PERSPECTIVE

FSMA Implications for Artisan Products

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The Food Safety Modernization Act (FSMA) is the most comprehensive update to food safety requirements in the United States since the Food, Drug, and Cosmetic (FD&C) Act was enacted in 1938. The changes stipulated by FSMA have broad implications for all food manufacturers and distributors. Since the bill was signed by President Obama on January 4, 2011, the U.S. Food and Drug Administration (FDA) has published numerous proposed and final regulations, along with guidance documents totaling over 7,000 pages. Reading through all of these materials is a task in itself, which is why it is important to appreciate the spirit of FSMA as opposed to all of the details—it is easy to overcomplicate FSMA and create a compliance burden. Because the FDA cannot define a food safety plan for every plant, the food industry, which knows the process and products better than anyone else, must develop the plan. For all its verbiage, FSMA is actually a fairly simple and straightforward set of concepts that defines the next steps in the evolution of food safety. Food safety needs FSMA, and the food industry needs to understand FSMA in order to implement its regulations in a practical manner that adds value and improves food safety for consumers without creating an unreasonable burden on the industry. The purpose of this article is to describe how this can be accomplished, with an emphasis on artisan bread producers.

FSMA applies equally to large and small food manufacturers. The challenge for small and very small producers is to find adequate expertise and resources to develop and implement the programs necessary to comply with the new regulations. To successfully attain compliance without over burdening the process requires that programs be kept as simple as possible. The food industry is already doing much of what is required by FSMA; all that remains to become fully compliant is to integrate programs and practices into a comprehensive food safety plan. FSMA introduces five basic concepts: risk assessment, preventive controls, food safety plan, assessment versus audit, and validation and verification.

As a food manufacturer the first step is to identify relevant compliance dates for your business. The FDA identifies three categories for FSMA compliance dates based on business size: very small businesses with less than $1 million in annual sales; small businesses with less than 500 full-time equivalent employees; and other businesses with more than 500 full-time employees. Identifying relevant dates is complicated because different dates have been set for each FSMA rule, and there are exceptions for each of them. There is substantial confusion about compliance dates, even among FDA inspectors. In fact, many inspectors are proceeding as if FSMA is already in effect, so it would be wise to establish a fully compliant program as soon as possible. A comprehensive table of compliance dates has been posted online by the FDA at FDA.gov (www.fda.gov/food/guidanceregulation/fsma/ucm540944.htm).

Risk Assessment

The foundation of FSMA is risk assessment. HACCP (hazard analysis and critical control points) provided the food industry with an introduction to the concept of risk assessment, but the new HARPC (hazard analysis and risk-based preventive controls) model is more comprehensive. Some are calling it HACCP on steroids. To get started, a comprehensive risk assessment of the process, plant, vendors, personnel, and products needs to be performed by a small multifunctional team of knowledgeable personnel in each production facility. A risk assessment must be performed in each facility—do not cut-and-paste assessments from other facilities, no matter how similar they are. Performing an assessment is a great learning process for a team. As they consider equipment, personnel practices, ingredients, products, recent failures, consumer complaints, etc., the team needs to go through the process step by step and ask, "What can go wrong?" This generally can be done effectively in a few hours.

After making a list of the risks, each risk should be rated for severity and probability. This helps separate risks based on how often a failure could occur and the magnitude of the potential loss if a failure were to happen. Focus your improvement efforts on reducing the risks with the highest likelihood of occurrence and highest potential loss, while also doing what is feasible to reduce or eliminate all risks. Necessary projects should be identified, including ones that require investment or outside involvement. Building awareness of the risks among other people throughout the organization, especially upper management, is essential. It is impossible to effectively reduce a risk until there is sufficient awareness of it. The goal is to identify what can be done to reduce risks in a reasonable and responsible manner. Resources are always finite, so it is not possible to do everything, but what can be done must be done. Not being aware of a risk that exists is ignorance and is unacceptable. Being aware of a risk but choosing not to act is negligence and is a civil crime. Being actively aware of a risk and doing what is reasonable is diligence. This is the appropriate behavior regarding risks.

When considering how to reduce a risk, think about both short term and long term scenarios. In the short term, what can be done in the next few months to reduce the risk? In the long term, if there were a five year horizon, could the risk be eliminated? Risk assessment is a process, not a one-and-done activity. Plan to review and update your assessment at least twice a year: review what has been done to reduce the risk, the effectiveness of implemented changes, the impact on the risk, and the next steps needed to further reduce the risk. More information on how to perform a practical risk assessment can be found in the chapter on "Risk Management" in *Juran's Quality Handbook*, 7th edition, by Joseph DeFeo (American Society for Quality, 2016).

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Artisan bread producers perform many manual operations and, therefore, may experience a higher risk of product contamination from misplaced dough scrapers, gloves, rags, pens, etc. These potential contaminants should be included in the risk assessment, with ways the risk can be minimized or eliminated identified. The risk of a dough scraper ending up in a mixer and becoming a foreign material, for example, can be minimized by making operators aware of the risk and giving them a place to put the scraper when it is not in use. Once established, there are only two acceptable places for the scraper to be: in the operator's hand or in the designated place. A scraper sitting on a bench or on top of a mixer is not allowed. If this is consistently practiced, the risk of a misplaced scraper can be greatly reduced or eliminated. To eliminate the risk of a pen or pencil becoming a foreign material in a product, documentation can be performed electronically, and pens and pencils can be banned in the facility. Rags are another foreign material risk that can be reduced by creating awareness and designating a place to keep them when not in use—sticking a rag in a pocket is not acceptable. The other advantage of having a designated place to put these items, is that every time someone walks past a designated place, it is possible to quickly look to see if an item is where it is supposed to be. If it is not in use or in its designated place, where is it? Consistently reinforcing this practice may also enable detection of a misplaced item before it can become a foreign material in finished product.

The following is a short list of specific situations, commonly encountered in artisan baking facilities, for consideration as potential risks that need to be minimized and controlled in the operation:

- Plastic tubs and buckets used for dough or ingredients can crack or fray, releasing fragments into the product. What steps can be taken to minimize or eliminate the risk?
- Upholstered couches can become dirty, moldy, or frayed. What are the practices for inspecting, cleaning, and replacing furniture as needed?
- Wooden peel boards and bagel boards crack and splinter, creating a foreign material risk. What steps can be taken to reduce or eliminate the risk?
- Proofing baskets can become dirty, moldy, or fall apart. What steps can be taken to reduce or eliminate the risk?
- Glass and hard plastics can crack or break. What steps can be taken to reduce or eliminate the risk? Is glass in any form allowed in the facility? Are all light bulbs covered with shatter shields? Can hard plastics be replaced with soft, unbreakable materials?
- Direct hand contact with product after baking poses a contamination risk. Are operators who handle product after baking required to wear sanitary plastic gloves? Is there a program to manage glove use and disposal in the facility?
- Loading and unloading racks poses a risk that foreign materials will drop onto product from the rack. There is a method for loading and unloading racks that can minimize this risk. Are operators aware of this practice and are they consistently performing it properly?
- Condensation on refrigeration coils and inside chilled boxes can support the growth of mold. Are coils cleaned frequently on a regular schedule? Is condensate piped away?
- Hand washing in utility sinks creates a contamination risk. Are there separate hand wash and utility sinks with adequate supplies of detergent and sanitizer and an appropriate method for hand drying?
- Pathogens may be present in the plant environment—introduced on people's shoes and hands, from ingredients and pallets, etc. FSMA requires that the environment in food manufacturing facilities be actively tested for the presence of pathogenic microorganisms, especially in areas where product is exposed. A program should be implemented to test drains, floors, and the non–food-contact sides of equipment for *Listeria* and *Salmonella* spp. If pathogens are found, the area should be cleaned and sanitized and retested, with these steps repeated until the contamination has been eliminated. Cleaning and sanitizing practices should be modified to assure that the procedures are adequate to prevent a reoccurrence. Without an effective program in place, it is likely that the FDA will perform testing during inspections. A small artisan operator may not have the expertise to collect surface samples, necessitating the use of an expert third-party lab.
- There is a risk of product contamination when food and food-contact surfaces are not isolated from non–food-contact surfaces and materials. What practices can be implemented to assure adequate separation? It is not advisable to test food-contact surfaces or the food itself. A positive pathogen test result must be reported to the FDA. In such an event, the minimum appropriate response would be to destroy the product on the line, and a recall might be triggered if there is a chance that product in the market could be contaminated. Testing alone cannot assure food safety because the sensitivity of the test is not sufficient to prove the absence of pathogens.
- Pests such as insects and rodents are a risk. Is there an effective program in place to monitor for the presence of these pests and to exclude them from the facility? It may be helpful to hire an expert third-party to set up and document a pest control program for the facility.
- Chemicals such as lubricants, solvents, pesticides, sanitizers, detergents, etc. in the facility are a risk. Is there a program in place to segregate these items from production areas and restrict access to only trained, authorized personnel?
- Intentional contamination is a risk. FSMA requires implementation of a program to assess and take steps to minimize the risk of intentional contamination. The program should be kept simple, such as taking reasonable steps to keep doors locked to prevent unauthorized external access. Cameras can also be an effective control element. Make personnel aware of the risk so they will question any unknown person in the facility.
- Rust and peeling paint are foreign material risks. Are steps being taken to minimize these risks by inspecting and cleaning ovens, proof boxes, ceilings, fans, etc.?
- Allergen cross-contamination is a risk if peanuts, tree nuts, dairy products, soy, fish, shellfish, or eggs are used in the facility. Are steps being taken to minimize or eliminate the risk, such as using proper labeling, cleaning, segregation, scheduling, separate equipment, etc.?
- Worker turnover creates a risk for the operation. Is there an adequate new hire training program to assure that new employees are aware of the food safety risks in their work area and know how to work in a safe manner around food products?

- Is there a trained food safety operator managing the program? FSMA requires that every food manufacturing facility have at least one qualified person who manages the food safety program. Experience can be helpful, but it is best to have at least one person attend a week-long training program to become certified as a qualified food safety operator. These courses are comprehensive and deep. When the person returns to work, remind them of the need to keep the process simple!

Preventive Controls

After identifying the risks, and doing what is reasonable to reduce or eliminate them, the next step is to put in place preventive controls. Preventive controls are needed whenever a risk cannot be eliminated. The purpose of the control is to manage the risk in order to prevent failure and enable rapid detection when a failure has occurred. FSMA avoids the confusion of designating control points as critical or noncritical. Effective controls are needed at all points where there is a risk of failure. Controls can be simple, such as visual inspection in the case of cleaning or temperature measurement to verify that the baking process is adequate to kill pathogens. Food manufacturers should consider how failure can occur and how it can be detected quickly. What corrective actions can be taken in the event of a failure to minimize or eliminate loss to the customer? Effective action could mean putting suspect product on hold until sufficient information on the failure can be gathered to assess what steps are needed to prevent loss to the customer. Some risks will not be controlled in the process and will be passed on to the customer. FSMA requires that customers be notified in writing of this fact. The customer then has the responsibility to implement an effective control for the risk and must advise the manufacturer that they have done so, closing the compliance loop. The same applies to the manufacturer. Suppliers may pass certain risks on to the manufacturer, and it is the responsibility of the manufacturer to implement an effective control. For example, wheat flour is a raw agricultural commodity (RAC) that may be contaminated with pathogenic microorganisms. The traditional milling process is not capable of controlling this risk unless additional processing is performed, such as a heat or sterilization treatment. If a manufacturer receives an RAC ingredient, they must implement an effective control to destroy pathogens that may be present. Baking is an adequate and validated control. The manufacturer need only reference the AIB International "Kill Step Validation" studies in their food safety plan and verify that their products are exceeding the time and internal temperature profiles defined in the studies.

Food Safety Plan

FSMA requires that every food manufacturing facility have a food safety plan. This is simply a list of the programs that have been implemented as a result of a risk assessment. It is not necessary to include the risk assessment or the program details; it is only necessary to list these. Manufacturers should be prepared to show FDA inspectors the details of their programs in case they are asked to do so. The food safety plan must include the list of programs and the employee training performed (both new hire and refresher training). The details should be included in the program documentation, including the procedure, utensils, and tools used; chemicals and concentrations used; frequency of performed procedure; failure detection; documentation of failures and corrective actions; and specific training performed for the program. For example, prerequisite programs such as chemical control should be listed in the food safety plan. In the program details, separate from the plan, list all of the details on what chemicals are included, how the inventory is controlled, what documentation is required, training topics, failure records (spills), and corrective actions that will be taken in the event of a failure. The food safety plan is simply a comprehensive list of the programs that have been implemented to manage food safety. Having the information listed all in one place makes it easier for the manufacturer and the FDA to understand and assess how food safety is being managed every day.

Assessment Versus Audit

FSMA is a paradigm shift for the food industry and for the FDA. The shift is from a food safety model based on audits to one based on assessments. In an audit model, there are predefined standards and practices. These standards are defined by the FDA in the Current Good Manufacturing Practices (CGMPs) and in the model Food Code. It is relatively easy to perform an audit and comply with the audit model, as the standards are defined and do not change often. The problem with the audit model is that compliance with the standards today does not provide assurance of compliance in the future—an audit provides a snapshot in time. Also, the standards may not be complete or adequate for all facilities and may become obsolete in an ever-changing environment.

Under the assessment model, the standards are defined by the manufacturer and embedded in programs and practices that assure compliance over extended periods of time. The programs are flexible and adaptable to the specific and changing needs of the manufacturer. Performing an assessment will be much more difficult for the FDA. In fact, it is likely that the assessment model will be more difficult for the FDA than for the food industry to implement.

Validation and Verification

FSMA introduces the requirement to validate and verify practices to assure adequacy and compliance. Validation proves that a practice is effective and must be performed at least every three years to assure that the practice is adequate to perform the desired task. For example, a cleaning and sanitizing practice for a mixer must be shown to be effective. The procedure for the practice should be performed exactly as written, assessed to determine whether it was effective, and the results documented. Keep it simple—a visual inspection may be adequate. Verification confirms that the practice is being performed according to the documented procedure every time the practice is used. Again, keep it simple—the person performing the procedure can check off the steps and initial it when the job is done to verify that they followed the procedure. A supervisor can follow up and initial the document as well to provide additional verification.

Verification is usually easy, whereas validation can be difficult. The food industry does not know how to validate some procedures and neither does the FDA. The FDA is relying on the industry to develop validation methods. This will take time. Do what you can and keep it as simple as possible.

FDA Inspections

As a food manufacturer, you need to be prepared for an FDA inspection. One person who will work with the inspector while they are in the facility should be identified, as well as an alter-

nate in case the first person is not available. When the inspector arrives, welcome them and bring them to a room where they can set up and you can meet in private. You should ask what kind of inspection will be conducted and whether the FDA is following up on a specific issue. You should be prepared to show your facility registration. The inspector may also ask to see records such as procedures, policies, consumer complaints, training records, or even formulas.

When the inspector asks to see proprietary documents, there are several options. It may be best to give them what they need, not necessarily what they want—no one wants a disgruntled FDA inspector in their facility. On the other hand, you do not want your competitors to gain access to proprietary information through a FOIA request for sensitive documents. Ask the inspector why they want to see a certain document. Usually they want to see a formula, for example, to confirm that the ingredients match the label. They do not need all of the percentages to do this, so ask whether they will allow blacking out of some of the formula percentages, leaving the ingredient names for them to see. They generally will agree, as this gives them what they need while protecting proprietary information. You can also ask the inspector to look at the document, but to please not take copies. As a last resort, if you really don't want to give them a document for some reason, you can ask them to make the request in writing. They almost never do.

Remember, they have a job to do too and treating them with respect goes a long way toward avoiding confrontation. If they find something wrong, they may issue a 483 form. This is an official notice of a deficiency. You must respond to it in writing within 30 days to advise them of how you will or already have corrected the deficiency. Make sure to correct it permanently, because the next time they visit the facility they will check to see whether it was corrected. If it was not corrected and they find a repeat violation, this is when they will get tough and shut down facilities.

Conclusions

If you have questions or need help, reach out. The FDA has published numerous guidance documents on various aspects of FSMA compliance. AIB International, the American Bakers Association (ABA), and even competitors can be good sources for help with compliance. Food safety compliance is not a competitive advantage. A failure anywhere impacts all manufacturers negatively. Having said that, finding a way to comply with FSMA in an efficient manner that does not burden your staff can indeed be a competitive advantage. Keep it simple!

Len Heflich retired from Grupo Bimbo in 2016 after a 42 year career in the food industry. He was most recently responsible for food safety, quality and crisis management for global operations. Len writes, teaches and consults on food safety, wheat quality, leadership and innovation. He will publish a book in April titled "Balanced Leadership: A Pragmatic Guide for Leading". Len is an AACCI member and can be reached at lheflich@hotmail.com.

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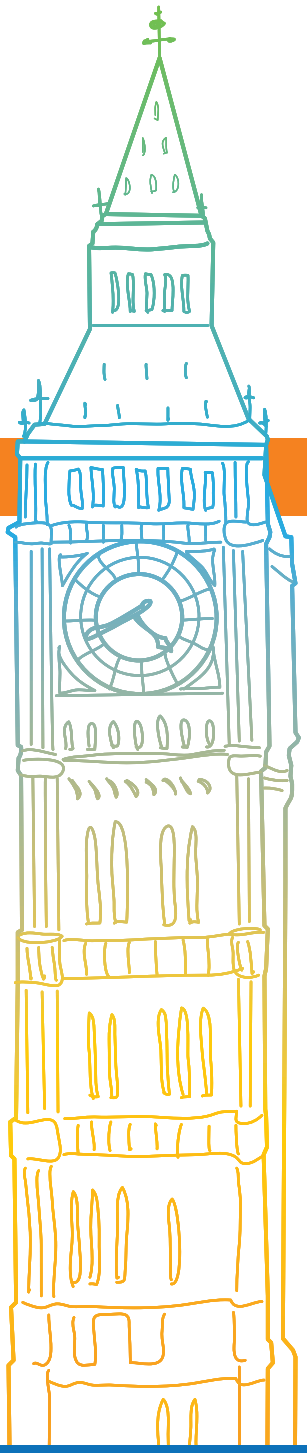

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