee on Food Additives and Contaminants
CCFH	Codex Committee on Food Hygiene
CCFICS	Codex Committee on Import and Export Food Inspection and Certification Systems
CCFL	Codex Committee on Food Labelling
CCGP	Codex Committee on General Principles
CCMAS	Codex Committee on Methods of Analysis and Sampling
CCNFSDU	Codex Committee on Nutrition and Foods for Special Dietary Uses
CCMH	Codex Committee on Meat Hygiene
CCNFSDU	Codex Committee on Nutrition and Food for Special Dietary Uses
CCPs	Critical Control Points
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Foods
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GEMS/Food	Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme
GMP	Good Manufacturing Practice
GSCTF	General Standard for Contaminants and Toxins in Foods
GSFA	General Standard for Food Additives
GPVD	Good Practice in the Use of Veterinary Drugs
HACCP	Hazard Analysis Critical Control Point
ICMSF	International Commission on Microbiological Specifications for Food
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
MRL	Maximum Residue Limit
PTWI	Provisional Tolerable Weekly Intake
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary Measures
WHO	World Health Organization

1. INTRODUCTION

A Joint FAO/WHO Expert Consultation on the Application of Risk Management to Food Safety Matters was held at FAO Headquarters in Rome from 27 to 31 January 1997. The Consultation participants are listed in Annex 1. The Consultation was opened by Dr. Hartwig de Haen, Assistant Director-General of FAO's Economic and Social Department, who welcomed the participants on behalf of the Directors-General of both FAO and WHO.

In welcoming the participants, Dr. de Haen noted that this was the second joint FAO/WHO expert consultation in the important subject area of the application of risk analysis to food safety, with the first, held in Geneva in 1995, having focused on the risk assessment component of risk analysis.* In this current consultation, the experts were being asked to address a central issue in food safety. Risk management, he observed, involves both the identification of the standards of acceptable risk appropriate to different types of food hazards, and the establishment of procedures to ensure that the risks are kept within the limits set by those standards.

Dr. de Haen drew two important underlying considerations to the attention of the participants. The first was the imperative to keep the interest and the well being of the consumer as a fundamental consideration at all times. The ultimate objective of food safety standards is the protection of the consumer, and it is essential not to lose sight of this. The second important issue was that it is in the basic interest of everyone that trade in food be facilitated. This was, Dr. de Haen noted, the fundamental intended outcome of the Uruguay Round Negotiations and had been an important goal of FAO since its founding over 50 years ago.

Dr. de Haen reminded the participants that they had been invited to the Consultation as independent experts charged with the responsibility of advising FAO, WHO and their Member Nations, and that their participation in the Consultation was to be in their personal capacities as international experts in this subject area, and not as representatives of their governments, institutes or other organizations.

The Consultation elected Dr. Stuart Slorach as Chairman and Dr. Steve Hathaway as Vice-Chairman. Dr. Christopher Fisher was appointed as Rapporteur. In his opening remarks Dr. Slorach pointed out that the main goal of the consultation was to arrive at a series of recommendations on the application of risk management to food safety. These should be addressed primarily to the standard setting activities of the Codex Alimentarius Commission (CAC), its subsidiary committees and advisory expert bodies, but they should also be of relevance to those involved in risk management at the national level. He urged participants to aim at providing a general framework for risk management, identifying the essential components in the process and the roles and activities of the principal parties. It was, he said, necessary to deal with the management of risk from both chemical and biological hazards in food, including the full range of acute and chronic adverse health effects. Likewise, it was essential to bear in mind the problems of both developing and developed countries.

* The first FAO/WHO expert consultation on risk, referred to elsewhere as the 1995 consultation, was the Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Safety Standards, held in Geneva, Switzerland, 13-17 March 1995. The conclusions and recommendations of that consultation are in Annex 2.

Dr. Slorach pointed out that, even when dealing with risks arising from chemicals that had been the subject of extensive toxicological studies, risk managers find that there still remain gaps in the available information. In other instances, of which bovine spongiform encephalopathy was a good example, it was perhaps more correct to speak of “islands of knowledge in an ocean of uncertainty”. The 1995 consultation had pointed out the need for risk managers to be aware of the uncertainty in risk estimates and to include this awareness in their management decisions.

Food safety risk analysis is an emerging discipline, and the methodological basis for assessing and managing risks associated with food hazards is still in a developing phase (1) (2). As discussed in the 1995 consultation, it is important to recognise the difference between “hazard” and “risk”. A hazard is a biological, chemical or physical agent in, or condition of, food with the potential to cause harm. In contrast, risk is an estimate of the probability and severity of the adverse health effects in exposed populations, consequential to hazards in food. Understanding the association between a reduction in *hazards* that may be associated with a food, and the reduction in the *risk* to consumers of adverse health effects is of particular importance in development of appropriate food safety controls.

2. BACKGROUND

Risk analysis is widely recognised as the fundamental methodology underlying the development of food safety standards. As recognised in the 1995 consultation, risk analysis is composed of three separate but integrated elements, namely risk assessment, risk management and risk communication. That consultation recognised risk communication as an interactive process of exchange of information and opinion on risk among risk assessors, risk managers, and other interested parties. Risk management is defined within Codex as the process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures. The outcome of the risk management process, as undertaken by Committees within the Codex Alimentarius system, is the development of standards, guidelines and other recommendations for food safety. In the national situation it is likely that different risk management decisions could be made according to different criteria and different ranges of risk management options. The overall objective of Codex is to ensure consumer protection and to facilitate international trade.

Risk managers, in developing approaches to managing risk, utilise the risk characterisation that results from the risk assessment process. An important principle that was recognised by the 1995 consultation was the functional separation of risk assessment from risk management.

The significant world-wide increase in foodborne illness that has been recognized in recent years, especially arising from enteric organisms, suggests the need for more effective control using internationally agreed risk management methods.

Scope of the consultation

The Consultation considered the entire scope of the application of risk management to food safety matters, including the interaction between risk management and risk assessment, and between risk management and risk communication. In doing so it took note of the report of

the March 1995 Joint FAO/WHO Expert Consultation on the Application of Risk Analysis to Food Standards Issues, which dealt primarily with risk assessment. The Consultation did not consider the subject of risk communication, except as incidental to its consideration of risk management. It considered risks arising from both chemical and biological agents, but did not consider risks arising from nutritional deficiencies or imbalances.

3. THE GOAL OF FOOD RISK MANAGEMENT

The primary goal of the management of risks associated with food is to protect public health by controlling such risks as effectively as possible through the selection and implementation of appropriate measures.

4. INTERNATIONAL TRADE

The rules that govern international trade are those that were agreed during the Uruguay Round of Trade Negotiations and apply to Members of the World Trade Organization (WTO). With respect to food safety matters, those rules are set out in the *Agreement on the Application of Sanitary and Phytosanitary Measures* (the SPS Agreement). The overall objective of the SPS Agreement is to permit countries to take legitimate measures to protect the life and health of their consumers (in relation to food safety matters), while prohibiting them from using those measures in a way that unjustifiably restricts trade. Thus the primary goal of the SPS Agreement is to limit the use of any measures that may restrict trade to those that are justified to provide the necessary level of health protection. It recognises the right of Members to protect their consumers at a level they consider necessary, subject to certain disciplines, such as consistency and transparency.

The standards, guidelines, and other recommendations of the Codex Alimentarius Commission are considered by the WTO to reflect international consensus regarding the requirements for protecting human health from foodborne risks. A Member's food safety measures are considered justified and in accordance with the provisions of the SPS Agreement if they are based on Codex standards and related texts. While the adoption and application of Codex standards remains technically non-mandatory, failure to apply Codex standards creates the potential for dispute if a Member applies standards that are more restrictive of trade than necessary to achieve required levels of protection.

Consideration of risk analysis will play a vital role in the future work of the WTO. The SPS Agreement requires "Members [to] ensure that their SPS 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 organisations". Members are expected to justify levels of protection higher than those in Codex standards by using risk assessment techniques. They are required to ensure that risk management decisions are transparent, and not arbitrary or unjustifiably different (i.e. are consistent). Furthermore, where different measures have equivalent outputs, the measure chosen should be the one that is the least restrictive of trade.

“Safe and wholesome”

Although industry and national regulators strive for production and processing systems which ensure that all food be “safe and wholesome”, complete freedom from risks is an

unattainable goal. Safety and wholesomeness are related to a level of risk that society regards as reasonable in the context, and in comparison with other risks in everyday life.

A Codex standard is the minimum standard for a food elaborated by CAC “so as to ensure a sound, wholesome product free from adulteration, correctly labelled and presented” (3). The word “minimum” does not have any pejorative connotations and simply means the level of quality and soundness of a product judged by consensus to be appropriate for trade internationally and nationally.

A review of current Codex standards and related texts suggests that in many cases there is insufficient quantitative information to translate requirements for “safety and wholesomeness” into a definitive quantitative assessment of the risks to human health in consumer populations. The inevitable default to more qualitative assessments of “safe and wholesome” is likely to be challenged as a basis for international trade restrictions, especially in an increasingly risk-based international trade environment.

The development of Codex-wide principles and strategies for risk management requires that explicit attention be given to the concept of “safe and wholesome”. Although Codex standards and related texts are generally aimed at the reduction of risks in food, these risks can rarely be quantified and any balancing of the risk reduction against other factors, such as costs and benefits of risk reduction, is normally a matter of judgement.

5. DEFINITIONS OF KEY RISK MANAGEMENT TERMS

Risk management: The process of weighing policy alternatives in the light of the results of risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures.

This definition of risk management, which has been proposed for inclusion in the *Codex Procedural Manual* (4), includes consideration of all the elements (listed below) that may be included in the risk management process (i.e. risk evaluation, risk management option assessment, implementation of management decision, and monitoring and review). However, in a practical context, it may not be necessary to include all the elements. For example, risk management decisions at the national level are likely to use all of the elements of this definition, whereas the risk management activities of Codex do not generally include implementation, monitoring and review.

Risk assessment policy: Guidelines for value judgement and policy choices which may need to be applied at specific decision points in the risk assessment process.

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

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

Risk profiling is the process of describing a food safety problem and its context, in order to identify those elements of the hazard or risk relevant to various risk management

decisions. The risk profile would include identifying aspects of hazards relevant to prioritising and setting the risk assessment policy and aspects of the risk relevant to the choice of safety standards and management options.

A typical risk profile might include the following: a brief description of the situation, product or commodity involved; the values expected to be placed at risk, (e.g. human health, economic concerns); potential consequences; consumer perception of the risks; and the distribution of risks and benefits.

6. RISK MANAGEMENT FRAMEWORK

ELEMENTS OF RISK MANAGEMENT

A. Risk evaluation

- Identification of a food safety problem.
- Establishment of a risk profile.
- Ranking of the hazard for risk assessment and risk management priority.
- Establishment of risk assessment policy for conduct of risk assessment.
- Commissioning of risk assessment.
- Consideration of risk assessment result.

B. Risk management option assessment

- Identification of available management options.
- Selection of preferred management option, including consideration of an appropriate safety standard.*
- Final management decision.

C. Implementation of management decision

D. Monitoring and review

- Assessment of effectiveness of measures taken.
- 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

* “Safety standard” here refers to the level of acceptable risk, which is adopted by risk managers or is implicit in the chosen risk management option. Examples include “zero-risk” standards (such as are usually implicit in *de minimis* and ADI levels), “balancing” standards (such as cost-benefit, cost-effectiveness, and ALARA), “threshold” standards (where a non-zero level of risk is stipulated as acceptable), or “procedural” standards (where the acceptable risk level is determined by an agreed process, such as a negotiation or referendum).

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** 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.

7. 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.

** These interested parties are commonly referred to as “stakeholders” in a number of countries.

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.

8. CURRENT RISK MANAGEMENT PRACTICES IN THE CODEX ALIMENTARIUS COMMISSION, ITS SUBSIDIARY BODIES, AND ADVISORY EXPERT COMMITTEES

The Joint FAO/WHO Expert Committee on Food Additives and the Joint FAO/WHO Meeting on Pesticide Residues (JECFA and JMPR)

FAO and WHO jointly convene sessions of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). Participants in sessions are eminent scientists selected by FAO and WHO to participate in these committees in their own personal capacity as scientific and technical experts. They have responsibility for providing FAO and WHO, after thorough evaluation of appropriate chemical, toxicological and other data necessary, with authoritative recommendations on the substances under review. These committees are completely independent of the Codex system and their advice is to FAO and WHO and to Members of FAO and WHO. In addition this meets the need

of the Codex system for independent scientific advice in arriving at science based Codex recommendations.

JECFA and JMPR are scientific advisory bodies which were established in the 1950's, prior to the establishment of the CAC. Over the past forty years they have provided independent scientific advice to all FAO and WHO Member Countries. They have also provided science based evaluations of substances which have been requested by CCFAC and CCRVDF in the case of JECFA, and CCPR in the case of JMPR. The traditional and current activities of JECFA and JMPR are mainly in the area of risk assessment, not risk management. The WHO components of JECFA and JMPR provide a permanent formal mechanism for assessing the toxicity of food additives, contaminants, veterinary drugs, pesticides, feed additives, solvents and processing aids in food. Their primary role is to evaluate toxicological data to determine a safe level of human exposure - normally an Acceptable Daily Intake (ADI) for food additives, veterinary drugs and pesticides and a Provisional Tolerable Weekly (or Daily) Intake (PTWI) for contaminants.

The activities of the FAO component of JECFA are mainly in the area of preparing specifications of identity and purity for food additives, estimating intakes of food additives and contaminants, and proposing maximum limits for residues of veterinary drugs in foods of animal origin. The activities of the FAO components of JMPR are mainly in the area of technological efficacy and minimum effective levels of pesticides as they are used in agriculture to control crop pests and diseases, and on likely residues on various crops based on Good Agricultural Practice (GAP). JECFA and JMPR evaluate data on the use and presence of the chemicals they assess in primary agricultural produce, food of animal origin and processed food based on GAP, Good Practice in the Use of Veterinary Drugs (GPVD) and Good Manufacturing Practice (GMP), respectively. This includes consideration of other relevant data such as plant and animal metabolism and analytical methodology. These activities contribute to the overall objectives of food safety by assuring that food additives, veterinary drugs and pesticides are used properly and pose the minimum risk to consumers. The levels recommended (MRLs and Maximum Levels) by the FAO components of JECFA and JMPR are used as the initial basis for exposure calculations, which are an essential component of risk characterisation. FAO and WHO jointly estimate intakes of food additives and contaminants.

Risk Assessment Policy in JECFA and JMPR

JECFA and JMPR utilise certain significant risk assessment policies at specific decision points in their work. Such risk assessment policies are properly the responsibility of CCFAC, CCRVDF, CCPR and CAC. They are, however, used by JECFA and JMPR and are described in detail in relevant WHO Environmental Health Criteria documents. They include the following examples:

- Reliance on animal models to establish potential human effects.
- Using body weight scaling for interspecies comparison.
- Assuming that absorption in animals and humans is approximately the same.
- Using a 100-fold safety factor to account for likely inter- and intra-species differences in susceptibility, with guidelines for deviations that are permitted in specified situations.

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- The decision not to assign ADIs to food additives, veterinary drugs and pesticides which are found to be genotoxic carcinogens. Quantitative risk assessment has not been employed for these substances. In effect, there is no recognized acceptable risk level for genotoxic food additives, residues of veterinary drugs or pesticides.
 - Permitting contaminants at levels “as low as reasonably achievable” (ALARA).
 - Establishing temporary ADIs for additives and residues of veterinary drugs pending submission of requested data. It should be noted, however, that this policy is not used by JMPR in the establishment of ADIs for pesticide residues.

In carrying out their work the experts in JECFA and JMPR continually need to select and utilise various scientific assumptions. This is necessary because there are inevitable gaps in the science of risk assessment that need to be filled with default assumptions in order to be able to conduct a risk assessment. These assumptions also need to be constantly re-evaluated to keep them up-to-date with scientific developments. Each of these represent scientific value judgements (“risk assessment policy”), and the assumptions embodied in them can significantly influence the outcome of the risk assessment. Each also represents a choice among a number of plausible alternatives.

Codex Alimentarius Commission (CAC)

The primary purpose of the Joint FAO/WHO Food Standards Programme of CAC is to protect the health of consumers and ensure fair practice in the food trade. CAC formally adopts Codex standards, guidelines and other recommendations which have been developed by its subsidiary bodies. In addition, CAC provides guidance to these subsidiary bodies, including that related to risk management.

The development of standards, guidelines and recommendations has been delegated by CAC to its subsidiary bodies. Normally, the general subject (“horizontal”) Codex committees are more routinely involved in risk management. These include the Codex Committees on Food Additives and Contaminants (CCFAC), Pesticide Residues (CCPR), Residues of Veterinary Drugs in Foods (CCRVDF), Food Hygiene (CCFH), General Principles (CCGP), Food Labelling (CCFL), Nutrition and Food for Special Dietary Uses (CCNFSDU), Import and Export Inspection and Certification Systems (CCFICS), and Methods of Analysis and Sampling (CCMAS). In addition, a range of commodity committees is also involved in risk management activities.

The work of these committees is supported by expert advisory groups, such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), as well as other expert bodies, such as ICMSF (International Commission on Microbiological Specifications for Food). In addition, FAO and WHO, usually jointly, convene consultations on specific matters of interest to Codex and member countries. However, the most important of these advisory groups for Codex are JECFA and JMPR. Recommendations of JECFA and JMPR are used by CCFAC, CCRVDF and CCPR as well as other Codex committees in the development of Codex standards, guidelines and other recommendations.

Standards may be for world-wide use, or for use by a given region or specific group of countries. All Members of CAC and interested international organisations are invited to comment on proposed standards, including possible implications for their economic interests. In considering such comments, CAC “should have due regard to the purposes of the Codex Alimentarius” (3). Members are encouraged to consult with interested and affected parties in their countries.

Provisions in Codex standards defining description, essential composition and quality factors should not be the subject of risk analysis within the context accepted by CCGP (4). However, the *Procedural Manual* of CAC notes that essential composition and quality factors can overlap with food safety i.e. “quality factors could include the quality of the raw material, with the object of protecting the health of the consumer” (3).

The production of genetically modified foods is expected to increase dramatically in the coming years. Biotechnology will be under consideration in several Codex committees and is expected to be addressed by CAC as a “horizontal” issue, taking into consideration the report of the Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety (30 September to 4 October 1996).

The CAC *Statements of Principle Concerning The Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors Are Taken Into Account*^{*} state that standards, guidelines and other recommendations of Codex shall be based on the principle of sound scientific advice and evidence, and where appropriate, Codex will have regard to *other legitimate factors* relevant to the health protection of consumers and for the promotion of fair practices in food trade (5). Codex principles of risk management must be guided by these statements, as well as by the provisions of the SPS Agreement. To date, these “other legitimate factors” have not been defined or considered in the risk management context.

Codex Committee on Food Additives and Contaminants (CCFAC)

The primary role of CCFAC is to recommend appropriate standards for food additives and contaminants to CAC. In the case of additives, CCFAC specifically considers technological justification and need for proposed levels of use. CCFAC also assigns priorities to additives and contaminants for JECFA evaluation.

Probable daily exposures and their relationship to the ADI need to be taken into account when endorsing or establishing permitted maximum levels of additives in food. Different approaches are required for risk management of additives and contaminants. In the case of additives, both the range of foods in which the additive is allowed and the concentration of the additive in individual foods can be specifically controlled by choosing particular risk management options.

^{*} The *Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors are Taken into Account* include the following:

1. The food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.
2. When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.
3. In this regard it is noted that food labelling plays an important role in furthering both of these objectives.
4. When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

In the case of contaminants, however, these control options are often not available, and the normal mechanism is for CCFAC to set levels of contaminants which are as low as reasonably achievable (ALARA).

Previously, CCFAC incorporated food additive usage into individual Codex food standards. CCFAC is changing its risk management approach and is developing general risk analysis approaches that can be applied to all foods or classes of food through the development of the *Draft General Standard for Food Additives* (GSFA) and the *Draft General Standard for Contaminants and Toxins in Foods* (GSCTF) (6). The GSFA covers the use of additives in all foodstuffs. The approach recommended to be used in the GSFA provides the framework in which exposure assessments will be considered. Annex I of the GSCTF refers to the need for maximum limits to be based on an evaluation of both public health considerations and the possibilities and problems of complying with a proposed standard. Maximum levels may be based on Good Manufacturing Practice (GMP), Good Agricultural Practice (GAP) considerations and an ALARA approach. CCFAC is working on risk management criteria for assigning maximum levels for contaminants in traded foods, but they are not yet agreed. Annex II of GSCTF presents “Procedures for Risk Management Decisions” that categorise necessary information requirements and actions by CAC in the elaboration of maximum limits for contaminants, but no guidelines are provided on risk management decision-making *per se*.

The CCFAC preamble to the *Codex General Standard for Contaminants and Toxins in Foods* provides an initial framework for risk management decision-making for these classes of hazards (7). It is suggested that new consideration should be given to acute and long-term toxicity. Economic aspects related to contaminant level management and control are also listed as relevant criteria. “Acceptability” generally refers to notionally zero health risk, although other criteria are listed for possible consideration in risk management decisions.

Codex Committee for Residues of Veterinary Drugs in Foods (CCRVDF)

The primary role of CCRVDF is to recommend MRLs for residues of veterinary drugs in food. CCRVDF relies on its expert committee (JECFA) to derive initial recommendations for MRLs. In this regard, CCRVDF has accepted some risk management decision-making by JECFA. This includes the decision to use different safety factors based on the amount and quality of data available to JECFA and the formulation of new guidelines when necessary to address new or emerging issues such as the establishment of microbiological end-points as a safety criterion for antimicrobial drug residues. CCRVDF reviews the basis for JECFA recommendations prior to deciding whether to accept the proposed MRL.

CCRVDF may determine that an MRL should not be adopted because adequate methods of analysis are not available for detecting the residues in specific animal-derived foods, or because pertinent new information has been generated which was not available to JECFA when it undertook its evaluation. CCRVDF may request that JECFA reassess the recommendation for an MRL based on concerns raised by CCRVDF. On occasion CCRVDF has elected not to accept the recommendations of JECFA, by retaining indefinitely the MRL at Step 4 or Step 7 of the Codex process. To date, however, CCRVDF has not attempted to change the numerical value of an MRL without the concurrence of JECFA.

In principle, CCRVDF considers socio-economic and political issues as does CCFAC. Health-based end-points which are not related to toxicity, such as allergenic potential,

pharmacological effects and antimicrobial effects of particular residues, are complex issues which often are addressed on a case-by-case basis.

When establishing an MRL, consideration is given to residues that occur in food of plant origin and/or in the environment. In the evaluation of substances that may have both veterinary drug and pesticide use, dialogue with CCPR is necessary and currently this is carried out on an *ad hoc* basis.

Codex Committee on Pesticide Residues (CCPR)

CCPR advises CAC on matters relating to pesticide residues affecting international trade, primarily by recommending draft Codex MRLs in food and animal feeds. Recommended ADIs and MRLs are provided to CCPR by JMPR after consideration of residue and other data.

Residue data are obtained primarily from supervised residue trials in accordance with nationally registered uses. Elaboration and acceptance of MRLs for particular pesticides rests on the premise of common agreement on what constitutes Good Agricultural Practices (GAP). There is a recognised need to accommodate those countries that have a legitimate need for GAP resulting in higher residues in food, as long as those residues do not present an “unacceptable” risk to human health.

There is no direct connection between the establishment of ADIs and MRLs. However, a comparison of dietary exposure estimates with the ADI should indicate that foods complying with MRLs are safe for human consumption.

Predictions of dietary exposure are used for deciding on the acceptability of proposed draft Codex MRLs. If the ADI is exceeded by the estimate of exposure after all relevant factors are applied, dietary exposure concerns become a risk management issue.

JMPR and CCPR use the 1989 *Guidelines on the Prediction of Dietary Intake of Pesticide Residues* on a routine basis in establishing MRLs. Each year JMPR publishes a summary of the dietary exposure estimates of the pesticides evaluated in that year in their report and makes detailed calculations available to CCPR. Whenever Members of CCPR express reservations against MRLs because their exposure estimates exceed the ADI, they are invited to submit their exposure calculations. In the case of pesticides the only risk management option is to amend GAP in order to ensure that the MRLs no longer give rise to exposure concerns.

Exposure calculations performed at the international and national level may give very different results. JMPR uses the GEMS/Food regional diets to calculate the exposure. These diets reflect average regional consumption patterns, however, national governments may use national diets, when available. Some Governments routinely calculate the exposure for higher percentiles of their population or may consider the exposure of sensitive sub-groups (e.g. young children).

Because of these different approaches in dietary exposure estimates, Members of CCPR may arrive at different conclusions about the acceptability of certain MRLs. Moreover, there are different policy views about the point at which concern for exposure becomes a risk management issue. The Guidelines explicitly state that a worst-case estimate is a gross overestimate of true exposure and that more refined calculations should be performed using other relevant data. However, some Members of CCPR reject MRLs when this additional data is not available. Others rely, for instance, on monitoring data, which may demonstrate that no exposure problems are to be expected.

Since 1992 CCPR has begun to deal with these issues in a more systematic way. As a consequence CCPR decided not to advance a number of MRLs through the Codex step procedure. It is recognised that harmonisation of exposure models at the international level is not feasible at present. The currently developed *Revised Guidelines for Predicting Dietary Intake of Pesticide Residues*, based upon the recommendations of a joint FAO/WHO consultation held 2-6 May 1995 in York, United Kingdom, has important risk assessment and risk management implications. The use of these revised guidelines should significantly reduce the number of cases where exposure assessments cause unnecessary concern. Nevertheless there is still a need for CCPR to reach consensus on these matters. The York Consultation identified acute food intake and sensitive consumer groups as new issues for dietary exposure.

Recent meetings of JMPR have established acute reference doses (acute RfD) for several pesticides which have the potential for causing acute effects after consumption of one meal or over the course of meals eaten during one day. The York consultation has recommended a general screening method for estimating exposure for acute hazards and details of implementing this method will be discussed at the Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment of Chemicals, 10-14 February 1997 at WHO Headquarters, Geneva. Consequently CCPR will face risk management decisions in these new areas.

It should be realised that, while amending GAP is the only management option for CCPR, CCPR cannot enforce changes in GAP and can only request Governments and manufacturers to do so. However, if this proves unsuccessful, CCPR may have no other option than to recommend deletion of MRLs from the Codex system.

The work of CCPR in elaborating guidelines for interpretation of residue findings in food consignments is an example of a risk management approach of a qualitative type.

Codex Committee on Food Hygiene (CCFH)

CCFH is a general purpose Committee that has the overall responsibility for all provisions on food hygiene prepared by Codex commodity committees, which are contained in commodity standards, codes of practice and guidelines. CCFH also develops general principles, codes of practice and guidelines for food hygiene as well as microbiological criteria for food, to be applied horizontally across Codex Committees. Food hygiene is defined as “all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain” (13, Appendix II).

According to deliberations at the 29th session of CCFH (8), the microbiological safety of foods is principally assured by control at the source, product design and process control and the application of good hygienic practices during production, processing (including labelling), handling, distribution, storage, sale, preparation and use, preferably in conjunction with the application of the Hazard Analysis and Critical Control Point (HACCP) system. This “preventive” system offers more control than end-product testing, because the effectiveness of microbiological examination in assessing the safety of food is limited.

When objectives for food safety have been established by Codex or national risk managers, these can be taken up by the industry, and by the application of HACCP (or an equivalent food safety management system) the industry can assure that these objectives are met. This is a use of HACCP as a “corrective” risk management option - a risk is identified and a management option selected and implemented. HACCP is also used as a “preventive” risk management tool. In this case, a hazard analysis (the first analytical step in the application of HACCP) identifies potential

hazards in raw materials, production line and line-environment that need to be controlled to prevent potential harm to the consumer. “Hazard analysis” is defined as “The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan”. (8, Appendix II) Input concerning the potential hazards and their control could come from risk analysis, but often such information is not available and industries need to apply best judgement.

The *Draft Revised Principles for the Establishment and Application of Microbiological Criteria for Foods* states: “Microbiological criteria should be established according to these principles, and be based on scientific analysis and advice, and where sufficient data are available, on a risk analysis appropriate to the foodstuff and its use.” (8, Appendix III) These criteria may be relevant to the examination of foods, including raw materials and ingredients of unknown or uncertain origin, or when no other means of verifying the efficacy of HACCP based systems and good hygienic practices are available. Microbiological criteria may also be used to determine that processes are consistent with the General Principles of Food Hygiene. Microbiological criteria are not normally suitable for monitoring Critical Limits as defined in the HACCP system.

Establishing microbiological criteria, and food safety objectives in general, is difficult because of the considerable knowledge gap relating to biological hazards and their relationship to adverse human health outcomes. This has led to many evaluations by CCFH which are based on subjective or qualitative assessments being used as the basis for recommendations. While aware of these limitations, CCFH is now developing a framework of principles and guidelines for the application of microbiological risk assessment. This was in response to the recommendation of the 1995 Joint FAO/WHO Expert Consultation on the Application of Risk Assessment to Food Standards, relating to application of risk assessment within the Joint FAO/WHO Food Standards Programme. ICMSF and CCFH delegations are also in the process of developing background papers on a number of foodborne pathogens, to better enable quantitative risk assessments and subsequent food safety objectives to be set. Notwithstanding the development of risk analysis approaches by these groups, it is apparent that the work of CCFH and all Codex committees would benefit from advice from an expert body on foodborne biological hazards for purposes of risk management. The committee could be modelled on JECFA and JMPR, allowing for the unique consideration of pathogens causing human illness, including epidemiological and clinical data and the dynamics of microbial populations in food throughout the food chain.

Control of *Listeria monocytogenes* in foods provides an example of the need to consider a structured risk management approach. *Listeria* are frequently consumed in small amounts by the general population without apparent ill effects. It is believed by many that only higher levels of *Listeria* have caused severe disease problems. It is also believed that *Listeria* is a bacterium which will always be present in the environment. Therefore, the critical issue may not be how to prevent *Listeria* in foods, but how to control its survival and growth in order to minimise the potential risk. Complete absence of *Listeria* is unrealistic and unattainable in many foods, and trying to achieve this goal can limit trade without having any appreciable benefit to public health. A relevant risk management option, therefore, is to focus on foods which have historically been associated with human disease, and foods that support growth of *Listeria* to high levels, rather than those that do not. Thus, establishment of tolerable low levels of *Listeria* in specific foods may be one food safety objective established by risk managers after a rigorous and transparent risk analysis. Such an approach is now being considered by CCFH based on an initial risk assessment by the ICMSF and certain CCFH delegations.

Although *Listeria* presents unique challenges in terms of its widespread occurrence and the particular susceptibility of vulnerable groups, CCFH is also addressing pathogens such as *E. coli* O157:H7, *Salmonella* and *Campylobacter*. These microbial pathogens produce acute foodborne illnesses and can also cause severe chronic sequela, creating a significant public health burden and food safety concern.

Codex Committee on General Principles (CCGP)

CCGP deals with procedural and general matters, including establishment of principles which define the purpose and scope of the Codex Alimentarius and the nature of Codex standards. Development of mechanisms to address any economic impact statements is also a responsibility of CCGP. However, at present, there is no guidance on how this should be done.

CCGP will have an increasing role in the evolution of a risk analysis approach and this is formally recognised in the report of the Twelfth Session (4). At this Session, CCGP proposed that CAC annex *The Statements of Principle Concerning the Role of Science in The Codex Decision-Making Process and the Extent to Which Other Factors Are Taken into Account* into its Procedural Manual. CCGP also proposed that the *Statements of Principle Relating to The Role of Food Safety Risk Assessment and Risk Analysis Definitions* be annexed to the Manual.

CCGP has recommended that the “Elaboration Procedures” section of the *Procedural Manual* should contain a new chapter on integrating risk management principles into the Codex decision-making process, outlining the responsibilities of the committees concerned (9).

Codex Committee on Food Labelling (CCFL)

Risk analysis concepts are being applied with greater rigour in the consideration of public health related matters. This was apparent in the way CCFL responded to the recommendations of the FAO Technical Consultation on Food Allergies, 13-14 November 1995, Rome. CCFL will be discussing the labelling of biotechnology products and the subject could serve as a model for the application of the risk management framework as elaborated in this report. Labelling is one important risk management option. For example, risk is reduced and/or avoided through the identification of allergenic substances and the display of preparation and storage instructions.

Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS)

Codex is increasingly recognising the need for application of the broad mandate of a risk analysis approach to *all* aspects of food safety. One aspect of this is reflected in the recent work of CCFICS. This Committee has stated that its programme of work is to be fully based on risk analysis principles and the draft *Proposed guidelines on the design, operation, assessment and accreditation of food import and export inspection and certification systems* states that “the frequency and intensity of controls by inspections systems should be designed so as to take account of risk and reliability of controls already carried out by those handling the products including producers, manufacturers, importers, exporters, and distributors.” (10). This suggests that Codex texts incorporating “horizontal” risk management issues should not be overly prescriptive, and should be focused on agreed food safety outcomes rather than processes.

CCFICS recognises that differences in food safety programmes between countries inevitably exist, and are often the result of a different spectrum and prevalence of foodborne hazards or different food production systems. However, a food safety programme in an exporting

country may achieve an importing country's appropriate level of sanitary protection and the concept of “equivalence” describes the justification for trade in such circumstances. CCFICS has defined equivalence as “the capability of different inspection systems to meet the same objectives” (11, Appendix 3).

CCFICS work in elaborating general principles and guidelines for the design and operation of food inspection systems has as a core component the application of risk analysis approaches. In assessing different food inspection systems it is recognised that different risk management approaches may produce the same food safety outcomes with the result that the different systems may be regarded as equivalent. These Codex “norms” therefore provide practical guidance for the broad application of risk management to the design and operation of food inspection programmes and are consistent with the provisions of the SPS Agreement relating to the use of scientifically based risk assessment procedures.

The Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU)

The CCNFSDU is responsible for developing guidelines, general principles and standards for food for special dietary uses, alone or in cooperation with other Codex committees, and for studying nutritional issues referred to it by the CAC, including endorsement of provisions covering the nutritional aspects of all draft standards or Codex texts. In considering the risk management option, the CCNFSDU must often contend with nutritional hazards posed by both under- and over-consumption of nutrients. Hazards posed by food intolerances are also difficult to assess, particularly in defining the population at risk. Moreover, great uncertainties surround nutritional risk assessment, especially with respect to appropriate levels of dietary intake for micronutrients.

The CCNFSDU has successfully addressed a number of potentially controversial topics which require skillful risk management and communication to achieve consensus. For example, a broad spectrum of views on foods for infants and children, including infant formula, is reflected in corresponding divergent views on their control. Another example is the standard for labelling of and claims for foods for special medical purposes which is an area that is replete with risk management concerns. This Committee is currently drafting “Guidelines on use of nutritional claims” and considering proposed draft “Guidelines on dietary supplements”, both of which involve substantial risk management judgement. In the future, the CCNFSDU will be asked to evaluate the nutritional aspects of foods derived by biotechnology which will present a significant risk management and communication challenge.

Codex Committee on Methods of Analysis and Sampling (CCMAS)

CCMAS considers, amends if necessary, and endorses methods of analysis and sampling proposed by specific committees. Performance criteria are selected as appropriate and guidelines for sampling systems must be practical in their application and have a sound statistical basis. Committees submitting sampling plans to CCMAS need to supply details that include decision rules, and “levels of risk to be accepted” (3).

Codex Committee on Meat Hygiene (CCMH)

CCMH provides one example of a commodity committee which will be increasingly concerned with risk management. The function of CCMH is to elaborate standards and/or codes of practice for meat hygiene. In CCMH’s recent review of its codes of practice, risk analysis principles were addressed. These principles recognise the fact that it is inconsistent to recommend subjective and generally non-quantified guidelines for controlling contamination, yet have very detailed but

unproven lists of procedures for post mortem inspection of *broad* classes of livestock for application on an international basis. HACCP is advocated as the risk management tool of choice to limit contamination and multiplication of pathogens during the production of meat.

Systematic application of risk analysis methodology is required to make an overall assessment of risks and benefits in a meat hygiene programme and allocate inspection resources accordingly . This places important risk management responsibilities on national controlling authorities. Unseen contamination of meat with enteric pathogens has emerged as the dominant cause of meat-borne diseases, and reallocation of resources within meat hygiene programmes is required to combat this source of hazards.

9. RECOMMENDATIONS

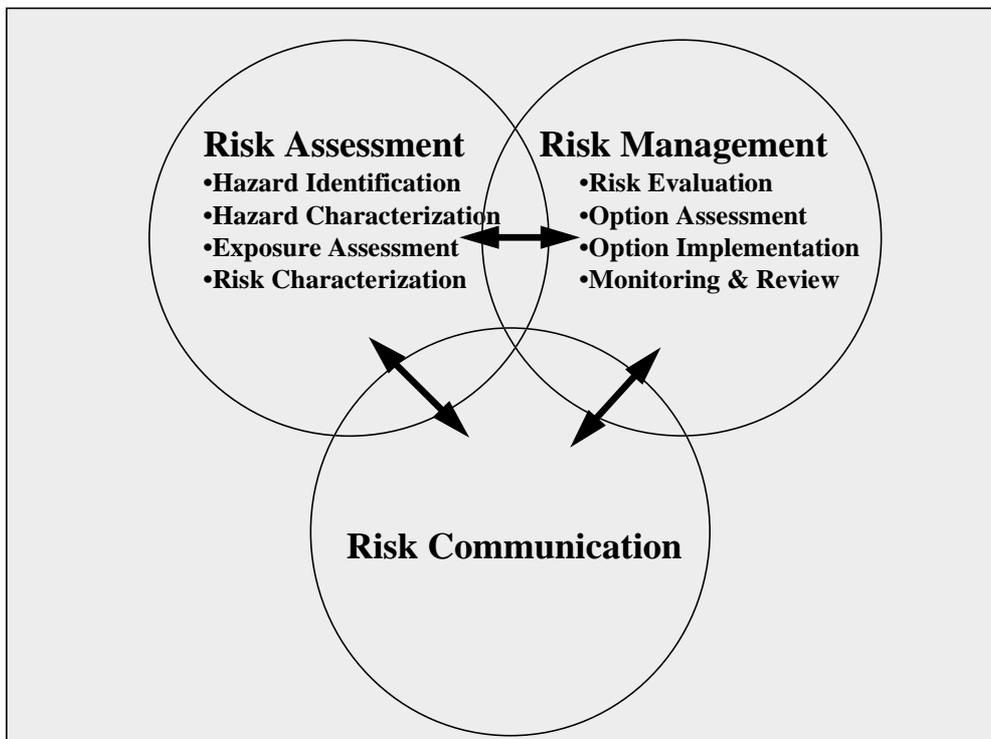
The Consultation made the following recommendations.

1. The CAC should adopt the definitions and principles contained in this report.
2. The potential for adverse effects on human health should be the overriding determinant in risk management decisions, and the CAC should continue to strive to encompass the diverse range of cultures in different countries in a consistent and equitable way in its elaboration of food standards and related texts.
3. The CAC should clarify for the guidance of Codex Committees how to apply the principle: “When elaborating and deciding upon food standards Codex Alimentarius will have regard where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade” (12, Appendix 3). In particular, this clarification should include explicit description of the factors which may be considered, the extent to which these factors should be taken into account, and the procedures to be used in this regard.
4. The CAC should make explicit the role of CCFAC, CCRVDF and CCPR in providing clear and unequivocal risk assessment policy guidance to JECFA and JMPR. This should include acknowledgement of the continuing need for risk assessment choices by JECFA and JMPR, but provide guidelines for value judgements and policy choices which may need to be applied in the risk assessment process.
5. The CAC should request Codex Committees to review the standards and advisory texts in their respective areas of responsibility in the light of the principles contained in this report.
6. The CAC should give a high priority to the development and adoption of recommendations for the risk management of microbial hazards in food since foods such as certain raw materials and fresh produce may occasionally contain pathogenic micro-organisms and this could lead to trade restrictions and public health concern if not properly managed.
7. FAO/WHO should establish a joint expert committee to provide microbial risk assessment information to support Codex risk management decisions and recommendations given the significant contribution of microbial pathogens to foodborne disease world wide. Such a committee could be modelled on JECFA and/or JMPR.
8. There should be greater collaboration between all parties involved in risk evaluation and risk assessment, especially including those in a position to provide clinical and epidemiological data, to establish the linkage between the level of hazard and the level of risk since such information is often essential for the development of appropriate risk management options.
9. FAO and WHO should assist developing countries in their application of risk management in the food safety area.
10. There should be maximum accessibility of published government documents on the subject via the Internet since risk analysis in foods is a newly emerging discipline.
11. FAO and WHO should complete the series of consultations on the application of risk analysis to food safety with a jointly sponsored consultation on risk communication in relation to food safety.

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STRUCTURE OF RISK ANALYSIS



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ANNEX 2

CONCLUSIONS AND RECOMMENDATIONS OF THE 1995 CONSULTATION*

8.1 General

The Consultation recognized that increased scientific, legal and political demands are being made on the standards, guidelines and other recommendations elaborated by Codex. This is, in part, due to:

- increased consumer interest in food safety
- the WTO's SPS and TBT Agreements
- harmonization initiatives
- calls for increased scientific rigour
- the need for transparency
- shrinking national regulatory resources.

To respond to these increasing demands, the greater application of risk assessment in the Codex decision-making process is essential. However, the generic framework for risk assessment described here represents a structural goal and may not be able to be fully utilized when adopting a risk assessment approach for some classes of hazards in food, such as biological hazards. In this respect, the Consultation recognized that Codex must be "technology forcing" if necessary data are to be developed.

An important principle is the functional separation of risk assessment from risk management. However, certain interactive elements are essential for a systematic risk assessment process. These elements may include ranking of hazards in the hazard identification step and risk assessment policy issues. Where risk management issues may intrude in risk assessment, the decision-making process should be transparent.

The broad mandate of a risk assessment approach to food safety encompasses a range of activities in addition to elaboration of standards, guidelines and other recommendations. Examples are the design of import and export inspection systems, acceptance/rejection criteria for foods, monitoring and surveillance programmes, development of information needed to formulate efficacious management strategies, and the overall allocation of food safety regulatory resources proportional to all classes of hazards in food. In the future strategic plan for utilization of risk assessment, this broad mandate should be addressed whenever appropriate in the Codex system.

Finally, the Consultation recognized that additional consultations would need to be convened regarding specific issues in risk assessment, as well as generally addressing the topics of risk management and risk communication. Nevertheless, the Consultation concluded that implementation of its recommendations would contribute significantly to the ability of Codex to meet its responsibilities of protecting consumers and facilitating international trade in food in a more consistent and open manner.

* Section 8 of *Application of Risk Analysis to Food Standards Issues, Report of the Joint FAO/WHO Expert Consultation, Geneva, Switzerland, 13-17 March 1995* (WHO/FNU/FOS/95.3).

Recommendations

- 8.1.1 Scientific risk assessment should be the basis for Codex risk management decisions involving health and safety aspects of food standards. An important principle in this regard is the functional separation of risk assessment from risk management, while recognizing the interactive elements that are essential for a pragmatic risk analysis approach.
- 8.1.2 In regard to chemical hazards, the Codex should assure harmonized approaches to the risk assessment of food additives, contaminants, and residues of pesticides and veterinary drugs, particularly in the assessment of exposure.
- 8.1.3 Codex should encourage the development of risk assessment for biological hazards with the recognition that scientific understanding and knowledge are not currently adequate to quantitatively assess risk in most instances.
- 8.1.4 To meet its obligations under the SPS Agreement, Codex must be "technology forcing" to develop the necessary scientific information for the risk assessment of chemical and biological hazards.

8.2 Chemical hazards

Risk assessment of chemical hazards in foods usually results in the selection of risk management options to ensure that foodborne risks to consumers are not appreciable (notionally "zero"). This approach to food safety needs to be carefully examined with respect to the intent of the SPS Agreement and the concepts of "acceptable risk" and equivalence. For chemical hazards not evaluated by means of an authentic quantitative risk assessment model, issues of equivalence may take the form of a comparison of equivalent margins of safety above this notionally "zero" risk baseline.

Recommendations

- 8.2.1 Exposure assessments for food additives, contaminants, and pesticide and veterinary drug residues should be considered an integral part of the Codex risk assessment procedure for these substances. Because this is primarily a scientific task, exposure assessments should continue to be carried out by the JECFA/JMPR. Where necessary, exposure assessment should be expanded to take into account differences in dietary patterns, both within and between countries, and include estimates of intake by especially vulnerable groups.
- 8.2.2 CAC should request all Member States to make available dietary exposure data, including information on levels of chemicals in various foods and intakes of those foods by their population. Where such information is not available, CAC should encourage countries to develop appropriate food contamination monitoring programmes consistent with national priorities and to obtain dietary intake information for the general population and, if feasible, sub-groups of interest.
- 8.2.3 The methodology and guidelines currently used for predicting the dietary intake of pesticide residues should be reviewed with a view to obtaining more accurate estimates of human exposure.
- 8.2.4 Consideration of exposure scenarios for acute and chronic adverse health effects should be applied wherever appropriate in risk assessment of residues of veterinary drugs.

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- 8.2.5 For contaminants for which adequate data exist and no threshold for adverse health effects can be established, JECFA should be requested to provide a quantitative estimate of the health risks associated with specified levels of intake, including attendant uncertainty.
- 8.2.6 The process by which the JMPR derives MRLs should be made more transparent.
- 8.2.7 To promote the transparency and credibility of the risk assessment process and to facilitate review of the proceedings when necessary, it is recommended that decisions be thoroughly documented and that all significant supporting data and other information be archived. This information should be available to Member States and to appropriate oversight international organizations.
- 8.2.8 To promote the quality and consistency of toxicological and other data, FAO and WHO should encourage the use of standardized test protocols and minimum data requirements that have been or will be recommended by recognized international expert groups.
- 8.2.9 WHO should review criteria for establishing safety factors, benchmark doses and generic cross-species scaling factors, taking into account the efforts that are being made by other international groups.
- 8.2.10 Scientific data are often necessary to depart from default assumptions, particularly in the evaluation of carcinogenic risk. Codex should encourage efforts to develop scientific criteria to help resolve differences in the requirements for and interpretations of such data.

8.3 Biological hazards

Biological hazards in foods continue to pose significant risk and have a high profile internationally. There is a need to reduce the risk to the minimum which is technically feasible and practical. International standards and guidelines developed to address risk reduction must be transparent and outcome oriented. To facilitate this, risk assessment techniques must be applied to determine the significance of hazards and be used as a tool to evaluate risk management strategies such as HACCP. The utilization of risk assessment techniques to provide an estimate of potential adverse health effects will be an essential component of the process for establishing international trade policies. Additional information must be developed in order to facilitate quantitative approaches to risk assessment for biological agents. At present however, a qualitative approach is the only one available for accomplishing such a risk assessment. Therefore, the CAC should produce an overall strategy and implementation plan to address the following recommendations.

Recommendations

- 8.3.1 The standards, processes and procedures relating to biological hazards and contained within Codex standards and codes of practice should be based on sound science and quantitative risk assessment to the maximum extent possible. This would imply an analysis of individual biological hazards in a broad range of foods, rather than the study of multiple risks associated with single foods.
- 8.3.2 Where Codex produces standards or codes of practice that contain processes and procedures, the intended outcome of the processes or procedures in terms of food safety should be clearly stated.
- 8.3.3 Guidance should be provided to enable assessment of equivalence of alternate processes or procedures that meet the intended outcome.

8.3.4 Consideration should be given to a means of comparing relative risk of different options being considered to control a hazard. Overall minimization of risk of adverse effects should be the goal and CAC should consider not only relative risks of biological origin but all potential risks.

8.3.5 A review should be undertaken of the risk analyses implied by the use of 2- and 3- class sampling plans for microbiological end-product specifications, especially in the light of the wider use of HACCP based systems and the improved process controls which result.

8.3.6 Specific research directed towards identifying and characterizing biological hazards of concern should be encouraged by the CAC to enable more quantitative risk assessment.

8.3.7 Quantitative methods of risk assessment should be developed for biological hazards to facilitate and improve the application of HACCP.

8.4 Uncertainty and variability

Many sources of both uncertainty and variability exist in the process of risk assessment of foodborne hazards to human health. Explicit consideration should be given to uncertainty and variability in the risk assessment process so that these may be taken into account in the formulation of risk management policies.

Recommendations

8.4.1 The limitations of the risk characterization methods presented here make clear that risk managers should be aware of the uncertainty in risk estimates and include this awareness in their decisions and their communications of risk to the public.

8.4.2 This situation suggests the need to consider carefully the uncertainties of model assumptions and inputs so that effort is directed at those components having the largest contribution to overall variance in model predictions.