Chapter 2
Preparation and Planning to Achieve Effective Food Safety Management

When the decision is taken to use HACCP within a company, there is often the inclination to charge ahead and start doing something without taking the time to consider the best approach for **your** company. It is important to have sufficient knowledge before getting started, i.e., to understand both the theory of HACCP and the practicalities of implementation. Therefore, if you are new to HACCP, you will want to read the remaining chapters of this book to gain an understanding of the entire process before planning your approach and preparing to get started. This chapter outlines the key stages in the HACCP process and considers both how to establish the current food safety status of the operation and plan the HACCP project.

The first thing you need to consider is where you are now and where you'd like to get to in terms of food safety management. In this chapter we will look at how to prepare and plan the application and implementation of the HACCP principles recognizing that for most companies this will be a revision or enhancement to an existing program. We'll include guidance on how to prepare, how to plan the project, how to evaluate and build effective support systems, and how to identify and train the people required in establishing and managing an effective system.

The way to implement the HACCP principles may at first seem obvious, particularly after an initial training course; but you should take time to consider the various alternatives in terms of the structure of the HACCP system and what your overall food safety program will look like. A degree of forethought at this stage will be beneficial later on, not least because it will give other people within the organization the chance to visualize what you are about to do and allow them to make relevant and valuable contributions to the program. This is more likely to result in the implementation of a successful system, which gains commitment for ongoing development and further improvement throughout the business.

S. Mortimore and C. Wallace, *HACCP*, DOI 10.1007/978-1-4614-5028-3_2,

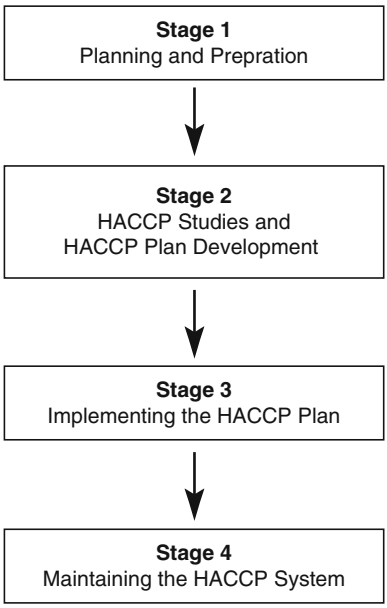

Fig. 2.1 The key stages of HACCP

2.1 The Key Stages of HACCP

Any company that is new to the HACCP techniques will go through four key stages to obtain an effective system (Fig. 2.1). This approach can also be used when updating the system.

In this chapter we will be discussing key stage one—Planning and Preparation (Fig. 2.2). This is where the foundations are laid and it is important to take time here to:

- Ensure that the appropriate people are identified and trained.
- Establish what support systems are already in place and what needs to be developed.
- Consider the most appropriate structure for **your** HACCP system.
- Plan the entire project, including a realistic timetable for development and implementation of the HACCP plan.

The first thing to do is to consider what you are trying to achieve. The path you take to a fully implemented HACCP system will then depend on where you are starting from and the maturity of your existing systems.

Another way to consider this is by way of Deming's Plan, Do, Check, Act (PDCA) cycle (Deming, 1993) where:

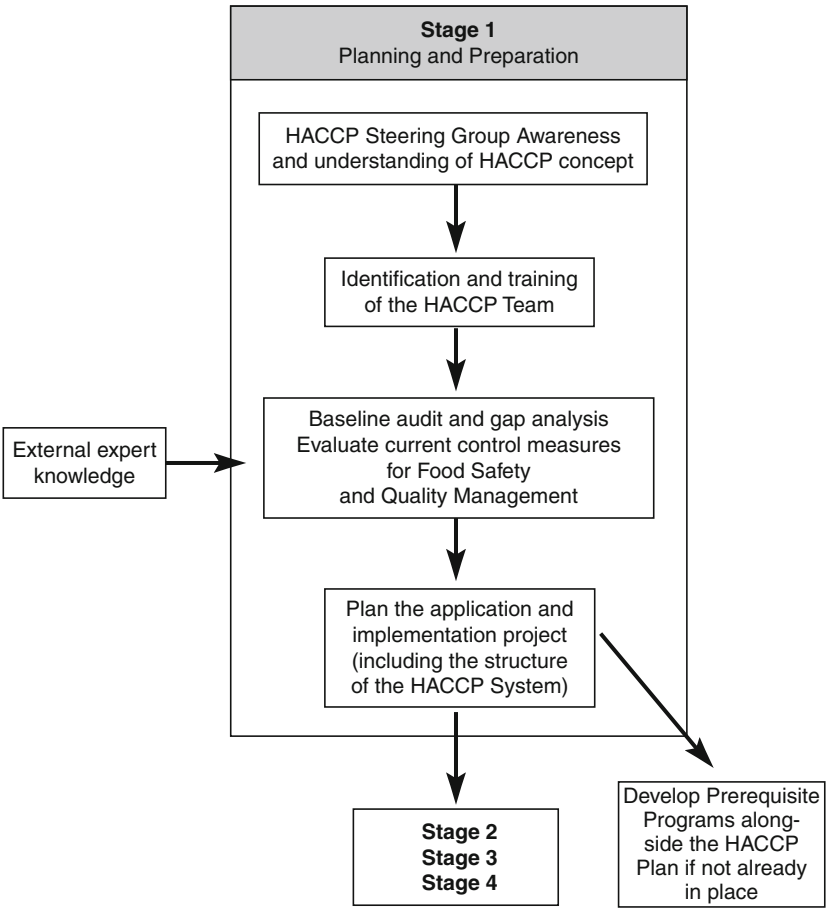

Fig. 2.2 HACCP Key stage one—planning and preparation

Key Stage 1 = The **Planning** stage (for HACCP and PRP requirements)
Key Stage 2 = The **Doing** Stage (both for HACCP program development and PRP upgrades)
Key Stage 3 = **Checking** that the HACCP plan is valid before implementation
Key Stage 4 = **Act** (24/7) to monitor and maintain the HACCP, PRP, and overall Food safety program

The PDCA cycle will be familiar if you have used the terminology already within your company. Choose a project framework that you are familiar and comfortable with using.

Although this chapter is focusing on the first key stage of planning and preparation (Fig. 2.2), for those who are learning the HACCP techniques it is easier to start with the HACCP theory and then go back and start planning the application of it. It is therefore recommended that those who are new to HACCP spend some time

reading the rest of the book before starting to plan their approach. However, it is also important to understand the resource implications of using HACCP so we will start by considering personnel involvement.

2.2 Preparing the Way: Personnel and Training

2.2.1 Personnel Resources

As we said at the start of this book, HACCP is a people-based system. As a tool, HACCP is used by people and if the people are not properly educated, experienced, and trained then the resulting HACCP system is likely to be ineffective and unsound. In this section we will discuss the people who need to be involved and assess their training requirements. Also we will help you to identify the right experts for your company.

(a) Senior management commitment

Early involvement of senior management is fundamental to the effective implementation of HACCP. Real commitment can only be achieved if there is complete understanding of what it takes to develop and maintain a food safety program and how HACCP fits into this. Senior managers do need a basic understanding of the most likely food safety hazards and ways to control them. This will include an understanding of what HACCP actually is, what benefits it can offer to the company, what is really involved, and what resources will be required. This understanding will be achieved not only by reading books such as this one (Chap. 1 contains much of the information they need) but also by attending a food safety and HACCP briefing and discussion session, as a senior management group. This may be undertaken by a reliable consultant if there is no one able to do it internally. Open discussion should be encouraged, with the end result that the decision to enhance the program is given full support by all members of the management team. This will be important in cascading commitment to everyone in the company.

Senior management from all disciplines must be encouraged to actively demonstrate their commitment and be unanimous in their support for the approach. It would be a pity if credibility was lost, for example, through the Sales Director continuing to make rash promises to the customer: "Yes, we can develop and produce this completely untried and untested high-risk product for you within 3 days, no problem," or through the Engineering Manager purchasing equipment that may be unable to achieve the process criteria needed to make a safe product or be cleaned properly due to unsanitary design.

Identification of a HACCP or broader food safety steering group followed by in depth education and training will provide a valuable and visible support to the

implementation of HACCP. Functional Senior Managers plus the HACCP team leader are vital to form this group.

(b) The HACCP team

It is important that HACCP is not carried out by one person alone but is the result of a multidisciplinary team effort—the HACCP team. The second preparatory activity, therefore, is to identify and train the HACCP team. It is recommended that as a minimum the core HACCP team consists of experts ("expert" meaning having knowledge and experience) from the following areas:

1. **Quality Assurance/Technical**—providing expertise in microbiological, chemical, and physical hazards, an understanding of risk and hazard significance assessment, and knowledge of measures that can be taken to control the hazards.
2. **Operations or Production**—has responsibility for and has detailed knowledge of the day-to-day operational activities required in order to produce the product.
3. **Engineering**—able to provide a working knowledge of process equipment and environment with respect to hygienic design and process capability.
4. **Additional expertise**—may be provided both from within the company and from external consultancies. The following areas should be considered:

    - Supplier Quality Assurance—essential in providing details of supplier activities and in assessment of hazard and risk associated with raw materials. The person responsible for auditing and approving suppliers will have a broad knowledge of best practices gained through observing a wide range of manufacturing operations. They will also need to know how the raw materials are used in your company.
    - Research and Development—if the company is one where new products and process development is a continuous activity, then input from this area will be essential. Early involvement and sharing of information at the product/process concept stage could prove invaluable.
    - Distribution/Logistics—for expert knowledge of storage and handling throughout the distribution chain. This is particularly important if distribution conditions, e.g., strict temperature control, are essential to product safety or if bulk shipments are made.
    - Procurement—participation of purchasing personnel will mean that they are made fully aware of the risks associated with particular products or raw materials and can assist with communication of any proposed change in suppliers. They will also be a partner for communication of your specifications and expectations.
    - Microbiologist—if the company has its own microbiologists, then their expert knowledge is absolutely needed on the HACCP team. Many smaller companies do not have this option and, where microbiological hazards require consideration, they should identify a source of expert help from outside, i.e., a food research association, a university, a reputable consultancy, or analytical laboratory.

- Toxicologist—in all but the larger companies, this knowledge is likely to be located in a consulting analytical laboratory or university. A toxicologist may be needed particularly for knowledge of chemical hazards and methods for monitoring and control.
- Statistical process control (SPC)—there are many classes available which will be sufficient to give members of the HACCP team or their colleagues enough knowledge to carry out basic SPC studies on their process operations. This will be important in assessing whether a process is capable of consistently achieving the control parameters necessary to control safety. In some instances, however, it may be advisable to have an external expert join the HACCP team as a temporarily co-opted member. This would be useful when setting up sampling plans or for a more detailed assessment of process control data.
- HACCP experts—it may be appropriate initially to co-opt an external HACCP specialist onto the HACCP team. This may be useful in helping the company team to keep on the right track and become familiar with the HACCP approach. It could also be extremely important in helping the company to determine whether they have got the right expertise on the team and as an early assessment of whether the initial HACCP studies are correct. Ultimately, the right thing to do is to develop internal expertise but an independent review is often extremely helpful when upgrading the system. Those who have worked with it for a long time are often too close or too vested in it to see the opportunities for improvement.
- Other—facilitation skills are extremely useful and often can be found within Human Resource or training departments if available. Also, needed is a scribe or notetaker who can capture the discussions and prepare all the documents during and in between meetings.

If the company does not already use team working, it may be difficult initially for individuals to adjust to this approach. It should be emphasized that as a team effort the HACCP study will have input from a much greater diversity of knowledge, skills, and experience, far beyond that of any one individual. The team is made up of people with a real working knowledge of what happens in each area and therefore any processes that cross over departments can be tackled more accurately. You should also consider that HACCP studies may well result in recommendations for changes to processes and products and capital expenditure. These recommendations are far more likely to be accepted by senior management if they are supported by knowledgeable people across all disciplines within the company.

We have now considered the disciplines required within the team and, in summary, it should be emphasized that expert judgment is essential in assessment of hazards and risks. What else is important with respect to the type of people involved in the team? Personal attributes will include:

1. Being able to evaluate data in a logical manner using expertise within the team and perhaps using published data for comparison.
2. Being able to analyze problems effectively and solve them permanently, treating the root cause not the symptom of the problem.
3. Being creative by looking outside the team, the company, and the country for information and ideas.
4. Being able to get things done and make recommendations happen.
5. Communication skills. The HACCP team will need to be able to communicate effectively both internally within the team and externally, across all levels of the company.
6. Leadership abilities. Leadership skills of some degree will be useful in all members of the team. After all, they are leading the company in its HACCP approach to food safety management. It is recommended that one member of the team is appointed to HACCP team leader. This is often the QA Manager but consider carefully what the leadership of a team entails. Your Personnel or Human Resources department may be helpful in identifying suitable courses for development of these skills if they are not already sufficient.

The HACCP team leader will have a key role in the success of the HACCP system and he or she is likely to become the company HACCP expert and be regarded as such. In the leadership role the team leader will be responsible for ensuring that:

- The team members have sufficient breadth of knowledge and expertise.
- Their individual skills and attributes are taken into account.
- Individual training and development needs are recognized.
- The team and work tasks are organized adequately.
- Time is made available for reviewing progress on an ongoing basis.
- All skills, resources, knowledge, and information needed for the HACCP system are available either from within the company or through identifying useful external contacts.

The behavior within the team must be supportive, encouraging all members to participate. With all team members fully committed to producing and maintaining an effective HACCP system there should be no time for arguments or internal politics.

Within the HACCP team itself, consider the range of disciplines required. In smaller companies the same person may be responsible for both Quality Assurance (QA) and Operations. In terms of ideal team size, four to six people is a good range. This is small enough for communication not to be a problem but large enough to be able to designate specific tasks.

In large organizations there may be more than one HACCP team. It was stressed earlier that the members of the team must have a good working knowledge of what actually happens in practice. In large companies the “experts” and senior people in

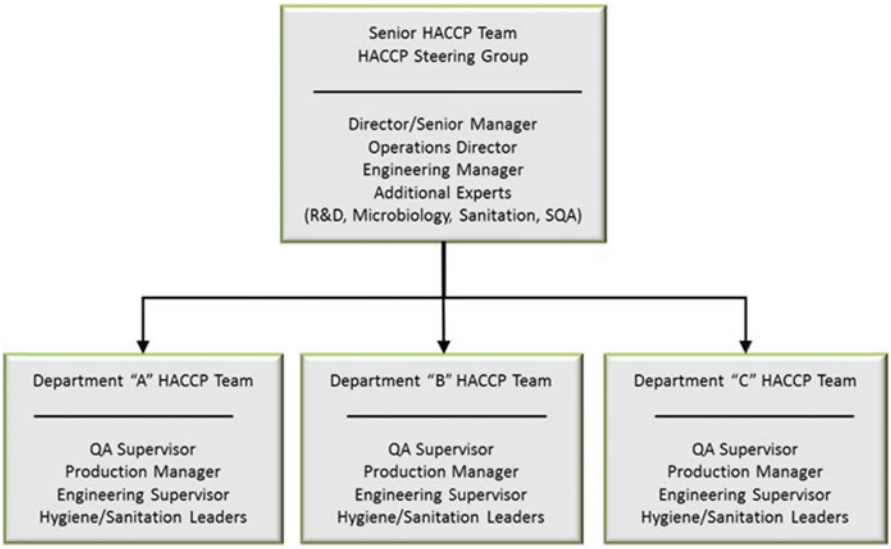

Fig. 2.3 Example of HACCP team structure in a large organization

the three main disciplines of QA, Production, and Engineering may not be close enough to the operation. It may then be more effective to have a series of smaller departmental teams, still made up of the three main disciplines but at a less senior level. The departmental teams then carry out the HACCP study for their own areas and, when satisfied with the resulting HACCP plan, pass it up to a more senior level HACCP team for approval. This ensures that the true working knowledge of activities is captured and subsequently reviewed by appropriate experts in each area. This approach is also common when HACCP is applied to the process in modular form (see Sect. 2.5.1). An example of this could be represented diagrammatically, as in Fig. 2.3.

(c) Additional personnel

In addition to the HACCP team(s) and senior management, personnel throughout the operation will need to be involved. This will include line supervisors, operators, incoming raw materials inspectors, cooks, and point of sale personnel. It is likely that these people will be involved later on, when HACCP moves into the implementation phase. It is important that they, too, are fully briefed on their role within the system, particularly if they are monitors of the controls critical to food safety.

The numbers of people needed in addition to the HACCP team will be dependent upon the type of operation and number of controls that need to be monitored. There should always be a sufficient number of people to ensure that the critical points are monitored effectively and that records are reviewed.

2.2.2 What Are the Training Requirements?

HACCP is only going to be effective as a means of managing food safety if the people responsible for it are competent. As a result, training and education becomes the single most important element in setting up a successful HACCP system. It not only provides the technical skills required in implementing HACCP, it also helps in changing attitudes of people where required. This cannot be stressed enough. Codex comments that the efficacy of any HACCP system relies on management and employees having appropriate HACCP knowledge and therefore, ongoing training is necessary for all levels of employees and managers and that this is an "essential element for the effective implementation of HACCP" (Codex, 2009b). ISO22000, *Food safety management systems—Requirements for any organization in the food chain*, states that the organization "shall identify the necessary competencies for personnel whose activities have an impact on food safety" (ISO 2005) and also requires that training be carried out to ensure that the competencies are met. Whilst this illustrates that training is clearly identified at the international level as being crucial to successful HACCP, there is no international standardization of HACCP training requirements. We believe that there is as much a need for international HACCP training standards as there is for international audit standards. Currently there is much variance in the levels and quality of training provided. A few countries, notably the UK, have oversight and core curricula for HACCP training, at least at some levels, but most countries do not.

In this section we will explore the training requirements for HACCP teams. In our experience, a number of key competencies are required of HACCP teams and a balance of these attributes throughout the team is necessary.

The training of these people is an investment and should be taken seriously. You should realize that the HACCP team members may need to be provided with many additional support skills in addition to the HACCP principle application knowledge such as project planning, SPC, audit skills, team working, communication, and influencing.

Table 2.1 outlines a HACCP training program which would usually be required for the various groups of people in the company. When choosing a course/class, it is vital to check that it covers all the required theoretical elements and includes practical, "hands-on" experience. If you have a strong internal training team, you may wish to use this book and other resources to develop your own training material, or use appropriate external HACCP courses or programs related to ISO 22000 (2005).

The HACCP team leader will need a more advanced level of HACCP knowledge to other personnel. This may be available through taught courses, but more likely it will be gained through an experiential approach, i.e., working with an experienced mentor on the application of the HACCP principles, perhaps within your own factory. More experience also comes through teaching the concept to others or being able to participate in the discussions and answering questions.

Table 2.1 Possible training subject matter and learning outcomes for HACCP by learner group (adapted from Wallace et al. (2011); after Mayes and Mortimore (2001))

Group	Learning outcome
Senior Management	1. Understand the general principles of HACCP and how they relate to the food business. 2. Demonstrate an understanding of the training and knowledge requirements for Food Safety team members and the workforce as a whole. 3. Demonstrate an understanding of the links between HACCP and other quality management techniques and programs and how a combined product management system can be developed. 4. Understand the need to plan the HACCP system and develop a practical timetable for HACCP application in the whole operation.
HACCP/Food Safety Team Leaders	*HACCP system and its management* 1. Demonstrate an up-to-date general knowledge of HACCP. 2. Explain how a HACCP system supports national and international standards, trade, and legislative requirements. Describe the nature of prerequisite programs (PRPs) and their relationship with HACCP. 3. Demonstrate the ability to plan an effective HACCP system. 4. Demonstrate a knowledge of how to lead a Food Safety team. 5. Demonstrate an understanding of the practical application of HACCP principles. 6. Demonstrate the ability to design, implement, and manage appropriate programs for verification and maintenance of HACCP systems. 7. Explain the methods to be used for the effective implementation of HACCP. *Additional topics* 1. Demonstrate an understanding of the nature of hazards and how they are manifested in food products/operations and give relevant examples. 2. Demonstrate an understanding of the intrinsic factors governing the safety of product formulations and methods that can be used to assess safety of new products. 3. Carry out the steps to identify significant hazards relevant to the operation and determine effective control measures, i.e., assessment of risk (likelihood of occurrence and severity). 4. Demonstrate an understanding of the training and knowledge requirements for Food Safety team members and the workforce as a whole. 5. Develop appropriate training programs for CCP monitoring personnel. 6. Demonstrate an understanding of the links between HACCP and other quality management techniques and how a combined product management system can be developed.
HACCP/Food Safety team members	*HACCP system* 1. Justify the need for a HACCP system. 2. Show how the legal obligations on food business proprietors to analyze food hazards and identify critical steps in the business activities should be met in their appropriate industries. 3. List and explain the importance of the principles of HACCP. 4. Describe the method by which hazard analysis may be carried out and appropriate control measures ascertained to assess the practical problems.

(continued)

Table 2.1 (continued)

Group	Learning outcome
	5. Identify critical control points including critical limits to ensure their control. 6. Develop suitable monitoring procedures for critical points and explain the importance of corrective action procedures. 7. Verify the HACCP system by the use of appropriate measures. 8. Carry out the steps to introduce and manage a fully operational HACCP system. *Additional topics* 1. Demonstrate an understanding of the nature of hazards and how they are manifested in food products/operations and give relevant examples. 2. Demonstrate an understanding of the intrinsic factors governing the safety of product formulations and methods that can be used to assess safety of new products. 3. Carry out the steps to identify significant hazards relevant to the operation and determine effective control measures, i.e., assessment of risk (likelihood of occurrence and severity). 4. Develop appropriate training programs for CCP monitoring personnel.
CCP monitors	Understand the general principles of HACCP and how they relate to the food handler's role. Perform CCP monitoring tasks, record results, and initiate appropriate actions.
Auditors of HACCP systems	*HACCP and regulatory Auditing* 1. Provide up-to-date general knowledge of HACCP and its relationship with national and international standards, trade requirements, and legislative requirements. 2. Examine the role of good hygiene practices as a foundation for HACCP-based food safety management systems. 3. Provide a comprehensive revision of the application of HACCP principles for the development of HACCP-based systems for food businesses. 4. Consider the design and management requirements associated with the application and implementation of HACCP-based food safety management systems in food businesses. 5. Enhance the skills required for the assessment of HACCP-based food safety management systems. 6. Consider the tools available to educate food business operators in the principles of HACCP and to provide advice and support during development and implementation of food safety management systems. *Additional topics* 1. Understand the need for audit preparation including the development of suitable checklists. 2. Perform HACCP audits using sampling, questioning, observation, and assessment skills. 3. Construct audit reports giving clear indication of findings and corrective action needed.
General workforce	Understand the general principles of HACCP and how they relate to the food handler's role.

Table 2.2 Suggested sources of additional HACCP team knowledge

Skill/knowledge	Means of providing it
1. Principles and techniques of HACCP	In addition to the training described in Table 2.1, reference books and scientific papers: Mortimore and Wallace (2001); Campden BRI (2009); Wallace et al. (2011)
2. Understanding of the types of hazards that could occur and methods of control. For example, in relation to foodborne pathogens this should include the frequency and extent of their occurrence in different foods; the severity and likelihood of transmitting foodborne pathogens and toxins through different foods; the means of and influence of contamination of all types and elimination or reduction by processing and procedures, i.e., the control measures	With a good mix of disciplines on the team this area should be covered, provided the team members, among them, have both academic backgrounds in microbiology or food science-related subjects and sufficient food industry experience. Useful courses in understanding hazards are provided by many training organizations if a refresher is needed. Use of hazard databases available through universities and NGO's organizations Use of the Internet Use of reference books: ICMSF (1980, 1986, 1996, 2002, 2010)
3. Detailed knowledge of good manufacturing practices	Essential food industry experience as above Reference books: IFST (2007), Shapton and Shapton (1991), ISO/TS 22002-1 2009, and PAS 222 (2011)
4. Team-working skills, including communication skills (especially important if this is a new way of working for most team members)	Personnel department may be able to assist with some in-house team-building training for the HACCP team External team-building courses are available, often lasting about 5 days Reference books: Lencioni (2002)
5. Project planning and management skills (the HACCP implementation project may have a separate Project Manager but, if the HACCP team itself is responsible, this skill will be invaluable)	External courses run by management consultancies or training organizations Use of an on-site consultant in the early stages Reference books: Bird (1992); Brown (1992); Oates (1993)
6. Auditor training—essential for the verification of the flow diagram and HACCP plan	A Quality Management Systems auditor course is recommended (internal auditors level is sufficient, which usually lasts 2 days). These can be run on your own site if numbers justify. Available from ISO 9000 assessment bodies, professional institutes, or training organizations Reference books: Chesworth (1997)
7. Statistic Process Control (a working knowledge in order to make valid process capability assessment and data handling)	External management consultancy groups who often provide training packages Reference books: Rowntree (1981); Price (1984)

(continued)

Table 2.2 (continued)

Skill/knowledge	Means of providing it
8. Problem-solving techniques—in order to tackle recurring problems in a structured way and ensure that permanent solutions are found. Can be very useful in learning how to draw process flow diagrams and in handling data	Training packages can be purchased from management and training consultancy groups Courses are also available through the above. Recommend an on-site session tailored to the need (HACCP) in order for it to be really understood and applied after the event
9. Change management—really important to be able to lead the transition. Here are a couple of books on change management and leadership that we've found to be very insightful	Reference books: Managing Transitions—Bridges and Bridges (2009) Superperformance—Guerra (2005) Strengthfinder—Rath (2007)
10. Trainer training skills—essential if HACCP training is to be carried out in-house	Food industry courses are now being run by many of the food training organizations. Management training consultancies may also be able to provide this type of training. Effective presentation courses may be a good foundation. Liaison with Personnel department recommended. Reference books: Jay (1993) Wick et al. (2006)
11. Documentation techniques for HACCP plans	HACCP Management Software (see listing in References, further reading, and resource material) Word-processing skills training
12. Understanding where others failed	Reference books: Mayes and Mortimore (2001); Wallace et al. (2011); Panisello and Quantick (2001)

Table 2.2 gives details of additional areas where training or knowledge may be required to support HACCP activities and provides suggestions on how these gaps may be filled. It may not be necessary for all HACCP team members to be trained in every area, but it will be helpful to have knowledge within the team.

Records should be kept of all training carried out along with a documented evaluation of its effectiveness. A written test is a measure of what people have learned in the classes but as important is verification of whether they can apply the theory in practice. For HACCP, this is an assessment of the resulting HACCP plan which can be undertaken by a reputable/competent third party—most often, as part of any HACCP audit. All of these activities will also be an assessment of the capabilities of the trainer and the suitability of the training program. As a reminder, it is essential to establish that HACCP trainers have the appropriate knowledge and experience of HACCP plus effective training skills and that the training program covers learning outcomes appropriate to the trainee group (Fig. 2.4).

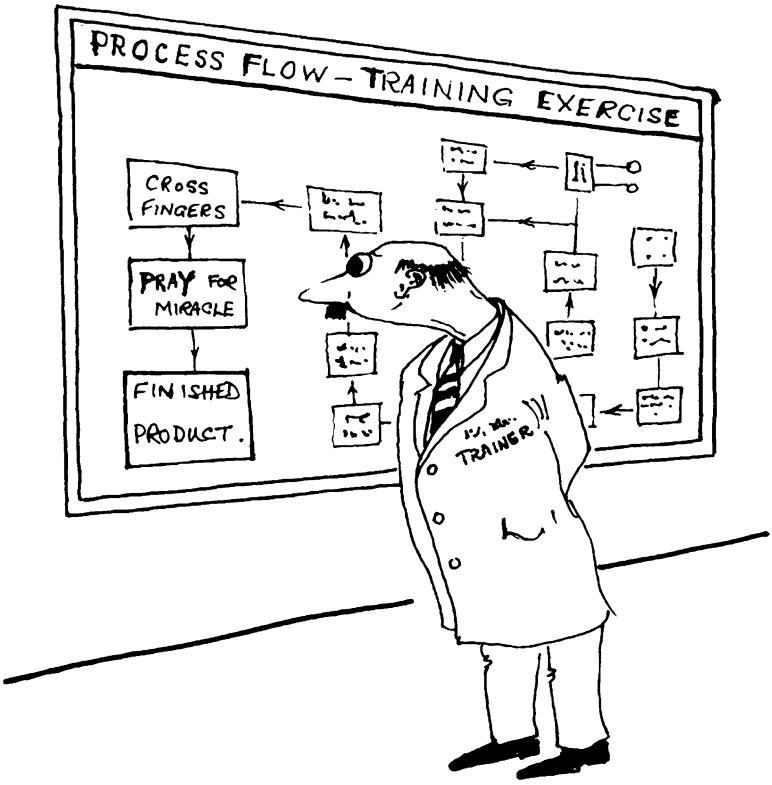

Fig. 2.4 Have you selected a good quality trainer?

2.3 What Is Our Current Status? Baseline Audit and Gap Analysis

It is important to evaluate the resources and systems in place and compare these against the requirements to manage HACCP effectively, before putting together a Project Plan for the HACCP initiative. This will include a review of your facility environment as well as an assessment of the current systems and personnel resources.

In order to plan the pathway to an effective HACCP system and food safety program, it is important to consider two basic questions:

1. What resources and systems (including PRPs) need to be in place for HACCP to work?
2. What resources and systems do I currently have?

The differences between 1 and 2 are the gaps that will need to be filled. A third question (How will I get there?) will be considered in Sect. 2.4. This sounds straight

forward but can be quite a lot of work if an in depth review hasn't taken place for some time.

The most effective way of identifying the gaps is to carry out a baseline audit of current control measures for food safety and quality management, using auditors with expert knowledge (ideally include a reputable independent expert who is external to the company or at least the facility) of the standards and systems required to support HACCP.

2.3.1 Performing the Gap Analysis: Questions to Consider for PRP Assessment

There are a number of questions to consider when assessing the effectiveness of existing systems. As a reference standard for gap analysis you could use, Codex (both the HACCP principles and PRP documents (Codex, 2009a, b)), ISO22000 (for the HACCP and management elements (ISO, 2005)), or one of the Global Food Safety Initiative (GFSI) benchmarked schemes which are HACCP based but are broader and also include the PRPs. Similarly you could use a PRP standard such as ISO/TS 22002-1:2009 *Prerequisite Programmes on Food Safety: Part 1 Manufacturing* (ISO, 2009a); formerly published as PAS 220 (BSI, 2008). Certification bodies for these schemes offer gap assessments but take care to choose a really experienced food safety auditor and acknowledge that a thorough review will likely take at least 3 days, possibly more, depending on the size of your operation. Some companies combine a GFSI gap assessment with an in depth pathogen control assessment and for this they use an experienced food microbiologist with proven field experience as well as food safety and HACCP systems audit skills.

An example of the types of questions that might be considered for the initial gap analysis assessment follows in Table 2.3 but this is very high level and in practice you'll need to expand out with particular focus on environmental and management controls.

If you already have a HACCP program and are planning to upgrade it, the checklist in Chap. 7 (HACCP audit) could also be used. As stated, these checklists are intended to serve as a starting point so you will likely want to add other assessment criteria before use.

Following the gap analysis, the Project Plan can be developed by using standard project planning techniques (Sect. 2.5). Most companies find that in carrying out a detailed gap assessment, improvements in the PRPs are needed. This should also be built into the project plan. As each gap is identified a risk evaluation should be done in order to aid with prioritization of corrective action. In some cases a short-term immediate action may be needed whilst the longer-term (capital) solution is being developed. This is where HACCP skills in terms of hazard analysis can be really helpful in managing food safety risk at a practical level.

Table 2.3 Prerequisite program and management status gap analysis checklist

Prerequisite program area	Questions	Status: in place (Yes/No)	Auditor notes
1. Environment			
(a) Facility design	Are your buildings, grounds, and equipment in good repair?		
	Is process flow logical?		

	Do you have a layout that enables the control of cross-contamination? Consider:
	• Traffic patterns—people, equipment
	• Air and drain flow
	• Personnel hygiene facilities
	  • Captive uniforms and shoes
	  • Hand washing stations
	  • Rest room and cafeteria		

	Do storage and distribution practices present a food safety risk?		
(b) Equipment	Is it of sanitary design? • Suitable for cleaning, maintenance, and preventative maintenance?		
	Is it capable of control as specified in your program?		
	Is there a calibration program?		
(c) Utilities/services	Are utilities such as air, water, energy effectively controlled for food safety?		
	Lighting—is it adequate for inspection and observation of cleaning needs?		
2. Programs			
(a) Supplier quality assurance	*The basic question to be answered is whether you have confidence in the safety of all raw materials used:* Do you have an approved supplier list detailing the source (manufacturing location) of all raw materials?		
	Do you understand the safety criteria governing your raw materials?		
	Does the raw material need to be handled in a specific manner when it arrives at your location (for safety)?		
	Do suppliers provide analytical information and is it valid? • Are any tests carried out and is the lab certified/approved?		

(continued)

Table 2.3 (continued)

Prerequisite program area	Questions	Status: in place (Yes/No)	Auditor notes
	Are approved specifications held for all raw materials? • Has the supplier signed their agreement to comply?		
	Are third-party audits carried out? • Who did them and to what standard?		
	Have all suppliers been audited? (and against which criteria?) • What training and calibration do your internal supplier approval auditors receive? • For the suppliers that were not audited, was a desktop review and approval undertaken?		
(b) Cleaning and disinfection (sanitation)	Are risk-based sanitation schedules in place?		
	Are cleaning procedures are complete including reference to the: • Equipment to be cleaned • Method of cleaning and materials used • Responsibilities for implementation • Validations and verification procedures		
	Are records complete and signed by responsible person?		
(c) Allergen control	Are allergens clearly identified in raw material specifications?		
	Are allergen production scheduling matrices up to date?		
	Have allergen cleans been validated?		
	Is the label verification program adequate?		
(d) Pest control	Is the building adequately proofed and protected against pest ingress or harborage?		
	Do you have a third-party contract with a licensed provider?		
	Is there someone on staff who has expertise and oversight of the program?		
	Are monitoring and corrective action procedures in place?		
	Has there been significant activity in recent or past history? • Was corrective and preventative action been taken in a timely manner?		

(continued)

Table 2.3 (continued)

Prerequisite program area	Questions	Status: in place (Yes/No)	Auditor notes
(e) Good laboratory practice	Does the laboratory (internal/external) operate to a good practice system?		
	Is the system independently accredited for the testing you need?		
	Are controls built into the sample testing procedures?		
	Is analyst performance monitored?		
	Are all laboratory staff routinely trained?		
	Is sampling carried out in a hygienic manner?		
(f) Preventative maintenance	Does a preventative maintenance schedule exist?		
	Does it cover all key equipment for food safety?		
(g) Food defense and bioterrorism	Is the plant secured against unauthorized access?		
	Is a food defense plan in place?		
	Has it been tested?		
(h) Trace, recall, and incident management	Would traceability systems ensure that all of the correct material could be identified and withdrawn/recalled in a timely manner?		
	Have lot traceability recall procedures been tested?		
	Is there a designated Incident Management team?		
	Are personnel trained in incident management and media handling?		
(i) Quality management systems	Is there a senior level supported Quality Policy?		
	Is there a Quality Management System in place?		
	Is it based on an accepted framework, e.g., ISO or a GFSI benchmarked scheme?		
	Is it externally and independently assessed?		
	Does it cover all parts of the operation?		
	Is there a well-established Corrective and Preventative Action (CAPA) program in place?		
(j) Other good practice program references	Should you be benchmarking against other externally recognized reference standards, e.g., for warehousing and distribution?		

(continued)

Table 2.3 (continued)

Prerequisite program area	Questions	Status: in place (Yes/No)	Auditor notes
3. People			
(a) Personal hygiene	Is there a program for restriction of jewelry, finger nail polish, hair, etc?		
	Is there a captive uniform and shoe program?		
	Is there an employee ill health monitoring and reporting program? Does it apply to visitors and contractors?		
	Have the programs been designed around product risk?		
(b) Personal behavior	Are rules in place?		
	Are they clearly communicated?		
(c) Training and education	Are employees trained commensurate with working activities?		
	Is training validated? • Are records in place to confirm this?		
	Is training verified? • Are records in place to confirm this?		
	How are training needs established?		
	Are job descriptions in place which include food safety roles and responsibilities?		
(d) Culture	Is there evidence of noncompliance with stated procedures?		
	Are employees engaged and knowledgeable about their food safety role?		
	Is action taken when irregularities/noncompliances are observed?		
	Does the environment appear to be well cared for?		
	Is there evidence that food safety is supported by functions other than quality?		
	Are adequate resources made available for food safety improvement?		

2.4 Use of the Hazard Analysis and Risk Evaluation Process as an Enabler to GMP Improvement

Sometimes it may feel like an impossible task even with full support and commitment from the senior management team. Don't worry, HACCP is the best place to begin and there is no right or wrong time to start using it. The normal use of HACCP is when PRPs are under control and it is fair to say that this view is widely accepted. A common misconception is that if you don't have any written specifications and procedures, and have very poor GMP and hygiene, then you are in no position to use HACCP. To the authors, it seems only common sense to say—use HACCP (or at least use the Hazard Analysis technique) to help you decide where to begin, i.e., in prioritizing against food safety risk and targeting resource.

So what happens when a plant has poor or limited PRPs? Can they not implement HACCP until everything is in place? Whilst it is most straightforward to work on the prerequisite foundations for HACCP first and then build the HACCP system, if a company has poor/no PRPs, as is often the case in developing markets, then it is important to prioritize the risks. We believe that a basic HACCP study, or at least the use of hazard analysis, can usefully be done as a means of ensuring that the likely hazards are under control. This can even be carried out as a desktop exercise. It will quickly identify which equipment is essential and help with prioritization, for example, in identifying a required metal detector or the need for rapid validation of a thermal process step. Working through the Codex list of hygienic requirements, i.e., the PRPs, can be quite daunting. It cannot all be done at once but, by truly understanding the HACCP concept and, in particular, hazard analysis and risk evaluation, focusing on the product itself, its intrinsic design factors that are making it safe, together with considerations of how to prevent product contamination (microbiological, chemical, and physical), rapid progress can be made in establishing foundational PRPs in a focused way—ensuring from the outset that food safety is not compromised. As an example, a foundational element of the PRP program is having a hygienic operating environment with appropriate hygienically designed equipment, building fabric, air, and traffic flow so as to prevent cross-contamination of the product. This is particularly important post-process and where the product may be vulnerable if contaminated, i.e., there is no further pathogen (or other hazards) control step.

You need to systematically walk the plant, ideally using a process flow diagram if you have one and identify gap areas for improvement together with establishing what the real hazard is that is associated with the gap. Once you have identified the hazard (remember to be as specific as possible) you can determine what the control measure should be, rather than simply recording what your process operation currently uses. Table 2.4 shows how this activity could be organized and used to help guide the organization in terms of short-term risk mitigation and longer-term capital spending. There is a column to indicate whether the control measure is currently present. There may be a long list of actions required so how should you prioritize and set the time scales? The cross functional team should carry out a risk

evaluation, i.e., what is the likelihood of the hazard being present (high, medium, low) and what would be the severity of that hazard if it was (high, medium, or low). The items with "high" or "medium" against them need the priority corrective actions, both now and longer term. For example, if the overall process environment is not as hygienic as you would like, you could build smaller more hygienic rooms within the plant around where the product is most vulnerable or depending on what the concern is, add line covers and catch trays under motors to protect the product. A longer-term solution might be different and require additional expenditure. This may perhaps seem obvious but it is particularly helpful where capital planning is involved.

Hazard analysis and risk evaluation of your processing operation will enable you to focus on high-priority areas for improvement and draw up a realistic action plan.

Another example is the immense challenge of setting up a prerequisite raw material control program (Supplier Quality Assurance) where use of a HACCP approach can again help to prioritize resources. Many companies purchase hundreds (often thousands) of raw materials (ingredients and packaging). Hazard Analysis can be used to identify which ingredients would have an impact on finished product safety if not effectively managed by suppliers. This enables the HACCP and SQA teams prioritize by risk, e.g., a microbiologically sensitive ingredient, such as chocolate or nuts, added to ice cream post-pasteurization. We will see later how some of the other HACCP tools and techniques, e.g., The raw material Decision Trees (Chap. 6), will be helpful in providing focus to SQA programs. This can be taking place at the same time as the HACCP team is drafting the Process Flow Diagrams and should involve those personnel responsible for purchasing. If you have no raw material specifications, use known data from reference books, a reputable hazard database, or bring in a HACCP expert to help you. A blank specification pro-forma can be sent to all suppliers for completion and cross checked against the external data but using the HACCP tools will help you to see where the priorities are in terms of your product safety, i.e., which suppliers should be audited first in order to assess their level of competence and where Certificates of Analysis are needed. It is important that this activity happens as quickly as possible because you might want to request that your suppliers of high-risk raw materials also upgrade their HACCP program. They can be working on their HACCP systems while you are working on yours.

With all of this information (PRP and management status gap analysis and the hazard analysis risk evaluation of the operating environment), you will have a lot of really focused and valuable information to help establish where you are in relation to the end goal. These activities can be done fairly easily in any size of business, whatever the level of maturity.

So, a number of parallel food safety improvement activities can be going on at the same time. Calibration of your key process equipment, for example, to control and monitor temperature process steps, can be done at an early stage, and this will likely have been identified during the baseline audit. Having HACCP knowledge to be able to prioritize through risk evaluation will be invaluable if not essential.

Table 2.4 Are all the required PRP controls in place? Case Study example from the Iced Delights (see Chap's 4 and 6)

Process area/issue	Hazard associated with operating environment	Likelihood			Severity			Significance ranking	Control measure PRP/OPRP	Currently in place?		Immediate action	Is it effective? (Validation)	Longer-term action	Is it effective? (Validation)	Responsibility	Capital plan and timing
		H	M	L	H	M	L			Y	N						
Cracked floors in the filling room	Harborage area for microorganisms (Listeria) which could cross-contaminate product		M			H		M/H Likelihood of happening was deemed to be medium because the product is enclosed up until filling. However this is post-pasteurization so the team felt that it is a significant issue.	Keep floors as dry as possible.		N	Remove all high pressure hoses from the filling room Increase environmental monitoring	Yes	Repair floor	To be determined (tbd) once completed	Engineering and QA	Cost tbd. Timing: within the next 6 months

Table format adapted with kind permission of Land O'Lakes, Inc.

2.5 How Do We Get There? Project Planning

The next step is to evaluate all the data and formally plan the entire project. We will focus here on planning the structure of the HACCP system.

2.5.1 What Structure Should the HACCP System Take?

One of the key issues to decide early on is the structure of the HACCP system. This will depend on the complexity of the operation and types of processes being carried out, along with the status of Quality Management Systems and PRPs already in place. There are three basic approaches:

(a) Linear HACCP plans

In this approach the HACCP principles are applied to each product or process on an individual basis, starting with the raw materials coming in and ending with the finished product. Depending on the type of operation, the HACCP plans may be extended to include distribution and customer/consumer issues.

Linear or individual product/process HACCP plans work best in simple operations, where there may be relatively few product types manufactured by a small number of processes. This approach is less likely to be helpful in larger, more complex operations. Here the application of HACCP principles to each product/process becomes repetitive and needlessly time-consuming and leads to a large number of similar HACCP plans, each with its own management requirements.

(b) Modular HACCP plans

If your products are manufactured using a number of basic process operations, it may be possible to use the modular approach when putting together a HACCP plan. This flexible approach allows the HACCP principles to be applied separately to each of the basic operations or modules. These HACCP plan modules are then added together to make up the complete HACCP system.

It is important to know where each module starts and ends so that no process step, and therefore no hazard, is missed when these are put together. Transfer steps from one module to the next can easily be missed and so should be clearly marked.

Since each module is specific to a part of the process and common to a number of products, the key issue is to ensure that the differences between products are picked up and all hazards addressed. Raw materials need to be assessed individually, considering their intrinsic hazards as they arrive and each use to which they will be put. Any special handling or processing measures used in a module for some products but not for others will also need to be considered.

An example, of how a facility may be broken down into process modules covering its basic process operations is shown below (Table 2.5). Throughout this book we are using a fictitious example of ice cream manufacture to illustrate the design and implementation of HACCP systems. This example assumes that the manufacturer is a medium-sized company producing a number of different varieties and operating to acceptable food industry standards. The products are packed in

Table 2.5 Process modules example—case study Iced Delights Ice Cream HACCP Modules (see Chap's 5 and 6)

1. Ingredient receipt and storage modules	HM1 Bulk ingredient receipt and storage HM2 Non-bulk ingredients receipt and storage HM3 Packaging receipt and storage
2. Preparation modules	HM4 Pumping HM5 Dry powders preparation HM6 Frozen concentrates preparation HM7 Ambient liquids preparation HM8 Dry particulates preparation HM9 Frozen fruit/puree preparation HM10 Pots, film, lids, and spoons De-box/de-bag
3. Manufacturing and packing modules	HM11 Ice cream base manufacture HM12 Filling room HM 13 Low-care finishing and storage

family-sized and individual tubs for retail sale. Here, at the preparation and planning stage, we introduce the modules that the company has identified when designing its modular HACCP system. We will go on to consider the application of HACCP principles to these modules for development and implementation of modular HACCP plans in the remaining chapters.

The modular approach is a very effective way of structuring the HACCP system and is commonly used in complex manufacturing operations, and in catering operations which also split logically into a number of modular parts.

(c) Generic HACCP plans

Generic HACCP plans are based on a framework approach that is intended to fit similar operations where the same product is manufactured or handled. This approach has limitations because no two operations are exactly the same, and HACCP is designed to be applied to specific processes.

The danger with using purely generic HACCP plans is that the issues that are specific to an operation may be overlooked, and therefore hazards may be missed out. In theory, generic HACCP plans can be used as a helpful starting point, and an effective HACCP system can be built up around them, ensuring that plant-specific hazards are managed in additional to generic hazards. This can work well in practice but requires care in tailoring the generic plan to the operation.

This type of approach is most commonly used in process sectors involving relatively simple operations; for example, primary meat processing. Bearing in mind the limitations discussed above, a generic HACCP plan can be drawn up within a company for application to several sites, or generic plans published in the scientific literature can be adapted (The Seafood HACCP Alliance in the USA is a very good example of this approach http://seafood.ucdavis.edu/haccpalliance.html). There has also been a growth in the use of generic approaches for catering and foodservice, with examples such as Safer Food Better Business (FSA, 2006)

and Cooksafe (FSA, 2009). These are intended for businesses with limited technical resource on site, so are designed to be easy to understand. However, the ability to tailor adequately to individual operations may be lacking in the target businesses for these types of generic approaches, leaving questions about whether all relevant hazards will be controlled.

Of the three approaches described above, the modular approach is usually the most practical for most companies. The process can be broken down into logical sections and looked at in detail. If the process being studied is common for a number of products, then these will be included in the scope, but it is essential that no hazards arising from slight differences in product formulation are overlooked. This means that all raw materials must be subjected to hazard analysis and considered with the process flow diagram. Potential issues should also be highlighted in the individual Product Safety Assessment (Chap. 5).

Most likely you will chose to break down your process into modules. These need to be determined as part of the planning activity. Think about how the system will be maintained once implemented and design with that in mind. The project plan should include the progression of any necessary PRPs (support systems) which were identified as gaps during the baseline audit.

2.5.2 Using Project Planning Techniques

When we use the word "plan" in this section, we are referring to the development of a Project Plan and action timetable for the application and implementation of a HACCP Project, as opposed to the HACCP plan.

The application and implementation of HACCP and supporting systems can be best managed as a project. It will have a definite life cycle with a start date and a finish date, a defined scope, and budget. In a larger organization, the project may be managed by a temporary project team and the timetable and costs estimated at the start. This will involve the appointment of key people and the documentation of the actions and time scale required. The roles needed in managing a typical project are two key personnel plus a supporting team.

The Project Sponsor

As the champion of the project, the Project Sponsor is likely to be your company CEO (with strong support from Quality) and Operations Vice President or Operations Directors. Whoever takes on the role is likely to sit on the senior management team and have budgetary control. The main responsibilities are to:

- Provide funds
- Approve and drive the company HACCP or food safety policy
- Approve the business issues and ensure that the project continues to move forward and remains valid
- Appoint a Project Manager and Team
- Ensure that adequate resources are made available to the Project Team
- Establish a progress reporting procedure

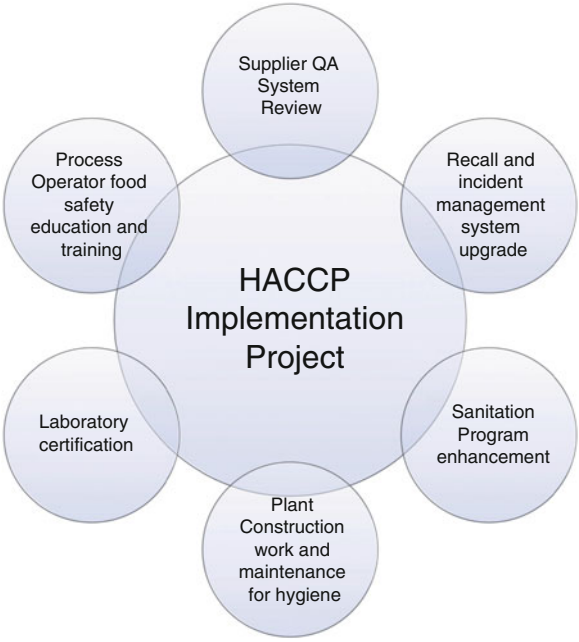

Fig. 2.5 HACCP interactions with business improvement projects

- Ensure that the Project Plan is realistic and achievable
- Approve any changes to the original project

The Project Manager

This role is likely to be taken by the Production or Quality Manager, who may also go on to become the HACCP Team Leader. The responsibility centers on ensuring that the Project Plan is drawn up and objectives achieved within the agreed time scale. This requires effective project management skills, specifically to:

- Lead and direct the Project Team
- Produce an achievable Project Plan
- Provide a regular progress report to the Project Sponsor
- Liaise with other Project Managers to ensure that areas of common interest are identified and resources are used effectively in these areas

As well as the HACCP Project itself, there may well be other business improvement projects going on within the business at the same time. These may include development of the systems required to fill the gaps in the HACCP Support Network, which we identified following the baseline audit (Sect. 2.3). It is useful to establish what these additional systems are early on, for example, as in Fig. 2.5.

Other projects may include the setting up or enhancement of a formal Supplier Quality Assurance program, facility environment upgrades, the introduction of SPC on certain lines, production rationalization, product development activities, cost of quality calculations, and so on.

As stated earlier, the project team will need a complete understanding of the starting point. This will be most simply achieved if all the project team members have already been involved in the baseline audit, including a review of documented procedures already in place, environmental issues, PRP status, resource availability, and current culture. In other words, the team will have an appreciation of the size of the task, the current capabilities, and the additional resource requirements.

2.5.3 Drawing up the Project Plan

Let's think about this in a little more detailed project terms as the discipline can be helpful.

What is a project?

- It has clear objectives based on need.
- It has a beginning and an end.
- It has defined goals and deliverables along its timeline.
- It requires resources in terms of time and money.
- It has a clearly defined scope.

In a food safety improvement project the scope is likely to include at least two, possibly three things:

- Product design review and improvement
- PRP review and improvement
- HACCP plan development

These are three separate projects or subsets of a larger Food Safety improvement project. Each element is highly related through the utilization of the Hazard Analysis process.

Each project element will have a defined lifecycle and can be simply described as having four main stages:

Initiating → Planning → Executing → Closing

In initiating the HACCP project you may choose to draw up a charter (Table 2.6) as a means of communicating the objectives to a wider audience. The key elements to include are **why** the project is being launched, and what **authority level** it is supported at. Ideally this will be a very senior member of the management team, i.e., someone other than the HACCP team leader. It can be a simple one page document and can be used as a reference point throughout.

For the HACCP component, once you have decided on the structure of the HACCP system and have an understanding of the additional tasks you will need to undertake, a detailed Project Plan can be drawn up. The complexity of this plan will relate to the amount of work to be done and it is important to ensure that sufficient time is allocated to develop an effective system.

The Project Plan may be divided into a series of main phases, with each phase further broken down into specific activities—a work breakdown structure, a schedule

Table 2.6 Example of a project charter—case study Iced Delights Ice Cream

Project charter: Iced Delights Ice Cream Manufacture	
Project Name: Project Eskimo: Food Safety system upgrade Key Assumptions: Food Safety is a foundation to the continued success of Ice Delights business. Building infrastructure, quality system, and cultural improvement are **all** needed.	Start date: Projected end date:
Scope: Ice Delights HACCP system and PRP upgrade	
Measure of success: – Third-party certification to a GFSI benchmarked standard – Compliance with all regulatory and customer expectations	
Project Team: HACCP Team Leader Human Resources manager Engineering Manager R & D Manager Sponsor: Manufacturing VP	Projected budget needs: – Capital improvements for PRP enhancements – Consultant – Training

of activities, and a communication plan. The start, finish, and activity time lines are determined, together with any dependencies (What needs to happen before this particular activity can take place?) and the resource allocated (Who will make it happen?). This can be plotted on paper to provide an implementation timetable or project schedule. A Gantt chart (a HACCP project example is given in Fig. 2.6) is an approach that many companies use for this purpose. In looking at the Gantt chart, it can be seen that whilst the duration of each task has been estimated, not all tasks can begin on Day 1. This is because some of them cannot start until another task has been completed.

TASK	MARCH w/c				APRIL w/c				MAY w/c					JUNE w/c			
	6	13	20	27	3	10	17	24	1	8	15	22	29	5	12	19	26
Identify and train HACCP team																	
Baseline audit and gap analysis																	
Preparation																	
Process Flow Diagrams																	
Hazard Analysis																	
Identify CCPs																	
Complete Control Charts																	
Set up monitoring systems																	
Train monitoring personnel																	
Training of operatives																	
Set up facilities and equipment																	
Audit to verify implementation																	
Start routine monitoring and records review																	

Fig. 2.6 Example of a Gantt chart—Generic HACCP Project Plan

The following are definitions of key terms introduced on the Gantt chart:

- Critical: This means that the task is critical in terms of timing. If these tasks do not run to time then the project completion date will be affected—there is no slack.
- Non-critical: This does not mean that the tasks are any less important than those referred to as Critical. It just means that there is some slack in the timing. If they don't finish at the precise date indicated, then depending on how long over they run, the end project completion date may not be affected.
- Milestone: This is usually an event or key decision date. It can be used as an indicator in terms of the project progress.

Gantt charts can be produced using computer software packages. They can also be drawn manually and kept fairly simple, e.g., this may be appropriate for a smaller business. The example shown here was developed using Microsoft Project™. The HACCP team and project leader (if different) are usually the people who draw up the plan.

The execution phase of the project is where the HACCP study is being carried out. It is important to communicate progress throughout.

Once complete, it is helpful to formally acknowledge that the implementation phase is complete, celebrate (!), and move straight away into a maintenance mode.

2.6 Continuous Improvement

Once the project is completed the team can start to focus on continuous improvement. This is a requirement of many formal food safety standards including ISO22000 (2005a). The model below (Fig. 2.7) shows how this is a cycle of activity from planning safe products (through design), conducting hazard analysis and developing the HACCP and PRP controls, validation that the controls are effective

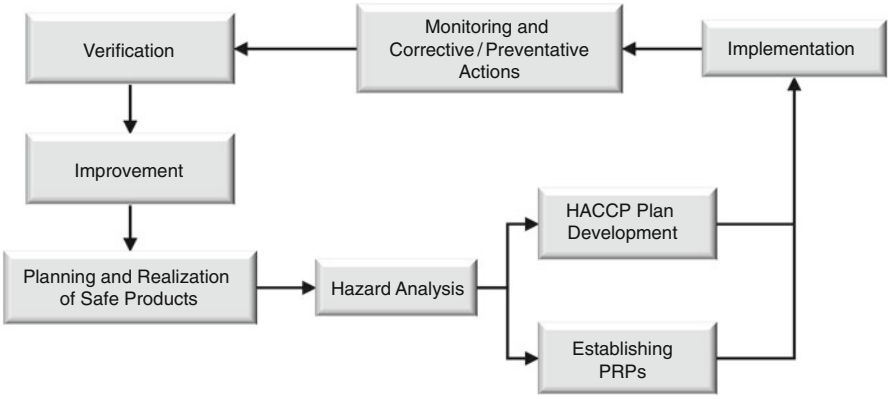

Fig. 2.7 Concept of HACCP continuous improvement

prior to implementation, monitoring, corrective and preventative actions, and verification lead to improvements where needed.

2.7 Key Point Summary

As we saw in Fig. 2.1, a successful HACCP system results from following four key stages. In this chapter we reviewed key stage one, Planning and Preparation (Fig. 2.2). To plan any system effectively, the scope of the entire project needs to be understood at the beginning.

The key things to remember are:

- Identify the key people involved and establish commitment
- Train and educate so the team understands the goal and has the skills needed to achieve it
- Undertake a gap assessment—from where you are now to desired future state
- Set priorities based on hazard analysis and risk evaluation
- Manage the implementation as a project in terms of discipline
- Reaffirm senior management commitment and alignment with regard to what needs to be done

http://www.springer.com/978-1-4614-5027-6

HACCP
A Practical Approach
Mortimore, S.; Wallace, C.
2013, XXX, 475 p. 112 illus., 27 illus. in color.,
Hardcover
ISBN: 978-1-4614-5027-6