

Using Your Laboratory to Protect Your Brand

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Summary

The food supply chain has become a complex global system consisting of small to large domestic and foreign manufacturers, processors, packers, distributors, and transporters with few common business practices. Con-

The cornerstone of the Food Safety Modernization Act is prevention. This will require facilities to place greater emphasis on traceability, creating urgency for them to take the lab to the field and deploy laboratory information management systems.

sumers now expect year-round supplies of fresh fruits and vegetables as well as more exotic foods. This has increased the risk of a major food safety incident. Compliance with differing government regulations and enforcement policies adds to the complexity. With such a convoluted value chain with multifaceted reporting requirements, how can consumer-facing suppliers demonstrate regulatory

compliance and protect their brands? Laboratory technology can play a key role in brand protection by efficiently managing test samples. Laboratory information management systems (LIMS) facilitate end-to-end traceability of samples and products and all associated laboratory processes; providing a central repository for data and test results for increased traceability and regulatory compliance.

What's at Risk?

While consumer brand preference is subjective, product safety is not. The implied contract between producer and consumer is that products are unadulterated and will not cause harm. According to the Grocery Manufacturers Association (GMA), the voice of the consumer packaged goods industry in the US, ensuring product safety is the industry's single most important goal. While this may be true, for producers, brand protec-



tion is also critical. Recall costs can range from tens to hundreds of millions of dollars and lost sales due to damage to the brand can be devastating.

The Peanut Corporation of America (PCA) -- a supplier of peanuts, peanut butter, peanut meal, and peanut paste -- provides a case in point. In 2008, the US FDA determined that one of the company's processing facilities was the source of the worst salmonella outbreak in US history, killing nine and sickening hundreds. Not only was PCA forced into bankruptcy, sources estimate the cost of the incident to the peanut industry at \$1 billion in lost product and sales. The domino effect throughout the food industry involved the recall of about 1,000 different products. This single incident wreaked havoc with not just one company, but an entire industry.

This incident alone demonstrates the expression that "an ounce of prevention is worth a pound of cure." In other words, it is far better to avoid problems in the first place than to have to fix them later. Experts cite the PCA incident as the impetus behind the Food Safety Modernization Act (FSMA).

FSMA Emphasizes Prevention

The cornerstone of the FSMA is to prevent incidents based upon risk assessment, as opposed to rapid response to an incident. The Act will require facilities to write, implement, document, and demonstrate a food safety

Prerequisite programs are in place to ensure food is produced in a safe and sanitary manner

Hazard analysis that identifies all potential risks throughout processing

Preventive controls that are implemented to mitigate risks

Monitoring of preventive controls to ensure they are properly implemented

Verification that the preventive controls have the intended reduction in risk

Re-analysis of the hazards and preventive controls when there are significant changes in the process or every three years

Major Elements of the FSMA Food Safety Plan

plan. It will likely require facilities to go deeper into the supply chain than the current "one up and one down" regulations. This deeper penetration of the food chain will impact several hundred thousand foreign and domestic facilities registered with the FDA.

For food processors, more stringent controls will be required, enabling a more proactive approach to quality. At minimum, preventive controls will require new practices with more control points and additional requirements for corrective action and preventive action (CAPA), root cause analysis, and more continuous documentation. Producers must also demonstrate crisis management preparedness, product traceability, batch coding, and

hazard analysis and critical control points (HACCP) plans. To improve effectiveness, these systems must interact with many applications throughout manufacturing and its supply chains such that the information can be quickly accessed to contain the scope of a recall in the event of an incident. Plans will differ from facility to facility based upon the level of risk to food safety.

Taking Lab Technology to the Field

Globalization of the food supply chain has not only increased the availability of more exotic foods, it has also increased the number of pathogens. The FDA has reported that there are five times more identified pathogens today than 50 years ago. Traceability of each product from raw material through production and packaging dictates that more pervasive use of laboratory technology in the field will be necessary.



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To minimize risk, food processors must be able to produce detailed and accurate records that identify the quality, quantity, disposition, and handling of products at each handover point. Raw material testing and identity verification at each handover point are critical to traceability and quality management. Portable optical analysis tools, such as those available from Thermo Scientific, bring the laboratory to the field for fast, accurate material identity verification. Handheld Raman, NIR, and FTIR spectrometers can help users quickly verify raw material identification to determine suitability for further processing. These handheld devices require little to no sample preparation, enabling technologies previously restricted to laboratory use to be used in the field to speed raw material identification and data synchronization. The ability to locate the source of a problem through good traceability can minimize the time to recover and avoid extensive damage to the brand and company reputation.

LIMS Secures the Data Environment

The increased traceability requirements mandated by FSMA not only require greater amounts of data, but also require turning that data into useful information. A laboratory information management system, like Thermo Scientific SampleManager LIMS™, can manage samples, act as a repository for records data and test results, and provide increased traceability and full chain of custody to help ensure regulatory compliance. For producers, a

LIMS can help verify that product quality meets regulatory standards while recording that data for subsequent inspections, if required. For auditors, a LIMS facilitates review of compliance reports and related certificates of inspection stored with the LIMS to verify safety. Integrating LIMS with enterprise systems such as ERP, PIMS and MES enables organizations to share information throughout the enterprise for faster and improved decision making.

FSMA increases the stakes to the point where home-grown systems and paper-based tracking methods could place food producers and processes at greater risk for non-compliance, which in turn could jeopardize not only the brand, but the entire operation. Commercial LIMS such as Thermo Scientific SampleManager™ LIMS that are specifically designed to help organizations comply with regulations such as GMP, GLP, HACCP, CODEX, and 21CFR Part 11 are likely to prove indispensable under the FSMA, since they provide a secure audit trail and document corrective actions. While the emphasis is on prevention, the ability to quickly react to a contamination incident minimizes recall costs and potentially protects brand reputation.

Conclusion

The current food supply chain not only increases consumer access to year round supplies of fruits and vegetables, it also increases the number of pathogens that could cause contamination. The FSMA requires tools that focus on prevention and provide a framework for regulatory compliance. LIMS provides a secure environment for monitoring batch relationships between raw materials, processed materials, and packaged good in the complex food supply chain. As the centralized system for collecting, storing, processing, and reporting all food lab-generated data, LIMS provides a complete overview of product quality in accordance with regulatory requirements.

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