

FOOD SAFETY RISK ANALYSIS: A GLOBAL ISSUE

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INTERNATIONAL ASPECTS OF FOOD SAFETY RISK ANALYSIS

In the past, control of human health hazards in fresh food of animal origin has generally depended on traditional principles of hygiene, with few attempts to draw quantitative associations between hygiene activities and their outcomes in terms of human health. However, "modernization" of food hygiene programs for fresh foods of animal origin is now a commercial and regulatory goal in a number of countries. The wider recognition of the high level of complexity of food safety issues and increasing demands from consumers for higher levels of protection from microbiological and chemical hazards are forcing industry and national regulatory authorities to adopt a more scientific and risk based approach to food hygiene. The development of inspection and hygiene systems that are both efficient and cost-effective is a parallel goal.

Inherent to the "modernization" of food safety programs is the qualitative recognition that unseen microbiological hazards constitute by far the greatest threat to human health. Primarily in response to this threat, the Hazard Analysis Critical Control Point System (HACCP) is rapidly becoming the cornerstone for design and implementation of modern process control systems for microbiological food safety. Risk analysis is an integral part of the design of a HACCP system for any class of hazard, and the complex association between a reduction in the level of hazards in food during a particular segment of food production or processing, and a reduction in risk

for consumers, is a primary consideration (Hathaway 1995). Guidance is also needed for the evaluation of alternate food safety practices or interventions in a HACCP system that meet the intended food safety outcome; whether it be on a site-specific, national, or international basis.

Modernization of food hygiene programs has implications far beyond national boundaries. In an emerging international trading environment regulated more according to food safety requirements than non-tariff trade protection barriers, food safety can now be considered a "global enterprise." In this respect, the Codex Alimentarius Commission (CAC) and the General Agreement on Tariffs and Trade/World Trade Organization (GATT/WTO) are actively responding to the need for "scientific analysis and advice, together with risk analysis, to form the basis of the development of standards, guidelines and recommendations" for international trade (Anonymous, 1994a). National governments are supporting the work of the CAC by increasingly investigating ways to determine the equivalence of foreign food safety programs applied to food in international trade.

The application of a risk analysis approach has the potential to improve the scientific elaboration of standards and guidelines for food safety, allow an overall assessment of risks and benefits in food hygiene programs, and facilitate allocation of inspection and monitoring resources proportional to their greatest ability to ensure food safety (Anonymous, 1986, 1994b, 1995;

Denner, 1992; Hathaway, 1993a, 1993b). "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 the principles of risk assessment and risk management have not been systematically applied (Hathaway, 1993a).

Food safety risk analysis is an emerging discipline, and the conceptual framework and methodological basis for assessing and managing the risks associated with particular categories of hazards in foods is in a phase of rapid evolution. The three elements of risk analysis are risk assessment, risk management and risk communication.

RISK ASSESSMENT

Risk assessment is the primary scientific process and is generally regarded as the estimation of the likelihood (probability) and severity (magnitude) of harm or damage resulting from exposure to hazardous agents or situations. Health risk assessment is a specific process (Anonymous, 1986) and four analytical steps are involved:

1. Hazard identification: the qualitative indication that a substance/agent may adversely affect human health;
2. Hazard characterization: the qualitative and quantitative evaluation of the nature of the adverse effects, and may include dose/response;
3. Exposure characterization: the qualitative and quantitative evaluation of the degree of human exposure likely to occur;
4. Risk characterization: integration of the above steps into a quantitative estimation of the adverse effects likely to occur in a given population, to be used in decision-making.

RISK MANAGEMENT

Risk management is concerned with the development and selection of policy options and the implementation of the food control program developed from the risk assessment. The options that are considered may be quantified solely in economic terms and risk management decisions made according to some risk balancing standard, e.g. the highest benefit/cost ratio. However, risk management decisions often have to consider human values and will require use of methodology such as threshold, comparative or as-low-as-reasonably-achievable risk (ALARA) standards. The latter technique typically adopts "zero risk" as an ideal but balances the ideal against "reasonable" cost limits on the resources needed for the obtained level of safety.

RISK COMMUNICATION

An effective risk communication program requires the interactive exchange of information and opinions on food safety risks, and this function is often neglected. Recent research indicates that scientists and risk managers should not simply dismiss public fears and concerns as "irrational." If a food safety hazard is perceived with fear and concern, there should be specific and regulatory efforts to increase people's control over the effects of exposure, and decrease the dread, unfamiliarity, scientific uncertainty, inequity, and other negative factors (Soby and others, 1994). Otherwise, public outrage is likely when the hazard is detected in food, undermining public confidence in the food supply. Adverse impacts on trade are a likely income.

It is clear from recent experiences in risk communication on a world-wide basis that the CAC and national governments must actively combat the public's desire/perception of "zero risk" for raw foods, and the unrealistic expectation of the effectiveness of regulatory action. Regulatory authorities have avoided challenging the "zero-defect" concept of the consumer in the past, largely because they themselves have had very little scientific data with which to quantify their empirical knowledge. Covello (1992) makes the important observation that in the public view, efforts to make a risk fairer, more voluntary, controlling mechanisms more inclusive of the public, etc., can be as important in determining an acceptable level of risk as are efforts to reduce the level of the risk.

FOOD SAFETY RISK ANALYSIS VOCABULARY

Despite the rapidly increasing recognition of food safety risk analysis and increasing reference in Codex, national regulatory and scientific literature, there is still a high level of confusion over structural elements and vocabulary. Even at the most elemental level, the difference between *hazard* and *risk* in terms of threats to human health is often not understood by different groups drafting guidelines and codes of practice for food hygiene activities. This is obviously a serious impediment to the advancement of the discipline of food safety risk analysis, and the CAC recognizes that adoption of definitions and other aspects of a common vocabulary is of paramount importance.

In this respect, the recent Joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues (Anonymous, 1995) has drafted definitions to be considered for adoption by the Codex system at the 21st Session of the CAC in July 1995. These are presented in Appendix 1.

THE INTERNATIONAL FOOD SAFETY ENVIRONMENT

The GATT SPS and TBT agreements

In a general sense, sanitary and phytosanitary measures as applied to the international trade in food are intended to be based on sound scientific principles that ensure food safety and do not compromise the productive base and resources of a particular country. These measures should not limit market access for non-scientific reasons, and are a necessary but not sufficient condition of trade (Walker and Ott, 1992). Before trade can proceed, mutual agreement as to the standards of each country, and/or the "equivalence" of food safety systems, must occur.

International debate over the role of science in designing and applying food control programs has increasingly focused the attention of the CAC on risk analysis in elaboration of standards and guidelines for the international trade in food. This is especially important in terms of the future multilateral trade work of the WTO resulting from the Uruguay Round Agreements on Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT). The role of risk assessment is a central tenet of the SPS Agreement and it is stated 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 organizations."

The internationally-developed standards, guidelines, and other recommendations of the CAC will be the basis for the future work of the WTO. In this respect, a Member government's SPS measures that are based on Codex standards, guidelines and other recommendations will be considered justified and in accordance with the provisions of the WTO. If a Member government justifies a measure solely for reasons other than protection of health, it will be judged by the rules of the TBT Agreement. While uptake of Codex standards by Member governments will remain technically non-mandatory, failure to become consistent with the SPS and TBT Agreements will create the potential for economic retaliation if a Member government applies standards that are more restrictive of trade than necessary to achieve required levels of protection.

Notwithstanding the above provision, Member governments "may introduce or maintain SPS measures which result in a higher level of SPS protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of protection a Member government determines to be

appropriate...(this level)...shall not be inconsistent with any other provision of the agreement." Therefore, the 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 protection, but also to recognize the fundamental right of Members to protect themselves at a level they deem necessary. In the latter case, Member governments are expected to justify the higher level of protection by utilizing risk assessment techniques and other scientific analysis as appropriate, and also demonstrate that the same level of protection cannot be achieved by alternative measures that are less restrictive to trade.

CODEX RISK ANALYSIS INITIATIVES

Following a report on "Risk assessment procedures used by the Codex Alimentarius Commission and its subsidiary and advisory bodies" (Hathaway, 1993a), a number of initiatives relating to the development and implementation of risk analysis have been explored. However, these have essentially been limited to statements of intent (Anonymous, 1993, 1994a, 1994c, 1994d, 1994e, 1994f). As yet, there has not been formulation of an overall food safety risk analysis strategy, or systematic development of appropriate methodology for use by the CAC and the WTO.

The "appropriate level of SPS protection" in the SPS Agreement can otherwise be referred to as "acceptable level of risk" and it is apparent from the above discussion that in the absence of Codex principles and guidelines for risk analysis, the CAC has yet to address this concept. Further, there are no specific procedures to guide Codex committees in translating scientific advice from Expert Advisory Panels into Codex standards. Currently, Codex committees often consider socio-economic and political issues as well as health and technical aspects of the safety evaluation of hazards in food but the consensus modality governing decision-making contains no formal elements of risk management.

It is noteworthy that the Codex is focused on attributes of food safety and wholesomeness that have universal application, and does not strive to harmonize consumer habits, customs, beliefs or political systems. Notwithstanding this, no consensus was reached at the most recent session of the Codex Committee on General Principles on the role of science in arriving at Codex standards, guidelines and other recommendations (Anonymous, 1994f). The debate pivoted on the differing intent of the SPS and TBT Agreements, and the separation of safety from other factors, thus the possibility of inclusion of non-safety-related factors (e.g. consumer, cultural, and ethical concerns) in the elaboration and adoption of standards intended for public health protection remains largely unresolved.

Against this background, the report of the recent

Joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues (Anonymous, 1995) makes a very positive contribution towards meaningful development of a risk analysis approach wherever appropriate within the Codex system, and thereby servicing the future needs of the WTO. The majority of the descriptive narrative in the Report is derived from chemical "risk assessment" and the overall mandate of a risk analysis approach to food safety is not addressed; however, there are strong recommendations for the future direction of Codex with respect to chemical and microbiological hazards in food. In these respects, the Consultation 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 harmonized 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 maximum extent possible;
- (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.

EQUIVALENCE AND HARMONIZATION

An evaluation of the equivalence of particular regulatory programs used by different trading partners will increasingly depend on risk assessment, and reference to Codex standards and advisory texts. As part of the quest to determining the equivalence of food hygiene programs applied in different countries, calls for "harmonization" of food standards and guidelines is a recurrent theme. Misconceptions about the intent of harmonization are common and the position recently taken by the International Program on Chemical Safety (IPCS) with respect to global harmonization of approaches to the assessment of risk from exposure to chemicals (Sonich-Mullin, 1995) provides a good description of the intent of harmonization:

1. Understanding the methods and practices used by various countries and organizations;
2. To develop confidence in and acceptance of assessments using different approaches;
3. A willingness to work toward a conver-

gence of methodologies as a long-term goal.

The IPCS further considers that harmonization cannot be dictated and will only result from scientific discussions, information exchange and understanding each other's goals and objective. The theme is "don't try to harmonize the past; rather, create the future." In this respect, the newly established SPS Committee of the WTO has a number of objectives related to equivalence and harmonization (Anonymous, 1994g):

1. Encouraging and monitoring the use of Codex standards, guidelines and other recommendations;
2. Sponsoring technical consultation to harmonize Codex and national standards, guidelines and other recommendations;
3. Liaising with the CAC to ensure the best available scientific and technical advice, and avoid duplication of effort;
4. Establishing a list of Codex standards, guidelines and other recommendations that have a major impact on trade;
5. Reviewing compliance with the SPS Agreement and recording instances and reasons for Member governments deviating from Codex standards, guidelines and other recommendations.

IMPLICATIONS OF RISK ANALYSIS FOR THE INTERNATIONAL TRADE IN MEAT

Application of a risk analysis approach to food safety has the potential to: establish internationally-harmonized standards and guidelines that are consistent and science-based; improve the safety and wholesomeness of meat and meat products in local and international trade; facilitate the distribution of pre-harvest and post-harvest inspection resources proportional to their greatest ability to ensure food safety; allow an overall assessment of risks and benefits in food hygiene programs; and achieve efficiency and cost-effectiveness in the implementation of hygiene programs.

Given the goal of an emerging international trading environment regulated more according to food hygiene requirements than non-tariff trade protection barriers, issues of food safety are increasingly likely to have international impact. The SPS Agreement is playing a pivotal role and it is clear that any food safety measures that are taken for food of animal origin in international trade are to be based on an assessment of the risks to health; i.e. are output driven rather than input driven, and the choices of measures with equivalent outputs is for those that are the least restrictive of international trade. Inherent in the quest for consistent improvements is the

realization that the global stakes in food safety are now higher than ever before, with the potential for huge commercial losses in the event of failure.

Intrinsic to the SPS Agreement is the expectation that there will be increased international acceptance of food hygiene programs individually designed by national regulatory authorities, as long as those programs are clearly specified, fully documented, scientifically valid, and subject to verification as to their delivery according to specifications. Achieving these objectives places much more responsibility on regulatory authorities and Codex than in earlier times. It should be widely recognized that the SPS Agreement only describes boundaries for risk management food safety and not methods for risk assessment or mechanisms of harmonization. In the short term, this will likely limit the determination of the equivalence of different national food hygiene programs to ad hoc decisions made within the framework of bilateral agreements. Inconsistencies in these decision-making processes carry the risk of undermining the intent and application of the SPS Agreement on a truly international basis, so causing a retreat from internationally-agreed Codex standards.

The economist's view that lack of information on food safety creates a "market failure" provides another perspective (Jensen and Unnevehr, 1995). It is contended that food producers have little incentive to provide greater levels of safety, since consumers will not pay for an attribute that they cannot verify. Another problem in the market is that the transaction costs of achieving safer foods are high, and it is difficult for any one private group to agree with another on the level or method to achieve safer food. The market failure (the lack of information about food safety and the high costs of privately achieving agreements) is the fundamental justification for public intervention to improve food safety, both on a national and international basis. In this respect, the size and complexity of the food safety problem (especially that caused by microbiological pathogens) requires careful consideration of alternative policy responses and possibilities for managing the risks in the food supply, and those alternatives should be evaluated using an economic framework (Jensen and Unnevehr, 1995).

The recent emergence of food safety risk analysis as a formal discipline has been due to a number of national factors but there is no doubt that the SPS Agreement has been a major catalyst. However, it appears from retrospective analysis that the SPS Agreement was predominantly written with animal health hazards rather than food-borne hazards to human health in mind, and the principles of risk assessment and risk management for these different groups of hazards are very different (Hathaway, 1993b; Morley, 1995). This is not generally recognized and as regards to food safety, the current lack of general principles, limited development of quantitative risk assessment approaches and the lack of decision-

making criteria tailored for food-borne hazards to human health and will seriously hamper the future work of Codex and the WTO unless there is a concerted effort to address these shortcomings.

It can be concluded that there is a priority need for development of internationally-agreed principles of risk assessment tailored to each class of food-borne hazards. The Report of the Joint FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues (Anonymous, 1995) has begun this task. There would logically be a progression to the development of a comprehensive strategy for incorporating a risk assessment approach wherever appropriate throughout the Codex system. Development of a similar strategy for incorporation of a risk management approach wherever appropriate would be a subsequent task. Failure to systematically address these priorities will severely limit the modernization and "internationalization" of meat hygiene programs.

The wider mandate of a risk analysis approach to food safety in addition to the elaboration of standards according to appropriate risk assessment principles must also be recognized. Examples are the design of import and export inspection systems, monitoring and surveillance programs for chemical residues and specific microbiological pathogens, accept/reject criteria for "lots" of food, and principles for the overall allocation of food safety regulatory resources proportional to hazards in all classes of food. With the "global" uptake of HACCP, there is also a priority need to recognize and address the essential linkages to a risk-analysis approach in the design and validation of generic and process-specific HACCP plans.

RISK ASSESSMENT AND MEAT HYGIENE

For the purposes of food safety risk analysis, food-borne hazards are considered to be of biological, chemical or physical origin. Risk analysis of potential public health hazards in meat and meat products can be conveniently separated into: hazards detectable by organoleptic inspection, microbiological hazards and chemical hazards. Some overlap will obviously occur, e.g. physical abnormalities detectable by organoleptic inspection may present a microbiological hazard.

Risk assessment is the primary scientific process within the risk analysis triad of risk assessment, risk management and risk communication. Because of the limited international framework that has been developed for application of a risk analysis approach to food safety, examples of risk assessment are best drawn from national studies. Risk management decisions for such examples and the implementation of appropriate food control programs will reflect national rather than international food safety policy.

Meat hygiene provides very fertile ground for a risk assessment approach (Hathaway and McKenzie, 1991; Harbers and others, 1992; Berends and others, 1993). Inspection programs are primarily engaged to ensure that meat is "safe and wholesome." In the case of raw meat, this is only a qualitative measure of freedom from hazards of human health. Ante- and post-mortem meat inspection cannot guarantee freedom from all clinically or grossly-detectable abnormalities, and monitoring programs have limited ability to detect all randomly-occurring violative levels of chemical hazards. Most importantly, some level of inadvertent microbiological contamination is inevitable in the slaughterhouse/processing environment.

ORGANOLEPTIC RISK ASSESSMENT

Maintenance of continuous post mortem inspection consumes the large majority of regulatory resources in most meat inspection programs, but its performance has not been evaluated in a modern epidemiological context and data on the outcomes of its application in terms of public health are rarely available. Comprehensive application of risk model for abnormalities detectable by post mortem inspection requires that the food safety responsibilities of all parties (producer, processor, regulator and consumer) should be evaluated at all key points in the meat production chain. As an example, development of on-farm systems that document the food safety responsibilities of the producer of slaughter pigs are well advanced in the Netherlands (Berends and others, 1993), and such systems will lead to risk-based post-mortem inspection programs that take on-farm health status into consideration. The critical role of the consumer in contributing to risk in the handling and preparing of meat for consumption must not be neglected.

Gross abnormalities detectable by organoleptic post mortem inspection consist of those potential public health (and animal health) importance, and those aesthetic defects that are unacceptable to the consumer. In many on-line inspection situations it is difficult to differentiate between true safety hazards and aesthetic "hazards." A risk assessment of a post mortem meat inspection program made up of a large number of procedures is concerned with the performance characteristics and scientific justification for the different procedures. The needs of industry, e.g. facilitation of processing efficiency and a low level of wastage, must be considered.

The requirements for field trials to establish the performance attributes of individual procedures (sensitivity, specificity and non-detection rate) have been previously reported (Hathaway and Richards, 1993; 1994) and this allows a quantitative characterization of exposure. A consideration of the difference between non-detection rates for all identified hazards for each procedure, together with a scientific assessment of the conse-

quences of each difference, provides the basis for the risk assessment. The risk assessment should quantify the precise non-detection rates that accompany different post mortem inspection procedures for a specific class of livestock, and provide the basis for the establishment of an acceptable defect level based on an assessment of the likely public health, animal health and aesthetic risks.

It will be clear from the above discussion that the exposure characterization is an integral part of the risk assessment. Unfortunately, comprehensive data on exposure of human populations to meat-borne microbiological pathogens, generated from epidemiological or clinical studies, are rare. Additionally, exposure to microbiological pathogens associated with abnormalities not detected by a particular procedure is very dependent on the particular processes and conditions that are applied to the raw meat prior to human consumption.

New Zealand has been advancing a risk analysis approach to modernization of meat hygiene for a number of years and some examples of organoleptic risk assessment can be drawn from that program. A major study to evaluate traditional post mortem inspection procedures for the viscera of lambs has been carried out and this involved more than 963,000 comparative evaluations in 37 export slaughterhouses (Hathaway and McKenzie, 1991). Notwithstanding the international inconsistencies in ovine meat inspection codes, a significant number of traditional procedures were demonstrated to have no scientific basis when routinely applied to the viscera of lambs slaughtered in New Zealand.

This study involved a rigorous analytical model and provides a good example of some of the implications of a risk analysis approach to food safety and international trade. In the absence of international guidelines on a risk analysis approach and a lack of decision-making criteria for establishing an acceptable level of risk, international trade can only be maintained if the proposed procedures are shown to perform at the same level (or better) compared with the procedures required for the particular foreign market. This is not genuine risk assessment; it only provides a means of comparison of methods that may in fact be poorly associated with public health risks, and it only includes risk management decisions to a very limited extent. In the lamb study, qualitative judgments on the public health risks associated with particular abnormalities only included "worst case" scenarios.

Despite this severe limitation, New Zealand was able to implement a new lamb inspection system that involved far less inspection resources, considerably decreased product wastage, provided industry with new and cost-effective processing options, and decreased microbiological cross-contamination and redistribution of carcasses. If a genuine risk assessment model had been able to be applied, it is likely that considerably less organoleptic inspection would have been found to be justified, espe-

cially in comparison to likely risks to public health arising from microbiological contamination incurred during slaughter and dressing.

A risk model for organoleptic inspection for bovine *Cysticerous bovis* provides a good example of a full risk assessment approach. New Zealand has an extremely low prevalence of *C. bovis* infection in cattle (5-30 cysts reported per year from post mortem meat inspection) yet applies the same intensive inspection procedures as those applied in countries with a relatively high prevalence of infection. The model was established to determine the annual risk to consumers of eating beef produced in New Zealand and compare that risk with a post mortem inspection regime that involved a reduced number of incisions in the heart and masseter muscles. For comparative purposes, the model should determine the equivalent risks in countries with relatively high prevalences of infection. An extensive literature review was required to establish the parameters used in the model.

A scenario tree displays the sequence of steps leading to the occurrence of the event under investigation and in the case of *C. bovis* this consists of:

1. The number of cattle slaughtered annually;
2. The prevalence of infection;
3. The prevalence of cysts/carcasses detected on post mortem inspection according to different inspection procedures: actual cysts in hearts and masseters/sensitivity of inspection and percentage of cysts in hearts and masseters versus the whole carcass;
4. The total number of undetected cysts;
5. The percentage of undetected cysts that are viable;
6. The annual volume of meat that is exported in chilled form, compared with domestic consumption;
7. A description of portions of beef eaten on an annual basis;
8. The percentage of viable cysts that survive preparation for consumption;
9. The percentage of viable cysts that establish human infection upon digestion.

Important considerations in managing the risk assessment process are ensuring full documentation and transparency in allocating quantitative values, keeping uncertain variables to a practical minimum, and testing the sensitivity of the result to uncertain parameters. The likelihood of human infection is modeled by applying probability distributions (in most cases triangular) to each step in the scenario tree and performing the quantitative risk assessment using Monte Carlo software such as @RISK (Palisade Corporation, New York). In the case of *C. bovis*, there are some data gaps in the relative distribution of cysts in different parts of the carcass compared to the masseters and heart; however, risk esti-

mates do not appear to be unduly sensitive to this source of uncertainty. The model is currently undergoing validation, and the risk assessment outcomes will be reported at the meeting.

CHEMICAL RISK ASSESSMENT

"Risk analysis" of chemical hazards has primarily been used to establish maximum permitted limits in target issues. General methods for "risk assessment" of chemical hazards in food have been widely published (Hathaway, 1993a; Anonymous, 1995). In summary, the "safe" dose is established as an acceptable daily intake (ADI) for a food and is expressed on a body weight basis. This dietary intake is not expected to result in any adverse health effects over the lifetime of an individual in the general population. In the case of contaminants inadvertently present in food, "provisional tolerable daily (or weekly) intakes" that denoted permissibility rather than acceptability are calculated.

Safety evaluations carried out using an ADI end-point are completed by imposing a specific margin of safety. This can only be considered a risk assessment in terms of establishing a "notionally zero risk" baseline. However, the use of safety factors does have the advantage of preventing problems that may be associated with determining an acceptable level of risk (as is the case with genuine quantitative models used for genotoxic carcinogens, etc.).

Examples of safety evaluations for chemical hazards are not presented in this paper. However, the wider application of a risk analysis approach to chemical hazards in foods has far-reaching implications. As an example, the establishment of MRLs for chemical hazards is the primary outcome of the majority of food safety evaluations but a risk assessment approach would dictate that these MRLs should generally be regarded as a monitoring tool for assurance that any risk management options taken to restrict exposure to the hazard in food(s) are in fact successful. Violative levels in individual "lots" of food are not directly related to the risk of adverse health effects (unless acute effects from a single violative exposure are a possibility); however, accept/reject criteria in heterogenous "lots" of carcasses or meat products are commonly based on single violative levels.

Application of a risk-assessment approach also raises issues of equivalence with respect to chemical hazards in internationally-traded food. The current limitations of genuinely applying risk assessment to chemical hazards in food may well reduce the judging of equivalence to a comparison of margins of safety around a "notionally zero risk" baseline. Codex and WTO need to fully understand the practical implications of this, and ensure that principles are developed to facilitate judgment of equivalence on this basis.

MICROBIOLOGICAL RISK ASSESSMENT

The problems associated with risk assessment of food-borne microbiological disease are very different to risk analysis of food-borne chemical or other hazards and in the short term, most microbiological risk assessments are likely to have a qualitative base. Construction of scenario trees describing all steps from processing through to intended end-uses of a food product collectively describe the risk model, and targeted research is required to accumulate appropriate microbiological data. Because of the variability and limited precision inherent in this type of data, stochastic modeling that allows estimation of outputs that are biologically realistic appears to offer the most promise. New PC software programs such as @RISK make such modeling a much more accessible proposition than in the past.

Some level of microbiological contamination of the carcass and offals is an inevitable consequence of slaughter and dressing and a more systematic regulatory approach is required if this source of hazards is to be kept to "the lowest practicable level possible" (Anonymous, 1993). This will require some form of microbiological risk assessment, either on a qualitative or quantitative basis. To date, the development of appropriate risk assessment models has been inhibited by lack of information and lack of a detailed conceptual framework (Hathaway, 1993a).

In considering a new approach to control of microbiological hazards of raw meat based on a risk assessment approach, risk analysis will mostly be concerned with evaluating different levels of the contamination that is continuously incurred from the processing environment. This should focus on:

1. Measuring microbiological levels that constitute current and reasonably achieve good manufacturing practice (GMP) for particular meat production and processing systems;
2. Measuring differences in these levels that may be brought about by altering processes and/or technological interventions;
3. Using microbiological risk assessment (as methodology becomes available) to determine the effect on public health of established levels, and any changes in established levels;
4. Introducing HACCP-based process control systems which ensure that the hygiene parameters chosen as representative of an acceptable level of microbiological risk are met on a continuous basis;
5. Investigating the ability to exclude sporadic contamination with known "high priority" pathogens by preventing their introduction into the processing environment via the raw material.

Outcomes from such an approach may not necessarily be concerned with setting specific pass or fail standards for a particular fresh meat product, according to microbiological criteria. The regulatory or commercial response to "unacceptable" microbiological levels (or prevalence of specific pathogens) in a HACCP-based process control system may equally be immediate imposition of better environmental hygiene, production controls or processing controls.

HACCP systems generally require application of on-line monitoring parameters that have an established (quantitative) association with "acceptable levels" of microbiological contamination or other hazards. Establishment of such monitoring parameters, especially for microbiological hazards, is much more difficult during slaughter and dressing than during further processing where physical monitoring parameters such as time/temperature, chemical preservation, pH, etc., are available. Applied research is needed to ensure that critical limits established in terms of on-line monitoring parameters, e.g. visible fecal contamination on carcasses, are in fact correlated with microbiological goals.

New Zealand is currently developing a HACCP slaughter and dressing model for sheep for control of microbiological contamination according to food safety goals. Inherent to the development of this model is the contention that application of genuine HACCP systems should be aimed at providing improved food safety assurances compared to those provided by adherence to good manufacturing practice (GMP) and/or should provide greater benefit/cost ratios for particular food safety characteristics than those achieved by GMP.

Research carried out over three years has yielded much information on the microbiological contamination associated with different processing steps and interventions, and the parallel relationship with visible contamination. Aerobic plate counts have been used as a microbiological indicator of general carcass hygiene, and *Escherichia coli* counts as a more direct microbiological indicator of the likely presence of human health pathogens originating from the gastrointestinal tract.

It has been found that the pre-slaughter presentation status of sheep is by far the most important factor in determining subsequent carcass microbiological loads. Compared with shorn visually clean sheep, those with long wool and visible dirt/feces produced carcasses with much higher microbiological loads and despite some smoothing, significant differences were maintained until carcass fabrication and packing. When woolly, dirty sheep were washed pre-slaughter, there was a further significant increase in microbiological loads; however, there also was a marked decrease in visible contamination of the carcass.

Considerable advantages were conferred by use of specific on-line dressing practices, e.g. prevention of roll-back of the pelt during skinning, removal of a perineal

skin piece during skinning, and delaying the "Y-cut." Other practices did not result in lower microbiological loads, e.g. shearing of the incision line prior to opening of the pelt. Inverted compared with traditional dressing systems provided a differential improvement that was most marked on the hindquarters. Hands of slaughtermen and meat inspectors made little difference to carcass microbiological loads when initial contamination levels resulting from pelting were high; however, they constituted a significant source of redistribution of contamination when initial microbiological loads were low.

Pre-visceration washing of carcasses was very effective in removing visible contamination with wool, but not so for visible fecal contamination. Microbiological loads directly at the site of visible contamination were significantly reduced; however, post-wash microbiological loads at sights of fecal contamination were still significantly higher than those at adjacent and visibly clean areas, and on control carcasses. Pre-visceration washing did not increase microbiological loads at dependent sites immediately adjacent to visible contamination.

Associations between microbiological and visible contamination further illustrated that traditional opinions on carcass hygiene were eliminated from the dressing system, improvements in A.C. and *E. coli* counts of 0.02% to 10% were achieved at different carcass sites under commercial conditions. Although there was smoothing of differences through subsequent chilling and carcass fabrication, significant improvements in carcass hygiene were maintained.

The outcome of the ovine slaughter and dressing model will be a validated generic HACCP plan for application under New Zealand conditions, with different combinations of dressing practices and processes having quantified effects. Any microbiological process targets that may be set would be practical and achievable and would establish an interim baseline against which further improvement could be measured. However, microbiological risk assessment methodology to assess the association between meeting these (or improved) targets and public health outcomes is unlikely to be available in the short term. Thus, assigning "acceptable levels" would suffer from an arbitrary distinction between the control of hazards and the control of risks. This illustrates the difficulty in incorporating HACCP microbiological targets into international guidelines, as HACCP ultimately deals with the uniqueness of each process.

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APPENDIX I: DEFINITIONS

The following draft definitions for risk analysis were agreed at the FAO/WHO Expert Consultation on Application of Risk Analysis to Food Standards Issues in Geneva in March 1995 (the final report of the Consultation contained amendments as suggested by the WHO Terminology Unit and the Consultation Secretariat. The amended definitions are being presented to the 21st Session of the Codex Alimentarius Commission in July 1995 for adoption by the Codex system, but at the time of writing, a number of delegations have expressed reservations over the amended definitions).

Further definitions that are needed for a wider understanding of risk analysis with respect to food safety are also listed (with asterisks).

HAZARD: A biological, chemical or physical agent in, or condition of, food with the potential to cause harm.

RISK: An estimate of the likely occurrence of an adverse effect, weighted for its severity, that may result from a hazard in food.

RISK ANALYSIS: A process to scientifically evaluate the probability of occurrence of known or potential adverse health effects resulting from human exposure to food-borne hazards (risk assessment), to weigh policy alternatives in light of the results of risk assessment and, if required, to select and implement appropriate control options (risk management) and to exchange information and opinion interactively among risk assessors, risk managers, and other interested parties (risk communication).

RISK ASSESSMENT: The scientific evaluation of the probability of occurrence of known or potential adverse health effects resulting from human exposure to food-borne hazards. The process consists of hazard identification, hazard characterization, exposure assessment, and risk characterization. The definition includes quantitative risk assessment, which emphasizes reliance on numerical expression of risk, and also qualitative expressions of risk, as well as an indication of the attendant uncertainties.

HAZARD IDENTIFICATION: The identification of known or potential adverse health effects in humans produced by biological, chemical and physical agents which may be present in a particular food or groups of foods.

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

EXPOSURE ASSESSMENT: The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents in food, as well as exposures from other food sources if relevant.

RISK CHARACTERIZATION: The qualitative and/or quantitative estimation, including attendant uncertainties, of the severity and occurrence of known or potential adverse health effects in a given population based on hazard identification, hazard characterization, and exposure assessment.

***RISK ASSESSMENT POLICY:** Pre-determined guidelines for scientific judgments and policy frameworks which may be applied at specific decision points in the risk assessment process.

***QUANTITATIVE RISK ASSESSMENT:** The estimation of risks as numerical or measured representations.

***QUALITATIVE RISK ASSESSMENT:** The estimation of risks as categorical representations.

SCENARIO SET: A construct characterizing the range of likely pathways affecting the safety of the food product. This may include consideration of processing, inspection, storage, distribution and consumer practices.

RISK MANAGEMENT: The weighing of policy alternatives in light of the results of the risk assessment and, if required, selecting and implementing appropriate control options.

RISK COMMUNICATION: The interactive exchange of information and opinions concern risk among risk assessors, risk managers, and other interested parties.

DOSE-RESPONSE ASSESSMENT: The determination of the relationship between the magnitude of exposure to a chemical, biological or physical agent, and the frequency and/or severity of adverse health effects.