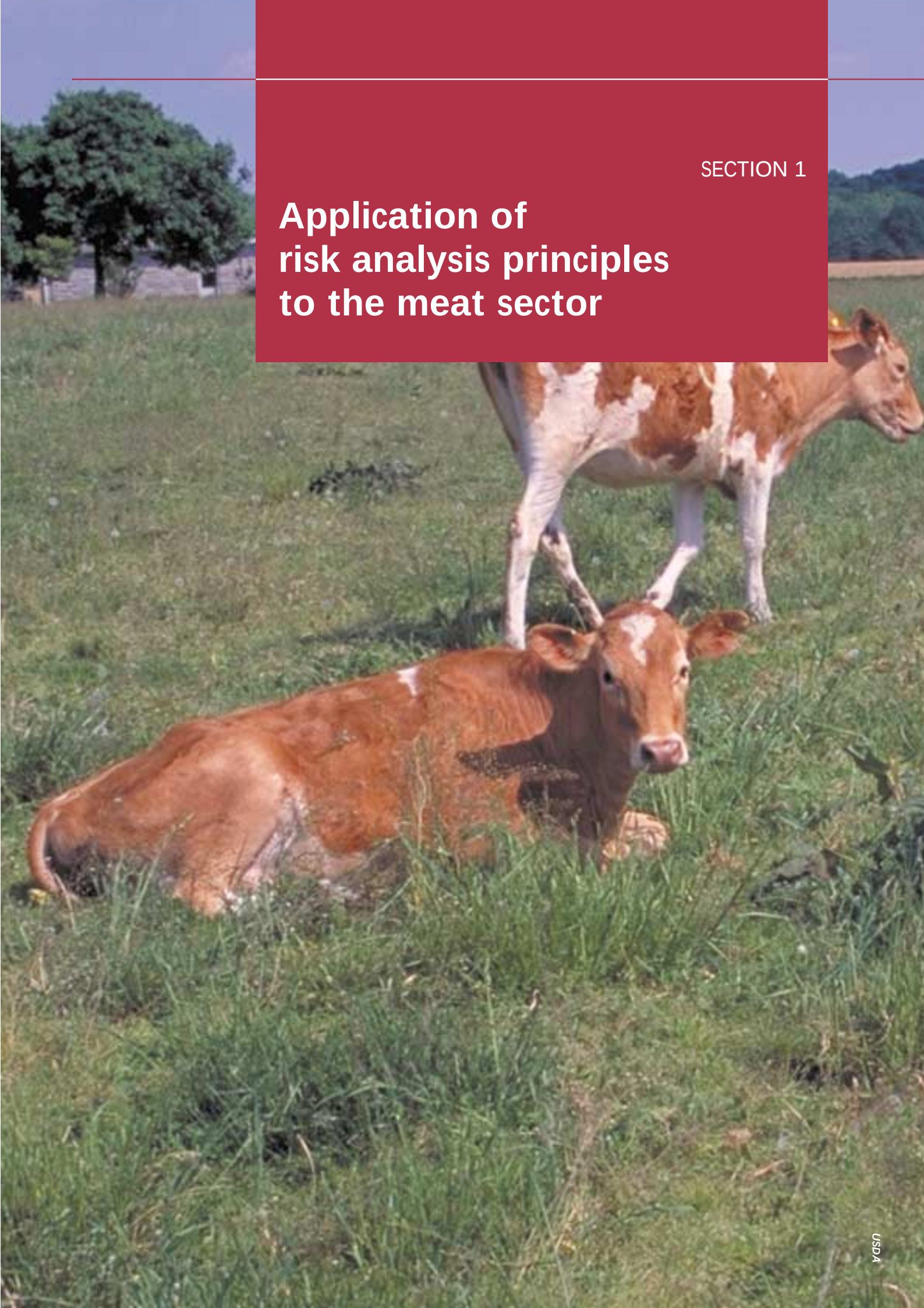
SECTION 1

Application of risk analysis principles to the meat sector



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INTRODUCTION TO MEAT HYGIENE

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" (FAO/WHO, 1999a). In the practical world of meat hygiene, this will require contributions from a range of stakeholders, including industry and government.

Meat hygiene is a demanding science and must deal with different classes of hazards. Chemical hazards entering the food chain at the level of primary production include: residues of veterinary drugs and pesticides, environmental and industrial contaminants and illegal growth promotants. For many years, meat inspection focused on forms of microbiological contamination that cause macroscopic lesions. This includes, for example, tuberculosis, anthrax, salmonellosis in pigs, and parasites such as *Cysticercus.* Now that these forms of contamination are under control in most countries, better monitoring and surveillance make it possible to deal with other microbiological pathogens that can be detected only by laboratory techniques. The type and prevalence of these pathogens change markedly with different production, processing and food-handling practices in different countries, and new zoonoses such as *Escherichia coli* O157:H7 and the infectious agent of bovine/transmissible spongiform encephalopathy (BSE/TSE) continue to emerge.

Recent reviews identify microbiological hazards carried primarily by healthy animals as causing the majority of meat-borne risks to human health, e.g. *Salmonella enteritidis, Campylobacter jejuni, E. coli, Clostridium perfringens, Yersinia enterocolitica* and *Listeria monocytogenes.*

Recently gained knowledge reveals that the median infectious dose for different meat-borne pathogens may range from a few cells, e.g. *E. coli* O157:H7, to many millions of cells, e.g. several *Salmonella* spp. For *Salmonella* serovars, the European Commission Scientific Committee on Veterinary Measures relating to Public Health estimates the infectious illness dose to range from 10^{1} to 10^{11} colony forming units (cfu). This has obvious implications for the implementation of food safety measures by industry.

In many situations, prevention and control of hazards of public health importance are achieved in parallel to prevention and control of diseases and conditions of animal health importance. This duality of functions becomes especially important in a "production-to-consumption" approach to food control, where veterinary competence and administration can be shared while achieving both public health and animal health objectives.

Risk management in meat hygiene only applies to safety aspects. Although risk management principles could be adapted to assist in management of suitability characteristics of meat, this will not be explored in this manual.

A RISK-BASED APPROACH TO FOOD HYGIENE

In recent times, both national governments and standard-setting bodies for food in international trade have introduced the risk-based approach to food hygiene (Box 1.1). This has largely been a consequence of the international trade provisions of the World Trade Organization Sanitary and Phytosanitary (WTO SPS) Agreement, and obligations to justify food hygiene measures on the basis of science and risk assessment.

Governments and industry have also been keen to adopt risk assessment as a tool to develop more efficient and cost-effective food hygiene programmes. Many countries now consider that food control measures should be proportionate to the risks presented by specific food-borne hazards, with regulatory programmes focusing in a preventive manner on those hazards that present the greatest risks to human health. Notwithstanding this, risk management must also consider the feasibility and practicality of available control measures. The outcome should be hygiene measures applied at those points in the food chain where they will be of greatest value in reducing food-borne risks to consumers.

The Codex Alimentarius Commission (Codex) is responsible for setting standards for food in international trade and has now developed a large body of work on risk analysis (FAO/WHO, 2001a). The Codex *General principles of food hygiene* (as reprinted in FAO/WHO, 2001b) state

that: "In deciding whether a requirement is necessary or appropriate, an assessment of the risk should be made". Risk analysis is also increasingly becoming cross-sectoral in nature, and risk-based "biosecurity" processes for public, animal and plant health should be applied with the greatest degree of consistency possible (FAO, 2002).

Risk analysis in food safety has its contemporary roots in the emerging global climate of "free trade" that is based on removal of barriers constituting unjustified protection of domestic economic advantage. However, the global community fully recognizes the sovereign right of countries to place appropriate controls on food products crossing their borders so as to protect human health. The WTO SPS Agreement represents an effort of the global community to establish principles and guidelines governing the establishment and implementation of such controls.

Box 1.1 **Risk-based approach**

A **risk-based approach** contains performance and/or process criteria developed according to risk analysis principles.

A ***performance criterion*** is the required outcome of one or more control measures at a step or a combination of steps that contribute to assuring the safety of a food.

Process criteria are the process control parameters (e.g. time, temperature, dose) at a specified step that can be applied to achieve performance criteria.

The process of **risk analysis** comprises three steps:

- **Risk assessment.** A quantitative evaluation of information on potential health hazards from exposure to various agents. It involves four interrelated steps:
  - Identification of the hazard and comprehension of the danger it represents, the impact in terms of human health and the circumstances under which the danger is present (hazard identification).
  - Qualitative and/or quantitative evaluation of the adverse effects of the hazard on human health (hazard characterization).
  - Qualitative and/or quantitative evaluation of the likely degree of consumption or intake of the hazardous agent (exposure assessment).
  - Integration of the first three steps into an estimate of the likely adverse effects on the target population (risk characterization).
- **Risk management.** A 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 goal of the risk management process is to establish the significance of the estimated risk, to compare the costs of reducing this risk with the benefits gained, to compare the estimated risks with the societal benefits derived from incurring the risk and to carry out the political and institutional process of reducing the risk. The outcome of the risk management process is the development of standards, guidelines and other recommendations for food safety.
- **Risk communication.** An interactive process of exchange of information and opinion among risk assessors, risk managers and other interested parties. Risk communication provides the private and public sector with the information necessary for preventing, reducing or minimizing food risks to acceptable levels through systems of food quality and safety management by either mandatory or voluntary means.

Source: FAO, 1998.

PRACTICAL APPLICATION OF A RISK-BASED APPROACH IN MEAT HYGIENE

The practical application of risk management principles in meat hygiene requires an understanding of:

- the components of a meat hygiene programme;
- application of a risk analysis framework;
- risk assessment;
- risk management;
- risk communication;
- the different roles of industry, government and other stakeholders in the design and implementation of a meat hygiene programme.

Implementing risk-based meat hygiene programmes presents particular challenges in developing countries, which are often under-resourced in terms of regulatory systems and scientific capacity. Codex has recommended that risk assessment "should be based on global data, including that from developing countries", and international standards "should take into account the economic consequences and the feasibility of risk management options in developing countries" (FAO/WHO, 1999b).

BUILDING A MEAT HYGIENE PROGRAMME

Most meat production, processing, storage, distribution and retail activities will require tailor-made programmes that document all hygiene requirements. Industry has the primary responsibility to document and implement such programmes, with overview and verification by the government regulatory authority having jurisdiction (hereafter referred to as the "competent authority"). Three "building blocks" can be used in the practical development of a specific meat hygiene programme:

1. Good hygienic practice (GHP)
2. The Hazard Analysis and Critical Control Point (HACCP) system, and
3. Risk assessment

GOOD HYGIENIC PRACTICE

Meat hygiene programmes have traditionally been based on good hygienic practice (GHP), which provides a baseline food control programme. GHP generally consists of a qualitative description of all practices regarding the conditions and measures necessary to ensure the safety and suitability of food. Many practices are based on empirical experience and practice, and cover both the food production process and the food production environment. It should be noted that GHP is the only component of a meat hygiene programme that addresses non-food safety issues.

Regulatory GHP requirements are generally prescriptive and describe process requirements rather than outcomes. Some quantitative specifications may be included, e.g. chlorine levels for potable water, aerobic plate counts for working surfaces, and acceptable defect rates for visible contamination on chilled carcasses. In most cases, the effectiveness of the GHP components of a meat hygiene programme will not be able to be validated in terms of achieving a particular level of consumer protection, i.e. they are not risk-based.

The Codex *Recommended international code of practice: general principles of food hygiene* (FAO/WHO, 1999a) provides a GHP platform for development of individual meat hygiene programmes. Generic GHP for meat hygiene is presented in the Codex proposed *Draft code of hygienic practice for meat* (FAO/WHO, 2004).

APPLICATION OF HACCP PRINCIPLES

HACCP is a more sophisticated food control system than GHP, which "identifies, evaluates, and controls hazards which are significant for food safety" (FAO/WHO, 1999a) (Box 1.2). Application of HACCP principles should follow development of the GHP component of a meat hygiene programme.

Application of HACCP principles may result in identification of one or more critical control points (CCPs) and implementation of the elements of a HACCP plan. Given the current evolution of HACCP, the designation of a CCP at a particular step in the food chain may be based on empirical scientific judgement, or it may be more genuinely based on risk assessment.

If no CCPs are identified, then the meat hygiene programme will remain as one based on GHP. Critical limits (CLs) at a CCP may be designated as "regulatory limits" by the competent authority.

Box 1.2 **The Hazard Analysis and Critical Control Point (HACCP) system**

HISTORY OF HACCP

HACCP has become synonymous with food safety. It is a worldwide-recognized systematic and preventive approach that addresses biological, chemical and physical hazards through anticipation and prevention, rather than through end-product inspection and testing.

The HACCP system for managing food safety concerns grew from two major developments. The first breakthrough was associated with W.E. Deming, whose theories of quality management are widely regarded as a major factor in turning around the quality of Japanese products in the 1950s. Dr Deming and others developed total quality management (TQM) systems that emphasized a total systems approach to manufacturing that could improve quality while lowering costs.

The second major breakthrough was the development of the HACCP concept itself. The HACCP concept was pioneered in the 1960s by the Pillsbury Company, the United States Army and the United States National Aeronautics and Space Administration (NASA) as a collaborative development for the production of safe foods for the United States space programme. NASA wanted a "zero defects" programme to guarantee the safety of the foods that astronauts would consume in space. Pillsbury therefore introduced and adopted HACCP as the system that could provide the greatest safety while reducing dependence on end-product inspection and testing. HACCP emphasized control of the process as far upstream in the processing system as possible by utilizing operator control and/or continuous monitoring techniques at critical control points. Pillsbury presented the HACCP concept publicly at a conference for food protection in 1971. The use of HACCP principles in the promulgation of regulations for low-acid canned food was completed in 1974 by the United States Food and Drug Administration (FDA). In the early 1980s, the HACCP approach was adopted by other major food companies.

The United States National Academy of Science recommended in 1985 that the HACCP approach be adopted in food processing establishments to ensure food safety. More recently, numerous groups, including for example the International Commission on Microbiological Specifications for Foods (ICMSF) and the International Association of Milk, Food and Environmental Sanitarians (IAMFES), have recommended the broad application of HACCP to food safety.

THE CODEX ALIMENTARIUS GENERAL PRINCIPLES OF FOOD HYGIENE

Recognizing the importance of HACCP to food control, the twentieth session of the Codex Alimentarius Commission, held in Geneva, Switzerland from 28 June to 7 July 1993, adopted *Guidelines for the application of the Hazard Analysis Critical Control Point (HACCP) system* (ALINORM 93/13A, Appendix II). The Commission was also informed that the draft revised *General principles of food hygiene* would incorporate the HACCP approach.

The revised *Recommended international code of practice: general principles of food hygiene* (CAC/RCP 1-1969, Rev 3 [1997]) was adopted by the Codex Alimentarius Commission during its twenty-second session in June 1997. *The Hazard Analysis and Critical Control Point (HACCP) system and guidelines for its application* is included as its Annex.

The Codex *General principles of food hygiene* lay a firm foundation for ensuring food hygiene. They follow the food chain from primary production through to the consumer, highlighting the key hygiene controls at each stage and recommending a HACCP approach wherever possible to enhance food safety. These controls are internationally recognized as essential to ensuring the safety and suitability of food for human consumption and international trade.

ADVANTAGES OF HACCP

The HACCP system, as it applies to food safety management, uses the approach of controlling critical points in food handling to prevent food safety problems. The system, which is science-based and systematic, identifies specific hazards and measures for their control to ensure the safety of food.

The HACCP system can be applied throughout the food chain from the primary producer to the consumer. Besides enhancing food safety, other benefits of applying HACCP include more effective use of resources, savings to the food industry and more timely response to food safety problems.

HACCP enhances the responsibility and degree of control at the level of the food industry. A properly implemented HACCP system leads to greater involvement of food handlers in understanding and ensuring food safety, thus providing them with renewed motivation in their work. Implementing HACCP does not mean undoing quality assurance procedures or good manufacturing practices already established by a company; it does, however, require a revision of these procedures as part of the systematic approach and for their appropriate integration into the HACCP plan.

The application of the HACCP system can aid inspection by food control regulatory authorities and promote international trade by increasing buyers' confidence.

Any HACCP system should be capable of accommodating change, such as advances in equipment design, changes in processing procedures or technological developments.

Source: adapted from FAO, 1998.

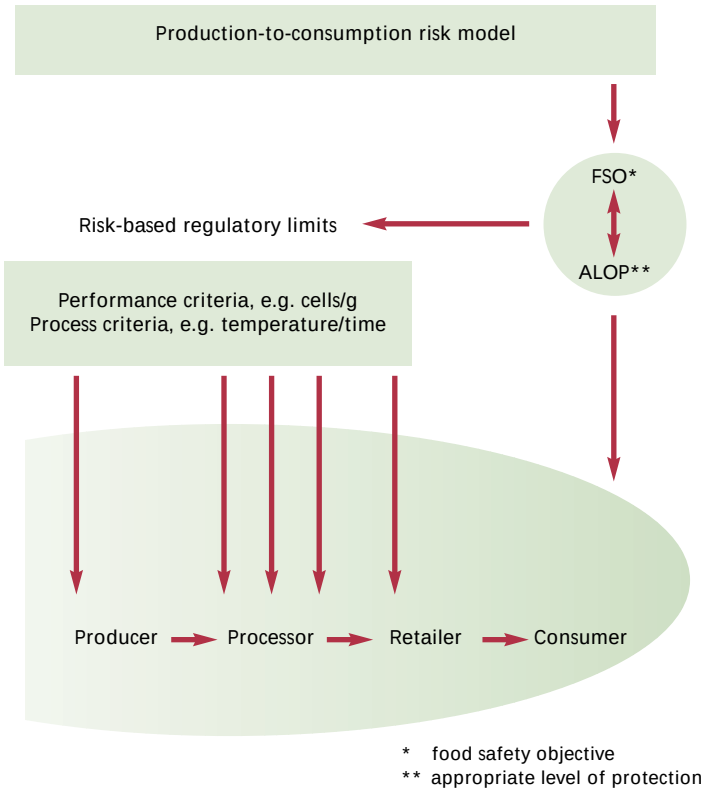
RISK ASSESSMENT

Food safety aspects of meat hygiene programmes should be based on considerations of risks to consumers to the extent possible and practical. A risk-based meat hygiene programme requires some understanding of the level of consumer protection that is to be achieved by particular measures. This entails knowledge of the level of control of hazards that is attained at a particular step in the food chain relative to the expected level of consumer protection. For food in international trade, this is called the "appropriate level of protection" (ALOP). Establishing this linkage will mainly be the domain of government and scientific institutions rather than industry. The linkage may be expressed in quantitative terms, e.g. by use of a risk assessment model linking hazard levels and consumer risks, or may be established in qualitative terms, e.g. by linking hazard levels to the level of consumer protection inherent in broader public health goals.

If a segment of a food chain has undergone risk assessment, implementation of a risk-based meat hygiene programme may involve establishment of regulatory limits for hazard control.

In other situations, the risk assessment model may be used to determine which hygiene measures have the most significant impact on reducing risk, and these could be specified in regulations independent of regulatory limits, e.g. a requirement to wash animals pre-slaughter.

FIGURE 1.1 **Use of risk-based regulatory limits in developing a food safety programme**



Source: S. Hathaway, New Zealand Food Safety Authority.

RISK-BASED REGULATORY LIMITS

Risk-based regulatory limits (Figure 1.1) can be expressed in several ways.

Performance criteria

A performance criterion is a quantitative expression of the hazard level at a particular step in the food chain that still provides the ALOP. It can be established at any step in the production-to-consumption food chain, as long as a link is established between the level of hazard at that step and the level of consumer protection that is afforded when the food is used according to its intended end use. This requires a risk model.

If the hazard is a microbiological pathogen, a performance criterion specified in terms of microbial numbers is unlikely to be of a nature that can be verified on a "real-time" basis as part of a HACCP plan. For biological hazards, a risk-based regulatory limit established by the competent authority is likely to be expressed as a process criterion.

Process criteria

A process criterion is a quantifiable characteristic at a specified step or combination of steps in the food chain that achieves a performance objective. Process criteria should be measurable in real time, e.g. temperature/time for retorting of cans, examination for zero visible faecal contamination on fresh carcasses, and will most likely constitute CLs at CCPs. In some cases, process criteria may be characteristics of the food, e.g. salt content, available water content.

Food safety objectives

A food safety objective (FSO) is a performance criterion at the point of consumption of the food. In most cases it will be derived from a risk assessment model, and provides the competent authority with a validated means of establishing performance criteria (and process criteria) at other points in the food chain. FSOs are unlikely to be specified in regulations.

Other regulatory limits

Maximum residue limits (MRLs) or maximum permitted levels for chemical hazards in foods may be established by the competent authority as monitoring tools to assess whether the acceptable daily intake (ADI), as established by the scientific advisory body such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA), is likely to be exceeded. In this case, the ADI reflects the FSO.

Microbiological criteria have long been used to determine the acceptability or otherwise of a consignment "lot" of food according to the microbiological results of a specified sampling plan. Despite some use as regulatory limits for processed meat by competent authorities, linkages between microbiological criteria and the ALOP for a particular food/hazard combination are rarely validated by use of a risk assessment model.

Non-compliance

Compliance with regulatory requirements by industry is an essential part of a risk-based meat hygiene system:

- Non-compliance with the GHP components of a meat hygiene programme should result in correction of process deficiencies within some reasonable time period.
- Non-compliance with a CL at a CCP should result in a review of the meat hygiene programme, and may result in non-acceptability of the product involved.
- Non-compliance with a regulatory limit derived from risk assessment should result in immediate and stringent review of the meat hygiene programme, with probable non-acceptability of the product involved.

It should be noted that in addition to regulatory use, risk-based limits can be established by industry for their own food safety purposes. In such cases, verification activities and responses to non-compliance should be fully documented. The competent authority may take compliance with industry limits into account when verifying regulatory requirements.

APPLYING A GENERIC FRAMEWORK FOR MANAGING RISKS

Design and implementation of risk-based meat hygiene programmes place specific demands on competent authorities and industry. Technical capability needs to be allocated to assess risks, and other components of risk analysis, i.e. risk management and risk communication, need to be effectively employed. Industry may choose to employ risk analysis independent of the activities of competent authorities.

Components of food safety risk analysis

Risk analysis constitutes an interplay of several multidisciplinary tasks. In a general sense, risk analysis is a structured process to determine:

- What can go wrong?
- How likely is it to go wrong?
- How serious would it be if it went wrong?
- What can be done to reduce the likelihood and/or seriousness of it going wrong?

Risk analysis is recognized as having three components: risk assessment, risk management and risk communication (Box 1.1).

Risk assessment

Risk assessment should, to the extent practicable, be a scientific exercise that generates a quantitative estimation of risks that may be associated with a particular food.

An estimate of risk is often described in terms of severity and frequency of adverse health effects, e.g. one death per million population per year. However, quantitative models are often unavailable because of resource or data constraints, and simplified tools can be useful as screening methods to generate qualitative risk assessments, e.g. high, medium and low risk, and risk rankings.

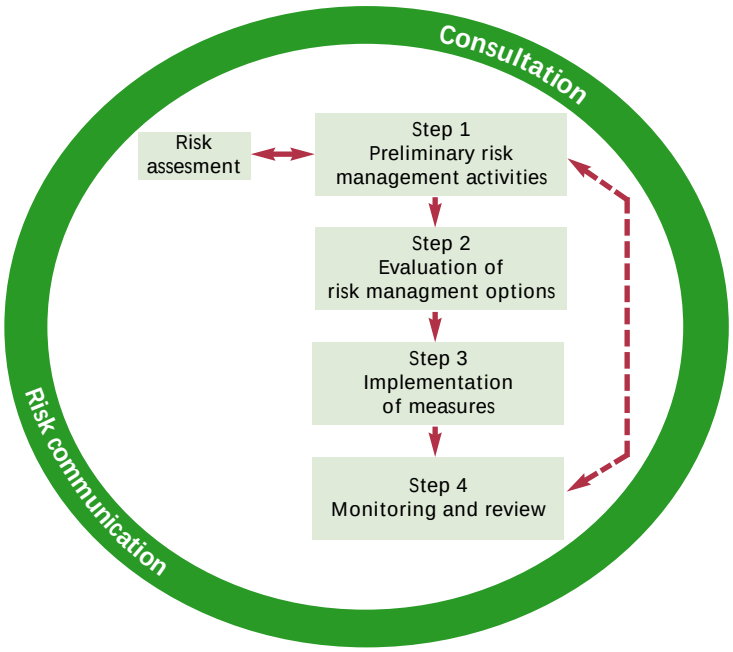
Risk management

An important part of risk management is a value-based decision on the desired level of public health protection, i.e. the ALOP. A range of factors need to be considered when evaluating the technical feasibility, practicality and cost of a meat hygiene programme compared to the desire to minimize food-borne risks to the greatest extent possible.

Risk communication

Risk assessment and risk management should be wrapped in a "sea of communication" that includes all stakeholders as appropriate, and facilitates the iterative and ongoing nature of all components of risk analysis.

FIGURE 1.2 **A generic framework for managing food-borne risks to human health**



Source: S. Hathaway, New Zealand Food Safety Authority.

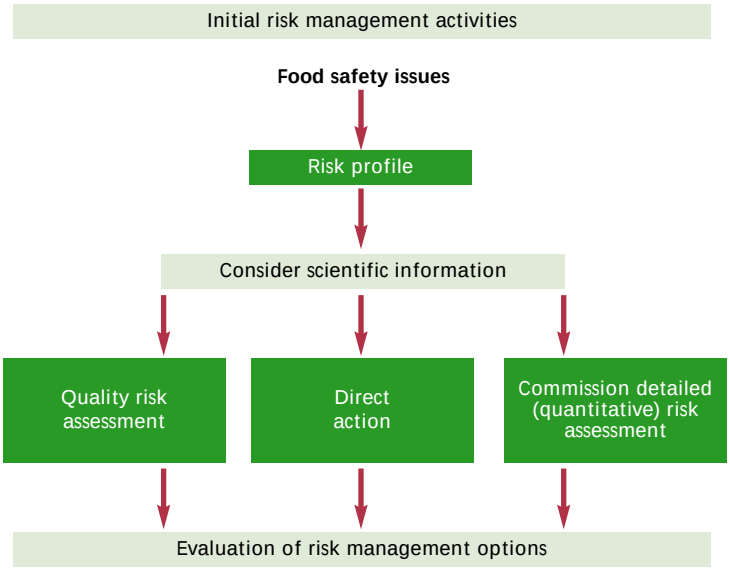
A GENERIC FRAMEWORK FOR MANAGING RISKS

The most important aspect of the design and implementation of a risk-based meat hygiene programme is systematic application of the principles of food safety risk management within the context of a generic framework for managing food-borne risks. This framework has four elements: preliminary risk management activities; evaluation of risk management options; implementation of measures; and monitoring and review (Figure 1.2).

Application of this framework will include the competent authority, industry and other stakeholders, e.g. science institutions and consumers. Each group will have different roles and responsibilities. The framework should be applied in an open, iterative and fully documented manner.

One of the most important practical reasons for implementing a generic framework for managing risks relates to the current lack of quantitative risk assessments for many hazards in meat products. Systematic application of a generic framework for managing risks, even in the absence of a quantitative risk estimate, will still result in most cases in enhanced meat hygiene programmes (Figure 1.3). Default or precautionary positions can be taken where data

FIGURE 1.3 **Initial risk management activities**



Source: S. Hathaway, New Zealand Food Safety Authority.

are limited or unavailable, pending further scientific studies.

Preliminary risk management activities

Following identification of a food safety issue, the initial process includes the establishment of a risk profile to place the issue within a particular context, and provide as much information as possible to guide further action by the competent authority. Risk profiling may also be used for ranking or prioritization of different food safety issues.

Risk profiling is one activity in preliminary risk management, and has been described as a systematic collection of information needed to make a decision on what will be done next and whether resources should be allocated to more detailed scientific assessment. Risk profiling is the responsibility of risk managers, and may contain information on the hazard, exposure to the hazard, adverse health effects, public health surveillance information, control measures and other information relevant to risk management decision-making.

Although not necessary in many cases, the risk manager may commission a detailed risk assessment as an independent scientific process to inform decision-making. If so, risk assessment policy should be established. Once a risk assessment has been received, the last task in preliminary risk management activities is for the competent authority to consider the results for completeness and appropriateness.

Risk assessment policy refers to the documented guidelines for policy choices and scientific value judgements that may be necessary at specific points in the risk assessment process, and which should preferably be agreed ahead of risk assessment.

Evaluation of risk management options

This is the process whereby potential risk management options are identified, and then selected according to appropriate decision-making criteria. It will usually involve balancing expectations in terms of minimizing risks against available food control measures, and may include reaching a decision on an ALOP. Although facilitated by the competent authority, both industry and consumers have critical inputs to this process.

"Optimization" of selected measures in terms of their efficiency, technological feasibility and practicality at the designated step in the food chain is an important goal. Meat hygiene measures should be implemented by industry at those steps in the food chain where there is maximum reduction of risk for the effort required. Various hygiene measures can be simulated in a risk assessment model to determine their individual impact on minimizing risks to consumers.

Implementation of measures

Implementation of meat hygiene measures by industry will usually be by means of a tailor-made programme that is built up as previously described. This will be based on GHP, and may contain one or more CCPs resulting from application of HACCP principles. Regulatory limits or procedures derived from risk assessment may be present. The final accountability for verification of the meat hygiene programme on an ongoing basis lies with the competent authority.

For some hazards, it may not be practical or cost effective for industry to implement hygiene measures on an individual premises basis, e.g. laboratory testing for chemical residues of one sort or another. National chemical residue programmes and a central laboratory administered by the competent authority can usually provide risk-based food safety assurances in such circumstances.

While flexibility in choice of individual meat hygiene measures at different steps in the food chain is a desirable element in a risk-based meat hygiene programme, the price of flexibility is validation. When a decision on a particular ALOP has been taken, different measures may be chosen by industry as long as they are capable of actually achieving that level of protection. This is at the heart of the principle of "equivalence" (see below). Following validation, ongoing verification of measures will assure that the ALOP is being achieved on an ongoing basis.

Monitoring and review

This risk management activity is represented by the gathering and analysing of data on human health so as to give an overview of food safety and consumer health. Monitoring (which includes surveillance) is usually carried out by national public health authorities and should identify new food safety problems as they emerge. Where there is evidence that required food safety goals are not being achieved, redesign of meat hygiene measures will be needed. Both the competent authority and industry will be involved in this task.

Unfortunately, there is a worldwide shortage of reliable monitoring data relating to meat-borne risks to consumers, and this has an impact on the ability to validate risk-based meat hygiene programmes.

RISK ASSESSMENT IN MEAT HYGIENE

It can be seen from the above description of a generic framework for managing risks that risk assessment is a separate and distinct scientific process. In most cases risk assessments will be commissioned by government and carried out by national science providers. Multidisciplinary skills are required. Risk assessments may employ qualitative and/or quantitative approaches, and vary widely in complexity. In some situations, industries may carry out their own risk assessments so as to enhance their meat hygiene programmes independently.

A comprehensive risk-based meat hygiene programme should address chemical, biological and physical hazards. Meat derived from different species of slaughtered animals, e.g. sheep and goats, and different types of slaughtered animals, e.g. farmed deer and wild deer, may have very different hazard profiles.

The risk assessment model

Ideally, a detailed risk assessment will incorporate four steps:

- **hazard identification:** the identification of biological, chemical and physical agents in food capable of causing adverse human health effects;
- **hazard characterization:** the qualitative or quantitative evaluation of the nature of the adverse health effects, ideally including human dose-response assessment;
- **exposure assessment:** the qualitative or quantitative evaluation of the likely intake of food-borne hazards by consumers, taking into account other hazard exposure pathways where relevant;
- **risk characterization:** the qualitative or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of adverse health effects in a given population.

Industry can provide important inputs to exposure assessment by assisting with modelling of all steps in the food chain from production to consumption. For microbial hazards, industry data are often the only source of detailed information on hazard levels at each step during processing of meat.

Numerical risk estimates allow direct comparison of risks and different intervention strategies, whereas non-numerical risk estimates provide a less definitive basis for risk management decision-making. In the latter case, risk assessments provide an essential point for discussion, debate and preliminary risk ranking. They provide a methodical approach when food safety has a high priority but numerical methods are not available.

Chemical risk assessment

Large numbers of quantitative standards for chemical hazards in foods have been established for many years. Most take the form of MRLs. The ADI or acceptable daily intake is established by a separate safety evaluation process. The meat industry itself is very unlikely to be involved in risk assessment of chemicals.

Following hazard identification, ADIs for chemicals in foods are generally determined by extrapolation from a "no adverse effect level"

animal model, and the ADI reflects the maximum amount of residues that can be absorbed daily by the consumer without risk to health, i.e. a pre-determined "notional zero risk". This effectively is hazard characterization, and it is arrived at by imposition of arbitrary "safety factors". Methods are now being developed for calculating reference doses for acute toxicity if this is a potential adverse health effect.

An ADI is a relatively crude estimate of the level of chronic dietary intake that is bearable without risk, and the impact of arbitrary safety factors that are embedded in the safety valuation process is not quantified. There is rarely an attempt to define the degree of uncertainty or describe the impact of this uncertainty on the standard-setting process. Thus the "worst-case scenario" that constitutes the general approach taken for intake of chemical hazards in foods is likely to be a marked overestimate of exposure in most cases.

Exposure characterization describes the exposure pathway for the hazard and predictions of dietary intake. It is usually composed of simple deterministic values for hazard levels at each step in the food chain; however, probabilistic models are emerging, e.g. for intake of pesticide residues.

Risk characterization corresponds in part to establishment of maximum limits for residues, e.g. MRLs for veterinary drugs, and ensuring compliance with the ADI. Maximum limits for chemical residues in foods are usually established so that the theoretical maximum daily intake of residues is lower than that allowable by the ADI. However, their establishment may be independent from the ADI-setting process (e.g. pesticides) and may involve a number of qualitative risk management factors. In some cases, risk characterization may include consideration of different types of chemical hazards and pathways. For example, when a substance is used as both a veterinary drug and a pesticide on plants, both routes can be taken into account when setting ADIs for animal-derived foods.

For unavoidable environmental contaminants, standards for chemical hazards are often related to "maximum permissible levels" (MPLs), i.e. there is tacit acceptance that it is not economically or technically feasible to apply the same "notional zero risk" model that is applied to other chemicals in the food supply.

Biological risk assessment

In the past, evaluation of food-borne risks associated with biological hazards in the food supply has been largely empirical and qualitative. The overall goal has been to reduce biological hazards to a level that is "as low as reasonably achievable", with commensurate minimization of risks. In most cases, the actual level of risk associated with particular food control programmes is unknown.

The advent of robust predictive microbiology and PC-based software for simulated risk modelling, coupled with rapidly increasing demands from all stakeholders for risk-based microbiological food safety measures, is fuelling an emerging era of microbiological risk assessment (MRA). The highly resource-intensive nature of MRA means that this is mainly the domain of competent authorities and science institutions.

In general terms, MRA involves combining the outputs of exposure assessment and hazard characterization to characterize risk. Risk estimates can be qualitative, e.g. high, medium or low rankings, or presented in quantitative terms, e.g. risk per serving(s), risk per year. Recently, FAO and WHO have embarked on a series of expert consultations on MRA that represent an extensive and ongoing commitment. This work is heavily dependent on MRAs already commissioned by national governments.

Considerable challenges lie ahead in carrying out detailed MRAs for pathogen/food commodity combinations that pose significant risks to human health. Modelling the exposure pathway from production to consumption is often adversely affected by substantial data gaps, and a particular problem lies in evaluating the impact of consumer food handling and cooking practices at the final step in the exposure pathway. Currently, relatively little human data are available to model dose-response curves, and independently validate risk estimates.

MRA is a new science and to date very few risk-based regulatory limits have been set on this basis.

RISK MANAGEMENT IN MEAT HYGIENE

Consideration of all available control options throughout the "production-to-consumption" continuum is the ideal scenario when managing meat-borne risks to human health. However, this may not be necessary or practical in cases where:

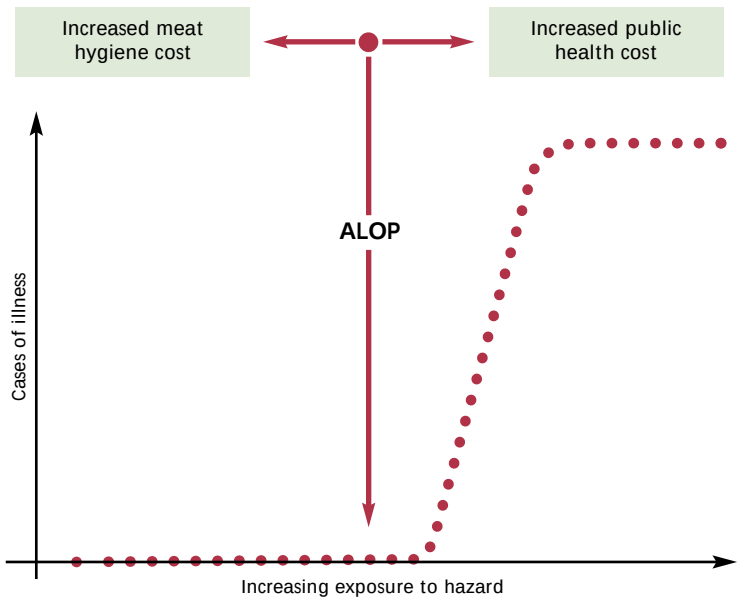
- available risk assessment models only cover a particular segment of the food chain;
- risk management objectives only relate to a particular step (or steps) in the food chain;
- different meat hygiene measures are being evaluated for equivalence.

The decision-making process

Although the decision-making process in risk management will be facilitated by the competent authority, specific mechanisms should be in place to include the expert advice and opinions of other stakeholders, particularly industry and consumers.

Risk assessors are likely to have examined the impact of different measures on minimizing food-borne risks, thereby providing risk managers with data that help them reach decisions on the optimal way to achieve the agreed level of consumer protection.

FIGURE 1.4 **Reaching a decision on an appropriate level of protection (ALOP) in meat hygiene**



Source: S. Hathaway, New Zealand Food Safety Authority.

Decisions on managing meat-borne risks should take into account, where appropriate, other factors that can be legitimately considered within a particular risk management framework, e.g. cost and practicality of proposed measures (Figure 1.4). In some cases, an ALOP may be "reflected" in the meat hygiene measures currently in place, and no further interventions are needed.

International considerations

In international fora such as the Codex Alimentarius committees, economic consequences and the technological feasibility of different measures may be considered when elaborating meat hygiene standards as benchmarks for international trade. Industry, consumers and other stakeholders can have their views represented through their national delegations.

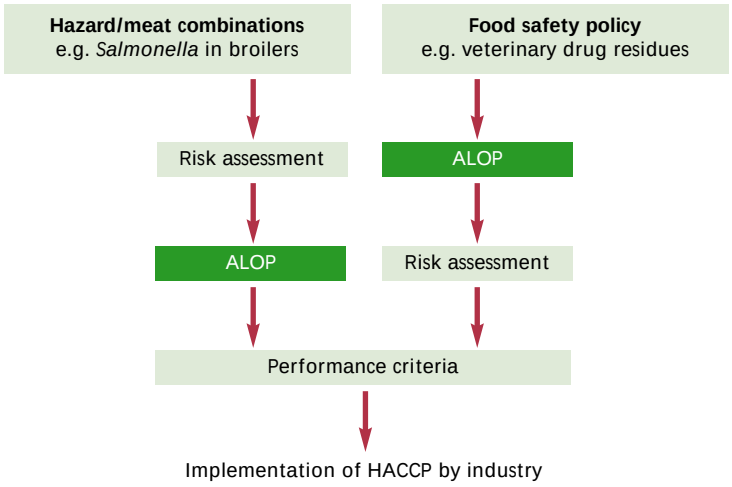
In addition to differences in choice of ALOP between countries, differences often occur in food production systems, technological capacity and food safety measures themselves. Such situations illustrate the importance of the concept of equivalence. If risk assessment can demonstrate that different practices in different countries can still result in the same level of consumer protection, there should be no impediment to international trade in the food concerned.

Application of a risk-based approach to demonstrate equivalence facilitates much greater flexibility in the use of new or alternative meat hygiene tests, procedures and technologies. If new or alternative measures that are more efficient or cost-effective can be shown to be as effective as existing measures, i.e. equivalent, industry can take advantage of all the gains available.

PRACTICAL APPLICATION OF RISK MANAGEMENT PRINCIPLES TO THE MEAT SECTOR

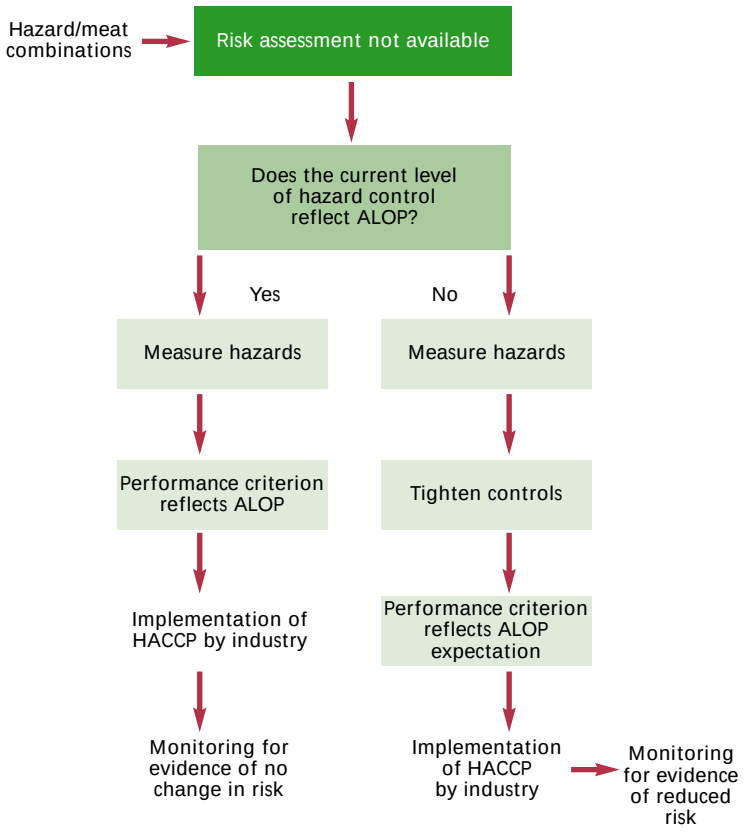
Despite the resource-intensive nature of meat hygiene programmes, assessment of their overall benefit is still limited by the lack of systematic data on the various elements of meat hygiene as they relate to public health. Application of risk management principles should gradually improve this situation, particularly in the area of process control.

FIGURE 1.5 **Pathway for establishment of risk-based performance criteria**



Source: S. Hathaway, New Zealand Food Safety Authority.

FIGURE 1.6 **Alternative pathways for establishment of risk-based performance criteria**



Source: S. Hathaway, New Zealand Food Safety Authority.

Stakeholder involvement

Application of risk management principles in the meat sector will involve all stakeholder groups in one way or another. The competent authority will facilitate application of all components of the generic framework for managing risks, set risk-based regulatory requirements as appropriate and verify that these are being met on an ongoing basis. The primary involvement of industry will be in contributing to risk management decisions, implementing meat hygiene programmes and ensuring compliance with regulatory requirements.

Risk management outcomes

Systematic application of a generic framework for managing meat-borne risks to human health can take several forms, depending on whether or not a detailed risk assessment is available. Risk management decisions can be based on:

- quantitative estimates of risk reduction;
- qualitative estimates of risk reduction;
- precautionary approaches.

The practical outcome of its impacts on the meat industry may be:

- accept current meat hygiene controls;
- set a risk-based regulatory limit for a particular hazard/meat product combination so as to provide a particular level of protection (Figure 1.5);
- prescribe a regulatory measure other than a regulatory limit that is likely to provide a particular level of protection;
- remove a regulatory measure that has been shown to have negligible impact on minimizing risk;
- set a provisional regulatory measure reflecting a precautionary approach (Figure 1.6);
- effect the implementation of risk-based measures by industry as part of their own meat hygiene programme.

PROGRESS TO DATE

To date, application of risk analysis principles has primarily focused on primary production and process control activities (the latter includes ante- and post-mortem inspection). Simulation modelling of risk management interventions in these areas is available for some hazard/product

combinations, but examples of regulatory uptake of outcomes are rare.

"Through-chain" modelling has resulted in a number of recommendations on regulatory measures, based on qualitative estimates of likely risk reductions. In the absence of regulatory uptake, industry can implement such measures of its own accord.

Several competent authorities have removed resource-intensive post-mortem inspection procedures where they have been shown to be of negligible benefit.

In the absence of robust risk assessment, precautionary measures have been established for particular hazards in some cases, e.g. surveillance and prevention of BSE.

APPLICATION OF RISK ANALYSIS PRINCIPLES TO PRIMARY PRODUCTION

Primary production is a major source of meat-borne hazards. Risk assessment utilizing a production-to-consumption approach is likely to illustrate the importance of hygiene activities at this level, but few examples of quantitative modelling are currently available.

Risk management based on quantitative estimates of risk

A risk model may demonstrate that application of a particular measure at primary production will have a significant impact on achieving an ALOP. Where difficulty in verification by a competent authority acts against setting of risk-based regulatory requirements, an industry-led quality assurance programme can be a useful vehicle for voluntary implementation.

Chemical hazards

In general terms, the "safety evaluation" process for chemical hazards in foods utilizes a "notional zero risk" approach and good agricultural practice (GAP)/good veterinary practice (GVP) at the farm level to ensure that residue levels in meat do not exceed the ADI. Monitoring of meat for compliance with MRLs, MPLs, etc., over time, provides verification that the ADI is not exceeded. This is a good practical example of risk management in action. Although the safety evaluation process for chemical hazards can be criticized as an uncertain risk assessment process, the measures that result (GAP and GVP) are intended to deliver a specified ("notional zero risk") level of consumer protection.

Risk management measures for chemical hazards at the level of primary production include marketing authorization, legislation on the delivery and issue of veterinary drugs and agrochemicals, and surveillance or control plans for animals and meat, and come within the competence of the authorities. Some aspects of GAP and GVP in relation to these measures may be verified by the competent authority, e.g. maintaining lists of animal treatments, but industry-led quality assurance schemes are more common vehicles for verification.

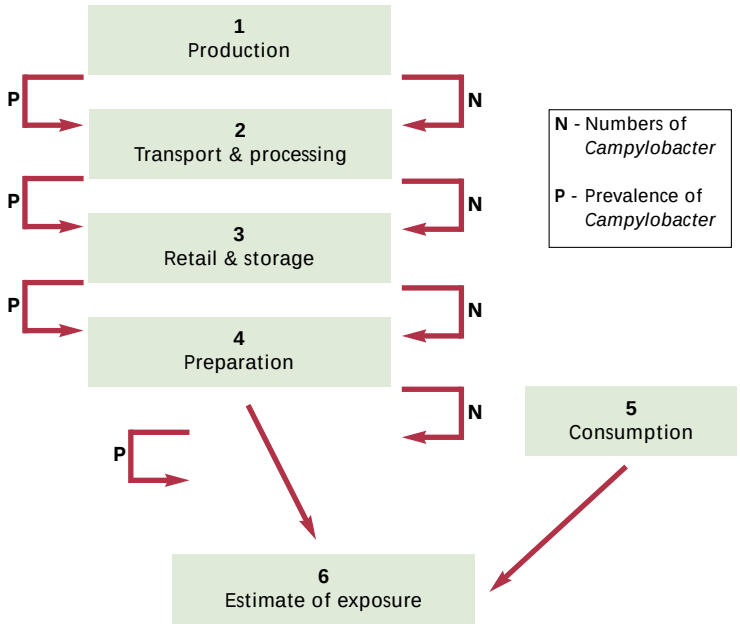
Biological hazards

An international FAO/WHO risk assessment of *Campylobacter* spp. in broiler chickens used modular modelling of the production-to-consumption food pathway to estimate risks to consumers, and to evaluate the impact of different interventions in each module (FAO/WHO, 2003c) (Figure 1.7). A reduction in flock prevalence had a proportional impact in reducing consumer risk and this indicates that any risk management programme that significantly reduces flock prevalence will be of measurable benefit to consumers. The challenge from this work is for regulators to facilitate risk management decisions on an ALOP, and for industry to find practical and cost-effective ways to implement optimal interventions. The model was constructed so that different countries could provide their own inputs and generate appropriate estimates of risk to their own consumers.

In the FAO/WHO risk assessment of *Campylobacter* spp. in broiler chickens, exposure assessment investigated possible pathways for contamination of chickens on the farm, and followed chickens through the various modules of rearing, transport, processing, storage, and preparation and consumption in the home. The level of hazard on the carcass at the end of processing was found to be a composite of *Campylobacter* spp. in the gut of colonized birds and the degree of exterior contamination pre-slaughter.

At the farm level, the effects of between-flock prevalence and within-flock prevalence on risks to consumers were modelled. As very high rates

FIGURE 1.7 **Exposure pathway for risk modelling of *Campylobacter* in broiler chickens**



Source: S. Hathaway, New Zealand Food Safety Authority.

of colonization occur following introduction of the hazard to a flock, avoiding initial contamination is a key mitigation strategy. It was found that reduction in flock prevalence had a proportional impact on reducing consumer risk.

A FAO/WHO risk assessment of *Salmonella* in broiler chickens (FAO/WHO, 2002a) estimated that any measure that sustainably reduced the level of contamination prior to the end of processing would proportionately reduce human illness. This suggests that hygiene measures implemented by industry at primary production level would have significant risk management value. Data inputs were only available from a small number of countries, and it was recommended that individual countries use their own data sets when applying the model.

The FAO/WHO risk assessment of *Salmonella* in broiler chickens characterized the probability of illness in a year owing to the ingestion of *Salmonella* on carcasses that are cooked in domestic kitchens. The model commenced at the end of slaughterhouse processing and included home handling and cooking. Risk estimates were generated for direct (cooked chicken) and indirect (cross-contamination in the kitchen) exposure pathways.

Inability to model the primary production and processing segments of the food chain meant that the impact of individual measures that reduced levels of *Salmonella* during these segments could not be quantitatively linked to changes in risks to consumers. Despite this, a one-to-one relationship was estimated between reduction in levels of contamination of carcasses at the end of processing and reduction in risk to consumers. This indicated that any measure that sustainably reduced the level of contamination prior to the end of processing would proportionately reduce human illness.

The Poultry Food Assess Risk Model developed by the United States Department of Agriculture (USDA) (Oscar, 1999) is a user-friendly tool for prediction of *Campylobacter* and *Salmonella* risks resulting from specified production-to-consumption scenarios. Baseline model settings are provided, and different production and processing scenarios can be modelled by the operator. Additionally, high-susceptibility human populations can be specifically assessed for poultry-borne risks. It is envisaged that this tool will be used by competent authorities and industry to make risk management decisions that could substantially reduce food-borne risks from poultry.

The Poultry FARM Model was used to simulate the use of competitive exclusion technology in the hatchery. The model predicted that there would be a reduction in contamination at the processing plant exit from 20 percent to 8 percent for *Salmonella*, and a reduction in consumer exposure of approximately one-third. This translated into a significant reduction in risks to consumers. In contrast, competitive exclusion technology would not result in any reduction in risks owing to *Campylobacter.*

A quantitative production-to-consumption risk assessment model for Shiga toxin-producing *E. coli* (STEC) O157 was prepared for steak tartare patties (Nauta *et al*., 2001), typically eaten raw or partially raw in Europe. Modelling of the exposure pathway indicated that about 0.3 percent of raw patties were contaminated at the time of consumption, and most of these had only 1 cfu of the pathogen. Although limited data availability rendered the final risk estimate uncertain, the model indicates that reducing

infection at the farm level will have a significant impact on reducing risks to consumers.

Risk management based on qualitative estimates of risk

It is well established that general attention to livestock management, environmental hygiene and transport will limit the numbers of live animals shedding and being contaminated with enteric pathogens such as *Salmonella, Campylobacter* and *E. coli* O157:H7. This can result in a commensurate decrease in pathogen numbers on dressed carcasses. A number of studies have now shown that minimizing the level of inadvertent microbiological contamination with enteric pathogens during processing will reduce meat-borne risks in most situations. A number of interventions have now been recommended on a qualitative understanding that they will reduce food-borne risks.

A range of risk management strategies for reducing risks from *Salmonella* in poultry have been suggested by the Codex Committee on Food Hygiene (CCFH). These include strict quarantine measures to keep breeder flocks free of *Salmonella*, use of probiotics, vaccination and withholding of feed prior to transport to slaughter. The relative value of each intervention is unknown.

The Food Safety and Inspection Service of the United States Department of Agriculture (FSIS USDA) has published guidance on minimizing risks due to *Salmonella* and *E. coli* O157:H7 in red meat, based on the qualitative understanding that reducing carcass contamination is an important risk management goal (FSIS USDA, 2002). A production-to-consumption approach is recommended with interventions in all segments of the food chain. FSIS expects industry to implement HACCP plans for process control that include stricter purchase specifications, more rigorous intervention methods, or a higher frequency of verification. At the production level, FSIS expects slaughter establishments to obtain cattle from farms or feedlots that employ production systems or feedlot controls shown to reduce carriage rates of *Salmonella* and *E. coli* O157:H7.

Risk management measures recommended for *E. coli* O157:H7 by competent authorities in several countries include:

- dietary and feeding practices;
- minimizing faecal contamination of drinking-water;
- probiotics and competitive exclusion bacteria;
- innovative vaccines;
- "Farm Waste Management Plans";
- farmer education.

Risk management based on precautionary approaches

Application of risk management principles by competent authorities may lead to provisional regulatory measures being imposed on a precautionary basis at the level of primary production.

The World Organisation for Animal Health (OIE) International Animal Health Code chapter on BSE provides a good example. A broad range of measures can be applied to animals and animal products in international trade, and many of these are precautionary in nature rather than being determined by quantitative risk modelling. The extent of measures that are required at the national level will depend on the BSE categorization of the country or zone. The extent of the ongoing monitoring and surveillance system for BSE also results from a "risk analysis" of the BSE status of the country or zone.

GHP that facilitates risk management

Aspects of GHP at primary production that facilitate a risk-based approach to meat hygiene include:

- animal identification and trace-back;
- integrated flow of information on hazards;
- official or officially recognized programmes for monitoring of zoonotic hazards;
- specific controls on animal feedstuffs where there is a likelihood of transmission of zoonotic agents.

APPLICATION OF RISK MANAGEMENT PRINCIPLES TO PROCESS CONTROL

Many aspects of slaughter and dressing procedures have the potential to result in significant contamination of meat, e.g. hide/feather removal, evisceration, carcass washing, post-mortem examination, trimming and further handling in the cold chain. Systems for process control should limit microbial cross-

contamination and growth in these circumstances to as low as practicably achievable, and reflect the proportional contribution of these controls in reducing meat-borne risks to human health.

Microbiological monitoring at specific points in the food chain is increasing in importance as a tool for ensuring a risk-based approach to food safety. Specification of risk-based regulatory limits ensures that required levels of consumer protection are achieved, while providing maximum flexibility to industry in terms of the detail of the process control systems that they employ.

Risk management based on quantitative estimates of risk

Chemical hazards

Routine monitoring and surveillance for chemicals, contaminants and residues in meat constitute important risk-based elements of process control. In most situations, these will be the responsibility of the competent authority rather than industry. Monitoring generally will be part of national rather than establishment-specific programmes. The competent authority should apply risk analysis principles in both the design of monitoring programmes and the response to non-complying tests.

Biological hazards

The FAO/WHO risk assessment of *Salmonella* in broiler chickens (FAO, 2002a) estimated that a percentage change in contamination of chickens at the end of processing would result in the same percentage change in risks to consumers. Individual aspects of process control were not modelled, but any intervention that significantly and sustainably reduced levels of *Salmonella* contamination prior to the end of processing would be expected to be an effective risk management measure.

In the FAO/WHO risk assessment of *Campylobacter* spp. in broiler chickens (FAO/WHO, 2003c), relative reductions in risk as a result of different risk management interventions during processing were estimated. The washing-off effect of water chilling was estimated to result in lower risks to consumers compared with those generated from air-chilled chickens, but there was uncertainty around the effect of cross-contamination in chill water. Industry would not be expected to respond to such predictions until high levels of uncertainty can be removed from the model outputs.

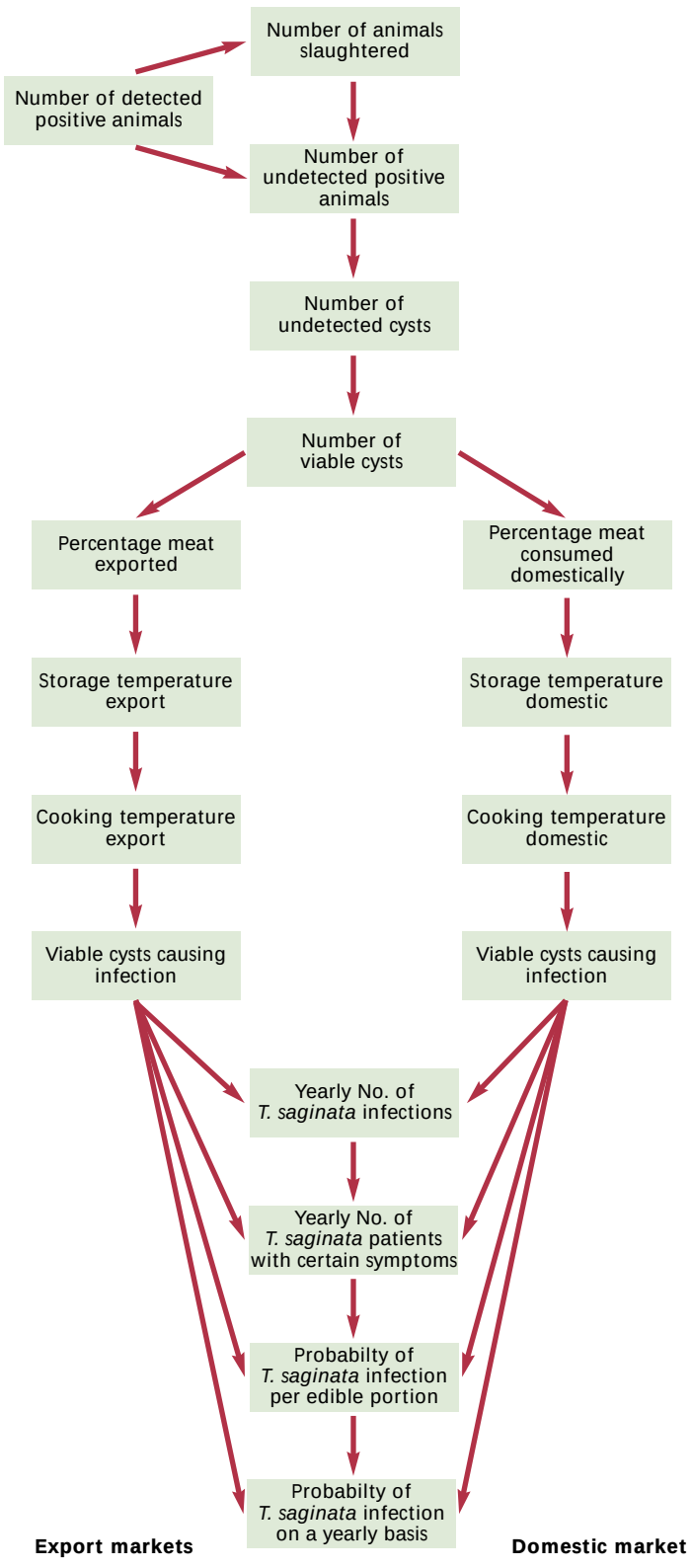
The Poultry FARM model developed by USDA (Oscar, 1999) is a user-friendly tool for prediction of *Campylobacter* and *Salmonella* risks resulting from specified production-to-consumption scenarios. This includes the opportunity to model different process control interventions. In a generic context, simulation of the impact of defined levels of contamination of poultry at the end of processing with subsequent risks to consumers can provide a quantitative basis for risk management decisions.

Modelling of *E. coli* O157:H7 in ground beef hamburgers was used to evaluate three hypothetical intervention strategies (Cassin *et al.*, 1998). A simulated reduction in temperature during retail storage resulted in an 80 percent reduction in the risk estimate and this was much more effective than a risk management measure aimed at educating consumers to cook their hamburgers more thoroughly (predicted reduction of 16 percent). Owing to limited data inputs, further work is needed on modelling this particular hazard/meat product pathway.

A risk assessment model for STEC O157 in steak tartare patties (Nauta *et al.*, 2001) indicates that reducing cross-contamination during process control will have a significant impact on reducing risks to consumers. Specific methods for achieving this were not evaluated in the model.

A draft international risk assessment of *Listeria monocytogenes* in ready-to-eat foods (FAO/WHO, 2002b) estimated risks associated with consumption of fermented meats as a generic food class. The traditional process does not have a lethal processing step, and moderate contamination exists at retail. However, lack of growth and inactivation of existing organisms during storage render risks extremely low compared with other classes of foods, e.g. smoked fish and milk. The risk model demonstrated that almost all cases of food-borne listeriosis result from ingestion of high numbers of pathogens, and existing regulatory standards of zero tolerance or 100 cfu/g could barely be separated in terms of their impact on reducing risks. Adoption of the higher level as a risk-based regulatory limit would facilitate a more targeted risk management response to this food-borne problem, and allow flexibility in terms of the specific interventions employed by industry.

FIGURE 1.8 **Risk model for *Taenia saginata* (human beef tapeworm) in cattle**



Source: S. Hathaway, New Zealand Food Safety Authority.

An important practical outcome of this risk assessment for industry is the need to demonstrate that a particular meat product is stabilized against the growth of *Listeria*. Repeated shelf-life studies at appropriate temperatures may be needed to verify that low levels of *Listeria* at the end of processing will not increase during retail and storage segments of the food chain. Industry would have a choice of the risk management measures it employs to achieve a FSO of less than 100 cfu/g at the time of consumption.

Post-mortem inspection

Post-mortem meat inspection procedures are a unique set of hygiene measures that are part of process control. Traditional inspection procedures are complex and resource-intensive, and a number of recent studies have used a risk assessment approach to determine their relative value in minimizing meat-borne risks. These studies are carried out by competent authorities and scientific institutions rather than industry. A risk-based post-mortem meat inspection programme that is tailored to the particular type and geographical origin of slaughtered animals should achieve essentially the same level of consumer protection as a traditional programme.

Practical outcomes for industry include: organoleptic inspection procedures that are cost-effective and proportional to risk reduction; judgement of the equivalence of different measures; more practical requirements for presentation of tissues by industry; and integration of post-mortem meat inspection into a "production-to-consumption" system for minimizing risks. Principles and guidelines for developing risk-based post-mortem inspection procedures are provided in an annex to the Codex proposed *Draft code of hygienic practice for meat* (FAO/WHO, 2004).

A risk assessment model has been used to investigate the value of traditional post-mortem inspection of cattle for cysts of the beef cestode *Taenia saginata* in New Zealand (Van der Logt, Hathaway and Vose, 1997) (Figure 1.8). These procedures have very low sensitivity in detecting cysts in regions where infection is rare, and the risk model demonstrated that post-mortem inspection has virtually no effect on decreasing the already extremely low risks to human health in the New Zealand situation. As a consequence,

routine incision of the cheeks and tongues of cattle is no longer a regulatory requirement and this markedly reduces head inspection costs and allows meat hygiene activities to be focused elsewhere. If industry does not wish to recover cheek meats, head skinning can be avoided.

Risk management based on qualitative estimates of risk

Biological hazards

FSIS USDA guidance on minimizing risks due to *Salmonella* and *E. coli* O157:H7 (FSIS USDA, 2002) is strongly focused on interventions during process control that minimize carcass contamination. While advocating a production-to-consumption approach, risk management interventions are based to a large extent on hygiene procedures and intervention methods that prevent carcass contamination during dehiding and later process steps. A zero-tolerance for visible faecal contamination is a regulatory requirement that must be achieved by industry, and slaughter premises are expected to include at least one HACCP-based intervention specifically targeted to reduce risks due to *Salmonella* and *E. coli* O157:H7. Innovative risk management options such as hot water and acid washes, steam vacuuming and steam pasteurization are encouraged, and their effectiveness either alone or in combination needs to be validated by industry. Regulatory monitoring limits based on performance criteria are set to ensure adequate process control.

TABLE 1.1 **Risk-based post-mortem inspection procedures for the heads of adult cattle slaughtered in New Zealand**

Tissue	Traditional	Risk-based
External surfaces/oral cavity	V	-
Eyes	V	V
Tongue	V, I	V, P*
Submaxillary lymph nodes	V, I	I
Parotid lymph nodes	V, I	I
Retropharyngeal lymph nodes	V, I	I
Muscles of mastication	V, P, I**	V, P*

V View
P Palpate
I Incise
* Only if intended for human consumption
** Incised according to the potential for infestation with cysts of *Taenia* spp.

Risk management strategies suggested by the CCFH for reducing risks from *Salmonella* in poultry include channelling of meat from infected flocks for heat treatment, decontamination of carcasses and microbiological monitoring. However, current risk models are insufficient to determine the relative value of such measures.

Minimizing contamination with *Campylobacter* is an important part of process control to minimize meat-borne risks according to a qualitative risk management approach. Given that risk models have demonstrated strong correlations between levels of carcass contamination and subsequent risks to consumers, several countries have initiated "evidence-based standard operating procedures" to prevent or minimize contamination during process control (Food Safety Authority of Ireland, 2002). It is interesting to note that risk management interventions such as irradiation and chemical disinfection may be acceptable to consumers in some countries but not in others.

Post-mortem inspection

Competent authorities in several countries have used qualitative risk-based approaches based on comparisons of hazard control to evaluate traditional post-mortem inspection procedures. Outcomes that have been translated into changes in regulatory requirements include "hands-off" carcass inspection for lambs in the United States of America, streamlined inspection of prime cattle in Canada, and visual inspection of the viscera of fattened pigs in Australia. A detailed example of risk-based changes in head inspection procedures for all hazards in cattle in New Zealand is given in Table 1.1.

Risk management based on precautionary approaches

Precautionary risk management measures may be imposed by competent authorities as a component of process control, e.g. routine condemnation of "specified risk materials" and prohibition of mechanically recovered meat, in regions where BSE is present in slaughter populations. These measures may result in considerable costs to industry, and should be regarded as provisional until more science-based measures can be developed.

GHP that facilitates risk management

Many aspects of GHP during process control facilitate a risk-based approach to meat hygiene. The most important of these include:

- hygiene measures that minimize cross-contamination of the carcass during dehiding/defeathering, etc. and subsequent dressing procedures;
- HACCP plans for control of specific hazards;
- product identification and trace-back;
- integrated flow of information on hazards to other segments of the food chain.

APPLICATION OF RISK MANAGEMENT PRINCIPLES TO PRODUCT INFORMATION AND CONSUMER AWARENESS

Risk management based on quantitative estimates of risk

A risk assessment model for *E. coli* O157 for steak tartare patties (Nauta *et al.*, 2001) indicated that while reducing infection at the farm level and minimizing cross-contamination during processing, advocating the consumption of "well done" steak tartare patties is not likely to reduce risks significantly.

The Poultry FARM Model developed by USDA (Oscar, 1999) was used to simulate the impact of improved consumer food practice in the home on reducing *Campylobacter* and *Salmonella* risks. A simulated reduction to 5 percent for rates of temperature abuse, incidence of undercooking and incidence of recontamination of poultry in the home resulted in marked reductions in estimates of risks.

A Food Handling Practices Model developed for the United States Food and Drug Administration Center for Food Safety and Applied Nutrition (FDA/CFSAN) provides a generic quantitative risk assessment tool to estimate the effects of food handling practices on the incidence of food-borne illness (RTI International, 2001). The model can be used for meat as well as a number of other food categories. The impact of retail and household practices on microbiological contamination can be combined with food-source levels of contamination to generate estimates of risk.

Risk management based on qualitative estimates of risk

Risk models for several enteric pathogens indicate that cross-contamination from the raw meat product to other foods in the home is a significant pathway for meat-borne risks to human health. Risk management interventions to avoid this are commonly recommended by competent authorities.

GHP that facilitates risk management

Aspects of GHP that facilitate a risk-based approach to meat hygiene in the home include:

- consumer education in safe food handling practices;
- avoidance of cross-contamination;
- labelling.

Summary

- A risk-based approach to food hygiene has been instituted by both national governments and standard-setting bodies for food in international trade largely as a consequence of the international trade provisions of the WTO SPS Agreement, and in fulfilment of their obligation to justify necessary food hygiene measures using science and risk assessment.
- The practical application of a risk-based approach in meat hygiene requires an understanding of:
  - The "building blocks" of a meat hygiene programme (GHP, HACCP and risk assessment):
    - GHP generally consists of a qualitative description of all practices regarding the conditions and measures necessary to ensure the safety and suitability of food requirements. The requirements are generally prescriptive and describe processes rather than outcomes.
    - HACCP identifies, evaluates and controls hazards that are significant for food safety. The system has designated CCPs at particular steps in the food chain, which may be based on empirical scientific judgement, or on risk assessment.
    - A risk assessment programme entails knowledge of the level of control of hazards that is attained at a particular step in the food chain relative to the expected level of consumer protection. The control points are science- and risk-based regulatory limits, which may either be performance criteria (e.g. allowable levels of microbial contamination, MRLs, zero tolerance for TSEs) or process criteria (e.g. specified time, temperature or dose at a specified process control step).
  - Application of a risk management framework, which includes:
    - preliminary risk management activities: risk profiling, risk assessment policy formulation, risk assessment;
    - evaluation of risk management options: reaching a decision on an ALOP in order to minimize risks using available meat hygiene measures. The meat hygiene measures selected for implementation are determined through risk assessment;
    - implementation of meat hygiene measures: by means of a tailor-made programme based on GHP, or one or more CCPs (HACCP), or regulatory limits or procedures derived from risk assessment;
    - monitoring and review: gathering and analysing data on human health so as to give an overview of food safety and consumer health.
  - Risk assessment: a separate and distinct scientific process commissioned by government in most cases and carried out by national science providers. It involves the four steps of:
    - **hazard identification:** the identification of biological, chemical and physical agents in food capable of causing adverse human health effects;
    - **hazard characterization:** the qualitative or quantitative evaluation of the nature of the adverse health effects, ideally including human dose-response assessment;
    - **exposure assessment:** the qualitative or quantitative evaluation of the likely intake of food-borne hazards by consumers, taking into account other hazard exposure pathways where relevant;
    - **risk characterization:** the qualitative or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of adverse health effects in a given population.
  - Risk management: decision-making on managing meat-borne risks in an optimal way to achieve the agreed level of consumer protection. The decisions are based on data generated by risk assessors on the impact of different measures on minimizing food-borne risks.
  - The different roles of industry, government and other stakeholders in the design and implementation of a meat hygiene programme, e.g.
    - The competent authority should facilitate application of all components of the generic framework for managing risks, set risk-based regulatory requirements as appropriate, and verify that these are being met on an ongoing basis.

  - The industry should be involved in contributing to risk management decisions, implementing meat hygiene programmes and ensuring compliance with regulatory requirements.

- Despite the resource-intensive nature of meat hygiene programmes, assessment of their overall benefit is still limited by the lack of systematic data on the various elements of meat hygiene as they relate to public health.
- To date, application of risk management principles in the meat industry has primarily focused on primary production and process control (including ante- and post-mortem inspection) activities. Simulation modelling of risk management interventions in these areas is available for some hazard/product combinations (e.g. *Campylobacter* and *Salmonella* risk assessment models for broiler chickens; models for *E. coli* species in beef products; and *Listeria monocytogenes* in ready-to-eat foods) but examples of regulatory uptake of outcomes are rare. The limited application of risk assessment models to other areas of meat hygiene to date means that few recommendations on risk-based interventions are available for these activities.
- The Codex proposed *Draft code of hygienic practice for meat* presents "through-chain" guidelines for meat hygiene, up to the point of retail. These generic guidelines are based on GHP, and risk-based concepts are introduced wherever appropriate. The guidelines stress that any risk-based measures that are employed should be matched to the local or national situation.

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