

Get Ready for the Food Safety Modernization Act:

How a Laboratory Information Management System (LIMS) Can Help You Be Prepared

Introduction

Do you know where your food comes from? How sure are you that it was grown, processed or produced with your safety as the priority? Increasingly this issue is headline news as we struggle with managing the outbreak of food-borne illnesses caused by the very stuff of our daily lives: salmonella contaminated peanut butter; e-coli contaminated beef and pork; contaminated spinach, lettuce and strawberries; melamine in milk.

In each instance, the grower or producer had inadequate methods in place to trace the original source of the contamination. The Mexican tomato business was devastated in 2009 when tomatoes were wrongly blamed for an outbreak of salmonella that was actually caused by tainted jalapeño peppers. Without proper systems in place to provide traceability, there was no way to know the contamination source. Several people died, many more became ill and a major business was destroyed for lack of information.

The ultimate price for those food producers is that not only have they lost revenue due to product recalls, but, more importantly, they have also

“The passage of the Food Safety Modernization Act has laid the critical foundation for a prevention-based 21st Century food safety system. This law makes everyone responsible and accountable at each step in today’s global food supply chain. Under this new law, FDA will now have new prevention-focused tools, as well as a clear regulatory framework, to help make substantial improvements in our approach to food safety. Preventing food-borne illness is a core public health principle that is especially critical in an increasingly complex and globalized world. This law helps us take the critical steps toward strengthening the food safety system that is vital to the health and security of the American people..”

—Statement by Margaret A. Hamburg, Commissioner of Food and Drugs (December 21, 2010)

lost the trust of the buying public – and governments around the world have taken notice.

In the United States, the oversight of food had fallen under a fractured network of agencies responsible for different parts of the production process, from site inspections and safe processing methods, to the documentation of calorie counts and ingredient listings. Some grown and produced foods fell under the auspices of the U.S. Food and Drug Administration (FDA), while food groups that contained a combination of meat, dairy

and produce fell under the oversight of the Department of Agriculture. Compound this regulatory environment with the fact that staffing for food inspections had been low compared to the volume of inspection needed to manage safe production. This lack of manpower and the separation of responsibilities exacerbated the ineffectiveness of the regulatory agencies and caused confusion amongst the consuming public.

The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it. The result of this legislation for consumers should be greater safety of their grown and produced foods. The impact for food producers will be mandates for upgraded business and operations plans, investments in instrumentation, software and manpower, and a safer food supply chain. This white paper discusses the new law, how to respond to it, the role that traceability plays in it, and how leading food producers have implemented best practice solutions.



Key Words

- Food Safety Modernization Act
- Consumer Safety
- Food Borne Illness
- Product Recalls
- Mandatory Inspections
- Reporting of Results
- Automated Traceability
- Data Collection & Storage
- Quality Assurance
- Regulatory Compliance

New Legislation

The Food Safety Modernization Act (FSMA) updates food safety laws to improve the Food and Drug Administration's supervision of the nation's food supply. The legislation requires more frequent inspection of food facilities, improves inspector access to records, and orders facilities to develop and implement safety plans to identify and protect against hazards. The FDA is to establish minimum standards for the safety plans. The bill compels all food plants to register with the FDA. Along with other measures that enhance the FDA's ability to prevent the distribution of unsafe food, the FSMA authorizes the agency to order mandatory food recalls of products that may cause adverse health consequences or death. Finally, the Act makes food origin easier to trace, improves oversight of fresh produce and imported foods, and boosts penalties for violations of food safety laws.

For the first time, FDA will have a legislative mandate to require comprehensive, **science-based preventive controls** across the food supply. This mandate includes:

- **Mandatory preventive controls for food facilities:** Food facilities are required to implement a written preventive controls plan. This involves: (1) evaluating the hazards that could affect food safety, (2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards, (3) specifying how the facility will monitor these controls to ensure they are working, (4) maintaining routine records of the monitoring, and (5) specifying what actions the facility will take to correct problems that arise.

The U.S. Food Safety Modernization Act: What It Means For Food Producers

Its scope is far reaching and non-negotiable: everyone must comply. For those food producers that have not had automated systems for monitoring their processes or do not have methodologies in place to verify batch content or origin of raw materials, the FSMA will impose new strictures which will have an immediate impact on their business. For example:

1. All food producers must register. Registration will identify every person involved in the production process so that a food tracing system can be established.
2. All records must be available on demand by the Secretary of HHS and/or delivered to the agency to verify that safety requirements and processes are being followed.
3. All foods and commodities will require regular testing and reporting of results that show compliance to new science based standards. Penalties may be imposed on facilities that falsify records or submit falsified records for the purpose of non-compliance.
4. Food importers will be required to produce certificates of compliance to the standards and ensure that accredited laboratories conduct proper testing, or else those food items will be refused entry to the United States.

- **Mandatory produce safety standards:** FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables. Those standards must consider naturally occurring hazards, as well as those that may be introduced either unintentionally or intentionally, and must address soil amendments (materials added to the soil such as compost), hygiene, packaging, temperature controls, animals in the growing area and water.
- **Authority to prevent intentional contamination:** FDA must issue regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points.

Employing a LIMS to Meet the Demanding FSMA Requirements

The most important common thread throughout the FSMA is traceability. Laboratory Information Management Systems (LIMS) play a critical role in the traceability of quality in the production process from farm to fork, providing such capabilities as:

- Automated data collection from testing and delivering the records of proof that are required for regulatory compliance
- A secure environment for monitoring batch relationships between raw materials, processed materials and packaged goods
- A centralized system that collects, stores, processes and reports all the data generated within food laboratories, allowing a complete overview of the quality of any product
- Automated checks for out-of-specification results and identification of suspect products to prevent release pending investigation
- Assurance that all (standard, fast turnaround and condition sensitive) samples are handled and processed correctly.



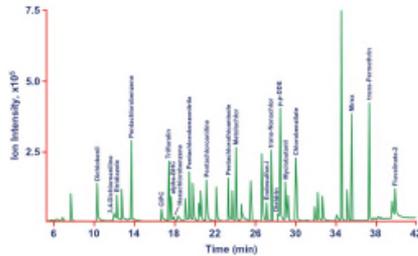
Food Safety Analysis Report

Thermo
SCIENTIFIC

Invoicing Address:
395 Royal Oak Lane
New Orleans, LA 15235

Pesticide Report

Date: Monday, March 03, 2008
Sample: Sample-28-02-2008-(1)
Method: Pesticides
Analyst: Don Crossett
Sample Collection Date: 2/25/2008 00:00:00
Sample Arrival Date: 2/28/2008 16:41:38
Sample Storage: 4 deg C **Signed:** drc
Sample Analysis Date: 2/28/2008 16:47:14



Internal Standards	R.T.	QIon	Response	Conc. Units
1) DB-Naphthalene	7.53	136	256561	0.50 µg/ml
8) D10-Acenaphthene	12.58	164	153677	0.50 µg/ml
Target Compounds	R.T.	QIon	Response	Conc. Units
2) Monolinuron IP frag	6.85	153	551	5.76 ng/g
3) Linuron IP fragment	9.40	187	181	3.45 ng/g
4) Dichlorobenz/Casoron	10.06	171	405876	1681.04 ng/g
5) 3,4-Dichloroaniline	11.75	163	118083	1334.43 ng/g

Signed: _____
Laboratory Director

Furthermore, a LIMS provides the producer with the knowledge that the quality of the product meets the standards set by the regulator, while recording that data for any subsequent inspection. Auditors can review uniform compliance reports and the certificates of inspection stored within the LIMS whenever required to confirm consumer safety.

Ultimately, a LIMS plays a key role in the integration of the laboratory environment with critical enterprise systems to facilitate faster, more informed decisions. This makes laboratory data available to process control systems, giving managers immediate accessibility to results, as well as cascading any release data through to enterprise resource planning systems.

For some food testing laboratories, commercial LIMS have been too costly for the business to absorb and support, forcing them to rely on inefficient manual and error-prone home-grown systems, spreadsheets or paper-based methods. The new legislation will put enormous strain on these labs to remain compliant. Investing in a LIMS will give food

testing labs, growers, producers and manufacturers the traceability they need to keep their products safe from contamination and to conform to the stricter regulations and reporting required of the FSMA.

Case Studies: LIMS Providing Traceability for Food Worldwide

Chr. Hansen is one of the world's top food ingredient companies. The company standardized on Thermo Scientific LIMS across all of its six culture production sites in the United States, Denmark, France and Germany to ensure optimum quality control in starter culture production. The LIMS implementation has delivered 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. Chr. Hansen has also integrated the LIMS with its existing ERP system, so that test results authorized in the LIMS by lab personnel can be immediately available for the processing facilities technicians and laboratory administrators.

Molkerei Alois Müller produces more than a third of all yogurt eaten in the UK from the Market Drayton factory. The Müller UK labs focus mainly on production Quality Control. Every step in the process undergoes quality checks, which are managed and stored with the LIMS. Müller UK selected Thermo Scientific LIMS to manage their QC data for raw materials, in-process, and finished dairy desserts. The LIMS reduced the amount of error-prone manual paperwork processes and expedited testing, while providing the necessary reports and documentation for a complete audit trail during regulatory inspections. By using a LIMS, Müller is able to trend all data and make quality and safety decisions, as well as any necessary improvements, much faster and more reliably.

Sino Analytica in 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. Sino Analytica historically managed data manually in the laboratory with a monthly load of over 1,200 samples. The company chose Thermo Scientific LIMS to support its food safety contract laboratory and meet the internal quality standards and accreditation requirements for food exports to countries including the United States. The LIMS has helped laboratory managers achieve faster assembly, collation, and review of information and data relating to QA/QC activities. The LIMS also demonstrates that the company meets the requirements of auditors and provides documentation for processing internal QC data.

The agrifood sector remains one of Ireland's most important indigenous industries. The Veterinary Laboratory Services that support the **Irish Department of Agriculture** are geographically spread throughout the country and as such, require timely and accurate flow of information and research results across all locations to fulfill the directives of the Department. The Irish Department of Agriculture and Food selected Thermo Scientific LIMS for its laboratory services to: improve the quality of information generated; improve efficiency in the operations of the laboratories as a

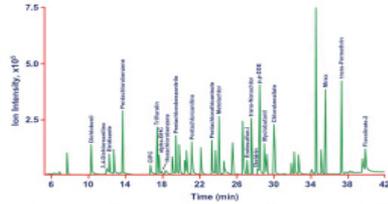
Food Safety Analysis Report



Invoicing Address:
395 Royal Oak Lane
New Orleans, LA 15235

Pesticide Report

Date: Monday, March 03, 2008
Sample: Sample-28-02-2008-(1)
Method: Pesticides
Analyst: Don Crossett
Sample Collection Date: 2/25/2008 00:00:00
Sample Arrival Date: 2/28/2008 16:41:38
Sample Storage: 4 deg C Signed: drc
Sample Analysis Date: 2/28/2008 16:47:14



Internal Standards	R.T.	QIon	Response	Conc. Units
1) DE-Naphthalene	7.53	136	256561	6.59 µg/ml
8) D10-Acenaphthene	12.58	184	153677	6.59 µg/ml

Target Compounds	R.T.	QIon	Response	Conc. Units
2) Monofluorac IP frag	6.85	153	551	5.76 ng/g
3) Linuron IP frag	9.40	187	181	3.45 ng/g
4) Dichlorobenz/Casosen	10.06	171	405876	1681.84 ng/g
5) 3,4-Dichloroaniline	11.75	163	118083	1334.43 ng/g

Signed: _____
Laboratory Director

consequence of the LIMS; improve communications between the various departments; and generate and store epidemiology and disease surveillance information.

Thermo Scientific LIMS was selected for its ease of use and because it could be easily configured and managed by the laboratory staff, without the need for specialist training or additional work provided by either the vendor or IT personnel. The LIMS solution provided the Department of Agriculture and Food's Central Veterinary Laboratory Services with a full laboratory data recording, management, retrieval, and reporting system.

At sample intake, the LIMS has improved the efficiency and security of data entry and has greatly assisted sample identification and tracking by printed and automated label generation. As all laboratory data is now recorded on a single electronic database, the LIMS has provided the Laboratory Services with a means to retrieve, analyze and report data in a way that would never have been possible with the previous paper-based system, including sending results

electronically to third parties and regulatory agencies. The LIMS now provides a database for national animal disease surveillance, reduces information transcription while enabling information sharing across labs and providing traceability of samples. The LIMS has also been integrated with the Department of Agriculture's existing ERP system, SAP, removing a large burden from the laboratory and administration staff in generating monthly invoices.

The Food and Environment Research Agency (FERA) is an executive agency of the UK government's Department for Environment, Food and Rural Affairs (DEFRA). The company selected Thermo Scientific LIMS to improve efficiencies, productivity and sample integrity in laboratories across its multi-site facility.

FERA manages over 600 research projects, analyzing over 50,000 plant and food samples a year and is the National Reference Laboratory for chemicals in food, pesticides, veterinary drugs, dioxins and polychlorinated biphenyls (PCBs) in feed.

FERA labs needed to deploy a central numbering system for samples across the entire site to ensure sample integrity. FERA needed a LIMS to ensure that there was only one #1 sample on site, and not multiple samples with the same number in the different areas of work. A LIMS would dramatically reduce the amount of error-prone paper work, minimize mistakes and expedite sample management.

FERA also required a LIMS to manage all samples on site within a single repository and manage the issue and reconciliation of laboratory worksheets across the laboratory. Analytical trend data was being recorded and assessed manually, so there was a need for a LIMS system that would readily generate trend data in an acceptable electronic format to support internal investigation and reporting functions.

At FERA today, samples are logged into a central repository which includes the following steps: setup, sample receipt, login, numbers, bar-codes, and ship to labs. The central login and sample reception facility is secure and allows in situ login to the LIMS and storage of the samples. Login of samples is now site-wide. The LIMS is used as a tool for operational sample management and helps make the laboratory more efficient. The lab realizes a reduction in costs by eliminating paper reports, working electronically and gains an increase in customer satisfaction by involving their clients in the project, giving them access to their results electronically in real-time.

For More Information about Thermo Scientific informatics solutions for the food and beverage industry, Visit: www.thermoscientific.com/foodsafetyresources
Or visit: www.thermoscientific.com/informatics to see our entire portfolio of informatics solutions.
Or you can email us at marketing.informatics@thermofisher.com

In addition to these offices, Thermo Fisher Scientific maintains a network of representative organizations throughout the world.

Australia/Asia Pacific

+61 8 8208 8200

China

+86 800 810 5118

France

+33 160924800

Germany/Eastern Europe

+49 6103 408 1110

India

+91 22 6742 94 94

Latin America and the Caribbean

+1 781 933 4689

Netherlands/Benelux

+31 76 579 5555

Spain/Portugal

+34 914 845 965

United Kingdom

+44 1619423000

USA/North America

+1 800 395 5467