10 Food Safety and Quality Assurance

Tonya C. Schoenfuss¹ and Janet H. Lillemo²
¹Department of Food Science, University of Minnesota, St Paul, Minnesota, USA
²Lillemo & Associates, LLC, Plymouth, Minnesota, USA

10.1 Introduction

In order to produce safe, high-quality food products, everyone involved with food products needs to understand their role in the process. There are many definitions for product quality, such as conformance to specifications and requirements, and fitness of a product for use. A more inclusive definition goes beyond the “product” to include everything that is involved from acquiring the product to customer service, to meeting the expectations of the customer (Feigenbaum, 1983). With food products, beyond product performance there is the additional expectation that food was produced in a sanitary manner and will be safe to eat. There are fundamental plant and equipment conditions that must be met, followed by programs that are developed to ensure safety and quality that everyone in the organization must understand and follow. Plant sanitation is just one of the programs under a total quality management system, and in modern food production, being in control of production to produce a safe product through a proactive program is a regulatory, customer, and consumer requirement.

This chapter will focus on the subjects most pertinent to producing food under sanitary conditions, and product quality assurance. Specifically, the sanitary design of plants and equipment, and the prerequisite programs important for food safety during processing are covered as well as quality basics.

10.2 Elements of total quality management

Before the advent of the Industrial Revolution, quality was determined by the expertise of the craftsman making the product. The success of their business rested on their ability to produce products the consumer was pleased with for the price paid. There are sectors where this is still the case, such as small producers of artisan products or producers of extremely high-value products. But as manufacturers grow in scale, the inclusion of processes that define the tasks and responsibilities of people making the product become necessary. Additionally, there is no longer the ability to manually examine every individual product that is produced.

The initiation of a system of scientific management of quality can be traced back to the teachings of people such as Frederick Taylor, who introduced the scientific method when evaluating workplace processes involved in quality and production. He advocated that each task should be standardized, workers trained, and job functions divided to maximize efficiency (Knouse et al., 1993). Walter Shewart is credited with the introduction of the control chart, in 1924, that can be used to monitor the variation of any process or quality factor (Best & Neuhauser, 2006). The control chart is instrumental in understanding the variability of a process, when something is “out of control” or irregular, and for optimizing a process to improve economic efficiency and product quality.

The need to produce supplies for the US war effort in the 1940s led to the development of ways to statistically analyze whether lots of products met specifications. The Military Standard 105D was developed by Harold Dodge and Harry Romig at Bell Labs, and the standard consists of tables that let a processor select a sampling plan based on the size of a sample lot, and the risk a manager is willing to take of accepting a lot when it should have been rejected (ASQ, 2013; Fisher & Nair, 2009). The less risk you are willing to accept, the more samples need to be evaluated within a given lot. Examples of these concepts in use are the acceptance sampling tables codified in the United States Code of Federal Regulations.
These are used by the United States Department of Agriculture as part of its grading service (USDA, 2013). The Food and Drug Administration (FDA) uses sampling plans for evaluating microbial hazards, processing compliance and label compliance for net weight and contents. Some standards of identity contain acceptance sampling plans such as Title 21 Part 155 for canned vegetables (FDA, 2013b).

Tools such as control charts and sampling plans go a long way towards improving product quality and consistency, but they do not necessarily lead to continuous improvement. The development of total quality management (TQM), which incorporates improving both the organization and people involved with producing the product, is attributed to the foundational work of both Edward Deming and Joseph Juran (ASQ, 2012). They both recognized that in order to create a quality product, leadership from the top down is critical. Every person involved in the process needs to understand their role in improving the quality of a product, and have the training, tools, and support from top management to continuously improve quality and delight customers. Modern examples of how food companies incorporate these principles can be seen in the applications of the winners of the Malcolm Baldrige Quality Award, administered by the National Institute of Standards and Technology (NIST) under the US Department of Commerce (NIST, 2012). In the manufacturing division, two companies have received the award: Cargill Corporation, twice, for their corn milling and Cargill Kitchen Solutions (formerly Sunny Fresh Foods) divisions, and Nestlé Purina PetCare (NIST, 2012).

The first global quality management system, designed to create a level playing field and enhance international trade, was ISO 9000 (ISO, Geneva, Switzerland). A quality management system specifically for food is ISO 22000, and third-party auditing schemes developed specifically for food production have the additional goal of enhancing food safety. The Global Food Safety Initiative (GFSI) was formed in 2000 by the Consumer Goods Forum (formerly CIES) of large retail conglomerates (such as Wal-Mart, Carrefour and Tesco) with the goal of reducing food safety risks by delivering equivalency between schemes and reducing duplicative audits (and thus reducing costs). They benchmarked third-party audit schemes to establish minimal standards, which were issued in 2007. They reviewed applications from auditing schemes to determine which met the GFSI standards. Once a scheme is GFSI certified, the retailers agree to accept audits from any of the certified schemes (GFSI, 2012). This system has revolutionized food production around the world in that in order to sell a product in any of the major retailers’ stores, firms must pass an audit by one of these schemes.

Compared with the past, where certain Good Manufacturing Practice (GMP) audits were sufficient, much greater level of scrutiny of the programs a plant has in place, in addition to GMPs, is required by the GFSI auditing schemes. Hazard Analysis Critical Control Point (HACCP), until recently a voluntary food safety system for most food producers in the US, is mandatory under these schemes. The result is an increased emphasis on hazard analysis and control, and the development of prerequisite programs and the standard operating procedures and documentation that go along with them. While the effect on food safety remains to be seen, it certainly has placed more attention on quality assurance and food safety by food manufacturers.

All the GFSI management schemes have the following basic requirements, with variations for processed foods and agricultural products.

1. Demonstration of management responsibility and commitment
2. Documented procedures and record control
3. Specifications, testing, and product development procedures
4. Sanitary design of plant and equipment
5. Proactive good manufacturing practices/prerequisite programs that include:
   a. Supplier approval (ingredients and packaging)
   b. Water quality
   c. Personnel:
      i. Hygiene practices
      ii. Processing practices
      iii. Training
   d. Calibration of equipment
   e. Management of pests and vermin
   f. Premises and equipment maintenance
   g. Cleaning and sanitation
   h. Control of physical contaminants
      i. Transport and delivery
      j. Waste management and disposal
   k. Allergen control
6. Food safety plan (HACCP)
7. Product identification and traceability (including organic, Kosher and Halal)
8. Market withdrawal and recall procedures
9. Site security/bioterrorism prevention
10. Product information/consumer awareness
11. Complaint management
In addition to the food safety components, some of the third-party auditing schemes under GFSI, and other, include other topics that are of concern to customers such as sustainability, organics, animal welfare, and fair trading practices. Global GAP (Good Agricultural Practices) is for certifying primary agriculture practices that meet food safety and traceability standards specific for the type of agriculture. Part of the auditing process includes evaluation of responsible water use and management of soil fertility (Global GAP, 2013). There are also additional auditing standards under Global GAP that include animal welfare and social practice (worker health and safety). Other organizations specialize in animal welfare such as the Professional Animal Auditor Certification Organization (PAACO) which certifies third-party auditors for dairy cattle and meat animal production. The USDA now governs organic certification in the US and certifies third-party auditors. Organizations such as Fairtrade USA develop standards to certify that the primary producers of a product are being compensated fairly. Generally, the quality function, if not involved with primary production directly, is involved in supplier approval and auditing and so is involved in these additional activities. Additionally, part of TQM is delighting the customer and these additional assurances about the product can be meaningful to them.

In addition to voluntary auditing of food safety, quality, sustainability, and animal welfare programs, companies that manufacture, hold, or ship food are also subject to regulatory inspections by local, state, and federal regulatory agencies. In general, food service and retail establishments are inspected by local and/or state agencies. Local and state regulatory agencies typically inspect against the FDA Food Code or some modification of it. Manufacturing facilities are inspected by state or federal agencies. At times, state agencies will inspect facilities under contract from a federal agency. At the federal level, the FDA Center for Food Safety and Applied Nutrition (CFSAN) has authority over most food products, under regulations outlined in the Code of Federal Regulations (CFR) Title 21. The US Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS) regulates primarily meat, poultry, and egg products under the jurisdiction of 9CFR.

### 10.3 Hazard Analysis Critical Control Point (HACCP) system

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) defines HACCP as "a systematic approach to the identification, evaluation, and control of food safety hazards" (NACMCF, 1997). HACCP involves a specific process for defining critical parameters about the food, identifying potential hazards, and determining control measures for those hazards that are reasonably likely to occur in the food processing system. It is a risk-based program that focuses on building food safety prevention into the manufacturing process, rather than relying on end-product testing for detecting food safety issues after they occur.

Until recently, HACCP was required by regulation for only meat, poultry, juice, and seafood. With the implementation of the Food Safety Modernization Act (FSMA), HACCP or a similar preventive control program will be required for all facilities that “manufacture, process, pack or hold food and that are required to register with the US Food and Drug Administration (FDA) under section 415 of the FD&C Act,” with a few exceptions for small and very small businesses (FDA, 2013a).

Development of a HACCP plan involves five preliminary steps and seven principles, as shown in Table 10.1. It is imperative, both from a practical level and because of regulatory requirements, that the development of the HACCP plan be led by an individual who is trained in HACCP and its supporting programs. Training is conducted frequently by many independent companies. Other members of the HACCP team should also be trained, although this training may be done internally by the HACCP team leader. A cross-functional approach

<table>
<thead>
<tr>
<th>Preliminary steps</th>
<th>HACCP principles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assemble the HACCP team</td>
<td>Principle 1: Conduct a hazard analysis</td>
</tr>
<tr>
<td>Describe the food and its distribution</td>
<td>Principle 2: Determine critical control points (CCPs)</td>
</tr>
<tr>
<td>Describe the intended use and consumers of the food</td>
<td>Principle 3: Establish critical limits</td>
</tr>
<tr>
<td>Develop a flow diagram which describes the process</td>
<td>Principle 4: Establish monitoring procedures</td>
</tr>
<tr>
<td>Verify the flow diagram</td>
<td>Principle 5: Establish corrective actions</td>
</tr>
<tr>
<td>Principle 6: Establish verification procedures</td>
<td>Principle 7: Establish record-keeping and documentation procedures</td>
</tr>
</tbody>
</table>
with shared responsibility across functions is essential for a fully functioning HACCP plan.

Hazard analysis is the basis on which the HACCP plan is built, but the preliminary steps are necessary to complete a thorough hazard analysis. It is important to have someone knowledgeable in food science and food safety involved in the hazard analysis. Thorough identification of hazards and assessment of their likelihood and severity are essential to developing a plan that ensures the food’s safety. Critical control points (CCPs) are steps in the process where control may be applied, and the step is required to prevent, eliminate or reduce hazards to an acceptable level (NACMCF, 1997). One of the “double-edged swords” of HACCP is that corrective actions are spelled out in advance for CCP deviations (situations where the critical limits are not met and therefore the hazard is not controlled). Since the corrective actions are already defined, there is no “management discretion” in determining the disposition of the affected product. This is good in that it ensures that food safety is non-negotiable; it is difficult because it may mean that a significant amount of product must be either destroyed or reworked, and there is no judgment involved in the decision.

Verification involves two parts: validation that the CCPs actually control the hazard for which they were designed (the plan is effective), and verification that the plan is being followed as designed (the plan is properly implemented and maintained). Verification typically involves a review of documentation and observation of those employees responsible for conducting monitoring activities. Validation requires scientific evidence that hazards are being controlled by the preventive controls, including CCPs. From the proposed preventive control rules for FSMA: “Proposed § 117.150(a)(2) would require that... the validation of preventive controls include collecting and evaluating scientific and technical information or, when such information is not available or is insufficient, conducting studies to determine whether the preventive controls, when properly implemented, will effectively control the hazards that are reasonably likely to occur” (FDA, 2013a). Clearly, scientific and technical knowledge of the product and process is necessary to ensure the HACCP plan successfully controls the hazards; outside experts may be helpful in conducting the validation. One final aspect of verification is a periodic review of the entire food safety plan, including both HACCP and its supporting prerequisite programs.

Prerequisite programs are “procedures, including Good Manufacturing Practices, that address operational conditions providing the foundation for the HACCP system” (NACMCF, 1997). Prerequisite programs create an environment in which safe food processing can occur. Some prerequisite program requirements are defined by regulations, such as Current Good Manufacturing Practice (cGMP), which are spelled out in 21CFR §110 (to be replaced by 21CFR §117 when FSMA goes into effect). Even for regulated prerequisite programs, each company must customize programs to be appropriate for their facilities. Together, prerequisite programs and HACCP represent a firm’s food safety plan.

### 10.4 Sanitary processing conditions

#### 10.4.1 Sanitary design and maintenance of plants and equipment

The Federal Food Drug and Cosmetic Act, Chapter IV, Section 402, specifically defines food as adulterated “if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” Maintaining the grounds, facilities, and equipment in a manner that prevents these conditions is not only a good idea, it is a legal and regulatory requirement for manufacturing foods.

There are many checklists (including in the regulations) that give specific requirements for premises and equipment conditions. Any of the GFSI audit schemes include this information. In general, the surrounding grounds must not have standing water, waste accumulation, or discarded equipment that could attract or harbor pests such as insects, rodents, or birds. Exterior walls, doors, and windows must be sealed so pests cannot access the facility. The food processing area must be physically removed from employee welfare areas such as rest rooms, lunch rooms, and locker rooms to prevent inadvertent contamination of the processing area. In the processing area, the floors, ceilings, walls, and any posts or support beams must be constructed in a way that prevents accumulation of food debris or water, and can be easily cleaned and sanitized. In general, wood and other porous materials are not allowed in the production area. Adequate hand washing sinks must be available and must provide warm water, soap, and a method for drying hands. Utensil washing sinks must be separate from hand washing sinks. Sinks must be labeled so their intended use is clear. Only potable water shall come into contact with food equipment. Condensation, dripping water, and inadequate drains can be a major source of contamination, and must be corrected.
Equipment needs to be constructed in a way that allows for easy disassembly for cleaning and sanitizing. There must not be any dead ends, rough welds, or other areas in the equipment that can allow accumulation of food debris and water. Additionally, the ability of equipment to withstand standard cleaning chemicals is important, not only for the food contact surfaces. Equipment can be easily corroded by cleaning and sanitation chemicals and even if not in direct contact with the food, deteriorated equipment can form niche environments for opportunistic food pathogens such as *Listeria monocytogenes* to survive and grow. Formation of biofilms (sticky films of bacteria that adhere to a surface) can contribute to potential cross-contamination of the food product. Additionally, corroded equipment can pose a physical contaminant hazard.

All equipment should be on a routine maintenance schedule. Documenting when equipment requires emergency maintenance can help to determine the proper maintenance frequency for that piece of equipment. User manuals for the equipment may also list a suggested frequency. Proper standard operating procedures (SOPs) for maintaining equipment are important, and the equipment should be formally handed off to the sanitation group after maintenance and before production resumes. It benefits the company to shut down for routine maintenance, as unscheduled repairs can be highly disruptive to the business.

One aspect of maintenance that is sometimes overlooked is equipment calibration. Some equipment can easily be calibrated by facility personnel (e.g. thermometers, pH meters). For other equipment (e.g. load cells, retorts), it is important to have equipment manufacturers calibrate their equipment on a periodic basis, often annually or as required by regulations.

### 10.4.2 Cleaning and sanitation

Cleaning and sanitation are covered by the regulations in 21CFR 110.35 (21CFR 117.35 after FSMA implementation). Adequate cleaning and sanitation are absolutely essential to maintaining safe, quality food. It is beyond the scope of this book to go into detailed directions for cleaning and sanitation. Proper cleaning and sanitation means that personal protective equipment is used and strict procedures, as outlined by the chemical supplier, are followed by all personnel at all times. Proper cleaning and sanitation will only take place if appropriate cleansers and sanitizers are selected, and specified dwell time, temperature, mechanical action, and concentration are followed. Any deviation can lead to either inadequate level of chemical action or chemical degradation, or both. For questions as to the best procedures for specific manufacturing equipment and environments, cleaning/sanitation chemical companies and state extension services are good sources of advice.

In general, the processing environment and equipment should be maintained in a clean and sanitary condition. Also, cleaning and sanitation activities should be conducted in a way that does not endanger or contaminate the food, equipment, or environment. Alkaline cleansers are effective in removal of organic soils, while acid cleansers are effective for removal of inorganic soils. Concentrations of cleaning and sanitizing chemicals should be tested for each batch of manually mixed systems, or on a daily basis for automatically mixed systems, to ensure they are within effective and safe levels. Evaluation of water quality on a monthly basis is important, as water quality influences chemical action. Proper dilution is important to the efficacy of some sanitation chemicals. While the tendency may be to think that more is better, in some cases using stronger solutions of chemicals than recommended may render the solution ineffective and/or corrosive.

Periodic housekeeping during production, such as wiping down dust and sweeping floors, will go a long way towards maintaining a clean working environment. There is an old saying in food manufacturing: “if you have time to lean, you have time to clean.” All employees should clean their areas when time is available. It is also essential that employees wash hands and replace gloves after handling cleaning tools and before touching food contact surfaces or food products.

Surfaces must be clean prior to sanitizing. Sanitizers do not work if there is organic matter on the surface to be sanitized. This applies to floors and drains as well as food and non-food contact equipment. Pouring sanitizer down a drain full of debris does not effectively control microbial growth in the drain.

Validation and verification of cleaning and sanitation methods of food contact surfaces are important for assuring that the methods are effective. There are many different methods used: visual inspection, ATP swabs, protein swabs, and microbiological swabbing. Use care when choosing which method to use. For example, it is usually unwise to swab for pathogens on food contact surfaces, especially for *Listeria monocytogenes* (*L. mono*), for non-ready-to-eat foods or foods that do not support its growth. There is no acceptable regulatory limit of *L. mono* on food contact surfaces. More information on microbiological testing is given in the upcoming section on environmental testing.
10.4.3 Personnel practices

Personnel practices are regulated in the US as part of the Good Manufacturing Practices, 21CFR 110.10 (to be replaced by 21CFR 117.10 when FSMA is implemented). The purpose of personnel practices is to prevent contamination of the food or the environment by employees.

Employees who are ill or who have open sores, infected wounds, or other sources of microbial contamination that could potentially contaminate food, food contact surfaces, or packaging must be excluded from working in food areas until the health issue is resolved. Minor cuts or injuries should be covered by an appropriate bandage. Bandages used in processing areas are typically colored blue, to be visible in the food, and are metal detectable.

Employees must maintain cleanliness when working in a food environment. Steps to be taken to achieve proper cleanliness include good personal hygiene; protective clothing; proper hand washing and glove use; removing jewelry; wearing hair restraints; refraining from eating, drinking, chewing gum, or smoking in processing areas; storing personal items and clothing in an area separate from the processing area; and avoiding contamination of food with perspiration, medicine, cologne or perfume, lotions, and other cosmetics.

One of the most common findings in warning letters from regulatory agencies is improper hand washing or glove use. Hands must be washed and gloves changed after use of the restroom. Hands must be washed or gloves changed after touching non-food contact surfaces such as cleaning utensils, pens, garbage, pallet jacks, or items that have been on the floor. In addition, hands must be washed or gloves changed after touching one’s hair or face, scratching one’s arm, etc. Gloves can give workers a false sense of security. If gloves are dirty or damaged, they need to be replaced. Removed disposable gloves should always be discarded, and never reused.

Employees and visitors must be trained in proper personnel practices, and supervisors should reinforce these rules and retrain as necessary.

10.4.4 Transportation and storage

Transportation and storage can play a significant role in the safety and quality of foods. Proper temperature control, pest control, allergen segregation, and lot code traceability aid in maintaining food safety during storage and transportation.

In 2005, Congress passed the Sanitary Food Transportation Act, but rule making was not initiated by the FDA until 2010, and proposed regulations have not yet been published. However, general guidance was issued in 2010 to assist food and transportation companies (FDA, 2010a). Despite the absence of specific regulatory directives, food companies are still responsible for food safety and security during the entire supply chain, including transportation.

Prior to loading a truck carrying raw materials or finished products, the truck should be inspected thoroughly to identify any conditions that could affect the safety or quality of the food. Employees should look for holes in the trailer that could allow access of pests, insects, rodent excreta, dirt, and debris such as pallet wood. Employees should check for unusual odors. For less-than-full load (LTL) trucks, be alert to the presence of chemicals or items already on the truck that could contaminate the food product. The author has rejected trucks containing new tires and pesticides due to the presence of strong odors that could have permeated the pallets of dry bakery mix that were being shipped, as well as a truck with scattered dog food and a water bowl in the back of the truck (the driver’s dog was living in the trailer). Record the results of the inspection for future reference. Shipment content, quantities, and associated lot codes should be included on the shipping documentation.

Before receiving a load, inspect the truck for the same issues as noted above. Pallets holding food product should be in good condition, and the load should not have shifted or damaged packages during shipment. The inspector should check to verify that the quantity and lot codes on the shipping documentation match the actual content of the load. Report any discrepancies or sanitation issues to the transportation company prior to accepting the load.

For refrigerated and frozen loads, the actual temperature of the trailer and food should be checked and documented upon receipt and before shipping to ensure the temperature is within the required range. Refrigerated foods should be no more than 5 °C (41 °F) although the maximum temperature is 7 °C (45 °F) in refrigerated products governed by the Grade A Pasteurized Milk Ordinance (FDA, 2011a). Foods shipped frozen should still be frozen upon receipt (US Public Health Service and FDA, 2013).

Bulk load and full truckload shipments should be sealed upon loading and the seal numbers recorded on the shipment documentation (e.g. bill of lading). Prior to unloading the shipment, seal numbers should be verified against the numbers on the documentation to determine if the seals have been removed during shipment. The inspector should reject loads with missing or changed seals.
Rail cars should be similarly sealed and inspected. It is common during the warm summer months to fumigate rail cars containing grain products, such as flour, during transportation with pesticides to prevent infestation with storage insects. Trained personnel should remove and discard the fumigant and allow for proper aeration of the rail car prior to unloading. Regulatory jurisdiction of the use of the fumigant chemicals is granted to the Environmental Protection Agency in the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food Drug and Cosmetics Act, and modified by the Food Quality Protection Act of 1996 (Public Law 104–170, 1996).

Shippers of bulk tanker loads should provide information on previous loads carried in the tanker, as well as wash tickets to show that the tanker was clean and compatible with the current product prior to loading. Bulk tankers should also be inspected thoroughly to identify unsanitary conditions or evidence of off-odors or previous loads. As with all food safety processes, inspections should be documented.

Ideally, LTL loads should be secured either by seals or a padlock between stops. This is, however, very difficult to enforce, as the driver can affix the seal or lock just before arrival at the dock.

Once a load is received, it should be stored properly to reduce the risk of temperature abuse or cross-contamination. Each pallet should be labeled with the material name and identification code, lot code, receiving date, and allergen content. Storage racks should be off the floor and far enough away from the walls to allow for sanitation and inspection activities. Dangerous chemicals should not be stored over food materials. If a package is damaged, it should be discarded and the pallet restacked. All dry materials should be inspected once per month to identify any issues with storage insects. Materials should be used on a first in-first out basis. Raw materials and products that are on hold should be segregated and secured to prevent inadvertent introduction into the supply chain.

Allergen-containing raw materials and finished products that have the potential to spill should be stored below non-allergen containing materials to reduce the risk of cross-contact. The rule for allergen storage is “same over same, less over more” – that is, only store materials containing the same allergens over other allergen-containing materials, and store materials with more allergens below materials with less. For example, a product with soy and wheat could be stored over a product with soy, wheat and egg, but they could not be inverted because there would be a chance of egg contamination onto the soy/wheat product. Remember that individual allergens need to be treated separately; there is not just one category of “allergens.” Individual tree nuts should be stored separately to prevent cross-contact.

### 10.4.5 Control of physical contaminants

Recalls from foreign materials are unusual, accounting for only 1.3% of all recalls in 2010 through 2012 (FDA Foods and Veterinary Medicine Program, 2013). Most incidents of physical contaminants are detected and removed in the manufacturing process, or are individual incidents involving only one consumer. Whatever the frequency or severity, the presence of physical contaminants in finished products is always a consumer issue, as well as a regulatory non-conformance.

When considering physical contaminants, one must differentiate between natural and unavoidable defects that do not pose a threat to humans and foreign matter introduced from the growing, harvesting, processing, packaging, storage or transportation environment. The latter includes such things as mold, insect or rodent damage, or preharvest infestation, and the FDA has established defect action levels for specific commodities because “it is economically impractical to grow, harvest, or process raw products that are totally free of non-hazardous, naturally occurring, unavoidable defects” (FDA, 2011b). Defect action levels are not average, allowable or acceptable levels; they “represent limits at which FDA will regard the food product adulterated; and subject to enforcement action under Section 402(a)(3) of the Food, Drug, and Cosmetics Act” (FDA, 2011b). Consider fresh, frozen, or canned cherries. Defect action levels are established for rot and insect filth, but not for cherry pits. Cherry pits have the potential to be hazardous, while rot and insect filth are simply aesthetic defects.

The supplier approval program may include a requirement that raw material suppliers include proper foreign material control practices in their manufacturing process. For raw materials that are prone to physical contaminants (such as shells in nuts or pits in cherries), it is common to require suppliers to conduct a formal inspection of the raw material prior to shipment, and to report the absence or presence and level of foreign matter in a Certificate of Analysis (COA). The COA should be compared for compliance to the product specification prior to receipt of the raw material. The receiving facility may also choose to sample and inspect the raw material to verify the content of the COA. Shipments of raw materials with foreign matter levels exceeding the product specification should be rejected.
The FSMA will require that, as part of the HACCP plan development, an assessment is conducted to identify physical hazards from raw materials and processing steps, and control measures are identified to prevent, eliminate, or reduce these hazards to an acceptable level (FDA, 2013a). There are many ways to accomplish this. Good manufacturing practices such as inspection of raw materials upon receipt, preoperational inspections of equipment and the operating environment, restrictions of glass and brittle plastics in production areas, rules for proper utensil selection and usage, and proper equipment maintenance go a long way towards preventing introduction of foreign materials into the product stream.

Foreign material may be detected and removed by a variety of equipment, such as metal detectors, magnets, filters and screens, cyclones or water tanks, destoners, X-ray machines, or other optical scanner or visual control systems (GMA, 2008). Metal detectors are the most common foreign material detection/removal devices. It is critical to place metal detectors as late in the process as possible, preferably after packaging, so as to detect and remove any metal contamination introduced by the production equipment itself. Procedures for validating, calibrating, verifying, and establishing corrective actions, should the metal detector fail to detect test probes, and documenting testing actions, should all be included in the HACCP plan.

10.4.6 Pest control

Pests are any organisms that should not be in food or food plants, and include such things as rodents, insects, birds, weeds, and microorganisms. 21CFR 110.35 c states that no pests shall be allowed in any area of a food plant, and that effective measures shall be taken to exclude them from the premises to protect against contamination. A good pest control plan includes multiple strategies to maintain sanitation, such as inspecting for evidence of pests, identifying them, implementing control procedures, and monitoring the effectiveness of the method. It must be a written plan that allows for monitoring and continuous improvement practices when deficiencies are found. Because of chemicals that may be required to effectively control pests, licensed contractors are often employed to help develop and implement a control system.

First and foremost, the food facility should be designed and maintained so as to not attract pests, and to exclude their entry. The facility grounds and premises should be kept free of waste material and clutter, and a clean weed-free perimeter maintained so that no nesting of rodents can occur on the sides of the building. Access points into the plant such as doors should be self-closing and fly-proofed with methods such as air curtains. The door should have a metal threshold and be flush with the entryway so rodents cannot get under the door. Mice are able to enter through a hole as small as a quarter of an inch. In areas with fork-lift traffic into warehouses, especially in grain facilities, rodent exclusion thresholds can help. When designing facilities, the ability to easily use alternative treatments, such as heat, to kill insects should be incorporated. Warehouses and racking systems should always be installed with an 18 inch perimeter, and with pallets off the floor, to allow for inspection around and underneath for signs of infestation.

In order to monitor and control pests, traps and bait stations are often used. Because of the dangerous chemicals used, bait stations should only be employed outside the food processing facility along the perimeter of the building. They kill rodents, and are used to monitor the level of activity. Chemical sprays are used within facilities to control insects like cockroaches, but the chemicals and the concentrations allowed are regulated (by the Environmental Protection Agency – EPA), so a licensed applicator must be used.

10.4.7 Water quality

Water is used in many ways during food processing, such as:

- for irrigation of crops
- for postharvest cooling of fruits and vegetables
- as a flume for transport of fruits and vegetables
- as an ingredient to rehydrate other ingredients or standardize a formula
- as a heating or cooling medium (either in direct contact with food or indirectly)
- rinsing, cleaning, and sanitation
- for hand washing and other sanitary functions.

The foremost concern with regard to water is its role in food safety. The quality attributes of water (flavor, pH, mineral composition, etc.) and the composition and amount of waste water from a facility are also important to food processors.

Drinking water from municipal sources that is generally considered safe has been a source of contamination and has led to outbreaks such as the 1993 Cryptosporidium incident that affected approximately 400,000 people and led to 100 deaths (CDC, 1997). Pathogens such as the hepatitis A virus from fecal contamination, as well as
nitrates and environmental pollutants such as arsenic, are a concern in well water. In the US, the Safe Drinking Water Act of 1974 is the law responsible for ensuring safety of water supplies serving 25 people or more, and is administered by the United States EPA; the regulations are found mainly in 40 CFR part 141. In 2008, organisms such as Salmonella, E. coli O157:H7, Shigella, Campylobacter and Legionella led to 16 disease outbreaks affecting 1672 people and three deaths in the US (CDC, 2013). New concerns are for “emerging contaminants” that are not removed by traditional municipal water treatments and are found in drinking water that, while not at toxic levels, present health concerns (EPA, 2013; Lapworth et al., 2012). These include:

- endocrine-disrupting compounds
- surfactants (from cleaning agents)
- hormones (from the animal industry and urine, especially from women on birth control – estrogen and estradiol)
- pesticides
- phthalates (plasticizers in plastics, used in inks and cosmetics)
- perfluoro-octane sulfonate (PFOS), a chemical used in fabric protectors.

Additionally, food plants contribute some of these chemicals to the aquatic environment in the form of waste water. This is also regulated by the EPA and local agencies. Quite often, plants need to be designed to mitigate the discharge of water that is untreated and need to conduct activities to adjust the pH, and reduce the chemical and biological oxygen demand. Many of the endocrine active compounds found in drinking water are the result of agricultural and food processing activities (Lundgren & Novak, 2009).

10.4.8 Allergens

Approximately 6–8% of children and 2% of adults have food allergies (NIAID, 2003). Allergic reactions to food can be life threatening. According to the FDA, approximately 150 people die from allergic reactions to food each year (FDA, 2010b). Clearly, it is imperative that food and ingredient manufacturers prevent the inadvertent introduction of undeclared allergens in their food.

In the year two report of the Reportable Food Registry (FDA Foods and Veterinary Medicine Program, 2012), the FDA noted that approximately one-third of recalls were due to undeclared allergens. Bakery items, frozen foods, and snack foods were most likely to contain undeclared allergens.

Allergen control needs a multifaceted approach to be successful. Equipment and the facility should be designed to be easily cleaned; this will aid in preventing allergen cross-contact between formulas with incompatible allergens. Air handling systems should be designed to prevent cross-contact from air-borne dust. Formulas should be developed to avoid allergens, if at all possible. Production should be scheduled so that non-allergen containing products are run before allergen-containing products. As described above, storage practices must prevent inadvertent cross-contact. Cleaning procedures should be validated to ensure that they remove allergens if followed diligently.

Labeling should be verified so that all allergens in the product are declared on the label, according to regulatory requirements. Label control includes two important processes: ensuring the ingredient statement and allergen statement on the label are accurate for the current formula of the product, and ensuring the proper, current label is affixed to the packaging.

Finally, consumer reports of allergic reactions should be taken seriously and investigated thoroughly to determine if product should be recalled, and to identify and resolve the root cause of failures in the allergen control system.

10.4.9 Environmental testing

In addition to verifying the effectiveness of cleaning food contact and non-food contact surfaces, the processing environment should also be monitored for environmental pathogens. There have been numerous food safety outbreaks in recent years where environmental pathogens have contaminated ready-to-eat products (FDA, 2013a).

Increased emphasis by regulatory agencies is being placed on environmental testing plans and proper corrective actions when contamination is discovered. Recalls have been initiated from only environmental pathogen contamination, not confirmed product contamination. The FSMA will not specifically require environmental testing as part of the preventive controls section (FDA, 2013a). However, it is essential that facilities, especially those producing ready-to-eat foods, have a robust environmental testing program.

Philosophies on environmental testing have changed over the past 5–10 years. It used to be that facilities were pleased if their environmental swabs came back negative; they recorded the information and filed it away for the next time. Now, emphasis is on using the environmental testing program to learn more about the production
environment, to seek out any potential microbial problems, and to solve them. In general, wet clean areas are swabbed for *Listeria* and dry clean areas for *Salmonella*.

The Grocery Manufacturers Association (GMA) has published a guide for controlling *Salmonella* in low-moisture foods, and this document contains excellent advice on developing an environmental program for dry cleaning environments (GMA, 2009). The principles presented can be adapted for wet cleaning environments as well. A four-zone approach is recommended, where Zone 1 represents food contact surfaces, Zone 2 represents non-product surfaces close to Zone 1, Zone 3 is in the processing area but more removed from the product contact surfaces, and Zone 4 is outside the processing area (such as locker rooms, storage rooms, labs). The GMA recommends increased sampling for *Salmonella* in the zone closest to product contact surfaces (Zone 2). Non-product contact surfaces such as Zone 2 or 3 should be tested during normal operating conditions, as swabbing after sanitation does not give good information about the operating environment, only about sanitation techniques. Food contact surfaces (Zone 1) should only be swabbed for indicator organisms such as aerobic plate counts or Enterobacteriaceae, not pathogens, unless there are special circumstances such as suspected product contamination. Before deciding to swab Zone 1, it is wise to determine what actions will be taken should a positive result be found. Swabbing sites should be randomly chosen or chosen on a rotating basis.

Corrective actions in the case of positive results should be spelled out for each zone before swabbing takes place. Root cause analysis, increased cleaning, sanitation, and swabbing are recommended until the environment consistently tests free of contamination. The GMA document includes detailed recommendations on corrective actions.

### 10.5 Supporting Prerequisite Programs

#### 10.5.1 Supplier Approval

In 2007, the FDA reiterated to food manufacturers that they are responsible for the safety of the ingredients and packaging materials they use in the production of their food products. Manufacturers have a responsibility to their customers, their consumers, their shareholders, and the public at large to ensure they are using the safest, highest quality raw materials available. Many large food companies have hundreds, if not thousands, of raw materials from an equally large number of supplier facilities. Most companies do not have the personnel or financial resources to inspect every supplier on a frequency that would guarantee that raw materials are consistently safe. Therefore, companies need to develop a risk-based approach to assessing the safety of their suppliers and raw materials.

A necessary component of a risk-based supplier quality system is the risk assessment process. There are many risk assessment tools available, but most include analysis of a combination of severity and likelihood/probability of risk. The Operational Risk Management (ORM) process, developed by the US Air Force for evaluating risk of military operations (Phillips, 1997), can be easily adapted to raw material and supplier risk. A common quality tool, Failure Modes and Effects Analysis (FMEA), can also be used for assessing the risk of suppliers or raw materials. FMEA includes not only severity and occurrence (likelihood), but also a rating of detection (Tague, 2005). Whatever risk assessment method is used, it is beneficial to choose one that provides a numerical ranking to the risks, allowing the user to prioritize actions based on the material or supplier’s risk level.

At the raw material level, risk factors to assess include the raw material’s inherent food safety risk, the importance of the ingredient to the product’s functionality, and the strategic sourcing risk (including the material’s availability and market conditions). At the supplier level, risk may include past complaints and how the supplier handled them, or responsiveness to shipping issues (e.g. incomplete orders, wrong products shipped, or incorrect receiving temperature).

Once the overall risk level is determined, supplier approval or periodic assessment activities can be based on the risk level. For example, all extremely high-risk suppliers may be audited by a company auditor, all high-risk suppliers required to be GFSI certified, all medium-risk suppliers required to complete a supplier questionnaire, and all low-risk suppliers required to only provide raw material specifications and other documentation. If a supplier provides multiple raw materials at different risk levels, it would be prudent to assign assessment activities based on the highest risk level.

The contribution of third-party audits and certification, such as GFSI, to this process should not be underestimated. Auditing by company personnel is expensive. Requiring third-party food safety certification allows the company to review the audit report, identify any deficiencies of concern, and address these issues with the supplier without the time and expense of an on-site audit. Do
keep in mind, however, that the audit represents only a snapshot in time. Most companies dedicate a significant amount of resources to getting prepared for third-party audits, which are usually scheduled in advance, so these reports represent the best possible situation.

Section 307 of the FSMA sets forth a process for accreditation of third-party auditors to ensure minimum requirements and performance management standards are met; however, since this section is included in Title III of the law, which covers improving the safety of imported food, it is yet unclear whether or not the accreditation requirement will apply to auditors of domestic entities as well as foreign entities (Public Law 111-353, 2011).

It is common to ask all suppliers for basic documentation, regardless of their risk level. Typical documentation requirements include product specifications, allergen information, nutritional values, lot code, shelf life, and storage information, technical and emergency contact information, and Kosher/Halal/organic certificates, if appropriate. Companies usually also require legal documents such as a letter of continuing guarantee, a signed statement saying that the supplier will not change the raw material without advance warning, evidence of liability insurance, and a signed statement agreeing to comply with the company’s supplier requirements.

A supplier questionnaire, which collects information about the supplier’s food safety programs and practices, may also be required. The questionnaire may identify areas of concern that require further investigation. It is helpful to tell the suppliers that the questionnaire is a pre-audit activity, and that completing it thoroughly may prevent an on-site audit. This increases the probability of thorough, honest responses. A signature should be required stating that the information provided in the questionnaire is true and accurate.

Once a decision is made to approve a new supplier, providing a periodic assessment of the supplier’s performance can be beneficial for both the company and the supplier. A balanced scorecard can be developed that focuses on whatever is most important to the company. The scorecard might include complaint rates, documentation status (complete/incomplete), timeliness in responding to issues, and shipping errors. Periodic assessment activities based on supplier/raw material risk should also be conducted to assure current and accurate information is on file.

Unfortunately, all supplier quality programs must include a process to disapprove or delist an existing supplier due to non-compliance or food safety issues. This process should be spelled out thoroughly and communicated both within the company and to suppliers. When a situation arises, no one should be surprised by the disapproval or delisting process. This process should include a cross-functional discussion of the implications of this action.

### 10.5.2 Complaint management

Complaints are not necessarily a bad thing. Complaints give insight into where a company’s quality and food safety systems fail and into what consumers want and expect from their food products. Companies that analyze and track complaints, and have a robust program for root cause analysis and corrective action, take advantage of the information provided from complaints to improve their products and processes.

Complaint tracking and analysis can vary greatly depending on the size and kind of company. A large international consumer packaged foods company could receive over a million consumer contacts a year. A small wholesale business might only receive one or two complaints a month. Obviously, the approach to addressing complaints in these two companies will be different.

In the consumer foods company, a consumer relations or customer service department will have sole responsibility for responding to consumer calls and emails. The consumer communication is mostly about resolving the consumer’s dissatisfaction to increase the probability of future sales. This group will also record critical information about the product and issue to allow trending and statistical analysis of similar complaints by the quality assurance team.

The small wholesale company will work one on one with the customer to solve a complaint issue, often including a visit to the customer’s business. These visits are made by a sales representative, a technical service person, or a research and development or quality assurance employee. This type of communication is very different from the large consumer foods company. In this situation, the visit is about solving the specific problem the customer is experiencing, and may involve hands-on laboratory or plant work. The two situations are similar, though, in that both provide an opportunity to satisfy the consumer or customer, retain their business, and learn more about how products are performing in the marketplace.

For serious complaints involving foreign material, illness, injury, or allergic reaction, it is common to involve the company’s risk management department or insurance company. These groups are best equipped to handle the liability risk to the company. If complaint analysis identifies trends in serious complaints, the company may need to conduct a market withdrawal or recall of the implicated product.
10.5.3 Market withdrawal and recall plan

If a company identifies issues from complaints, from internal testing, or from regulatory interventions that put the public health at risk, it has a legal and moral responsibility to remedy the situation.

Every company that manufacturers, holds, or ships food should develop a recall manual. Development of this plan in advance of an actual incident is critical. During an emergency, a company does not have time to search for information on how to conduct a recall. As with food safety plans, a recall plan needs to be developed and managed by a cross-functional team. The recall manual should list roles and responsibilities for recall team members, as well as emergency contact information for all key employees and their back-ups, for customers and suppliers, and for local/state/federal regulatory agencies.

The FDA website provides resources that should be included in the recall manual, including detailed lists of recall information to compile, sample press releases, and even sample recall and effectiveness check letters to send to customers. (FDA, 2011c). Another important resource on the FDA website is the contact information for the District Recall Co-ordinators. As soon as a company suspects that it may need to conduct a recall, the District Recall Co-ordinator should be contacted. They are well equipped to guide companies through the recall process.

The company’s internal recall team should conduct mock recall drills at least once a year to ensure that all contact information is current and that everyone understands their role and responsibilities.

Specific actions to include during a food safety incident depend on the severity of the situation. The FDA (2009) classifies recalls according to the following definitions.

- **Class I recall**: a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.

- **Class II recall**: a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

- **Class III recall**: a situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.

- **Market withdrawal**: occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

USDA definitions are similar, with the exception that they do not define market withdrawals (USDA, 2011).

- **Class I**: involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death.

- **Class II**: involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food.

- **Class III**: involves a situation in which eating the food will not cause adverse health consequences.

In general, for FDA-regulated recalls, press releases are issued in the case of Class I recalls. For USDA-regulated recalls, press releases are issued for Class I and Class II recalls (USDA, 2011). State requirements vary. The regulatory agency working with individual companies on the recall will guide them.

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA), which established the Reportable Food Registry (RFR) (FDA, 2010c). The purpose of the RFR is to track food safety incidents to identify trends and better allocate limited regulatory resources. Food companies are required to report food safety incidents that meet the definition of a “reportable food,” which basically matches the definition of a Class I recall. The RFR is an electronic portal that allows consistent reporting of incidents. The food company is required to submit the report as soon as possible, but not longer than 24 hours after determining that the food is reportable (FDA, 2010c).

The FSMA grants the FDA significant increases in regulatory power. The FDA is now able to mandate recalls and revoke the registration of facilities that do not comply (FDA, 2013a). Prior to the FSMA, the FDA could only recommend that firms recall dangerous product, and seize the product if the firm refused. The FSMA also requires companies to have recall programs. The USDA does not have the authority to mandate recalls, but can seize product in commerce (USDA, 2011).

### 10.5.4 Traceability

In the case of a recall, one of the most important pieces of information required by the regulatory agencies is the list of consignees – the customers, distribution centers, or stores that received the violative product. The Bioterrorism Act 2002 requires that FDA-regulated companies record and be able to retrieve within 24 hours of request a list of all previous non-transporter sources and subsequent non-transporter recipients of food that the FDA
has reasonable suspicion to believe is adulterated (FDA, 2004). In order to fulfill this requirement, firms need to have proper traceability of all incoming raw materials and outgoing finished products. Traceability must include the following elements for the previous source or subsequent recipient (FDA, 2004).

- The contact information for the immediate non-transporter source or recipient,
- including their company name, address, telephone number, fax number and email
- address, if available.
- Specific variety, brand name, quantity and type of package for the raw material or food.
- Date received or released.
- The same contact information as above for the immediate transporter previous source or subsequent recipient.
- Lot code information of raw materials linked to finished products, linked to customer shipments.

During a recall, regulatory agencies expect food companies to account for the entire quantity of the affected lot of raw material received, whether it is still on hand in the warehouse, has been used to manufacture finished product, was discarded, was used for testing, or was subsequently distributed as a raw material. A full mass balance of material coming in, material still on hand, material used, and material going out for these various uses is required. In order to do this, companies must track lot codes throughout the supply chain from initial receipt to subsequent disposition, including which customers received finished product lots containing the raw material in question. The firm has 24 hours from the time of the regulatory agency request to provide the data. This requires a fool-proof system of record keeping.

Electronic lot code tracking systems reduce the amount of time and increase the accuracy and speed of compiling the data. Lot code tracking also facilitates problem solving and quality improvement. As noted above, information from complaints allows trend and root cause analysis. Tying a lot code from a complaint product back to the finished product batch and, if necessary, the raw materials used to make that batch can be very helpful in solving quality and food safety issues.

### 10.6 Product quality assurance

It should be obvious that in order to be successful, food companies must produce safe food that meets regulatory requirements. However, product quality is also essential for earning repeat business and sustaining growth. Consumers expect food to taste and look good, to maintain its quality throughout its shelf life, and to perform as expected. Food manufacturers can use a similar approach to quality as they do for food safety: create a risk-based preventive program. The same basic process and steps used in HACCP can be used to create the quality plan.

Quality “hazards” should be identified and once again, they should include biological, chemical, and physical factors. For biological risks, non-pathogenic bacteria, yeast, and molds can affect product quality and reduce shelf life, and should be controlled in the manufacturing process. For example, lactic acid bacteria can produce sour flavors and create performance issues in dairy products and frozen or refrigerated bakery batters. For chemical risks, manufacturing processes must be controlled so that chemical reactions occur at the proper time and at the proper reaction rate. For example, chemical leavening in a cake batter relies on proper batter temperature, mixing time, and batter holding time so that the leavening produces carbon dioxide during the proper stage of baking, making the cake rise once the starch has set so the cake does not fall. Frozen vegetables must be blanched and cooled prior to freezing to inactivate enzymes that could result in off-flavors, colors, or textures. Physical risks may include factors such as excessive sheer, incorrect particle size distribution or striation, dry ingredient bridging, or unwanted physical phase changes. Food scientists and engineers should identify these undesirable effects and determine where and how to control them in the manufacturing process. Again, as with food safety control, the focus should be on building quality into the process (quality assurance) rather than attempting to test finished product for adherence to specifications (quality control).

However, in-process and finished product testing are fundamental for assuring that critical quality attributes have been met. For example, the performance of the product can be evaluated by baking tests (i.e. dry baking mixes) or by viscosity measurements (i.e. yogurt, fillings, etc.). For microbial quality, coliform testing is a standard practice to monitor sanitary quality, but other tests such as total aerobic plate count or yeast and mold counts would be advised. Putting products in abusive storage conditions to evaluate if mold growth or swollen containers occur can help predict if shelf life will be achieved. Ensuring that products meet sensory specifications requires a sensory program in which trained tasters evaluate products post manufacture or at the end of shelf life. These programs are critical to catch sensory defects due to factors such as incorrect dosing of ingredients, improper processing conditions, and ingredient lot variation. These tests are
not designed to be “test and release” – they are for monitoring to ensure customer satisfaction.

It is beyond the scope of this chapter to cover all aspects of quality assurance, and the reader is directed to books on the subject for more information (Luning & Marcelis, 2009; Vasconcellos, 2004).

### 10.7 Conclusion

Producing safe, high-quality food does not happen by accident. It depends on a commitment from all employees at all levels to develop and consistently implement processes to ensure food is being produced in a safe environment with a focus on building safety and quality into the process. As regulatory requirements become more demanding, as science discovers new risks, as industry develops new methods for ensuring safe and quality food, and as consumers become even more selective about what they eat, food manufacturers will need to continually improve their food safety and quality systems. After all, the goal is to keep consumers safe and pleased with the products, and to protect the company’s reputation.

### References


