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PREVENTIVE CONTROLS & RECORD KEEPING:

COMPLYING WITH FSMA

More than two years ago, the Food Safety Modernization Act (FSMA) was signed into law by President Barack Obama. FSMA was enacted in response to a number of food safety issues that led to product recalls and, in some cases, to foodborne illness outbreaks and deaths. The law transforms the Food and Drug Administration (FDA) into a proactive instead of reactive agency, authorizing the issuance of rules and regulations to prevent foodborne illness and outbreaks.

The agency has become, in essence, a preventive authority with responsibility for assuring the food industry's compliance with rules and regulations designed to identify hazards and prevent outbreaks. FSMA places the compliance burden on all parts of the supply chain, from food processors and manufacturers to growers and importers. Compliance under the law will require extensive food safety training of employees and supporting documentation as proof to satisfy the FDA.

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Since FSMA's enactment, food processors and manufacturers have waited for proposed rules that clarify the expectations of the FDA. In January 2013, two years after the act became law, the FDA provided some of its expectations by issuing two proposed new "science-based" rules for preventive controls (FSMA Section 103) and "standards for growing, harvesting, packing and holding produce on domestic and foreign farms" destined for human consumption (FSMA Section 105). Later this year, the FDA is expected to issue a third rule that will apply to food safety standards for imports.

The importance of training, which is essential to meet the standards of the proposed rules, is of special concern to the FDA. These proposed rules are subject to a 120-day time period in which public comments about the proposal can be submitted. As the FDA reviews those comments, it will, no doubt, be examining the role of training since the agency posed specific questions about it. The possibility exists that the FDA may eventually decide to establish training as a separate preventive control.

"What this tells me is that training is absolutely critical," said David Acheson, M.D., the former associate commissioner for foods at FDA. "The FDA is expecting that training be an important part of any food establishment controlling risk." Whatever the agency decides, thorough and documentable training will be an essential to support the implementation and execution of a plant's food safety plan when the proposed rules are eventually implemented.

FSMA Section 103: Beyond HAACP to Comprehensive Preventive Controls

Prior to the advent of FSMA, the FDA had relied on companies' voluntary adoption of Hazard Analysis Critical Control Point (HAACP) principles, which were already mandatory for the meat, juice and seafood industries. However, FSMA constitutes an acknowledgement that assurance of food safety requires more oversight.

Section 103, "Preventive Controls for Human Food: Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food" clearly defines the extent and justification of preventive controls in a 680-page document. According to the FDA's Fact Sheet accompanying the proposed rule, companies must "evaluate hazards, identify and implement preventive controls to address these hazards, verify that the preventive controls are adequate to control the hazards identified, take corrective action when needed, and maintain a written plan and documentation."

Public comments could lead to some modification of these rules, but proactive companies clearly recognize the importance of planning their implementation now rather than waiting for their eventual adoption. Under the proposed rule, companies are required to develop and implement a written food safety plan and make it available should the FDA request to see it.

The FDA's proposed rule is comprehensive in its listing of plan components. These include:

- Hazard analysis—identification and evaluation of "known or reasonably foreseeable hazards" for every type of food that is manufactured, processed or packaged at the facility. The implication for training should be obvious. All supervisors and employees will require food safety training to prevent any foodborne illness or other threat based on the plan's identification of hazards.
- Preventive controls for any hazard that is "reasonably likely" to occur. Among these are controls governing process, food allergens, sanitation and a recall plan.
- Monitoring procedures that represent proof of consistent performance of preventive controls and "records to document the monitoring."
- Corrective actions in the event that preventive controls are not properly implemented.

- Verification activities that ensure preventive controls have been properly implemented and are effective.
- Recordkeeping—the requirement for a written food safety plan that includes the hazard analysis. Companies will be mandated to have documented plans and evidence of all of the above plan components. Electronic copies of records would have to meet already established requirements.

"Qualified Individual" & Training Impact

One provision in Section 103 is of particular interest because of its impact on training. It is a requirement for the plan to be either developed or supervised by a "qualified individual." That individual is also responsible for being able to prove the effectiveness of the controls, review and update the plan as necessary every three years, and verify its implementation. The FDA defines the qualified individual as someone who would be required "to successfully complete training in accordance with a standardized curriculum or be otherwise qualified through job experience to develop and apply a food safety system."

Also noteworthy is the requisite that the qualified individual, who does not have job experience, receives training equivalent to a training program eventually approved by the FDA. The individual's training and completion will have to be thoroughly documented and accessible in the event of an FDA audit.

Current Good Manufacturing Practices (cGMP) Proposed Revisions & Training

This provision emphasizes the FDA's view on the importance and necessity of ongoing training. The agency is asking for public comments about ***mandatory*** training for employees and supervisors under Current Good Manufacturing Practices. Statistics from the FDA explain why the agency believes the revision is needed.

The agency reports that 24 percent of cGMP-related food recalls during 2008-2009 were attributable to deficiencies in employee training.

The FDA is also seeking public comments on two other training provisions within cGMP: one requirement to maintain records that fully document training and another that would mandate training's frequency. Once again, the FDA is emphasizing easily presentable and verifiable documentation of training as an important element for ensuring the effectiveness of preventive controls.

FSMA Section 105: Produce & Farm Training

Section 105, the second of the proposed rules released under FSMA, applies to produce, specifically "Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption." FSMA grants the FDA the authority to set science-based "standards" for the safe production and harvesting of fruits and vegetables. FDA standards must minimize "the risk of serious adverse health consequences or death." They would cover most fruits and vegetables in a raw or unprocessed state, excluding those produced for on-farm consumption or those agricultural foods that "are rarely consumed raw." The proposed rules of Section 105 become effective 60 days after the final rule is published in the Federal Register, but compliance dates will vary depending on the size of the farm business.

Training would be mandatory under this proposed rule. Farm personnel who handle produce or food-contact surfaces will have to undergo training as would their supervisors. It is easy to understand why when examining two sources of microbial contamination the FDA addresses:

- Health and Hygiene. The proposed rule requires that farm personnel use "hygienic practices including hand washing and maintaining adequate personal cleanliness." Hygiene has long been a focus of training in the food processing and manufacturing industry, and the FDA's concern about it in the agricultural industry will necessitate the need for training there as well.
- Equipment, tools and building. Section 105 sets standards for all three including "sanitation used for produce operations on farms," an obvious potential hazard if employees are untrained.

"They've got to be trained to recognize potential problems and what to do about them. It doesn't work to say 'there's a problem there...carry on,'" Acheson said. "You've got to see it, recognize it, take action (and) monitor to see that it's been implemented."

As is the case with preventive controls, recordkeeping is mandatory so that the FDA can determine that "certain standards are being met." This is likely to be a matter of concern for all agricultural entities including the larger operations that will be required to produce records when the FDA demands them. The FDA estimates that more than 34,000 farms that sell less than $25,000 of food annually will be excluded from Section 105. That leaves 90 percent of "covered produce acreage grown and consumed by Americans," which Section 105 would cover according to the FDA fact sheet.

Training Technology & Recordkeeping—Complying with FSMA

FSMA makes it abundantly clear: there has to be an evaluation of the effectiveness of training and employee comprehension whether in a food processing facility or in the agricultural environment. That is especially true for those facilities that employ a large number of workers for whom English is a second language. Of equal importance is thorough recordkeeping that is documented and verifiable in establishing that training did occur and comprehension was achieved, to meet the standards likely to be imposed by FSMA Sections 103 and 105 as well as by GMPs.

No doubt there are many facility and farm owners and operators who probably consider training , remediation for those employees who need it and documentation an overwhelming burden. For those who have relied mostly on large volumes of paperwork to document their training and remediation efforts, the problem may seem next to impossible to resolve given the new requirements and the emphasis the FDA has placed upon them. Companies in food manufacturing or farming do have an alternative that meets FDA standards under FSMA. Training technology can help them efficiently navigate this complex terrain and do it with provable results to help assure FSMA compliance—all of it electronically.

In this case, the technology is interactive, easily adaptable and does not require employees or supervisors to be computer literate to use it. Each employee receives an intuitive remote control device for use in answering questions designed to confirm understanding of the topics presented certifying their engagement throughout the training event. This electronic platform, a great example of applied technology, can be used to train up to 150 employees at the same time. Additionally for those workers not as fluent in English, the technology can provide multilingual information if needed on key food safety topics involved in food handling and processing. After the FDA approves a standardized curriculum, the training technology can integrate the curriculum and document training of the person who will be designated the "qualified individual" under the preventive controls rule. After earning the designation, the qualified individual can oversee and administer the training program as a vital component of the food safety plan mandated by the FDA.

Training based on this type of technology is designed to assure complete comprehension, a necessity for FSMA compliance as well as for food safety. It validates comprehension and will accept nothing less than perfect scores. Remediation through this process is immediate. If any employee answers incorrectly, the program launches automatically into remediation and confirms that every employee truly understands what is being taught.

What makes this technology a powerful tool for FSMA compliance is its record-keeping algorithms. It is an automated documentation process that can be easily accessed by a company's quality assurance team or FDA inspectors. Having defensible

documentation verifying individual training to control potential hazards by taking temperatures, calibrating metal detectors and measuring sanitizer concentrations, is critical to demonstrate an effective food safety plan. The platform is capable of being customized to suit a company's unique training goals while recording every training session—all paperless.

Equally important, a record of each individual's performance is automated and retained giving the company a clear picture of its workers' current level of knowledge and the FDA an insight into company compliance with FSMA. Documentation issues are completely eliminated through the automation process and meet FDA/FSMA regulations.

Acheson, who now oversees the food and import safety practice for Leavitt Partners, suggests that companies recognize the return on investment from training activities through the new technology. "If you automate it (training) and document it so you take some of the labor out of it, it means you can make change that is good change and protect your product without incurring massive costs," the former FDA official said. "We become more efficient using technological advances to be able to do that."

One of the many examples of the effective use of this recordkeeping technology comes from Ralcorp Frozen Bakery Products (RFBP) and Ralcorp Snacks, Sauces and Spreads (RS3). The two companies, headquartered in St. Louis, Mo., had relied on Word Documents and PowerPoint presentations with online questions and answers for the their training. A GAP assessment by RFBP revealed an inconsistency in message and content according to Melissa Smith-Tate, director of food safety and quality. She was also concerned about the variation in the experience level of trainers at each of the Ralcorp facilities as well as the consistency of presentations, affirmation of comprehension, the ability to revise and upgrade learning, and capturing performance and accurate completion of training by employees.

Ralcorp solved its issues through its purchase of interactive technology consisting of hand-held remotes, interactive courseware and robust online learning management software. Results from RFBP's use of the fully automated technology and its recordkeeping capabilities have been overwhelmingly positive. "We can demonstrate training and accountability at a plant more seamlessly than in the past," Smith-Tate said.

The technology used by RFBP is easily applicable to training and compliance under FSMA proposed rules. It can help assure the selection of the "qualified individual" under preventive controls by verifying training, comprehension and experience. The same is true for the individual's use of the same software for training facility employees. All recordkeeping is automated, immediate and easily acceptable—all of which will be essential should a facility receive a records request from an FDA inspector.

Conclusion

For many food industry companies and farm businesses, issuance of the FSMA rules for preventive controls and produce will require proactive planning beginning with an implementation plan. It starts with assembling a team to examine how FSMA will impact the organization. A GAP analysis such as the one conducted by RFBP is highly recommended followed by comparison of the analysis with the standards indicated under FSMA rules.

Knowing that this FSMA compliance plan could take time, experts recommend starting the plan now instead of waiting for the FDA to act. That means a GAP assessment needs to be reiterative should the rules' implementation be delayed. Firms should also do a comprehensive hazard analysis as required by the preventive controls proposals and pinpoint those areas where training will be necessary to avert contamination or foodborne illnesses.

Another issue that warrants study is the supply chain. Such examination needs to include the origin of the supplier's ingredients and the company's method of validation that the supply chain complies with FSMA preventive controls. After all, it is nearly impossible to identify "reasonably foreseeable hazards" unless the quality and safety of the supplier's ingredients are completely understood.

It is certainly possible that these new legal obligations will require an investment in time and resources to create the necessary infrastructure to achieve compliance. That is why the timeline for implementation of FSMA's rules is an opportunity for businesses to begin their budgeting, planning and preparation for the inevitability of FSMA rules adoption. Companies and farm businesses should consider how today's training and documentation technology can be their welcome ally and valuable tool in achieving compliance under FSMA as well as creating an effective and successful food safety culture for themselves and the public.

About Alchemy

Alchemy is the global leader of training, development, and education products and services essential to successful food safety cultures. By partnering with our customers throughout the supply chain, we increase productivity, create safer working environments, and ensure regulatory compliance from farm to fork. Alchemy protects your employees, products, customers and bottom line.

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