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Development of Food Safety Risk Assessment Guidelines for Foods of Animal Origin in International Trade†

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ABSTRACT

The international food safety environment is currently in a unique period of reevaluation and change. In an emerging trading environment regulated more according to food safety requirements than nontariff trade protection barriers, food safety risk analysis is pivotal to future Codex activities and implementation of the World Trade Organisation (WTO) Sanitary and Phytosanitary (SPS) Agreement. Development of guidelines for food safety risk assessment requires determination of scope, internationally agreed definitions, general principles, guidelines tailored for each class of foodborne hazards, and linkages and interactions with risk management and risk communication. Food safety risk assessments need to be soundly based on science, should incorporate the four analytical steps of the risk assessment paradigm, and should be documented in a transparent and readily understandable form. The particular needs of Codex, the WTO, national governments, industry, and consumers need to be taken into account, and this includes identification of the essential linkages between risk assessment and the design of HACCP plans. With respect to chemical hazards in food, a risk assessment approach provides the opportunity to broaden the understanding of acceptable daily intakes, maximum residue levels, and their public health significance. Guidelines for chemicals in foods will inevitably have to address the differences between safety evaluation and a genuine risk assessment approach. With respect to microbiological hazards, the unique problems associated with risk assessment of living organisms in food make it likely that application of guidelines in the medium term will more commonly use qualitative approaches. In the absence of a history of safety evaluation according to a notionally zero risk baseline, as is the case with chemicals, the objective of microbiological risk analysis to reduce microbial risks to "the minimum which is technologically feasible and practical" represents a genuine focus for risk assessment. As risk assessment is increasing applied and internationally accepted guidelines become established, decision criteria for risk management arguably present the greatest challenge in establishing and maintaining quantitative SPS measures for food in international trade and judging their equivalence. However, the desire of all interested parties for scientifically justified food safety measures may be tempered according to the ability of the global scientific community to generate the necessary data and the political will to accept food safety programmes in different countries that have equivalent outputs.

Key words: Food safety, risk, guidelines

The international food safety environment is currently in a unique period of reevaluation and change. In particular, increased scientific, legal, and political demands are being made on the standards and rules applying to food in international trade because of

- Greater public concern over real or imagined foodborne hazards to health,
- More rigorous scientific assessment of traditional principles of food hygiene as applied by national regulatory authorities,
- The increasing need for food hygiene and inspection systems to represent efficient and cost-effective use of government funds,
- Inclusion of risk assessment principles in national legislation,
- New legislative conditions that will facilitate product liability claims,
- The advent of bilateral and multilateral trade agreements that require scientific validation of sanitary and phytosanitary (SPS) measures, and
- Public intolerance of the concept of "risk."

Against a background of consumers' growing more concerned about foodborne health "hazards" and more sceptical of both the assurances and warnings that are provided by scientists, national governments and international standard-setting agencies such as Codex must address the above-mentioned issues within a framework of enhanced food safety and facilitation of international trade.

The internationally developed standards, guidelines, and other recommendations of Codex are the basis for the future multilateral trade work of the World Trade Organisation (WTO) resulting from the Uruguay Round Agreements on Sanitary and Phytosanitary Measures and Technical Barriers to Trade *(3, 4)*. Codex standards technically remain voluntary, but countries not in compliance probably will be required to defend their standards before WTO panels.

In an emerging trading environment regulated more by food safety requirements than by nontariff trade protection barriers, Codex and the WTO are actively responding to the

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need for "scientific analysis and advice, together with risk analysis, to form the basis of the development of standards, guidelines and recommendations" for that trade *(6)*. Additionally, national governments are supporting the work of Codex by increasingly investigating ways to determine the equivalence of food safety programmes applied to food in international trade *(13, 15)*.

The intent of the SPS Agreement is to ensure that any food safety measures applied to the international trade in food are based on sound scientific principles and do not compromise the productive base and resources of a particular food-producing industry or country. Although the Agreement recognises the fundamental right of members to protect themselves at a level they deem necessary, any measures that may restrict trade should be limited to those that are justified to provide the necessary level of protection. The role of risk analysis is particularly important. The Agreement states that "Members shall 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."

It is clear that food safety risk analysis is pivotal to future Codex activities and implementation of the WTO SPS Agreement, and development of risk assessment guidelines for foods in international trade is an important task.

FOOD SAFETY RISK ANALYSIS

Application of the risk analysis paradigm to hazards to human health in food is a relatively new discipline, and the methodological basis is in a phase of continuing development.

Risk assessment is the primary scientific process and represents an evaluation of the probability of occurrence (likelihood) and severity of known or potential adverse health effects resulting from human exposure to foodborne hazards.

Risk management is concerned with the weighing of policy alternatives in light of the results of risk assessment and, if required, selection and implementation of appropriate control options. Thus risk managers must make a choice about what is an "acceptable" level of risk.

Risk communication is the interactive exchange of information and opinions concerning risk among risk assessors, risk managers, and other interested parties.

Industry, Codex, and many national governments are now adopting the hazard analysis/critical control point (HACCP) approach as the foremost system for control of hazards in food, and the design of HACCP plans has essential links to risk analysis. HACCP provides a preventive approach to food safety rather than an unqualified reliance on end-product testing *(5)*.

OBJECTIVES OF FOOD SAFETY RISK ASSESSMENT

Codex

The need for development of internationally agreed guidelines for food safety risk assessment tailored to each class of foodborne hazards is now well recognised within Codex, and the recent joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues *(7)* emphasised this need. Various Codex committees are elucidating the role of risk analysis in their development of standards and guidelines at the request of the Codex Executive Committee *(11)*, and an international drafting group led by the United States is currently preparing a draft paper on "Principles and Guidelines for the Application of Microbiological Risk Assessment" for presentation to the next session of the Codex Committee on Food Hygiene. There will logically be a progression to development of an overall strategy for incorporating a risk analysis approach wherever appropriate throughout the Codex system.

Because Codex will be the primary beneficiary of internationally agreed food safety risk assessment guidelines for food in international trade, it is important to consider the scope and application of such guidelines if they are to be successfully used for this international body. In this respect, the joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues *(7)* has recommended that

(8.1.1) Scientific risk assessment should be the basis for Codex risk management decisions involving health and safety aspects of food standards;

(8.1.2) In regard to chemical hazards, Codex should assure harmonised approaches to the risk assessment of food additives, contaminants, and residues of pesticides and veterinary drugs, particularly in the assessment of exposure;

(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;

(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 [with respect to biological hazards];

(8.3.3) Guidance should be provided to enable assessment of equivalence of alternate processes or procedures that meet the intended outcome [with respect to biological hazards];

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

The wider mandate of a risk analysis approach to food safety in addition to the elaboration of particular standards according to risk assessment principles must also be recognised. Examples are the design of import and export inspection systems, accept/reject criteria for "lots" of noncomplying food and subsequent regulatory actions, and principles for the proportional allocation of food safety regulatory resources relative to hazards in *all* classes of food.

WTO SPS Agreement and national governments

When food safety risk assessment guidelines are developed, the scope and application for successful use by WTO

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and national governments must also be considered. In encouraging different countries to base their SPS measures for food as much as possible on Codex standards and guidelines, it is hoped that the WTO Agreement will foster global harmonisation of such measures.

The SPS Agreement requires transparency in the development and application of measures that may restrict trade and specifically requires that member governments apply the principle of equivalence. However, the agreement only refers in generic terms to risk assessment and does not address methodological frameworks or mechanisms of harmonisation. In the absence of food safety risk assessment guidelines, this often limits determination of the equivalence of different national food safety programmes to ad hoc decisions made within the framework of bilateral agreements.

Provisions of an advisory nature in the form of codes of practice, guidelines, and other recommended measures are the most extensive texts produced by Codex and commonly describe hygiene requirements without quantifying or specifying what is considered to be in compliance. Instead, terms such as "adequate" and "acceptable" are used. While providing for flexibility in application of codes of practice, this qualitative approach will create difficulties in application of the provisions of the SPS Agreement, particularly in attempts to determine equivalence.

Although Codex standards and maximum residue limits (MRLs) are intended for formal acceptance by member governments *(10)*, national implementation is not mandatory *(2)*. As an example, Codex has been successful in elaborating a large number of MRLs for chemical residues in food. However, it has been less successful in gaining formal acceptance of those MRLs by national governments. Recent provisions for varying levels of acceptance have improved the situation; the "free distribution" provision is the most significant *(9)*.

"Free distribution" allows differences in good agricultural practice (GAP) between countries to be taken into account, recognising that small differences in MRLs consequential to these differences will not adversely affect consumer safety. Under this process, the importing country accepts an established Codex MRL for imported foods while maintaining a lower domestic limit (because of country-specific GAP considerations) or a zero domestic limit (because the chemical is not registered for use in the importing country).

Under the WTO SPS agreement, if the MRL of an importing country is more stringent than the Codex MRL for the same food, the important country may be required to justify scientifically why it does not accept the Codex MRL. The need for scientific justification would appear particularly relevant in the case of "zero" default tolerances or MRLs established by other than rigorous scientific procedure. (It can also be envisaged that the present acceptance procedures for Codex standards and MRLs may become redundant in the future, taking into account the provisions of the WTO SPS Agreement to resolve national differences.)

As part of the quest to determine the equivalence of food safety programmes applied in different countries, calls for harmonisation of food standards and guidelines are a recurrent theme. Misconceptions about the intent of harmonisation are common, and the position recently taken by the International Programme on Chemical Safety with respect to global harmonisation of approaches to the assessment of risk from exposure to chemicals provides a good description of the intent of harmonisation (C. Sonich-Mullin, personal communication):

- Understand the methods and practices used by various countries and organisations
- Develop confidence in and acceptance of assessments using different approaches
- Work toward convergence of methodologies as a long-term goal.

Industry and HACCP

Given the increasing importance of HACCP to contemporary food safety programmes and to judgement of the equivalence of these programmes in different countries, development of food safety risk assessment guidelines must address the essential linkages between HACCP and risk assessment.

The newly revised draft Codex guideline document on application of HACCP is an advisory text that defines HACCP as "a system which identifies, evaluates, and controls hazards which are significant for food safety" *(8)*. This definition does not establish a distinction between the control of hazards and the control of risks. However, any hazards considered must be of "such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food" *(8)*. Similarly, application of a decision tree to identify critical control points (CCPs) includes consideration of the question "could contamination with identified hazard(s) occur in excess of acceptable level(s), or could these increase to unacceptable level(s)?" Thus the concept of an acceptable level of risk is implied but not elaborated in the Codex HACCP guidelines, yet consistent decisions on CCPs and critical limits will rest largely on application of a practical and systematic risk analysis process *(14, 17)*.

For achievement of the recommendation from the Joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues *(7)* that "quantitative methods of risk assessment should be developed for biological hazards to facilitate and improve application of HACCP," the setting of food safety objectives for the particular segment of the food chain to which a HACCP plan is being applied would appear unavoidable *(15)*.

Zero risk

In an international food safety environment in which application of a risk assessment approach is a specified regulatory activity, Codex and national governments should actively combat the public's desire/perception of "zero risk" for all food and unrealistic expectations of the effectiveness of regulatory action. In fact, there is no zero-risk: if a hazard exists, there is some probability that it will cause an adverse effect, no matter how small. Colloquial use of the term zero risk should express the notion that the risk is extremely low;

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however, this often is not understood by the consumer. Although the notion of zero risk is primarily a risk communication problem, food safety risk assessment guidelines would provide a useful and transparent tool for consumer education purposes.

GUIDELINES FOR FOOD SAFETY RISK ASSESSMENT

Development of guidelines for food safety risk assessment requires

- Determination of the scope,
- Internationally agreed definitions,
- General principles,
- Guidelines tailored for each major class of foodborne hazards, and
- Linkages and interactions with risk management (and risk communication).

A number of national and international organisations have published guidelines for "risk assessment" of chemical hazards that are usually considered as working documents that foster consistency and help to resolve scientific controversy. In contrast, guidelines for making risk management decisions on the basis of socially and/or politically based determination of an acceptable level of risk are rarely available.

Published guidelines are not as yet available for risk assessment of microbiological hazards; however, guidelines for the elaboration of microbiological criteria *(1)* contain a number of qualitative elements of risk assessment.

Scope

A food safety risk assessment may be carried out for a particular hazard or may encompass all the potential hazards to human health that may reasonably be expected to occur in a particular food. The risk assessor will need to use information and data sets that vary markedly in quantity and quality, particularly with respect to microbial hazards, and this raises the question of what actually qualifies as a food safety risk assessment process.

A description of the scope of the risk assessment should include careful consideration of the class of hazard(s) involved and the quality and extent of information deemed necessary to achieve the stated purpose and particular circumstances of application.

Definitions

The definitions elaborated by the joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues *(7)* have been endorsed in slightly amended form by the Codex Executive Committee *(11)*. Subject to final review, these provide the first comprehensive list of working definitions for Codex-wide use and will foster worldwide consistency in risk analysis terminology.

General principles

It is readily apparent that food safety risk assessments need to be soundly based on science, should incorporate the four analytical steps of the risk assessment paradigm to the greatest extent possible, and should be documented in a transparent and readily understandable form. When guidelines are developed, the particular needs of Codex, the WTO, national governments, industry, and consumers must be taken into account. This includes identification of the essential linkages between risk assessment and the design of HACCP plans. The purpose of risk assessment and form of the risk estimate should be stated clearly at the beginning of the process.

Risk assessment is generally regarded as a quantitative exercise and may incorporate detailed mathematical models. However, a wide range of situations exist in food safety in which there is a need for more direct application of risk assessment principles and guidelines. Although inclusion of quantitative information to the greatest extent possible is a goal, use of qualitative information and ranking of risk in qualitative categories may be useful outcome of the risk assessment process.

It is generally agreed that risk assessment should be functionally separated from risk management, thereby preventing undue influence on the scientific process by the risk manager *(7)*. Notwithstanding this, certain interactions with risk management and risk communication are often necessary to successfully conduct a risk assessment. However, any scientific value judgements and policy bounds that are involved at particular decision points should be clearly identified and documented. Examples of such decision points are the range of hazards included in hazard identification, judging the scientific adequacy of the data set that is available, treating uncertainty, and deciding on the statistical basis for the standard of proof.

The four analytical steps of the risk assessment paradigm *(7)* that are essential to the risk assessment process are

- Hazard identification, identification of known or potential adverse health effects associated with a particular agent;
- Hazard characterization, qualitative and quantitative evaluation of the nature of the adverse effects, which may include a dose/response assessment;
- Exposure characterisation, qualitative and/or quantitative evaluation of the degree of dietary intake likely to occur; and
- Risk characterisation, integration of the above steps into an estimation of the adverse effects likely to occur in a given population, including attendant uncertainties.

The utility of the risk estimate depends in part on attendant uncertainty, and guidelines need to expressly address aspects of variability and uncertainty in data sets. Mathematical models also contain inherent uncertainties that can have an adverse impact on the utility of risk estimates; however, probabilistic approaches can generate biologically realistic outcomes. When mathematical models are used, sensitivity and uncertainty analyses should be applied to offer insights into the source and magnitude of uncertainty in the risk estimate and allow ranking of input parameters relative to their contribution to this uncertainty.

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Risk assessments should be substantially reviewed if significant new information on hazards and/or their likelihood of occurrence in a particular food becomes available. This is of particular importance when risk assessment has been used in the design of an HACCP plan dedicated to a particular food process.

Recognition of the technical resources necessary to carry out satisfactory food safety risk assessments and availability of peer review are important considerations.

Chemical hazards

Chemical and microbial hazards are the two most important classes of hazards in foods. Risk analysis in one form or another has ostensibly been applied to assessment of chemical hazards in foods for many years, but a critical evaluation suggests that apart from quantitative models applied to genotoxic carcinogens, the principles of risk assessment and risk management have not been systematically applied *(13)*.

Codex is the foremost agency elaborating levels of use, acceptable daily intakes (ADI), provisional tolerable weekly intakes, and MRLs for chemicals and residues in food. WHO/FAO Expert Panels provide a baseline "safety evaluation" methodology for standard setting. In the general case, the ADI for a food is the health endpoint and represents an estimate of the amount of a chemical or residue that can be ingested daily over the lifetime of an individual in the general population without appreciable health risk.

When an ADI is being set, experimental studies are usually carried out in test animals and acute, subacute, and chronic health effects are monitored to determine the no observable effect level (NOEL). A safety factor is then applied to the highest NOEL seen in the most sensitive animal species tested. The safety factor is intended to compensate for uncertainties in the safety evaluation, and the normal factor of 100 may be increased in a number of circumstances, e.g., an inadequate toxicological data set or irreversible embryotoxic effects. Certain evaluations and assumptions are then made about dietary intake, and different mechanisms are used for different types of chemicals to establish a maximum permitted level or MRL for a food so that the ADI is not exceeded.

Irrespective of the work of Codex, ADIs and MRLs for national use are often set by individual governments. Although Codex provides a methodological baseline, there is a diversity of national approaches with respect to specific elements of safety evaluation, and this often leads to different standards in different countries.

It should be recognised that the ADI is not a quantitative measure of risk; it is derived by imposing a specific margin of safety around a notional zero risk baseline *(13)*. Conservatism is inherent to each analytical step, and this usually combines in a deterministic sequence to represent a "worst case" scenario in the setting of standards.

A detailed scenario set for human exposure is often ignored in standard setting for chemical residues in food. As an example, potential exposure to residues of veterinary drugs will be very different according to different patterns of drug use in the slaughter population, and in most cases only a proportion of animals will have been treated or will have residues at the time of slaughter. Additionally, the standard setting process often does not include consideration of likely consumer end use. Most food is processed, cooled, frozen, or cooked, and these treatments may lead to a substantial decrease in the level of residues.

Although the current standard setting process for chemicals in food has well served the needs of food producers, regulators, and consumers, a risk assessment approach as advocated by Codex and WTO provides the opportunity to broaden the understanding of ADIs, MRLs, and their public health significance. Thus, risk assessment guidelines for chemicals in foods will inevitably have to address the differences between safety evaluation and a genuine risk assessment approach. As an example, safety evaluations have generally focused on the possibility of chronic exposure, but it is clear that a single exposure above an MRL (or a small number of repeated incursions) will not result in an adverse health effect unless there is the possibility of acute single-dose toxicity.

Development of risk assessment guidelines for chemical hazards in foods that extend the current safety evaluation approach will likely have a protracted genesis and may have fat-reaching implications for WTO and national governments. Estimates of risk should primarily focus on the ADI, and MRLs should be generally recognised as audit tools for assurance that risk management programmes are controlling identified hazards. In this respect, judgment of the equivalence of different food safety programmes according to a comparison of MRL-based standards (and rates of noncompliance) may be invalid because it is likely that this would only reflect a comparison of margins of uncertainty above a "notionally zero risk" baseline.

The limited progress in harmonising the different standards for chemicals in foods that are set by national governments reflects the difficulties that face the development and international acceptance of guidelines for this class of hazards. Guidelines for risk assessment of each type of chemical hazard (e.g. additive, contaminant, veterinary drug, pesticide) will specifically need to address, in risk assessment terms,

- Minimum data requirements,
- Standardised test protocols,
- Criteria for establishing safety factors,
- Dietary intake estimation (regional and national diets), and
- Scenario sets for exposure.

Microbial hazards

It is inevitable that many foods, either in the raw or ready-to-eat form, will have some level of microbial contamination (or microbial toxin) at the point of consumption. A plethora of Codex and national hygiene requirements have been established, mostly based on good manufacturing practice (GMP) and end-product testing, to control foodborne illness attributable to this contamination. These GMP-based requirements have evolved from general principles of hygiene, are usually qualitative, and are rarely formulated

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according to a quantitative assessment of risks to human health.

The problems associated with risk assessment of foodborne microbiological hazards are unique. Microorganisms multiply and die, and the biological interactions are complex. The contamination levels of the raw material entering the food chain dictate the character of the initial microflora, but this can be markedly modified by subsequent events. Additionally, there are marked differences in the virulence and pathogenicity of animal and environmental strains for humans, and the interaction of host and microbial pathogen is highly variable. Because of these factors, the development of appropriate risk assessment models has been inhibited by lack of information and lack of a detailed conceptual framework *(12, 15)*.

Development of guidelines for microbiological risk assessment will be a logical outcome of the high level of international interest in microbial risks associated with food. Although the lack of an animal model is impeding systematic application of the risk assessment paradigm, especially in the area of hazard characterisation, the greater availability of human epidemiological data is an advantage not found in chemical risk assessment.

Construction of detailed scenario sets describing all steps from production and processing to intended end uses of a food describe exposure, and targeted research is required to accumulate appropriate microbiological data. Predictive modelling of the fate of microbial hazards in a food produced according to a specified process is playing an important role in this respect. In some cases, it will be necessary to generate several risk estimates using different scenario sets of exposure to the hazard. Because of the variability inherent in much microbiological food safety data, Monte Carlo simulation modelling that generates probabilistic risk estimates offers considerable promise.

With respect to raw food commodities such as fresh meat, some level of microbiological contamination is an inevitable consequence of harvest and processing, and the determination of "acceptable levels" with respect to food safety objectives of HACCP plans presents problems *(15)*. In the medium term, microbiological risk assessment will be concerned mostly with evaluation of different levels of the contamination that are incurred from the harvesting and processing environment by

- Measuring microbiological levels that constitute current and reasonably achievable GMP,
- Measuring differences in these levels that may be brought about by altering processes and/or technological interventions,
- Using microbiological risk assessment to determine the effect on public health of the current levels and any changes to those levels, and
- Introducing HACCP-based systems that ensure that the hygiene parameters chosen as representative of an acceptable level of microbiological safety are met on a continuous basis.

In the development of microbiological risk assessment guidelines, it is important to acknowledge that application in the medium term will more commonly use qualitative approaches rather than complex mathematical models. Currently, the basis for control of microbiologically sensitive foods is generally through application of codes of practice, and microbiological standards have only been incorporated in Codex codes of practice in which epidemiological evidence has demonstrated a "significant" risk to public health (e.g., for specialised egg products and dried milk). Codex committees are aware that unless robust risk assessments (and risk management decision-making criteria) are available, microbiological standards based on fixed numbers of microorganisms often result in excessive waste of essentially wholesome raw food commodities.

Guidelines for risk assessment of microbial hazards need to specifically address, in risk assessment terms,

- Definition of the food safety problem (especially in relation to severity of effect),
- Minimum information for qualitative assessments,
- Availability of dose/response data, and
- Scenario sets for dietary exposure, including use of predictive microbiology.

In the absence of a history of animal modelling and safety evaluation according to a notionally zero risk baseline, as is the case with chemicals, it is acknowledged that the objective of microbiological risk analysis is to reduce microbial risks to "the minimum which is technologically feasible and practical" *(7)*. This represents a genuine focus for risk assessment, the output of which can be used to design HACCP plans and facilitate international trade according to harmonised food safety requirements.

FOOD SAFETY RISK MANAGEMENT

The development of internationally agreed guidelines for food safety risk management arguably presents the biggest challenge in the quest for harmonised standards and guidelines for the international trade in food. The transaction costs of achieving safer foods are high, and it is difficult for any one industry sector or group to agree with another on the level or method to achieve safer food. In the economists' view, this "market failure" is the fundamental justification for public intervention to ensure acceptable levels of food safety on both national and international bases *(16)*. In this respect, the size and complexity of the food safety problem requires careful consideration of alternative policy responses and possibilities for management of all foodborne risks.

The options considered may be quantified solely in economic terms, and risk management decisions may be made according to some risk balancing standard, e.g., the highest benefit-cost ratio. However, management of foodborne risks to human health inevitably involves social and political values, and formal decision making will require use of methodology such as threshold, comparative, or as low as reasonably achievable (ALARA) risk standards.

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The Codex Alimentarius Commission has adopted four statements of principle concerning the role of science in the Codex decision-making process that include the provision that where appropriate, "other legitimate factors" relevant to the health protection of consumers and to the promotion of fair practices in trade may be considered in the elaboration of standards *(9)*. This provision may introduce considerable complexity to the task of elaborating guidelines for risk management.

FOOD SAFETY RISK COMMUNICATION

Effective risk communication is a function that is often neglected and is an important area for future work. Development of guidelines for risk communication by agencies such as Codex will require a different range of skills than those usually applied to more technological aspects of food safety and assessment of risk. If a potential hazard is perceived with concern by consumers, there should be specific scientific and regulatory efforts to decrease that concern. Otherwise, public outrage is likely when the hazard is detected in food, thereby undermining public confidence in the food supply and probably leading to adverse impacts on trade.

CONCLUSIONS

The recent ratification of the WTO SPS Agreement is arguably the most important factor that will influence the development of new approaches to food safety over the next decade. There is a markedly increased desire for quantitative data on the risks associated with different foods, and traditional GMP-based food hygiene requirements are coming under increasing scientific scrutiny. As the risk assessment paradigm is increasingly applied and internationally accepted guidelines for risk assessment become established, decision criteria for risk management arguably present the greatest challenge in establishment and maintenance of quantitative SPS measures for food in international trade and judgement of their equivalence.

The application of a risk assessment approach has the potential to improve the scientific elaboration of food safety standards and guidelines and allow an overall assessment of risks and benefits in food hygiene programmes. Additionally, inspection and monitoring resources can be allocated in proportion to their greatest ability to ensure food safety. Internationally accepted guidelines are an important prerequisite to achievement of these goals on a global basis. However, the desire of Codex, WTO, and national regulatory authorities for scientifically justified food safety measures may be tempered according to the ability of the global scientific community to generate the necessary data and the political will to accept food safety programmes in different countries that have equivalent outputs.

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