Application Note

Food Safety: The Value of LIMS in This Regulated Environment

he U.S. Food and Drug Administration (FDA) has issued a number of regulations to ensure the safety of food manufactured, distributed, exported, and imported in the U.S. The Federal Food, Drug and Cosmetic Act (FFDCA) prohibits the adulteration or misbranding of any food, drug, device, or cosmetic intended for interstate commerce. It also bans the manufacture, import, and export of any food, drug, device, and cosmetic that is adulterated or misbranded. The Egg Products Inspection Act (EPIA) mandates continuous inspection of products, business premises, facilities, inventory, and operations. Suspicious products can be retained, segregated, and reinspected. All adulterated products must be either destroyed or reprocessed.

The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) have been introduced to ensure that meat and poultry products distributed to consumers are wholesome, not adulterated, and properly marked, labeled, and packaged. According to the rule, the FDA performs examinations of animals prior to slaughter, and makes sure that humane methods of slaughter are used. Diseased animals must be slaughtered separately and carcasses examined. In addition, the FDA performs sanitary inspections and regulation of slaughtering and packing establishments.

The Food Protection Plan builds in prevention first, then intervention, and finally response. It is a forward-oriented concept that uses science and modern information technology to facilitate the identification of potential hazards ahead of time, improve intervention methods, and trigger immediate response. The plan presents a robust strategy to protect the U.S. food supply from both unintentional contamination and deliberate attack. The Food Protection Plan aims to address the changes in food sources, production, and consumption prevalent in today's world.

The U.S. EPA enforces the Food Quality Protection Act (FQPA) to regulate pesticides (*Figure 1*). The legislation sets maximum amounts of pesticide residues allowed to remain in or on food products, with the goal of ensuring that pesticides can be used with "reasonable certainty of no harm." The U.S. EPA establishes tolerances for each pesticide based on the potential risks to human health posed by that pesticide. Tolerances established for meat, poultry, and some egg products are enforced by the U.S. Department of Agriculture (USDA), while the FDA enforces tolerances established for other foods.

With U.S. food imports projected to total an impressive \$6 trillion by 2015, consumers are faced with even greater safety challenges. In response, the FDA introduced the Import Safety Action Plan to establish a stronger certification process, provide incentives to encourage good importer practices, increase transparency by publishing the names of certified producers and importers, and strengthen penalties for both foreign and domestic entities. All food imported into the U.S. is required to meet the same standards as domestic goods, namely, to be pure, wholesome, safe to eat, produced under sanitary conditions, and have informative and truthful labeling in English.

In order to ensure finest product quality and compliance with food safety legislation, U.S. food producers and importers must perform precise, real-time product safety testing at all stages of production, processing, and distribution. Laboratory information management systems play a critical role in this process.

LIMS in the food industry

Major food producers importing and exporting between the U.S. and Europe are guided by the U.S. FDA and the European Food Law. Batch traceability is key in the effort to monitor product quality, effectively manage any recalls, and limit product loss. The



Figure 1 The U.S. EPA enforces FQPA to regulate pesticides.



Figure 2 Substandard components should be detected during crop growing, preventing unfit products from reaching the public.

term "traceability" in European Food Law (178/2002) is defined as the ability to trace and follow a food, feed, food-producing animal, or substance intended to be or expected to be incorporated into a food or feed, through all stages of production, processing, and distribution. Ideally, any substandard components should be detected during the crop-growing, raw materials collection, or processing stages, preventing unfit products from reaching the public (*Figure 2*). In cases in which substandard products have been released, the traceability of the product batches affected can lead to a much more effective recall and prevention program, thus limiting the manufacturer's exposure to costs and possible litigation.

Sophisticated LIMS solutions are designed to efficiently manage batch relationships

between raw materials, processed materials, and packaged goods, enabling analysts to identify which batches are affected by any contamination and automatically suspend release of a product during investigation. LIMS are designed to manage and control the quality assurance process, organizing and storing analytical data, and facilitating the conversion of data to information. This process is fully automated, ensuring that the majority of sample results will be within acceptable limits and filtering and highlighting failures to initiate follow-up investigation. The LIMS work flow automatically schedules an analytical review for samples with positive results, addressing the need for fast screening techniques to identify potential contaminants.

Food analysis techniques produce large quantities of different types of data. LIMS are used to automatically gather, store, manage, and report on these data, including sample preparation data, instrumentgenerated data, standards, reagents and media, reference data for users and management, and metric reports. Notes can be used to attach Standard Operating Procedure (SOP) documents to instruments and operators within the LIMS, while links to external repositories and Web sites can also be configured. Certificates are stored within the LIMS for traceability and reissue while templates are used to generate consistent formats of analytical reports.

Food samples used for safety testing are often time- and condition-sensitive, requiring fast turnaround or storage in suitable conditions. LIMS are capable of identifying each sample, uniquely generating labels, bar codes, and hazard data, and storing metadata and sample life-cycle transactions. Freeze-thaw cycles and preparation steps are logged, sample inventory is maintained, and work for laboratory staff is prioritized. Overall, the use of LIMS in the food safety work flow ensures that samples are handled correctly and processed within allowed time frames.

Because automating the collection and analysis of laboratory data is a primary function of LIMS, the LIMS helps laboratory analysts avoid any transcription errors associated with conventional manual data management techniques (*Figure 3*). The LIMS is also capable of tracking instrument status, identifying any requirements for calibration and/ or service, and reporting on the specific parts needing replacing.

In large organizations, a LIMS plays a key role in the integration of the laboratory environment with enterprise resource planning (ERP) and other critical systems. This allows laboratory test data to be automatically available to plant process and control systems, giving managers immediate accessibility to results and providing a more automated environment. LIMS offers a flexible technological solution to suit different laboratory and industry requirements and enables both the R&D and manufacturing QA/QC functions to meet the regulatory requirements of the industry with audited data.

Real-life examples

 Chr. Hansen (Hørsholm, Denmark) is one of the world's top food ingredient companies. In 2003, a significant increase in productivity led the company to standardize on Thermo Scientific SampleManager LIMS (Thermo Fisher Scientific, Waltham, MA) across all of its six culture production sites in Denmark, France, Germany, and the U.S. to ensure optimum quality control in starter culture production. In total, the system is being used by more than 100 research scientists.

Since the implementation of the LIMS, the company has experienced considerable benefits, including real-time, automated entry and processing of laboratory data, and fast extraction of results, leading to increased laboratory productivity and accelerated sample turnaround. Identical product specifications and performance indicators are being used across all sites, allowing for timely identification of global bottlenecks.

Chr. Hansen has also integrated the LIMS with the existing ERP system. Quality control data are maintained in the LIMS rather than in the ERP, and a custom code facilitates laboratory and plant-specific log-in, i.e., samples can be assigned to a designated laboratory or plant. Samples can be logged in without assigning any tests, and production labels are generated without logging them into the ERP. Overall, this system integration means that as soon as the test results are introduced and authorized in LIMS by the laboratory personnel, the information can be immediately available for the processing facilities' technicians and other personnel and laboratory administrators.

2. Sino Analytica (Qingdao City, China) is a world-class food analysis laboratory that provides contract analytical services to a wide range of food suppliers, trading companies, and retailers from China and all over the world. In addition to providing food analysis, the company engages in analysis to support the entire food chain. For example, it is engaged in the analysis of pesticide residues, drug residues, heavy metals, microbiological contaminants, colors, physical testing, and formaldehyde release from wood composite products. The company also employs food analysis to support the advisory and consulting activities to food growers and processors. Sino Analytica has historically managed data manually in the laboratory, with a monthly load of over 1200 samples.

The company chose Thermo Scientific Nautilus LIMS to support its food safety contract laboratory and meet the internal quality standards and accreditation requirements. The LIMS has helped laboratory managers achieve faster assembly, collation, and review of information and data relating to QA/QC activities. The dissemination and sharing of data have increased so that multiple user inputs and resulting actions are more quickly realized. The system also supports accreditation activities such as audit trails and traceability, demonstrating that the com-



Figure 3 Food samples used for safety testing require fast turnaround in the laboratory, and use of LIMS in the work flow ensures that samples are handled correctly and processed in allowed time frames.

pany meets the requirements of auditors and providing documentation for processing internal QC data.

3. Ingredia (Cedex, France) is one of Europe's largest dairy ingredient processing companies, with an annual processing capability of 100,000 tons of ingredients. The company operates two R&D and manufacturing QA/QC laboratories that support six European sites: four in France, one in Switzerland, and one in Poland. The laboratories run approximately 5000 unique tests each week using 200 different methods of analysis to evaluate product appearance, performance, texture, and taste. All products, samples, and test results must be monitored in the most accurate and timely manner.

The company has standardized on Thermo Scientific SampleManager LIMS to control the laboratory testing procedures and ensure repeatable production levels, all while keeping track of information. The LIMS provides Ingredia with the necessary tools to report data in a format that satisfies the entire organization, ensuring that it can continue its operations without interrupting production. In addition, the system handles hundreds of test method definitions that are applied to the many different sample matrices received from the company's customers. The LIMS also integrates the laboratory environment with ERP and other critical systems to allow immediate, real-time access to results.

A built-in audit trail capability permits laboratory staff to monitor all data trail activity within the LIMS database, ensuring maximum protection against inadvertent changes, malicious alterations, and damage to archived data. Audit-ready information is kept within special read-only tables in the LIMS and can be directly accessed by regulatory authorities. This secure auditable environment facilitates regulatory compliance with GMP, NAMAS, EPA, FDA, and GLP guidelines.

Conclusion

It is essential that the health and welfare of consumers be protected by ensuring optimum food quality. U.S. regulatory bodies have introduced strict regulations to ensure that all foods produced, sold, imported, and exported in the U.S. do not pose any health risk to consumers. In order to comply with these regulations, companies in the food industry need a powerful LIMS to facilitate batch traceability, automatic collection, storage, analysis and reporting of results, and seamless integration of instrumentation and enterprise systems. Thermo Fisher Scientific has developed LIMS that are purpose built for food, beverage, and agricultural applications, which are currently implemented in major global food companies to ensure the quality and safety of food sold to consumers.

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