*Richard F. Stier*
*Sonoma, CA, U.S.A.*
*Rickstier4@aol.com*

# Validating Food Systems to Ensure Safe Products

Cereals, grains, nuts, and foods produced from these ingredients have traditionally been considered among the safest of all foods produced for human consumption. Recent events have caused the food industry, especially processors utilizing these ingredients, to rethink this position. As an example, within the last six months the following recalls have been initiated:

- Turkish pine nuts due to *Salmonella* contamination
- Black bean tortillas due to *Clostridium botulinum*
- Soybean flour and soybean meal due to *Salmonella* contamination
- Sesame sticks due to pieces of wire
- Frozen pizzas due to foreign materials (plastic)

If the number of recalls for undeclared allergens discovered over this same period, especially in baked goods, were listed, it would take up most of the first page. One would need to research each incident to determine the root cause of the problem, but educated guesses may be made. Based on these guesses, we can talk about what could be done to address these problems.

When developing a food safety management system (FSMS), processors need to clearly define potential hazards and develop and implement preventive measures (Fig. 1). These preventive measures must also be properly validated to ensure they will control the hazards that have been identified. As a reference, several key terms are described below (Source: ISO 22000a, 2005).

- **Validation:** A combination of tools used to ensure the total food safety management system (FSMS) is working to evaluate food safety data prior to the release of the product using or either internal or external audits.
- **Verification:** A series of planned activities designed to verify whether the FSMS is operating properly: determine where the FSMS needs to be improved, identify trends in the data to determine whether the process is breaking down and take corrective action before a food safety problem arises, identify areas for focusing the efforts of an internal audit, and provide evidence that corrections and corrective actions are effective.
- **Critical Control Point (CCP):** A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

- **Operational Prerequisite Program (oPRP):** A prerequisite program identified by hazard analysis as essential to control the likelihood of introducing food safety hazards to and/or the contamination or proliferation of food safety hazards in the product(s) or processing environment.

Let's look at what processors can do to properly validate the steps in the process or activities that are deemed essential for food safety. The steps in the process are the critical control points (CCPs), and the activities are those prerequisite programs deemed essential for ensuring safety—the operational prerequisite programs (oPRPs).

## Processes to Eliminate Biological Hazards

The best method of ensuring product safety is to eliminate the hazard. With biological hazards, heat traditionally has been the most effective method for eliminating microorganisms of public health significance. The U.S. FDA low-acid canned food regulations found in the *Code of Federal Regulations* Title 21, Part 113 are designed to ensure that foods in hermetically sealed containers do not contain viable spores of *C. botulinum*.

The 2001 and 2004 *Salmonella* outbreaks from contaminated raw almonds caused that industry, through the Almond Board of California (ABC), to develop programs aimed at ensuring the safety of almonds. Today, all almonds must be processed sufficiently to ensure that *S. enteriditis*, a non–spore-forming pathogen, is eliminated. The ABC Technical Advisory Board has approved a number of processes for use with almonds, including oil roasting, dry roasting, steam treatments, and the use of



Fig. 1. Food safety management system development.

chemical sterilants. In addition, ABC has evaluated and approved persons to be process authorities for the industry. ABC defines a process authority as

> A person who has expert knowledge of pasteurization processes or other treatment requirements for the safety of foods. The expert knowledge can be obtained from education or experience or both. Anyone who is establishing treatments must use adequate facilities for making the determinations. Anyone who is evaluating treatment deviations must utilize procedures recognized by competent process authorities as being able to detect any potential hazard to public health.

Almond processors, be they primary processors or those using almonds as an ingredient and processing them in-house, must utilize an approved process developed by an approved process authority. Processors must also maintain records that can be used to verify that the process is being followed. These approved processes include programs to ensure that processed almonds are not recontaminated, which was an issue in the 2007 and 2008 peanut butter recalls.

The work done by ABC has had a ripple effect on the food industry. It has not only affected how processors of other nuts, grains, seeds, seasonings, and spices do business, it has resulted in the development of new processing systems designed to deliver sufficient lethality to ensure the safety of these foods. These systems have also been designed to minimize thermal damage to products so they retain the properties essential for acceptance, in particular their sensory properties.

Manufacturers seeking to validate their processes need to be sure that the validation processes are appropriate for their products. This includes selecting the proper target organisms, designing rigorous testing procedures that fully document the tests and test parameters, and ensuring proper data collection. Based on the U.S. Food Safety Modernization Act signed into

law in early 2011, it is very likely that all processors are going to be asked to defend their validation work. Ingredient suppliers that have made the investment in these new technologies and taken the time to properly validate their systems will have a competitive advantage in the marketplace. With food safety being pushed down the supply chain, processors who can provide real data confirming that their processes are safe will be in an enviable position.

As mentioned earlier, bakers and others using grains and other ingredients in their products have assumed that the processes used to prepare their products were sufficient to kill pathogenic bacteria. However, many processors are reevaluating their processes to ensure they are adequate. Part of this is due to the nature of baked products. Many baked products have low water activity ($a_w$), and it is an unfortunate characteristic of bacteria that their heat resistance tends to increase as $a_w$ decreases. Processors, therefore, are going back to the laboratory and using thermocouples, portable sensors, inoculation studies, and other methods to gather data that either support the lethality of existing processes or can be used to create new processes to ensure food safety. Without proper validation, one can never know if a process is effective.

### Processes to Reduce Food Hazards to Acceptable Levels

Reduction of food hazards to acceptable levels can be a challenge. Recent work has shown that people can become ill through the ingestion of less than 10 microorganisms (food pathogens) of public health significance. This is especially true if the person is someone who is from an at-risk group (young, old, or immunocompromised). When dealing with pathogens such as enteropathogenic *Escherichia coli*, *Salmonella*, or *Listeria*, elimination is essential. There are pathogenic organisms that may be controlled by making the environment hostile to growth. Spore formers such as *Bacillus cereus* are not able to germinate when $a_w$ is reduced to less than 0.85. This is the case for a large percentage of the foods produced using cereals, grains, nuts, and seeds.

There are several technologies available that can be used to reduce food hazards to acceptable levels. One of the most common unit operations in food processing today is the metal detector. Some processors deem this step in the process to be a CCP, whereas others treat it as a control point, i.e., a means of enhancing quality. One of the common mistakes that processors make when setting up their FSMS is to state in their plan that products will contain no metal. Metal detectors (and other devices such as X-ray machines) have a lower limit of sensitivity. The type of machine and the product being passed through the detector will affect sensitivity. These sensitivities generally range from 1.0 to ≈5.0 mm for ferrous metals. The devices are less sensitive when it comes to detection of nonferrous metals and stainless steel. It is always a good idea to work with the equipment manufacturer when determining how to set up a machine. One processor with whom I worked was passing frozen cased goods through a detector prior to palletizing. Their customer wanted them to run at sensitivities of 1.0 mm for ferrous and 1.5 mm for nonferrous metals. The end result was a significant number of false positives and a lot of extra work. The equipment manufacturer provided them with a guidance document, which they shared with their customers. The end result was that the system was adjusted to a higher sensitivity. Their products were still safe, and the system ran more smoothly.

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#### Verification of Metal Detection

Most metal detectors can be described as a tunnel with a conveyor. Validation data should ensure that the equipment can detect metal of the appropriate size at different locations on the belt and at different locations in or around the package. For example, if a 50 lb sack of flour is to be tested, the system could be validated by testing the standards at the leading edge, the tailing edge, and on top of and under the bag. This needs to be done for each product type. The standards might even be tested by inserting the magnetometer into the bag at different locations. Multiple tests, a minimum of 10, should be done at each location. The persons doing the testing must also confirm that the settings remain the same throughout the test. Settings should be recorded throughout the test. The result should be the determination of the best location to place the test wands during the calibration check during normal production. The test standard, for future verification, must placed in the location where the magnetometer receives the weakest signal. Rigorous test protocols like this will provide confidence that the system was set up properly and is doing its job.

Metal detectors and X-ray machines must be validated for each product that is passed through them. This can be a great deal of work for systems used for multiple products. An example of how one might validate a metal detector used for bulk products such as flour, whole grains, or seeds is provided (see "Verification of Metal Detection" box).

In the 4th edition of the *Fish and Fishery Products Hazards and Controls Guidance*, the FDA has provided guidance on how to write a hazard analysis and critical control point (HACCP) plan if metal fragments are considered to be a CCP. The FDA has supported regulatory action against metal fragments that are between 7 and 25 mm. Thus, the critical limit for the HACCP plan can be classified as metal fragments greater than 6 mm. The plant can set the operational limits for any metal that is detectable by the metal detector, and corrective actions would then be taken if the metal detector detects any metal.

### Validating Systems to Control Potential Food Hazards

One of the concepts developed in the ISO 22000 standard, "Food safety management systems—Requirements for any organization in the food chain," is that of oPRPs. Food safety professionals acknowledge that these prerequisite programs are the foundation of an FSMS (Fig. 1). This is underscored by the fact that the Codex Committee on Food Hygiene document and regulations mandating HACCP include oPRPs or Good Manufacturing Practices.

oPRPs are those activities deemed essential for ensuring safety and, therefore, must be validated. It is not possible to validate all prerequisite activities (think hand washing), but if the hazard analysis determines that an oPRP is crucial to safety it must be validated. One area that many companies have decided to monitor and control with an oPRP are allergens. Allergen control programs should include, but need not be limited to, the following elements:

- Vendor approval, certification, and partnership
- Product development programs that identify potential allergens
- Proper labeling
- Receiving
- Storage
- Production control and scheduling
- Cleaning and sanitizing
- Verification of cleaning
- Control of rework
- Product identification and recalls
- Education and/or training of management and staff

The program will vary based on the type of allergen being handled, its packaging, and the products being manufactured. Processors must design programs to make sure that the elements making up the program are effective. Perhaps the most important element is the cleaning program. When the program is being developed, the process should be validated using tools such as allergen test kits. There are a number of manufacturers currently producing allergen test kits, so finding such tools

should not be difficult. Once the process has been established, there should be ongoing verification activities, which would include monitoring the cleanup crew on a regular schedule to ensure they are following established protocols.

## Conclusions

When designing your FSMS, there are three simple rules:

1) Validate when developing the program to ensure that the CCPs and oPRPs are effective.
2) Monitor the system daily to provide a record that the work is being done and done properly.
3) Verify after the fact using tools that will provide evidence that the work was done properly. Management must support each and every one of these activities—without support the system will probably crash and burn.

## Resources

1. International Organization for Standardization. ISO 22000: Food safety management systems—Requirements for any organization in the food chain. ISO, Geneva, Switzerland, 2005.
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