Chapter 1
An Introduction to HACCP and Its Role in Food Safety Control

HACCP is the well-known acronym for the Hazard Analysis and Critical Control Point system. It has been frequently written about and talked about at conferences and within companies over the last 50 years but is still often misunderstood and poorly applied in real situations.

Since we last updated this book there have continued to be many failures in the food supply chain. Some of these are world renowned (e.g., melamine in milk powder from China), many were significant national failures (e.g., Salmonella in peanut butter in the USA, Salmonella in chocolate in the UK, *E. coli* in sprouted seeds in Germany), and many, many more were small, isolated, and sometimes tragic events occurring in countries all around the world. So what has gone wrong? Is HACCP not working? Sadly, the answer to this question is that it hasn't had a chance to work. Far from being "done," HACCP has been poorly implemented and under-utilized in probably the majority of food companies.

The HACCP concept has been around in the food industry for a long time, yet food safety control continues to be debated rigorously at the international level and there continues to be calls for new committees, new agencies, and new laws to fix the problem. Twenty years ago developments in HACCP were fairly major, and some governments saw its implementation as a remedy for all of their country's food safety issues. In reality, use of the HACCP approach does offer a practical and major contribution to the way forward, but **only** if the people charged with its implementation have the proper knowledge and expertise to apply it effectively. Foodborne illness continues to be a major problem that must be addressed. We cannot go another 20 years and still be searching for solutions. **Consumers have a right to expect that each product produced and sold will be safe for consumption.**

HACCP is a tool that can be used to reduce the risk of a food safety failure. However, the food industry has failed to use it effectively to do that, often by spending time in writing and updating the documents, as opposed to recognizing that the thought and application process is the key to food safety assurance. Many companies think they have a HACCP system because they have a written HACCP plan, yet frequently the content of the plan is poor and adds little value in terms of

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food safety risk reduction. In these cases HACCP needs to be revisited, upgraded, and properly implemented before it can have an impact on food safety risk reduction.

In this chapter, we will consider some of the most common questions asked not only by those who are new to HACCP but also by those who want to take a fresh look and upgrade their food safety systems. We will endeavor to explore some of the reasons for using the system—for the management of product safety, to meet government and customers' expectations and, perhaps less obviously, because it makes good business sense.

1.1 HACCP: The Basic Questions Answered

1.1.1 What Is HACCP?

HACCP is a logical system of food control based on prevention. In identifying where the hazards are likely to occur in the process, we have the opportunity to put in place the measures needed to **prevent** those hazards from affecting the consumer. This facilitates the move towards a preventative quality assurance approach within a food business and reduces the traditional reliance on end-product inspection and testing.

In brief, HACCP is applied by taking a number of straightforward steps:

- Understand **your** product—what is making it safe?
- Look at your production process from start to finish—understand your operating environment and process activities.
- Identify potential hazards and decide where they could occur in the process.
- Put in preventative control measures with defined safety limits.
- Monitor the controls.
- Write it all down and keep records as evidence that you've done it.
- Ensure that it continues to work effectively.

All types of food safety hazards are considered as part of the HACCP system—biological, chemical, and physical. Effective implementation of a HACCP-based food safety system should, therefore, give the growers, manufacturers, food service operators, and retailers' confidence that the food they provide is safe. This can and should involve everyone in the company as each employee has a role to play. This is a fundamental requirement that is often forgotten: the systems element is not just about documentation, it is also a "people system." The people who use it own it—they maintain it and keep it current. Our first edition of this book was published in 1994, nowadays there are few people in the industry who haven't heard of HACCP but there are many who have lost sight of the fact that you need people who know how to get it done and who are accountable. The culture that evolves through this systems/people approach not only makes it more likely to succeed but makes it

much simpler to progress to additional programs such as quality improvement, productivity, and cost reduction.

1.1.2 What Are the Principles of HACCP?

The HACCP system consists of seven principles which outline how to establish a HACCP plan for each operation under study. The HACCP principles have international acceptance and details of this approach have been published by the Codex Alimentarius Commission (1993, 1997, 2003, 2009b) and the National Advisory Committee on Microbiological Criteria for Foods (NACMCF, 1992, 1997).

We are now going to introduce a number of terms which may be unfamiliar to you if you are just starting out. There is a glossary in Appendix C and an abbreviations list in Appendix D, and we will be discussing these again in full in Chap. 6 when we look at applying the principles.

Principle 1. Conduct a hazard analysis. Prepare a list of steps in the process, identify where significant hazards could occur, and describe the control measures.

Principle 1 describes where the HACCP team should start. A Process Flow Diagram is put together detailing all the steps in the process, from incoming raw materials to finished product. When complete, the HACCP team identifies all the hazards that could occur at each step, considers the likelihood of their occurrence, and considers the severity of effect to the consumer. This determines the significant hazards and enables the team to go on to describe preventative measures for their control. These may be existing or new control measures.

Principle 2. Determine the Critical Control Points (CCPs). When all the significant hazards and control measures have been described, the HACCP team establishes the points where control is **critical** to assuring the safety of the product. These are the Critical Control Points or CCPs.

Principle 3. Establish Critical limits for control measures associated with each identified CCP. The critical limits describe the difference between safe and potentially unsafe product at the CCPs. They must involve a measurable parameter and may also be known as the absolute tolerance or safety limit for the CCP.

Principle 4. Establish a system to monitor control of the CCP. The HACCP team should specify monitoring requirements for management of the CCP within its critical limits. This will involve specifying monitoring actions along with monitoring frequency and responsibility.

Principle 5. Establish the corrective actions to be taken when monitoring indicates that a particular CCP is not under control. Corrective action procedures and responsibilities for their implementation need to be specified. This will include action **both** to bring the process back under control and to deal with potentially unsafe product manufactured while the process was out of control.

Principle 6. Establish procedures for verification to confirm that the HACCP system is working correctly. Procedures must be put in place to both **validate** that the CCPs will control the hazards of concern and **verify** that the system is working day-to-day as planned.

Principle 7. Establish documentation concerning all procedures and records appropriate to these principles and their application. Records must be kept to demonstrate that the HACCP system is operating under control and that appropriate corrective action has been taken for any deviations from the critical limits. This will provide evidence of safe product manufacture.

1.1.3 Where Did HACCP Come from?

HACCP was developed originally as a microbiological safety system in the early days of the US manned space program. It was vital to ensure the safety of food for the astronauts—imagine suffering foodborne illness in a zero gravity environment! At that time, most food safety and quality systems were based on end-product testing, but it was realized that this could only fully assure safe products through testing 100 % of the product, a method which obviously could not have worked as all product would have been used up! Instead it became clear that a preventative system was required which would give a high level of food safety assurance, and the HACCP system was born (Fig. 1.1).

The original system was pioneered by The Pillsbury Company working alongside NASA and the US Army Laboratories at Natick. It was based on the engineering system, Failure, Mode and Effect Analysis (FMEA), which looks at what could potentially go wrong at each stage in an operation together with possible causes and the likely effect. Effective control mechanisms are then put in place to ensure that the potential failures are prevented from occurring.

Like FMEA, HACCP looks for hazards, or what could go wrong, but in the product safety sense. Preventative control measures are then implemented to ensure that the product is safe and cannot cause harm to the consumer.

1.1.4 So, Why Should You Use HACCP?

A simple answer to this question is "because product safety cannot be tested in." HACCP is a proven system which, if properly applied, will give confidence that food safety is being managed effectively. Implemented properly, it will enable you to focus on product safety as the highest priority always and allow for forward planning to prevent things going wrong, rather than waiting for problems to occur before deciding how to control them.

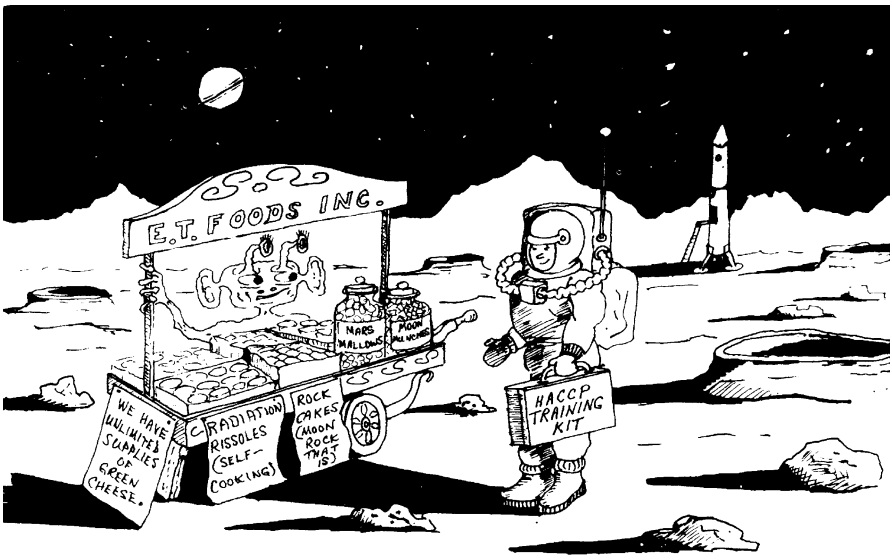

Fig. 1.1 Origins of HACCP

HACCP was developed as a straightforward method of helping manufacturers assure the provision of safe food to the consumer, but many companies have not fully realized the full potential of the system. By not committing to full and detailed implementation of the HACCP system we risk not achieving the benefits (Sect. 1.1.6), and of seeing HACCP as an on-cost to business rather than a fundamental element that is core to food business practice.

Despite progress, foodborne disease continues to be one of the largest public health problems worldwide. There are a number of reasons for this including:

1. The proportion of the population who have increased susceptibility to foodborne illness is increasing, for example, the elderly community in many parts of the world (including Japan and many western countries), the number of immunocompromised consumers (for example, AIDs, cancer patients), and the malnourished, not just in less developed countries but also surprisingly in many developed countries due to the economic challenges in recent years.
2. Changing lifestyles have resulted in a number of changes to our eating habits:
   (a) More people now regularly eat out or snack on the move, which has led to an increased demand for food service establishments of varying standards.
   (b) Many people work outside the home and rely on processed foods for fast meal preparation; this has meant that knowledge of how to handle and prepare foods has decreased in recent years.
   (c) Increased mass production of foods has increased the potential for larger numbers of consumers to be affected in the event of an outbreak of foodborne disease.

(d) Increased tourism has meant that people are exposed to foodborne hazards from other areas.

3. Emerging pathogens (such as *Cronobacter sakazakii*) and increased awareness of the persistence and survival of pathogens in low moisture foods.
4. Global sourcing of finished products and ingredients has increased the complexity of the supply chain and made it more difficult to trace and recall in the event of a failure.
5. Increased testing capabilities combined with improved laboratory communication schemes mean that previously unidentified issues can both be detected and also linked together across states and countries to reveal an outbreak that would otherwise have gone unrecognized.
6. Whilst new technologies, processing methods, and work practices are generally intended as improvements to provide better food products, we must not lose sight of the fact that, without careful safety evaluation, changes could also result in unsafe practices that might contribute to foodborne disease.

The importance of the HACCP approach as the most effective means of preventing foodborne illness has long been recognized by the World Health Organization and many governments worldwide (WHO, 2007). Despite this, many companies are not using the concept to identify and manage food safety risk—they may have HACCP systems, perhaps due to customer or legal requirements, but are not really using HACCP to its best effect.

Consumer awareness of the right to purchase food that is safe has increased significantly over the past few years. Similarly their awareness is raised of quality failures or wholesomeness, for example, the presence of unwanted harmless physical contaminants, such as extraneous vegetable matter. Here the controls used to prevent the presence of a harmful contaminant, such as glass, are often likely to prevent the occurrence of less harmful contaminants, therefore providing brand quality protection as well as consumer protection.

1.1.5 Why Can't We Rely on Inspection and Testing?

So, what is wrong with what we continue to do—inspecting and testing? From a consumer perspective, 100 % inspection, where every single product manufactured is inspected would seem to be the ultimate approach to product safety, or would it? We often rely on visual inspection, particularly for finished products going down the production line, or ingredients during the weighing-up stage. Fruit and vegetables are good examples, where we look for physical contamination such as stalks, stones, leaves, insects, etc. Reasons why the technique is not as effective as we would like include the following: employees get distracted in the workplace by other activities going on around them, such as the noise of the production line or field environment, fellow workers talking about their holiday plans, or what was on television the night before. The human attention span when carrying out tedious

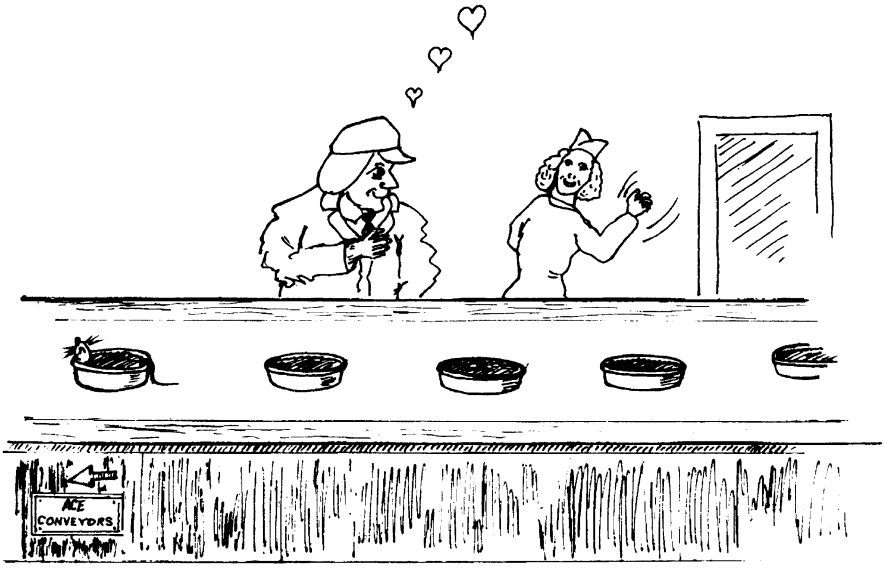

Fig. 1.2 The limitations of inspection and testing

activities is short (generally recognized to be 10–20 min) and "hazards" could be easily missed during visual inspection (Fig. 1.2). Because of this, people are often moved from task to task, in order to give some variety. However, this in itself brings problems along with line changes or shift changes; different personnel may be more aware of one hazard than another. Increasingly, electronic sensing techniques are being used to replace human input. These systems are more reliable but are still not widely used except in large, more developed food plants and need to be accurately calibrated to be effective.

Of course, the main difficulty with a 100 % inspection when it is applied to biological and chemical hazards is that it is impractical because biological and chemical testing is nearly always destructive. This leads us on to the use of sampling plans.

Many businesses "randomly" take a sample(s) from the production line. This can be daily, by batch, or even annually in the case of a seasonal vegetable, fruit, or grain crop. Statistically the chance of finding a hazard is usually very low based on typical practice. Sampling products to detect a hazard relies on two key factors:

1. The ability to detect the hazard reliably with an appropriate analytical technique.
2. The ability to capture the hazard in the sample chosen for analysis.

Analytical methods for the detection of hazards vary in their sensitivity, specificity, reliability, and reproducibility. The ability to trap a hazard in a sample is, in itself, dependent on a number of factors, including:

1. The distribution of the hazard in the batch.
2. The frequency at which the hazard occurs in the batch.

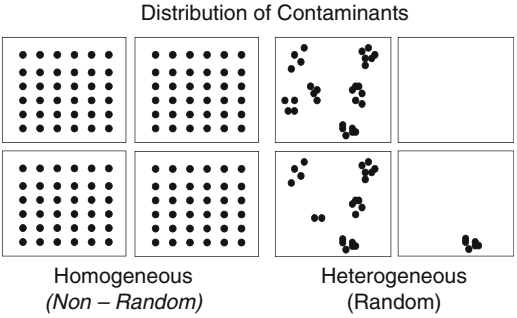

Fig. 1.3 Distribution of contaminants

Hazards distributed homogeneously within a batch at a high frequency are naturally more readily detectable than heterogeneously distributed hazards occurring at low frequencies (Fig. 1.3).

It is easy to come up with examples which might follow the distribution patterns shown in the diagram—some chemical contaminants such as heavy metals coming in with ingredients might be homogeneously distributed through a batch. More often, contaminants such as allergens (particularly in the particulate form), foreign material, or microorganisms are heterogeneously distributed which means that it is difficult to trap the contaminants within a sample.

For example, as illustrated in Table 1.1, in a batch of milk powder contaminated with Salmonella distributed evenly at a level of 5 cells/kg, a sampling plan involving testing ten randomly selected samples, each of 25 g, would have a probability of detection of 71 %. For powder contaminated at 1 cell/kg, the probability of detection using the same sampling plan would be only 22 %.

This naturally assumes that the detection method is capable of recovering the Salmonella serotype contaminating the batch. Few of the traditional testing methods for Salmonella detection would claim an ability to detect in excess of 90 % of the >2,500 serotypes, and most of the methods probably have a success rate of less than 75 %. Therefore the low probability of 22 % will be further reduced. Now that we have the availability of polymerase chain reaction (PCR) methods the testing capability has improved somewhat since targeting common DNA is quite

Table 1.1 Detection probabilities—end product testing, milk powder contaminated with Salmonella

	Contamination rate	Number of random samples	Probability of detection (%)[a]
Homogeneously contaminated	5 cells/kg	10	71
	1 cell/kg	10	22
Heterogeneously contaminated	5 cells/kg in 1 % of batch	10	<2
	10,000 cells/kg in 1 % of batch	10	<15

[a]Assuming detection test is 100 % effective (most are <90 %)

specific and accurate—more accurate than biochemical reactions. For method validation work, the Association of Analytical Communities (AOAC) methods must test at least 100 strains for Salmonella—this will be at least as good and probably better than traditional culture techniques, but still not 100 %.

The probability of detecting a hazard distributed homogeneously in a batch is improved quite simply by increasing the overall quantity of the sample taken and is relatively unaffected by the number of samples taken. Therefore, ten samples of 25 g would have the same probability of detection as one sample of 250 g.

However, as stated earlier, in the majority of cases, hazards, particularly microbiological hazards, are distributed heterogeneously, often present in small clusters in a relatively small proportion of a batch. The probability of detecting a hazard distributed in this way is extremely low if low numbers of samples are taken. Using the example above (Salmonella at 5 cells/kg), and assuming that the contamination is restricted to 1 % of the batch, the probability of detecting the hazard by taking ten samples of 25 g would be lower than 2 %. Interestingly, even if the hazard occurred at high levels within 1 % of the batch (10,000 Salmonella cells per kg), the probability of detection would still be lower than 15 %.

Such a situation cannot be rectified without recourse to a higher number of samples. In fact the probability of detecting the hazard in this scenario is greatly improved by merely taking more frequent samples from a batch, using a continuous sampling device. For example, if 100 g of the milk powder was removed from every ton by a continuous sampler and a well-mixed subsample was tested (5 g from each ton), the probability of detecting Salmonella heterogeneously distributed at 5 cells/kg would increase from 2 % to greater than 90 %. However, even with exhaustive statistical based sampling techniques, detection can never be absolute unless the entire batch is analyzed, and in most cases few manufacturers understand or can afford to operate rigorous statistical sampling procedures.

In summary, if you look for hazards just by taking random samples, there is a high probability that they will go undetected and you will have a false sense of security about the safety of your product.

1.1.6 What Are the Benefits?

The real benefit is that HACCP is a very effective method of reducing risk of failure and maximizing product safety. Traditionally the benefits are described as follows:

- HACCP helps with prioritization in making informed judgments on food safety matters and removes bias, ensuring that the right personnel with the right training and experience are making the decisions.
- HACCP will also help to demonstrate effective food safety management through documented evidence which can be used in the event of litigation.
- HACCP can, after the initial setting up of the system, be extremely cost effective.

  - First, by building the controls into the process, failure can be identified at an early stage and therefore less finished product will be rejected at the end of the production line.
  - Secondly, by identifying the CCPs, a limited technical resource can be focused on their management.
- HACCP enables food companies to meet their legal obligations to produce safe, wholesome food.
- The disciplines of applying HACCP are such that there is almost always going to be an improvement in product quality. This is primarily due to the increased awareness of hazards in general and the participation of people from all areas of the operation.
- Finally, food safety failure is very costly. HACCP and food safety systems are a sound business investment.

1.1.7 Is HACCP All I Need to Do for Food Safety?

HACCP alone will not assure the production of safe food. In your overall food safety program you need management commitment first and foremost and to be operating within the boundaries of good manufacturing practices (GMPs) although these are nowadays referred to as prerequisite programs (PRPs) for HACCP implementation, or PRPs to use the acronym. PRPs are described as the:

> **Basic conditions and activities that are necessary to maintain a hygienic environment throughout the food chain suitable for the production, handling and provision of safe end products and safe food for human consumption (ISO 22000:** 2005**, section 3.8)**

PRPs and more will be covered in detail in Chap. 4 but basically, HACCP needs the support of all the programs and practices that are needed to operate in a safe and hygienic environment.

In terms of management commitment, ISO 2000 (2005) describes this as "management responsibility" which includes provision of appropriate human resources and suitable infrastructure, as well as the ability to plan for and realize safe products.

1.1.8 Can HACCP Be Used to Reduce Food Safety Risk in the Absence of Adequate PRPs?

What if I don't have a well-developed food safety program or hygienic work environment—can I still use HACCP? Our advice would be not to wait until you think the factory is perfect, but start with Principle 1, conduct a Hazard Analysis. One of the main benefits in the early stages of implementation is its help in setting

priorities. Mistakenly, many people feel that HACCP can only be used by mature businesses who have well-developed PRPs and Quality Management Systems already in place. Whilst it is true that a certain level of maturity is needed to develop and implement a fully operational HACCP program, there are significant benefits to using a hazard analysis approach early on in a less mature business. Understanding where hazards may arise and how they may be controlled will help with developing preventative control measures, e.g., for cross-contamination control, where positive air pressure is needed, effective personnel traffic patterns, decisions on where to site hand washing sinks, and CCP monitoring stations. In this way, knowledge of food safety control and the hazard analysis technique can be used to prioritize areas for improvement and as an aid to understanding food safety issues. By systematically analyzing the hazards at each stage in any food production chain and determining at which points control is critical to food safety, you can see whether you already have these controls in place or not (see Chap. 6).

1.1.9 Is HACCP Applicable to Everyone?

Yes, absolutely. You may be a multinational food corporation who incorporates it within a sophisticated quality management system with documented procedures and well-defined practices. Or you may be a grower of salad crops, a small manufacturer of goat's cheese on the farm, a street vendor of ready-to-eat pizza slices, or a five star restaurant. No matter, the HACCP approach can be applied effectively to all food businesses. Those not familiar with hands on practical application of HACCP often hold the misconceived belief that it is a difficult, complicated system which must be left to the experts, and can only be done in large companies with plentiful resources. True, you do need a certain level of expertise to carry out a HACCP study, but this expertise includes a thorough understanding of your plant, kitchen, products, raw materials, and processes, along with an understanding of the factors (hazards) that could cause a health risk to the consumer. This latter point is the common weakness in small businesses and **this** is what needs to be addressed in initiatives geared toward improvement of food safety management in this sector. There is a sizeable lobby who think HACCP is not applicable to small businesses. We disagree. The key is flexibility in application and appropriateness of documentation, i.e., measuring and recording information that adds value as evidence of food safety control. The HACCP technique itself is a straightforward and logical system of control, based on the prevention of problems—a common-sense approach to food safety management. HACCP is a key element of all company product safety management systems and, with good training and education, everyone ought to be able to at least understand the concept.

HACCP is logical in its systematic assessment of all aspects of food safety from raw material sourcing through processing and distribution to final use by the consumer. Various terms are used to describe the scope of the HACCP system. "Farm to fork," and "gate to plate" illustrate the fact that food safety control must

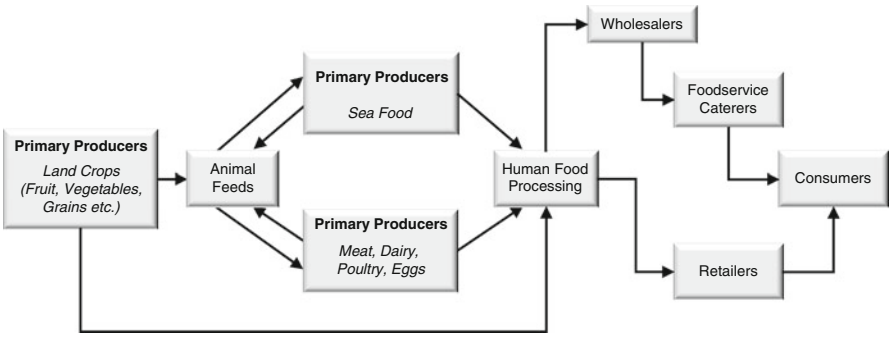

Fig. 1.4 Simplified supply chain model

encompass the entire food chain if you don't want to be in a "crop to court" situation!

If we consider a simple supply chain model (Fig. 1.4), we can see that there are various sectors within the food industry.

This book will largely deal with HACCP application within the processors sector, but it is essential that HACCP is applied to the whole of the supply chain if food safety is to be assured. We will now consider briefly how the Principles may be applied within the other areas and will discuss more detail, with the input of sector specialists, in Chap. 8.

Primary Producers

These are the fish producers and the land farmers, either raising livestock for the meat industry or the growers of the crops and vegetables that will be used by the processors in their conversion into finished products or sent direct to retail or food service. The individual steps within the on-farm process can be assessed systematically for the potential for hazards to occur, just as with any other area of the food-processing industry. Control measures can then be identified, and the control points that are critical to food safety established. Critical limits may be harder to identify, but here the farmer is often helped by legislative limits, for example, in the case of herbicide and pesticide application.

Monitoring the CCPs can sometimes require some ingenuity. Staying with our example of herbicide and pesticide application, this may be done through signing off application record sheets or, when using aerial application, through use of regularly placed pieces of test paper across the land being sprayed, in order to record the spread of the application.

For primary producers there may be added difficulty in understanding the impact of their actions further down the supply chain. Yet for the processors it is almost impossible to anticipate what potential new hazards may arise at their stage in the chain if they do not know what has occurred earlier on during primary production.

An issue that may not appear to be a hazard on the farm may well have an impact further down the chain and require control measures to be implemented at the stage of the earlier primary process. For example, presenting animals for slaughter in an unfit state may increase the likelihood of *E. coli* contamination of the meat. Application of hazard analysis at the primary-producer stage is useful to identify likely hazards and how they will be controlled either through prerequisite hygiene programs or specific control measures. This is probably best done by use of a team approach. This could involve both the primary producers themselves, but also their customers (i.e., the processors, retailers, and caterers).

For further specific information, the Campden BRI Produce and Feed HACCP guideline (Campden BRI, 2010) and sector certification schemes (e.g., Global Good Agricultural Practice—GAP) may be of value. For most producers there are very few CCPs in this sector as most of the food safety control is achieved through PRPs. However, that doesn't mean that the discipline of systematically carrying out a hazard analysis isn't helpful.

Food Service and Catering Operations

Food service and catering operators, large and small, usually have a vast number of raw materials and menu items, and a high turnover of staff. The principles of HACCP remain very relevant to this environment, however, the implementation may differ somewhat from a large food-processing establishment, as shown in the Chap. 8 example.

Although not all food service operators will have the in-depth technical knowledge to conduct what some might refer to as a "real HACCP study," an attempt to understand and adopt the HACCP principles should make significant improvement to the level of food safety control possible. The output of the studies may look less technical, the critical limits may not have been established through in-depth testing or research, but with a certain degree of external support, a simple but effective HACCP plan can be put in place and will add value to the overall food safety program. This external support may include use of pre-developed generic models; however, it is essential that these are customized to the operation. Developers of models need to provide resources that assist in the hazard analysis and not just documentation templates which are of little value by themselves. They also need to appreciate that pre-prepared hazard analyses may not cover all options within specific businesses and should advise businesses to seek appropriate professional advice where the model doesn't fit the operation.

Appropriate training and education is also essential including coverage of food safety hazards in an accessible way. People need to be **compelled** to do the right thing and to do it properly.

Retailers

As seen with the food service and catering example, retailers should also be able to adopt HACCP (and many do) to ensure that they sell safe food which the primary producers and processors have endeavored to ensure reaches them in good condition. Purchasing from reputable suppliers, correct temperature control, and prevention of cross-contamination will be essential control measures in both large and small premises. The HACCP application may be perceived as difficult for smaller vendors. In some countries, for example, both raw and cooked products have historically been sold by the same staff and from the same counter. However, in such examples changes to operating standards will almost certainly be required and these can be identified in a systematic way through use of the HACCP principles. Like the food service and catering operators, for some of the smaller and independent retailers, the application is likely to be less technical, given the lower level of technical expertise available. However, the HACCP principles, if truly understood and linked to good hygiene practices, should help to improve food safety control and hence significantly reduce risk. Effective training in both of these sectors is essential.

Consumers

This is a difficult area, as consumers do not necessarily have access to reliable sources of education and training in food safety. HACCP techniques can be applied very successfully in the home environment (Griffiths and Worsfold, 1994; Wallace et al., 2011), and to some extent there is much similarity between a domestic kitchen and that of the small caterer. It is important that consumers should take responsibility for storing, preparing, and cooking foods properly, rather than expecting all products to be completely free of microorganisms at the point of purchase. However, it is equally vital that they are provided with correct usage instructions that allow adequate cooking to be carried out. Reliable sources of consumer education may exist, but, other than the product labels themselves, the process of obtaining this information is ad hoc, and sometimes the consumer is subjected to conflicting messages. Television cookery programs are often very poor role models for good hygiene practice, and consumers are left to seek out literature from government bodies or retailers, if they want to know more (Mortimore, 1995).

Food hygiene education of the consumer is a vital element in prevention of foodborne illness. Education should include the principles of good consumer practices (GCPs), i.e., good hygiene practice in the home, how to prevent cross-contamination, the importance of temperature in controlling microbiological food safety and of reading labels. Some governments are starting to work with industry and trade organizations in acknowledgement that improved understanding and consumer ownership of preventative control measures will result in a decrease in the number of food poisoning outbreaks.

Additionally, the food industry is a major employer and the possibility of potential employees having a greater awareness of basic good hygiene practice is a real benefit.

Some schools have (re)introduced topics such as cookery, food technology, personal hygiene, and food safety into the curricula but it is often not mandatory and many children miss out. There are some freely available and excellent resource materials available to schools and the general public, such as those developed through the partnership for Food Safety Education (www.fightbac.org) in the USA. These include scripts for teachers and at time of writing the developers were working on "Apps" which would appeal to the younger generation. Targeting the schools education system seems to be a good strategy. Parents used to teach their children how to handle food but with less people cooking, this knowledge is being lost in the general population and is solely the province of the professional food safety scientist.

1.1.10 Why Should I Revisit My HACCP Program? I've Done This Already

At a simplistic level, the answer to this question is that you will need to routinely revisit your existing program because things change—new products, alternative raw materials, changes at the facility or in the process, and of course new information about hazards. But in addition to all that which will be discussed in detail in Chap. 7, consider whether you are **really using HACCP as a means of reducing food safety risk**. Be honest. There are some companies who have best practice programs—vibrant and fully integrated deep within the core of all that they do. Others have rather lack-luster documentation, a hazard analysis which is very general and lacking in any real detail, and they dutifully update the paperwork each year in time for customer or third-party audits, which may not challenge them in any depth.

These companies are also likely to have gaps in their PRPs, i.e., they have not utilized their HACCP skills to develop a risk-based program. HACCP needs to be a part of a wider food safety program. PRPs are essential, as is safe product design and a host of essential management support practices (Wallace et al., 2011). Above all, you need a culture of real commitment to food safety in order to get the best out of your program. Given the continued high numbers of foodborne illness, it seems that many companies are not yet using HACCP properly—be open to continually seeking out best practice to make an existing program even better.

In summary, HACCP is a well-known and widely used tool which when properly implemented can reduce likelihood of food safety failure. It is preventative in that the approach requires that food safety hazards are identified throughout the process thus avoiding the unreliable end-product testing method of assuring safe food.

1.2 External Position and Drivers for HACCP Use

Increasingly, as HACCP becomes a regulatory requirement around the world, this may be the main driver for its implementation along with customer pressure. However, the primary driving force should come from within the company and nothing should be more motivating than the genuine desire to reduce food safety risk and to improve consumer protection.

Panisello and Quantick (2001) report that HACCP needs to be built on four "Pillars," i.e., management commitment, education and training, availability of resources, and external pressures, and that sustainable HACCP can only be built as a result of internal pressure and support (i.e., the decision to apply HACCP is internal to the company and its management), the alternative being an unsustainable model that is the result of external pressure (i.e., the company is pushed into HACCP application by others, e.g., customers or regulators) (Fig. 1.5).

Additionally, there is an increasing amount of global media interest in food safety issues primarily focusing on the food-processing industry and therefore brand protection and company reputation are major concerns. This makes the business case for food safety, i.e., maintaining consumers (and customers) trust. Years ago we were all concerned about newspapers and television channels, today we worry about the Internet—both through formal news media and the much less easy to manage, social media where stories spread very quickly.

We will go on to look at the main external driving forces for HACCP implementation.

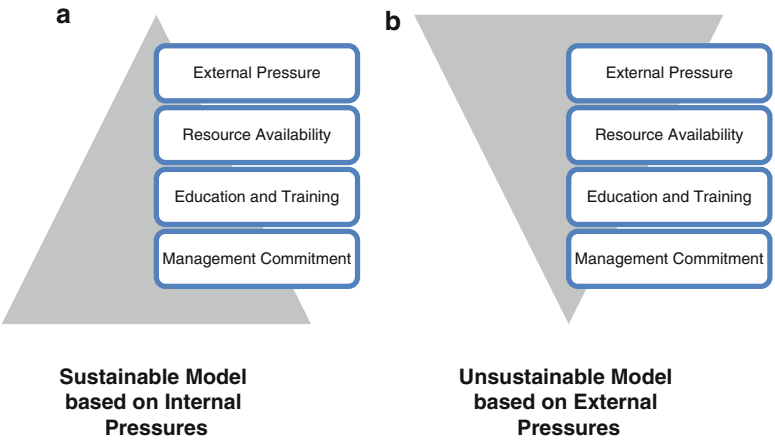

Fig. 1.5 HACCP success factors—prioritization of the four support "Pillars" (adapted from Panisello and Quantick, 2001)

1.2.1 Customers and Consumers

Consumers expect, and have a right to expect safe, wholesome food. We in the food industry have a responsibility to meet their expectations. The safety of our products must, without question, be considered our highest priority. That food is "safe" is often an unwritten requirement of many customer specifications. It goes without saying and, unlike many of the other attributes of the product (appearance, taste, cost), it is **not** negotiable.

While the end consumer may not know what HACCP means, those of you who are supplying private label products to retail and food service customers are most likely required to implement a HACCP system through the need for certification to one of the Global Food Safety Initiative (GFSI) benchmarked standards.[1] This tends to be carried out either as a part replacement or as an enhancement of the customer's own inspection activities. There can be a benefit to the supplier being audited in that the certification bodies often have considerable experience within the industry sector and can provide a useful challenge to the HACCP system but the limitation needs to be understood. The audits are carried out over a typical 1–3-day period (depending on the size of the business), often using one auditor (there is still variable competency) and they are usually announced (the auditee can get ready for it).

For both the retailer and food service operator the customer is at the end of the supply chain, i.e., is also the consumer of the food. For the grower and food manufacturer, quite likely the customer is a food service operator, a retailer, or another industry manufacturer. Whatever the situation, customers have to be confident that the food being purchased is safe. They want to trust and have confidence in their supplier.

Long gone are the days when a customer inspection meant a walk around the factory to check hygiene and housekeeping, followed by a pleasant lunch, although as we will discuss later, audit time is still often insufficient to fully challenge the systems, understand the environmental control requirements, and assess food safety risk. Even with the emergence of GFSI, larger customers are still likely to issue their own "Codes of Practice" which almost certainly will include the requirement for a HACCP system to be in place. A crucial factor in any supplier inspection these days is an assessment of the competence of the management and overall culture of the organization. An **effective** HACCP system can go a long way in demonstrating to the customer that their supplier is managing the food safety hazards.

Whilst your customers are auditing you, you will be auditing your suppliers. No one wants to be buying-in a problem. If a food safety incident was attributed to your product, but was eventually traced to an ingredient, would it be you or your supplier who was held responsible? It may turn out to be the supplier's fault, but what

[1] GFSI is the Global Food Safety Initiative. Formed by the Consumer Goods Forum in 2000, the initiative aimed to harmonize good safety standards and audit schemes by benchmarking against the GFSI reference.

damage will have been done to your business in the meantime if the media have taken an interest and your brand is involved? There are many examples where a single ingredient failure led to numerous product recalls and a high cost of failure to all involved. One of the most recent examples is that of is the Salmonella contaminated peanut products in the USA in 2009. The manufacturing company supplied peanuts, peanut butter, peanut meal, and peanut paste to food processors to use in a wide range of products including cookies, ice cream, and snack items. These were sold to institutions such as hospitals, nursing homes, and schools as well as directly to consumers. This resulted in over 3,900 individual consumer product recalls from more than 350 companies, 9 people died and over 650 became ill as a result (Powell et al., 2010).

Where does the consumer feature with respect to food safety control? Sometimes not much at all as in the example shown above. The consumer has typically played the role of lobbyist in demanding assurance of safe food, and hence has been a driver for implementation of food safety management systems by the industry. However, consumer perception of risk severity does not necessarily always correlate with that of the food industry experts (Chap. 3). These perceptions are important for a number of reasons. Clearly, if consumers do not perceive themselves as being exposed to or the cause of a food safety risk, then they aren't going to adopt the necessary control measures.

1.2.2 International Government Regulation

Government recognition of HACCP as the most effective means of managing food safety continues to develop on a global basis. The difficulty in focusing on specific pieces of legislation in detail is that legislation is ever changing. HACCP is not governed by international legislation, but is being increasingly included in the food control legislation of many countries around the world. The development of food safety control systems has featured increasingly in the literature over the last 20 years and this is being reflected in food control legislation in a number of countries. Most countries adopt similar models for food control, based on international guidance.

In the USA, the HACCP techniques were used originally in the 1970s and 1980s to identify the controls specified in the Low Acid Canned Food Regulations. In 1998, the US Department of Agriculture (USDA) decreed that HACCP programs were required for all meat- and poultry-processing facilities. It was also required by law in the area of seafood inspection and processing (Federal Register, 1995, 1996) and for fruit juice in 1998.

In January 2011, Congress passed the Food Safety Modernization Act ("FSMA").

Food companies will generally be required to: (1) formally consider and identify all reasonably foreseeable food safety hazards; (2) develop written plans addressing

each of those hazards; and (3) closely follow those plans to reduce or eliminate such hazards to the greatest extent possible.

The Food Safety Modernization Act (FSMA) generally does not apply to the meat, poultry, or egg products regulated by the USDA but at the time of writing, it is reported that the Administration is reviewing some of the requirements.

FSMA is divided into four main areas:

1. Prevention of food safety hazards
2. Detection of and response to food safety problems
3. Improving the safety of imported foods
4. Various other miscellaneous provisions including new fees applying to food companies and importers (Table 1.2)

Table 1.2 Overview of the FSMA requirements (USA)

1. New preventative control responsibilities	• Food Safety Plans o Companies are expected to conduct a hazard analysis of hazards reasonably likely to occur. This includes microbiological, chemical, and physical hazards and also the new category of exposure to radiation as a hazard. o Controls designed to significantly reduce or prevent those hazards must be put in place. o Implementation of the preventative controls includes monitoring, corrective actions, and verification activities. Verification activities may include environmental and finished product testing. o Update of the program is required every 3 years. o The food safety plan and all related records are available to FDA during inspection. • Supply Chain Management/Supplier QA o You need to know who your suppliers are (not just the distributors) at the production location level and have a plan for assuring adherence to their food safety requirements. o The objective is to assure product that is not adulterated or misbranded (e.g., due to undeclared allergens). • Records Maintenance and Access o FDA will have legal access to see and copy records related to the food safety plan and related documents such as: – Environmental and finished product testing – Corrective actions and related rationale – Supplier QA activities • Food Defense Plans o At time of writing the detailed expectations are still unknown but it is expected that food defense should be included in hazard analysis, including hazards that may be introduced by acts of terrorism.

(continued)

Table 1.2 (continued)

2. New controls over imported food	• Each importer is required to perform risk-based supplier verification of compliance with the hazard analysis and prevention controls requirements. • Third-party certification can be used to assure that the food complies with US requirements. • There is a provision for a Voluntary Qualified Importer Program which will expedite movement of food through the import process.
3. Enhanced enforcement powers likely mean	• More frequent and risk-based FDA inspections. • Mandatory recall authority. • That the FDA can suspend a facility registration when it finds that foods present a reasonable probability of causing a serious adverse health consequence or death.
4. New fees on food companies and importers includes	• Reimbursement to FDA for re-inspections and recalls. • Provision for export certificates. • Imports voluntary program which will expedite imports.

FSMA refers to the development of a "Food Safety Plan" which companies with HACCP, PRPs, a Food Defense program, and a supportive culture will be able to demonstrate.

At the time of writing, regulatory frameworks under the FSMA are only now being developed but there are many other much needed areas (such as laboratory accreditation, traceability, whistle blower protection) that are mentioned in the FSMA. Whilst there is an exemption under FSMA for very small businesses (those who turn over <$500,000 per annum) the FDA does have the ability to withdraw the exemption in the event of a major failure. It would be hoped that the industry implements the regulations as a level playing field recognizing that food safety hazards do not take account the size of the food business operation.

Historically, in Europe, one of the most powerful legal driving forces to entrench HACCP requirements in legislation was the European Community Directive 93/43 EC (1993) on the hygiene of foodstuffs. The Directive, while not using the precise wording of Codex Alimentarius or NACMCF, in Article 3 stated that "*food business operators shall identify any step in their activities critical to ensuring food safety and ensure that adequate safety procedures are identified, implemented, maintained, and reviewed*." In essence the Directive listed the first six principles required to develop the system of HACCP and could be interpreted in virtually the same way as Codex/NACMCF, with the exception of any specific reference to record keeping. The Directive stated that competent authorities shall carry out official controls to ensure that this Directive was being complied with by food businesses; obviously evidence of compliance was required, i.e., records. Where failure to comply resulted in risks to the safety or wholesomeness of foodstuffs, appropriate measures should have been taken which extended to the withdrawal and/or destruction of the foodstuff or to the closure of the business for an appropriate period of time.

The adoption of the 1993 Directive meant that all food businesses throughout Europe were directed to use the HACCP approach in that it enabled them to meet the requirements of the legislation. In the European Union, the legislative position regarding HACCP changed on 1 January 2006 with the introduction of *Regulation (EC) No. 852/2004 on the Hygiene of Foodstuffs*. This EU legislation consolidated and replaced a number of previous pieces of national legislation, including the UK's 1995 *Food Safety (General Food Hygiene) Regulations*.

HACCP requirements of the Regulation 852/2004 are as follows:

Regulation (EC) No. 852/2004 on the Hygiene of Foodstuffs

Article 5

1. *"Food business operators shall put in place, implement, and maintain a permanent procedure or procedures based on the HACCP principles.*
2. *The HACCP principles referred to in paragraph 1 consist of the following:*
   (a) *Identifying any hazards that must be prevented, eliminated, or reduced to acceptable levels.*
   (b) *Identifying the CCPs at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels.*
   (c) *Establishing critical limits at CCPs which separate acceptability from unacceptability for the prevention, elimination, or reduction of identified hazards.*
   (d) *Establishing and implementing effective monitoring procedures at CCPs.*
   (e) *Establishing corrective actions when monitoring indicates that a CCP is not under control.*
   (f) *Establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively.*
   (g) *Establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).*

   When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.
3. *Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing, and distribution of food after primary production and those associated operations listed in Annex I.*
4. *Food business operators shall:*
   (a) *Provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business.*
   (b) *Ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times.*
   (c) *Retain any other documents and records for an appropriate period."*

Annex 11 Chapter XII Training

"Food business operators are to ensure:

1. *That food handlers are supervised and instructed and/or trained in food hygiene matters commensurate with their work activity.*
2. *That those responsible for the development and maintenance of the procedure referred to in Article 5(1) of this Regulation for the operation of relevant guides have received adequate training in the application of HACCP principles.*
3. *Compliance with any requirements of national law concerning training programs for persons working in certain food sectors."*

Annex II also contains General Hygiene Requirements for all Food Business Operators—i.e., the prerequisite programmes requirements.

Essentially, the legislation now requires that all food business operators apply HACCP principles to their operations and have appropriate training to do so. However, the flexibility allowed, especially for small businesses, means that a range of food safety management systems will be acceptable from the implementation of good hygiene practices for small low-risk businesses to the requirement for full Codex HACCP to be applied to large food manufacturing.

Although the Codex HACCP principles are not reproduced word for word, paragraph 2 (a–g) of article 5 has the same general meaning. Some commentators have noted that the legislation requires **identification** of hazards while Codex requires **analysis** of hazards. However, it could be argued that the only way to know which hazards **must** be prevented, eliminated, or reduced to acceptable levels is to analyze them.

It is important to remember that the caveats in respect of HACCP entrenched in Regulation (EC) No 852/2004 also have implications in respect of other interrelated legislation such as Regulation (EC) No 853/2004 which deals specifically with the approval of premises and laying down specific rules for foods of animal origin.

In the UK, the statutory defense of Due Diligence was contained within the Food Safety Act (1990) and despite recent amendments to the Act to take account of European Directives, legislation in the UK still retains this provision and requires that the business operator proves that he took "*all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control*." A defendant using this defense in case of litigation would certainly have a stronger case if it could be proved that HACCP was in place.

Policies and standards, governing the safety and nutritional quality of all food sold in Canada are set by the Canadian Government's Health Canada. These statutes and regulations are maintained by the Department of Justice. The Canadian Food Inspection Agency is responsible for administering and enforcing all Acts pertaining to food production.

The Food Safety Enhancement Program (FSEP) is the Canadian Food Inspection Agency's (CFIA) approach to encourage and support the development, implementation, and maintenance of Hazard Analysis Critical Control Point (HACCP) systems in all federally registered establishments.

FSEP applies to the following groups: meat and poultry, dairy, processed fruit and vegetables, shell eggs, processed eggs, honey, maple, and hatcheries, and is voluntary in all other product sectors.

The CFIA verifies industry compliance with federal acts and regulations through activities that include the registration and inspection of abattoirs and food-processing plants and the testing of products. The CFIA encourages industry to adopt science-based risk management practices to minimize food safety risks. If a food safety emergency does occur, the CFIA, in partnership with Health Canada, provincial agencies and the food industry, operates an emergency response system.

Australia and New Zealand share food safety policy and regulation in many areas. In December 2003, when detailed research into the costs and benefits of HACCP-based food safety programs was completed, the Australia New Zealand Food Regulation Ministerial Council endorsed the *Policy Guidelines on Food Safety Management in Australia: Food Safety Programs* (Ministerial Policy Guidelines). The guidelines identified those food businesses that should be required to have a food safety management program based on the food safety risk they pose. As part of this process of policy development, the following four food industry sectors were identified as being high risk by the Regulators:

- Food service in which potentially hazardous food is served to vulnerable populations—hospitals, schools, nurseries care homes, etc.
- The harvesting, processing, and distribution of raw oysters and other bivalves.
- Catering operations serving food to the general public.
- The production of manufactured and fermented meat.

In determining policy in respect of which businesses should be required to have a HACCP-based food safety management system in place, a series of data was used to examine the costs to businesses of having a food safety management system and the benefit to consumers. Other systems which might have delivered a similar level of food safety were also reviewed as part of this process.

Irrespective of this particular piece of regulatory work aligning HACCP-based food safety management program requirements to risk, all food businesses in some States in Australia are still required to have in place a food safety management system based on HACCP with exceptions only noted for retail businesses selling low-risk pre-packaged food.

It is clear that international legislation continues to move towards making HACCP, or a HACCP approach, a mandatory requirement for the food industry. Key indicators include the legal requirement for use of HACCP in specific sectors of the food industry and the strong recommendation from many governments through directives and food safety reports and surveys.

1.2.3 Government Inspectors and Enforcers

The role of government inspectors is to ensure that legislation is being complied with correctly and to ensure that official controls are carried out in a risk-based,

competent, and consistent manner. In the UK this is the responsibility of the Local Authority Environmental Health Departments, but there are equivalent or similar bodies elsewhere, e.g., the Food Safety Inspectorate Service in the USDA and Health Canada.

The importance of enforcement officer competency in being able to evaluate the suitability and effectiveness of a food businesses HACCP system should never be underestimated and is entrenched in the overarching responsibility both central and local government has for the assurance of safe food. In several countries, enforcement officer HACCP audit competency is imbedded in the legislation associated with the administration of official controls itself, providing a legal framework for HACCP evaluation as part of food law enforcement practice. The way in which food law is enforced will inevitably have an impact on the way in which food businesses approach the legislative requirements for HACCP. Enforcement officers within the UK specifically are required to undertake HACCP training to a level commensurate with their inspection responsibilities and the guidance for this is laid down in The Food Law Code of Practice.

In nations where the implementation of food law enforcement is undertaken by numerous agencies and/or refracted by State and Federal Government infrastructure, the requirement to maintain consistency in enforcement practice becomes increasingly more challenging. Coupled with this are the difficulties inherent in the statutory obligations of many central and local government agencies to ensure that oversight of enforcement approaches and officer competency are independently maintained and reviewed. It is widely acknowledged that a failure by authorities to deliver risk-based, consistent, and competent enforcement to businesses of all sizes results in a fiscal detriment being sustained and the drive to ensure better regulation in the area of food safety in particular is being recognized as critical to economic stability and business growth the world over (Hampton, 2005; Macrory, 2006; Young, 2010).

1.2.4 International Standardization

Improvements in distribution technology have contributed to the increased globalization of food trade. The primary international reference standard for HACCP is published by Codex (2009b). The intent of the Codex Alimentarius Commission (CAC) is to facilitate international trade by providing a documented standard that is based on improved consumer protection and fair trade practices (Hathaway, 1995). The CAC is able to influence food regulation worldwide and utilizes the food safety best practice standards adopted by member governments in drawing up the Codex Alimentarius standards.

Since the early days in Pillsbury, HACCP principles have become accepted internationally, and the common understanding has been assisted by the publication of the seven HACCP principles within the CAC documents first published in 1993. From these documents, many manufacturing companies, food standards and

schemes, committees, consultancy groups and food research associations, large and small, have taken a lead. This has steered the way towards harmonization in HACCP worldwide and has been helpful with respect to international trade. As a result of the completion of the General Agreement on Tariffs and Trades (GATT) Uruguay Round and the establishment of the World Trade Organization (WTO) in January 1995, mutual agreement of the standards of each trading partner's country and/or the equivalence of food safety systems must occur before trade can proceed. Use of the Codex HACCP principles as the international standard means that the HACCP system implemented by one company is based on the same principles as those installed by its competitors, suppliers, and customers, wherever in the world they happen to be based. What remains then is the detailed interpretation of the principles which, to date, the CAC has not taken on as a role.

More recently, the International Organization for Standardization developed and published a certification standard for HACCP, ISO 22000 (2005). The standard is based on Codex (2009) and enables companies to have their systems certified to the standard by independent assessors. Probably the main difference between ISO 22000 and Codex is the inclusion of the management elements of the system. In summary it includes:

Food safety management system: requires the control of documents and records.

Management responsibility: requires evidence of management commitment, a Food safety policy, food safety management system planning, defined responsibility and authority (for food safety), an appointed food safety leader, established external and internal communication arrangements for food safety. Also includes Emergency preparedness and response (that the organization has established, implemented, and maintained procedures to manage food safety related events), and "Management review" ensuring that senior management use appropriate inputs (e.g., audits, verification activities, external events) to periodically review the food safety system with a view to continuous improvement.

Resource management: ensuring that suitable resources are provided for food safety—including trained and educated personnel, infrastructure, and operating environment.

Planning and realization of safe products—this includes PRPs, all the HACCP preliminary steps (see Chap. 6), the requirements of the (Codex, 2009) HACCP principles with the exception of validation and verification, and traceability.

Validation, verification, and improvement of the food safety management system—this is a set of requirements that we have covered in Chap. 7.

Because HACCP is a recognized, effective method, it will give you, your regulatory partners and your customers confidence in the safety of your operation and will indicate that you are a professional company that takes its responsibilities seriously.

1.2.5 Media Issues and Brand Protection

Most companies are aware of the power of the media but perhaps feel complacent when it comes to their own businesses, thinking "it will never happen to us," "we are in control", etc. Food safety scares have become big business; the media are always looking for a good story and consumers feel encouraged to go to the press, lured by the thought of cash rewards and a moment of fame.

Increasingly companies have to guard against stories being spread through social media such as Twitter™, Facebook™, and YouTube™ where it is hard to control any damage to the reputation. Some companies have been targeted by undercover journalists posing as workers in food plants. This has resulted in schemes such as "whistle blower" hotlines where workers and consumers can call anonymously to report any misdeeds that they have seen and are uncomfortable with. The details of several recent high profile events in a number of countries have emerged as a result of employees being willing to act as "whistle blowers," including the peanut ingredients example described earlier.

Sometimes the issues may be very real, but not always. If a consumer goes to the press you will need to have evidence in order to dispute any claims made against you. This is particularly important if the consumer has falsified claims and the police are drawn into the case. Fully documented evidence, through HACCP records which have been efficiently maintained, is essential. Further product testing may also be needed, e.g., to establish whether a foreign object has entered a product before or after cooking.

Someone within the company who is trained in media handling plus an effective incident management system could be vital in ensuring that the company remains in business and the risk to the public is minimized in the event of an incident occurring.

1.3 Problems with Effective Implementation of HACCP: Why HACCP Fails

HACCP has been publically available as a technique for more than 40 years and was in use within Pillsbury and NASA for 10 years before that (Wallace et al., 2011). Given the number of foodborne illnesses that are still reported, is it not working as well as initially expected? The problem is not with HACCP but with how it has been misused and abused. If HACCP is not properly and fully applied, implemented, and maintained, then it will not result in an effective control system. This may be due to improperly trained or untrained personnel not understanding the principles correctly; it may be that the outcome of the HACCP study is not implemented within the workplace; or it may be that the implemented system fails through lack of maintenance, i.e., if a company implements a system and stops there, paying little or no heed to changes that occur in the operation, then new hazards may be missed. The effectiveness may also be lost if the company carries out the hazard analysis and then tries to make its findings fit with existing controls.

As we will discuss, HACCP is compatible with existing quality management systems but you must ensure that product safety is always given priority and that new HACCP-based recommendations are not ignored because they differ from existing programs. Problems may also arise if HACCP is carried out by only one person, rather than a multidisciplinary team with more comprehensive knowledge of what really happens in the plant. This is also true where it is done at the head office or external consultant level with little or no input from or connection to the processing facility.

Another reason for failure is because the hazard analysis process takes little account of the need for prerequisite hygiene and other support programs.

Let us consider some examples where food safety systems appear to have failed and some reasons for this.

1.3.1 Examples of Food Safety Incidents

When something goes wrong with a food product there may be localized or widespread illness and suffering, and alongside the effect on consumers, the cost to the company concerned can be huge. Even when no illness has been caused, the discovery of safety hazards in a product intended for consumption can lead to prosecution and damage the reputation of the company. Microbiological hazards generally have the potential to cause the greatest impact on consumer safety though more recently there have been a number of significant chemical hazard events—melamine in infant formula in China being just one example. However, frequent product withdrawals and prosecutions often result from failure to adequately declare allergens on packaging or foreign material being discovered in food. Table 1.3 compares a number of food safety incidents that have occurred worldwide. The true costs associated with such incidents are seldom documented, but where they have been established they can be shown to be substantial both to the industry and to society. For example, in the case of the *Salmonella* Napoli outbreak in chocolate, the quoted costs relate solely to the health care costs and do not include the costs associated with withdrawing 2.5 million chocolate bars from the market nor the cost in terms of reputation damage.

In the USA the latest estimates (CDC, 2011) are that one in six Americans are affected by foodborne illness each year. This is based on 48 million cases of illness, over 127,000 hospitalizations and over 3,000 deaths annually. The economic burden of this is in the $billions. It is significant that the incidents listed in Table 1.3 involved both large and small companies and crossed international boundaries. Many of the companies involved received enormous publicity for the wrong reasons and not all are still in business. No company can afford to be a statistic in someone else's table. It is also noteworthy that many of the incidents included here enable other companies to learn from the failure, yet there are numerous examples of the same mistakes being made by other companies. This may be because the real findings from incident investigations are seldom published in the public domain.

Table 1.3 Examples of failure—past and present

Past incidents			More recent incidents			
When	Where	What	When	Where	What	Discussion
1982	UK/Italy	Salmonella Napoli (low numbers) in chocolate. Cross-contamination. 245 people ill. $750,000 cost. (Shapton, 1989)	2006	UK	Salmonella Montevideo in chocolate. Cross-contamination through poor GMP (roof leaks). 60 people ill. $40 Million (Hingley et al. 2009)	These are both cases which involved post-process cross-contamination. There are a number of other cases of Salmonella in chocolate and often associated with poor environmental conditions. Kill step is at roasting of beans for Salmonella in cocoa and with no kill step during the chocolate process, the ingredients have to be sourced from reputable suppliers and GMPs in the plant need to be appropriate for high risk food products. Very low numbers are often found to be the cause of outbreaks associated with chocolate or other high fat products suggesting that the mere presence of the organism is a concern.
1985	UK	Salmonella Ealing in infant's dried milk. Cross-contamination due to defective spray dryer. *S. ealing* isolated from	2009	USA	Potential Salmonella in dried milk powder for industrial sale. The company voluntarily recalled instant nonfat dried milk, whey	Dried milk powders are often used as ingredients in products which receive no subsequent kill step so they are highly sensitive.

		scrapings taken from a silo into which waste powder and sweepings were stored. 76 people ill; 1 death. $$Millions. (Shapton, 1989)			protein, fruit stabilizers, and gums (thickening agents) that it had manufactured over a 2-year period, because they might be contaminated with Salmonella. No illnesses reported. (Gieraltowski et al. 2012) Cost unknown but significant given the number of recalls.	Salmonella was isolated in a dairy shake product and then traced it back the plant. The regulatory inspection resulted in an expanded recall due to conditions observed.
1998	UK	Salmonella Enteriditis in shell eggs (Statement by Government Minister). Poor farm practices. 60 % reduction in egg sales. Cost > $Millions. (North and Gorman, 1998)	2010	USA	Salmonella Enteriditis in shell eggs. Poor farm practices. 1,939 illnesses. Cost unknown. (CDC Web site)	This led to the development of Lionbrand eggs in the UK and vaccination of young birds. This was not done on a global basis through best practice producers did follow the approach.
2007	USA	Salmonella Tennessee in peanut butter. Route cause said to be due to cross-contamination. Congressional Research Service (2010)	2009	USA	Salmonella Typhimurium in peanut butter. Cross-contamination. Over 650 people ill; 9 deaths. Company bankrupt. 350 other companies impacted, cost to one major manufacturer was $75 million. (Powell et al., 2010)	These two plants are situated just 80 miles from each other yet Peanut Corporation of America (PCA), the 2009 plant involved took no action based on earlier events.

(continued)

Table 1.3 (continued)

Past incidents			More recent incidents			
When	Where	What	When	Where	What	Discussion
1989	UK	*Clostridium botulinum* toxin in hazelnut yogurt. Thermal process inadequate for reduced sugar recipe—design failure. 27 people ill; 1 death. (Shapton, 1989)	2006	USA	*Clostridium botulinum* toxin in carrot juice. Inadequate pH control—design failure. 4 people ill. (Kaye, 2006)	Both of these cases illustrate the need for safe product design and design review systems.
1998	USA	Salmonella Agona in breakfast cereal. Environmental cross-contamination. 400 cases (ill). (Breuer, 1999)	2008		Salmonella Agona in breakfast cereal. Same plant as in 1998. Environmental cross-contamination. (Powell et al., 2011)	This was the same company and they had taken significant measures to prevent a reoccurrence. However, various operational events combined and a second event occurred but with no illnesses. The example is interesting however because it shows that more than 10 years ago, Salmonella shows up in dried foods as a hazard. Yet when standard developers defined a "high risk food" it was nearly always short shelf life and temperature controlled. This is very slowly changing but only as a result of numerous outbreaks in the low water activity shelf stable foods category.

1999–2000	France	Listeria in rillettes (a pate-like product) and pork tongue—two outbreaks (de Valk et al., 2001)	2008	Canada	*Listeria monocytogenes* in Maple Leaf Foods cooked, sliced delicatessen meats. Sanitary design failure on meat slicing equipment. (Powell et al., 2011)	Sanitary design was a root cause of the Canadian event. The company has since become a champion for food safety and freely shares its learnings.
2005	USA	July 1, 2005—Cold Stone Creamery together with the FDA notified the public that products containing "cake batter" ice cream sold at Cold Stone Creamery stores may be associated with outbreaks of Salmonella Typhimurium infection in four states. As a precautionary measure, Cold Stone Creamery was quick to respond and voluntarily removed all cake batter products from all of its stores throughout the country. Cake Batter's possible contamination with this organism came to light after outbreaks of infection with this form of Salmonella were reported in Minnesota, Washington state, Oregon and Ohio. (FDA, 2005)	2009	USA	Nestlé. Cookie Dough U.S. Food and Drug Administration announced that it had found *E. coli* O157:H7 in a sample of pre-packaged Nestlé Toll House refrigerated cookie dough. Whilst the manufacturer undertook a recall, the warning was based on an epidemiological study conducted by the CDC and several state and local health departments. Subsequent tests determined the genetic fingerprint of the *E. coli* O157:H7 found in the FDA sample was different than *E. coli* O157:H7 linked to the outbreak strain in patients. Over 70 people from 30 plus states were infected with the outbreak strain. (FDA, 2009)	These are interesting as cookie dough and cake batter are not designed to be eaten raw but it is a known consumer behavior and therefore the HACCP study would need to account for that. An ingredient of cookie dough is flour—a minimally processed agricultural commodity. However this was never confirmed as root cause despite numerous tests.

(continued)

Table 1.3 (continued)

Past incidents			More recent incidents			
When	Where	What	When	Where	What	Discussion
1996/1997	UK	*E. coli* 0157:H7 in cooked meat products from a small butchers shop in Scotland. Inadequate heat process and/or cross-contamination suspected. 20 deaths. (The Pennington Group, 1997)	2005	UK	157 people, primarily children became ill in an outbreak caused by *E. coli* O157:H7 in cooked meats. 31 people were hospitalized and 1 child died. The meats were supplied to schools by John Tudor. A packaging machine on the premises used for both raw and cooked meats was identified as the probably source of the contamination. In addition however the lack of a food safety culture was reported as significant. (Powell et al., 2011)	See Case studies in Appendix
2008	USA	Salmonella St. Paul in fresh jalepeno peppers. May have been cross-contamination on farm. 1,442 ill, 286 hospitalized, and 2 deaths.	2011	Germany	Sprouted seeds in Germany and other European countries contaminated with *E. coli* O104:H4. More than 4,000 illnesses and 40 deaths. (Giordano, 2011)	Many instances of contaminated ready to eat produce—too many to list here but clearly a problem that industry has to address. Cross-contamination on farm either through poor irrigation practices or from animals are common themes.

						In the jalapeno peppers case the source was originally thought to be tomatoes. In the German case, there was also confusion during the initial investigation Blame veered from Spanish cucumbers back to German sprouts and eventually to Egyptian fenugreek seed. Investigators were criticized for their handling of the investigation which may have resulted in the case being more widespread than necessary.
1993	Germany	Salmonella (90 serotypes isolated) in paprika powder mix used on potato chips. 1,000 cases of illness. Cost unknown. (Lehmacher et al., 1995)	2010	USA	Salmonella isolated in Crushed red pepper sold as an ingredient to the industry. No confirmed illnesses. Cost unknown but multiple recalls so likely significant. (Gieraltowski et al. 2012)	In the case of the paprika low numbers were involved.
2006	Worldwide	Sudan red in spices. Economic adulteration. No deaths but widespread recalls. $100 millions. (Davies et al., 2006)	2008	China/ worldwide	Melamine contamination of dried milk. Estimated 54,000 sick children, 13,000 hospitalized, and 4 deaths. $100 millions. (Congressional Research Service, 2008)	Economic adulteration has occurred since records began—in fact watered down beer in the UK resulted in some of the first food-related legislation. (Scarce and high price) High value items are most vulnerable. This can be built into your raw material risk assessment.

In looking at these examples and many others not listed here it is clear that cross-contamination or re-contamination following processing is a frequent cause of failure. We'll focus on this in Chap. 4 but the primary sources and vectors of contamination can be categorized as contaminated raw materials, airborne contamination, pests, food-processing environment (ILSI, 2005)—all managed by PRPs.

Currently there appears to be a move towards a more open sharing of information which will be helpful. This supports the fact that food safety should not be seen as a competitive advantage and it is in all our interests to do better.

1.3.2 Failure to Understand HACCP: Common Misconceptions

This section is adapted and abridged from Wallace et al. (2011) **and Motarjemi and Käferstein** (1999)**.**

HACCP is a tool that was designed to help, not hinder, food safety management yet many years after it was developed many misconceptions remain. Here are a few of the most commonly heard:

"HACCP has been "done" already"

Mostly larger, more mature companies hold this view along with regulators who assume that the larger companies are in great shape. This is a BIG MISTAKE.

"Having a HACCP plan = HACCP"

The HACCP plan is just the document and that is all. Having a HACCP system is much more—it is about the way the company thinks and works 24/7 to analyze hazards and continually implement preventative controls. The document just captures those activities and thought processes.

"HACCP costs too much"

Try not having a system! Cost of failure is well documented as being significantly more than the investment in prevention. Putting in a food safety management system where there is no system actually saves money.

"HACCP is complicated and requires a huge amount of paperwork"

Usually this is because the system is unfocused. HACCP can help you to identify and document only what matters in terms of food safety.

"HACCP requires too many resources"

It requires the "right" resources. This is a concern of both large and small companies. It does take time during the startup and implementation phase but that reduces once up and running.

"HACCP by itself will control food safety"

Not at all. HACCP is at the center in the way that risk-based program requires hazard analysis and risk evaluation skills but many prerequisite and management support activities are needed—more than that—are essential as can be seen by the examples of failure (Table 1.3).

"HACCP is a one-time activity"

This fallacy is common in practice. Whilst HACCP training will explain that HACCP systems need to be updated, many plans are out of date because updating is seen as a once a year activity at best and is often done much less frequently.

"HACCP is not suitable for small companies"

Ask the consumer whether this should be true! Food must be safe whoever produces it and the HACCP mindset will add value to any food processor, large or small.

"Zero risk is possible"

If only that were true, life in the food industry would be so much easier. Zero risk is unattainable but that doesn't mean we shouldn't have that as the ultimate goal. HACCP and robust PRPs are the surest way of getting close.

"Farm to table HACCP is not possible"

There is some debate around this. Definitive control measures are not always possible either on the farm or at the consumer table. However, the process of undertaking a Hazard Analysis is very helpful and with scientific advances the control measures available will continue to develop.

"HACCP will slow down our product development process—we don't have time for that"

This is why it is important to build HACCP into the product development activities such that it isn't an "add on" activity once the product is presented in the final stages. Having to go back to the bench and start again at the request of the HACCP team will definitely add to the timeline.

1.4 Key Points Summary

- HACCP can be used by everyone and is an excellent tool for reducing food safety risk. Many companies have not taken full advantage of this.
- The HACCP process itself is fairly logical and it is the hazard analysis step that can be the most difficult to get right without the proper expertise, i.e., knowledge of hazards and control measures. Determining critical limits can also cause problems, but the application of HACCP techniques outlined within the remainder of this book can be interpreted for all sectors of the food industry.
- PRPs are **essential** alongside HACCP for prevention of cross-contamination from the environment or people. Just how essential needs to be determined through a hazard analysis and risk evaluation but typically, PRPs after any pathogen reduction step or in any high risk ready to consume product environment will be critical for food safety assurance.
- Food safety programs (HACCP and PRPs) require ongoing management commitment if they are to be sustainable and effective. This includes provision of resources and application of all the normal management practices that will provide an essential operating framework.
- There are many external pressures for using HACCP but none more important than the real desire to keep consumers safe. Regulatory requirements, media

interest, brand protection, and customer requirements are all external drivers for its use.

- There are many examples of failure to learn from—some where we could have prevented the events and some that pose more challenge, requiring research and collaboration.