Current Food Industry
Good Manufacturing Practices

Prepared by the CGMP Coalition  August 19, 2011

Scope of Principles and Practices to Supplement Existing Regulatory Requirements
DISCLAIMER

The recommended principles and practices contained herein are intended as guidelines, not standards or requirements. Every company must determine which practices are most effective and appropriate for the products that it manufactures and/or distributes. This guidance document is not intended as, and should not substitute for, legal advice. Companies should consult their own legal counsel to ensure compliance with applicable laws and regulations. The companies and organizations that have developed these guidelines do not warrant that they will ensure that the products they or their members manufacture and/or distribute are safe, wholesome, or correctly labeled, and they expressly disclaim any such warranties.

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SCOPE

Background

The Current Good Manufacturing Practices (CGMP) Coalition was founded in 2004 when it began working with the Food and Drug Administration (FDA) to move forward with revising the existing Current Good Manufacturing Practices ("cGMPs") (21 CFR 110). The Coalition is comprised of over 60 food industry companies and trade associations. Representing leaders from throughout the food industry, the Coalition has a strong interest in the development of sound and effective revisions to the cGMPs.

The cGMPs have formed the basis for safety assurance programs in food manufacturing, packing and holding facilities, and have been very effective to date. Given the emergence of new food safety concerns and the development of new technologies for addressing these concerns, the Coalition supports FDA’s efforts to update and revise the food cGMPs. In doing so, we urge the agency to build upon and enhance the existing regulations, which should continue to serve as foundational, prerequisite conditions for producing safe food.

This document presents the industry’s current thinking with regard to several topics that are already addressed by FDA and U.S. Department of Agriculture (USDA) regulations, and several topics that are not currently addressed. These topics include: employee training, environmental pathogen monitoring, sanitation, allergen control and temperature monitoring/control. The principles, practices and recommendations described herein are intended to be used as a supplement to the existing cGMP requirements prescribed by both agencies. And, because they are intended to be voluntary, they should be interpreted and applied in a way to provide companies sufficient flexibility to tailor their food safety assurance programs as appropriate to their unique products, processes, and the size of the processing operations and company, like the cGMPs.

Summary of Principles and Recommendations

Employee Training. Proper and adequate employee training is absolutely essential for GMP implementation. Without effective training, safe production of foods is jeopardized. The approach companies may take for training on GMPs is to work in partnership with industry, academia and government so that issues remain current and data are relevant and up-to-date. GMPs for training should focus less on providing specific content and standards and rather assure that the knowledge and expertise necessary to produce safe food products is provided to supervisors and workers in a manner appropriate for the intended audience. The training content, comprehension and attendance should be documented.

Environmental Monitoring. Development of a comprehensive and effective food facility environmental monitoring program for potential foodborne pathogens plays an important role in the production of refrigerated and frozen ready-to-eat foods
(including ready-to-serve) and low moisture foods. Such programs will help ensure that hazardous microorganisms are not transferred from floors, drains, equipment, etc., into the product stream by finding real or potential pathogen harborage sites and thus allowing a better understanding of the microbial environment and how well the organisms are controlled through cleaning and sanitation. The program for environmental monitoring of pathogens should include listing of objectives, monitoring and verification procedures, a corrective action process, a root cause analysis and preventive action process, and recordkeeping and review.

Sanitation Practices. Sanitation is another essential component of any food safety program, needed to help ensure that the food production environment and equipment are free from pathogens and other unwanted microorganisms that could potentially contaminate the product. In order to maintain good sanitation practices, sanitation programs should be written and include the sanitation objective, sanitizing procedures, schedules, monitoring programs, corrective action processes and documentation.

Allergen Management. Some individuals are highly sensitive to certain foods or ingredients in foods and can develop serious allergic reactions after consuming products containing these allergens. Milk and egg protein, shellfish and peanuts are a few examples. Therefore, companies should maintain allergen management programs to prevent unintentional inclusion of these allergens in products. In cases where strict control is not possible and there is a reasonable chance that a product may be cross-contaminated during production, storage or distribution, allergen warning statements should be used according to FDA regulation. Key personnel should have specific training and there may be a need for some degree of segregation of food allergens in facilities. In order to help control allergens, validation of cleaning procedures, prevention of cross contact, and product label review and usage may be necessary. Supplier control programs for ingredients and labels should also be developed.

Temperature Monitoring. Temperature monitoring is critical for controlling the growth, multiplication and, in some cases, toxin production of microorganisms in some products, under certain conditions. Companies should determine the relevance of temperature control for their specific products and validate specific temperatures used in manufacturing, storage and distribution of food by referencing applicable regulatory and/or nationally recognized documents or valid scientific research. Accurate temperature monitoring devices and equipment, as well as adequate recordkeeping, are also essential for the control of microorganisms.
**EMPLOYEE TRAINING**

**Introduction**

For many years, the food handling and processing industries have demonstrated a long-held and established practice of training staff and employees to ensure food safety and protect product integrity. There are many well known, highly respected food safety training programs and workshops available across the country where handlers and processors can learn the latest advancements and scientific information available concerning existing and emerging food safety issues. These training programs and workshops are offered by universities, trade associations, consultants, government agencies, third party audit/educational companies, and other allied professional and trade organizations, as well as by the companies themselves. They feature participation by subject matter experts and others well known as experts within their chosen fields. They offer excellent opportunities for firms in train-the-trainer mode to learn the latest information relating to food safety, transfer that learning into improved programs and systems within their own firms, and build the necessary improvements into their internal food protection programs.

For decades, food processors have used and refined this information to develop and deliver cost effective in-house training programs. While the current GMPs recommend training of food handlers and supervisors to assure the necessary level of competency to produce safe food, the vast majority of food processors have established a well-developed training culture to assure reliable and consistent execution of food safety programs and systems. In many companies, food safety training has been integrated into existing training programs, such as quality, system operation, or human safety training, as a means of making the overall training experience more complete, well-rounded, and cost effective. Well-developed, coordinated, in-house training programs have long been recognized as a key element in successfully assuring a safe food supply. Although much of the guidance provided in this section may be more relevant to group training, one-on-one, individualized training can also play a key role in employee development and should not be overlooked.

While training may be targeted to food handlers and supervisors, experience has shown it must also include the training of new hires, seasonal workers, contractors, maintenance employees, transportation workers, office and support employees, and literally everyone who is involved with the processing/packaging facility, food materials, and production system. The depth of detail included in the training will necessarily be dependent on the degree of interaction with specific food materials and processes, as determined by the facility, and also depend on the job duties of the person(s) being trained.

This emphasis on employee training to achieve the necessary level of food protection continues to be a key element of achieving customer and consumer
satisfaction, as well as regulatory compliance, and will continue in importance due to recurring, as well as future trends:

- Changes continue to occur within facility staffing levels and line accountability. For efficiency and quality reasons, modern work systems now include sanitation and food safety expectations for line operators since they are vital, integrated elements to effective line/system performance. As a result, food safety and sanitation are integrated into work processes and instruction as part of operator line and system ownership.
- Shortened supply chains, combined with the global aspects of food distribution, make food safety and sanitation losses within the supply chains unacceptable. As a result, a culture of heightened food safety awareness has created a need to prevent potential disruptions within these distribution networks. One key component necessary to prevent these damaging disruptions is through effective supervisor/employee training programs.
- New issues and regulations continue to emerge requiring new learning, which in turn leads to development and implementation of new programs and procedures and the demonstrated skills to execute them. Newer issues, such as allergens, food defense, and newly recognized microbial risks, all challenge the status quo and require firms to upgrade their knowledge, assess training gaps, and deliver improved training programs to effectively deal with these new business demands.

The overall purposes of training are many, including improving the transfer and application of knowledge to all employees, changing behaviors, reinforcing proper behaviors and creating a sustainable facility culture, which enables the workforce to consistently execute well-designed food safety systems. The purpose of training programs is to achieve a clearly-defined goal or objective related to the skill sets necessary to produce a specific desired end result. Training programs that are effective are custom-designed to the educational level and language skills of the targeted employee population. There are several steps that need to be implemented in the development of cost-effective training programs, as shown in the process map below.
Training Process Map

Continuous Improvement

Identify Training Objectives
- Identify level of training
- Identify training needed
- Identify desired outcomes and behaviors

Develop and Prepare Content
- Review course content
- Create course objectives
- Develop outline
- Determine delivery mode
- Revise / Create materials
- Schedule sessions
- Identify attendees & target audience
- Prepare materials and aids
- Coordinate technical needs / supplies

Content Delivery
- Lecture
- Role play and simulation
- Computer assisted instruction
- Program learning
- Audio visual methods
- Job qualification / rotation
- Hands on Methods

Evaluation
- Measurement – written test, participation, attendance register, problem solving, hands on demonstration, etc.
- Verification of working knowledge, direct observation, participation, implementation etc.

Trending Results
- Build / maintain data
- Track
- Trend
- Reporting
Identify Training Objectives

A first step in training development involves assessment of training gaps. While there are other means of determining these gaps, for example, from observation or feedback related to current performance, many companies use the Job Task Analysis tool to determine what needs to be known, as well as the depth of detail required, for each job level across the facility operation. While there are staff/employees who need to demonstrate an expert level of knowledge on a particular topic, others may only need to be highly proficient or even generally aware of the issue involved. For example, while the team leaders and operators may need to know about handling allergens, including specific steps necessary to remove allergen components from a process/packaging system, the employees in distribution or transportation may only need to be aware of the general issues surrounding allergens through the distribution network.

Levels of training detail and depth necessary for specific jobs and tasks can be classified as follows:

<table>
<thead>
<tr>
<th>Competency Level</th>
<th>Competency Level Expectations and Attributes</th>
</tr>
</thead>
</table>
| Expert           | • Individuals who possess detailed knowledge, training, experience, and understanding of the target area, including:  
  • Fundamental principles  
  • Science and technical aspects  
  • Consumer and regulatory aspects and implications.  
  • Individuals demonstrate their expertise through their previous training and ability to:  
    • Develop policies and standards  
    • Lead training initiatives  
    • Develop verification and validation procedures  
    • Advise the company in the targeted area.  
  Examples of positions at this level would be employees with accountability for technical leadership in areas of Food Safety, Quality and Sanitation, such as a Quality Manager or HACCP Coordinator. |
| Proficient       | • Individuals who understand the key principles and company policies in the target area and demonstrate their ability to:  
  • Monitor / audit operations for compliance  
  • Guide and train others in targeted operations/activities  
  • Lead corrective action processes  
  • Develop procedures for implementation and consistent execution of expected practices in their functional area  
  • Lead execution of verification and validation activities  
  Examples of positions at this level could be plant managers, production managers, supervisors or leaders. Also, production workers who are engaged in critical work streams focused on the target operation, such as HACCP CCP monitoring, microbiological sample collection or allergen sanitation may need training to this level. HACCP Team members would also typically be at this level. |
### Competency Level Expectations and Attributes

#### Application
- Individuals who understand the general principles of the targeted area and demonstrate their knowledge and ability in focused work activities:
  - Compliance with practices and procedures
  - Awareness of company policies
  - Conduct monitoring and reporting
  - Support correction action procedures
  - Share knowledge with co-workers

Examples of positions at this level are typically general production workers engaged in the targeted operation/activity, transportation/warehouse personnel and maintenance workers.

#### Awareness
- Individuals who are not directly engaged in the operations/activities, but may interact with operations on some periodic basis and demonstrate an understanding of the company practices required for compliance when this interaction is necessary. These individuals should be provided guidance to understand where and when compliance is required.

Examples of positions at this level are typically facility office staff, external visitors, etc.

The CGMP Coalition Employee Training Working Group recommends training for two major classes of food production personnel: plant managers/supervisors and food production workers. While the list of necessary training topics has to be determined by company need, the following is a list covering the majority of relevant training topics, but it is not an all-inclusive content outline for training programs. Training may be structured in a train-the-trainer format to assist supervisors and managers in training of food production workers. This format allows smaller processors the ability to minimize training costs to the operation. It also allows all processors flexibility in tailoring training to their operation and food sector. See Appendix D at the end of this section for a suggested training matrix.

### Supervisors, Managers

Supervisors and managers in food production plants should be trained to expert / proficient level in principles of:

- food hygiene
- food protection
- cross contamination prevention including microbiological and allergen
- personal hygiene
- food defense

### Food Production Workers

Food production workers, defined for the purposes of this document as those workers having direct contact with the food product and/or product contact surfaces, should be trained to the level required by the job task analysis on:

- basic principles of food hygiene
- food protection
- cross contamination prevention
- personal hygiene
- basic principles of HACCP
<table>
<thead>
<tr>
<th>Supervisors, Managers</th>
<th>Food Production Workers</th>
</tr>
</thead>
<tbody>
<tr>
<td>• sanitary design: food safety hazards associated with equipment design and facility</td>
<td>• mandatory regulatory HACCP requirements (where applicable)</td>
</tr>
<tr>
<td>construction, including utilities and pest control</td>
<td>• cleaning and sanitization/disinfection</td>
</tr>
<tr>
<td>• advanced principles of HACCP</td>
<td></td>
</tr>
<tr>
<td>• mandatory regulatory HACCP requirements (where applicable)</td>
<td></td>
</tr>
<tr>
<td>• cleaning and sanitization/disinfection</td>
<td></td>
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<tr>
<td>• maintenance and sanitation monitoring effectiveness</td>
<td></td>
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<tr>
<td>• management of purchased goods</td>
<td></td>
</tr>
<tr>
<td>• control of non-conforming product</td>
<td></td>
</tr>
<tr>
<td>• corrective action</td>
<td></td>
</tr>
<tr>
<td>• training knowledge</td>
<td></td>
</tr>
<tr>
<td>• expectations of the supervisory role including microbiological and allergen</td>
<td></td>
</tr>
<tr>
<td>management</td>
<td></td>
</tr>
</tbody>
</table>

Transportation and Warehouse workers should be trained in food safety aspects of bulk conveyance and containers, including food defense, cross contamination prevention, personal hygiene, and food hygiene.

Maintenance workers should be trained in basic principles of food hygiene, food protection, personal hygiene, basic principles of HACCP, food safety hazards associated with equipment design and facility construction (i.e. “sanitary design”), including utilities and pest control, and maintenance and sanitation monitoring effectiveness.

While there are substantial benefits to general training across all areas, it is recognized there may be practical limitations, especially in operations with temporary employment or frequent turnover. In some cases group training may be appropriate and in others individual instruction can be more practical and effective. In all cases, the employees should be trained at a minimum in those areas described that are directly related to the employees function. The depth of training should be commensurate with the employee’s exposure to the product. Training of food production workers should be administered at new hire orientation, with refresher training conducted at least annually, and may be provided by supervisory personnel. It should be designed to be readily understandable by all personnel.

**Develop and Prepare Content**

Personnel training should be based upon the company’s documented plans for assuring the necessary level of food protection, as determined by the product and
process system, for example, by including training programs such as sanitation, allergen control, control of foreign materials, pest management, personal hygiene/operational practices and environmental pathogen plans, as developed by the company and appropriate to their circumstances. Certain processes may require more in-depth training for specific job functions. For example, thermal process facilities should continue to have training requirements for individuals running retorts and performing records verification; dairy facilities should have individuals trained in the details of pasteurization and dairy standards; all facilities should have specific individuals with in-depth training on selection and use of proper cleaning and sanitation products for their applications. Universities, trade associations or qualified supplier programs can conduct this specific training in a cost-effective manner.

**Content Delivery**

There are two broad types of in-house training that are typically applied by food manufacturing facilities: off-the-job and on-the-job training. Off-the-job-training is characteristically employed by removing the employees from the work environment with sessions held in a class room setting. It is more formal and may utilize a trainer or other audio-visual / computer method to disseminate information. On-the-job training is usually conducted in the actual work environment and typically involves direct observation of a task by both the employee and the trainer accompanied by hands-on or practical demonstration.

In many cases, in-house training is the responsibility of plant management, supervision and employees. Plant trainers should be competent to effectively conduct training and possess a basic awareness of how adults learn and how best to communicate with them.

Since adults are generally the target of these training activities, it needs to be recognized not all adults learn in the same ways. Research studies have shown there are three basic learning styles, each requiring differing training delivery systems for maximum learning, skill development and retention:

- Visual learners need ‘to see’ something to know it. This group benefits from visuals, written directions, graphics, illustrations, props, flowcharts, etc.
- Auditory learners prefer to receive information by ‘hearing it.’ This group benefits from discussions, tapes, lectures, question and answer panels, and interactive role play, for example.
- Kinesthetic learners prefer hands-on training so they can ‘do it’ to know it. This group benefits from being physically and actively involved, engaged with hands-on activities, model making, role plays, etc.

Since training can come and be tailored to fit in many forms, and since the target audience will consist of various learning styles, it is important to use a variety of training styles and approaches to maximize learning and impact. Most manufacturers employ some—if not all—of the following modes of delivery:
- Lecture
- Role-play and simulation
- Computer-assisted instruction
- Programmed learning
- Audio / visual methods
- Job qualification / rotation
- Hands-on methods

A number of factors should be considered when deciding on the appropriate mode of delivery in order to provide the audience with the most effective transfer of knowledge. Appendix A contains a chart from Bersin & Associates’ Media Selection Guide, which highlights various criteria to be considered.

The following is a breakdown of how off-the-job and on-the-job training may be utilized, both formally and informally, in a manufacturing facility.

**Formal Training**

- New Hire Orientation
  - May be conducted in a class room setting and may include a plant tour of the area the employee will be working in. Includes an in-depth introduction to food safety procedures in visual, audio and written format to accommodate all learning types.
    - Evaluation – written test, completion of all appropriate paperwork
    - Verification – demonstration of knowledge gained during orientation during first day(s) work in the facility

- Scheduled Annual Training and Refresher Training
  - May be conducted in a class room setting utilizing a trainer or computer generated curriculum. Includes a deep dive into current food safety procedures at least once a year and generally is applied to all employees. Material typically covers plant specific information depending on audience.
    - Evaluation – written test
    - Verification – passing score on test and direct observation of proficiency

- Train-the-Trainer
  - Subject Matter Expert (SME) conducts knowledge exchange to other employees that show aptitude in training peers and subordinates. May be conducted in a class room setting utilizing appropriate methods (lecture, computer, audio/visual, etc.). This type of training is typically done to provide consistency to delivery and content and to provide enough trainers for large facilities or across multiple facilities.
    - Evaluation – written test, participation, hands-on-demonstration
    - Verification – direct observation (training session surveillance, role-playing exercises, etc.)
- **Workshops/Seminars/Conferences**
  - May be brought in-house, but typically attended outside the facility or company. Offered through training organizations, universities, industry trade groups, working groups, etc. May cover a wide variety of subjects and offer the opportunity to network and ask questions of Subject Matter Experts (SMEs).
    - Evaluation – attendance register, testing
    - Verification – application of knowledge

- **Plant-to-Plant Training**
  - Employees from one facility will travel to another facility to share key learnings and practices. Formal training may consist of classroom followed by hands-on. Typically involves installation of new equipment, new software, new technology, transfer of products, etc.
    - Evaluation – attendance
    - Verification – active participation and demonstrated application of knowledge/skills

- **Employee-to-Employee Training**
  - Formal ‘Buddy’ or mentoring system that may be set up for new hires to work with a seasoned employee or for a transferred employee to pair up with an employee that is familiar with department standards/expectations. Involves information exchange and expertise sharing between employees.
    - Evaluation – participation
    - Verification – effective application of key learnings, hands-on-demonstration

- **Kaizen or problem solving exercises**
  - Formal session involving all levels of plant employee (management, supervision, hourly) across all applicable functional areas to work together to discern root cause and corrective actions to an area of manufacture where challenges exist.
    - Evaluation – root cause problem solving is documented
    - Standard Work Instruction is modified as needed
    - Verification – improvements are measured, tracked and trended

- **Corporate sponsored/conducted**
  - Includes training sessions, such as an annual meeting of all management levels, from a multi-plant company where best practices, new procedures, technologies, changes to regulation, industry news, etc., are communicated.
    - Evaluation – attendance, testing
    - Verification – dissemination and application of information at the manufacturing facility

- **Supplier-conducted training**
  - Suppliers of raw materials (ingredients, processing aids, packaging) or equipment (manufacturing, laboratory, etc.) provide training for
applicable plant employees. May include in plant hands on type training, supplier plant visits for knowledge exchange, classroom training or other applicable method to teach employees.

- Evaluation – attendance
- Verification – demonstrated ability to perform task subsequent to training

- **Contractor training**
  - Formal training provided for all contractors that may impact operations on the necessary food safety policies and procedures in effect at a manufacturing facility. Typically occurs initially and then on an annual basis. May be held for all contractors or as a train-the-trainer session, depending on level of complexity and number of contractors being utilized.
    - Evaluation – all contractors must physically attend training and sign-off on ability to meet the standards, written testing as necessary
    - Verification – direct observation that all contractors are following the policies and procedures

- **Plant meetings**
  - Held as regularly occurring or special occasion. Plant management/supervisors should meet with all employees on all shifts to offer important communications to impart knowledge, expectations, or reinforce behaviors or skills.
    - Evaluation – attendance
    - Verification – improved demonstrated behaviors/skills

**Informal Training**

- **Supervisor-directed during operations**
  - Direction given to employees by supervisor during the normal course of a day.

- **Huddle/team/line meetings**
  - Typically a short meeting with supervisory and line/area employees to discuss challenges or change in direction relevant to the operation of the line/area during that day’s production.

- **Departmental meetings**
  - Conducted by each department in a manufacturing facility for all employees.

- **Shift change meetings**
  - Hand off that occurs between shift workers when one shift has completed its time and provides information to the next set of workers that will take over the operation.
- Coaching
  - May occur in relation to a problem or issue, or when preparing an employee to move to a higher level of responsibility.

- Job qualification
  - Jobs within a facility need to have qualified individuals to complete the tasks assigned. Job qualification typically requires some type of test or apprentice type program.

- Corrective action
  - When deviations occur, training may occur if the initial training was not well understood or if a change to process or procedure is required.

- Product reviews
  - Review of products produced with line personnel offer a visual method of training.

- Employee to Employee Training
  - Informal sharing of information between co-workers.

Following any training program, it is important to recognize the critical role direct supervisor follow-up and reinforcement plays in producing lasting knowledge retention, skill implementation and behavior modification. Studies have shown this level of immediate and consistent reinforcement of the training content and message is the most important aspect of producing a lasting positive result from the training activities. Arranging and planning for this interactive, direct follow-up and reinforcement should be an established part of training program development and delivery.

**Evaluation**

Evaluations are an important part of the training process flow through verifying and measuring the understanding and implementation of training activities. Evaluation can be defined as a tangible method of determining that training not only occurred, but was well-understood by the trainees. Although there are different methods of evaluating training, a record of training activities with documentation maintained, where appropriate, is the usual mode. It is important to note the continuing trend toward use of some form of testing, e.g. written or proficiency demonstration, to prove the trainees actually absorbed and understood the training content. Depending on the delivery method, appropriate testing can involve quizzes such as true-false, multiple choice, fill-in-the-blanks, essay answers, actual hands-on demonstrations or other methods to gauge the depth of trainee understanding. These forms of evaluation are increasingly being viewed as proof an impactful training event occurred and are an important part of training program documentation.

Verification, on the other hand, is a way to determine whether the attendees in a training session not only learned what the facilitator intended for them to learn, but also measures the degree to which the material is being actively implemented.
Verification measures whether or not the targeted knowledge is being retained, improved skills are being used, and/or desired behaviors are being demonstrated, thus measuring whether the training objectives were met. Ongoing verification activity serves as confirmation that participants have acquired the required knowledge and skills to carry out their job functions, as well as identifies what may be needed to support further implementation. If, after training, the desired skills or behavior are not being demonstrated, additional evaluation should determine whether additional remedial training may be necessary, or whether improved performance could be achieved through improved follow-up, or it was actually a performance issue, or related to some other non-training factor. Verification methods should be designed to measure change in the participants’ knowledge, attitudes, skills, and behaviors over time, related to implementation of the specific competencies targeted for improvement.

While the standard methods of using attendance, or attendance in combination with some form of written testing format, have become the common evaluation methods, demonstrated learning through hands-on demonstration can present difficulties in documenting the acquisition and retention of new skills. This is particularly important in evaluation of task- or equipment-specific training where one-on-one training events, conducted by experienced employees who have recognized expertise on a system, operational step, or set of procedures, are used to train other employees. As shown in Appendix C at the end of this section, there are acceptable methods of documentation that can be used to measure and verify a trainee has learned, understood, and is able to demonstrate to the trainer the required skill sets involved. These forms of documentation are particularly important in verification of knowledge and skills for line operators, sanitation workers and others directly involved with the product handling, processing or packaging systems where hands-on-demonstrations verify expected mastery of the skills necessary to safely, successfully and consistently interact with the materials and systems.

**Trending Results**

Tracking and trending results over time allow for continuous improvement of any training process and may be employed where feasible and appropriate. Employees who are not benefiting from the exchange of knowledge can be identified and remediated (i.e. retrained). It also makes possible the identification of other non-training factors as reasons for a lack of performance or refusal to change. Not all performance issues are necessarily related to a lack of training. It may well be a lack of implementation is related to follow-up and reinforcement, work system or some other employee or personnel situation. In any event, if it is related to gaps in the training content or delivery system, any ineffective training can be quickly identified, course content modified and delivery / facilitation method reviewed and improved.
## Appendix A

### Selecting Training Mode of Delivery

<table>
<thead>
<tr>
<th>Media Type</th>
<th>Instruction Value</th>
<th>Scalability</th>
<th>Time to Develop</th>
<th>Cost to Develop</th>
<th>Cost to Deploy</th>
<th>Assessment Capable</th>
<th>Trackable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classroom Training</td>
<td>High</td>
<td>Low</td>
<td>3-6 weeks</td>
<td>Medium</td>
<td>High</td>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>WBT Courseware</td>
<td>High</td>
<td>High</td>
<td>4-20 weeks</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>CD ROM Courseware</td>
<td>High</td>
<td>High</td>
<td>6-20 weeks</td>
<td>High</td>
<td>Medium</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Conference Calls</td>
<td>Low</td>
<td>Medium</td>
<td>0-2 weeks</td>
<td>High</td>
<td>Medium</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Webinars</td>
<td>Medium</td>
<td>Medium</td>
<td>3-6 weeks</td>
<td>Low</td>
<td>Medium</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Software/Simulations</td>
<td>Very High</td>
<td>Medium</td>
<td>8-20 weeks</td>
<td>High</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Lab Class Simulations</td>
<td>Very High</td>
<td>Low</td>
<td>3-6 weeks</td>
<td>High</td>
<td>High</td>
<td>Medium</td>
<td>Medium</td>
</tr>
<tr>
<td>Job Aids/Checklists</td>
<td>Low</td>
<td>High</td>
<td>0-3 weeks</td>
<td>Low</td>
<td>Low</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Web Pages</td>
<td>Low</td>
<td>High</td>
<td>1-8 weeks</td>
<td>Low</td>
<td>Low</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Mentors/Tutors</td>
<td>Medium</td>
<td>Low</td>
<td>2-3 weeks</td>
<td>High</td>
<td>Very High</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Chat-Discussion Services</td>
<td>Medium</td>
<td>Medium</td>
<td>4-6 weeks</td>
<td>Medium</td>
<td>Medium</td>
<td>None</td>
<td>Low</td>
</tr>
<tr>
<td>Video (VCR or online)</td>
<td>High</td>
<td>Medium</td>
<td>6-20 weeks</td>
<td>High</td>
<td>High</td>
<td>None</td>
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<td>EPSS Systems</td>
<td>Medium</td>
<td>Medium</td>
<td>8-20 weeks</td>
<td>Medium</td>
<td>Medium</td>
<td>None</td>
<td>Medium</td>
</tr>
</tbody>
</table>

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Appendix B
Checklist for Developing Effective Employee Training

Define Outcome
☐ Meet with management to discuss needs
☐ Define training results

Design the Training
☐ Select mode of training
☐ Select location and time required
☐ Develop course materials
☐ Request managers schedule attendees to attend the course
☐ Build in a variety of engaging activities

Deliver for Application
☐ Incorporate relevant job-related information and examples
☐ Add case studies or other job-related activities
☐ Build in time for participants to review what they are learning
☐ Include a method of verification and validation
☐ Communicate expectations for application and follow-through

Drive Follow-Through
☐ End training with brief summary of subject and expected outcomes
☐ Schedule department leader to kick-off the training if possible
☐ Contact participants after training to remind them of key points
☐ Set specific activities for validation as appropriate
☐ Communicate progress to participants’ managers
☐ Develop and offer refresher courses and / or materials

Deploy Active Support
☐ Involve managers in the training process before the course
☐ Plan and carry-out instructor communications to participants post-training
☐ Post course-related materials for easy review by attendees

Document Results
☐ Define results in business terms before training
☐ Compare actual results with expected results
☐ Provide additional assistance to unsuccessful learners
☐ Follow up with managers to see what behaviors have changed
☐ Share results
Appendix C
Hands-On-Demonstration Training Documentation

Dept., Line, Equipment: ________________
Duty-Step: ________________

Hands-On-Demonstration: Duty-Step

**Tools:** [Only if special tools are required.]

**Safety Equipment:** [Specify any necessary to job or task.]

**Date:**

<table>
<thead>
<tr>
<th>Task Step</th>
<th>Satisfactory Performance</th>
<th>Evaluation Criteria</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td></td>
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<tr>
<td>2.</td>
<td></td>
<td></td>
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<td>3.</td>
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<td>4.</td>
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<td>5.</td>
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<td>6.</td>
<td></td>
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<tr>
<td>7.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comments:**

__________________________________________________________________
__________________________________________________________________
__________________________________________________________________
__________________________________________________________________
__________________________________________________________________

**Signatures:**

Evaluator: ___________________________________________  Trainee: ___________________________________________

Management Coordinator: ___________________________  Team Training Coordinator: ___________________________
Appendix D
Suggested Food Safety Training Matrix

<table>
<thead>
<tr>
<th>Training Matrix</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Production</strong></td>
<td>• Environmental hygiene</td>
</tr>
<tr>
<td>(includes those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing)</td>
<td>• Hygienic production of food sources</td>
</tr>
<tr>
<td></td>
<td>• Handling, storage, and transport</td>
</tr>
<tr>
<td></td>
<td>• Cleaning, maintenance</td>
</tr>
<tr>
<td></td>
<td>• Personnel hygiene</td>
</tr>
<tr>
<td><strong>Food Processing Establishment:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Sanitary Design and Facility Construction</strong></td>
<td>• Location</td>
</tr>
<tr>
<td></td>
<td>• Premises and Rooms</td>
</tr>
<tr>
<td></td>
<td>▪ Design and layout</td>
</tr>
<tr>
<td></td>
<td>▪ Internal structures and fittings</td>
</tr>
<tr>
<td></td>
<td>• Equipment</td>
</tr>
<tr>
<td></td>
<td>• Food control and monitoring equipment</td>
</tr>
<tr>
<td></td>
<td>• Containers for waste and inedible substances</td>
</tr>
<tr>
<td></td>
<td>• Sanitary design of facilities &amp; equipment</td>
</tr>
<tr>
<td></td>
<td>• Water supply</td>
</tr>
<tr>
<td></td>
<td>• Drainage and waste control</td>
</tr>
<tr>
<td></td>
<td>• Cleaning facilities</td>
</tr>
<tr>
<td></td>
<td>• Personnel hygiene facilities and toilets</td>
</tr>
<tr>
<td></td>
<td>• Temperature control</td>
</tr>
<tr>
<td></td>
<td>• Air quality and ventilation</td>
</tr>
<tr>
<td></td>
<td>• Lighting</td>
</tr>
<tr>
<td></td>
<td>• Storage</td>
</tr>
<tr>
<td></td>
<td>• Construction</td>
</tr>
<tr>
<td></td>
<td>• Maintaining a controlled environment during construction</td>
</tr>
<tr>
<td></td>
<td>• Maintaining a sanitary environment of neighboring productions lines</td>
</tr>
<tr>
<td></td>
<td>• Pest Control</td>
</tr>
</tbody>
</table>
# Training Matrix

## Control of Food Safety Hazards in Food Production and Processing
- **Food Safety Awareness**
- **Biological, Chemical, Physical hazards and sources**
- **Hazard Analysis and Critical Control Point (HACCP) Systems**
  - Basic principles and advanced topics
- **Validation, verification, monitoring**
- **Mandatory regulatory requirements (as applicable)**
- **Food Hygiene Control Systems**
- **Time and temperature control, as necessary**
- **Processing steps**
  - Microbiological and other specifications
    - Product monitoring
    - Environmental monitoring
    - Microbiological control programs & strategies
- **Incoming material expectations**
- **Ingredient and Finished Product Specifications and requirements**
  - Inspection
  - Testing
  - Packaging
  - Water
  - Food contact
  - Ice and steam
- **Cross-contamination sources, potential**
- **Labeling (cooking instructions, allergen statements, etc.)**
- **Allergen control procedures (written per Food Allergen Controls Workgroup guidelines, company-generated as necessary by the presence of any listed allergenic ingredients/products)**
- **Documentation and records**
- **Crisis Management & Recall procedures**
- **Food Defense**

## Food Processing Establishment: Maintenance and Sanitation
- **Hygienic practices during operation**
- **Maintenance and cleaning**
  - Preventative Maintenance
  - Sanitation During and Following Repairs
- **Pest control systems**
  - Preventing access
  - Harborage and infestation
  - Eradication, Monitoring and Detection
- **Waste management**
- **Sanitation procedures**
- **Monitoring Effectiveness of Sanitation & Maintenance**

## Food Processing Establishment: Personal Hygiene
- **Personnel**
  - Employee health status & illness procedure
  - Footwear, Clothing, Hair covering
  - Hand washing & Glove Usage
  - Injuries, wound management, and hygiene procedures
  - Inappropriate behavior (smoking, eating, coughing, etc.)
  - Jewelry
- **Visitors & Contractors Procedures**
<table>
<thead>
<tr>
<th>Training Matrix</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transportation</strong></td>
<td>• General Protection of Food Conveyance, Containers</td>
</tr>
<tr>
<td></td>
<td>• Design and Construction for Bulk Conveyance</td>
</tr>
<tr>
<td></td>
<td>• Use and maintenance of transportation conveyances and</td>
</tr>
<tr>
<td></td>
<td>containers</td>
</tr>
<tr>
<td></td>
<td>• Food Defense</td>
</tr>
<tr>
<td><strong>Training Organization</strong></td>
<td>• Training fundamentals</td>
</tr>
<tr>
<td></td>
<td>▪ Designing message to be readily understandable to personnel</td>
</tr>
<tr>
<td></td>
<td>▪ Language hurdles</td>
</tr>
<tr>
<td></td>
<td>• Instruction during supervision</td>
</tr>
<tr>
<td></td>
<td>• Refresher training</td>
</tr>
<tr>
<td></td>
<td>• Supervisory training</td>
</tr>
<tr>
<td></td>
<td>• Food production worker training</td>
</tr>
<tr>
<td></td>
<td>• New Hire Training</td>
</tr>
<tr>
<td></td>
<td>• Documentation</td>
</tr>
<tr>
<td></td>
<td>• Assessment</td>
</tr>
<tr>
<td></td>
<td>• Trending</td>
</tr>
</tbody>
</table>
ENVIRONMENTAL MONITORING

The purpose of an environmental monitoring program (EMP) is to evaluate the effectiveness of hygienic zoning practices, sanitation and other cGMP controls utilized in food manufacturing areas to prevent contamination of the finished product. EMPs should be implemented in cases where the food being produced has the potential to support the growth and/or survival of pathogenic microorganisms. Routine monitoring is conducted to detect potential pathogen harborage or growth areas. Examples include, *Listeria spp.* (indicator of possible presence of the pathogen) or *Listeria monocytogenes* monitoring in refrigerated and frozen ready-to-eat (RTE) (including ready-to-serve) foods and *Salmonella* monitoring in low-moisture foods. If a target organism is detected during routine monitoring, investigational sampling is conducted to direct corrective action and to verify that corrective action was effective. A well-designed and executed environmental monitoring program will allow for the proactive correction of deficiencies (e.g., escalation steps for repeat positives) and thus reduce opportunities for product cross-contamination from the environment, in turn minimizing public health risk.

1. Each food producer should perform a risk assessment that incorporates the following considerations in order to determine pathogen(s) of concern:
   a. Product characteristics\(^{11,16}\) (e.g., water activity (\(a_w\)), pH, formulation – intrinsic compounds, antimicrobial substances) and other relevant extrinsic factors (e.g., aseptic filling/packaging, storage conditions, etc.) that could impact pathogen survival or growth.
   b. Processes within the manufacturing facility having the potential to reduce or increase a biological hazard (e.g., heat processing, cooling/freezing, the degree of handling or exposure of the product between a lethal step or a process without a lethal step and final packaging, etc.).
   c. The way the product is expected to be handled, used or consumed after it leaves the manufacturing facility (e.g., distribution, consumer handling, and alternative use).
   d. Identify the pathogen(s) of concern, for example, *Listeria monocytogenes* in refrigerated or frozen ready-to-eat (including ready-to-serve) products and *Salmonella* in low moisture products (\(a_w\) below 0.85).

2. Food producers should consider examining the history of foodborne illnesses associated with the type of product produced or related products (e.g., listeriosis with luncheon meats\(^{10}\), salmonellosis with peanuts\(^{15}\) and peanut butter, with intrinsic factors preventing *Salmonella* growth but allowing its survival in finished product). The risk assessment should identify where proper controls are needed to reduce/mitigate the potential for post-processing contamination and whether an EMP is necessary to verify the adequacy and proper functioning of these controls.\(^{1,4,5,11,16}\)
Product category examples and recommended monitoring practices include, but are not limited to:

a. Manufacturers of processed, refrigerated or frozen ready-to-eat (including ready-to-serve) products that are exposed to the manufacturing environment before packaging should monitor for *Listeria* spp. or *Listeria monocytogenes* to verify sanitary equipment design, sanitation practices (see Sanitation Practices section of this document), segregation of raw processing areas from post lethal step areas, employee practices, etc.\(^{16,20}\)

b. Manufacturers of low-moisture products (aw below 0.85) that have been determined through the risk assessment process to be a potential public health risk for *Salmonella* contamination should institute an environmental monitoring program for *Salmonella* to verify this organism is being adequately controlled in the post-lethality environment, as well as verifying the programs mentioned above.\(^{1,4,5,11}\)

c. Manufacturers of sensitive ingredients used in powdered infant formula products should monitor for the presence of *Salmonella* and/or *Cronobacter (Enterobacter) sakazakii* to verify the controls mentioned above.\(^6\)

3. Environmental testing for aerobic plate counts (APC), total plate counts (TPC), coliforms, *Enterobacteriaceae*, yeast and mold, etc., can be of great value as an indication of plant hygiene\(^9\) and assists with monitoring the effectiveness of the sanitation procedures or the level of contamination during processing. Detection does not necessarily indicate the presence of pathogens such as *L. monocytogenes* and *Salmonella*. Non-pathogen environmental monitoring can include sampling and testing of clean and/or operational equipment, room air, compressed air, plant water, hands and clothing.

4. EMPs should be product, process and plant-specific. In developing environmental monitoring programs, food processors should consider the type of product manufactured, likelihood of pathogen survival and/or growth in the product, history of association with known pathogens, the building design, traffic control, equipment design, and handling of exposed product.

5. Environmental monitoring plans should utilize a risk-based approach\(^{1,4,5,7,8,11}\) in determining which components, such as sampling, testing, corrective actions, root cause analysis, and long term preventive actions, may be used to verify the effectiveness of the pathogen control programs.

**Key elements of an EMP written plan might include:**

- Target organism
- Sampling location, frequency & method
- Test result acceptance criteria
- Applicable products or processes
- Testing methodology
- Corrective action plans, including increased control procedures and verification requirements
6. It is recommended that food producers adopt the product zoning definitions for sampling the plant environment based on proximity to equipment as outlined in the Grocery Manufacturers Association’s documents on controlling *Salmonella* in low moisture foods\textsuperscript{4,5,11}, the Almond Board of California PEM document\textsuperscript{1}, the International Commission on Microbiological Specifications for Foods\textsuperscript{8} and other published articles and trade association training courses on environmental sampling\textsuperscript{2,12,13}. Product contact, near product contact, non-product contact surfaces within a line or room area, and non-product contact surfaces outside of the room should be used to facilitate program development, provide focus to appropriate sampling areas, and direct appropriate corrective actions\textsuperscript{1,4,5,11}.

7. Site specific sampling locations and number of samples to be collected are dependent upon the product produced, plant structure, equipment design, traffic patterns and previous findings to aggressively identify potential harborage sites. For raw, unprocessed products or raw processing areas (e.g., raw meat, poultry, fish, cocoa beans, and unpasteurized milk) sampling is not required since contamination would be expected in these areas, but may be included where applicable. Sample site locations should be audited and changed on a periodic basis.

8. Sampling frequencies should be based on the risk associated with the product (e.g., whether or not the product supports growth, receives a post-lethality treatment, likelihood of product contamination based on processing, filling and packaging conditions) and its product history. The need to conduct product contact sampling should be evaluated individually taking into consideration the factors listed above as well as access to the line equipment (closed vs. open exposure). Increased environmental monitoring (frequency and/or number of samples), as well as other control isolation measures, in response to plant events such as construction, equipment installation and major repairs, should be included.

9. The written plan should include a corrective action section that describes the steps to be taken in the event of detection, and assigns responsibility for taking those steps, to ensure that the cause of the contamination is corrected. The actions taken may be dependent on a number of factors related to the product, facility, and the likelihood that the finding may lead to contamination by the pathogen(s) of concern.

10. The written plan should also include root cause analysis for determining risk factors that may have contributed to a positive result during the monitoring process. Appropriate actions are then determined and implemented for preventive control of potential environmental contamination.

11. Food producers should maintain appropriate records of actions taken in implementing the program, to allow the firm to verify the proper implementation of the program by those responsible (e.g. review of sampling and testing records, investigative findings, corrective actions, preventive measures, etc.).
12. The environmental monitoring program should include a verification of the program (increased and intensive sampling) on a prescribed frequency (e.g., annually or based on repeat positive lines or areas) to assure control.

13. The environmental monitoring program should at a minimum be reviewed and validated whenever a change occurs to the process or product or at a prescribed frequency (e.g., every 2 years) if no changes are made.

14. For some facilities with more sensitive microbiological risk products, food producers should maintain a plant risk assessment map\cite{1,4,5,11} that identifies and differentiates processing areas within the facility based on requirements for different degrees of food safety stringency to control potential ingress, spread and/or multiplication of pathogens (i.e., the hygienic zoning concept). In addition, the controls identified and implemented with the corresponding environmental sampling and testing plan should be included.

15. Increased environmental control procedures and action steps should be taken in cases of new plant construction, new equipment installation or modification, and facility infrastructure damage (e.g., overhead leak, flooding, etc). Examples include:
   - Reinforced hygiene practices and traffic patterns with outside contractors.
   - Setting up temporary control barriers within the plant as applicable.
   - Increased cleaning frequency of adjacent areas during construction, after equipment installation, and after major repairs are completed.

16. Environmental sampling should be performed on areas during and after construction, after equipment installation, and after major repairs are completed. The sampling sites and frequency are determined based on the following:
   - Plant location of construction activities
   - Type of construction (e.g., installation, demolition, material removal, etc.)
   - Time duration of construction activities
   - Types of environmental controls implemented

   Note: Plant traffic controls, room air pressure, sanitation activities, etc. are also assessed during construction activities.
SANITATION PRACTICES

Effective cleaning and sanitation practices are essential components of food safety programs. To help ensure that food contact surfaces, equipment and utensils are free from pathogens and other unwanted microorganisms that could potentially contaminate product, facilities should have well-designed and effective programs in place. Such sanitation programs should be written, accessible to responsible personnel and include the sanitation objective, sanitizing procedures, schedules, monitoring programs, corrective action processes and indicate documentation requirements. Proper cleaning and sanitation requires specific knowledge and skills and should be performed by trained personnel.

Definitions

1. *Adequate* means that which is needed to accomplish the intended purpose in keeping with good public health practice.

2. *Food* means food as defined in section 201(f) of the Food, Drug, and Cosmetic Act (FDCA) and includes raw materials and ingredients.

3. *Food-contact surfaces* are those surfaces that contact human food and those surfaces from which drainage onto the food, or onto surfaces that contact the food, ordinarily occurs during the normal course of operations. “Food-contact surfaces” includes utensils and food-contact surfaces of equipment.

4. *Microorganisms* means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, subject food to decomposition, indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of the FDCA. Occasionally in these regulations, FDA uses the adjective “microbial” instead of using an adjectival phrase containing the word microorganism.

5. *Master Sanitation Schedule or Periodic Cleaning Schedule* is that schedule that identifies the frequency of cleaning and maintenance for all equipment, utilities and building infrastructure.

6. *Pest* refers to any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.

7. *Plant* means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.

8. *Sanitation Standard Operating Procedures or SSOP’s* are written, established sanitation procedures needed to maintain sanitary conditions.

9. *Cleaning* is the process that will remove soil(s) and prevents accumulation of food residues that may support the growth of unwanted microorganisms or pests.
10. *Sanitizing* is the process that destroys disease causing organisms which may be present on equipment and utensils after cleaning. Chemical sanitizers used shall meet the EPA requirement of 40 CFR 180.940.

11. *Shall* is used to state mandatory requirements.

12. *Should* is used to state recommended or advisory procedures or identify recommended equipment.

**Sanitation Program and Sanitation Standard Operating Procedures (SSOPs)**

1. *Development of a Sanitation Program and SSOPs* (adapted from 9 CFR 416.12)

   a. A written sanitation program, including related policies, and detailed SSOPs should be maintained by facilities. In an FDA-inspected plant, the sanitation program and SSOPs could be one in the same. However, in a USDA/FSIS-inspected plant, under HACCP regulations, these documents should be two separate documents. The overall sanitation program and its policies should describe the scope of the operation, appropriate sanitation objectives and all cleaning and sanitizing procedures (SSOPs) a facility will conduct before and during operations, sufficient to prevent direct contamination or adulteration of product(s). The program should also include verification of SSOP completion as well as maintenance of documentation.

   b. The sanitation program should outline the corrective actions necessary to demonstrate food is protected against contamination.

   c. The sanitation program should address recordkeeping including, at a minimum, documentation of the monitoring and corrective action taken. Sanitation records should be stored in an adequate location to allow for accessible review for a minimum of the shelf life of the product.

   d. The sanitation program should be signed and dated upon initially implementing the program and procedures (SSOPs) and upon any modification.

   e. Detailed procedures (SSOPs) within the scope of the sanitation program that are to be conducted during sanitation activities should be identified as such, and address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

   f. A master cleaning schedule or periodic cleaning schedule should identify how frequently the SSOPs will be performed. SSOPs should identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

2. *Implementation of SSOPs* (adapted from 9 CFR 416.13)

   a. Each facility should conduct pre-operational verification procedures. These can include ensuring that the cleaning and sanitizing procedures were followed as specified; visual/sensory inspection; microbiological testing, such
as swabbing for indicator organisms; and the use of new technologies, such as ATP testing, in the SSOPs before the start of operations.

b. Each facility should conduct all other procedures in the SSOPs at the frequencies specified.

c. Each facility should monitor and document the implementation of the procedures in the SSOPs at the frequencies specified.

3. *Maintenance of SSOPs (9 CFR 416.14)*

Each facility should validate their SSOPs by routinely evaluating the effectiveness of the SSOPs and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

**Sanitary facilities and controls**

In addition to the requirements provided in the current CGMPs (21 CFR 110) regarding the water supply utilized in a facility, water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.
ALLERGEN MANAGEMENT

Exposure to certain allergens in foods can result in a range of allergic reactions in different people—from mild irritation of the skin and mouth to anaphylactic shock and death—therefore allergen control and proper labeling of product is critical for food processors that handle allergenic foods and/or ingredients. FDA Current Good Manufacturing Practice (cGMP) requires food processors that handle any of the major food allergens to develop and adopt allergen control practices for their facilities. The Food Allergen Labeling Consumer Protection Act (Public Law 108-282, Title II) (FALCPA), which amended Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), defines “major food allergen” to include the following:

1. Milk, egg, fish (e.g., bass, flounder, or cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

2. A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

   (A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

   (B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).

FDA has offered a detailed list of what it considers a “tree nut,” which can be found in the “Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4).”

Food processors can develop robust allergen control programs by incorporating techniques in the six key areas noted below. Although implementing all techniques may not be appropriate for all processors, using multiple techniques for allergen management provides redundancy that enhances protection for the food allergic consumer:

1. Training of personnel, including, but not limited to, processing supervisory personnel, maintenance staff, contractors and visitors
2. Segregation of food allergens during storage and handling
3. Validated cleaning procedures for food contact equipment
4. Prevention of cross contact during processing through measures such as:
   a. scheduling of production runs
   b. control of rework
c. use of dedicated production lines

d. use of dedicated utensils and maintenance tools

e. control of employee traffic

5. Product label review, usage and control

6. Supplier control program for ingredients and labels

1. Training of processing and supervisory personnel

Supervisors and managers in food production plants should be trained in each of the key areas of allergen management so that they have the knowledge and ability to train production workers. Food production workers should be provided with appropriate training in each of the six key areas above relevant to their job responsibilities. Regular repetition of food allergen training is needed both to reinforce proper practices and to remind workers of the importance of these practices to food allergic consumers. Training practices and recordkeeping suggestions may be found in the Employee Training section of this document.

2. Segregation of Food Allergens During Storage and Handling

Segregation of the eight major food allergens during receiving, storage and handling can be effective in managing cross contact of food allergens in the food manufacturing setting. In certain situations, the presence of an allergen may be pervasive and not reasonably addressed by segregation. Thus, using some of the following practices, as appropriate to the segment of the industry and processing environment, can be useful tools in allergen management within a processing facility:

- Where appropriate within a processing facility, properly identify containers holding materials that contain any of the eight major food allergens. This may include containers for ingredients, rework and “in process” materials. This identification may include a simple text label, a color-coded label or an icon that identifies the allergen across multiple languages. A combination of identification methods may be used. If marking a pallet of material, assure that the allergen identification will remain with the pallet, should only a portion of it be used.
- Minimize cross contact between allergenic ingredients (e.g., dairy and nut ingredients), and between allergens and non-allergens, by storing allergens within closed containers and, where appropriate, physically separating ingredients in designated areas in the plant or storage facility, as necessary. In some instances, this segregation might be accomplished by simply storing allergens below non-allergens.
- Identify food-handling tools and sanitation devices for use with materials with one or more of the eight major food allergens through color-coding, labeling, dedication, single use containers or other appropriate techniques.
As noted above, depending on the allergens present in the plant, the processes used, and the space available for storing materials, a given facility may use some, all, or none of these methods of segregation. Determining which of the specific methods to use should focus on the final outcome of using techniques to minimize cross contact of materials with one or more of the eight major food allergens.

3. Validated Cleaning Procedures for Food Contact Surfaces

Validated cleaning procedures are an integral part of an effective food allergen management program. Fundamentally, a cleaning procedure should be designed to remove food allergens from food contact surfaces. This may require extraordinary techniques, such as disassembly of equipment or hand-cleaning of surfaces that normally might be sprayed with a hose. In dry operations, allergen cleaning can be more complicated and may involve the use of vacuums or hand-brushing. Cleaning is enhanced when equipment and facilities incorporate principles of sanitary design; not only does this make cleaning more effective, it can make changeovers faster.

Validation evaluates effectiveness of the cleaning procedure by allergen-specific analytical methods, if available, or through visual or other methods deemed appropriate by the manufacturer. Validated methods may not be readily available for all allergens. Therefore, validation may depend exclusively on using sensorial methods. The method or combination of methods will be dictated by the facility conditions and allergens used. In all cases, a validated process needs to be documented to assure consistent implementation.

One of the challenges of analytical testing is that, if a section of the processing equipment is not available for visual inspection, it also may not be accessible for surface swabbing. In such instances, the cleaning procedure may be validated using an indirect method—such as testing non-product material that has been sent through the system after cleaning. In liquid systems cleaned via CIP, a similar technique is to test the CIP rinse water. Make sure to sample and test only clear rinses because detergents and sanitizers can interfere with allergen test methods.

4. Cross Contact During Processing

Allergen cross-contact may potentially occur at any point during food processing. Although some facilities may determine that dedicated production lines are an appropriate option, effective ingredient management and sanitation programs allow effective allergen control with mixed-use production lines. In addition, the following cross contact prevention measures enhance allergen segregation:

- Minimize allergen cross-contact potential by segregating production areas, if possible. This segregation may be achieved with walls or even curtains provided they are of a suitably cleanable material. Sometimes simply allowing extra space between lines offers appropriate segregation.
- Configure processing lines so that the product flow limits cross-contact. One of the most common examples to avoid is having conveyors of different products cross over one another. If a crossover is unavoidable, make sure
the conveyors are fitted with covers.

- Schedule production runs to minimize the number of changeovers. For example, run non-allergen products first after a sanitation cycle, then changeover to allergen-containing products at the end of the run.
- Control rework so that it will not result in an undeclared allergen. This means making sure the rework is clearly marked as to what it is, and what allergens it contains. Ideally, rework should only be used in the exact same product. However, facilities that make a large variety of products less frequently may have to rework allergen-containing material into other products. Here, a “like-into-like” approach where the same allergens are contained in both the rework and the target product is helpful. Some facilities may choose to track rework by such “allergen profiles” for greater rework flexibility. However, the identification and tracking system should be very robust.

The allergen management plan should be reviewed regularly and updated, when necessary. Updates are indicated in many circumstances but most commonly when a new ingredient is introduced, processes or protocols changed, or when a new product or new equipment is introduced into the facilities.

To minimize the number of significant updates to an allergen control plan, a manufacturer should familiarize technical staff with food allergen concerns and support product development strategies that reduce allergen risk. Some of these include:

- Use alternative ingredients for allergens whenever possible.
- Only add allergens to a formulation when the allergenic ingredient makes a material difference to taste, functionality or consistent product quality.
- Question ingredient suppliers on the functionality and necessity of allergens.
- Understand allergens and absence thereof in manufacturing facilities when formulating new products.
- Create a process to review allergens in new products with the manufacturing facility before ordering ingredients for start up.
- Avoid using allergenic ingredients in such low amounts that they have no or minimal functional effect in the finished product.

5. Product Label Review and Label Usage and Control

FALCPA requires the eight major food allergens be labeled when present at levels that cause an allergic response that poses a risk to human health. Although products under USDA jurisdiction are not affected by FALCPA, USDA allows processors the option of following FALCPA labeling guidelines. In addition to being identified on the label, FALCPA requires the major allergens to appear in “plain language.” This assists the food allergic consumer in identifying allergens that may be an unfamiliar derivative of the source allergen. For example, “casein” would have to be identified as “milk.” Tree nuts, fish and crustacean shellfish must also be identified by the specific nut or seafood species. Food manufacturers may accommodate plain language requirements in one of two ways:
Parenthetically note the plain language in the ingredient statement. (e.g. “...casein (milk)...”)
Include the plain language in a Contains statement immediately under the ingredient statement. (e.g. “Contains: Milk”)

Be aware that the FDA has addressed the issue of labeling allergens that may result from trace amounts of cross contact. This appears in the Questions and Answers issued by FDA on December 14, 2005 to supplement the agency’s earlier Guidance on compliance with the FALCPA:

“FALCPA's labeling requirements do not apply to major food allergens that are unintentionally added to a food as the result of cross-contact. In the context of food allergens, ‘cross-contact’ occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food. Cross-contact may result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment.”

This statement should not be construed to absolve the manufacturer from following Good Manufacturing Practices to assure allergen segregation. It refers specifically to low-level agricultural cross contact. An example of this is the low levels of soybeans that occur in wheat due to shared harvesting and transport equipment.

Some manufacturers may choose to use a “May Contain” advisory statement when facility cross-contact is unavoidable. Although FDA has expressed no objection to this practice, the agency is clear that such statements are not a substitute for Good Manufacturing Practice, as stated elsewhere in the guidance referenced above:

“FDA advised that advisory labeling such as "may contain [allergen]" should not be used as a substitute for adherence to current Good Manufacturing Practices (cGMPs).”

In addition to assuring labels and their ingredient statements have accurate allergen information, manufacturers should assure that the correct labels are applied to the correct products. Although it may seem obvious, mispackaging and labeling errors are leading causes of food allergen-related product recalls. For this reason, manufacturers should institute processes for tracking label versions when packaging is designed as well as managing how packaging materials are received, stored and used. Some techniques for packaging control include:

- Double-check packaging materials to verify they are correct. Workers might easily do this, for example, by checking a stack of cartons while loading the cartoner to make sure it has either the right color or correct pattern of stripes.
- Have packaging designers apply a version code to packaging to help workers assure the correct version of a package is being used.
A best practice to make sure the package matches the product being made is the use of bar-code scanners or vision systems electronically linked to the formula system. Train workers to re-check packaging during the production run. This may be performed, for example, when taking check-weigh samples or testing metal detectors.

When product formulas change, destroy old packaging. Of course, sometimes packaging changes for other reasons—such as special promotions, etc. In these cases, destruction is not necessarily appropriate. Transparency in the packaging update process helps determine if it is appropriate to destroy packaging.

6. Supplier Control Programs for Ingredients and Labels

GMPs apply to the manufacture of raw materials and ingredients that supply food processors. It is current business practice for processors and manufacturers to require their suppliers to be in compliance with applicable federal and state food and drug regulations, including current Good Manufacturing Practices. With respect to allergen management, manufacturers should require suppliers to accurately identify major food allergens and notify the manufacturer of any changes in the presence of major food allergens in the products supplied. Allergen identification may take the form of a disclosure statement from the ingredient supplier. Some manufacturers have customized forms they require suppliers to complete. Often, these customized forms ask information about other allergens in the facility and, in particular, those used on common equipment. This helps the manufacturer determine the potential cross-contact risk at a supplier.
TEMPERATURE MONITORING

1. Microorganisms (e.g., bacteria, yeast and molds) rely on three main factors for growth and multiplication: time, nutrients (i.e., food and water), and temperature. The first two factors can be controlled through frequent and effective cleaning and sanitation practices, and the third—temperature—can also be controlled by food facilities and help prevent the rapid growth of organisms (spoilage and/or pathogenic) that might be present in the environment or in product. Temperature control is especially important during storage and distribution, which can sometimes be for extended periods of time.

2. Specific times and temperatures found in the FDA Food Code\textsuperscript{17}, the Grade “A” Pasteurized Milk Ordinance (PMO)\textsuperscript{18} and other nationally-recognized and accepted regulatory documents, may be referenced for specific processing steps, storage and distribution, where appropriate and applicable, and require no further validation by food processors and distributors.

3. If it is determined, based on product characteristics, that a specific product is a “potentially hazardous food” (requires time/temperature control for safety), the validity of the specific temperatures used to ensure the product does not become unsafe or otherwise adulterated should be supported by scientific information or analysis (e.g., published papers, scientific studies) or comply with "safe harbor" guidance (e.g., Food Code, PMO) or other nationally recognized and accepted regulatory documents. Industry should determine the validity of the temperatures used in manufacturing, storage and distribution.

4. Temperature monitoring equipment and devices should be accurate and reliable to verify that foods are stored at appropriate temperatures. The validation and verification section of the Hazard Analysis and Critical Control Point (HACCP) system stated in the Code of Federal Regulations (9 CFR 417.4, 21 CFR 123.8, 21 CFR 120.11) specifies that instruments used for monitoring critical control points must be calibrated. It should be clarified that many times temperature measuring devices are checked for accuracy, but not always calibrated. Calibration is the process of standardizing a temperature monitoring instrument to ensure that it will measure within the specific temperature range in which the instrument is designed to operate. Accuracy of a thermometer is its ability to measure temperature repeatedly within a narrow range. While not regulated, it is strongly recommended that a thermometer be within $\pm 2^\circ F$ ($\pm 0.5^\circ C$) of the actual temperature to be considered an accurate device.

5. Facilities should monitor food temperatures and keep records to the extent needed to ensure product temperatures are being adequately controlled.
CONCLUSION

To conclude, and as a final reminder to users of this document, the contents represent recommended principles and practices that may be voluntarily instituted by the food industry to supplement current GMPs and should be interpreted to provide maximum flexibility to manufacturers to adapt programs to their unique product, processes and facilities. If implemented properly, the guidance and recommendations described can help to ensure the production, marketing and distribution of safe, wholesome, properly labeled foods.

CITATIONS & REFERENCES


   http://www.fda.gov/downloads/Food/FoodSafety/Product-SpecificInformation/MilkSafety/NationalConferenceonInterstateMilkShipmentsNCIMSModelDocuments/UCM209789.pdf

   http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059116.htm

   http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm