Introduction

Microorganisms in Foods 7: Microbiological Testing in Food Safety Management was written by the International Commission on Microbiological Specifications for Foods (ICMSF/the Commission) with assistance from a limited number of consultants.

Microorganisms in Foods 7 is based upon Part I of *Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and Specific Applications (2nd ed. 1986)*. In the 1980s, control of food safety was largely by inspection and compliance with hygiene regulations, together with end product testing. *Microorganisms in Foods 2* put such testing on a sounder statistical basis through sampling plans, which remain useful at port-of-entry when there is no information on the conditions under which a food has been produced or processed. At an early stage, the Commission recognized that no sampling plan could ensure the absence of a pathogen in food. Testing foods at ports-of-entry, or elsewhere in the food chain, could not guarantee food safety.

This led the Commission to explore the potential value of Hazard Analysis Critical Control Point (HACCP) for enhancing food safety, particularly in developing countries. *Microorganisms in Foods 4: Application of the Hazard Analysis Critical Control Point (HACCP) System to Ensure Microbiological Safety and Quality (1988)*, illustrated the procedures used to identify the microbiological hazards in a practice or a process, to identify the critical control points at which those hazards could be controlled, and to establish systems by which the effectiveness of control could be monitored. In addition, recommendations were included for the application of HACCP from production/harvest to consumption, together with examples of how HACCP could be applied at each step in the food chain.

Effective implementation of HACCP requires knowledge of the hazardous microorganisms and their response to conditions in foods (e.g., pH, a_w, temperature, preservatives). The Commission concluded that such information was not collected together in a form that could be assessed easily by food industry personnel in quality assurance, technical support, research and development, and by those in food inspection at local, state, regional, or national levels. *Microorganisms in Foods 5: Characteristics of Microbial Pathogens (1996)* is a thorough, but concise, review of the literature on growth, survival, and death responses of foodborne pathogens. It is intended as a quick reference manual to assist in making judgements on the growth, survival, or death of pathogens in support of HACCP plans and to improve food safety.

Microorganisms in Foods 6: Microbial Ecology of Food Commodities (1998) is intended for those primarily involved in applied aspects of food microbiology such as

National Beef Ex. 1045
121 of 482

food processors, food microbiologists, food technologists, veterinarians, public health workers, and regulatory officials. Addressing 16 commodity areas, it describes the initial microbial flora and the prevalence of pathogens, the microbiological consequences of processing, typical spoilage patterns, episodes implicating those commodities with foodborne illness, and measures to control pathogens and limit spoilage.

This book, *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management (2002),* illustrates how systems such as HACCP and good hygiene practices (GHP) provide greater assurance of safety than microbiological testing, but also identifies circumstances where microbiological testing still plays a useful role in systems to manage food safety. It continues to address the Commission's objectives to: (a) assemble, correlate, and evaluate evidence about the microbiological safety and quality of foods; (b) consider whether microbiological criteria would improve and ensure the microbiological safety of particular foods; (c) propose, where appropriate, such criteria; (d) recommend methods of sampling and examination; (e) provide guidance on appraising and controlling the microbiological safety of foods.

This book introduces the reader to a structured approach for managing food safety, including sampling and microbiological testing. The text outlines how to meet specific food safety goals for a food or process using GHP and the HACCP system.

The concept of a food safety objective (FSO) is recommended to industry and control authorities to translate "risk" into a definable goal for establishing food safety management systems that incorporate the principles of GHP and HACCP. FSOs provide the scientific basis for the industry to select and implement measures that control the hazard(s) of concern in specific foods or food operations, for control authorities to develop and implement inspection procedures to assess the adequacy of control measures adopted by industry, and for quantifying the equivalence of inspection procedures in different countries.

Microbiological testing can be a useful tool in the management of food safety. However, microbiological tests should be selected and applied with knowledge of their limitations, as well as their benefits and the purposes for which they are used. In many instances other means of assessment are quicker and more effective.

The need for microbiological testing varies along the food chain. Points in the food chain should be selected where information about the microbiological status of a food will prove most useful for control purposes. Similarly, in a food operation, samples may be collected from different points in a process for control purposes.

Finally, a framework is provided by which importing countries can assess whether foods from other countries have been produced in a manner that provides a level of protection equivalent to that required for domestically produced foods.

This book illustrates the insensitivity of even statistically based sampling plans and encourages a rational approach to the use of microbiological testing in systems that manage food safety through GHP and HACCP. Several new chapters are based on the experience of the food industry in controlling salmonellae, *Listeria monocytogenes* and *Escherichia coli* O157:H7, on tightened or investigational sampling, on microbiological testing of the processing environment, and the use of statistical process control to detect trends and work toward continuous improvement.

The book is intended to be useful for anyone who is engaged in setting microbiological criteria for the purpose of governmental or industry food inspection and control. For students in food science and technology it offers a wealth of information on food safety management and many references for further study.

EDITORIAL COMMITTEE

R. B. Tompkin (Chairman)
T. A. Roberts
M. van Schothorst
M. B. Cole
L. Gram
R. L. Buchanan
S. Dahms

ICMSF Members during Preparation of Book 7

Chairman	T. A. Roberts (1991–2000)	M. B. Cole (from 2000)
Secretary	M. van Schothorst	
Treasurer	A. N. Sharpe (1989–1998) F. F. Busta (1998–2000)	J. M. Farber (from 2000)
Members	A. C. Baird-Parker (retired 1999) R. L. Buchanan J.-L. Cordier S. Dahms (from 1998) M. P. Doyle (resigned 1999) M. Eyles (resigned 1999) J. Farkas (retired 1998) R. S. Flowers B. D. G. M. Franco (from 2000) L. Gram (from 1998)	F. H. Grau (retired 1999) J.-L. Jouve A. M. Lammerding (from 1998) S. Mendoza (retired 1998) Z. Merican J. I. Pitt F. Quevedo (retired 1998) P. Teufel R. B. Tompkin

Consultants

J. Braeunig (2000)
S. Dahms (1997, 1998)
P. Desmarchelier (1999)
J. M. Farber (1998)
B. D. G. M. Franco (1998, 1999)
W. Garthwright (1999)
L. G. M. Gorris (2000)
L. Gram (1997, 1998)
H. Kruse (1999, 2000)
A. M. Lammerding (1997, 1998)
B. Shay (1999)
K. Swanson (2000)
A. von Holy (1997)

Contributors

D. Kilsby, R. B. Smittle, J. H. Silliker

Chapter 1

Microbiological Hazards and Their Control

1.1 Introduction
1.2 History
1.3 The Concept of a Food Safety Management System
1.4 Historical Development
1.5 Status of Foodborne Illness: Etiologic Agents or Contaminants
1.6 Practices Contributing to Foodborne Illness
1.7 Importance of Effective Control Measures
1.8 Effectiveness of GHP and HACCP
1.9 Would an FSO Improve Food Safety and Reduce Foodborne Illness?
1.10 Use of FSOs in Food Safety Management
1.11 Performance, Process, Product, and Default Criteria
1.12 Establishment of Control Measures
1.13 Assessment of Control of a Process
1.14 Acceptance Criteria
1.15 Microbiological Criteria
1.16 Microbiological Tests
1.17 Summary
1.18 References

1.1 INTRODUCTION

The purpose of this book is to introduce the reader to a structured approach for managing food safety, including sampling and microbiological testing. In addition, the text outlines how to meet specific food safety goals for a food or process using Good Hygienic Practices (GHP) and the Hazard Analysis Critical Control Point (HACCP) systems.

The International Commission on Microbiological Specifications for Foods (ICMSF/the Commission) is recommending that industry and control authorities adopt the concept of a food safety objective (FSO). This concept translates *risk* into a definable goal for establishing food safety management systems that incorporate the principles of GHP and HACCP. FSOs provide the scientific basis for industry to select and implement measures that control the hazard(s) of concern in specific foods or food operations, for control authorities to develop and implement inspection procedures to assess the adequacy of control measures adopted by industry, and for quantifying the equivalence of inspection procedures in different countries.

Microbiological testing can be a useful tool in the management of food safety. However, microbiological tests should be selected and applied with knowledge of their

National Beef Ex. 1045
124 of 482

limitations, as well as their benefits and the purposes for which they are used. In many instances, other means of assessment are quicker and equally effective.

The text provides guidance to the food industry on how to establish effective management systems to control specific hazards in foods. This approach will similarly be of interest to control authorities with responsibility for assessing whether industry has developed and implemented adequate systems of food safety management.

The need for microbiological testing varies along the food chain. Points should be selected in the food chain where information about the microbiological status of a food will prove most useful for control purposes. Similarly, in a food operation, samples may be collected from different points in a process for control purposes.

A framework is provided by which importing countries can assess whether foods from other countries have been produced in a manner that provides a level of protection equivalent to that required for domestically produced foods.

Guidance is provided for establishing sampling plans based on risk to consumers. In Chapter 8, 15 cases are described that take into account whether the hazard will increase, decrease, or not change between when a food is sampled and when the food is consumed. These same principles are useful for foods at port-of-entry and in domestic situations when the safety and acceptability of a food are uncertain.

1.2 HISTORY

The ICMSF was asked in 1995 by the Codex Alimentarius Committee on Food Hygiene to write a discussion paper on The Management of Pathogens in Foods in International Trade. During its meeting in 1996, the ICMSF concluded that such management should use existing Codex documents and should be in line with the requirements of the World Trade Organization Agreement on the Application of Sanitary and PhytoSanitary Measures (WTO/SPS agreement) (WTO, 1995), which stated that foods could freely be imported if they would not endanger the country's appropriate level of (consumer) protection (ALOP). In the same agreement, risk assessment was identified as a tool to determine whether a food would or would not endanger the ALOP. How an ALOP needed to be expressed or how it should be established was not elaborated on in the agreement.

A procedure for microbiological risk assessment was already described in a Codex document. Other documents in the Codex system included the General Principles of Food Hygiene, with its annex on HACCP, and the Principles for the Establishment and Application of Microbiological Criteria for Foods.

The ICMSF recognized that it would be difficult for the food industry to prove that a product would meet the ALOP of an importing country if that ALOP was expressed in terms such as "the number of illnesses per 100,000 of a population, caused by a hazard/food combination." However, the Codex tools to ensure the safety of the food were the GHP and HACCP systems.

In the HACCP system, hazards are controlled by their elimination from the food or reduction to acceptable levels. It was the Commission's understanding that these acceptable levels would not endanger the ALOP. However, as long as an ALOP was not expressed as "the level of a hazard in a food which would be acceptable," the industry would not know what the acceptable level in the HACCP system would be. The ICMSF thus felt the need to develop the concept of an FSO, following the concept of *quality objectives* in quality assurance and quality management standards (Jouve, 1992) and the introduction of FSOs in broad terms (Jouve, 1994, 1996). At that time, the same wording had

been proposed at congresses to express some form of justification for sanitary measures with respect to determining equivalence, and later in refereed publications (Hathaway, 1997; Hathaway & Cook, 1997).

The intention was that the FSO would convert the ALOP or acceptable (tolerable) level of risk (number of illnesses) into the maximum frequency and/or concentration of a hazard considered to be tolerable for consumer protection. That FSO could then be translated into the performance of a food process that would ensure that, at the moment of consumption, the level of the hazard in a food would not be greater than the FSO. Risk assessment was considered to be helpful in establishing the FSO, because the risk characterization would be expressed as "the estimated number of illnesses per year," in terms similar to the ALOP. Moreover, risk assessment could be used to select control measures that would ensure that the FSO would be met.

Consequently, in 1996, the ICMSF recommended to the Codex secretariat that a stepwise procedure should be used to manage pathogens in foods. The first step would be to perform a microbiological risk assessment; the second step would be to develop an FSO. Step three should confirm that the FSO would be technically achievable by the application of GHP and HACCP. Step four was the establishment of microbiological criteria, when there was a need, and step five was establishing other acceptance criteria for foods in international trade.

In 1997, an additional step was introduced between steps one and two, i.e., the use of the newly developed concept of risk management. Through the introduction of this step, it was recognized that the establishment of an FSO was not only a scientific risk assessment exercise, but also a societal decision in which the various stakeholders (consumers, industries, etc.) should participate.

At the same time that the FSO concept was brought into discussion in the Codex Alimentarius Committee on Food Hygiene, the term *food safety objectives* was also introduced in the Codex Committee on Import and Export to deal with the outcome of all kinds of sanitary measures. This situation has led to great confusion about the nature of FSOs, why they are needed, what they should accomplish, etc. The Codex Alimentarius Commission finally decided in 2000 that the term FSO would no longer be used in the broader sense, but would only be used by the Codex Committee on Food Hygiene for its own purposes. In 2001, that Committee agreed upon a definition of an FSO as an initial step toward incorporating the concept into its future recommendations.

The ICMSF decided that in the present revision of ICMSF Book 2 (ICMSF, 1986), the FSO concept should be introduced as the basis for establishing a food safety management system. Discussions within the ICMSF of how an ALOP should be developed, the use of risk assessment within food safety management, and the use of FSOs and how they would be established concluded that establishing FSOs should be broader than just converting an ALOP into a level of a hazard in a food. It was also recognized that a full risk assessment, according to the Codex procedures, would in many cases not be necessary to determine control measures required to meet an FSO, but that an expert panel and a less detailed risk evaluation would often suffice.

Although the FSO concept was originally linked to the ALOP concept as described in the WTO/SPS agreement, it was later recognized that the Codex not only had the task of producing procedures and guidelines that could be used by WTO, but that it also should help nations to improve their food safety. In this light, the food safety objectives were not only seen as levels of hazards that were already achieved in a country, but also as levels that should be achieved as part of a food safety enhancement program. This

situation has also led to confusion. On the one hand, a country cannot ask of an exporting country that the exported foods should meet higher requirements (more stringent FSOs) than are achieved in the importing country. Such FSOs would merely reflect the status quo. On the other hand, FSOs used in food safety enhancement program within a country should be regarded quite separately from FSOs used to manage foods in international trade.

The ICMSF recognizes this situation and recommends that FSOs can be used for both purposes, and that governments establish them to communicate to industries the maximum level of a hazard in a food that must not be surpassed. The ICMSF recommends that FSOs should be established on the basis of epidemiologic evidence that a certain level of a hazard in a food does not cause an intolerable public health problem. If evidence exists that a certain level of a hazard in a food is indeed unacceptable, lower levels should be set if they can be obtained by control measures that are technically achievable with acceptable costs. How FSOs for the various purposes should be established might vary from situation to situation. In this book, the ICMSF gives some general guidelines.

1.3 THE CONCEPT OF A FOOD SAFETY MANAGEMENT SYSTEM

Chapters 2–5 describe in detail a sequence of activities for establishing a comprehensive food safety system, as summarized in Figure 1–1. The respective roles of industry and government are described because it is through their collective activities that effective food safety systems are developed and verified. A series of steps is described.

Risk managers in government use epidemiologic evidence to link human illness with a microbiological agent and, if possible, a food. A decision is then made that a new policy is needed to prevent or reduce future illnesses of the same nature or to prevent deterioration of public health, e.g., through imported foods. Additional information may be required to understand better the options available for control. Depending on urgency, severity, risk, likelihood of further occurrences, the hazard-food combination, and other factors, risk managers may establish an expert panel to develop recommendations or ask risk assessors to perform a risk profile.

If possible from available information, risk managers in government, with input from other stakeholders, perform an evaluation to decide whether an FSO should be established that will reflect existing or improved control of the hazard-food combination. Using information obtained from epidemiologic studies, knowledge of the hazard, and conditions leading to foodborne illness, risk managers in government develop an FSO for the hazard-food combination, i.e., the maximum frequency and/or concentration of a microbial hazard in food considered tolerable for consumer protection.

Risk managers in industry and government assess whether the FSO, communicated in verifiable terms, is achievable with current or improved technologies, processes, and practices. FSOs define the level of a hazard at the moment of consumption. This implies that preparation and use should be an integral part of the food safety management considerations.

If the FSO is achievable, the next step is to establish criteria that can be used to assess whether the control measures will control the hazard and meet the FSO. The criteria may consist of performance criteria (e.g., 5D kill, no greater than a 100-fold increase in numbers), process criteria (e.g., 71 °C for 2.5 minutes), or product criteria (pH, a_w). The criteria are met through application of GHP and HACCP, including procedures for monitoring to ensure or check control, while taking account of process variability (see Chap-

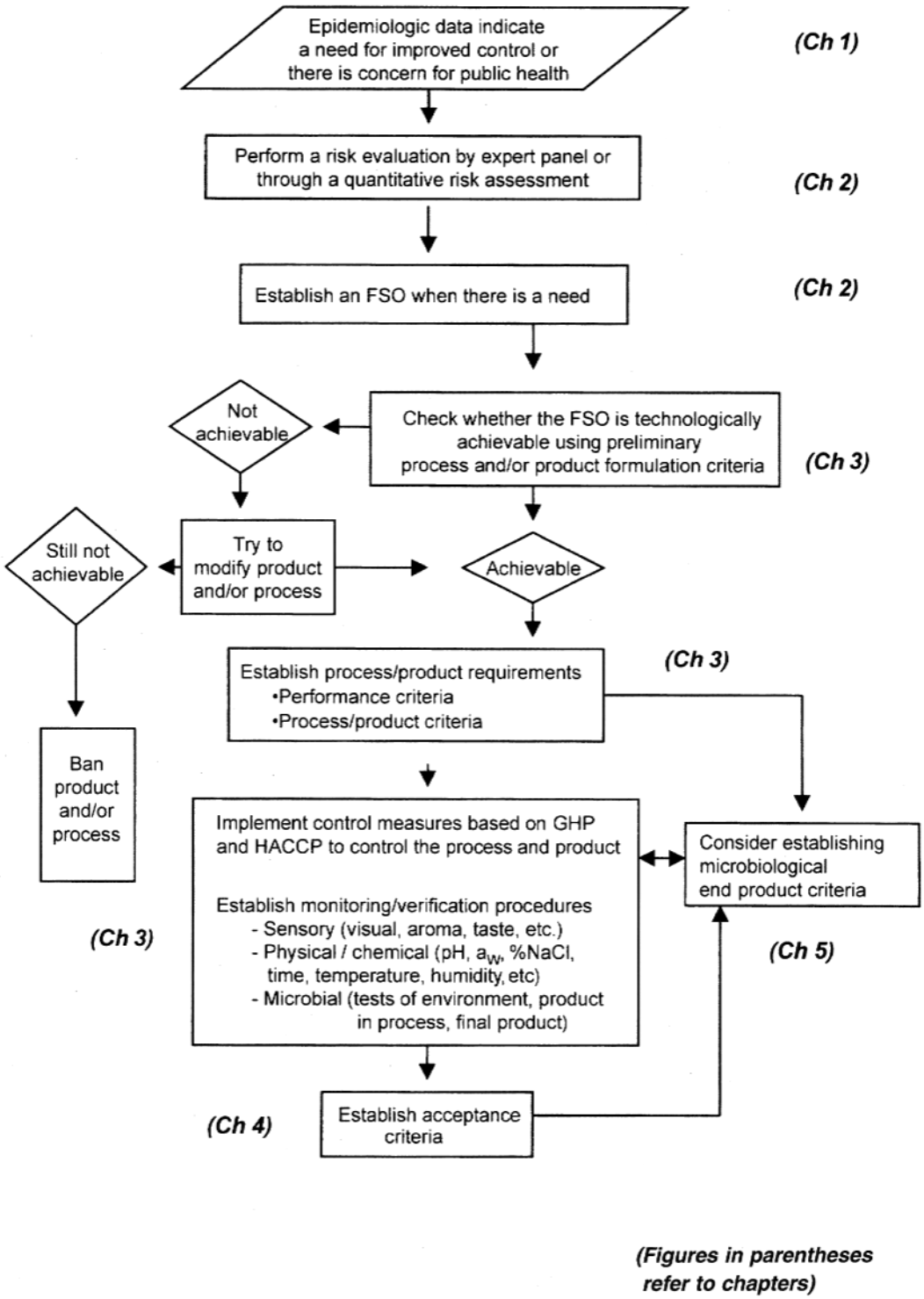


Figure 1–1 Proposed scheme for managing the microbiological safety of food.

ter 13). If knowledge is lacking and process or product criteria cannot be soundly based, default values may be used to ensure food safety. Those values are often conservative, e.g., very low pH or a_w, a severe heat treatment.

The foregoing criteria should be incorporated into auditing/inspection procedures to assess the adequacy of an operation to control the hazard(s) and meet established FSOs. In addition, lot acceptance criteria should be established that are based on parameters of the food that determine whether a hazard is controlled (e.g., pH, a_w) and, if judged appropriate, microbiological criteria.

If the FSO is judged to be *not* technically achievable, the options are to:

- reassess the FSO,
- modify the process or product and its use to achieve the FSO,
- ban the product/process, or
- establish acceptance criteria for assessing the adequacy of an operation to control the hazard(s) and meeting established FSOs and, if appropriate, establish lot acceptance criteria based on parameters of the food that determine whether a hazard is controlled (e.g., pH, a_w) and, if judged appropriate, microbiological end product criteria.

1.4 HISTORICAL DEVELOPMENT

Microbiological criteria for foods in international trade are addressed in the joint Food and Agriculture Organization/World Health Organization (FAO/WHO) food standards program, as implemented by the Codex Alimentarius Commission (CAC, 1997). That program (established in 1962, the same year as the constitution of the ICMSF) was the direct result of conflict between national food legislation and the general requirements of the main food markets of the world. Serious non-tariff obstacles to trade were caused by differing national food legislation. At that time, the Commission's objectives were to develop international food standards, Codes of Practice and guidelines, anticipating that their general adoption would help to remove and prevent non-tariff barriers to food trade.

Several aspects of food control are covered in Codex standards and Codes of Practice, including composition, labeling, additives, and hygiene. Subsidiary bodies of the Commission, the Codex committees, develop the standards and codes. Although the period from drafting a standard or code to its adoption is lengthy (normally four to five years), the system has worked well, and many international food standards and codes of practice have been established. Others are being developed. The Codex Committee on Food Hygiene (CCFH) has the major responsibility for all provisions on food hygiene in Codex documents, including microbiological criteria and codes of hygienic practice (effectively, good hygienic practices (GHP)). The CCFH needs expert advice in dealing with highly specialized microbiological matters and especially in developing microbiological criteria. Such advice has been provided by the ICMSF through its publications on sampling plans and principles for the establishment and application of microbiological criteria for foods and several other discussion papers (CAC, 1997; ICMSF, 1998b).

The microbiological safety of food is principally ensured by selection of raw materials, control at the source, product design and process control, and the application of GHP and HACCP during production, processing, distribution, storage, sale, preparation, and use. This comprehensive preventive system offers much more control than end-product testing. Examples of measures that have successfully controlled foodborne hazards are given in Table 1–1.

Table 1–1 Measures That Have Successfully Controlled Foodborne Hazards

	Hazard	*Control measures*	*Other measures*
Bacteria	*B. cereus*	Time-temperature control during cooking, cooling, and storage	
	brucellae	Eradication of brucellosis	Animal health
	Campylobacter (thermophilic)	Raw material selection, avoid cross-contamination	GHP
	C. botulinum (proteolytic strains)	Retorting, acidification, low water activity	HACCP
	C. botulinum (non-proteolytic strains)	Cooking, time-temperature control, pH and a_w of products	HACCP
	C. perfringens	Time-temperature control during cooking, cooling, and storage	HACCP
	E. coli (pathogenic)	Cooking, controlled fermentation and aging, chilled storage, avoid recontamination	GHP
	L. monocytogenes	Cooking, controlled fermentation and aging, chilled storage, avoid recontamination	GHP
	M. bovis	Eradication of TB in cattle, pasteurization of milk	
	Salmonella (non-typhoid)	Cooking, controlled fermentation and aging, chilled storage, avoid recontamination	GHP
	S. typhi	Personal hygiene	
	Shigella	Cooking, water quality, waste water management, personal hygiene	
	S. aureus	Cooking, controlled fermentation and aging, chilled storage, avoid recontamination	GHP
	V. cholerae	Water quality, waste water management, personal hygiene	GHP
	V. parahaemolyticus	Raw material selection, avoid eating raw fish	GHP, HACCP
	V. vulnificus	Avoid certain foods	
	Y. enterocolitica	Separation of raw from ready-to-eat, extra hygiene at slaughter	GHP

continues

National Beef Ex. 1045
130 of 482

Table 1–1 continued

	Hazard	*Control measures*	*Other measures*
Viruses	Hepatitis A	Water quality, personal hygiene, consumer education	Controls at harvesting
	Norwalk and other SRSVs	Water quality, personal hygiene, consumer education, cooking	Controls at harvesting
Parasites	*Trichinella spiralis*	(at farms) limit access to farms, rodent control, freezing, cooking, control at slaughter for animals at risk (outdoor farmed pigs, game, esp. wild boars), freezing, cooking	Animal health
	Toxoplasma gondii	Meat: freezing, cooking; vegetables: wash thoroughly	
Toxigenic fungi	*Aspergillus, Fusarium, Penicillium* spp.	Raw material selection, sorting, dry storage, dehydration	GHP
Seafood toxins	Ciguatera	Controls on harvesting, consumer education	GHP, HACCP
	Scombroid poisoning	Hygiene, temperature control	GHP
	Shellfish intoxication	Controls on harvesting, consumer education	

National Beef Ex. 1045
131 of 482

Microbiological testing is time-consuming, often lacks sensitivity and specificity, and the levels of sampling routinely applied have a low probability of detecting defective lots when the proportion of defectives within the lot is low (see Chapters 6–7). Recognizing the limitations of end-product testing to ensure microbiological safety at port-of-entry, the ICMSF proposed a system of verification based on the use of GHP in combination with the HACCP system as a more reliable means of assuring product safety in the modern food industry (ICMSF, 1988).

Much of the information needed in HACCP to judge whether microorganisms grow, survive, or die during food processing, distribution, and use is contained in the scientific literature, but this information is not organized in a way that is convenient for those in the food industry needing to use that information. Hence, the ICMSF compiled published information that was judged by experts to be reliable in a series of easily used tables (ICMSF, 1996). This was a conscious step towards promoting the newly emerging concept of food safety management systems, based on Codex documents. The ICMSF then recognized that much of the information in the ICMSF Book 3 (1980a,b) was out of date and did not consider the newly emerged pathogenic bacteria, such as *Listeria monocytogenes* and *Campylobacter jejuni/coli*, or many of the newer processes used in food manufacture. Consequently, the ICMSF updated its reviews of commodities in ICMSF Book 6 (1998a), but deliberately omitted consideration of sampling plans and microbiological criteria to emphasize that food management systems were replacing the earlier approach of end-product testing and offered better control of microbiological hazards. That evolution of management systems continues in this book, with end-product testing merely one of several components of ensuring food safety. Different types of sampling plans are considered, some more intensive than attributes plans used at port-of-entry, and intended for use when attempting to identify a problem and its source.

1.5 STATUS OF FOODBORNE ILLNESS: ETIOLOGIC AGENTS OR CONTAMINANTS

1.5.1 Bacteria

Periodically, overviews summarize trends in foodborne disease (CAST, 1994, 1998; POST, 1997; Bean *et al.*, 1990, 1997). Diseases caused by foodborne pathogens constitute a worldwide public health problem (Tauxe, 1997; WHO, 1997) influenced by demographics, industrialization and centralization of food production and supply, travel and trade, and microbial evolution and adaptation. The symptoms of foodborne illness range from mild to severe gastroenteritis, to life-threatening disease. Foodborne disease is commonly acute, but also can become chronic with long-term sequelae. In industrialized countries, the most common causes of foodborne illness are salmonellae, *Staphylococcus aureus*, *Clostridium perfringens*, and *Vibrio parahaemolyticus*, with thermophilic *Campylobacter* spp. assuming greater importance (Altekruse *et al.*, 1999). Until the mid-1990s in many countries, the combined annual number of outbreaks of illness attributed to *Salmonella* spp., *S. aureus*, and *C. perfringens* often represented 70–80% of the reported outbreaks due to bacteria. *C. jejuni/coli, E. coli* O157:H7, *L. monocytogenes* and *Cyclospora cayetanensis* were not recognized as pathogens 20 years ago (Mead *et al.*, 1999).

Salmonellae have for many years been considered the most important foodborne pathogens worldwide. Foods implicated in outbreaks of salmonellosis include meat and poultry, eggs and egg products, milk and milk products, fresh produce (de Roever, 1998), and spices. In many countries, *Salmonella enteritidis* [*Salmonella enterica* serovar Enteritidis]

in poultry and in eggs increased greatly from the mid-1980s to become a serious problem, but outbreaks and sporadic cases attributed to this pathogen have apparently declined in the UK from 1996–1997 (ACMSF, 1993, 1996, 2001).

In recent years, the incidence of disease caused by thermophilic *Campylobacter* spp. has exceeded that due to salmonellae in some industrialized countries. Outbreaks of campylobacteriosis are rare, most cases being sporadic, and commonly attributed to undercooked poultry or cross-contamination from raw poultry. Other foods, untreated water, and raw milk also have been implicated (Altekruse *et al.*, 1999).

In countries where raw fish is an important part of the diet, disease caused by *V. parahaemolyticus* is frequent. Occasional outbreaks occur in western countries, but there the vehicle of transmission is usually processed rather than raw seafoods. *Vibrio cholerae* is endemic in many tropical countries, and water plays a major role in the epidemiology of cholera.

Shigella spp. also represent an important public health problem in many developing countries. Cases of shigellosis reported in developed countries are often associated with traveling, food handlers, and day care centers. Because the reservoir of *Shigella* spp. is restricted to humans, the source of infection is food or water contaminated by human carriers.

Disease caused by *Yersinia enterocolitica* occurs worldwide and has been primarily associated with the consumption of raw or undercooked pork.

Escherichia coli strains are a common part of normal microbial flora of animals, including humans. Most strains are harmless, but some cause diarrhea. Strains carrying particularly virulent properties have emerged as a serious hazard, with consumption of even low numbers of these organisms bearing a risk for life-threatening illness. During the last two decades, enterohaemorrhagic *E. coli* (EHEC), producing verocytotoxins (VTs), also called Shiga-like toxins (SLTs), have emerged as a serious foodborne hazard. Many different serotypes of *E. coli* produce VTs or SLTs. Initially, most human outbreaks were due to *E. coli* O157:H7, although in Australia serogroup O111 is the most common cause of illness. Human illness has now been associated with many verocytotoxin-producing serotypes of *E. coli*. Human cases of EHEC were initially associated with consumption of undercooked ground beef (Bell *et al.*, 1994) and, occasionally, unpasteurized milk. Outbreaks have also been traced to unpasteurized apple juice ("apple cider" in the US), vegetable sprouts (Mahon *et al.*, 1997), yogurt, fermented sausage, water, and contact with farm animals (Doyle *et al.*, 1997).

Disease caused by *L. monocytogenes* is not frequent, but can be severe, with a high mortality rate in populations at risk, such as infants, pregnant women, and the immunocompromised. The bacterium is ubiquitous. Foods implicated in outbreaks have included products made from raw milk, butter, ready-to-eat meat products, surimi, smoked mussels and trout, and vegetables.

Botulism occurs relatively infrequently, but remains a serious concern because of the life-threatening nature of the disease and the impact on trade of the incriminated product type. For many years, commercially processed foods were less frequently involved than home-canned or home-prepared foods, but more recently several commercially prepared products have been implicated. Faulty processing and/or inappropriate storage temperatures have been the most common reasons for botulism, with home-processed foods and foods mishandled in food service establishments also responsible. For example, hot sauce containing jalapeño peppers prepared without adequate heating, potato salad prepared with foil-wrapped baked potatoes previously stored at room temperature, sautéed onions

in butter stored unrefrigerated and then served on a sandwich, and tiramisu-mascarpone cheese.

With improved refrigerated storage during food distribution and use, *S. aureus* and *C. perfringens* now cause illness only when there has been temperature abuse. Also with improved refrigeration, the shelf-life of many foods has lengthened, leading to a new concern that psychrotrophic pathogens may increase to dangerous levels without spoilage being evident to the consumer. Microorganisms of most concern are nonproteolytic strains of *C. botulinum* types B, E, and F, *L. monocytogenes* and *Y. enterocolitica*, all of which cause little or no deterioration of the food supporting their growth.

Other foodborne bacterial pathogens include *Streptococcus pyogenes*, *Mycobacterium tuberculosis*, *Brucella abortus*, and *Bacillus cereus*.

1.5.2 Viruses

Hepatitis A virus and viruses known as Small Round Structured Viruses (SRSV), including Norwalk virus, are known causes of foodborne illness. Viruses are occasionally involved in large outbreaks (Weltman *et al.*, 1996), but the true extent and importance of viruses in foodborne illness has not been adequately assessed (ACMSF, 1995). Mead *et al.* (1999) estimated that viruses are more important than bacteria and protozoa as a cause of foodborne illness. As methods of detection improve and national initiatives on surveillance and ascertainment are intensified, SRSVs have been recognized as the most important cause of nonbacterial gastroenteritis throughout the world (Caul, 2000). Live bivalve molluscs are often implicated in viral foodborne disease outbreaks (Halliday *et al.*, 1991).

1.5.3 Protozoa

Foodborne protozoa have also been incriminated in large outbreaks, e.g., *Cryptosporidium parvum* from apple juice and water (Osewe, 1996), and *Cyclospora cayetanensis* from raspberries, lettuce, and water (Speer, 1997). In immunocompromised persons, diarrhea may be severe, making the illness serious and difficult to treat. Large outbreaks in North America have had a huge impact on international trade in soft fruit and salad vegetables because if present on the initial crop, these protozoa are almost impossible to eliminate. Illness due to *Toxoplasma gondii* is also much more serious in immunocompromised persons and pregnant women. Sporadic cases of protozoal infection have been linked to consumption of undercooked meat or fish products.

1.5.4 Seafood Toxins

Disease caused by histamine and other biogenic amines can arise from several foods, notably scombroid fish species. In North America, illness attributed to histamine is the second most common disease from fish, excluding shellfish (MMWR, 2000).

The principal intoxications having a microbiological origin in seafoods include paralytic shellfish poisoning (PSP), diarrhetic shellfish poisoning (DSP), neurotoxic shellfish poisoning (NSP), amnesic shellfish poisoning (ASP) (also known as domoic acid poisoning), ciguatera, and scombroid (histamine) fish poisoning. PSP, DSP, and NSP are caused by toxins produced by dinoflagellates, and ASP by a diatom. All these diseases typically result from consumption of bivalve mollusks that have been feeding on the tox-

igenic algae. The toxin(s) causing ciguatera are derived from toxigenic microalgae growing in and around tropical coral reefs and passed up the marine food chain through herbivorous reef fish to more far-ranging carnivorous species. Humans typically become intoxicated from eating the toxic fish. Histamine or scombroid poisoning is caused by consumption of fish containing high levels of histamine (and other biogenic amines) resulting from histidine dehydrogenase activity of bacteria multiplying on the fish after death. With the exception of histamine and other biogenic amines, toxin accumulation is passive. All the seafood toxins are resistant to heating and, therefore, cannot be destroyed by cooking. They are undetectable organoleptically (ICMSF, 1996; Liston, 2000; Whittle & Gallacher, 2000).

1.5.5 Toxigenic Fungi

Mycotoxins that have a role in human disease are toxic metabolites produced by common fungi when they grow in susceptible crops. The most important compounds are aflatoxins, produced by *Aspergillus flavus* and *A. parasiticus* in peanuts and maize, which cause primary liver cancer and are responsible for many deaths annually, especially in developing countries. A role in human disease is also probable for fumonisins, produced by *Fusarium verticilloides* and *F. proliferatum* during growth in maize, which have been implicated in human esophageal cancer. Other mycotoxins with a role in human disease include ochratoxin A, produced by *Aspergillus ochraceus* in stored foods, *A. carbonarius* in grapes and grape products, and *Penicillium verrucosum* in cereals, which probably has a role in kidney disease in wide areas of Europe. Trichothecene toxins, produced by *Fusarium graminearum* and related species in cereals, cause immunosuppresssion and consequently have an ill-defined but potentially important role in reducing disease resistance. Some evidence indicates that aflatoxins are also immunosuppressive; these compounds are widespread in foods in some countries and may have an important but largely unsuspected role in susceptibility to a wide variety of diseases.

1.5.6 Surveillance of Foodborne Disease

Although foodborne infections have been recognized as a major cause of human illness for many years, the true incidence remains unknown (Motarjemi & Käferstein, 1997; Clark *et al.*, 2000). In Canada and the US, for example, the number of cases and outbreaks that actually occur is estimated to be many times greater than the reported figures (Todd, 1996, 1997; Buzby & Roberts, 1997; Mead *et al.*, 1999). Recent studies of infectious diseases estimating the extent of underreporting include Notermans & Hoogenboom-Verdegaal (1992) for the Netherlands, and Wheeler *et al.* (1999) and FSA (2000) for England.

Such underreporting is unfortunate, for in addition to providing a continuing assessment of trends in etiologic agents and food vehicles, as indicated above, prompt reporting and investigation of outbreaks provides for (a) identification and removal of contaminated products from the market, (b) correction of faulty food-preparation practices in food-service establishments, processing plants, and homes, (c) identification and appropriate treatment of human carriers of foodborne pathogens, (d) possible detection of new agents of foodborne disease, (e) a better understanding of the effectiveness of regulatory policy and/or its implementation, and (f) improved understanding of the epidemiology of various pathogens.

Common systems for detecting and monitoring foodborne illness are essential for identifying trends in different countries. In the US, there was a decline in foodborne illness in 1999 compared with 1996–1998 (MMWR, 2000), primarily due to decreases in campylobacteriosis and shigellosis, with salmonellosis not changing. In the UK, campylobacteriosis has remained at approximately the same level since 1995, while cases due to *S. enteritidis* and *S. typhimurium* have declined dramatically since 1997 (www.phls.co.uk). Campylobacteriosis has become recognized as the most common cause of bacterial foodborne illness in many developed countries. Also, the predominant salmonellae strains vary with each country, but for the past 5–10 years the two mentioned have been of greatest concern worldwide. The data for the UK may not apply to the US or to other countries. Each country tracks all the strains of salmonellae and may show a figure for trends for the top one or two or all of them. A greater awareness worldwide of foodborne diseases and consumer concerns points to the need for more effective control measures using internationally accepted methods of risk management.

1.6 PRACTICES CONTRIBUTING TO FOODBORNE ILLNESS

A relatively low proportion of illness is traced back to a particular food. Where that has been possible, the common contributory factors are very similar in different countries. For example, inadequate thawing prior to cooking occurred on numerous occasions with large Christmas turkeys. The subsequent cooking failed to kill salmonellae in the center of the partially thawed bird, resulting in salmonellosis.

Inadequate temperature control after cooking includes preparation too far in advance of consumption; storing at warm ambient (not refrigeration) temperatures; and attempting to cool large amounts of heated food that cannot be cooled quickly, resulting in growth of surviving bacteria during the slow cooling, and consumption without reheating above ca 63 °C to kill the vegetative cells of, e.g., *Bacillus cereus* in rice or *C. perfringens* in meat or gravy.

Contamination of a cooked, safe food with microorganisms from raw food has resulted in illness, e.g., at barbecues.

1.7 IMPORTANCE OF EFFECTIVE CONTROL MEASURES

An effective food safety management system almost always comprises a number of control measures, such as raw material selection, hygienic handling prior to a process, correct application of the process, and GHP during and subsequent to processing (see Chapter 3).

At the industrial level, heat processes have been developed for low-acid canned foods to control *C. botulinum* spores. Less severe heat processes are adequate for acid or acidified foods (pH 4.5 or below) because *C. botulinum* spores are unable to multiply at those low pH values.

Spores of *C. perfringens* in beef survive most cooking processes and are able to multiply if the cooked meat is held at suitable temperatures. Growth is minimized by cooling quickly through the range of temperatures supporting growth (50–15 °C).

At the catering level, other controls can be applied. *Escherichia coli* O157:H7 occurs sporadically in ground (minced) beef used in hamburgers. Heating sufficiently will eliminate the hazard, and appropriate heat processes have been developed to ensure that the center of the meat patty reaches a temperature that is lethal to pathogenic *E. coli*, taking

account of the weight, thickness, and initial temperature of the patty, the temperature of the grill, and the duration of cooking.

To prevent salmonellosis from *S. enteritidis* in eggs at the domestic level, vulnerable persons, such as the elderly and the immunocompromised, should consume only eggs that have been cooked until the yolk is solid, or use a commercially pasteurized product. Numerous cases of salmonellosis have been traced to using raw eggs in homemade mayonnaise and tiramisu. Handling raw poultry in the kitchen can spread thermophilic *Campylobacter* spp. to other working surfaces. Hands should be washed frequently and thoroughly after handling raw poultry.

1.8 EFFECTIVENESS OF GHP AND HACCP

HACCP has proven very effective as a control system for many food processes, especially those with a step that eliminates the hazard (e.g., canning of low-acid foods, cooking to eliminate salmonellae or *L. monocytogenes*), or foods that are formulated to prevent microbial multiplication (e.g., low a_w, low pH). Of greater concern are processes that contain no step that can prevent or eliminate a known hazard.

Reporting foodborne illnesses in the media and prompt distribution of information via the Internet fuel public perception that food safety is declining. In reality, today's food safety systems are stronger than ever before due to better implementation of GHP and HACCP. Where records are available, the majority of recalls are due to failures to adhere to GHP, rather than in failures in the GHP/HACCP plans. In addition improved laboratory and detection methods allow better recognition of potential problems, possible agents, and hazard-food combinations. Hence the safety of foods is improving, despite recognizing new agents and new hazard-food combinations. Some new pathogens force reconsideration of traditional control measures, e.g., VT-producing *E. coli*, present sporadically and usually in low numbers in cattle, are difficult to detect and control. When new agents are recognized, government and the food industry respond to control them, but the consumer must also recognize that it may take time to understand the conditions leading to illness and the changes necessary to control them.

The current trends in food processing—to reduce the extent of heating, to minimize the use of chemical preservatives, and to provide foods that require little or no preparation or are ready-to-eat and consequently not subjected to heating prior to consumption—all increase the likelihood of pathogens reaching the consumer. Even with the greatest care in agricultural practices, it is not possible to eliminate all pathogens from raw agricultural and seafood commodities. In ICMSF Book 4 (1988), critical control points (CCPs) were divided into those that eliminate the hazard, CCP1, and those that can reduce but cannot prevent or eliminate the hazard, CCP2. Many HACCP plans would be better understood if that differentiation were reintroduced.

1.9 WOULD AN FSO IMPROVE FOOD SAFETY AND REDUCE FOODBORNE ILLNESS?

Although HACCP plans are now more widely implemented, the main weaknesses are that the level of control needed is not stated clearly, and there is little or no guidance on what is expected of an adequately designed and implemented HACCP plan. This omission is widespread in documents prepared by Codex, many advisory groups, and in governmental regulations. An FSO would indicate the level of control needed for adequate GHP and HACCP systems.

Another issue of concern in relation to food safety management is the continued indiscriminate use of microbiological testing of the end products. That testing is usually inadequate in terms of sampling and the number of samples tested and often poorly targeted in terms of the hazard(s) most likely in the particular product. With the integration of HACCP and GHP in the 1990s, there has been no decrease in end-product testing that might have been expected with increased control. If anything, such testing has continued to increase.

No risk management options will provide absolute safety (i.e., there will always be some risk).

1.10 USE OF FSOs IN FOOD SAFETY MANAGEMENT

When considering the level of tolerable risk for a given hazard-food combination, risk managers should seek input from risk assessors and stakeholders, such as the affected industry and consumers. Risk is an estimate of the probability and severity of the adverse effects in exposed populations that may result from a hazard in a food. The ALOP is the achieved or achievable level proposed following consideration of public health impact, technological feasibility, economic implications, and comparison with other risks in everyday life.

Food operators cannot address an objective that states, for example, "there shall be no more than 20 domestic cases of a certain foodborne illness per 100,000 inhabitants per year in a country" (i.e., tolerable level of risk). While this may be a desirable goal, it requires the collective efforts of many parties. Food operators can only address factors over which they can exercise control. While all operators along the food chain must understand their role and manage their operation to satisfy an FSO, they cannot assume responsibility for the actions of all others along the food chain. It is important that each FSO clearly communicates the level of hazard that is considered tolerable in such a manner that food operators can effectively establish control measures to meet the objective.

FSOs are a relatively new concept offering considerable advantages when incorporated into a risk management framework. They are statements of the maximum frequency and/or concentration of a microbiological hazard in a food considered tolerable for consumer protection. Whenever possible, FSOs should be quantitative and verifiable.

FSOs can play an important role in modern food safety management systems by linking information from the risk assessment and risk management processes with measures to control the identified risk(s). Basic information is provided in Chapter 3 that can be used to establish scientifically based control measures.

FSOs should be flexible because information is often lacking on the relevant properties of the hazard, the factors that lead to adverse public health effects, the conditions necessary to control the hazard, and how control measures can be implemented effectively in the food chain. This is a common situation with newly recognized or emerging hazards, e.g., VT *E. coli*. As more information becomes available, risk assessments should be updated and FSOs adjusted accordingly.

For foods in international commerce, FSOs should be developed within the Codex framework. This is consistent with the concepts of the World Trade Organization and the SPS agreement and provides a framework for harmonization of acceptance criteria for foods in international trade. Food safety criteria developed in one country frequently differ from those of other countries. The principles presented in this text can lead to a sci-

entific basis for comparing the relative level of protection afforded by different food safety systems. These principles are applicable to issues of equivalency, levels of protection, and non-tariff trade barriers. Their application should facilitate the harmonization of international trade where the practices of one country may differ from those of another, yet the practices of both countries provide safe products. Furthermore, they can be applied by control authorities and food operators for the establishment of equivalent criteria. FSOs are a preferred approach to food safety management because they focus on protection of human health while offering flexibility in achieving that goal.

FSOs differ from microbiological criteria by communicating the level of hazard that is considered tolerable for consumer protection. FSOs specify goals that can be incorporated into the design of control measures (e.g., GHP, HACCP) for the production and preparation of foods. FSOs can also provide the basis for assessing the adequacy and effectiveness of control systems adopted by industry and inspection systems adopted by regulatory authorities. FSOs are limited to food safety and do not address quality.

1.11 PERFORMANCE, PROCESS, PRODUCT, AND DEFAULT CRITERIA

When designing and controlling food operations, it is necessary to consider pathogen contamination, destruction, survival, growth, and possible recontamination. Consideration should also be given to subsequent conditions to which the food is likely to be exposed, including processing and potential abuse (time, temperature, cross-contamination) during storage, distribution, and preparation for use. The ability of those in control of foods at each stage in the food chain to prevent, eliminate, or reduce food safety hazards varies with the type of food and the effectiveness of available technology. Since GHP and HACCP are the primary tools available to help industry control microbial hazards in food operations, it is essential that the technical achievability of the FSO be confirmed.

A *performance criterion* is the required outcome of one or more control measures at a step or combination of steps that contribute to ensuring the safety of a food. When establishing performance criteria, account must be taken of the initial levels of the hazard and changes of the hazard during production, processing, distribution, storage, preparation, and use. An example of a performance criterion is a 6D kill of salmonellae when cooking ground beef or $<10\%$ of fresh or frozen broilers contaminated with salmonellae.

Process criteria are the control parameters (e.g., time, temperature, pH, a_w) at a step or combination of steps that can be applied to achieve a performance criterion. For example, the control parameter for milk pasteurization in the US is 71.7 °C for 15 s (FDA, 1997). This combination of temperature and time will ensure the destruction of *Coxiella burnetii*, as well as other non-spore-forming pathogens that are known to occur in raw milk.

Product criteria consist of parameters that ensure that the level of a hazard does not increase to unacceptable levels before preparation or consumption. They also can be used to assess the acceptability of a food. There is increasing recognition and acceptance that the microbial response in foods is dependent on the composition and environment in the food. Consequently, measurement of pH, water activity, temperature, and gas atmosphere affords a more rapid means of judging the safety of particular foods in which those factors are the main factors determining food safety. A food could be considered acceptable, for example, if it has been determined that a certain pH (e.g., pH 4.6 or below) or a_w (e.g., 0.86 or below) ensures that the food will meet an FSO for growth of a pathogen (e.g., *C. botulinum* or *S. aureus*).

Default criteria are conservative values established to ensure the safety of a process or a food. If insufficient resources are available to perform the research needed to arrive at sound process or product criteria, then default values can be applied. An example of a default value is heating for 10 min at 90 °C internal temperature to destroy nonproteolytic *C. botulinum* in extended shelf-life ready-to-eat chilled foods (ACMSF, 1992). Default values have most commonly been developed by control authorities or advisory groups. The values specify the minimum criteria that must be met to ensure the production of safe food.

1.12 ESTABLISHMENT OF CONTROL MEASURES

Control measures are actions and activities that prevent or eliminate a food safety hazard or reduce it to a tolerable level. One or more control measures may be necessary at each stage along the food chain to ensure that a food is safe when consumed.

From the information provided in an FSO, regulatory authorities and food operators can select appropriate control measures to achieve the intended results. In practice, FSOs are met through the establishment and implementation of performance, process, and product criteria, through the application of GHP and HACCP. To compensate for process variability and ensure that FSOs are consistently met, industry may implement more stringent performance criteria for their end products.

Because of increasing recognition of the importance of contamination from the environment in which ready-to-eat foods are produced, information is provided on methods to assess the effectiveness of the GHP control measures (Chapter 11).

1.13 ASSESSMENT OF CONTROL OF A PROCESS

Food management systems that incorporate the above principles will require some means of verification to ensure that the systems are being implemented as planned. Criteria, e.g., process, product, etc., may have been established to serve as a basis for meeting an FSO and can be used to assess whether a process is under control. A process is deemed to be under control when correct procedures are being followed and established criteria are being met. The procedures that are followed for assessing and adjusting control of a process will ideally be based upon the same principles applied in selecting the control measures. Statistical process control may be necessary when validating, monitoring, and assessing control of a process. Information on the use of statistical process control charts to monitor the performance of food operations is provided in Chapter 13.

1.14 ACCEPTANCE CRITERIA

Acceptance criteria are statements of conditions that differentiate acceptable from unacceptable food operations. Acceptance criteria may be sensory, chemical, physical, or microbiological and should specify ancillary information, such as the number of samples to be collected, how and where the samples are collected and held prior to analysis, the analytical unit, the method of analysis, and the range of values considered acceptable. The assessment can be performed by a control authority, a customer, or even by an independent auditor hired by the food operator, each for a different purpose. Acceptance criteria are also used to assess the acceptability of individual lots or consignments of food (Chapter 5).

1.15 MICROBIOLOGICAL CRITERIA

Under certain circumstances, microbiological criteria may be established to determine the acceptability of specific production lots of food, particularly when the conditions of production are not known. Microbiological criteria should specify the number of sample units to be collected, the analytical method, and the number of analytical units that should conform to the limits (Chapter 5). Criteria may be established for quality as well as safety concerns (CAC, 1997). The composition of a *lot* (batch) of food product is considered in Chapter 6. Only in well-mixed liquid foods does the distribution of microorganisms approximate to homogeneity. If the distribution of microorganisms differs greatly from log-normal, the sensitivity of attributes plans is affected (see Chapter 7). The number of microbiological tests applied routinely to a lot of food product at port-of-entry is rarely adequate, in a statistical sense, to detect low levels of defectives (e.g., salmonellae in dried milk or dried egg). Moreover, random sampling is often not possible, which influences the statistical interpretation of the results. Greater reliability can be attained by acquiring food from suppliers known to have HACCP and GHP in place and with a record of trouble-free production. If a lot is sampled, the stringency of the sampling plan should reflect risk to consumers (Chapter 8).

In the event samples are collected for microbiological analysis, the method of collecting and handling the samples is very important. Otherwise, the analytical results may have no bearing on the acceptability of the food. These factors are briefly summarized in Chapter 12.

Chapters 14 to 17 provide four examples to illustrate how the principles can be applied. Each example discusses a different aspect of control that may be necessary in a food safety management system.

1.16 MICROBIOLOGICAL TESTS

Microbiological tests are used for different purposes. It is very important to consider for which purposes microbiological testing is used. The purpose determines the type of test (indicator or pathogen), the method (rapidity, accuracy, repeatability, reproducibility, etc.), the sample (line-residue or end product), the interpretation of the result, and action to be taken (rejection of a lot, investigational sampling, readjustment of the process, etc.). Table 1–2 shows some of the many different aspects of microbiological testing that are discussed in the following chapters.

1.17 SUMMARY

The purpose of this book is to introduce the reader to a structured approach to managing food safety. The uses and limitations of testing for control of microbiological hazards are discussed. In addition, lot acceptance testing within such safety management systems is discussed with reference to its strengths and weaknesses. The text describes the use of existing Codex documents to develop stronger, more reliable food safety management systems.

Application of Codex documents in a logical sequence, together with FSOs, can provide the basis for addressing issues of equivalency, levels of protection, and non-tariff trade barriers.

Table 1–2 Examples of Microbiological Testing in Food Safety Management

Type of testing	*Purpose*	*User*	*Sample type*	*Sampling plan*	*Microbes*
Acceptance	Lot inspection	Government	End products	Attributes	Pathogens, indicators
Acceptance	Verification, lots (batches) of known history	Government	End products	Attributes	Pathogens, indicators
		Industry	Raw materials	Attributes	Pathogens, indicators
Monitoring, checking	CCPs, lines	Industry	Line samples	Variables, attributes	Indicators
Environmental sampling	Line, environments	Industry	Residues, dust, water	Targeted, to find source of contamination	Indicators
Verification	HACCP	Industry	End products	Attributes	Pathogens, indicators
Surveillance	Compliance	Governments, industry	Products in commerce	Attributes (usually $n=1$)	Pathogens
Investigation	Food chain	Governments, industry	All types of samples	Investigational, rarely statistically based	Pathogens

1.18 REFERENCES

ACMSF (Advisory Committee on Microbiological Safety of Food, UK) (1992). *Report on Vacuum Packaging and Associated Processes.* London: HMSO.

ACMSF (Advisory Committee on Microbiological Safety of Food, UK) (1993). *Report on* Salmonella *in Eggs.* London: HMSO.

ACMSF (Advisory Committee on Microbiological Safety of Food, UK) (1995). *Report on Foodborne Viral Infections.* London: HMSO.

ACMSF (Advisory Committee on Microbiological Safety of Food, UK) (1996). *Report on Poultry Meat.* London: HMSO.

ACMSF (Advisory Committee on Microbiological Safety of Food, UK) (2001). *Second Report on* Salmonella *in Eggs.* The Stationery Office, London.

Altekruse, S. F., Stern, N. J., Fields, P. I. & Swerdlow, D. L. (1999). *Campylobacter jejuni*—an emerging foodborne pathogen. *Emerg Infect Diseases* 5, 28–35.

Bean, N. H., Goulding, J. S., Daniels, M. T. & Angulo, F. J. (1997). Surveillance for foodborne disease outbreaks—United States, 1988–1992. *J Food Prot* 60, 1265–1286.

Bean, N. H., Griffin, P. M., Goulding, J. S. & Ivey, C. B. (1990). Foodborne disease outbreaks, 5 year summary 1983–1987. *J Food Prot* 53, 711–728.

Bell, B. P., Goldoft, M., Griffin, P. M. *et al.* (1994). A multistate outbreak of *Escherichia coli* O157:H7-associated bloody diarrhea and hemolytic syndrome from hamburgers: the Washington experience. *J Am Med Assoc* 272, 1349–1353.

Buzby, J. C. & Roberts, T. (1997). Economic costs and trade impacts of microbial foodborne illness. *World Health Stats Quarterly* 50, 57–66.

CAC (Codex Alimentarius Commission) (1997). *Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene. Food Hygiene, Supplement to Volume 1B-1997. Principles for the Establishment and Application of Microbiological Criteria for Foods*. CAC/GL 21–1997. Secretariat of the Joint FAO/WHO Food Standards Programme. Rome: Food and Agriculture Organization of the United Nations.

CAST (Council for Agricultural Science and Technology, USA) (1994). *Foodborne Pathogens: Risks and Consequences*. Task Force Report No. 122. Ames, IA: CAST.

CAST (Council for Agricultural Science and Technology, USA) (1998). *Foodborne Pathogens: Review of Recommendations*. Special Publication No. 22. Ames, IA: CAST.

Caul, E. O. (2000). Foodborne viruses. In *The Microbiological Safety and Quality of Food*, Vol. II, pp. 1457–1489. Edited by B. M. Lund, T. C. Baird-Parker & G. W. Gould. Gaithersburg, MD: Aspen Publishers, Inc.

Clark, J., Sharp, M. & Reilly, W. J. (2000). Surveillance of foodborne disease. In *The Microbiological Safety and Quality of Food*, pp. 975–1010. Edited by B. M. Lund, T. C. Baird-Parker & G. W. Gould. Gaithersburg, MD: Aspen Publishers, Inc.

de Roever, C. (1998). Microbiological safety evaluations and recommendations on fresh produce. *Food Control* 9, 321–347.

Doyle, M. P., Zhao, Z., Meng, J. & Zhao, S. (1997). *Escherichia coli* O157:H7. In *Food Microbiology: Fundamentals and Frontiers*, pp. 171–191. Edited by M. P. Doyle, L. R. Beuchat & T. J. Montville. Washington, DC: ASM Press.

FDA (Food and Drug Administration) (1997). Milk and cream, pasteurized (21 CFR 131.3b), *Code of Federal Regulations*. Washington, DC: U.S. Government Printing Office.

FSA (Food Standards Agency (UK)) (2000). *A Report of the Study of Infectious Intestinal Disease in England*. London: The Stationery Office.

Halliday, M. I., Kang, L. Y., Zhou, T. K. *et al.* (1991). An epidemic of hepatitis A attributable to the ingestion of raw clams in Shanghai, China. *J Infect Diseases* 164, 852–859.

Hathaway, S. C. (1997). Development of risk assessment guidelines for foods of animal origin in international trade. *J Food Prot* 60, 1432–1438.

Hathaway, S. C. & Cook, R. L. (1997). A regulatory perspective on the potential uses of microbial risk assessment in international trade. *Int J Food Microbiol* 36, 127–133.

ICMSF (International Commission on Microbiological Specifications for Foods) (1980a). *Microbial Ecology of Foods. Vol. 1. Factors Affecting Life and Death of Microorganisms*. New York: Academic Press.

ICMSF (International Commission on Microbiological Specifications for Foods) (1980b). *Microbial Ecology of Foods. Vol. 2. Food Commodities*. New York: Academic Press.

ICMSF (International Commission on Microbiological Specifications for Foods) (1986). *Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and Specific Applications*, 2nd edn. Toronto: University of Toronto Press.

ICMSF (International Commission on Microbiological Specifications for Foods) (1988). *Microorganisms in Foods 4. Application of the Hazard Analysis Critical Control Point (HACCP) System to Ensure Microbiological Safety and Quality*. Oxford: Blackwell Scientific Publications Ltd.

ICMSF (International Commission on Microbiological Specifications for Foods) (1996). *Microorganisms in Foods 5: Characteristics of Microbial Pathogens*. Gaithersburg, MD: Aspen Publishers, Inc.

ICMSF (International Commission on Microbiological Specifications for Foods) (1998a). *Microorganisms in Foods 6: Microbial Ecology of Food Commodities*. Gaithersburg, MD: Aspen Publishers, Inc.

ICMSF (International Commission on Microbiological Specifications for Foods) (1998b). Principles for establishment of microbiological food safety objectives and related control measures. *Food Control* 9, 379–384.

Jouve, J. L. (1992). HACCP et Systèmes Qualité (ISO 9000). *Option Qualité*, 97, 11–15.

Jouve, J. L. (ed.) (1994, 1996). *La Qualité Microbiologique des Aliments: Maitrise et Critères*. 1st edn., 2nd edn., Paris: Centre National d'Etudes et de Recherches sur la Nutrition et l'Alimentation/Centre National de la Recherche Scientifique.

Liston, J. (2000). Fish and shellfish poisoning. In *The Microbiological Safety and Quality of Food*, Vol. II, pp. 1518–1544. Edited by B. M. Lund, T. C. Baird-Parker & G. W. Gould. Gaithersburg, MD: Aspen Publishers, Inc.

Mahon, B. E., Ponka, A., Hall, W. N. *et al.* (1997). An international outbreak of *Salmonella* infections caused by alfalfa sprouts grown from contaminated seeds. *J Infect Diseases* 175, 876–882.

Mead, P. S., Slutsker, L., Dietz, V. *et al.* (1999). Food-related illness and death in the United States. *Emerg Infect Diseases* 5, 607–625.

MMWR (Morbidity and Mortality Weekly Reports) (2000). Preliminary FoodNet data on the incidence of foodborne illnesses—selected sites, United States, 1999. *Morbidity Mortality Wkly Rpts* 49, 201–205.

Motarjemi, Y. & Käferstein, F. K. (1997). Global estimation of foodborne diseases. *World Health Stats Quarterly* 50, 5–11.

Notermans, S. & Hoogenboom-Verdegaal, A. (1992). Existing and emerging foodborne diseases. *Int J Food Microbiol* 15, 197–205.

Osewe, P., Addiss, D. G., Blair, K. A. *et al.* (1996). Cryptosporidiosis in Wisconsin: A case-control study of post-outbreak transmission. *Epidemiol & Infect* 117, 297–304.

POST (Parliamentary Office of Science and Technology, UK) (1997). *Safer Eating: Microbiological Food Poisoning and Its Prevention*. London: POST.

Public Health Laboratory Service, UK. http://www.phls.co.uk.

Speer, C. A. (1997). Protozoan parasites acquired from food and water. In *Food Microbiology: Fundamentals and Frontiers,* pp. 478–493. Edited by M. P. Doyle, L. R. Beuchat & T. J. Montville. Washington, DC: ASM Press.

Tauxe, R. V. (1997). Emerging foodborne diseases: an evolving public health challenge. *Emerg Infect Diseases* 3, 425–434.

Todd, E. C. D. (1996). Worldwide surveillance of foodborne disease: the need to improve. *J Food Prot* 59, 82–92.

Todd, E. C. D. (1997). Epidemiology of foodborne diseases: a worldwide review. *World Health Stats Quarterly* 50, 30–50.

Weltman, A. C., Bennett, N. M., Ackman, D. A. *et al.* (1996). An outbreak of hepatitis A associated with a bakery, New York, 1994: The 1968 "West Branch, Michigan" outbreak repeated. *Epidemiol & Infect* 117, 333–341.

Wheeler, J. G., Sethi, D., Cowden, J. M. *et al.* (1999). Study of infectious intestinal disease in England: rates in the community, presenting to general practice, and reported to national surveillance, The Infectious Intestinal Disease Executive. *Brit Med J* 318, 1046–1050.

Whittle, K. & Gallacher, S. (2000). Marine toxins in health and the food chain. Edited by D. I. Thurnham & T. A. Roberts. *Brit Med Bull* 56, 236–253.

WHO (World Health Organization) (1997). Foodborne Safety and Foodborne Diseases, *World Health Stats Quarterly* 50, 154 pp.

WTO (World Trade Organization) (1995). The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

Chapter 2

Evaluating Risks and Establishing Food Safety Objectives

i2.1 Introduction
2.2 Tolerable Level of Consumer Protection
2.3 Importance of Epidemiologic Data
2.4 Evaluation of Risk
2.5 Food Safety Objectives (FSOs)
2.6 Establishment of an FSO Based on a Risk Evaluation by an Expert Panel
2.7 Evaluation of Risk by Quantitative Risk Assessment
2.8 Establishment of an FSO Based on Quantitative Risk Assessment
2.9 Stringency of FSOs in Relation to Risk and Other Factors
2.10 Summary
2.11 References

2.1 INTRODUCTION

Although food products should be enjoyable and healthy, they sometimes cause illness. Consequently, societies charge institutions or organizations with defining the level of protection that should be achieved to ensure the health and safety of the public. In the case of food safety, this responsibility usually resides with food control authorities given this mandate by national or local legislation. Companies are responsible for ensuring the safety of their products. Government and industry* function as risk managers and share the common goal of ensuring that consumers can enjoy safe and wholesome foods.

Control authorities may use different approaches when responding to an emerging food safety concern or when seeking to enhance current levels of food safety. Their choice of actions to minimize risk to consumers depends on the circumstances and urgency of the situation. This flexibility is necessary because the factors surrounding food safety concerns vary (e.g., nature of the hazard, population affected, severity of the disease, frequency of occurrence, and potential for wider dissemination of the disease agent). It is neither possible nor desirable to prescribe specific steps for control authorities to follow when responding to food safety concerns. However, some general guidelines can be given.

*The term "industry" will mean an organization, company, or group of individuals (cooks) working professionally in the food chain from primary agricultural production to the sale to, or preparation of food for, the consumer. The particular meaning in the text will depend on the context in which it is used.

National Beef Ex. 1045
145 of 482

In addressing a food safety concern, risk managers must evaluate whether the situation—either a current concern or an increasing risk—is under sufficient control or whether there are sound reasons for concern. In many situations, concerns are raised that, upon closer examination, are already adequately managed by existing control measures or that do not constitute a public health issue. In the latter instance, a rapid decision must be made to avoid wasting time and money on issues that have little impact on public health.

As new food safety concerns are recognized, some understanding of the nature and properties of the hazard and how it leads to foodborne illness are essential for control. Risk managers in government and industry have been obliged to consider the frequency or concentration of the hazard that would be acceptable in foods and not cause illness when the food is handled and prepared as expected. Food safety managers have depended on epidemiologic studies to identify problems and determine their cause. This information then forms the basis for control options that could be applied to prevent, minimize, or reduce the hazard.

A formal process has seldom been applied to determine what a society or country would consider an appropriate level of consumer protection in regard to a foodborne microbiological hazard. Yet risk managers have such goals in mind when developing and implementing policies and strategies for control of microbiological hazards. There is a long history of implicitly, or intuitively, selecting public health protection options that provide the basis for existing, robust food safety management systems.

The level of protection may not be explicitly expressed, but may be estimated from data on incidences of domestically occurring illnesses. Taking foodborne listeriosis as an example, the reported prevalence in a number of countries ranges from 0.1–1.3 cases per 100,000 (Table 2–1). Most case are considered to be sporadic and not associated with identified outbreaks. Although foods are recognized as the primary source of listeriosis, little is known about factors leading to sporadic cases or how they may be reduced. Most

Table 2–1 Reported Incidence of Listeriosis in Selected Countries

Nation	*Incidence estimate (cases/100,000/year)*	*Period*	*Comment*
Australia	0.18–0.39	1991–2000	
Canada	0.1–0.2	1990–1999	
	0.17–0.45	1987–1994	
Denmark	0.48 / 0.64	1991/1992	
	0.75–0.88	1996–1998	
Germany	0.34	Pre –1984	
	0.25	Late 1990s	
France	0.68 / 1.30	1991/1992	
	0.38 / 0.67	1995/1996	
Italy	0.35	1991/1992	
Netherlands	0.13–0.19	1996–1999	
New Zealand	0.4/0.61	1991/1992	
Sweden	0.42	1990s	
UK	0.14–0.23	1984–1996	excludes outbreaks 1987–1989
	0.40–0.46	1987–1989	includes outbreaks 1987–1989
US	0.46	1983–1992	active reporting
	0.14	1983–1992	passive reporting

countries have, therefore, albeit perhaps not deliberately, set protection at current levels and respond to unusual increases above the country's baseline. This does not mean that future reductions in the incidence of listeriosis cannot be a goal of a country's food safety enhancement program. As the factors causing sporadic cases become clearer, food safety policies can be modified to reduce the incidence of listeriosis and thereby achieve a higher level of protection.

Knowledge of the actual level of protection in a society depends on the disease surveillance system. Not all countries have detailed epidemiologic data describing the current situation for every foodborne pathogen; however, some level of surveillance is in place in most countries. Moreover, analysis of a particular food production system will allow identification of the hazards and factors either increasing or controlling a particular risk.

Understanding the level of protection requires evaluating the public health risk associated with a concentration or frequency of the hazard in a food. The evaluation may be done in different ways depending on the issue, the understanding of the scientific basis, and the extent of disagreement between the parties involved. In practice, the evaluation ranges from a simple qualitative estimation of risk to a quantitative risk assessment (see sections 2.4 and 2.7).

Existing or enhanced food safety goals may be expressed in terms of risk. The risk that society regards as tolerable in the context of, and in comparison with, other relevant risks in everyday life is called the *tolerable level of risk* (TLR). The TLR is established following consideration of public health impact, technological feasibility, economic implications, etc. The TLR can be expressed as the number of illnesses occurring per annum due to a certain microbial hazard per 100,000 inhabitants of a country. A hypothetical example could be 0.5 case of listeriosis per 100,000 population per year. Although deciding on a TLR is a societal issue, sound scientific principles should underline the evaluation of risk.

The World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO/SPS agreement) (WTO, 1995) defines the *appropriate level of sanitary or phytosanitary protection* (ALOP) as "the level of protection deemed appropriate by the Member [country] establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory." The agreement recognizes that "many members refer to this concept as the acceptable level of risk." The International Commission on Microbiological Specifications for Foods (ICMSF) prefers the term *tolerable level of risk* (TLR) instead of *acceptable level of risk,* because risks related to the consumption of food are seldom accepted, but at best tolerated.

However, food operators cannot use a public health goal or level of protection to control the conditions of food processing to eliminate, prevent, or reduce microbiological hazards that may contribute to the incidence of a disease. In this book, the concept of a *food safety objective* (FSO) is introduced to allow risk managers to communicate effectively to industry and trade partners precise food safety goals. FSOs are stated as the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection. FSOs are typically expressions of concentrations of microorganisms or toxins at the moment of consumption; the concentrations at earlier stages of the food chain are considered to be *performance criteria*. As described in Chapter 5 (Table 5–1), FSOs differ from microbiological criteria in being suitable to help design control of food operations, but FSOs are not intended for determination of lot acceptance. FSOs are useful when comparing the safety goals of different

countries or trade partners and can assist in determining equivalence of seemingly different control measures used for health protection that may, in fact, be equivalent.

Depending on the urgency of the situation, the complexity of the hazard, and the level of disagreement, the FSO may be derived by advice from a few specialists, by larger expert panels, or by conducting a quantitative risk assessment. The FSO may be based on a realistic estimate of the risk, but can also, when time and/or knowledge are short, be based on a detailed examination of the frequency or concentration of a hazard that is expected to keep the situation under control.

Below, the concept of FSO is introduced as a tool to express and communicate in practical terms the desired level of consumer protection. The following sections also provide information on some of the tools that have been used to characterize the public health situation.

2.2 TOLERABLE LEVEL OF CONSUMER PROTECTION

The food chain—from primary production through harvesting, processing, marketing, distribution, and preparation for consumption—is complex. Hazards may enter along that entire chain, starting with the source of the food and ending with its final preparation. In particular, effective control measures do not exist for the many pathogens that occur on raw agricultural commodities and seafood. At best, it is possible to reduce, but not prevent or eliminate, their presence in these foods and still provide them to consumers in a raw, unprocessed state. Eliminating foodborne hazards is further complicated by the fact that controlling one hazard may increase the potential for other hazards or other adverse consequences. Thus, food control programs are oriented toward ensuring that foods are as free as practicably possible from hazards through appropriate hazard management.

For a number of foodborne diseases, the TLR is effective absence of disease (e.g., < 0.1 case per 100,000). This typically occurs when Good Hygienic Practices (GHP) and Hazard Analysis Critical Control Point (HACCP) procedures and other sanitary measures completely control the pathogen and effectively eradicate it from the food chain, as has occurred with foodborne brucellosis in certain regions.

Food safety management is similar to managing other risks in human life. For a range of hazards, society balances the risks and benefits and, although rarely stated publicly, accepts that a certain risk has to be tolerated. For example, the risk of injury while driving a car can be reduced by designing safer vehicles, regulating traffic, setting speed controls, wearing seat belts, and driving defensively. However, despite all such efforts, society has come to accept that a certain number of accidents will occur. However, many consumers expect food to be safe and have little or no tolerance for purchasing food that may cause illness.

Managing tolerable risk implies balancing public health considerations with other factors such as economic costs, public acceptability, etc. Based on the epidemiologic data and evaluation of risk, managers should decide whether the risk is so small that no further action need be taken or that the risk only needs to be contained (to keep it at the present level because systems already in place are adequate). Alternatively, managers may decide that the risk needs to be reduced. When deciding to reduce microbiological risks, managers should consider control measures that reduce the level of a hazard in a food. However, it must be realized that there will be a point at which further reductions in risks associated with specific foods may have additional "costs" that society is not willing to bear. Therefore, there is a need to balance the benefits of risk reduction with the costs incurred.

The most obvious cost is economic impact. For example, assume a proposal has been made to reduce the maximum allowable concentration of aflatoxin in peanuts from 15 parts per million (ppm) to 5 ppm, and it has been estimated that this change would reduce the lifetime risk of liver cancer per person from 10^{-11} to 10^{-12}. If implementation of this new standard increased the average cost of peanuts by $0.01 per pound, society might consider the additional cost warranted and reduce the lifetime risk of liver cancer due to aflatoxin in peanuts to 10^{-12}. However, if the change increased the cost of peanuts by $2.00 per pound, society might consider this to be an unacceptable additional cost and the lifetime risk level tolerated would remain 10^{-11}. Various tools for cost-benefit analysis have been developed to estimate the economic impact of decisions of this nature.

A key component of any estimate of economic costs is the impact that foodborne disease has in terms of medical costs, lost productivity, loss of consumer confidence, etc. In recent years, attempts have been made to estimate the economic cost associated with foodborne illness. As an example, one study estimated that between 3.3 and 12.3 million cases of foodborne illness occurred each year in the US due to six bacteria (*Campylobacter jejuni/coli*, *Clostridium perfringens*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, salmonellae, and *Staphylococcus aureus*) and one parasite (*Toxoplasma gondii*). The medical costs and losses of productivity, in 1995 US dollars, associated with the seven pathogens were estimated to be between $5.6–9.4 billion (Buzby & Roberts, 1997).

Costs are not limited to economic concerns. As another hypothetical example, suppose that changing a traditional, religiously based food handling practice would reduce the risk of foodborne illness. While modifying these practices might provide a small reduction in risk, the cost associated with the loss of choice based on religious beliefs may be considered unacceptable, and the affected population may prefer to tolerate the slightly higher risk.

Similarly, the impact that food control requirements have on the freedom of consumers to make decisions on the foods they eat must be recognized. However, there are several instances where the potential public health consequences of specific foods or food handling practices are so severe that consumers' choices are restricted; that is, society will not communally tolerate the risks that some consumers as individuals are willing to take. For example, a number of countries prohibit the commercial sale of non-pasteurized milk for direct consumption. Other examples of societally enforced risk reductions are the prohibition in a number of countries on the sale of uneviscerated salted fish due to the potential risk of growth and toxin production by *C. botulinum* or on the import of fish from the order *Tetraodontiae* (e.g., puffer fish) due to potential risk of tetrodotoxin poisoning.

In these examples, the products inherently exceed the risk tolerated and, other than prohibition, there are no viable control measures. The foods have a long history of public health problems and risk managers in some governments have concluded that the risks were not tolerable within the context of their society. Nevertheless, it is equally possible that another society values these foods highly and would be willing to tolerate the associated public health consequences.

Another cost that must be considered is when reducing the risk of one hazard is likely to increase the risk associated with another hazard or produce other adverse effects, e.g., on nutritional properties. A pertinent microbiological example is the use of chlorine for the treatment of water for drinking and food processing. While chlorination reduces risks associated with waterborne microbial diseases, there is a concentration-dependent risk that results from formation of organo-chlorine compounds. These situations require

risk management decisions that balance two competing hazards such that the benefits outweigh the risks to the affected population and environment.

Most societies consider consumer protection a moral responsibility deserving high priority. With increased reporting of foodborne illness by the media, consumers have become more aware of its frequency and public health impact. This increased awareness has led to greater pressure on governments and industry to make changes that will further reduce risk. This could be reflected in the future levels of risk that will be tolerated for various foodborne microbiological hazards.

A decision not to take an action also has its costs in relation to all of the categories identified above.

The net result of balancing the various risks and benefits is a decision on which actions have to be taken. To implement the actions, an objective must be defined. This objective may be expressed in terms of a level of a hazard in a food or as a tolerable level of risk. Expressing the objective in terms of risk (i.e., cases per 100,000 per annum) does not provide the guidance required by producers, manufacturers, or control authorities. The most effective means to ensure that the actions taken will be effective is to express the objective in terms of the level of hazard. This is the basis of the FSO concept.

2.3 IMPORTANCE OF EPIDEMIOLOGIC DATA

Tolerable levels of risk are generally articulated in relation to the mortality or morbidity of a disease, expressed as a number of cases or deaths per 100,000 population per year. For many reasons, the *true* incidence of foodborne disease is not known. At best, reasonable estimates can be developed for particular diseases because the impact on the consumer is profound and the characteristics of the disease are sufficiently evident.

This information is very important to understand the burden on a population and to assess the effect of policies instituted to thwart foodborne disease. Several approaches are currently used to monitor and report the incidence of foodborne diseases:

- passive notification systems
- active surveillance systems
- case-control studies
- outbreak investigations
- sentinel studies

None of these systems yield all the data necessary for a quantitative risk assessment, and some (e.g., passive notification systems) often fail to identify food as a source. Passive notification systems follow trends in disease and can be useful for measuring the impact of changes in technology, preventive measures, and regulatory policies. For example, Figure 2–1 shows the reported incidence of salmonellosis and shigellosis in the US from 1939–1998. The data were developed through reports from local sources in each state and then submitted from the state to the Centers for Disease Control and Prevention. In addition, physicians have been required to report particular *notifiable* diseases. This mandatory requirement can strengthen the accuracy of the data, but many cases remain unreported. Similarly, reports from laboratories can identify trends in *Salmonella* serovars and identify for public health officials changing risks to the population (Figure 2–2).

Another approach to collecting data on the incidence of disease is through active surveillance systems such as EnterNet or FoodNet. EnterNet (http://www.enter-net.org.uk) was established to determine more accurately the incidence of salmonellosis and infections caused by *E. coli* O157 in Europe. Another goal of EnterNet is to identify out-

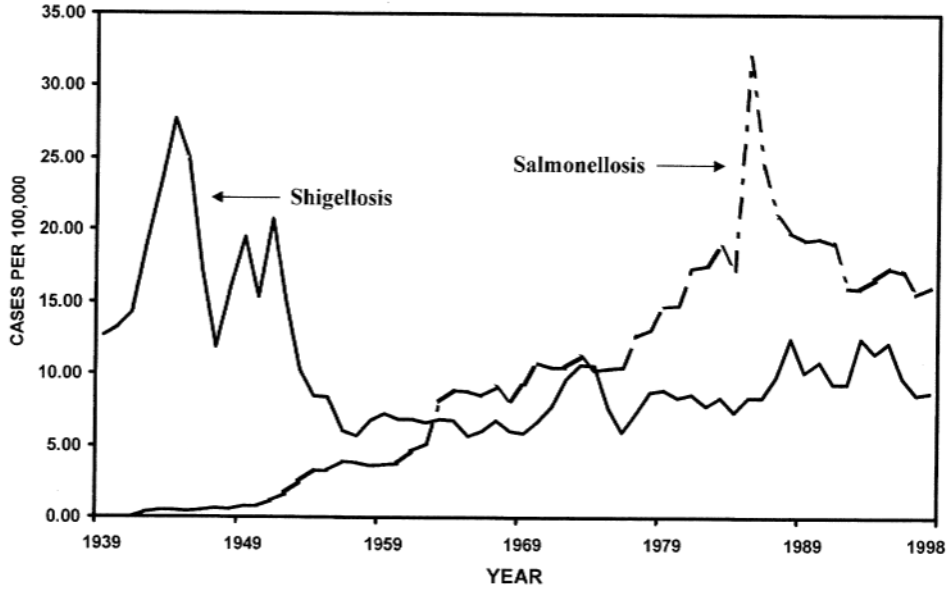


Figure 2–1 Trends in salmonellosis and shigellosis in the US, 1939–1998.

breaks in Europe from a common food source. The US surveillance program, FoodNet (http://www.cdc.gov/foodnet/), is an active, sentinel site program that collects weekly updates from clinicians in certain regions of the country for gastroenteritis and listeriosis. Isolates of selected pathogens are compared for commonality to identify outbreaks due to a common food source. These systems are relatively new and the data are just becoming available. Table 2–2 summarizes the data from 1996–1999 for FoodNet. Data from the older passive system (Morbidity and Mortality Weekly Report-MMWR) are provided for comparison, including several diseases not covered by FoodNet.

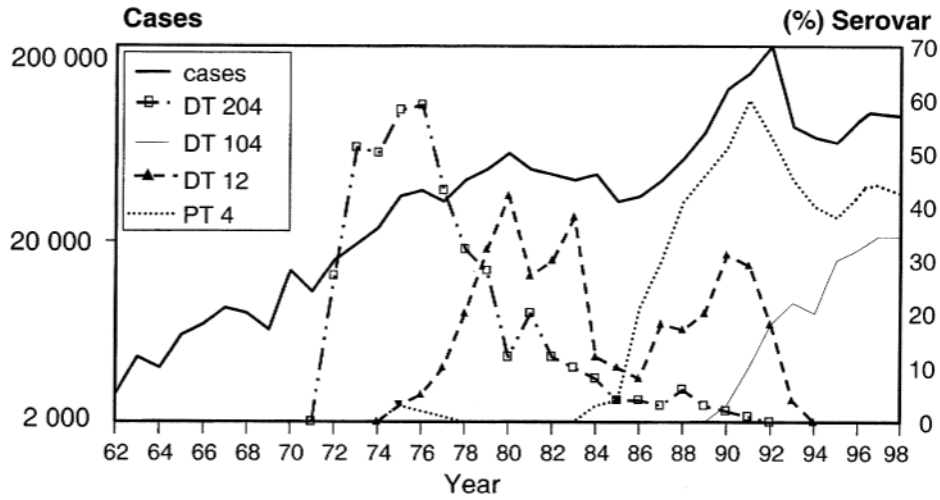


Figure 2–2 Trends in *Salmonella* serovars in Germany, 1962–1998. DT serovars *S. typhimurium*. PT serovars *S. enteritidis*.

Table 2–2 Annual Incidence of Selected Diseases in the US Following Two Different Reporting Systems

Disease	*Cases / 100,000 / year MMWR 1986–1998*	*FoodNet 1996–1999*
Cholera	0.00–0.04	
Botulism	0.01–0.02	
Trichinosis	0.01–0.05	
Brucellosis	0.03–0.05	
Typhoid fever	0.14–0.22	
Listeriosis		0.50– 0.60
Yersiniosis		0.80–1.00
E. coli	0.82–1.18	2.10–2.80
Shigellosis	7.11–12.48	5.00–8.90
Hepatitis A	8.59–12.64	
Salmonellosis, non-typhoid	15.70–20.73	12.40–14.80
Campylobacteriosis		17.30–25.20

Data on foodborne disease are also collected through case-control studies by interviewing patients to learn their food consumption history and to identify problem food sources. In parallel, a number of individuals are selected to serve as controls. This methodology has been used to identify not only the foods that may be involved, but also risk factors that the patients may share and that may explain increased susceptibility to the disease. Case-control studies are useful for identifying pathogen-food combinations where it has been difficult to isolate the causative organism from the food source or the role of foods in diseases with long incubation times before onset of symptoms (e.g., listeriosis).

The identity of the problem food source and conditions leading to foodborne illness may also be determined through epidemiologic investigations of outbreaks. Unfortunately, not all outbreaks are adequately investigated or described fully in the scientific literature, particularly those that do not provide new information. Consequently, that literature is often of limited usefulness in establishing the true frequency of outbreak occurrence and thus the risk associated with the disease agent. Case-control studies can also be used to help identify the source(s) of sporadic cases of foodborne illness and the factors that contribute to their frequency. Different sources may be more important in sporadic cases than in outbreaks. In the US, outbreaks of *Campylobacter jejuni* infections in the spring and fall are typically caused by drinking raw unpasteurized milk or untreated water, whereas sporadic cases occurring in the summer are usually related to touching or consuming uncooked or undercooked poultry (Potter & Tauxe, 1997; Tauxe, 1992).

A sentinel study monitors selected health events in a group of persons representative of the whole population. Laboratory testing may be limited, for example, to patients reporting diarrhea or may include examination of all fecal samples for a range of pathogens. This approach has been used to estimate the incidence of campylobacteriosis and salmonellosis in the Netherlands (Notermans & Hoogenboom-Verdegaal, 1992) and in England (Wheeler *et al.*, 1999; FSA (UK), 2000).

International conferences (e.g., Noeckler *et al.*, 1998) have highlighted the value of national reporting systems for foodborne disease and provide a snapshot of national disease

patterns. Their longer-term goal is to establish a multinational system of cooperation that would facilitate the transfer of information and expertise. With such a system in place, the possibility of establishing TLRs and/or FSOs on a regional basis would be greatly enhanced.

2.4 EVALUATION OF RISK

2.4.1 Introduction

When a food safety problem occurs, or an improvement in food safety is desired, a risk evaluation can determine the magnitude of the problem so that a decision can be made whether to take action and which actions should be taken. An evaluation of risk may be via one or more experts, an expert panel, or a more in-depth quantitative risk assessment.

Effective management of microbial food safety hazards requires identification of the hazards, assessment of the risks associated with those hazards (i.e., their significance, their severity, their likelihood of occurrence), and estimation of the effectiveness of potential control measures. The stringency of the control system should be proportional to the risk to public health (risk = the severity of an illness and the likelihood of its occurrence). This principle also underlies modern food safety systems, such as HACCP, that are based on preventive strategies.

Historically, food control agencies and industry have relied on the judgment of one or more experts to estimate the risk and the corresponding level of control needed to manage it. Although this approach has often been successful, it can be biased or inconsistent. Furthermore, it can be difficult to communicate adequately the underlying scientific basis and rationale for the decisions to interested parties because such evaluations were rarely documented.

An improved approach is the use of structured safety assessments, typically including broader scientific expertise and more formal consideration of available data and information. This approach has been widely used in recent years where expert panels have been called to address various food safety issues, e.g., psychrotrophic *C. botulinum* in refrigerated foods with extended shelf-life (ACMSF, 1992) or *Listeria* in ready-to-eat foods (ICMSF, 1994).

In recent years, quantitative microbial risk assessment has been initiated to evaluate more systematically the impact of various factors, such as the host, the pathogen, and the type of food (liquid, solid, or fat), that contribute to the risk associated with a foodborne microbiological hazard.

Risk assessment is mentioned as a tool in the WTO/SPS agreement to ensure that international trade in food is not hampered by unjustifiable safety requirement demands. This has led to an international harmonization of the concept of risk assessment and its practical implications by the Codex Alimentarius Commission (CAC, 1999), although there is, as yet, no general (or international) agreement on when a quantitative risk assessment is necessary or which statistical/mathematical approaches are appropriate.

The first step in any evaluation of risk is the identification of a food safety problem from one or more sources, e.g., accumulated epidemiologic data, regulators, public health sectors, the food industry, expert opinion/scientists, or consumers. Background information is generally assembled by a risk manager, who then provides a summary of the food safety problem and its context to the risk assessor. Risk managers must decide whether to direct risk assessors to initiate a qualitative or quantitative evaluation to obtain the information necessary for risk management decisions. It is important that there is a com-

mon understanding of the problem, including the approach to be taken (qualitative or quantitative assessment, deterministic or probabilistic), the available resources, time constraints, and the desired form of the output, e.g., a risk estimate (probability of disease per exposure or per year to the population or a sub-population) and/or suggested control measures. Circumstances may lead a risk manager to seek the information needed for a short-term fix through a qualitative evaluation (e.g., expert panel) and then rely on a more detailed quantitative assessment to assemble the information that may lead to longer-term solutions. Both qualitative and quantitative risk assessments will be discussed below. The use of expert panels as a form of qualitative risk assessment will be discussed first.

2.4.2 Use of Expert Panels

Control authorities, and others, have found expert panels to be an effective means to assemble information, interpret its content, and develop recommendations in a relatively short period of time. Expert panels have been used extensively by governments and international bodies (e.g., FAO/WHO consultations) to address concerns about the safety of a particular hazard-food combination. In addition, expert panels (e.g., Nickelson *et al.*, 1996) have been used extensively by industry to consider the factors leading to foodborne disease and to develop recommendations for their control. Assessments by expert panels are often appropriate, especially if a decision is needed quickly to address a newly recognized concern, or if resources and/or data for a quantitative risk assessment are limited, or perhaps where there are few management options. Such panels are called upon when epidemiologic evidence indicates that a hazard is not under control and there is need for increased consumer protection. Concerns may be raised following change in food habits, food processing technologies, and food packaging or distribution systems. Such concerns must be addressed and, if reasonable and supported by scientific evidence, an evaluation of the risk must be undertaken.

In practice, risk managers will call upon people with expertise on the particular pathogen and/or food in question. The panels established usually consist of epidemiologists, public health specialists, food microbiologists, and food technologists with knowledge about actual food processing operations important for the evaluation. The panels typically go through a range of steps very similar to conducting a hazard analysis when developing a HACCP plan to address the concerns presented by risk managers. In some instances, a rough estimation of the risks associated with different likely scenarios is sufficient. One approach is to assign relative probability and impact rankings, such as negligible, low, medium, or high, to the factors used to determine likelihood of exposure and likelihood of an adverse outcome. If such a system is used, definitions and rationale for assigned rankings must be clearly described and justified to avoid misinterpretations of the information by users. An example appears in Chapter 8, where different hazards are ranked in categories, depending on the severity of the disease.

The examples in Chapters 14–17 illustrate the tasks of expert panels. The panel will be asked to provide the best information available at that given point in time considering several aspects. Due to the more simple nature, the procedure is faster than a quantitative risk assessment, described in section 2.7 below. Although the complexity of the risk evaluation may vary, any risk assessment or risk evaluation comprises four steps: hazard identification, exposure assessment, hazard characterization, and risk characterization (CAC, 1999). In addition, the expert panel should provide information on the conditions that lead to haz-

ardous food. The outcome from an expert panel may be to recommend to risk managers one or more measures to control a hazard or, if necessary, ban the product or process. Where appropriate, an expert panel may recommend the establishment of an FSO where this can be an effective means to enhance the safety of the food under consideration.

2.5 FOOD SAFETY OBJECTIVES (FSOs)

Governments and food industries have a significant influence on the incidence of foodborne disease by controlling the frequency and extent of contamination of foodstuffs and other conditions that minimize or control foodborne diseases. Consequently, public health goals must be converted into parameters that can be controlled by food producers and monitored by government agencies. A food safety objective provides such a conversion. While FSOs can obviously be set for any food hazard (e.g., carcinogens, pesticides, toxins, microorganisms), in the context of this book, only hazards of microbial origin are considered. Therefore, it is implicit that the FSOs dealt with are microbiological food safety objectives.

2.5.1 Basic Concept

A microbiological FSO is the maximum frequency and/or concentration of a microbial hazard in a food considered tolerable for consumer protection. It is important to reemphasize that the primary purpose of an FSO is to translate a public health goal (i.e., a desired level of consumer protection) to measurable attributes that allow industry to set control measures for processes and that allow comparison between countries. Examples* of FSOs are:

- the amount of staphylococcal enterotoxin in cheese must not exceed 1 μg 100 g^{-1}.
- the concentration of aflatoxin in peanuts must not exceed 15 μg kg^{-1}.
- the level of *L. monocytogenes* in ready-to-eat foods must not exceed 100 cfu g^{-1} at the time they are consumed.
- the concentration of salmonellae must be less than 1 cfu 100 kg^{-1} of milk powder.

While the FSOs at first glance seem similar to microbiological criteria, they differ in several ways (see Chapter 5). FSOs are not applied to individual lots or consignments, and they do not specify sampling plans, number of analytical units, etc. FSOs define the level of control that is expected for a food operation and can be met through the implementation of GHP and HACCP systems and application of performance criteria, process/product criteria and/or acceptance criteria (see Chapter 3).

Whenever possible, FSOs should be quantitative and verifiable. However, this does not mean that they must be verifiable by microbiological testing. For example, an FSO for low-acid canned foods might be established in terms of the probability of a viable spore of *C. botulinum* being present as being less than 0.000000000001 per can. It would be impossible to verify this by end-product testing, but it would be verifiable by measurement of time/temperature protocols that are based on a performance criterion (see Chapter 3).

The FSO allows control authorities to communicate clearly to industry what is expected of foods produced in properly managed operations. The FSO establishes the stringency

*These examples are hypothetical and are intended only to illustrate the concept of FSOs.

under which food control systems must operate by specifying the frequency or concentration of a microbiological hazard that should not be exceeded at the moment of consumption. It thereby forms the basis by which control authorities can establish standards or guidelines and assess whether an operation is in compliance and is producing safe foods, i.e., the foods will under normal conditions of commercialization and use meet the established FSO. Thus, the FSO has very practical value and can be commonly understood and applied by industry and regulators alike. Since an FSO does not specify how an operator achieves compliance, the concept offers considerable flexibility of operation. This would enable one operator to use formulations, equipment, and procedures that differ from other operators, so long as the FSO is met. Furthermore, there can be a high level of confidence in the acceptability of food being produced by operations that have been designed and validated to meet the relevant FSOs. The foods from such operations need seldom be tested for the relevant pathogen(s) to verify compliance. Instead, verification can be achieved through record review and observation of GHP and HACCP (see Chapter 4).

2.5.2 Use of FSOs

In summary, the concept of an FSO offers many advantages for both control authorities and industry because they can be used to:

- translate a public health goal into a measurable level of control upon which food processes can be designed so the resulting food will be acceptable;
- validate food processing operations to ensure they will meet the expected level of control;
- assess the acceptability of a food operation by control authorities or other auditors;
- highlight food safety concerns, separate from quality and other concerns;
- force change in a food commodity and improve its safety; and
- serve as the basis for establishing microbiological criteria for individual lots or consignments of food when the source or conditions of manufacture are uncertain.

It is not necessary to establish an FSO for all foods or known hazard-food combinations. In some cases, the potential microbiological hazards associated with a food represent so little risk that an FSO is not needed (e.g., granulated sugar, sweetened condensed milk, most breads, pineapple, carbonated beverages). In other cases, the sources of a pathogen are so variable that identifying the foods for which FSOs should be set is not possible. An example of the latter is shigellosis, which can be transmitted by many routes, most of which are more important than food (e.g., water, person-to-person), and it is unpredictable which specific food may next be implicated.

Investigation of foodborne disease continues to identify new pathogens and new pathogen-food combinations. The emergence of listeriosis as a foodborne disease during the 1980s as a result of outbreaks traced to coleslaw and Mexican-style cheese is an example of a recently recognized foodborne pathogen. The finding that nonpasteurized juices and raw vegetables can be vehicles for *E. coli* O157:H7 is an example of a new pathogen-food combination. In such situations, a quick decision may be necessary to prevent more cases or outbreaks. Establishment of an interim FSO could be an initial step to communicate to the food industry, or exporting countries, the maximum level of a hazard considered acceptable. As further knowledge about the hazard, the food, and conditions leading to illness become available and effective control measures can be determined, the interim FSO can be adjusted.

FSOs also can be used to force change in an industry and enhance the safety of certain products. Many examples could be cited where epidemiologic data indicated that certain foods were linked to foodborne illness. In response to this information, governments used various mechanisms at their disposal to bring about the changes necessary to reduce or eliminate the risk of disease. In some cases, modifications in commercial practices were necessary, including the adoption of new or more reliable technologies. The establishment of an FSO could be used by risk managers in government to communicate to industry the level of control expected and thereby force the change. The FSO may require some operators to modify their operation, implement more effective technologies, adopt tighter control systems, or even cease operation.

The WTO/SPS agreement recognizes that governments have the right to reject imported foods when the health of the population may be endangered. The criteria used to determine whether a food is considered to be safe or unsafe should, however, be clearly conveyed to the exporting country (transparency) and should be scientifically sound. Integral to the treaties is the concept of *reasonableness*, a requirement that is inherent to the establishment of realistic FSOs. An exporting country can contest an FSO that does not reflect conditions existing in the importing country and argue that the FSO is an unjustified trade barrier. However, because an FSO also reflects commercialization conditions, eating habits, preparation, and use practices, FSOs may vary considerably between countries. Nevertheless, a country cannot demand that imported foods are "safer" than similar domestically produced foods. For example, if the tolerance for aflatoxin in domestically grown and processed peanuts is 15 $\mu g\ kg^{-1}$, then imported peanut products cannot be rejected if contaminated to the same or a lesser concentration. FSOs provide a means for implementing the concept of equivalence in Article 4.1 of the WTO/SPS agreement: "Members (countries) shall accept the SPS measures of other Members as equivalent, . . . , if the exporting Member objectively demonstrates . . . that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection."

FSOs provide a maximum frequency or concentration for a hazard that is judged as tolerable for consumer protection, without prescribing how an exporting country or company should achieve this level of protection. The FSO also becomes useful when the safety of new products is evaluated. To put new products or novel foods on the market, their safety should be substantially equivalent to existing similar products.

2.6 ESTABLISHMENT OF AN FSO BASED ON A RISK EVALUATION BY AN EXPERT PANEL

Some risk evaluation must be conducted prior to the establishment of an FSO. Due to the time and money required to do quantitative risk assessments, FSOs will often be based on the advice of an expert panel. For a large number of hazard-food combinations, there is no need to do a quantitative risk assessment, as there is already agreement on the factors determining risk.

FSOs contain three elements, namely, the hazard, the food, and the frequency or concentration of the hazard that is considered tolerable. Some basic knowledge is necessary before an FSO can be established. For this reason panel members should be selected based on their knowledge, experience, and access to information that can ensure these basic needs are met. At a minimum, the panel must have knowledge about the microbiological hazard (e.g., infectious agent, toxic metabolite), its source, and the conditions along the food chain that lead to foodborne illness. The relationship between the micro-

biological hazard, the food, and the disease may be elucidated through a combination of passive and active epidemiologic programs, case-control studies, and other pertinent public health studies as described above. Investigations of foodborne illness should also provide information about whether certain populations are at risk for greater frequency and/or severity of the disease. This knowledge should be supplemented with data derived from laboratory research and from steps in the food chain that may be relevant to the disease. Records of foods processed for safety may provide useful data concerning the level of consumer protection normally achieved. This knowledge can form a solid basis for a risk evaluation and determination of an FSO.

If it is known, for example, that the source of a pathogen (e.g., *S. aureus*) is humans and animals, and that growth on cooked ham during storage at room temperature to a high concentration (e.g., 10^6 cfu g^{-1}) is necessary for toxin production, then this information can be used in establishing an FSO. Additional information about the concentration of toxin (i.e., dose) required to cause illness would be needed before a meaningful FSO could be developed. In this case, it would be necessary to determine whether to base the FSO on the concentration of *S. aureus* or the concentration of staphylococcal enterotoxin in the food.

As another example, the incidence of listeriosis in a number of countries has been between 0.1–1.3 per 100,000 people per annum (Table 2–1) (Ross *et al.*, 2000). When the vehicles were identified, high numbers of the organism were present in the food (McLauchlin, 1995, 1996; Anonymous, 1999). As *L. monocytogenes* is ubiquitous and low numbers are prevalent and ingested daily by consumers with no adverse effect, ICMSF, acting in the capacity of an expert panel, suggested that such low numbers are unlikely to pose a risk to healthy consumers and, therefore, proposed an FSO of 100 cfu g^{-1} at time of consumption (ICMSF, 1994). Based on data from Germany for the incidence of listeriosis, as well as prevalence and levels of the organism in foods, a hazard characterization was developed (Figure 2–3) (Buchanan *et al.*, 1997).

2.7 EVALUATION OF RISK BY QUANTITATIVE RISK ASSESSMENT

2.7.1 Quantitative Risk Assessment

Quantitative risk assessment typically involves persons similar to those of an expert panel, plus others with mathematical/computing skills. The process takes longer than a qualitative assessment. Quantitative assessments are normally undertaken for complex interactive situations, when there may be uncertainty over where control can best be exercised or the effectiveness of various control options, and/or when there is substantial disagreement among stakeholders concerning the level of control needed to achieve a tolerable level of consumer protection. The purpose of a quantitative risk assessment is the same as that discussed for expert panels, i.e., to provide scientific advice to the risk managers who will use the information to decide upon the risk management option(s) that will be implemented to achieve the desired level of consumer protection.

Risk assessment comprises four steps: hazard identification, exposure assessment, hazard characterization, and risk characterization (CAC, 1999). Each involves a systematic process for collecting, assembling, and providing the necessary knowledge to evaluate the public health significance of a microbial hazard in food. The final outcome of the four steps is a risk estimate, i.e., a measure of the magnitude of risk to a population attributable to the food, with the attendant uncertainties. It is impossible to predict the risk to an individual. The estimates are derived mathematically by calculating the

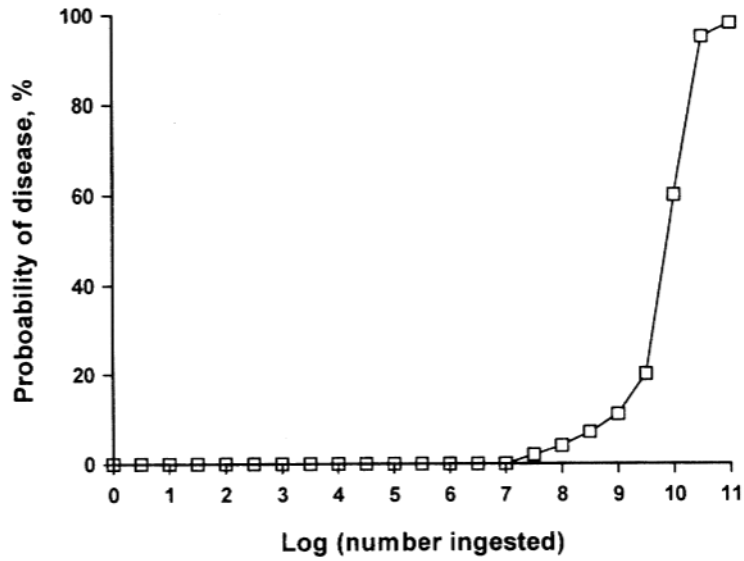


Figure 2–3 Hazard characterization of *L. monocytogenes*. Probability of disease as a function of ingested numbers.

likely frequencies and/or concentrations of the hazard in food at the time of consumption, combined with an estimate of the probability that disease will occur after the food is consumed.

Of necessity, assumptions will be made during the assessment when data or other information are missing. Data used and assumptions made should be clearly documented and their effect on the final risk estimate clearly stated. It is also important that risk assessors identify, describe, and, if possible, quantify sources of variability and uncertainty that affect the validity of the risk estimate.

2.7.2 Hazard Identification

The first step of risk assessment, *hazard identification*, assembles the knowledge about the pathogen and/or food in question and its association with adverse health effects. Sometimes epidemiologic data clearly indicate that foodborne transmission plays a role and which foods are implicated. Conversely, if a particular food is suspected, epidemiological and microbiological data may indicate which pathogens have been, or potentially could be, associated with the product. Epidemiologic data from disease monitoring programs or investigations of foodborne outbreaks are often the first indication of a food safety problem; in such a case, adverse effects associated with the pathogen are relatively well documented. Information may also come from animal disease monitoring when the pathogen is a zoonosis.

2.7.3 Exposure Assessment

Exposure assessment estimates the prevalence and levels of microbial contamination of the food product at the time of consumption and the amount of the product consumed at each meal by different categories of consumers. Programs for nutrition and consump-

tion habits are often available nationally to gauge food intake; these can be used to estimate exposure. The exposure assessment may be limited to measurements of pathogen levels at the time of consumption. However, models are available that estimate how certain factors, such as prevalence of pathogens in raw ingredients, the potential growth of the pathogen in the food, and impact of handling and preparation practices, affect the frequency and levels of pathogens consumed (Product/Pathogen/Pathway (PPP) ("Farm to Fork") analysis). Data from baseline surveys of pathogens in foods and predictive microbial modeling techniques have proven to be valuable sources for deriving probable exposure estimates for pathogenic bacteria (ICMSF, 1998). Substantial amounts of information on microbial levels have been accumulated in food inspection data in many countries and could provide an additional source of information on the microbiological status of foods just before consumption.

The sensitivity, specificity, and validity of sampling and testing methods used to collect empirical information should be considered to assure that results from different studies are comparable. Some apparent differences in pathogen prevalence in the food chain may be attributable to underreporting or methods employed, however, there may be real variation due to ecological situations or differing food safety control measures and animal health control programs. For example, food distribution systems vary from country to country with respect to temperature control. Exposure assessments should also consider differences in the cultural, social, economic, or demographic structures of societies that may influence consumption patterns and practices.

2.7.4 Hazard Characterization

Hazard characterization describes the severity and duration of adverse health effects that may result from the ingestion of a microorganism or its toxin in food. A dose-response assessment provides an estimate of the probability that disease/illness will occur in a certain category of consumers after exposure to a certain number of a pathogenic microorganism and/or its metabolites/toxin (i.e., dose). The consequences of being exposed to a microbial pathogen or microbial toxin in a food will vary, ranging from no discernible effect to infection (colonization and growth in the intestinal tract) without symptoms of illness, to acute illness (usually gastroenteritis, but sometimes septicemia and meningitis), to long-term effects or sequelae (chronic illness such as reactive arthritis, Guillain-Barré syndrome, or hemolytic uremic syndrome), to death. The likelihood that exposure to a particular dose (i.e., number of cells) of a specific pathogen may have any one of these consequences is dependent on three factors:

1. characteristics of the microorganism itself (e.g., mechanism(s) of pathogenesis, virulence factors, ability to resist the host's defenses) that vary among strains and may be altered by prior conditions;
2. the susceptibility of the host (e.g., immune status, predisposing conditions, age); and
3. characteristics of the food in which the pathogen is carried (e.g., fat content, acidity, or other factors that affect the microorganism's capacity to resist acidity of the stomach, competing bacteria in the food, etc.).

In practice, estimates of the numbers of pathogen that may cause illness and the severity of illness relative to dose are derived from experimental studies with humans, animal models, and epidemiological data (and accumulated knowledge and experience) (see Chapter 8).

To perform the final risk characterization (see below), the relation between frequency of exposure of the population (or subpopulation) with various numbers of the pathogen in the food at the moment of consumption and the number of illnesses (diarrhea, death) per annum has to be established. Figure 2–4 depicts such a relationship. It is a hypothetical curve, not based on real data for any food-pathogen combination.

2.7.5 Risk Characterization

Risk characterization combines the information generated in hazard identification, exposure assessment, and hazard characterization to produce a complete picture of risk. The result is a risk estimate that is an indication of the level of disease (e.g., number of cases per 100,000 per year) resulting from the given exposure.

Whenever possible, the resulting risk estimate should be compared with epidemiological data or other reference information to assess the validity of the risk assessment's models, data, and assumptions. The risk estimate should reflect a distribution of risk that represents the range of contamination of a food product, factors that might affect growth or inactivation of the pathogen, and the variability of the human response to the microbial pathogen.

Risk characterizations should also provide insights about the nature of the risk that are not captured by a simple qualitative or quantitative statement of risk, e.g., identifying the most important factors contributing to the average risk, the uncertainty and variability of the risk estimate, and gaps in data and knowledge. The consequences of any default assumptions provided to the risk assessment team should be documented. The risk assessor may also compare the effectiveness of alternative methods of risk reduction, enabling the risk manager to consider risk management options.

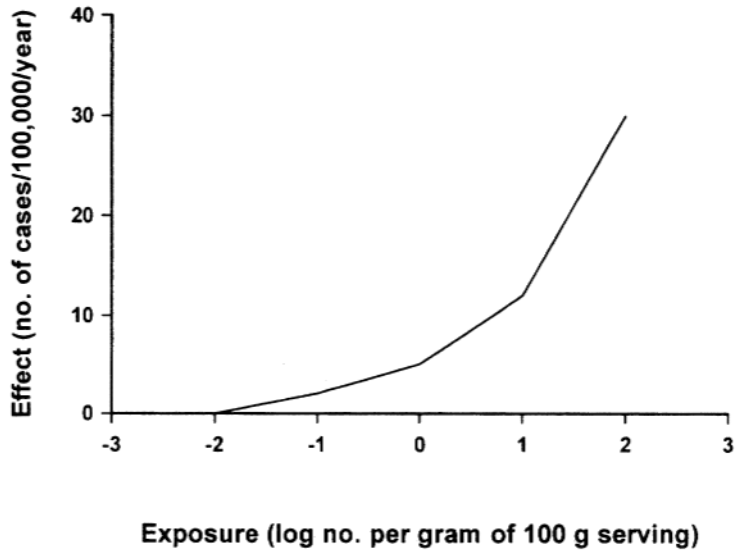


Figure 2–4 Hypothetical hazard characterization curve for a pathogen that causes gastroenteric infection.

The resulting risk estimate must be compared to the tolerable level of risk decided upon, and if the risk estimate is higher than that which can be tolerated, obviously actions must be taken to reduce the risk. Establishing a food safety objective (see section 2.5) is recommended.

2.7.6 Mathematical Approach to QRA

Quantitative risk assessments use mathematical models to estimate risk as a function of one or more inputs. Point estimates, or single values, such as the mean or maximum value of variable data sets, have been used historically to generate a single numerical value for the risk estimate.

Until recently, the most common approach was to use either the mean or worst-case (95th percentiles) estimate calculated from the available data for each step of the assessment. These values were then used to calculate an overall mean or worst-case single value estimate (e.g., 1 per 100,000 exposures will result in illness; 100 cases/100,000 population). Such risk estimates were termed *deterministic* or *point estimate* risk assessments. A major shortcoming of these approaches is that the variability of diverse and dynamic biological phenomena is ignored and consideration is not allowed for how much uncertainty there may be about the data and how it may influence the risk estimate.

Probabilistic assessments represent all the information available for each parameter (i.e., information or data sets about a factor that is important in determining risk) described as a distribution of possible values. A mathematical description of the production and consumption of a food using probability distributions is very difficult to calculate analytically. While some analysis is practical on very small and simple models, a compound model of food production involving pathogen growth, destruction, and infection is too complex to interpret without computational tools. Probabilistic risk assessments for food safety are feasible using commercial software. Monte Carlo simulation is a computational tool that aids in the analysis of models involving probability distributions.

2.8 ESTABLISHMENT OF AN FSO BASED ON QUANTITATIVE RISK ASSESSMENT

Risk assessments can help to identify how the frequency and/or concentration of a microbiological hazard in a food or group of foods can influence the incidence of a disease. There is a relationship between the level of a hazard in a food and the incidence of the disease it causes in a given population. This relationship may be represented by a hazard characterization curve (e.g., Figures 2–3 and 2–4). The slope of this curve is specific to the hazard, the food, the illness, and the category of consumers for which the curve has been determined. If such curves are available for the incidence of disease for a specific pathogen-food combination, the selected TLR can be positioned on the y-axis, and the corresponding level of the hazard (FSO) can be obtained on the x-axis.

However, the uncertainties associated with the assumptions in the estimations used in elaboration of the exposure-disease relationship may oblige risk managers to take a more cautionary approach, and a more stringent (lower) FSO may be adopted. In many situations, the public health goal is to have nearly zero cases from a given pathogen-food combination (e.g., botulism from commercially canned shelf-stable low-acid foods), and consequently a very conservative FSO may be adopted. However, the costs to realize this goal may be higher than a society will accept (see section 2.2). It must be remembered

that the FSO will reflect the balance between the costs associated with reducing risk and the costs associated with accepting risk.

When interpreting graphs such as those depicted in Figs. 2–3 and 2–4, it is important to note that for infectious agents seldom, if ever, will the relationship between risk and the level of the hazard reach zero unless the hazard has been eradicated. Instead, as the predicted incidence falls below unity, the population size and the timeframe need to be adjusted. Even when the risk to a population falls to the level where the predicted value is less than 1 case per year, the risk is not zero. For example, a predicted incidence of 0.2 cases per year would be more appropriately expressed as 2 cases per 10 years.

Ideally, an FSO would be based on the frequency or concentration of a pathogen in a food that would not produce disease. This would be equivalent to finding a no-effect dose, the value that is used for setting tolerable levels of daily exposure for acutely toxic chemicals. It is clear that certain foodborne pathogens have clearly definable threshold levels below which they pose no risk to the consumer. In general, it is assumed for certain toxigenic foodborne pathogens (i.e., microorganisms that cause disease through the production of a toxin) that there is a threshold concentration of cells below which the microorganism does not produce sufficient toxin to cause an adverse effect. For example, it is generally accepted that low levels (i.e., $< 10^4$ cfu g^{-1}) of *S. aureus* in a food do not represent a direct risk to humans, whereas higher levels ($> 10^5$ cfu g^{-1}) do so through the production of enterotoxin to levels that will probably cause staphylo-enterotoxicosis.

For infectious pathogens, most current models are based on the assumption that there is a chance, however remote, that one single cell may cause disease. For *L. monocytogenes*, current dose-response data indicate that the chance of illness varies from 1 in 10^{-5} (of contaminated butter causing listeriosis in a vulnerable population) to 8 in 10^{-15} (US Food and Drug Administration (FDA) model for listeriosis in the elderly population) (FAO/WHO, 2000). Establishing microbial FSOs is substantially more complex when a no-effect level cannot be assumed; however, the basic process for establishing an FSO remains the same.

2.9 STRINGENCY OF FSOs IN RELATION TO RISK AND OTHER FACTORS

Examples of hypothetical FSOs are provided throughout this book to describe the FSO concept and how it can be used as a food safety management tool. Some of the hypothetical FSOs are more restrictive for a food-pathogen combination, even though another food-pathogen combination may be of greater risk. Ideally, as risk increases, the corresponding FSO would become more restrictive. Thus, there would be a quantitative relationship, reflecting risk, in the allowable frequency and/or concentration of the various hazards.

The ICMSF has not endorsed the FSOs provided as examples in this book, except for the FSO for *L. monocytogenes* (see section 2.5.1) (ICMSF, 1994). To illustrate the use of the concept, FSOs are provided for *Salmonella* in milk powder (< 1 cfu 100 kg^{-1}), *E. coli* O157:H7 in raw ground beef (≤ 1 cfu per 250 g or not to exceed -2.4 $\log_{10}$ g^{-1}), *L. monocytogenes* in ready-to-eat foods ($\leq$ 100 cfu g^{-1}), staphylococcal enterotoxin in cheese (≤ 1 µg 100 g^{-1}), and aflatoxin in peanuts (15 µg kg^{-1}).

Relative risk is not reflected in the stringency of the FSOs. For example, the FSO for ground beef (recognizing that as many as 15% of the US population consumes undercooked ground beef) is much less stringent than the FSO for milk powder. In addition, the risk associated with *Salmonella* is lower than *E. coli* O157:H7. In the case of milk

powder, there is about 30 years of commercial experience in identifying and implementing the necessary controls for *Salmonella*. The FSO is commercially achievable with current technology and equipment, and processes can be validated as meeting an FSO of this stringency. The available control measures are much less effective for *E. coli* O157:H7 from slaughter through grinding (mincing). In the absence of an effective kill step (e.g., irradiation, high pressure), a more stringent FSO is not achievable. Due to the many factors influencing the decisions of risk managers, it is uncertain whether an internationally recognized system can be developed for FSOs that would be based on relative risk ranking.

2.10 SUMMARY

Establishing an FSO for hazard-food combinations provides an element that is missing from current food safety management systems based on GHP and HACCP. Hitherto, rarely has there been any expression of the expected level of control in a food operation. Instead, reliance has been placed on using process or product criteria as specified in regulations, or in end-product testing to ensure compliance with microbiological criteria. While those criteria will continue to be used, food processors that use the FSO concept will have the capacity/facility to design management systems to achieve specific food safety goals based on an expected level of consumer protection. This approach will further strengthen the scientific basis of existing systems.

Having established and communicated an FSO to enhance the safety of a food, industry must verify that the FSO is achievable, by a process that must necessarily be iterative. Information must be exchanged between those proposing an FSO (and possible control measures) and the affected industry. If the FSO is not achievable and/or the possible control measures are not possible, for example, with existing equipment, then some adjustments may be necessary. The adjustments may involve modifying the FSO and/or changing equipment or industry practices.

The process of verifying that an FSO is achievable and then establishing and validating the effectiveness of control measures is discussed in the next chapter.

2.11 REFERENCES

ACMSF (Advisory Committee on Microbiological Safety of Food, UK) (1992). *Report on Vacuum Packaging and Associated Processes*. London: HMSO.

Anonymous (1999). *Management of* Listeria monocytogenes *in Foods*. Draft document prepared by a Codex working group, hosted by Germany, for the 32nd session of the Codex Committee on Food Hygiene.

Buchanan, R. L., Damert, W. G., Whiting, R. C., & van Schothorst, M. (1997). The use of epidemiologic and food survey data to estimate a purposefully conservative dose-response relationship for *Listeria monocytogenes* levels and incidence of listeriosis. *J Food Prot* 60, 918–922.

Buzby, J. C. & Roberts, T. (1997). Economic costs and trade impacts of microbial foodborne illness. *World Health Stats Quarterly* 50, 57–66.

CAC (Codex Alimentarius Commission) (1999). *Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene. Principles and Guidelines for the Conduct of Microbiological Risk Assessment.* CAC/GL 30–1999. Secretariat of the Joint FAO/WHO Food Standards Programme. Rome: Food and Agriculture Organization of the United Nations.

CDC (Centers for Disease Control and Protection) (2000). Preliminary FoodNet data on the incidence of foodborne illnesses—selected sites, United States, 1999. *MMWR Morb Mortal Wkly Rep* 49, 201–205.

FAO/WHO (Food and Agriculture Organization/World Health Organization) (2000). *Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods*. FAO Food and Nutrition Paper 71. Rome: FAO.

FSA (Food Standards Agency, UK) (2000). *A Report of the Study of Infectious Intestinal Diseases in England*. London: The Stationery Office.

ICMSF (International Commission on Microbiological Specifications for Foods) (1994). Choice of sampling plan and criteria for *Listeria monocytogenes*. *Int J Food Microbiol* 22, 89–96.

ICMSF (International Commission on Microbiological Specifications for Foods) (1998). Potential application of risk assessment techniques to microbiological issues related to international trade in food and food products. *J Food Prot* 61, 1075–1086.

McLauchlin, J. (1995). What is the infective dose for human listeriosis? In *Proceedings of the XII International Symposium on Problems of Listeriosis*, Perth, Australia, pp. 365–370. Promaco Conventions Ltd., Canning Bridge, Australia.

McLauchlin, J. (1996). The relationship between *Listeria* and listeriosis. *Food Control* 7, 187–193.

Nickelson, R., Luchansky, J., Kaspar, C. & Johnson, E. (1996). *Update on Dry Fermented Sausage* Escherichia coli *O157:H7 Validation Research*. Research Report No. 11–316. Chicago: National Cattleman's Beef Association.

Noeckler, K., Teufel, P., Schmidt, K. & Weise, E. (1998). *Proceedings of the 4th World Congress on Foodborne Infections and Intoxications*, Vol. I, Vol. II. Federal Institute for Health Protection of Consumers and Veterinary Medicine, Berlin.

Notermans, S. & Hoogenboom-Verdegaal, A. (1992). Existing and emerging foodborne diseases. *Int J Food Microbiol* 15, 197–205.

Potter, M. E. & Tauxe, R. V. (1997). Epidemiology of foodborne diseases: tools and applications. *World Health Stats Quarterly* 50, 24–29.

Ross, T., Todd, E. & Smith, M. (2000). *Exposure Assessment of* Listeria monocytogenes *in Ready-to-Eat Foods. Preliminary Report for Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods*. Rome: FAO.

Tauxe, R. V. (1992). Epidemiology of *Campylobacter jejuni* infections in the United States and other industrialized nations. In Campylobacter jejuni*: Current Status and Future Trends*, pp. 9–19. Edited by I. Nachamkin, M. J. Blaser & L. S. Tompkins. Washington, DC: American Society for Microbiology.

Wheeler, J. G., Sethi, D., Cowden, J. M. *et al.* (1999). Study of infectious intestinal disease in England: rates in the community, presenting to general practice, and reported to national surveillance, The Infectious Intestinal Disease Executive. *Brit Med J* 318, 1046–1050.

WTO (World Trade Organization) (1995). The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm

Chapter 3

Meeting the FSO through Control Measures

3.1 Introduction
3.2 Control Measures
3.3 Confirm That the FSO Is Technically Achievable
3.4 Importance of Control Measures
3.5 Performance Criteria
3.6 Process and Product Criteria
3.7 The Use of Microbiological Sampling and Performance Criteria
3.8 Default Criteria
3.9 Process Validation
3.10 Monitoring and Verifying Control Measures
3.11 Examples of Control Options
3.12 Assessing Equivalency of Food Safety Management Systems
3.13 References

3.1 INTRODUCTION

Effective food safety management systems are designed to meet:

- FSOs established by control authorities through the risk management processes or
- objectives established by food processors during the development of a HACCP plan.

These objectives are achieved through the application of control measures intended to prevent, eliminate, or reduce microbiological hazards such as those discussed in this chapter.

3.2 CONTROL MEASURES

While microbiological criteria have played an important role in defining what has been considered acceptable, their use in testing of food has seldom proven to be effective for control of microbial hazards. The food manufacturers controlled their processes to ensure that their products would meet the criteria if sampled. Greater emphasis was placed on lot acceptance testing than the conditions of operation. Despite the weakness of relying on end-product testing, advances have been made in preventing or reducing foodborne illness. In ICMSF Book 4 (ICMSF, 1988) it was recognized, however, that more emphasis should be placed on the use of selected, targeted control measures and less on microbiological testing of food.

National Beef Ex. 1045
166 of 482

Historically, the major advances in consumer protection have resulted from the development and implementation of selected, targeted control measures at one or more steps along the food chain, from the farm up to the consumer. These advances have followed periods of extensive investigation to gain the information necessary to understand the pathogens (e.g., sources, life cycle, parameters influencing growth, survival, death or metabolite production).

Control measures are the actions and activities used to prevent, eliminate, or reduce a food safety hazard to a tolerable level. They generally fall into three categories:

Controlling Initial Levels

- avoiding foods with a history of contamination or toxicity (e.g., raw milk, raw molluscan shellfish harvested under certain conditions).
- selecting ingredients (e.g., pasteurized liquid eggs or milk).
- using microbiological testing and criteria to reject unacceptable ingredients or products.

Preventing Increase of Levels

- preventing contamination (e.g., adopting GHPs that minimize contamination during slaughter, separating raw from cooked ready-to-eat foods, implementing employee practices that minimize contamination, using aseptic filling techniques).
- preventing growth of pathogens (e.g., proper chilling and holding temperatures, pH, a_w, preservatives).

Reducing Levels

- destroying pathogens (e.g., freezing to kill certain parasites; disinfectants, pasteurization, irradiation).
- removing pathogens (e.g., washing, ultra-filtration, centrifugation).

One or more of the above activities may be necessary to control a hazard. In addition, one or more may be applied at different steps along the food chain to eliminate, prevent, or reduce a hazard to an acceptable level. Each participant along the food chain has a responsibility to apply those control measures that contribute to providing safe foods.

These control measures also fall into one of two programs applied by food manufacturers, the Good Hygienic Practices (GHP) and the Hazard Analysis Critical Control Point (HACCP) systems discussed below.

The first program, GHP, can be viewed as the basic sanitary conditions and practices that must be maintained to produce safe foods. It also includes certain support activities such as raw material selection, product labeling, and coding or recall procedures. Effective application of GHP provides the foundation upon which the second program, HACCP, is developed and implemented. The development of an effective HACCP system involves, therefore, a systematic approach to the identification, evaluation, and control of food safety hazards in a food operation.

HACCP is not implemented in lieu of GHP, and failure to maintain and implement GHP can invalidate a HACCP system and result in production of unsafe food. It is nec-

essary to consider the hazards that are most likely to occur in each particular food operation and to pay particular attention to those elements of GHP and HACCP that will contribute most to controlling those hazards.

3.2.1 Good Hygienic Practices (GHP)

The General Principles of Food Hygiene (CAC, 1997b) describe the major components of GHP as:

- design and facilities (location, premises and rooms, equipment facilities)
- control of operation (control of food hazards, key aspects of food hygiene control, incoming material requirements, packaging, water, management and supervision, documentation and records)
- maintenance and cleaning (maintenance and cleaning programs, pest control systems, waste management, monitoring effectiveness)
- personal hygiene (health status, illness and injuries, personal cleanliness and behavior, visitors)
- transportation (general requirements, use, and maintenance)
- product information and consumer awareness (lot identification, product information, labeling, consumer education, handling/storage instructions)
- training (awareness and responsibilities, training programs, instruction and supervision, refresher training)

As previously stated, effective application of GHP provides the foundation upon which HACCP systems are developed and implemented. Failure to maintain and implement GHP can invalidate a HACCP system and result in production of unsafe food.

Effective control of a hazard in a food necessitates consideration of the components of GHP likely to have significant impact in controlling the hazard. For example, incoming material requirements would be very important to control the risks of certain hazards in seafood (e.g., paralytic shellfish poisoning, ciguatera toxin, scombroid poisoning). Incoming material requirements would be of lesser importance for a food that will be cooked sufficiently to eliminate enteric pathogens (e.g., salmonellae in raw meat or poultry) that may be present. Thus, the various components of GHP do not carry equal weight in all food operations. It is necessary to consider the hazards that are most likely to occur and then apply those GHPs that will be effective for controlling the hazards. This does not mean that the other components of GHP, such as equipment maintenance or calibration of temperature probes, are ignored. Some may be very important to ensure that a food meets established quality requirements.

In certain situations, selected components of GHP may carry particular significance and should be incorporated into the HACCP plan. For example, equipment maintenance and calibration are important for large, continuous ovens used in cooking meat products. The procedure and frequency (e.g., monthly, quarterly) for conducting checks on heat distribution during cooking could be incorporated into the HACCP plan as a verification procedure. In addition, it is normally necessary to verify the accuracy of the thermometers used for monitoring oven temperatures during cooking.

Information on hygienic design of facilities and equipment, cleaning and disinfection, health and hygiene of personnel, and education and training are discussed in ICMSF Book 4 (ICMSF, 1988).

3.2.2 Hazard Analysis and Critical Control Point (HACCP)

The Codex document on the Hazard Analysis and Critical Control Points (HACCP) System and Guidelines for its Application (CAC, 1997a) lists the following seven principles of the HACCP system:

1. Conduct a hazard analysis.
2. Determine the critical control points.
3. Establish critical limits.
4. Establish monitoring procedures.
5. Establish corrective actions.
6. Establish verification procedures.
7. Establish recordkeeping and documentation procedures.

The development of an effective HACCP system involves a systematic approach to the identification, evaluation, and control of food safety hazards in a food operation. HACCP plans specify the actions to be taken in a food operation to control food safety hazards. HACCP plans also specify records to be generated during the operation for use in verification that critical limits have been met at critical control points in the operation. In the event that a deviation occurs at a critical control point, the deviation should be detected in time to ensure that corrective actions will prevent unsafe food from reaching consumers. This may necessitate collecting and analyzing samples from across the questionable quantity of food. The principles described in this text for sampling food can be applied to help assess the safety of a suspect lot and lead to appropriate disposition of the food (see Chapter 11, Tightened Inspection).

The production of safe food requires food operators selectively to apply GHP and the principles of HACCP to develop and implement a total food safety management system that will control the significant hazards in the food that is being produced.

The Codex Alimentarius Commission has defined a critical control point as "a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level" (CAC, 1997a, p.19). The interpretation of what is considered an acceptable level has been left to the judgment of the HACCP team and respective control authority. The FSO concept can be used to communicate the level of control necessary for a hazard to be reduced to "an acceptable level."

3.3 CONFIRM THAT THE FSO IS TECHNICALLY ACHIEVABLE

Following the development of an initial FSO for a particular food or food category, risk managers in industry and government must confirm that it is technically achievable through GHP and HACCP (see Figure 1–1). This decision should be based on preliminary process and product requirements and exchanges of information between industry and government.

If the proposed FSO is (or seems to be) technically achievable, then final requirements for product and process can be developed to ensure that this objective is met. Individual food manufacturers can then implement the necessary control measure(s) to fulfill the overall performance criteria.

However, if the proposed FSO is not technically achievable, then modifications of the product, the process, if technically possible, and/or the FSO may be necessary. Modifications should result from discussions between industry and government aiming at achieving optimal public health protection based on a tolerable level of risk. If no technically achievable solution can be found, then it may be necessary to ban the product

and/or the process. In addition, as new information regarding a particular hazard or product emerges, FSOs may be modified.

3.4 IMPORTANCE OF CONTROL MEASURES

Historically, the major advances in consumer protection have resulted from the development and implementation of selected, targeted control measures at one or more steps along the food chain. Appendix 3–A summarizes a number of foodborne diseases and the measures that have been found to be most effective for their control. Certain biological hazards are influenced by environmental conditions that are beyond the control of a food operator (e.g., ciguatera toxin, scombroid poisoning, and shellfish intoxication, mycotoxin formation in crops in the field). For these hazards, it has been essential to understand the effect of climatic conditions in the affected regions of the world. This information is used to determine when to screen for the hazard during periods of higher risk. Thus, to avoid these hazards, raw material selection is an important control measure. In addition, dehydration of certain crops can be used following harvest to prevent mycotoxin development during subsequent storage and distribution. For certain pathogens associated with livestock, selected on-farm practices have led to reductions in human disease. For example, brucellosis and trichinosis in the US and Europe have been reduced by specific control measures (Figures 3–1 and 3–2).

3.4.1 Examples of the Effectiveness of Control Measures

Historically, foods have been preserved by salting, pickling, curing, heating, drying, etc., to save the foods for those periods when they would not normally be available. These

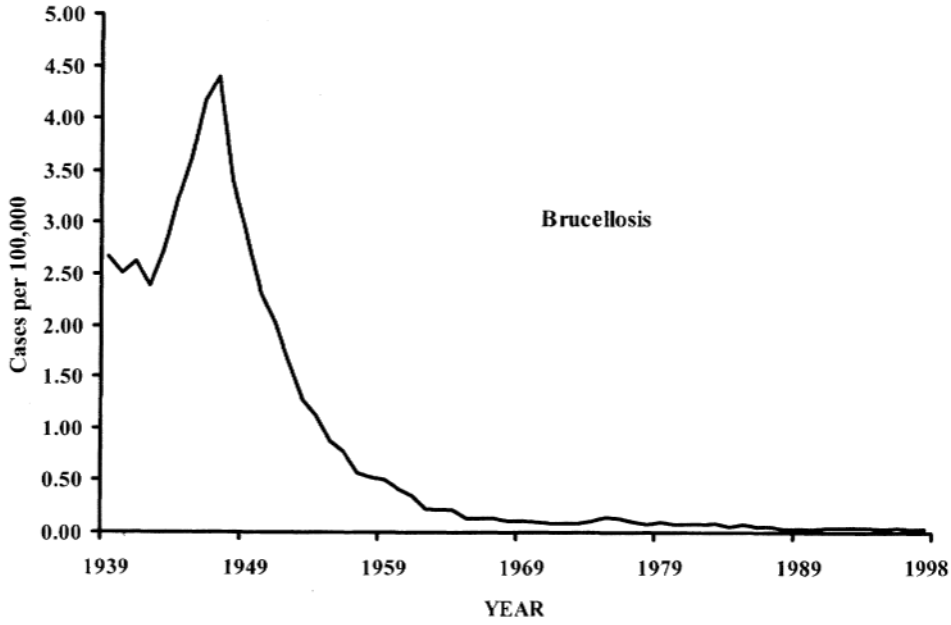


Figure 3–1 Cases of human brucellosis per 100,000 population in the US, 1939–1998.

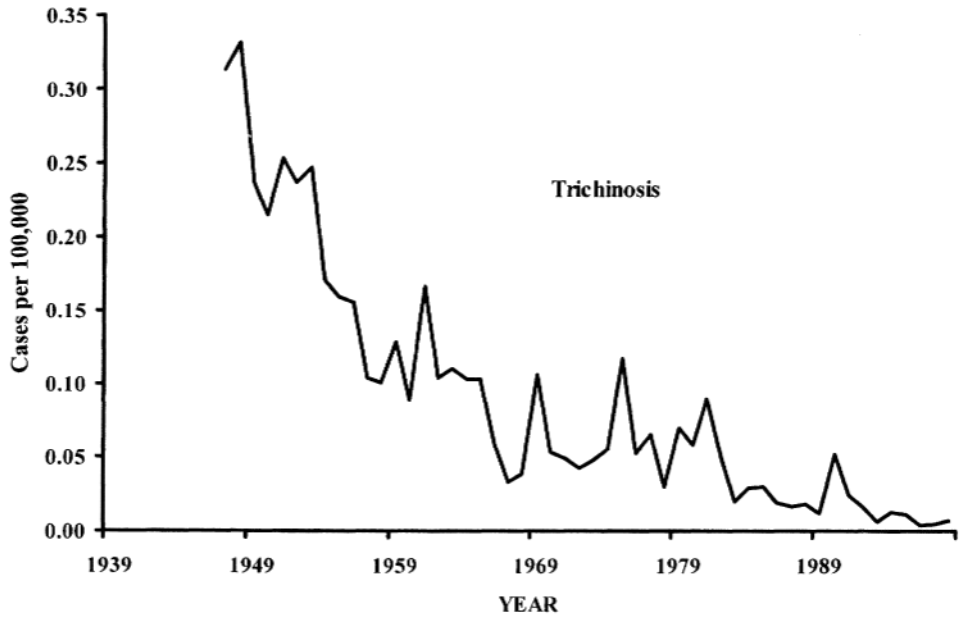


Figure 3–2 Reduction of trichinosis in the US after World War II.

basic technologies have led to considerable diversity in the world's food supply. They also can be viewed as control measures that have evolved through experience and, when applied correctly, have been found to yield safe food for later use. Table 3–1 summarizes the control measures that have been used to produce a wide variety of shelf-stable foods (Tompkin & Kueper, 1982). In some cases, a single important control measure has been adequate. In most, however, combinations of factors have been used to achieve shelf stability.

Another means of demonstrating the importance of control measures is to examine trends of foodborne disease. For example, Figure 3–1 shows the number of cases of human brucellosis per 100,000 population in the US from 1939–1998. A marked increase occurred during World War II that was attributed to greater movement of livestock among farms in response to the increased demand for meat and higher livestock prices and diversion of veterinarians to the war effort (Simms, 1950). Similar disruptions in on-farm pathogen control practices would have been commonplace elsewhere in the world during that time period. During the period 1940–1947, human brucellosis was strongly associated with animal contact. For example, in Iowa, the rate per 100,000 population during 1940–1947 was 562 for veterinarians, 276 for packinghouse employees, 59 for male farm workers, and 2 for the "no contact" group (Jordan, 1950). Following the war, efforts resumed for control of brucellosis through a combination of on-farm practices and culling of livestock. Increased use of pasteurization of milk for manufacture of dairy products provided an additional important control measure that led to reduced consumer exposure.

Prior to 1940, the incidence of human trichinosis in the US also decreased due to specific on-farm control measures, processing requirements in commercial meat establishments, and education of consumers of the necessity to cook pork adequately. After investigations demonstrated the significance of household kitchen garbage containing raw

Table 3–1 Processes That Have Been Used for Making Commercially Prepared Foods Shelf-stable

Food	*Process*	*Food*	*Process*
Milk	D, H	Vegetable juices	B, D
Eggs	H	Vegetables, pickled	A
Natural cheese	J	Peanut butter	I
Processed cheese and cheese sauce	C	Ham, bacon	A, E
		Beef	B, E
Cake, bread	K, L	Pork sausage	E, G
Cookies, crackers	H	Dry and semi-dry sausage	E, F, G
Fruit	A, C, J, H	Franks, viennas, meat spreads	B
Fruit juices	C, D	Luncheon meats, cured	A
Jams, jellies	C	Fish, smoked salmon, pickled herring, salt cod	B, E, H
Vegetables	A, B, H		

Process Codes:

A. Mild thermal process ($F_0 = < 2.78$) in hermetically sealed container.
B. High thermal process ($F_0 = \geq 2.78$) in hermetically sealed container.
C. Thermal process, hot fill, seal and hold before cooling.
D. Thermally process, chill, then aseptically package.
E. Salted, perhaps cured, at low temperature then dried during heating or at ambient temperatures. Smoke commonly applied.
F. Fermented at 20–40 °C, perhaps heated to ≥ 46 °C, then dried at cool temperature (e.g., 13 °C).
G. Fermented and/or cooked, dried, then sealed in lard.
H. Thermal process and dehydration.
I. Roasted, ground, and filled at moderate temperature.
J. Dehydration.
K. Filled into container, sealed, then heated sufficiently to bake product.
L. Baked in container, then sealed while hot.

pork as a source of infection for pigs, regulations were implemented that required cooking garbage before feeding to pigs (Leighty, 1983). Figure 3–2 shows the reduction of trichinosis in the US after World War II.

Trichinosis is an interesting example illustrating the differences in control measures adopted by the US and Europe to achieve similar levels of protection. While in the US control measures have been focused on destruction, e.g., by cooking, in Europe, microscopic and later immunologic methods have been used to detect and eliminate carcasses with *T. spiralis* (Pozio, 1998). The different approaches have led to differences in regulatory requirements, quality characteristics of pork products, and culinary habits. In this particular example, however, the European approach was much more effective and achieved more rapid reductions in the prevalence of *T. spiralis* in the hog population and human trichinosis than in the US. It is only in recent years that the prevalence of human trichinosis in the US has begun to approach the levels found in Europe before 1940. In the European Union (EU), 74.4% of domestic pigs are raised on industrialized farms where *Trichinella* infection has not been diagnosed. The reservoir for *Trichinella* in the EU consists of pigs raised on small family farms or grazing in wild areas, as well as wild boars and horses (Pozio,

1998). The prevalence of trichinellae in pigs in Germany has been three or fewer infected pigs among about 40 million pigs slaughtered each year (Rehmet *et al.*, 1999). In a review of trichinellosis in the Netherlands, it was stated that such infections had not occurred in humans or animals during the previous 40 years (Ruitenberg & Sluiters, 1974). For comparison, farm-raised swine in the US, which comprised 98.5% of the swine production, had prevalence rates of about 0.125% (Zimmerman, 1974).

The third example is the sharp decline in typhoid fever in the US from 1939–1998 (Figure 3–3). The source of *Salmonella typhi* is the intestinal tract of humans. Growth outside the human host has not been an important factor. The primary routes of infection have been fecal-oral routes involving untreated water and infected food handlers or health care providers. Thus, improvements in waste water management; availability of safe, potable water for drinking and food processing; and education on the importance of hand washing have led to reductions in the prevalence of typhoid fever. This enabled a more directed approach toward identifying and treating individuals who harbored the pathogen due to infection or as asymptomatic carriers. Finally, vaccination of individuals traveling to regions where typhoid fever was endemic reduced the likelihood of reintroducing the pathogen into the population.

In Figure 3–4, the trends for shigellae and nontyphoid salmonellae are provided. While progress was initially made after World War II toward reducing the rate of shigellosis, there has been no improvement over the past four decades. Shigellae are similar to *S. typhi* in that humans are the source, and transmission involves contaminated water and food. An additional significant route involves person-to-person transmission via the fecal-oral route, particularly in institutional settings (e.g., child care centers). Can effective control measures be implemented that would decrease the prevalence of shigellosis below the level of 5–8.9 cases per 100,000 (CDC, 2000a)?

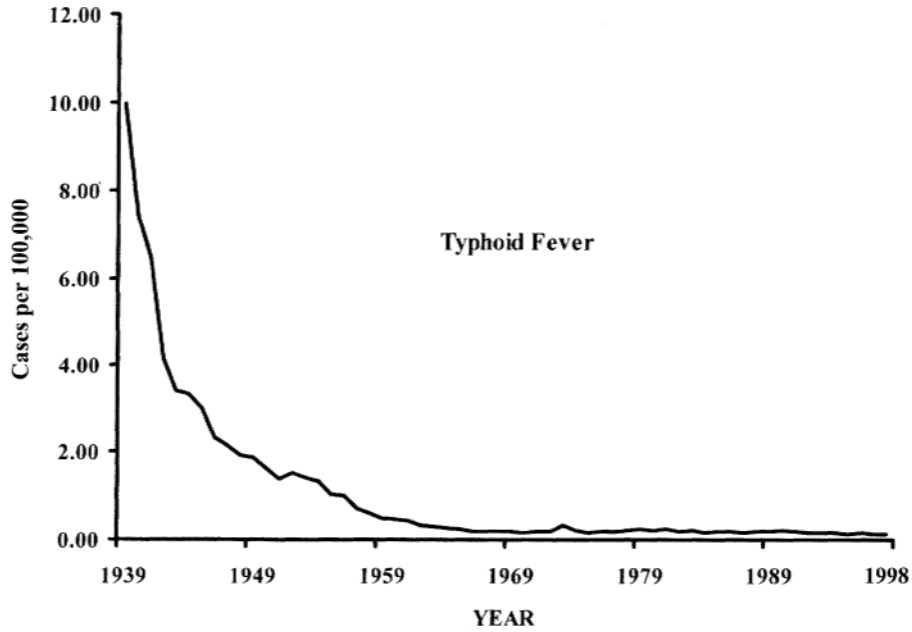


Figure 3–3 Reduction in typhoid fever in US from 1939–1998.

The data for nontyphoid salmonellae show an increase of salmonellosis until about 1990, followed by a decrease (Figure 3–4). The decrease may be attributed to reductions in egg-borne transmission of *S. enteritidis* through improved on-farm controls (CDC, 2000b). In addition, some reduction may eventually prove to be due to improved controls implemented by the meat and poultry industry following the establishment of performance standards by the US Department of Agriculture (USDA)-Food Safety and Inspection Service in 1996 (USDA, 1996a). The performance standards in Table 3–2 specify the maximum frequencies for salmonellae on carcasses and in ground meat. In this case, the performance standards were incorporated into a regulation and assumed the nature of a regulatory standard, but not a microbiological standard, as described in Chapter 5.

In anticipation of the regulation and other requirements, the meat and poultry industry in the US invested extensively to modify its processing equipment, plant layouts, and processing procedures. This included the use of antimicrobial treatments, such as improved control of chlorinated processing water for poultry and the use of steam or hot water pasteurization for beef carcasses. Some modifications were implemented well in advance of the effective dates for the regulatory requirements.

All categories of raw meat and poultry for which performance standards were established have shown reductions in the prevalence of salmonellae in large plants from 1996–2000. The prevalence rate for salmonellae in broilers in large plants, for example, declined to approximately 10% (USDA, 2000). Thus, it would appear that the performance standards have led to reductions in the prevalence of salmonellae while allowing the industry to decide how to modify its processing conditions. The question remains whether the reductions in salmonellae in raw meat and poultry will lead to a measurable reduction in human salmonellosis. In addition, it is uncertain whether further reductions will be possible in the absence of new technology or improved control at the farm level.

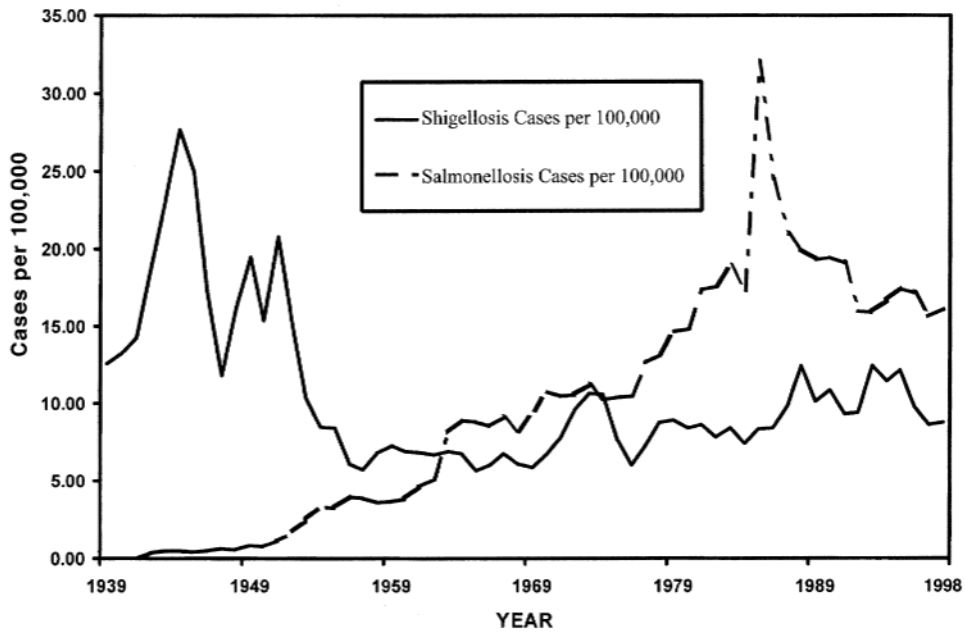


Figure 3–4 Incidence of shigellosis and salmonellosis in the US, 1939–1998.

Table 3–2 Maximum Allowable Frequencies for Salmonellae on Carcasses and Ground Meat and Poultry

	Allowable percent positive samples	*Number of samples*	*Maximum allowable number of positives*
Carcasses:			
Steer/heifer	1.0	82	1
Cows/bulls	2.7	58	2
Hogs	8.7	55	6
Broilers	20.0	51	12
Ground products:			
Beef	7.5	53	5
Chicken	44.6	53	26
Turkey	49.9	53	29

In Finland, Norway, and Sweden, greater emphasis has been placed on testing and control at the farm level to achieve on-farm prevalence rates of less than 1% for salmonellae in livestock and poultry. These control measures are intended to meet a performance standard of less than 1% prevalence rate for salmonellae in foods of animal origin (Kruse, 1999).

A final example of an effective control measure has been the apparent 40% reduction in human yersiniosis in Norway following a rather simple but effective change in the slaughtering procedure for hogs. Data indicate that the reduction occurred after about 90% of the hog slaughterhouses implemented a procedure of sealing off the rectum with a plastic bag immediately after the rectum was cut free. A similar decline (about 30%) reportedly occurred following adoption of the same practice in Sweden (Nesbakken, 2000).

3.5 PERFORMANCE CRITERIA

To achieve the defined FSO, it is necessary to implement one or more control measures at one or more steps in the food chain. At these steps, hazards can either be prevented, eliminated, or reduced. If appropriate control measures are not applied at these steps, then the hazards may increase. The outcomes of these control measures are defined as *performance criteria*.

Examples of published performance criteria include:

- 12 D reduction of proteolytic *Clostridium botulinum* in low-acid canned foods (Stumbo, 1973; Brown, 1997).
- 6 D reduction of *Listeria monocytogenes* in ready-to-eat chilled foods (Lund *et al.*, 1989).
- 6 D reduction of psychrotrophic strains of *Clostridium botulinum* in pre-prepared chill-stored foods with extended shelf-life (ACMSF, 1992; Gould, 1999).
- 5 D reduction of *Escherichia coli* O157:H7 for fermented meat products (Nickelson *et al.*, 1996).
- the frequency of salmonellae in/on raw meat and poultry shall not exceed those specified in Table 3–2 (USDA, 1996a).

When establishing performance criteria, consideration must be given to the initial level of a hazard and to changes occurring during production, distribution, storage, prepara-

tion, and use of a product. A performance criterion is preferably less than but at least equal to the FSO and can be expressed by the following equation (1):

$$H_0 - \Sigma R + \Sigma I \leq FSO \quad (1)$$

Where: FSO = Food safety objective

H_0 = Initial level of the hazard

ΣR = Total (cumulative) reduction of the hazard

ΣI = Total (cumulative) increase of the hazard

FSO, H_0, R and I are expressed in $\log_{10}$ units.

These criteria are usually not established for control measures designed to avoid certain foods, although they may be applied to ensure that the initial level of hazards in ingredients is not excessive. Microbiological testing may thus be used to select ingredients or to obtain information on the initial level of a hazard.

3.5.1 Examples of Performance Criteria

For examples 1 to 3 below, a hypothetical dose-response curve for a certain infectious pathogen has been included at the top of each figure (Figures 3–5, 3–6, and 3–7). In these examples, the estimated number of cases per 100,000 population increases as the pathogen concentration in the food exceeds the minimum infectious dose of 1 cfu g^{-1}. In all three examples, the FSO has been established at 100-fold less than this dose, i.e., < 1 cfu 100 g^{-1} at the time of consumption.

These examples could be representative for *E. coli* O157:H7 in products submitted to heat treatment and/or other processing steps.

3.5.1.1 Example 1

In this example, the initial population (H_0) in the raw material is estimated to be as high as 10^3 cfu g^{-1}, but growth (ΣI) can be prevented. The required performance criterion would be expressed as:

$$H_0 - \Sigma R + \Sigma I \leq FSO$$
$$3 - \Sigma R + 0 \leq -2$$
$$\Sigma R \leq -5$$

Based on equation (1), the process must result in an overall reduction of 5 $\log_{10}$ to meet the FSO. This corresponds to a performance criterion of a 5 D reduction of the pathogen and could be achieved by one, or a combination of, control measures (Figure 3–5).

3.5.1.2 Example 2

In this example, the initial population (H_0) in the raw material can be controlled to ≤ 100 cfu g^{-1} and growth (ΣI) can be prevented. Here, a sampling plan allowing for raw material selection can be used. The required performance criterion would be expressed as:

$$H_0 - \Sigma R + \Sigma I \leq FSO$$
$$2 - \Sigma R + 0 \leq -2$$
$$\Sigma R \leq -4$$

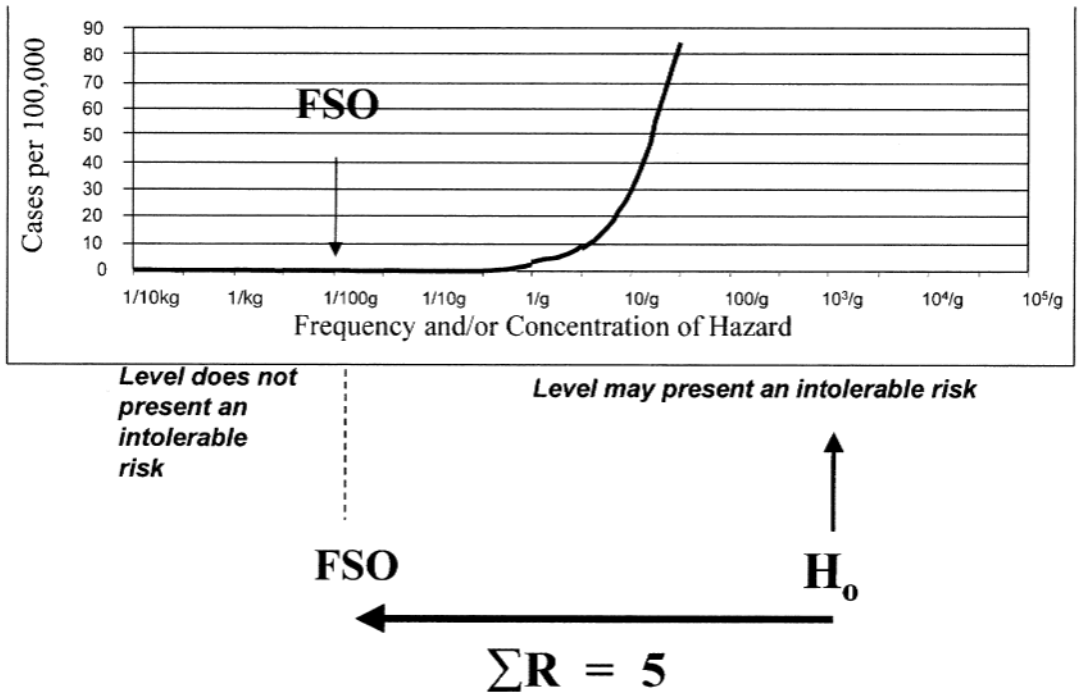


Figure 3–5 Example 1.

Based on equation (1), the process must result in an overall reduction of 4 $\log_{10}$ units to meet the FSO. This corresponds to a performance criterion of a 4 D reduction of the pathogen and can be achieved using selected raw materials and other control measures (Figure 3–6).

3.5.1.3 Example 3

In this example, the initial population (H_0) in the raw material is 10^3 cfu g^{-1}, and recontamination or growth (ΣI) leading to not more than a 100-fold increase is possible. The required performance criterion would be expressed as:

$$H_0 - \Sigma R + \Sigma I \leq FSO$$

$$3 - \Sigma R + 2 \leq -2$$

$$\Sigma R \leq 7$$

Based on equation (1), the process must result in an overall reduction of 7 $\log_{10}$ units (i.e., from 10^5 cfu g^{-1} to 1 cfu 100 g^{-1}) to meet the FSO. This corresponds to a performance criterion of a 7 D reduction of the pathogen and can be achieved by various control measures (Figure 3–7).

For examples 4 and 5, a hypothetical dose-response curve is included at the top of each figure (Figures 3–8 & 3–9). In these examples, the estimated number of cases per 100,000 population increases as the pathogen concentration in the food exceeds the minimum infectious dose of 10^3 cfu g^{-1}. In the two examples, the FSO has been established at 10-fold less than this dose, i.e., $<$ 100 cfu g^{-1} at the time of consumption.

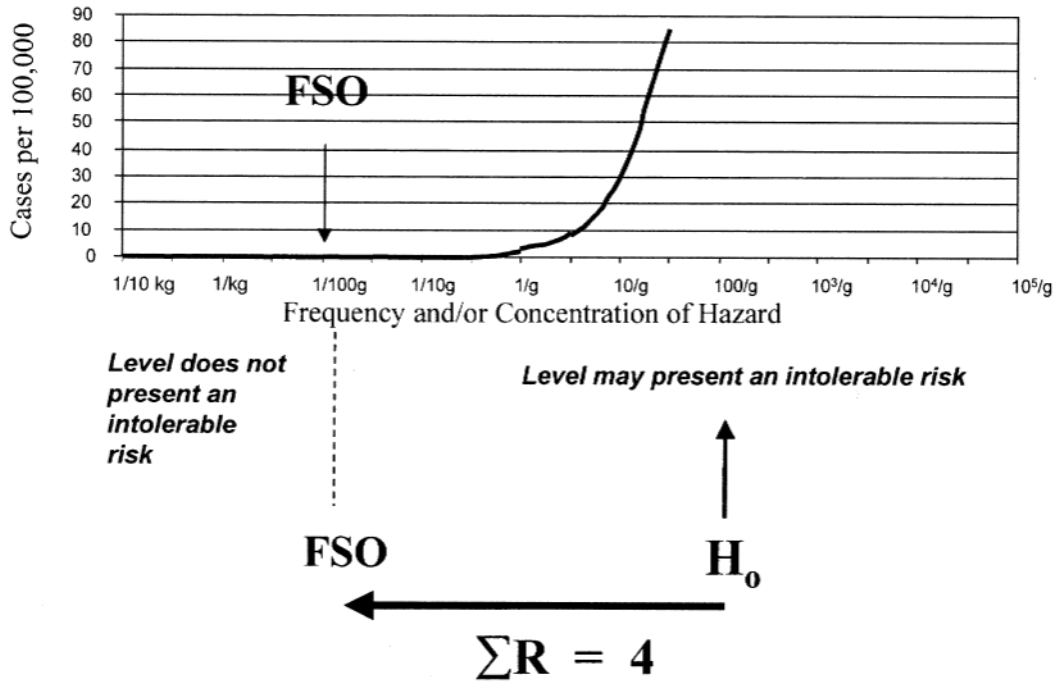


Figure 3–6 Example 2.

These examples could be representative of *Listeria monocytogenes* and of ready-to-eat product not submitted to any killing effect ($\Sigma R = 0$) before the food is consumed.

3.5.1.4 Example 4

In this example, the initial level (H_0) is unknown but there is no recontamination or growth (ΣI) up to the time of consumption. The required performance criterion would be expressed as:

$$H_0 - \Sigma R + \Sigma I \leq FSO$$

$$H_0 - 0 + 0 \leq 2$$

$$H_0 \leq 2$$

Based on equation (1) and to ensure that the FSO is met, the pathogen level must not exceed 100 cfu g^{-1}. This could be achieved through the application of microbiological criteria. In this case, the performance criteria must be below the FSO (Figure 3–8).

3.5.1.5 Example 5

In this example, the initial level (H_0) of the pathogen can be controlled to $\leq$ 10 cfu g^{-1} and growth (ΣI) can be prevented. Here, a sampling plan allowing for raw material selection can be used. The required performance criterion would be expressed as:

$$H_0 - \Sigma R + \Sigma I \leq FSO$$

$$1 - 0 + \Sigma I \leq 2$$

$$\Sigma I \leq 1$$

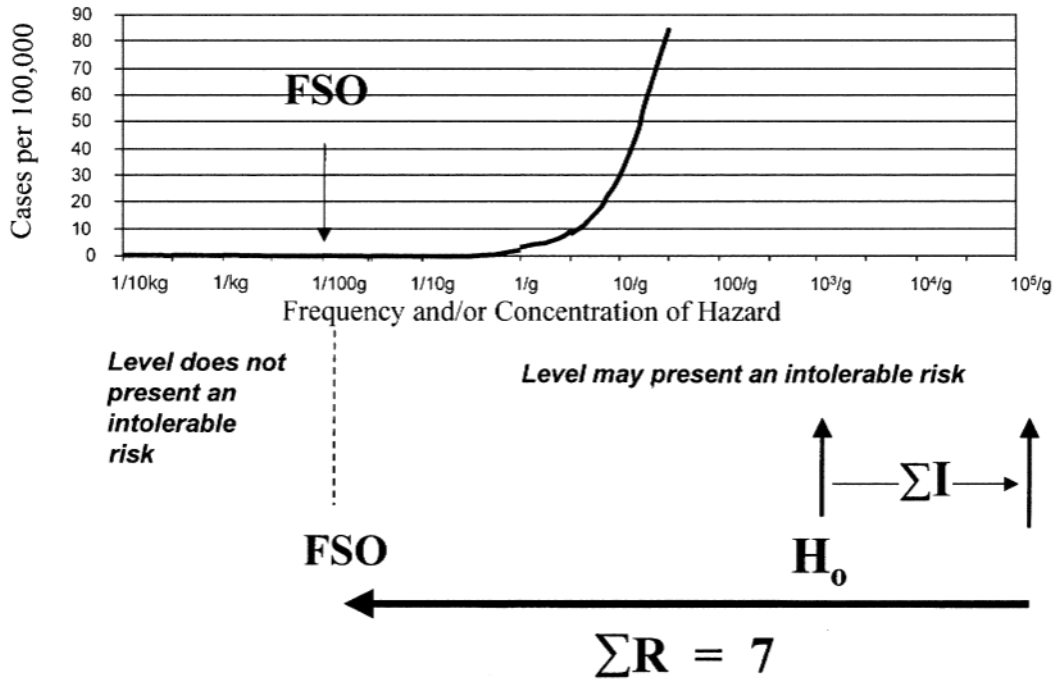


Figure 3–7 Example 3.

Based on equation (1) and to ensure that the FSO is met, the pathogen level must not increase more than 10-fold. This could be achieved through the establishment of product criteria such as a_w or pH, alone or in combination (Figure 3–9).

It should be recognized that the parameters that may be used in equation (1) are point estimates, whereas in practice, they will have a distribution of values associated with them. If data exist for the variance associated with the different parameters, then the underlying probability distributions may be established using an approach similar to that in risk assessment.

Certain aspects must be considered when determining the elements of equation (1). For the initial level of the hazard (H_0), there is a temptation to use the highest level reported in the literature. However, care should be used in this approach as this can lead to an unnecessarily restrictive (conservative) performance criterion. H_0 may vary from one situation to another and should be considered as the initial upperlevel that can be expected under normal conditions at a specific operation. The level of hazard detected in one situation may have no relevance to another. Thus, the value for H_0 in one food operation may differ from other operations. H_0 may range from zero (undetectable) to its upper level in the absence of any effort for its control. It may be necessary to establish a maximum value to assure the production of safe food, as shown in Example 4.

In the case of ΣR, any type of reduction needs to be considered, such as killing by thermal treatments, washing, or filtration.

In the above examples, the increase in a hazard (ΣI) was through pathogen growth. While growth is likely to be the most significant factor in many foods, an increase in a hazard through recontamination also must be considered.

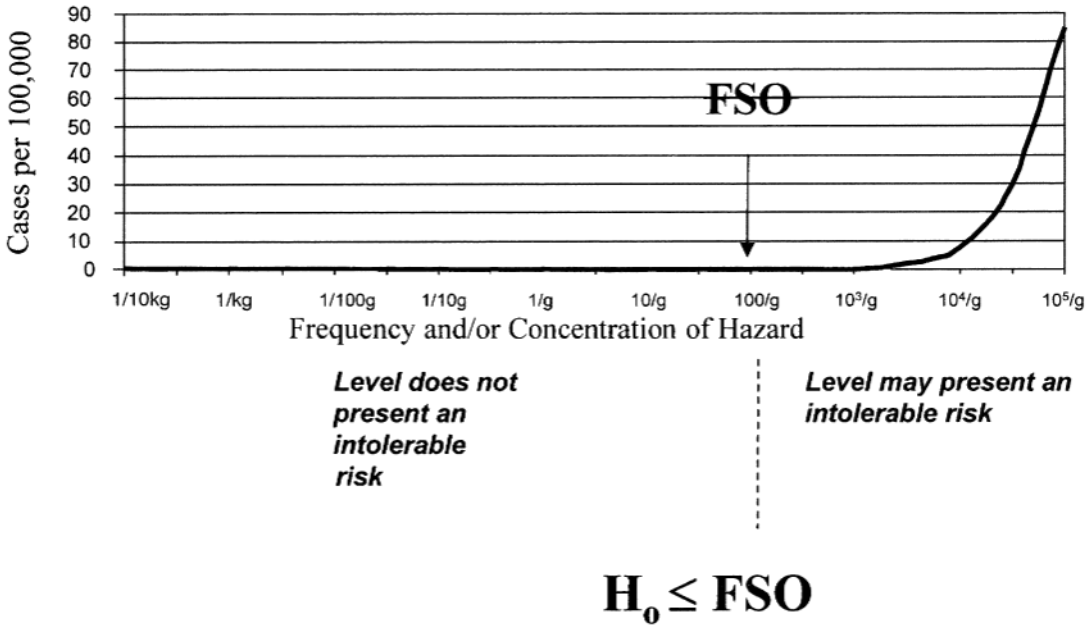


Figure 3–8 Example 4.

3.6 PROCESS AND PRODUCT CRITERIA

A performance criterion is met by implementing process criteria, such as time and temperature of a heat treatment, and/or product criteria, such as the water activity of the product, alone or in combination, to achieve control over a specific hazard. For example, the process criterion for milk pasteurization is 71.7 °C for 15 s; this criterion has been adopted as a regulatory requirement in numerous countries. It defines the processing conditions considered necessary to ensure inactivation of *Coxiella burnetti.* This process criterion will also ensure elimination of other non-spore-forming pathogenic enteric bacteria known to occur in raw milk.

An example of a product criterion is pH $\leq$ 4.6 in canned shelf-stable acidified foods, which is the parameter known to inhibit growth of *C. botulinum.*

In the case of minimally processed refrigerated foods, combinations of process and product criteria have been proposed to ensure the safety of products. In these cases, heat-treatments milder than 90 °C for 10 min in combination with other factors, such as reduced pH, water activity, or shelf-life (AMCSF, 1992; Gould, 1999), are recommended.

3.7 THE USE OF MICROBIOLOGICAL SAMPLING AND PERFORMANCE CRITERIA

Increasingly, it has been realized that food safety management systems based on preventing hazards through GHP and HACCP are much more effective in ensuring safe foods than is end-product testing.

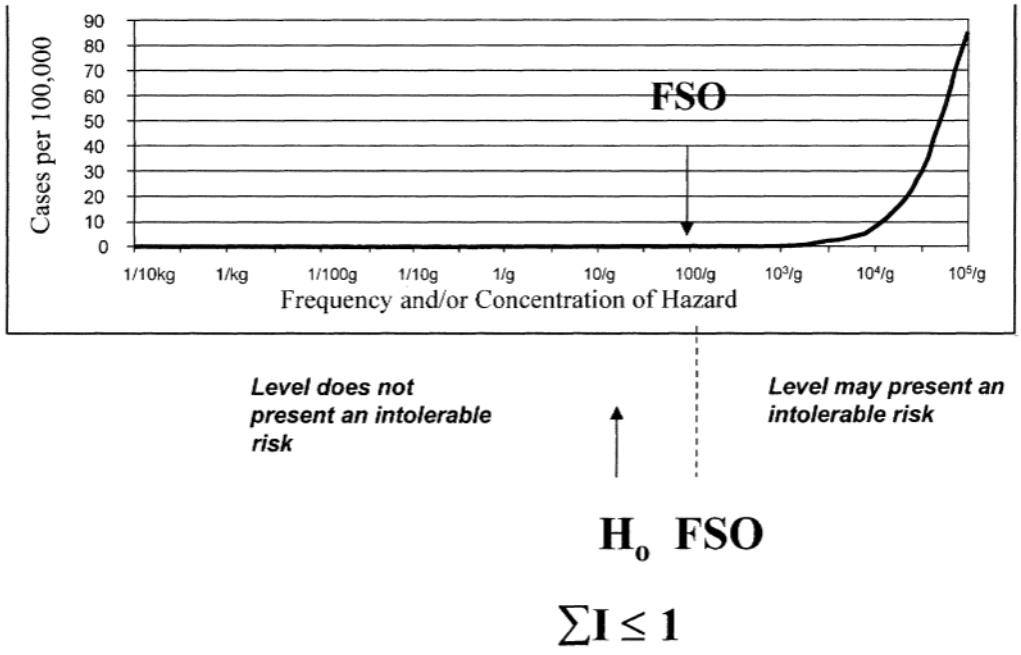


Figure 3–9 Example 5.

In the ICMSF scheme for managing microbiological risks (Figure 1–1), two uses of microbiological criteria are identified:

1. to validate that control measures meet the performance criteria.
2. to determine acceptability of a food when no more effective means of providing such assurance of safety is available, i.e., in the absence of knowledge that GHP and HACCP have been properly applied (see Chapter 4 for more details).

Different control measures or options can be applied to manufacture safe foods to meet the FSO. However, the equivalence of these measures, in comparison to the established performance criterion, needs to be established. For a number of processes and products, this can be expressed in terms of frequency or concentration of a microbiological hazard in the food.

Traditionally, the performance of sampling plans and microbiological criteria have been expressed in terms of their ability to detect defective sample units within a lot and, thereby, determine acceptance or rejection of the lot. The proportion of defective sample units can be used to estimate the concentration of the hazard within the food (Foster, 1971; Legan *et al.*, 2001); however, homogeneous distribution of the defective units throughout the lot and random sampling (Chapter 7) must be assumed.

Figure 3–10 shows the number of 25 g samples that must test negative to be able to conclude (with a confidence of 95%) that the concentration of organisms is at a given level or below. For example:

- 13 × 25 g negative corresponds to < 1 cell 125 g^{-1}
- 29 × 25 g negative corresponds to < 1 cell 250 g^{-1}
- 60 × 25 g negative corresponds to < 1 cell 500 g^{-1}

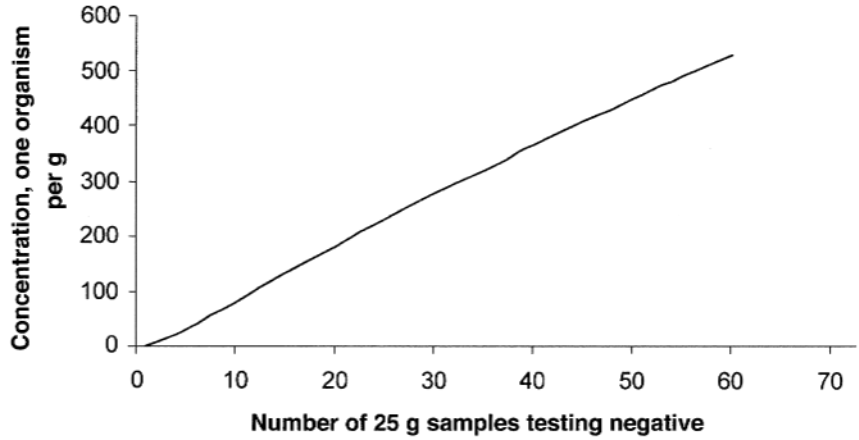


Figure 3–10 Number of 25 g samples testing negative to have 95% confidence in meeting standard.

Using this approach, microbiological testing can be used to ensure that the initial concentration of the hazard (H_0) in an ingredient does not exceed a given concentration (assuming a homogeneous distribution or random sampling, as per Chapter 7). In this way, a microbiological criterion can be used as a control measure to help meet a performance criterion and, thereby, an FSO as in Example 5.

It must, however, be realized that for a number of foods, the application of effective control measures will allow the achievement of much lower defect rates and that under such circumstances, testing remains questionable.

3.8 DEFAULT CRITERIA

In the absence of an FSO, it may be appropriate to establish default criteria for certain control measures. These fail-safe criteria, developed by advisory bodies of experts or control authorities, are intended to control hazards under "worst-case" situations and will, of necessity, be less flexible. They may assume a higher than normal initial level of a hazard (H_0) and/or increase (ΣI) during processing or prior to consumption.

An example of a default criterion is cooking roast beef to an internal temperature of 62.8 °C to destroy enteric pathogens, such as salmonellae and pathogenic *E. coli* (USDA, 1999). Another example is in-pack thermal treatment for 10 min at an internal temperature of 90 °C for ready-to-eat chilled foods with extended shelf-life to destroy nonproteolytic *Clostridium botulinum* (ACMSF, 1992; Gould, 1999).

Default criteria provide a safe harbor for food operators lacking either the resources or the desire to develop information necessary for alternative criteria that may be more appropriate for their specific operation or product.

3.9 PROCESS VALIDATION

Control of food operations depends upon operator knowledge and the conditions that influence the production of safe and unsafe food. A considerable amount of information is available in the literature and other sources. For novel processes it may be necessary to develop information to verify the efficacy of the control measures. Some operations may

be so unique and different from other operations producing similar foods that control is less certain. In other situations, an operator may wish to use minimal processing techniques for improved product quality or reduced cost. In such instances, it may be necessary to validate the efficacy of the adopted control measures.

Validation can involve:

- developing data through challenge tests in the laboratory that are intended to mimic the conditions of operation.
- collecting data during normal processing in the food operation.
- comparison with similar processes/products.
- other expert knowledge.

Each method has its strengths and weaknesses, and in certain cases, two or more methods may be desirable. Data developed through laboratory challenge tests can involve the food, culture media, or other material that may be appropriate. Challenge studies in a food processing environment can provide a higher degree of assurance concerning the ability to meet performance criteria; however, this requires the use of surrogate test microorganisms (see below). Pathogenic microorganisms should never be introduced into the food production or processing environment for the purpose of process validation. In some cases, it may be possible to follow changes in the population of naturally occurring pathogens throughout a process. Such studies, for example, could be conducted during the preparation and processing of raw agricultural commodities into ready-to-eat foods. Ideally, validation could involve laboratory challenge tests with pathogens in the laboratory and then revalidation after the control measures have been implemented. This, however, may be impractical in situations where the prevalence of a pathogen is very low and large numbers of samples are necessary to develop meaningful data.

3.9.1 Laboratory Challenge Tests

When conducting laboratory challenge studies, factors such as the following should be considered:

- intrinsic resistance of the pathogen;
- use of nonpathogens for validation;
- composition of the food; and
- conditions of storage, distribution, and preparation for use.

3.9.1.1 Intrinsic Resistance of the Pathogen

Studies to evaluate the resistance of a pathogen to different parameters (e.g., heat, cold, acid) that may be incorporated into a control measure should be performed using several strains (e.g., five or more), including outbreak-associated isolates from the food in question. Resistance of the strains used for testing is a key factor when establishing effective control parameters. The inocula should be prepared under conditions that yield resistance of the pathogen appropriate to the process. Vegetative cells of salmonellae and pathogenic *E. coli*, for example, exhibit a maximum resistance to heat and acidic conditions when in the stationary phase after having been grown at elevated temperatures. Sufficient numbers of the pathogen (e.g., cells, spores, viral particles, oocysts) should be used to eliminate biovariability effects.

Strains to be tested should not include isolates with unrealistically extreme resistances or growth characteristics when these are not associated with public health concerns. For

example, *Salmonella senftenberg* 775W should not be used as the basis for thermal processing requirements for liquid egg products because of its unusually high heat resistance and rare occurrence, but is appropriate to evaluate survival in chocolate and similar products (ICMSF, 1998).

3.9.1.2 Use of Nonpathogens for Validation

Validation of control measures in a food operation can be accomplished through the use of nonpathogenic microorganisms if they have been shown to have the same growth pattern or resistance as the pathogen of concern.

3.9.1.3 Composition of the Food

The composition of the food can affect inactivation, survival, and/or growth of pathogens and therefore must be known and taken into account. Factors such as pH, a_w, Eh, humectants, acidulants, solutes, antimicrobials, substrates, and competing microflora can affect the chemical and physical properties of the food and subsequently the pathogen of concern. Normal variation in the concentration and distribution of food constituents and microorganisms also must be known and understood.

3.9.1.4 Conditions of Storage, Distribution, and Preparation for Use

Factors affecting the safety of a food during storage, distribution, and preparation for use must be identified and controlled. Information on the intended use and an estimate of likely misuse of the product may be necessary. Examples of parameters that often have a significant effect include time and temperature, the potential for contamination, and faulty preparation before consumption.

3.9.2 Data Collected from Food Operations

A considerable amount of data can be collected from a food operation to better understand the potential microbial hazards. The data can consist of a variety of chemical, physical, and microbiological measurements. For example, if the chemical composition of a food is known as it undergoes processing, estimates can be made of the potential for certain pathogens to survive or multiply in it. Similarly, measurements of processing times and temperatures must be understood if the potential for survival and growth during processing is to be estimated. While generalizations often can be made from published data, the source and type of raw materials may differ among food operators. The best means to establish H_0 is to analyze raw material samples from an operation. Opportunities also may exist for collecting microbial data from samples collected as a food is being processed. Such in-plant data can be used to validate a process or to verify results obtained in the laboratory. For a variety of reasons, however, it may be necessary to measure changes in the population of a nonpathogen that has similar or greater resistance than the pathogen. This may be necessary, for example, when the numbers or prevalence of the pathogen are too low to develop meaningful data. The variability in a pathogen population can be influenced, for example, by season, geographic location of the operation, source and type of raw materials, and processing conditions. These and other factors should be considered when collecting data for use in process validation.

3.9.2.1 Process Variability

The variability that occurs in a food operation must be considered when establishing the critical limits associated with control measures. Examples of factors that can influence

variability of a process include equipment performance and reliability, integrity of container seals, processing times and temperatures, pH, humidity, flow rates, and turbulence.

It is essential that the variability of process parameters and product formulation be considered when setting critical limits. In general terms, the critical limits at a CCP for a process operating under a high degree of control (low variability) can be closer to the conditions necessary for control of a hazard, as discussed above. Conversely, the critical limits for a less controlled process (high variability) must be more conservative and more restrictive. In other words, critical limits must be based on the capability of the process to achieve a given criterion under normal operating conditions taking into account variability. Monitoring and verification procedures specified in a HACCP plan should be designed to determine when the process is operating outside this normal variability so appropriate corrective actions can be taken.

These principles are illustrated in Figure 3–11. Three different process/product capabilities are illustrated, each of which must meet a product criterion of pH < 4.6 to ensure the safety of a high-acid product with respect to *C. botulinum.* In the first example, there is poor control of final product pH and a high variation (distribution a), hence the operating target pH (mean) or *set point* must be at pH 3.8 to be sure that pH < 4.6 will always be met. In the second example, there is better control of the process and resulting final product pH (distribution b); hence, the set point for the process is pH 4.0 and closer to the required product criterion. In the final example, there is excellent control of the process (distribution c), and the set point can be at pH 4.3.

An effective process control system is a key element in the management of food safety and can also provide economic benefits. Processes under control are less likely to yield foods that will cause harm to consumers. Food processors who understand the factors that can cause variability in their operations have established monitoring systems to detect and prevent unacceptable loss through inefficiencies, reduced yield, or poor quality. Similarly, by incorporating the elements of GHP and HACCP into their process control systems, food operators can ensure the production of safe foods. Whether for economic gain or food safety, criteria are established at selected points in the operation to enable the operator to assess control. The operation is considered under control while established criteria are being met. If they are not, adjustments must be made to bring the

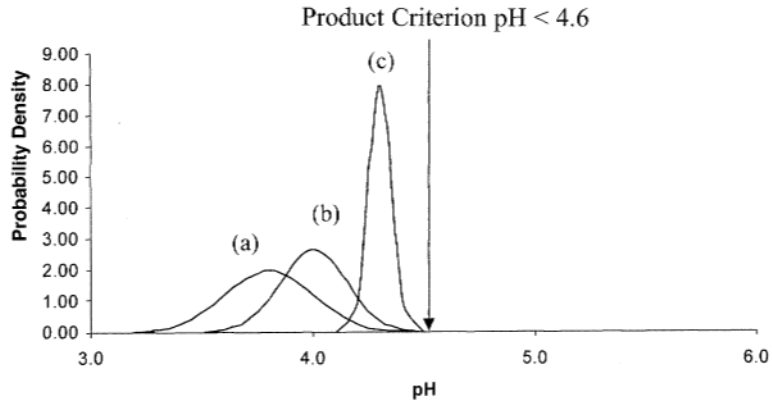


Figure 3–11 Set point depends on the variability in the process.

process back under control. A number of statistical tools can be used to aid in the evaluation of process control and trend analysis both for microbiological testing and for the physical and chemical parameters (see Chapter 13). Through knowledge of the process and use of the data, operators can plan for and achieve continuous improvement, thereby further reducing variability and achieving greater control.

Process control systems can involve two types of measurement—real time and delayed time. In the former, data are collected and used to adjust processes during the operation. Examples include measurements for pH, temperature, and humidity. Ideally, there is continuous feedback to provide automatic adjustment as the operation proceeds. Delayed time measurements do not yield data that permit adjustment to an ongoing operation. Examples include measurements using conventional microbiological methods and certain chemical analyses. Due to the time lapse between when samples are collected and results are obtained, these methodologies yield historical data and document what has happened rather than what is happening. While of less value for current production, the data can be used to detect trends, and with proper adjustments, reduce the likelihood that future lots will be unacceptable. These concepts will be discussed more fully in Chapter 13.

3.10 MONITORING AND VERIFYING CONTROL MEASURES

After effective control measures have been established, it is necessary to establish procedures to monitor each CCP in HACCP plans and verify that the control measures are being implemented as planned. Monitoring and verification can consist of a variety of measurements, such as:

- sensory assessments based on visual inspection, aroma, taste, touch, and sound
- chemical measurements, such as for sodium chloride, acetic acid, or water content
- physical measurements, such as pH, a_w, humidity, temperature
- time measurements
- packaging, such as integrity of the container closure (e.g., hermetical seal)
- records for incoming raw materials (e.g., records showing an ingredient is from an approved source or region)
- microbial tests, including tests for toxic metabolites
- environmental sampling (see Chapter 10)

It is important to note that the microbiological safety of most foods can be assessed by a variety of methods besides microbiological testing. These determinations can be used for monitoring or verifying that the specified control measures in a food operation are or have been implemented correctly. For example, measurements of pH and/or acid content are commonly used for monitoring fermentation processes and foods that are acidulated.

Some of these methods also are satisfactory for assessing the acceptability of foods at port-of-entry or upon receipt for use in a food operation. For example, the acceptability of a high-acid, canned, shelf-stable food can be easily determined by performing a pH measurement. Many foods of relatively low moisture content that are intended to be distributed and sold at ambient temperature can be assessed by a measurement of a_w or moisture content (see Chapter 4). Food operators become very familiar with the normal appearance, aroma, and feel of the foods with which they are involved. Foods that appear atypical should raise doubts in the operator's mind and indicate a need for additional evaluation.

3.11 EXAMPLES OF CONTROL OPTIONS

Two examples will be used to demonstrate the relationship between performance criteria, product/process criteria, and microbiological criteria (Baird-Parker & Tompkin, 2000). The first is a recommendation to industry by the UK Advisory Committee on the Microbiological Safety of Foods (ACMSF, 1992) about four options to control the risk of psychrotrophic *C. botulinum* in refrigerated cooked foods having an extended shelf-life of more than 10 days. The recommendations were:

1. A heat treatment of 90 °C for 10 min, or equivalent lethality.
2. A pH of 5 or less throughout the food and throughout all components of complex foods.
3. An a_w of 0.97 or less throughout the food and throughout all components of complex foods.
4. A combination of heat and preservative factors that can be shown consistently to prevent growth and toxin production by *C. botulinum.*

Option one is directed toward killing vegetative cells and spores of psychrotrophic strains of *C. botulinum* that may be present in the raw materials used in the production of the foodstuff. Options two and three are intended to prevent the growth of the organism and hence prevent toxin production. Option four could involve thermal destruction/thermal injury of spores and/or inhibitory factors to prevent the outgrowth of surviving *C. botulinum* spores.

Underlying each control option is an unstated performance criterion. Thus, the performance criterion for option one could be stated as a 6 D reduction of spores of psychrotrophic strains of *C. botulinum,* as this is the intended result of a heat treatment of 10 min at 90 °C. For options two and three, the performance criterion could be stated as less than a 1 log increase of *C. botulinum* within the use-by-date when stored at the recommended storage temperature. The ACMSF report provides considerable background information on the likely occurrence of the hazard and factors that can be used for control.

The second example concerns the risk of *E. coli* O157:H7 and similar enteric foodborne pathogens in fermented sausages. In December 1994, an outbreak of foodborne illness caused by *E. coli* O157:H7 in a fermented sausage product occurred on the West Coast of the US. In response, the U.S. Department of Agriculture established a requirement that all manufacturers use processes that control the risk of illness from *E. coli* O157:H7. In this case, the agency proposed a performance criterion (i.e., 5 D kill of *E. coli* O157:H7) and left it to industry to decide how to satisfy the criterion and still produce products of acceptable quality. The agency's proposal of a 5 D kill was based on very limited evidence suggesting that up to 1000 g^{-1} of *E. coli* O157:H7 could occur in the raw meat used for processing. Industry-sponsored research led to five options that were accepted by the agency (Nickelson *et al.*, 1996):

1. Apply an existing, approved heat treatment as specified in former USDA Regulation 9CFR 318.17 (i.e., heating to an internal temperature of 62.8 °C for 4 min or to a lower temperature for such time to obtain an equivalent level of safety (USDA, 1996b)).

2. Apply a process that is validated by research to cause a 5 D kill of *E. coli* O157:H7 before the product is released for distribution.
3. Combine raw material testing with a process that is validated by research to cause a 2 D kill of *E. coli* O157:H7 before the product is released for shipment. The sample procedure must ensure that the level of *E. coli* O157:H7 in the raw sausage blend does not exceed 1 cell per g. One such sampling procedure could consist of analyzing 15 samples (25 g each) collected at the time of stuffing the meat blend into casings.
4. Apply a program of holding the product until the test results become available indicating the lot has met the criteria of acceptance (i.e., a hold and test program). Products intended to be heated before serving (e.g., pepperoni for pizza) would be sampled at a rate of 15 samples per lot. Products normally consumed without heating before serving (e.g., salami) would be sampled at a rate of 30 samples per lot. The analytical unit for each sample tested would consist of 25 g.
5. To allow for new technology or ideas, this option permits the use of alternate processes that provide the equivalent of a 5 D reduction.

All of the options are intended to ensure that the level of *E. coli* O157:H7 is 1 cell in 100 g or less when the products are released for distribution. This was considered by the agency at the time to provide an acceptable level of consumer protection for this class of product. The five options include process criteria, performance criteria, and microbiological criteria. Options one and two assume an initial level of 1,000 *E. coli* O157:H7 per g in the raw sausage blend. The process criterion for option one (heating to an internal temperature of 62.8 °C and holding for 4 min) is derived from an existing regulation for roast beef and is based on research data demonstrating a 5 D kill of salmonellae and *E. coli* O157:H7 in beef. The 4-min hold time was an added requirement since the roast beef regulation does not require a hold time at 62.8 °C. Processors choosing this option would not take advantage of the faster rate of kill that would occur with the reduced pH of a fermented product. The performance criterion in option two specifies a 5 D kill of *E. coli* O157:H7. To satisfy this option, the processing plant must have on file, and available for review, research data that validate that the process being used will achieve a 5 D kill. The validation research must have been developed with a protocol approved by the USDA.

Option three incorporates both a reduction step and an elimination step based on microbiological criteria. It involves a performance criterion of a 2 D kill, in combination with microbiological testing to verify that the level of *E. coli* O157:H7 in each production lot does not exceed 1 cell per g in the raw sausage blend. Collectively, the net result is equivalent to the 5 D kill of option two, which assumed an initial level of 1,000 per g in the raw sausage blend. Subsequent industry-sponsored research has demonstrated that fifteen 25 g samples of raw sausage blend can be composited for analysis with no significant loss in sensitivity of detection. If, for example, a processor elects to collect 15 samples from across a lot during stuffing and have each tested using a 25 g analytical unit (375 g total), then this would provide 95% confidence that the level of *E. coli* O157:H7 in the blend is no more than 1 cell in 125 g if a negative result is obtained (Foster, 1971). While this may be a prudent sampling plan for some operations, this level of sampling exceeds by approximately 100-fold the detection level required in option three.

Option four establishes microbiological criteria for the finished product and assumes no prior knowledge of the level of *E. coli* O157:H7 in the raw sausage blend or the lethality of the process. Reliance is placed solely on the use of a sampling plan that may detect *E. coli* O157:H7 if it is present in the finished product. The sampling plans are based upon information in ICMSF Book 2 (ICMSF, 1986) and an assignment of *E. coli* O157:H7 to cases 13 and 14 for pepperoni and salami, respectively (see Chapter 8). Case 13 involves n = 15 and c = 0. Case 14 involves n = 30 and c = 0. A negative result with fifteen 25 g samples (375 g total) provides a 95% confidence of no more than 1 cell in 125 g. A negative result with thirty 25 g samples (750 g total) provides a 95% confidence of no more than 1 cell in 250 g (Foster, 1971).

3.12 ASSESSING EQUIVALENCY OF FOOD SAFETY MANAGEMENT SYSTEMS

Food safety management systems based upon an FSO and the use of performance criteria provide greater flexibility in how food operators can control hazards. An assessment for equivalency of systems that use performance criteria may require a holistic approach when the food operation involves multiple steps. In another situation, an assessment for equivalency may be limited to a single step in a process (e. g., pasteurization). The assessment should involve a review of data that demonstrate the scientific basis for the alternative process and processing records that demonstrate the control measures are being implemented as planned. Finally, the product must be able to meet any acceptance criteria that may have been established.

It should be evident that the TLR, FSO, and measures subsequently established by a country can serve as one basis for assessing the equivalency of a country's food control system.

3.13 REFERENCES

ACMSF (Advisory Committee on Microbiological Safety of Foods) (1992). *Report on Vacuum Packaging and Associated Processes*. London: HMSO.

Baird-Parker, A. C. & Tompkin, R. B. (2000). Risk and microbiological criteria. In *The Microbiological Safety and Quality of Food*, pp. 1852–1885. Edited by B. M. Lund, A. C. Baird-Parker & G. W. Gould. Gaithersburg, MD: Aspen Publishers, Inc.

Brown, B. E. (1997). Thermal processes—development, validation, adjustment and control. In *Food Canning Technology*, pp. 451–488. Edited by J. Larousse. New York: Wiley-VCH.

CAC (Codex Alimentarius Commission) (1997a). *Joint FAO/WHO Food Standards Programme. Codex Committee on Food Hygiene. Food Hygiene, Supplement to Volume 1B-1997. Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application*. CAC/RCP 1–1969, Rev. 3 (1997).

CAC (Codex Alimentarius Commission) (1997b). *Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene. Food Hygiene, Supplement to Volume 1B-1997. Recommended International Code of Practice, General Principles of Food Hygiene*. CAC/RCP 1–1969, Rev. 3.

CDC (Centers for Disease Control and Prevention) (2000a). Preliminary FoodNet data on the incidence of foodborne illnesses—selected sites, United States, 1999. *MMWR Morb Mortal Wkly Rep* 49, 201–205.

CDC (Centers for Disease Control and Prevention) (2000b). Outbreaks of Salmonella serotype Enteritidis infection associated with eating raw or undercooked shell eggs—United States, 1996–1998. *MMWR Morb Mortal Wkly Rep* 49, 73–79.

Foster, E. M. (1971). The control of salmonellae in processed foods: A classification system and sampling plan. *J Assoc Off Anal Chem* 54, 259–266.

Gould, G. W. (1999). Sous vide foods: conclusions of an ECFF Botulinum Working Party. *Food Control* 10, 47–51.

ICMSF (International Commission on Microbiological Specifications for Foods) (1986). *Microorganisms in Foods 2. Sampling for Microbiological Analysis: Principles and Specific Applications*, 2nd edn. Toronto: University of Toronto Press.

ICMSF (International Commission on Microbiological Specifications for Foods) (1988). *Microorganisms in Foods 4. Application of the Hazard Analysis Critical Control Point (HACCP) System to Ensure Microbiological Safety and Quality*. Oxford: Blackwell Scientific Publications Ltd.

ICMSF (International Commission on Microbiological Specifications for Foods) (1998). *Microorganisms in Foods 6: Microbial Ecology of Food Commodities*. London: Blackie Academic and Professional.

Jordan, C. F. (1950).The epidemiology of brucellosis. In *Brucellosis. A Symposium under the Joint Auspices of National Institutes of Health of the Public Health Service, Federal Security Agency, United States Department of Agriculture, National Research Council*, pp. 98–115. Washington, DC: American Association for the Advancement of Science.

Kruse, H. (1999). Globalization of the food supply—food safety implications. Special regional requirements: future concerns. *Food Control* 10, 315–320.

Legan, J. D., Vandeven, M. H., Dahms, S. & Cole, M. B. (2001). Determining the concentration of microorganisms controlled by attributes sampling plans. *Food Control* 12, 137–147.

Leighty, J. C. (1983). Public-health aspects (with special reference to the United States). In Trichinella *and Trichinosis*, pp. 501–513. Edited by W. C. Campbell. New York: Plenum Press.

Lund, B. M., Knox, M. R. & Cole, M. B. (1989). Destruction of *Listeria monocytogenes* during microwave cooking. *Lancet* (Jan. 28), 218.

Nesbakken, T. (2000). *Yersinia* species. In *The Microbiological Safety and Quality of Food,* pp. 1363–1393. Edited by B. M. Lund, A. C. Baird-Parker & G. W. Gould. Gaithersburg, MD: Aspen Publishers, Inc.

Nickelson, R., Luchansky, J., Kaspar, C. & Johnson, E. (1996). *Update on Dry Fermented Sausage* Escherichia coli *O157:H7 Validation Research*. Research Report No. 11–316. Chicago: National Cattleman's Beef Association.

Pozio, E. (1998). New strategies for reducing the cost of the control of trichinellosis in the European Union. In *Proceedings of the 4*th *World Congress Foodborne Infections and Intoxications,* Vol. 1, pp. 526–530. Edited by K. Noeckler, P. Teufel, K. Schmidt, & E. Weise. Berlin: Federal Institute for Health Protection of Consumers and Veterinary Medicine.

Rehmet, S., Sinn, G., Robstad, O. *et al.* (1999). Two outbreaks of trichinellosis in the state of Northrine-Westfalia, Germany, 1998. *Eurosurveillance* 4, 78–81.

Ruitenberg, E. J. & Sluiters, J. F. (1974). *Trichinella spiralis* infections in the Netherlands. In *Trichinellosis. Proceedings of the Third International Conference on Trichinellosis*, pp. 539–548. Edited by C. W. Kim. New York: Intext Educational Publishers.

Simms, B. T. (1950). Federal aspects of the control of brucellosis. In *Brucellosis. A Symposium under the Joint Auspices of National Institutes of Health of the Public Health Service, Federal Security Agency, United States Department of Agriculture, National Research Council*, pp. 241–246. Washington, DC: American Association for the Advancement of Science.

Stumbo, C. R. (1973). *Thermobacteriology in Food Processing*, 2nd edn. New York: Academic Press.

Tompkin, R. B. & Kueper, T. V. (1982). Microbiological considerations in developing new foods. How factors other than temperature can be used to prevent microbiological problems. In *Microbiological Safety of Foods in Feeding Systems*. ABMPS Report No. 125, pp. 100–122. Washington, DC: Advisory Board on Military Personnel Supplies, National Research Council, National Academy Press.

USDA (United States Department of Agriculture) (1996a). Pathogen reduction; hazard analysis and critical control point (HACCP) systems; final rule. *Federal Register* 61, 38806–38989.

USDA (United States Department of Agriculture) (1996b). Requirements for the production of cooked beef, roast beef, and cooked corned beef. *Federal Register* 61, 19564–19578.

USDA (United States Department of Agriculture) (1999). *Compliance Guidelines for Meeting Lethality Performance Standards for Certain Meat and Poultry Products*. Appendix A to Compliance Guidelines, January 1999, updated June 1999. Washington, DC: US Department of Agriculture, Food Safety and Inspection Service.

USDA (United States Department of Agriculture) (2000). *HACCP Implementation: First Year* Salmonella *Test Results, January 26, 1998 to January 25, 1999*. Washington, DC: US Department of Agriculture, Food Safety and Inspection Service.

Zimmerman, W. J. (1974). The current status of trichinellosis in the United States. In *Trichinellosis. Proceedings of the Third International Conference on Trichinellosis,* pp. 603–609. Edited by C. W. Kim. New York: Intext Educational Publishers.

Appendix 3–A

Control Measures Commonly Applied to Foodborne Diseases

National Beef Ex. 1045
192 of 482

Group	Agent	Common vehicles	Control measures: Controlling initial level	Control measures: Reducing level	Control measures: Preventing increase in level
PRIMARY SOURCE: HUMAN					
Bacteria	*V. cholerae, S. typhi*	Untreated water, foods contaminated by infected food handlers	Treat waste water, provide potable water for drinking and food preparation; educate food handlers in proper personal hygiene	Cook	Pathogen increase in the implicated food is not an important factor
	Shigellae	Foods contaminated with untreated waste water or by infected food handlers	Educate food handlers in proper personal hygiene; exclude infected persons from high risk positions (e.g., food preparation, day care centers)	Cook	Pathogen increase in the implicated food is not an important factor
Virus	Hepatitis A, SRSV, Norwalk virus	Ready-to-eat foods, bivalve molluscs	Treat waste water, provide potable water for drinking and food preparation; educate food handlers in proper personal hygiene; avoid bivalves from contaminated waters	Cook	Viruses cannot multiply in food
PRIMARY SOURCE: SEAFOOD					
Bacteria					
	C. botulinum type E *V. parahaemolyticus*	Seafood, meat from marine mammals, fresh water fish	Avoid certain traditional fermented foods (e.g., muktuk) and fish dried with intestines intact; consumer education	Apply thermal process sufficient to kill spores (e.g., canning of seafood)	Safety depends on preventing growth to levels sufficient for toxin production; apply combinations of temperature, a_w, pH and time that inhibit growth (e.g., temperature < 3 °C; $a_w < 0.97$; 3.5% NaCl on water at 5 °C; or pH below 5.0); control fermentation conditions to prevent growth and toxin production

National Beef Ex. 1045
193 of 482

	V. vulnificus	Raw seafood, recontaminated cooked seafood	Avoid uncooked fish where pathogen is prevalent	Cook	Avoid recontamination, maintain low storage temperatures
		Oysters	Avoid bivalves from regions of higher risk, avoid wounds to hands when handling crustaceans	Cook	Increase of *V. vulnificus* in oysters post-harvest is not a factor
Toxin	Scombrotoxin	Tuna, mackerel, mahi mahi	Select freshly harvested and properly chilled fish; specification for histamine: mean of 100 ppm, 2 of 9 samples tested may be $>$ 100 but $<$ 200 ppm, no sample $>$ 200 ppm	Histamine level cannot be reduced after harvest	Cool fish rapidly and maintain at low temperature ($<$ 8 °C; preferably lower) to prevent histamine formation
	Tetrodotoxin	Puffer fish	Avoid fish from the Tetraodontidae family	Toxin cannot be reduced after harvest; toxin is stable	Toxin cannot increase
	Ciguatera	Certain tropical reef fish	Avoid tropical reef fish from regions and seasons of high risk	Toxin cannot be reduced after harvest; toxin is stable	Toxin cannot increase
	Shellfish toxins (PSP, DSP, ASP, NSP)	Bivalves	Monitor shellfish harvesting areas for toxic phytoplankton, suspend harvesting if necessary, specification PSP 80 μg 100 g^{-1}, ASP 20 μg 100 g^{-1}	Toxin cannot be reduced after harvest; toxin is stable	Toxins cannot increase
Parasites	*Anisakis*	Herring, cod	Inspect and discard infected fish	Freeze (−18 °C for 24 hrs); hold in combination of NaCl and acetic acid; cook	Parasite cannot increase
PRIMARY SOURCE:					
	Brucellae				

continues

National Beef Ex. 1045
194 of 482

Group	Agent	Common vehicles	Control measures: Controlling initial level	Control measures: Reducing level	Control measures: Preventing increase in level
LIVESTOCK, POULTRY					
Bacteria					
	M. bovis	Unpasteurized milk and cheeses made therefrom, contact with infected livestock (e.g., cattle, goats)	Eradicate brucellosis from domesticated animals; avoid cheeses made from unpasteurized milk in regions where brucellae are endemic	Pasteurize milk	Brucellae do not increase during cheese manufacture or subsequent storage
	C. jejuni/coli	Unpasteurized milk	Eradicate bovine TB	Pasteurize milk	*M. bovis* cannot increase during storage of milk or milk-containing foods
	Salmonellae, non-typhoid	Raw or undercooked poultry, unpasteurized milk	Effective on-farm and slaughtering control measures for raw poultry and meat are uncertain; education of food handlers	Cook; pasteurize milk	*C. jejuni/coli* are not likely to multiply in food due to the high temperature (≥ 32 °C) and other requirements for growth; cross contamination to ready-to-eat foods is a significant concern
	Pathogenic *E. coli*	Wide variety of foods	Select foods and ingredients from suppliers with effective control systems; understanding the limitations of current control measures to prevent or eliminate salmonellae from raw agricultural commodities	Cook; pasteurize; acidify; other combinations (e.g., a_w, pH, temperature, preservatives); irradiate	Use of inhibitory factors (preservatives, a_w, acidifiers, low temperature storage) alone, or in combination, to inhibit growth; minimize cross contamination
		Undercooked ground beef, raw produce, unpasteurized juice, sprouts, untreated water, contact with ruminants	Effective on-farm control measures have not been identified; control measures during slaughter can reduce but not eliminate these pathogens; effective GAPs (good agricultural practices) for crops have yet to be	Cook; pasteurize; wash and disinfect (e.g., fruits, vegetables)	Multiplication can occur in many foods, but this has not been a significant factor; survival and low infective dose among the more sensitive populations are much more important

National Beef Ex. 1045
195 of 482

	Y. enterocolitica		demonstrated; selecting raw agricultural commodities from suppliers with a system of comprehensive control measures can minimize but not prevent the presence of these pathogens; avoid untreated water and contact with livestock.		
	S. aureus	Raw or undercooked pork, untreated water, milk	Improve slaughter hygiene (i.e., sealing off rectum in plastic bag)	Cook	Minimize contact of ready-to-eat foods with raw pork
	Taenia	Cooked foods contaminated with *S. aureus* and held at conditions permitting growth and enterotoxin production; *S. aureus* does not compete well against the normal flora associated with raw agricultural commodities and, thus, these foods are rarely involved	Selecting foods and ingredients that are likely to have lower initial numbers; preventing food handlers with boils, infected cuts from handling food	Cook, pasteurize, acidify, etc. to reduce the number of *S. aureus* in food; staphyloccocal enterotoxin is very stable and cannot be reduced by normal methods of food preparation	Control temperature and time of holding cooked perishable foods to prevent sufficient growth for enterotoxin production; use inhibitory factors (e.g., a_w, preservatives, acidifiers, smoke) to inhibit growth; control conditions for manufacture of certain cheeses and dry sausages where growth during fermentation and, in the case of cheese, pressing is important
Parasites					
	T. spiralis	Raw or undercooked pork and beef	Break epidemiologic chain at final host (man) or intermediate host (cattle, pigs); animal husbandry; treat sewage and sludge; meat inspection	Cook to > 60 °C; freeze to -10 °C 6 days	This parasite cannot increase during processing or storage

continues

National Beef Ex. 1045
196 of 482

Group	Agent	Common vehicles	Control measures: Controlling initial level	Control measures: Reducing level	Control measures: Preventing increase in level
		Raw or undercooked pork, wild game, horse meat	Select pigs from sources (e.g., industrialized farms) and regions of little or no risk; eradicate infested pigs and manage the risk of consumer exposure to infested wild game; avoid feeding uncooked kitchen waste to pigs; adopt meat inspection procedures to eliminate infested carcasses	Freeze −25 °C for 10–20 days; cook to 58 °C minimum	*T. spiralis* cannot increase in food
PRIMARY SOURCE: SOIL Bacteria	*L. monocytogenes* (Sources include the soil, environment of food establishments and homes, raw agricultural commodities, animals, including humans) *B. cereus*	Perishable ready-to-eat foods in which growth can occur (e.g., certain soft cheeses, milk, cooked meats and poultry, smoked seafood)	Select foods subjected to a kill step, where possible; control the ready-to-eat environment to minimize contamination; educate consumers about foods to avoid	Cook; pasteurize milk; pasteurize in the container in which a food will be sold; formulate foods to create listericidal conditions during subsequent processing, storage and distribution (e.g., acidification, dehydration); wash and disinfect	Formulate foods with additives or create conditions that can prevent multiplication; store perishable foods at low temperatures that can retard or prevent growth; manage the environmental conditions of the operation to minimize the likelihood of contamination from raw foods/ingredients or contaminated surfaces; use controlled fermentations that prevent growth

National Beef Ex. 1045
197 of 482

	Rice, cereal products, certain dairy products, sauces, cooked pasta, vegetable or meat dishes	Control measures cannot ensure the absence of this pathogen in the foods commonly involved	Cooking can kill the vegetative cells, but spores may survive	Cool rapidly from 50 °C to 10 °C after heating; store below 10 °C or above 60 °C
C. botulinum type B (non-proteolytic)	Dry, cured ham and other salt cured meats and seafood	Control measures cannot ensure the absence of this pathogen in the foods commonly involved	Apply thermal process sufficient to kill spores (e.g., canning)	Safety depends on preventing growth to levels sufficient for toxin production; apply combinations of temperature, a_w, pH and time that inhibit growth (e.g., temperature < 3 °C; $a_w < 0.97$; 3.5% NaCl on water at 5 °C; or pH below 5.0). Control fermentation conditions to prevent growth and toxin production
C. botulinum type A, B (proteolytic)	Low-acid foods, meat, home-canned vegetables and low-acid fruits	Control measures cannot ensure the absence of this pathogen in the foods commonly involved; consumer education to avoid tasting suspect food	Apply thermal process sufficient to kill spores (e.g., canning)	Safety depends on preventing growth to levels sufficient for toxin production; apply combinations of temperature, a_w, pH and time, etc. that inhibit growth (e.g., temperature < 10 °C; $a_w < 0.94$; 10% NaCl on water; pH below 4.6); sodium nitrite in cured meats
C. perfringens	Cooked, uncured meat or poultry, meat pie, stew, gravy	Control measures cannot ensure the absence of this pathogen in the foods commonly involved	Cook to kill vegetative cells, retort to kill spores; storage at low temperatures can cause significant decrease in vegetative cells	Cool rapidly from 51 °C to 15 °C after cooking; store below 10–12 °C or above 51 °C, preferably at or above 60 °C
A. flavus, *A. parasiticus*				

continues

National Beef Ex. 1045
198 of 482

Group	Agent	Common vehicles	Control measures: Controlling initial level	Control measures: Reducing level	Control measures: Preventing increase in level
Fungi		Corn, peanuts	Monitor weather and test crops when conditions indicate higher risk; minimize insect infestation; reject moldy products	The myco-toxins are very stable	Rapid drying and dry storage to prevent growth of fungi and toxin production
	A. ochraceus				
	A. versicolor	Beans, dried fruit, nuts, cereals, biltong, dried fish	Monitor weather and test crops when conditions indicate higher risk; reject moldy products	Toxins are stable	Rapid drying and dry storage to prevent growth of fungi and toxin production
	Fusarium graminearum	Wheat, corn, flour, rice, nuts, spices, fermented meats, cured meats, biltong, cheese	Prompt harvest when ready; reject or test suspect foods for the toxin	Toxins are stable	Rapid drying and dry storage to prevent growth of fungi and toxin production
	F. moniliforme	Wheat	Prompt harvest when ready; reject or test suspect lots for the toxin	Toxins are stable	Rapid drying and dry storage to prevent growth of fungi and toxin production
	F. sporotri-choides	Rice, sorghum, sugar cane, corn	Prompt harvest when ready; reject or test suspect foods for the toxin	Toxins are stable	Rapid drying and dry storage to prevent growth of fungi and toxin production
	Penicillium citrinum,	Cereals, peanuts, soya beans	Prompt harvest when ready; reject or test suspect foods for the toxin	Toxins are stable	Rapid drying and dry storage to prevent growth of fungi and toxin production
	P. crustosum, P. islandicum, P. verrucosum	Ubiquitous, especially rice, wheat and corn	Prompt harvest when ready; reject or test suspect foods for the toxin	Toxins are stable	Rapid drying and dry storage to prevent growth of fungi and toxin production

National Beef Ex. 1045
199 of 482

Chapter 4

Selection and Use of Acceptance Criteria

4.1 Introduction
4.2 Equivalence
4.3 Establishment of Acceptance Criteria
4.4 Application of Acceptance Criteria
4.5 Determining Acceptance by Approval of Supplier
4.6 Examples To Demonstrate the Process of Lot Acceptance
4.7 Auditing Food Operations for Supplier Acceptance
4.8 References

4.1 INTRODUCTION

Available statistics for the volume of food crossing borders between countries, or being shipped from a seller to a buyer, are estimates that may represent only the tip of the iceberg. For example, the number of formal customs entries for foods imported into the US is about 1.5 million each year (Schultz, 1997). All these products should be safe and of suitable quality. However, the safety of a product is seldom verifiable by tasting or other organoleptic examination, although appearance and odor can suggest a hazardous product under certain circumstances. Foods of questionable safety should never be tasted. Thus, buyers and consumers must rely on the supplier to deliver ingredients or food with the expected level of safety or on government control for domestic and imported foods. This expectation occurs all along the food chain. In many instances, the buyer (a food manufacturer, retailer, etc.) or an inspector, for example, at port-of-entry has no reliable means to check the safety of incoming raw materials or finished products. There is, however, a difference in the relationship between commercial buyers and consumers. Usually, there is a business deal between commercial partners, and product liability is an important issue. Also, industry buyers can impose specifications for the food being purchased and a variety of options to verify compliance.

To harmonize food control systems and facilitate trade, World Trade Organization (WTO) members are encouraged to adopt international food standards. Governments also can impose standards or guidelines for imported food. Governments often have a working relationship with the exporting country's food control authority that can lead to various forms of verification. Thus, governments may intervene in the transfer process between buyers and suppliers at the port-of-entry. Also, governments can impose criteria for acceptance on local food products, such as those produced at the retail level.

This chapter will discuss the use of criteria to determine the acceptability of individual lots or consignments of food and operations where they are produced. Criteria for assessing the acceptability of a lot of food can take several forms based on sensory, chemical, physical, or microbiological parameters. Acceptance criteria should include

National Beef Ex. 1045
200 of 482

additional information, for example, such as the number of samples to be collected, how and where the samples are collected and held prior to analysis, the analytical unit, the method of analysis, and what is considered acceptable. The acceptability of a food operation can be assessed through inspections by control authorities or through audits by buyers. The inspection or auditing processes are very similar in nature but are for different reasons, i.e., to assess compliance with regulations vs. approval of a supplier. The results of an inspection or audit can influence whether the food(s) or ingredients being produced should be sampled.

4.2 EQUIVALENCE

For foods received at a port-of-entry, the origin (i.e., country or region) of the food is an important factor influencing acceptance. It is impossible for the control authorities of an importing country to inspect and approve foods while they are being produced, harvested, processed, and readied for shipment. Reliance must be placed on the system of inspection in the exporting country or region. Thus, to facilitate the movement of foods across international borders, it is necessary to develop a mechanism for acceptance based on mutual agreement between the authorities in the participating countries. While it is not possible for historical and cultural reasons to have identical regulations and codes of practice, it is necessary to assess whether they result in an equivalent level of consumer protection. Equivalence is the capability of different inspection and certification systems to meet the same objectives (CAC, 2000).

The equivalency concept was introduced in the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures. According to the agreement, each member of the WTO must accept as equivalent to its own the food regulatory systems of other members as long as they provide the same level of public health protection. Thus, equivalent regulatory systems need not be identical. The outcome, however, of the exporting country's food control system must meet tolerances established for a particular hazard or hazards for the same foods within the importing country. The burden of demonstrating equivalence is on the exporting country. The importing country has the right to decide whether the evidence provided to demonstrate equivalence is adequate.

The following information derived from a proposed Codex Alimentarius Commission draft (CAC, 2000) to describe a framework for determining equivalence suggests how the material in this book can be used when food safety issues of microbiological origin are the focus of a determination. A determination of equivalence requires establishment of a relationship between two "building blocks": the appropriate level of protection (ALOP) and the sanitary measures. It is the sovereign right of an importing country to set any level they deem appropriate in relation to their food supply, while having regard to Codex standards as international benchmarks. An ALOP can be expressed in qualitative or quantitative terms. In determining equivalence, the ALOP of the importing country must be met by the exporting country. For the purposes of determining equivalence, the sanitary measures that comprise a food control system can be broadly categorized as follows:

- infrastructure, including the legislative base (e.g., food and enforcement law), and administrative systems (e.g., organization of national and regional authorities);
- program design/implementation, including documentation of systems, performance, decision criteria and action, laboratory capability, and provisions for certification and audit; and

- specific requirements, including individual facilities (e.g., premises design), equipment (e.g., design of food contact machinery), processes (e.g., retorting, Hazard Analysis Critical Control Point (HACCP) plans), procedures (e.g., post mortem inspection) and tests (e.g., tests for microbiological and chemical hazards).

Sanitary measures are often narrowly focused and specific while the ALOP is more flexible. It may be expressed in specific terms (e.g., number of cases of disease per year in a defined population) or far less specific terms (e.g., broad goals relating to food safety). Irrespective of the expression of the ALOP, an objective basis for comparison of sanitary measures must be established.

Presentation of an objective basis for comparison may include the following elements:

1. the reason/purpose for the sanitary measure;
2. the relationship to the ALOP, with quantitative expression wherever possible;
3. where risk assessment information is available, expression of the risk;
4. the level of a hazard in a food that is tolerable in relation to an ALOP (i.e., a food safety objective (FSO), as described in Chapter 2 and elsewhere).

Any sanitary measure or combination of sanitary measures can be identified for determination of equivalence.

Determination of equivalence presumes that the exporting country has already reviewed all applicable importing country requirements for the food involved and has identified those it will meet and those for which it seeks a determination of equivalence. The determination of equivalence is facilitated by both exporting and importing countries following a sequence of steps such as those illustrated in Figure 4–1.

The exporting country should present a submission for equivalence that facilitates the judgment process applied by the exporting country. Importing and exporting countries should utilize an agreed process for exchange of information. This information should be limited to that which is necessary to facilitate the determination of equivalence and minimize administrative burden. When achievement of equivalence is agreed upon by the importing country, the importing and exporting countries may enter into a formal agreement to the effect of that decision.

Further development of the concept of equivalence and the establishment of international standards for food are activities of the Codex Alimentarius Commission. Since these concepts and their application continue to evolve, the most recent documents of the Commission should be reviewed for more information and for their current status.

4.3 ESTABLISHMENT OF ACCEPTANCE CRITERIA

4.3.1 Role of FSO in Lot Acceptance

As described in the previous chapters, an FSO specifies the outcome expected of food operations that have implemented a system of effective control measures. The outcome may be expressed as a frequency or maximum concentration of a microbiological hazard in the food. Furthermore, the FSO is based on what is considered acceptable for consumer protection. Thus, an FSO is a goal that food operators use when designing and implementing their food safety management systems. Operators who can demonstrate their ability consistently to meet an FSO will be more reliable as suppliers. Shipments of

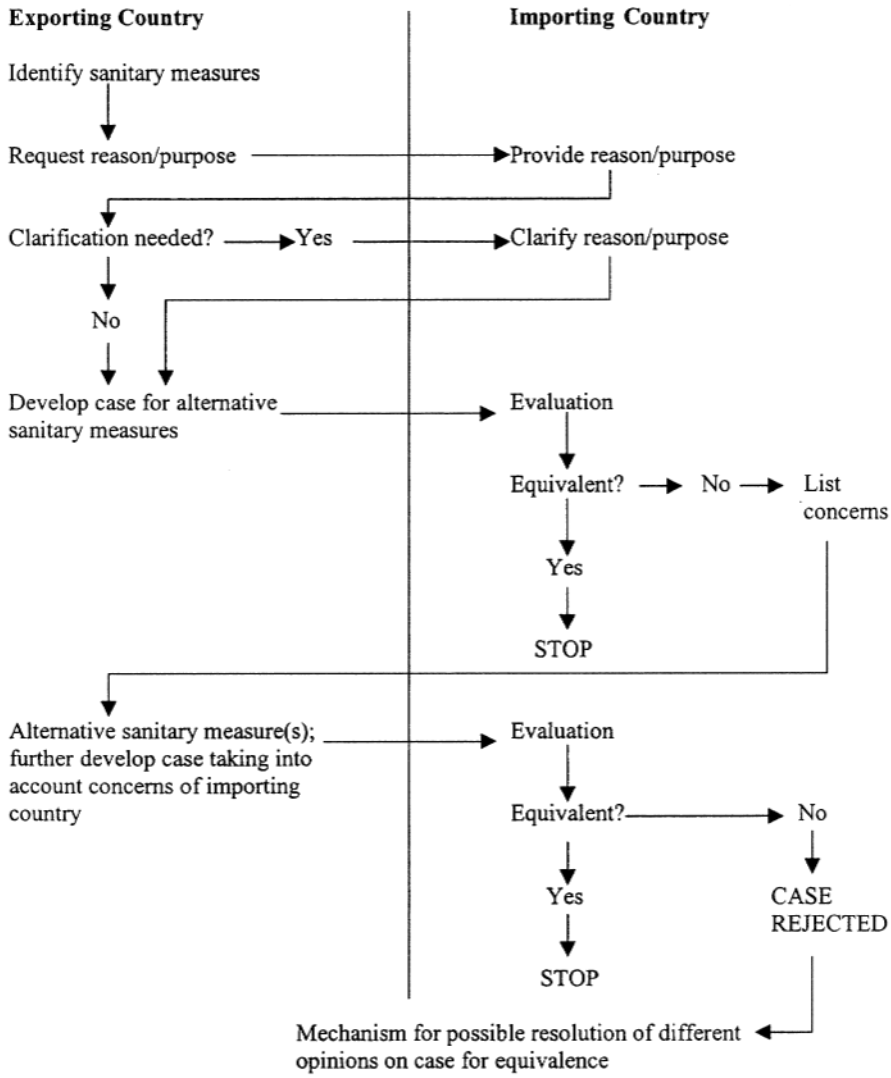


Figure 4–1 Flow diagram for the determination of equivalence.

food from these suppliers can be sampled at a much lower frequency. FSOs can therefore be used as the basis for establishing lot acceptance criteria.

4.3.2 Types of Acceptance Criteria

Governments are responsible for establishing food regulations and policies that ensure the safety of the foods for which they have regulatory responsibility. Thus, food control authorities serve as risk managers and establish FSOs for hazards in foods. This information is then used to develop standards (e.g., performance, process, product, default criteria) or guidelines that can be used by both industry and government as the basis for

assessing the acceptability of a food operation or food. These criteria are applied to domestic and imported foods.

Industry must produce foods that meet regulatory requirements. This includes regulations that define the conditions of operation as well as standards that may have been established for the food. To ensure compliance with regulatory requirements and the operator's own requirements for quality, food operators frequently establish purchase specifications for food ingredients and other materials. Under certain circumstances, an operator may specify the conditions of operation in the form of an operating instruction or best practices guideline, particularly when the supplier needs to assure that a critical control point (CCP) is controlled for the buyer.

Acceptance criteria can involve a variety of parameters (sensory, physical, chemical, biological) and generally fall into three categories, namely:

- **Standard**—a mandatory criterion that is part of a law or ordinance.
- **Guideline**—an advisory criterion issued by a control authority, industry association, or food producer to indicate what might be expected when best practices are applied.
- **Specification**—Part of a purchasing agreement between a buyer and supplier of a food; such criteria may be mandatory or advisory according to use.

The Codex document on the "Principles for the Application of Microbiological Criteria for Foods" (CAC, 1997a) recognizes only one category, i.e., a *microbiological criterion* (see Chapter 5).

4.3.2.1 Standards

Standards may be established for a wide variety of reasons, but are best applied when risk to consumers is sufficiently high and compliance with the standard is essential for consumer protection. Standards are established by governments and define the parameters that processes or foods must meet to be in compliance with regulatory policies or regulations. In the case of a process (e.g., pasteurization of eggs or milk), the conditions of operation, including design and performance of the equipment, may be defined. Processes that do not meet the standard conditions of operation must be brought into compliance or may be subject to rejection. A standard for a food defines the acceptance criteria (e.g., pH, a_w, coliform or *Escherichia coli* concentration) that must be met. Foods that do not meet the standard are in noncompliance and would be subject to removal from the market. Depending on the circumstances (e.g., severity of the noncompliance), the food may be reprocessed, have restrictions imposed on its use, or be destroyed. Standards that define criteria of importance to the microbiological safety or quality of a food should be established following the principles outlined by Codex (CAC, 1997a) and as further elaborated in this book. Thus, standards could be developed following a qualitative or quantitative risk assessment and establishment of an FSO.

4.3.2.2 Guidelines

Guidelines may be established for a process or product. In the case of a process (e.g., production of cheese, fermented sausage, sprouts), the conditions that should be controlled are described so the resulting food will be safe. A guideline for a product normally provides the product characteristics (e.g., pH, a_w) and microbiological criteria (e.g., *E. coli*), that the operator should strive for to produce an acceptable product. Thus, the criteria are advisory in nature and do not necessarily lead to rejection of a food. Such cri-

teria describe the characteristics of a food when best practices are applied. Guidelines may be the preferred means to inform food operators that change is needed within a segment of the industry. In other situations, guidelines may be used to describe the conditions believed to correct a newly recognized microbiological problem but for which insufficient data prevent the establishment of a standard. Thus, guidelines can serve as an interim measure providing guidance to food operators until sufficient information and technology is available to establish standards. A guideline alone may be adequate to bring about the changes necessary to improve food safety and quality, thereby negating the need to establish standards.

4.3.2.3 Specifications

Implicit in the transfer process between buyer and supplier is the necessity for the buyer to make a decision whether to accept or reject ingredients, food, and other materials. This decision involves a variety of factors, most important of which is the buyer's experience with the material being purchased. As buyers become more sophisticated and familiar with the risk(s) associated with certain foods, they recognize the utility of having preestablished acceptance criteria that are agreed upon with their supplier(s). The purpose of such purchase specifications is to reduce the likelihood of accepting an unacceptable ingredient or food. Purchase specifications define the expected characteristics of an ingredient, for example, so that when it is added, the final product will meet all requirements for safety, quality, wholesomeness, and other requirements of concern to the buyer (e.g., cost, nutrition, compatibility with ingredient listing on label). It is now common for buyers along the food chain to establish their own specifications for the materials they purchase, particularly when the safety of a raw material or ingredient is a CCP in the buyer's HACCP plan.

4.4 APPLICATION OF ACCEPTANCE CRITERIA

A variety of criteria traditionally have been used to decide whether to accept individual lots of food. These criteria define what is considered acceptable, preferably taking into account how the food will be used. As will be discussed later, there may be no need to test each lot of food produced by a supplier. In other situations, adherence to the specifications may be essential for safety or quality concerns. In extreme situations, this may even involve product testing by the supplier prior to delivery and providing a certificate of analysis with the shipment. In other situations, the buyer may analyze the material after it is received. Tests that are typically performed may involve a variety of parameters, such as product pH, a_w, and moisture content. Other tests may involve microbiological analysis for indicator microorganisms or pathogens.

Regardless of the criterion, consideration must be given to the factors influencing the analytical results (e.g., method of sampling, transportation and storage of samples, analytical procedure, etc.; see Chapter 12). These important factors determine the utility and reliability of criteria to differentiate acceptable from unacceptable lots. Considering the limitations of microbiological testing to ensure the safety of individual lots food (see Chapters 6, 7, and 8), greater emphasis is now being placed on the conditions under which foods are produced–the application of Good Hygienic Practices (GHP) and HACCP.

Control authorities are responsible for verifying that the established regulations and policies are being met. This can involve inspections of food operations and, if deemed necessary, sampling and testing the food. Operations that are in compliance are typically

granted a certificate or permit that is required for continued operation. Failure to comply with the regulatory requirements may result in the certificate or permit being revoked and, thereby, closing the operation. Ideally, governments organize the results of their assessments to determine if trends indicate a need for change in the regulations or enforcement actions. These data can influence the control authority's stance on sampling and testing certain categories of food for compliance with established criteria.

Today, food operators recognize the necessity for assessing suppliers of sensitive ingredients or foods to consistently control the food safety hazards. Assurance that suppliers control the hazards is best accomplished through a system of auditing and approving a supplier's total system for the management of food safety, such as described in Chapter 3. Suppliers that are considered unacceptable are removed from the list of approved suppliers. In certain cases, this may still lead to sampling and testing (verifying) incoming lots of purchased food. Lots that fail to meet the established specifications can be rejected. In general, however, this approach shifts the decision to accept or reject individual lots of food to supplier approval.

4.5 DETERMINING ACCEPTANCE BY APPROVAL OF SUPPLIER

4.5.1 Role of FSO in Supplier Approval

If an FSO has been established for a commodity, the first step is to determine whether the FSO is being met. If there is agreement on the achievement, further detailed information can be shared on the control measures that have been adopted to meet the FSO. Specifically, this would involve evaluating whether the adopted control measures (i.e., GHP, HACCP) can be expected to meet the FSO. Thus, auditors can incorporate the information in Chapter 3 into their auditing procedures as the basis for evaluating whether the operation being audited has established effective controls that can be justified. For example, will the system meet established performance criteria? Can the critical limits at CCPs (i.e., process criteria) be expected to prevent, eliminate, or reduce the hazard(s) to acceptable levels? If default criteria are selected as a basis for control, are they being correctly applied?

During the auditing process, the FSO provides a common yardstick for evaluation. The supplier and buyer of an ingredient or food share the same values with regard to safety, and the supplier considers the buyer's risk equal to his own. The buyer is aware of the intended use and performance criteria that may be necessary to ensure that safety can be mutually agreed upon. This will influence the HACCP plan and GHP procedures that are applied. Ideally, this information can be used for auditing by a mixed team of experts from both companies. If laboratories are involved, they would be expected to use the same or comparable (validated) methods and, perhaps, even participate in the same proficiency-testing program.

Assessment of incoming raw materials and ingredients in such a situation by the buyer may be limited to verifying accuracy and completeness of data concerning the lot and inspection of the shipment upon receipt. For certain foods, very critical parameters (e.g., temperature, moisture content) may be checked, but microbiological testing would seldom be used as an acceptance procedure from approved suppliers.

It is not always possible to have such an integrated quality assurance system between two business partners. This integrated approach requires a step-by-step approach over time until a level of mutual trust and acceptance is achieved. Preferably, such partner-

ships should be applied along the entire food chain. Very effective partnerships of this nature have been established among suppliers of certain major retail and fast food operators who rely upon a limited core of approved suppliers.

In situations where an FSO has not been established, conventional systems must be used to determine whether to accept a supplier. These include inspection and auditing of GHP and HACCP systems and licensing of the production site. Where necessary, such an approach may be supported by testing representative lots of production from the supplier to determine consistency of compliance with purchase specifications. Chemicophysical and/or microbiological tests may be used for this purpose. The number of lots that should be tested should reflect hazards and risks and the consequences of noncompliance with the criteria. When it has been determined that the supplier can reliably meet purchase specifications, then product testing can be discontinued or sharply curtailed.

In contrast to the FSO, microbiological criteria are of limited value in the approval process for a potential supplier. This is because microbiological criteria can be applied to specific lots of product to determine their acceptability, but this information provides only a point-in-time snapshot and provides little or no confidence for what may be produced over an extended period of time. By continued testing of incoming raw material from a supplier, it would be possible to establish a history of compliance with established criteria. However, when evaluating a new supplier, microbiological testing of current production lots would not be adequate to assess variability and, in particular, the presence of a pathogen that may occur intermittently and at low frequency. Thus, confidence in a supplier's ability to meet an FSO has greater value than reliance upon microbiological testing of incoming lots.

4.5.2 Approval Procedures

At each transfer point in the food chain, there is normally a buyer and a supplier. Ultimately, the final buyer will be a consumer. Buyers and suppliers can be in government as well as in industry. Suppliers may be domestic or in another country.

The preferred approach to managing the safety of food is to select suppliers who can be relied upon consistently to provide ingredients or foods that meet food safety requirements. Food safety systems based on prevention are much more effective than attempting to differentiate safe from unsafe lots by microbiological testing. While there may be a role for testing certain ingredients or foods, microbiological testing should be applied cautiously and used as a supplement to other information, particularly the conditions under which the material is produced. A listing of parameters that can be used to approve suppliers appears in Table 4–1. Many of these parameters can be verified by auditing experts that the conditions under which the ingredient or food is produced are acceptable. This could lead to licensing or certification.

The net result of these activities is to develop a base of suppliers that can be consistently relied upon to provide ingredients and foods that will be safe when used as intended. This approach requires that all parties be knowledgeable of the significant hazards that may be associated with the ingredient or food. The FSO concept can be an effective means to communicate the significant hazards that must be controlled to ensure consumer protection.

Certificates may be used for foods in international trade in the form of an export certificate. An example of a certificate appears in Exhibit 4–1 (CAC, 1997b). In addition to the expected information about the source of the food, the mode of transportation, and

Table 4–1 Parameters That Can Be Used To Assess the Acceptability of a Supplier

Component of the Food Control System	*Expectation*
Good Hygienic Practice	In place and designed to help control known hazards
HACCP plan	In place and designed to control significant hazards
FSO	Process is designed and validated to meet an FSO
Performance criteria	Validated process(es)
Process criteria	Process criteria incorporated into HACCP plan as critical limits
Product criteria: Organoleptic, chemical, physical, and biological specifications	Meets specifications
Records	Records are complete, accurate, and facilitate validation and verification

the quantity involved, the sanitary or phytosanitary status of the food are attested to by an issuing authority. The certificate is a legal document that specifies that the lot is in conformity or meets:

1. the specified product standards required by the importing country;
2. provisions of bilateral or multilateral agreements between the importing and exporting countries; and
3. in the absence of such provisions, the standards and requirements as agreed upon, with emphasis on the use of standards and codes of practice of the Codex Alimentarius Commission.

4.6 EXAMPLES TO DEMONSTRATE THE PROCESS OF LOT ACCEPTANCE

The decision to accept or reject foods upon receipt at port-of-entry or at a buyer's operation is influenced by a number of factors. Among the most common is prior experience with the supplier for compliance with all established criteria. Another is the likely impact if an incorrect decision is made to accept a defective lot. The extent of an adverse impact will depend on the likely presence and severity of a hazard in the food and whether its intended use can result in a decrease, no change, or an increase in the hazard prior to consumption as described in detail in Chapter 8. The following examples describe the decision making process for food being received at port-of-entry or at a food operation when there are different degrees of knowledge about the source.

4.6.1 Ideal Situation—Extensive Knowledge

- Food is produced applying control measures as described in Chapter 3.
- Supplier is on approved list.
- Supplier has a history of consistent compliance with all established criteria during operation and for finished product.
- There is a favorable history of audit results.

- All pertinent records are complete, accurate, and facilitate verification.
- Supplier is from a country judged to have an equivalent inspection system and to provide the same level of protection and FSO for the food in question.
- Product and packaging looks normal. No evidence of spoilage or damage to the product during shipment (e.g., excessive humidity and mold growth, collapsed cartons indicating thawing of frozen product).
- Product is received within time-temperature limitations that have been specified for perishable items.

The extensive knowledge available in this example leads to a high level of confidence that the ingredient or food will meet the FSO and provide the expected level of protection. In this case, it would be redundant and nonproductive to sample and test the incoming material.

Exhibit 4–1 Example of a Certificate for the Export of Food and Food Products

Exporter/Consignor		Certificate No.
Consignee		**TITLE** Name and address of issuing authority
	Port of loading	Country of origin of goods
Vessel/ Aircraft	Date of departure	
Port of discharge	Final destination (if on carriage)	
Identification, Shipping marks	No. and kind of packages	Description of goods / Quantity
Container number, Seal number		
Details of producing establishments		
Details of treatment		
Attestation		
DECLARATION Dated at _____ (place) On _____ (date) _____ Signature of signing officer _____ Printed name		

4.6.2 Less Than Ideal—Some Knowledge

- It is uncertain whether the food is produced applying the control measures described in Chapter 3.
- Supplier does not appear on the list of approved suppliers.
- Supplier has a history of compliance with established criteria for finished product.
- Supplier is infrequently audited.
- All pertinent records accompanying the lot are complete and accurate.
- Supplier is from a country judged to have an equivalent inspection system and to provide the same level of protection and FSO for the food in question.
- Product and packaging looks normal with no evidence of spoilage or damage to the product during shipment (e.g., excessive humidity and mold growth, collapsed cartons indicating thawing of frozen product).
- Product is received within time-temperature limitations that have been specified for perishable items.

Considering the limited knowledge available, the decision to accept the lot may be determined by the consequences of an incorrect decision. It may be prudent to test the incoming material if the chance of a food safety problem is sufficiently high and testing can be expected to provide useful information. The tests that may be performed would depend on the material and the significant hazards that may be expected to occur.

4.6.3 Uncertain Situation—No Knowledge

- No knowledge of how the food is produced.
- Supplier is not on approved list.
- A history of compliance with established criteria is not available.
- There is no history of auditing results.
- Available records accompanying the lot meet minimum requirements.
- Supplier is from a country that has yet to be judged on whether it has an equivalent inspection system.
- Product and packaging looks normal. No evidence of spoilage or stress to the product during shipment (e.g., excessive humidity and mold growth, collapsed cartons indicating thawing of frozen product).
- Product is received within time-temperature limitations expected of perishable items

In the absence of knowledge that can be used to decide whether to accept the lot, it is necessary to develop information for the lot. The tests that should be conducted should be based on the hazards that may be expected to occur. There is little choice but to place greater reliance on the use of a sampling plan that reflects potential risk as described in Chapters 5 and 8.

4.6.4 Factors Influencing Whether a Lot Should Be Tested

Criteria of various types are commonly established for foods at different stages along the food chain. In many cases, the criteria serve as purchase specifications and are intended to inform suppliers of the expected safety and/or quality characteristics for the food. In a similar manner, a standard may be developed by governments that food oper-

ators are required to meet. Despite these criteria, foods are not sampled at each step to verify compliance. In reality, the majority of foods are not sampled. The decision to sample a lot of food depends on a wide variety of factors, as outlined in Exhibit 4–2. The specific use of sampling and testing for compliance with microbiological criteria is dealt with in Chapter 5. Several aspects of Exhibit 4–2 are also incorporated into Figure 8–1.

To respond differently to the questions in Exhibit 4–2 would decrease the likelihood that a lot of food would be sampled and tested. Thus, foods believed to be of low risk to consumers would be sampled infrequently or not at all.

4.6.5 Situations Warranting Reduced/Tightened Inspection or Testing

Foods being received from suppliers that meet the characteristics described in section 4.6.1 would be of low risk and would warrant a reduced level of inspection and testing. Changes in the characteristics that lead to uncertainty about the safety of the food (e.g., an unfavorable audit report) would indicate a need to increase the level of inspection and/or testing. As described above, the degree of inspection and/or testing would depend on the risk associated with an incorrect decision. The factors outlined in Exhibit 4–2 would influence the decision whether to sample and test the food. Further discussion on tightened inspection is found in Chapter 9.

4.7 AUDITING FOOD OPERATIONS FOR SUPPLIER ACCEPTANCE

4.7.1 Basic Stages of Auditing To Determine Acceptability of a Supplier

Regardless of the availability and application of an FSO, the method of auditing is principally the same. This chapter will not discuss in detail how audits should be organized and executed, because text books and international standards are available on this subject. However, some aspects considered to be important will be mentioned. Part of the following text is adapted from the report of an FAO/WHO Consultation (WHO, 1998).

The auditing process is a formal procedure that is agreed upon by both parties and conducted in accordance with a format that is specific to the circumstances. Auditors should ensure that they plan the process properly, and that:

- sufficient time is allocated;
- the required skills are available within the audit team (in accordance with resources available);
- arrangements are agreed upon with the management of the site being audited.

There are typically two stages to auditing a production, processing, or preparation business. The first stage consists of an initial review of documentation that may be carried out on- or off-site. Although it is possible to carry out an audit without a preassessment or document review, experience has shown that a review of pertinent documents before visiting the site leads to a more focused, thorough and informed assessment. The second stage is the on-site determination of whether the company applies Good Hygienic Practices and HACCP as documented, and whether the company can consistently deliver the product as specified and when expected for delivery.

It is helpful to prepare an agenda for the audit program to ensure that relevant personnel are available during the assessment and can participate in the on-site discussion.

Exhibit 4–2 Factors that Can Influence the Decision Whether to Sample and Test a Lot of Food

Factor influencing decision to sample and test	**Condition that would increase the likelihood of sampling the lot**
What is the expected outcome if the food is not sampled and is accepted?	Illness among consumers is probable.
Has the food commonly been involved in foodborne illness?	The food has a recent history of causing illness.
What is the severity of the hazard(s)?	The expected hazard is of high severity.
Is there reason to suspect the food will not meet established criteria?	Certain lots occasionally fail established criteria.
Is the food intended primarily for a sensitive population?	The food is designed and intended for high risk populations.
Is the food from a country or region with endemic disease of importance to food safety?	Recent reports indicate that endemic disease has resulted in foodborne illness among consumers of an importing country.
Is the country or supplier known to exercise control over the food?	The exporting country's inspection program is considered inadequate for the expected hazard(s) in the food.
What is known about distribution of the hazard (e.g., homogeneous, heterogeneous, stratified)?	The hazard is expected to be homogeneously distributed throughout the lot, thereby increasing the likelihood of detecting an unacceptable lot.
Can a sampling plan be used to detect unacceptable lots, particularly when a small number of defective units are expected?	When defective lots occur, the number of defective units is sufficiently high to be detected.
Can the sampling plan detect a low prevalence of a pathogen of concern?	When present, the pathogen occurs in sufficiently high prevalence that it can be detected.
What is the expected complexity, accuracy, sensitivity and time for the result?	The laboratory method is easily performed, accurate, sensitive, and the time to obtain a result will not lead to a decrease in the quality of the product.
Does the laboratory have the equipment and expertise to analyze the samples?	Yes.
Where is the food located; can the lot be easily sampled?	The lot is located nearby and can be easily sampled.
Can samples be transported to the laboratory easily?	The laboratory is situated locally.
What is the cost of the product that will be sampled?	The product samples need not be purchased.
Are there sufficient funds, personnel, and laboratory support to collect and analyze the samples?	These resources are available.
Are there any outside influences to consider (e.g., political, supplier/buyer relationship)?	There are no outside influences.

4.7.1.1 Preassessment Document Review (Stage 1)

This initial stage is, in fact, more than a document review. It is a "desktop assessment" of the quality and safety assurance system. Ideally, all documentation relating to the scope of the audit should be reviewed by the auditor before an on-site assessment. This important activity may enable the design of an initial assessment checklist. Even a quick scan may allow the auditor to get an idea of the standards being applied, whether all the hazards have been identified by the supplier, and whether CCPs are well under control.

Typically, the documents reviewed might include:

- the site layout plan,
- the process flow diagram and specifications relating to it,
- a brief description of the GHP procedures, and
- the HACCP plan.

The preassessment documentation review may help the assessor identify the personnel required for detailed discussions, the specific questions to be asked, and which areas are to be focused on when carrying out the on-site assessment activities. If the auditor finds through the document review that there are obvious inadequacies, it may be decided to stop the assessment at this point instead of proceeding to the on-site audit. Based on these preliminary findings, the auditor may decide not to approve the supplier. Alternatively, the auditor may ask the potential supplier to review its quality and safety assurance system and make adjustments based on the preliminary findings.

4.7.1.2 Audit Protocol (Stage 2)

On-site Initial Meeting

It is helpful to have a brief opening meeting with the key people of the operation being assessed to confirm the scope, timetable, facilities and personnel requirements for the audit. The time and location of the next meeting could be confirmed and any additional documents required for the on-site document review could be requested.

Activities

It is important at an early stage of the audit to verify that the process flow diagram truly reflects what actually occurs. This is facilitated by an initial walk-through to observe the operation. The auditor will subsequently need to engage responsible staff in a range of questioning and investigative activities to assess the efficacy of the quality and safety assurance system, particularly the HACCP system and prerequisite control measures.

Often a form of memory aid or checklist may be used to focus these activities. The questions should cover, for example, the seven HACCP principles (see Chapter 3). Auditors must adapt other supplementary questions/activities to the scope and purpose of the audit.

The auditor should use a range of recognized questioning and auditing techniques to obtain the information required. For example, have previous audits been conducted, what were the findings and how has the operator responded? It is important that the auditor maintain sufficiently detailed records during the audit to support subsequent recommendations.

Such records could typically include:

- personnel interviewed
- records examined

- equipment examined
- product/process details
- areas not included within the assessment
- defects/inadequacies noted.

Auditors

Auditing large operations may require a team of auditors because the complexity of the operation may require a range of skills. In smaller operations of less complexity, the scope of the audit may be limited and an individual auditor is often used.

However, certain principles always apply:

- auditors should be independent even if employed by the supplier's organization; and
- auditors should be sufficiently skilled for the activity in question (e.g., proven auditing skills, knowledge of quality and safety assurance systems, experience with the technology being applied in the operation, HACCP as applied in commercial operations, and relevant GHP procedures).

Outcome and Follow-up

A closing meeting to discuss and agree on initial findings and identify corrective actions should be held with the responsible manager. It also is necessary to discuss and agree on the mechanism and timetable, accompanying documentation, and product liability concerns. If certain improvements must be made before products are accepted or resumed, a timetable should be set and, if necessary, plans made for a follow-up visit.

Frequency of Audits

An initial audit is conducted as part of a supplier approval system.

Further audits may be triggered by:

- changes in the buyer's or supplier's products/process/formulation, etc.;
- poor performance;
- a minimum baseline frequency for audits regardless of other factors.

4.7.2 Example of Auditing a Supplier When an FSO Has Been Established

Manufacturers that produce food for which an FSO has been established must assure that performance and process criteria are being met for their specific processes and conditions. The process criteria are typically used as critical limits for CCPs in the HACCP plan. Other criteria for less critical factors may appear as GHPs or prerequisite procedures.

Although most processes and practices for which process criteria have to be established will normally be the responsibility of a food operator, some may be controlled by suppliers of critical raw materials. For example, a producer of dried milk used as an ingredient in a dry mixed infant formula will have to assure that the number of *Salmonella* is below a certain level. If an FSO for infant formula was established as < 1 *Salmonella* in 10^8 g of product, then the performance criterion for the milk powder would be, for example, < 1 *Salmonella* in 10^9 g of product. Meeting such a criterion would require pasteurization of the milk at a temperature of 80 °C for 5 s as a minimum before spray drying (see Chapter 15). Recontamination must be prevented through the application of GHP. For some GHPs (e.g., air filtration), a process criterion can be set, but for others (e.g., dry cleaning practices), criteria cannot easily be established and monitored.

The selection of an acceptable supplier of a sensitive raw material is of great importance to assure the safety of a product such as a dry mixed infant formula. Audits are essential for selecting reliable suppliers with effective control measures. Once a supplier is approved, it is necessary that buyer and supplier agree on the practices to be followed. Audits at regular intervals would be a normal aspect of the partnership.

The checklist in Exhibit 4–3 demonstrates how a general audit can be targeted for a specific food operation. During an initial audit to determine the acceptability of a supplier, emphasis will be on whether the supplier can be trusted to deliver ingredients or foods needed to produce a safe product. Follow-up audits will clearly be targeted toward confirming that the supplier can indeed be trusted. The checklist outlined in Exhibit 4–3 shows how an audit can be adapted to these specific needs and provides examples of questions that should be raised. The production of dry milk (see Book 4, Chapter 11.7 and Chapter 15 in this book) is used as the example to illustrate some of these points.

While this example describes the approval of a potential supplier of an ingredient, the same procedures can be applied to other situations (e.g., auditing to approve a contract manufacturer or a manufacturer of a food for retail sale or institutional use). In addition, the concepts could serve as a basis for assessments of food operations by control authorities.

Exhibit 4–3 General and Specific Questions that Could be Considered during an Audit of a Potential Supplier of Dried Milk to be Used in the Manufacture of a Dry Mixed Infant Formula

Stage of audit	General questions to be considered when conducting an audit	Additional specific questions when auditing a dried milk operation
Stage 1: Off-site preparation for audit, study of documentation	What evidence is there of management commitment to comply with requirements? Does the company have a food safety policy? Have the food safety requirements been clearly defined? Are written documents on GHP and HACCP available and up to date? Who is on the HACCP team? Are all appropriate disciplines represented? What is the likely knowledge level of the individuals (evidence of training, qualifications, experience, etc.)? Was external expertise sought? Have performance and process criteria been properly established and validated? Are monitoring and verification data available?	Is the dried milk producer a supplier to other manufacturers of products similar to dry mixed infant formula or where dried milk is considered a sensitive ingredient? Have critical aspects of the production been worked out together? Who validated the process and performance criteria? Are monitoring data obtained with reliable methods?
Stage 2: On-site audit	What is the general standard of GHP? Are the personnel properly trained? Do they apply the rules?	Are the wet and dry zones properly separated, with overpressure of air in critical areas?

continued

Exhibit 4–3 continued

Stage of audit	General questions to be considered when conducting an audit	Additional specific questions when auditing a dried milk operation
A. Good Hygienic Practices	Are the zones with different requirements sufficiently separated? Is the pest control program functioning effectively? Are chemicals being safely controlled? How is rework, if any, being handled? How is waste treated material being handled?	Is any wet cleaning being performed in dry areas? Is the air handling system adequate? Is there evidence of infestation with insects? Does it appear that the conditions will lead to recontamination with *Salmonella?*
B. HACCP plan a. Hazard Analysis	Have the hazards of significance been correctly identified? Have any hazards been overlooked that may have an adverse affect when used in the buyer's product? Will the product meet an established FSO? Has the product been properly described? Is the PFD complete and accurate? How and when was the PFD last verified for accuracy and by whom? Are all raw materials, process/storage activities, and the use of rework included in the flow diagram? Have changes in the operation been properly analyzed to identify new hazards?	Were hazards other than *Salmonella* identified? Does the process flow diagram (PFD) indicate the various zones and personnel movements that are important to control of *Salmonella*? Does it appear that product from this operation will meet the FSO for dried milk?
b. Control measures	Are the CCPs adequately identified and do they control the hazard(s) of importance? How were the critical limits established? Are they adequate to meet any performance criteria that have been established? Have the critical limits been validated and how was this done? Are the monitoring procedures adequate to assure that deviations are detected and product is not released without appropriate review? What are the statistical methods used in monitoring? Have the monitoring methods been validated, and are the tests included in a proficiency testing program? Are the GHPs adequate to support the HACCP plan and control the hazard(s) of importance?	Is the pasteurizer identified as a CCP? What critical limits are being used for pasteurization? Are the times and temperatures of operation continuously recorded? Will the operating conditions achieve an 8 log reduction of *Salmonella*? What is the specification of the air filters for the cooling air, and is the effectiveness of the filters maintained?

continues

Exhibit 4–3 continued

Stage of audit	General questions to be considered when conducting an audit	Additional specific questions when auditing a dried milk operation
	What is the nature of the deviations that occur? Are corrective actions properly described and are the personnel adequately trained to carry them out? Does adequate documentation exist to show that when deviations occur they are detected and corrective actions are properly implemented to prevent their reoccurrence?	
c. Verification	Have verification procedures been clearly and appropriately established? Do they include tests for indicators and/or pathogens? Are the methods validated and is the laboratory included in a proficiency testing program? What are the microbiological criteria and actions taken when lots do not meet them? How are consumer complaint data being used within the verification system? Who is responsible for reviewing the HACCP verification data? How often are the HACCP records verified? What is the frequency of review of the HACCP plan?	Is the product analyzed for Enterobacteriaceae (as indicators) and for *Salmonella*; how often and how many samples? What is the sampling plan? Is the line-environment examined for the same bacteria; do tests indicate absence of *Salmonella*? What do the consumer or customer complaints indicate?
d. Packaging and shipping	Will the packaging material protect the product under expected conditions of shipping, storage, and use? Are the packaging materials as specified? Is the product correctly labeled for ingredient content and are production codes legible? Are storage conditions adequate? Are distribution procedures in-house or third party? Are good distribution practices being maintained? Is a recall procedure in place and has it been recently tested?	Are the bags water tight? Are pallets in good order, preventing damage to the bags of dried milk? Can the supplier trace the source of raw milk, production codes containing different sources/lots of milk, and where dried milk has been shipped? Have any incidents occurred where unacceptable product was shipped and, if so, were customers timely informed?

4.8 REFERENCES

CAC (Codex Alimentarius Commission) (1997a). *Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene. Food Hygiene, Supplement to Volume 1B-1997. Principles for the Establishment and Application of Microbiological Criteria for Foods*. CAC/GL 21–1997. Secretariat of the Joint FAO/WHO Food Standards Programme. Rome: Food and Agriculture Organization of the United Nations.

CAC (Codex Alimentarius Commission) (1997b). *Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene. Criteria for a Generic Certificate for the Export of Food and Food Products. Alinorm 97/30A, Appendix III, Annex 1*. Rome: Food and Agriculture Organization of the United Nations.

CAC (Codex Alimentarius Commission) (2000). *Proposed Draft Framework for Determining the Equivalency of Sanitary Measures Associated with Food Inspection and Certification Systems*. CCFICS/CX/FICS 00/6, Attachment 1. Joint FAO/WHO Food Standards Programme, Codex Committee on Food Import and Export Inspection and Certification Systems. Rome: Food and Agriculture Organization of the United Nations.

Schultz, W. B. (1997). Draft guidance on equivalence criteria for food. *Fed Register* 62, 30593–30600.

WHO (World Health Organization) (1998). *Guidance on Regulatory Assessment of HACCP, Report of a Joint FAO/WHO Consultation on the Role of Government Agencies in Assessing HACCP*. WFO/FSF/FOS/98.5. Geneva, Switzerland: WHO.

Chapter 5

Establishment of Microbiological Criteria for Lot Acceptance

5.1 Introduction
5.2 Purposes and Application of Microbiological Criteria for Foods
5.3 Definition of Microbiological Criterion
5.4 Types of Microbiological Criteria
5.5 Application of Microbiological Criteria
5.6 Principles for the Establishment of Microbiological Criteria
5.7 Components of Microbiological Criteria for Foods
5.8 Examples of Microbiological Criteria
5.9 References

5.1 INTRODUCTION

As described in the previous chapter, microbiological criteria represent one form of acceptance criteria. This chapter will focus on the use of microbiological criteria as a basis for determining acceptability of individual lots or consignments of food. Other uses of microbiological testing will not be addressed in this chapter.

Ideally, criteria that address food safety concerns should be based upon a food safety objective (FSO). The FSO is a statement of the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection. FSOs are very suitable for the design and control of a food operation, but they are not intended for lot acceptance determinations. FSOs, however, can be used as the basis for establishing microbiological criteria. Indeed, it is important that microbiological criteria are compatible with the FSO for a food. Microbiological criteria should not be so lenient that the intended public health goals cannot be achieved. Conversely, a microbiological criterion that is excessively stringent relative to an FSO may result in rejection of food even though it has been produced under conditions that provide an acceptable level of protection. While very similar at first impression, FSOs and microbiological criteria differ considerably in function and content as can be seen in Exhibit 5–1.

An FSO can be used as a basis for the establishment of microbiological criteria. Certain information will be known from the FSO—namely, the food, the microbial hazard, and the maximum frequency or concentration that is considered tolerable. To fulfill the requirements of a microbiological criterion, additional information must be provided. The information provided in this chapter and in Chapters 6, 7, and 8 must be considered before a meaningful microbiological criterion can be established from an FSO.

National Beef Ex. 1045
219 of 482

Exhibit 5–1 Characteristics of Microbiological FSOs and Microbiological Criteria

FSO	Microbiological Criterion
A goal upon which food processes can be designed so the resulting food will be acceptable	A statement that defines acceptability of a food product or lot of food
Applied to food processing operations	Applied to individual lots or consignments of food
Components: —Maximum frequency or concentration of a microbiological hazard	Components: —Microorganism of concern and/or their toxins/metabolites —Sampling plan —Analytical unit —Analytical method —Microbiological limits —Number of analytical units that must conform to the limits
Can be used to establish microbiological criteria	Cannot be used to establish an FSO
Used only for food safety	Used for food safety or quality characteristics
Based on what risk managers believe will ensure the safety of a food	Based on an FSO or what risk managers believe will ensure a food to be safe or acceptable for the intended use
Can be used to cause change in processing conditions for a food commodity and improve its safety	Can be used to cause change in processing conditions so individual lots or consignments will meet established criteria
Very suitable for assessing a food safety system of a food operation	Not very suitable for assessing a food safety system of a food operation; sampling lots of food from an operation provides a snapshot of the level of control at the time of collection, but provides little confidence for past or future lots
A high level of confidence is possible when processes are designed and validated to meet an FSO	Confidence may be less certain if an FSO is not used when processes are designed and validated to meet a microbiological criterion

Since they are a relatively new concept, FSOs are not yet in broad use. In the interim, traditional approaches must be used by governments and industry to ensure food safety. The traditional approach is similar to that used in connection with an FSO. However, traditional methods often permit varying interpretations that may directly lead to non-tariff trade barriers and add to the burden of irrelevant specifications between trade partners. According to the World Trade Organization Agreement on the Application of Sanitary and PhytoSanitary Measures (WTO/SPS agreement) (WTO, 1995), every criterion that