Chapter 5
Designing Food Safety

Whenever a company is designing a new food product it is important to ask if it is possible to manufacture it safely. Effective HACCP systems will manage and control identified food safety issues on an ongoing basis but what they cannot do is make safe a fundamentally unsafe product**. The most effective way to ensure safe food is to design out the likely hazards.**

Safe design might first seem a relatively straightforward operation; however, when we look at all the necessary elements to achieving safety, the complexity of getting this right starts to emerge and we can see that there are several elements that need to be effectively designed for food safety, and which will need to operate within a supportive food safety culture (Fig. 5.1).

Figure 5.1 illustrates that HACCP cannot work in isolation. It needs to be accompanied by safe design control procedures and prerequisite programs (PRPs), and supported by a range of essential activities which go into making up a culture of food safety. This will include management commitment as demonstrated by investments in the operating environment, programs, people and training, a continuous improvement approach, and a strong documented quality management system.

The "safe product/process design" element is particularly aimed at the safe design of individual products being produced within the safety management framework of HACCP systems and PRPs and this will be the main focus of this chapter. However it is important to also consider the safe design of prerequisite programs in that we need to consider the safe design of the food process equipment and the facility where products will be produced, handled, and/or packed. Many of the necessary elements for safe equipment and facility design will overlap with PRPs; however it is useful to also consider the facility in this chapter to provide a complete picture of the safe food system. We have already considered HACCP system structure design in Chap. 2 and will follow through on HACCP application and implementation in Chaps. 6 and 7.

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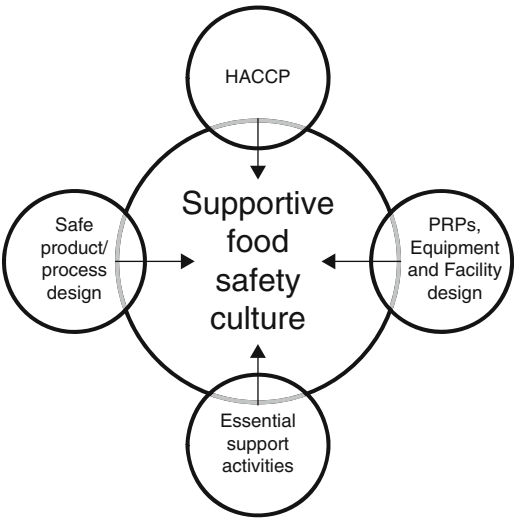


Fig. 5.1 Designing food safety programs

5.1 Product Safety Design

It is essential that food safety is designed into a product at the development stage and this should be the responsibility of the product development and HACCP teams working together. Ideally HACCP teams will include a member(s) from the product development team whose responsibility includes informing them about new product/process ideas at an early stage. There is no point in new product prototypes being shown to marketing departments or to customers if there are inherent safety risks which cannot be controlled. Lack of early cross functional food safety assessment lengthens the overall timeline for new product development if reformulations or process changes are found to be needed during a later HACCP study. Not only could this be embarrassing for the commercial teams but development ideas which have not had early food safety risk assessment could be responsible for foodborne illness in the marketing or customer buying departments through consumption of unsafe samples made in the development kitchen. The presence of product development specialists on the HACCP team is not only essential for bringing information about new developments to the team's attention but also ensures that the philosophy of and requirement for safe design are taken back to the product development team, where they become a cornerstone of future developments. As stated earlier, the most effective way of preventing foodborne illness is to design out as many of the likely failure modes as possible. The product development team needs to fully embrace this philosophy.

Several factors must be considered when designing food safety into a product, and the HACCP team and other relevant specialists must be involved at the outset. In this section we will consider the product formulation and process technologies,

along with the importance of ensuring raw material safety. We will also discuss the establishment of a safe and achievable shelf-life and provide an example of how this information may be organized into a formal product safety assessment record.

5.1.1 Designing Your Recipe Formulation

Most companies will be manufacturing or packing a specific type of product within a particular sector of the food industry and so will have detailed knowledge and experience of their likely hazards and appropriate control measures. Often new product development will be around (simple) variations to an existing range of products, in which case it is tempting to assume that the same controls will be suitable for control of food safety hazards. However it is important to note that this will not always be the case and to remember that changes to product formulation have been the cause of previous food safety incidents (see also Chap. 1).

A good example of a catastrophic product development error is associated with an outbreak of botulism in the UK in 1989. This outbreak (Shapton, 1989; O'Mahoney et al., 1990) involved the change from a standard hazelnut yogurt formulation to a low calorie version, and both the yogurt manufacturer and the hazelnut puree supplier were at fault in their product formulation safety design. The puree manufacturer should have understood what was making the puree safe in terms of the product's intrinsic safety factors and process. By taking out the sugar and replacing with artificial sweetener, questions should have been asked about the impact of the changes on safety, e.g., what was preserving the puree and preventing the growth of spore-forming organisms such as *Clostridium botulinum* and did this new formulation change that. The yogurt manufacturer should also have been asking questions about the safety of his or her new raw materials very early in the redesign. However, no change to the heat process of the hazelnut puree was put in place by the puree manufacturer, so an inherently unstable and unsafe product was produced and supplied to the yogurt company, where it was simply mixed into the yogurt and resulted in 27 cases of botulism and one death (Shapton, 1989; O'Mahoney et al., 1990). Whilst this example happened more than 20 years ago, it remains a useful lesson to those involved in the product development process of the need to review safety for all new developments, no matter how simple they may seem at first.

The important point is the need to review in detail each change to a product formulation and consider both what new hazards might be introduced and what impact the proposed change has on overall formulation safety. From the above example it is important to remember that changes can also result in removal of existing control measures as well as introducing potential new hazards.

Often hazards are being controlled by a combination of formulation controls within the recipe and other control measures. Chapter 3 introduced some of the ways that product formulation is used to control microbiological hazards, e.g., pH and acidity, organic acids, addition of preservatives, and water activity. It is important that HACCP and product development teams understand the intrinsic

recipe factors being used to control safety within food products and review the impact of proposed recipe changes on these control systems.

The other key element to consider is whether the proposed new formulation will mean that there are new significant hazards that need to be controlled. This will require appropriate knowledge within the HACCP team to evaluate the potential for new hazards and may mean that additional specialist expertise has to be brought in, for example when product developments move into areas of limited experience for the specific food business or when a completely new product or process type is being considered.

5.1.2 Designing Safe Processes

Most food companies (human or animal foods) will have well-established manufacturing processes in operation and these may involve a variety of technologies, such as heating, cooling, fermentation, etc. Often these processes will have been used for many years and their safety, therefore, is taken for granted. However, when starting out with HACCP or any certified formal quality management system, gathering evidence that your processes have been confirmed as safe (i.e., that you have documented proof of it) is a key requirement. We will see the importance of validating process safety where CCPs are involved in Chap. 7 and it is best practice to start building up a dossier of evidence that processes used to control significant hazards are valid and effective across the normal operating conditions. This may be done with reference to legislative or literature values, and will also always require local on-site testing and monitoring to demonstrate that the intended process parameters are met.

For proposed new processes where there is limited knowledge and experience, the safety of each application needs to be researched and validated in the same way before the proposal can be implemented. Again, it may be necessary to bring additional specialist help into the product development and/or HACCP teams to help with understanding the implications of the findings and assist with the safety evaluation.

5.1.3 Safe Raw Materials for Safe Product Design

Hazards are brought into our facilities by people, through the environment (dust on air, etc.) and through raw materials. Product safety starts with knowledge about the safety status of raw materials that we use. Whilst control of raw materials is normally via supplier quality assurance procedures as part of PRPs, it is important first to understand the likely hazards that specific raw materials might present so that appropriate controls can be built in. This might be through supplier quality assurance or it might be through processing controls in the food operation,

depending on what is appropriate for the specific hazard. For example, raw ingredients such as raw meat will almost always carry a risk of contamination with microbial pathogens and these will need to be controlled at some stage before consumption of the final product; however it would be unrealistic to require that all microbial pathogens of concern were absent from the raw meat on delivery due to the absence of processing steps in primary production. Nevertheless, where no control for specific significant hazards can be built into the food process then the raw materials must be safe at the point of delivery and this will require control measures to be part of the raw material supply chain. In this case the supplier assurance procedures must be able to demonstrate that control measures have been applied. See Chap. 4 for further discussion of supplier assurance as part of prerequisite programs.

5.1.4 Establishing a Safe and Achievable Shelf-Life

When you are designing your products, you will need to consider the shelf-life that you and your customers would like for each product, and then go on to establish whether or not this proposed shelf-life is safe and achievable. Criteria that can influence your product's shelf-life include:

- Raw materials
- Process technology used
- Product intrinsic factors
- Type of packaging
- Conditions during storage, distribution, and retail
- Customer storage and handling

The shelf-life will be limited by factors that cause the product to become unsafe or deteriorate, and these will be influenced by the criteria listed above. Rancidity of fats can cause revulsion when consumed, but these are normally associated with spoilage rather than safety. As we are concentrating on safety in this text, we will consider here only factors that cause the product to become unsafe. As with the other aspects of product safety design, you need to ensure that you have the correct expertise available to take shelf-life decisions. For example, if you are a small manufacturer of high-risk products, you may wish to consider the use of external experts to help with shelf-life determination.

What Factors Could Cause the Product to Become Unsafe?

The main factors that can cause products to become unsafe during their shelf-life are pathogenic microorganisms. We have already discussed microbiological pathogens as hazards and have looked at intrinsic factors as control measures in Chap. 2. The Pathogen Profiles Appendix may also be helpful in deciding whether

the product is likely to provide an environment favorable to pathogen growth. Pathogenic microorganisms may be present in your product from the raw materials, or from contamination during processing. These may be able to grow, depending on the intrinsic factors and packaging, along with the storage, distribution, and handling conditions to which the product is subjected.

If you consider that a pathogen is likely to be present in your product, and that it will not be prevented from growth by the product's intrinsic factors, then you will need to investigate the degree of growth that is possible in the product. This, along with knowledge of the infectious dose for the organism in question, can be used to evaluate whether the product will become potentially unsafe for consumption and under what circumstances. It is important to note that if pathogens with a low infectious dose are likely to be present (i.e., the mere presence of them is a significant hazard) at the start of shelf-life, and the product is not likely to be cooked thoroughly by the consumer, then the product is potentially unsafe and should be redesigned. A good example of this is Salmonella in low-moisture foods, particularly those that are minimally processed, e.g. peanut butter, flour, spices. Technologies are available which can be used to improve safety, such as irradiation, steam sterilization, and heat treatments, but this is a change in traditional practice for many of these categories and more research is needed. This is an area that in recent years has been the subject of discussion regarding the role and responsibility of industry versus the consumer. In the past, we might have said that the consumer was responsible for thoroughly cooking raw foods (i.e., the kill step). However, there have been a number of outbreaks in the raw products category (such as vegetables and ground meats for barbeque cooking) which might lead us to consider that there are very few foods where the consumer should have that responsibility—perhaps raw grains or meats and even then we have to consider known likely consumer use such as consumption of raw homemade cookie dough or meats preferred rare. Companies producing products that have traditionally been considered as 'raw' but which may be consumed without proper cooking are challenged with this particular scenario.

How Do You Know When Pathogens Reach Unsafe Levels?

Information on growth potential in foods, and with varying proportions of inhibitory intrinsic factors, can be found in the scientific literature. This can give you a good idea of the likely situation in your product but should not be relied on absolutely for a safe shelf-life. Mathematical modelling of pathogen growth in various concentrations and combinations of intrinsic factors can also be carried out. A number of computer models have been developed which can also be used or accessed but these do require microbiological expertise for interpretation and your HACCP team may need additional expert help depending on the existing team makeup.

The theoretical safe shelf-life obtained from literature values or mathematical modelling should be confirmed in practice for the product in question. This can be done through examination of the product for each microorganism of concern

throughout and beyond the proposed shelf-life. Product samples should be held under the expected storage and handling conditions, and it is prudent to build in an element of abuse, e.g., elevated temperature storage, to reflect possible product mishandling.

Where the microorganism(s) of concern may not be present all the time, or may be present at very low levels, it is more appropriate to carry out product challenge testing to evaluate potential for growth. Here each individual pathogen is inoculated into the product, which is then held at the expected storage and handling conditions. As for standard shelf-life examination, the product is tested at various intervals throughout and beyond the proposed shelf-life and an element of abuse should be built in.

It is important to note that shelf-life should always be confirmed on product samples which have undergone the same treatment as all product which goes on sale. This means that any shelf-life proposed through theoretical studies, or through examination and challenge of development samples, must be verified on product which has been manufactured on production lines at the factory, and under the normal manufacturing conditions.

5.2 Prerequisite Program Design

As with all other parts of the food safety program, it is important that prerequisite programs (PRPs) and, where appropriate, OPRPs, are carefully designed to ensure that they will control the necessary issues every day. Chapter 4 provides a detailed breakdown on some of the key PRP elements and it is not proposed to repeat the detail here. However, it should be remembered by all food businesses that the development and/or review of PRPs is an opportunity to strengthen the level of control they provide for food safety. This means that it is not sufficient just to accept existing systems that have been in place for some time, without asking the question: "Can we do this better?" The HACCP system is an approach to continuous improvement and this will also be the case for its supporting systems.

Additional detail to help in strengthening PRPs can be found in a range of other publications such as food safety and prerequisite audit standards, e.g., standards meeting the Global Food Safety Initiative requirements (GFSI, 2011) or specific prerequisite standards such as the ISO (2009) publication, *Prerequisite Programmes on Food Safety: Part 1 Manufacturing,* ISO/TS 22002-1:2009 (formerly PAS 220:2008), or other books and guides, e.g., Sprenger (2012).

5.3 Equipment and Factory Design for Product Safety

Linked to PRPs for providing the general hygienic operating conditions necessary for safe food production is the concept of hygienic/sanitary equipment and factory environment design. This is clearly essential in all product handling areas and will

also be important in other ancillary areas of a food facility, particularly with regard to areas where food handling personnel have access. Modern food processing facilities are normally designed with a good level of hygienic/sanitary standards; however many of us are challenged with operating out of facilities which were built long before the concepts of sanitary design were being developed. It is important to keep up to date with developments in best practice and knowledge on the behavior of hazards in food-handling environments. HACCP techniques can really help with understanding the impact on product safety if the product does encounter environmental contamination, i.e.: What is making the product safe and very importantly, what would cause it to be unsafe?

Hygienic design considerations might be product specific since there will be particular considerations for different product sectors and links in the food supply chain (see also Chap. 8). This might include the need for specific environmental standards and equipment or, for example, for segregation/zoning of different processing areas in certain product/process types.

As discussed in Chap. 4, segregation of areas (sometimes called zoning) is a common control measure to manage the hygienic/sanitary standards in food facilities. This involves building in a gradient of product protection systems and procedures, with the highest degree of hygiene used where the product is most vulnerable to contamination, e.g., after cooking but before packing. This type of system is common in the production of perishable ready-to-eat products. It is important to recognize that for some products the mere presence of a pathogenic microorganism at low numbers can cause severe illness, even mortality. Control of Salmonella in low-moisture foods requires a zoning approach to prevent cross-contamination of the finished product. Design of food facilities for high care zones needs to be carefully thought through at the site planning stage as it will be much more difficult to build in appropriate controls as an afterthought in a completed building. Specific considerations when designing segregation zones will include traffic patterns for product, equipment, and personnel, the need for dedicated changing areas and/or "air locks," the need for dedicated equipment for production and maintenance, and the need for positive air pressure and appropriate drainage and waste management design.

For both the facility environment design and equipment design, perhaps the most important aspect in a food operation is ensuring that all areas, plant, and equipment can be effectively cleaned and disinfected. Inability to clean due to inappropriate surfaces, "dead-ends" or areas in pipework, equipment that cannot be dismantled fully or successfully cleaned in place, etc. will mean that food debris and microorganisms start to build up and this could cause safety implications via product contamination.

Further supporting information on hygienic design of food facilities and equipment can be found in other publications such as Campden BRI Guideline No 39, *Guidelines for the Hygienic Design, Construction and Layout of Food Processing Factories* (CCFRA, 2003), Shapton and Shapton's *Principles and Practices for the Safe Processing of Foods* (1998), and Holah and Leileveld's *Hygienic Design of Food Factories* (2011). Additional helpful guidelines can be found via Web sites run

by expert groups, such as the European Hygienic Engineering and Design Group (http://www.ehedg.org/), which offers a range of guidelines with particular reference to hygienic equipment design, or the US Grocery Manufacturers Association, which provides checklists for *Facility Design* and *Equipment Design for Low Moisture Foods* (http://www.gmaonline.org/resources/research-tools/technical-guidance-and-tools/).

5.4 Product Safety Assessment

Most companies nowadays use the modular approach to HACCP system design (see Chap. 2). In addition to HACCP plans it is essential that all companies ensure that the safety of individual products has also been properly assessed. In modular systems, the HACCP plans usually cover a **process**, which means that a number of different products are included within each module. It is also important to consider each individual product through a form of product safety assessment. This is intended to pick up any product-specific hazards and can be used to document recommendations to the HACCP team. Product safety assessments may be carried out either before HACCP plan development, where all existing product varieties will be assessed, or after HACCP implementation, when new varieties are added to a product range. In the latter case it is particularly important to ensure that the existing HACCP plan is still valid for the new product.

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 family-sized and individual tubs for retail sale. Here, at the development and safety design stage, we again refer to the case study and specifically, a chocolate-chip ice-cream product which will be managed by the modular HACCP plan outlined in Chap. 2.

The Product Development personnel can be assisted by the HACCP team in establishing the product criteria early on in the design of a new product. This will often involve the drafting of a development specification.

5.4.1 Development Specification

In many cases the product safety assessment will be based on a development specification, such as the example given in Fig. 5.2 for chocolate-chip ice cream.

In most cases the suppliers of the raw materials will be known and outline or full specifications may be available. This is important as the next step in the assessment is the evaluation of likely raw material hazards.

Iced Delights Ice-Cream Manufacturers
Development Specification: Chocolate-Chip Ice-Cream

Recipe

Skimmed Milk Powder (SMP)
Cream (40% fat)
Liquid sugar (80º Brix)
Milk chocolate chips (5 mm discs)
Water
Vanilla flavouring (liquid)
Stabilizer (lecithin)

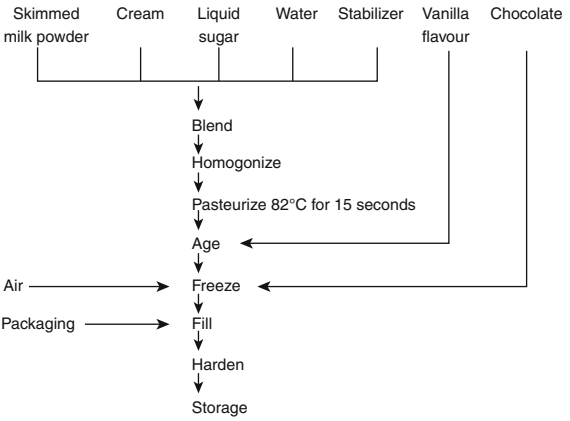
Packaging

1 litre plastic tubs
500 ml waxed cartons
100 ml waxed cartons
Sealing film
Lids
Plastic spoons

Target Consumers

A high quality ice-cream for family or individual use

Provisional Manufacturing Outline



Provisional microbiological guidelines

	n	*c*	*m*	*M*
TVC	3	1	5×10^4	5×10^5
Coliforms	3	1	10	1×10^3
E. coli	3	0	Absent/g	Present/g
Salmonella spp.	3	0	Absent/25 g	Present/25 g
L. monocytogenes	3	0	Absent/25 g	Present/25 g
S. aureus	3	1	1×10^2	1×10^3

For definitions of *n*, *c*, *m* and *M* refer to Appendix D

Required Shelf-Life 12 months
Storage/Distribution Temperature <–18°C

Fig. 5.2 Development specification example

5.4.2 *Product Concept Safety Considerations*

A product safety assessment may be carried out and documented in a number of ways, but usually comprises consideration of:

- Target audience and food sector
- Raw materials
- Legal issues
- Recipe and intrinsic factors
- Process conditions and cross-contamination issues
- Distribution and final customer/consumer handling

(a) *Target audience and food sector*

Most foods are targeted at the general public but not all. If producing for certain segments of the population such as infants, children, or the elderly, you may need to capture this in terms of there being a need for heightened controls. For example, products designed for young children will have the additional concern of choking hazards; for the immunocompromised consumer, a higher degree of environmental hygiene might be needed. Also consider the food sector. Food service and catering operations will be different to retail. Products being used in commercial kitchens may be subject to abuse through more frequent handling, but conversely, you may be able to ensure more consistent user practices by working with your customers and providing handling instructions and training. With retail products, the consumer at home is the target and more difficult to educate in terms of safe handling practice as we've discussed earlier.

(b) *Raw material evaluation*

Considerations of ingredient sensitivity during the design of a new product can assist in targeting the SQA activities to work with new suppliers at an early stage. A number of issues are likely to be discussed, for example:

Sensitivity status:

- Why is the ingredient considered "sensitive"?
- What (specifically) are the microbiological hazards of concern?
- What likely chemical and physical hazards exist?

The team should review literature for guidance and also for indications of outbreaks or events in the raw material categories that they are using. They should also expect their raw material suppliers to be knowledgeable about the safety of what they are producing.

Supplier control:

- What is the approval status of the factory or the agent?
- What is the specification status—has the supplier signed off to indicate agreement?
- Are certificates of analysis required? If so, is the testing laboratory approved/certified?

- Have previous audit reports been considered? Evaluate any third-party reports as well as any that you have generated yourself in previous years.
- Are there any shelf-life criteria associated with the ingredients that would impact your product?

Bearing this in mind, let's now look at the ingredients and packaging for the ice-cream case study. Table 5.1 shows how the information may be organized as each ingredient is evaluated.

(c) *Legal constraints*

These may not strictly relate to product safety, but it is important to be aware of relevant legislation, particularly if exporting for distribution and sale in other countries:

- Are you making any claims about the product? This may be important if the company is planning to reduce salt or sugar in the formulation. It could be a very early indicator to the HACCP team that important intrinsic safety factors are likely to change.
- Consider ingredient usage concentrations, e.g., whether there are any maximum usage restrictions. This will be the case with chemical preservatives and other additives.
- Review product compositional requirements. In some countries there are formal standards of identity for certain categories of foods.
- Understand the regulatory position with regard to processing requirements, e.g., pasteurization. Ensure that this is the same in the country of manufacture versus where it will be sold. Irradiation is a good example where there are differing requirements by country.
- Review microbiological criteria—especially if exporting to a country which has differing regulatory requirements and test protocols.
- Chemical criteria—same as above, i.e., specifications may vary across national borders. An example may be antibiotic residues in dairy products, and also use of chemicals such as ethylene oxide which is still permitted in some countries but banned by many.
- Use of technologies—such as biotechnology. Here the regulatory and consumer acceptance may vary and this is also worth a team review and discussion.
- Labeling requirements differ across countries and this is important too for food safety criteria such as allergen communication.

(d) *Recipe/intrinsic factors*

It is important for the team to be really clear on what is making the product safe—and of course, what therefore might make it unsafe in terms of the intrinsic formulation safety factors. As a processor, you need to be really expert in your food category, so this is an area for the team to spend some time on. Consider the criteria outlined in Chap. 3 such as a_w, pH, chemical preservatives, and organic acids.

Basically at this stage the team needs to answer the question: Which intrinsic factors control the product safety and at what levels?

Table 5.1 Chocolate-chip ice cream—raw material hazard considerations

Raw material	HACCP team notes
Skimmed Milk Powder (SMP)	
Salmonella	When we consider SMP, there is an associated risk of salmonella from historical data; however, the ingredient will undergo a heat process which is lethal to vegetative pathogens. There is no cross-contamination risk at this facility as there is already full segregation of the raw materials before pasteurization from the post-process area, and from other sensitive raw materials such as chocolate chips. This raw material therefore does not require a heightened level of control at the SQA stage for this hazard though the team acknowledges the importance of strong hygiene protocols at their plant.
Allergens (Dairy)	The product must be labeled.
Foreign material	Foreign material is not normally associated with SMP because the milk is filtered before drying and powder is sieved and passed over a magnet immediately before bagging. If foreign material were present it will be due to an equipment malfunction though that should be considered.
Antibiotic residues	Antibiotic residues may carry through to the final product and will not be removed by the heat process. So, as part of SQA, the raw milk supply into the dairy must be monitored.
Cream	
Vegetative pathogens (e.g., *Salmonella*, *Listeria*, *E. coli*)	This hazard is most likely to occur through post-process contamination, e.g., through poor tanker hygiene. However, for the same reasons as SMP, there is no requirement for a heightened level of control at the supplier. The control must be in place at the Iced-delights facility.
Foreign material	There is an in-line filter in place at the supplying dairy.
Antibiotic residues	As per SMP.
Allergen (Dairy)	The product must be labeled.
Liquid sugar	No hazards were identified.
Milk chocolate chips	
Salmonella	For chocolate chips there is a hazard of Salmonella being present, which is recognized from historical data in chocolate. The chocolate chips will be added to the ice cream after the heat process, and the consumer will eat the product without any further preparation. This leads us to the decision that a high level of control is required with this raw material, and we should focus SQA resource here accordingly.
Chemical—pesticide residues	These hazards could occur at the growing and raw material storage stages. However, this would be routinely controlled through the prerequisite SQA program.
Allergens (Dairy)	The product must be labeled.

(continued)

Table 5.1 (continued)

Raw material	HACCP team notes
Water	
Protozoa	As an ingredient in this product there would be minimal risk from bacteria due to the heat process. The temperatures may not be sufficient for protozoan parasites such as Cryptosporidium but the risk is considered to be minimal due to the quality of the mains water supply and no history in the region.
Chemical, e.g., toxic metals, pesticides, nitrates	As an ingredient, control of the supply is critical as these hazards may not be processed out. However, this would be routinely controlled through the prerequisite SQA program.
Vanilla flavor	
Microbiological Physical	The processing by the supplier will eliminate any risk of either microbiological or physical hazards.
Stabilizer (lecithin)	No hazard identified other than acknowledging that this is soy lecithin and needs to be considered as an allergen in some countries (labeling control).
Plastic tubs and film	
Chemical (plasticizers and additives)	The SQA process must ensure that all chemical constituents are legal and within chemical migration limits for a high-fat ice-cream product.
Waxed cartons, waxed lids, plastic lids	No hazard identified.

(e) *Process conditions*

Having understood the intrinsic safety factors, it is equally important to be expert in your process:

- Does the process affect the safety intrinsic factors?
- Does the process make the product safe and why?
- Are any hazards likely to be introduced due to the process? Think here about not only the new product but also any existing products in the facility.

(f) *Cross-contamination*

We considered this in Chap. 4 and the HACCP team need to draw on their expert knowledge of the plant and process activities here:

Are there any obvious risk factors from or to existing products, packaging, and the process environment? Allergen control in addition to pathogen contamination would be an appropriate consideration.

(g) *Intended shelf-life*

Think about all the data gathered together so far as you answered the questions above. It is likely that the Product Development team will be conducting shelf-life studies and will build in some simulated abuse as part of the study. The HACCP team needs to understand:

- How susceptible is the product to food safety failure (or spoilage—whilst not food safety, this can be an indicator of abuse through the shelf-life of the product) if and when it was abused during the course of its intended shelf-life?
- What governs the shelf-life, i.e., are the limiting factors sensory attributes or microbiological deterioration?

(h) *Distribution*

This builds on the previous considerations; once the team has a detailed knowledge of the intrinsic safety factors, and the shelf-life criteria, it will be easier to consider the distribution stage of the product life cycle. Basically the team needs to understand whether the product is susceptible to damage or abuse. If you are producing a product that will be further processed or packed at another location and therefore perhaps transported in bulk, then this is a really important step in the process to consider.

(i) *Customer/consumer-intended and unintended use*

Similar to above:

- Could additional hazards be introduced?
- Is control necessary for any hazards at this stage?
- Although not normally considered as a food safety hazard, could packaging cause health and safety hazards, e.g., injury while opening cans?
- Basically, do you understand all the potential uses of the product, e.g., in different recipes, etc.? This is a really important element, particularly if there are known "unintended" uses for the product, e.g., consumption of raw cookie dough that is designed to be cooked, or the preference for meats that are not fully cooked through.

This information could be recorded in report format or using a simple table, as in the following example (Table 5.2).

When you have established the safety of your individual product designs, and decided on the likely shelf-life, you can move on to look at how safety will be controlled from day to day during manufacture. This is through the establishment, implementation, and maintenance of an HACCP plan for the process, which we will begin to consider in Chap. 6, along with the operation of PRPs and management programs within a hygienically designed facility.

Table 5.2 Product safety assessment: Chocolate-chip ice cream

Example							
PRODUCT chocolate-chip ice cream			FORMULA			DATE 5-11-96	Page 1 of 4
Stage	Considerations	Criteria	Likely hazard	Control measures	Is control possible?	Validation of control	Recommendations to HACCP team
Concept	Targeted at general population including high-risk groups. Domestic use	Frozen product to be eaten without any further process	Vegetative pathogens with low infective dose	Pasteurization, filtration, supplier assurance	Yes		Whilst it is pasteurized at the facility, there will be many ingredients added post pasteurization that **must** be made safe by the supplier
Ingredients	Sensitive ingredients and supplier control:						Careful control at supplier →effective supplier management (including audit of processing site for hygiene assessment and microbiological test facilities)
	SMP	Dried	Vegetative pathogens (*Salmonella*) Allergen (Dairy)	SQA	Yes	Supplier's microbiological tests and antibiotic monitoring procedures	Verify that antibiotic monitoring procedures satisfactorily covered during SQA audits
	Cream	Pasteurized, chilled	Antibiotic residues	SQA	Yes		
	Chocolate chips	Ready to use	*Salmonella* Allergen (dairy)	SQA	Yes	Supplier audits and Certificates of Analysis received with each batch	As above: Careful control at supplier → effective supplier management (including audit of processing site and microbiological test facilities)
	Water	Mains	Chemicals, heavy metals, etc.	Supplier control	Unknown	Legal obligation	Ensure proactive relationship with water authority

	Stabilizer	White powder	No hazard identified though white powders that look the same could be substituted by mistake	Labeling in plant	–	–	Controlled labeling of all ingredients must be in place in the factory
	Packaging	Plastic tubs and film	Plasticizers and additives	SQA	Yes	Supplier testing results	Ensure that product suitability testing has occurred and is documented as complying with legal requirements
Legal	Ingredients/product	Thermal process, and control of recipe	Food safety		Yes	Regulations as per manufacturing country	Check compliance
Recipe/ intrinsic factors	a_w, pH, chemical preservatives, organic acids	None that will control product safety. Insufficient sugar to prevent microbial growth totally	No—product is frozen	–	–	–	–
Process	Process conditions	Pasteurization failure	Survival of vegetative pathogens	Correct heat process	Yes	Required	Ensure that the effectiveness of the heat process is validated for this formulation. Critical limits will need to be established
		Poor temperature control during ageing	Spore outgrowth	Effective temperature control and stock rotation	Yes	Audited on a monthly schedule. Calibrated temperature recording already in place	None

(continued)

Table 5.2 (continued)

Example							
PRODUCT chocolate-chip ice cream			FORMULA			DATE 5-11-96	Page 1 of 4
Stage	Considerations	Criteria	Likely hazard	Control measures	Is control possible?	Validation of control	Recommendations to HACCP team
	Contamination	Air filtration failure	Introduction of pathogens	Effective filtration	Yes	Required	Check filter size and performance criteria. Microbiologically filtered air necessary
Post-factory	Shelf-life	Product consumed beyond shelf-life	No hazard identified	–	–	–	–
	Customer abuse	Temperature abuse	Unlikely—sufficient abuse for growth will render product inedible	–	–	–	–
		Contamination with serving spoon	Unlikely—only low numbers; will not grow in freezer	–	–	–	–
			Slight risk perhaps from leaving serving spoons in water between servings which would be a cross-contamination concern	None possible	No	–	The product is targeted to the domestic market rather than catering; therefore hazards associated with mass servings are unlikely to be realized. Revisit if a "catering" version is launched

Signed: *J. Smith* (Position) Development Manager Date: 21-02-12

5.5 Key Points Summary

As we have seen, food safety design requires that you think about a diverse set of systems, procedures, and resources in order that you achieve both a practical and effective food safety management system. The most effective way of assuring food safety is to design it in. There is some complexity here in achieving an effective and best practice system/operation and it is important that all the elements described above are considered when designing for food safety, or when reviewing effectiveness of the existing product and supporting PRP designs.

- Safe design of products, processes, facilities, and management systems and procedures is essential for delivering safe food products to the consumer.
- Key elements of a Food Safety Program include Safe product/process design, HACCP, and prerequisite programs, supported by a culture of supportive management practices. Careful design and planning are essential to the effectiveness of all these elements.
- Product safety design includes consideration of how recipe formulation can control hazards and this needs to be reviewed when changes to existing products or product range extensions are proposed. Establishment of a safe and achievable shelf-life needs to be achieved as part of product safety design.
- Safe process design needs to be confirmed by validation that the process can control all relevant significant hazards.
- Safe raw materials and knowledge of the safety status of all incoming goods are essential when designing food safety systems and controls.
- A formal and methodical approach to product safety assessment for all food products provides the discipline needed to assure that all products can be managed safely within the framework of the food safety program. This is particularly important for businesses operating modular HACCP systems to ensure that all individual product variants are safe.
- All food processing and handling facilities need to be designed to facilitate hygienic/sanitary conditions. Working together with strong PRPs, these provide the basic foundations needed for the manufacture of safe food.