

Get Ready for the Food Safety Enhancement 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 Food Safety Enhancement Act would indeed transform our nation’s approach to food safety from responding to outbreaks to preventing them. It would do so by requiring and then holding companies accountable for understanding the risks to the food supply under their control and then implementing effective measures to prevent contamination.”

–Margaret A. Hamburg, Commissioner, FDA (June 3, 2009)

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

In the United States, the oversight of food has 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 fall under the auspices of the U.S. Food and Drug Administration (FDA), while food groups that contain a combination of meat, dairy and produce have fallen under the oversight of the Department of Agriculture. Compound this regulatory environment with the fact that staffing for food inspections has been low compared to the volume of inspection needed

to manage safe production. This lack of manpower and the separation of responsibilities has exacerbated the ineffectiveness of the regulatory agencies and caused confusion amongst the consuming public.

U.S. President Obama stated that the current regulatory framework “... is a hazard to public health.” New legislation has been proposed which will overhaul the U.S. approach to consumer safety. The result of this legislation for consumers should be a greater trust in the 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 legislation, how to prepare for it, the role that traceability plays in it, and how leading food producers have implemented best practice solutions.

New Legislation

The Food Safety Enhancement Act (FSEA) 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.



Key Words

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

The bill compels all food plants to register with the FDA and pay an annual fee which, along with fees for food inspection and recall, will help pay for the expansions of oversight. Along with other measures that enhance the FDA's ability to prevent the distribution of unsafe food, the FSEA authorizes the agency to order 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.

Employing a LIMS to Meet the Demanding FSEA Requirements

The most important common thread throughout the FSEA 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

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

In order to correct the inadequacies inherent in the current system for regulating the production of food, the Food Safety Enhancement Act is intended to be all encompassing in its oversight. No longer will parts of the food chain be siloed for oversight by specialized agencies. For the first time, all parts of the food chain will be under one regulatory authority – from growing, manufacturing and processing, to packing, transporting, distribution and storage, and the FSEA will extend to both domestic and imported foods alike. 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 FSEA will impose new strictures which will have an immediate impact on their business. For example:

1. All food producers must register for mandatory inspections. 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 Agriculture and/or delivered to the agency to verify that safety requirements and processes are being followed.
3. Fees will be imposed on food producers, including an annual inspection fee, as well as additional fees if a facility fails inspection and requires surveillance by the agency. Civil penalties may be imposed for those facilities involved in product recalls which include not only monetary fines, but also plant shutdowns and imprisonment.
4. 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.
5. 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.

- Assurance that all (standard, fast turnaround and condition sensitive) samples are handled and processed correctly.

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.

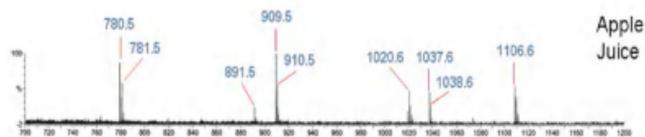


Invoicing Address:
395 Royal Oak Lane
New Orleans, LA 15235

Pathogen Report

Date: Monday, March 03, 2008
Sample: Sample-28-02-2008-(1)
Method: Pathogens/Toxins
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



Target Compound: Staphylococcal Enterotoxin D (SEB)
Sample Matrix: Apple Juice
Internal Standard: Leu-enkephalin
QA: Duplicate runs

Results: **14 ng/ml (ppb)** Signed: _____
Laboratory Director

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. Thermo Fisher Scientific has made the full functionality of LIMS available on-demand via the internet for a low monthly subscription fee (www.limsondemand.com).

Providing Traceability for Food Producers Worldwide

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. 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.

Chr. Hansen in Hørsholm, Denmark 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 Denmark, France, Germany, and the U.S. 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.

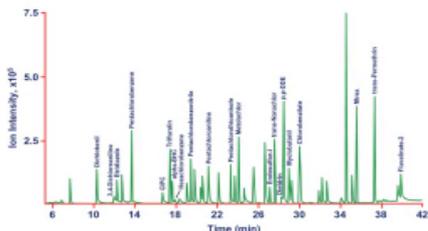
The agrifood sector remains one of Ireland's most important indigenous industries. The Veterinary Laboratory Services that support the Irish Department of Agriculture are geographically spread throughout the country and as such, require timely and accurate flow of information and research results across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

Thermo Scientific Nautilus 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 Nautilus 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.

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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) D8-Naphthalene	7.53	136	256561	0.50 µmol
8) D10-Acenaphthene	12.58	164	153677	0.50 µmol

Target Compounds	R.T.	QIon	Response	Conc. Units
2) Malathion IP frag	6.85	153	551	5.76 ng/g
3) Lincos IP Fragment	9.40	187	181	3.45 ng/g
4) Dichlorodiphenyl Ether	10.06	171	405876	1681.04 ng/g
5) 3,4-Dichloroaniline	11.75	163	118083	1334.43 ng/g

Signed: _____
 Laboratory Director

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. Nautilus 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 Nautilus 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 dra-

matically 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, barcodes, and ship to labs. The central login and sample reception facility is secure and allows in situ login to Nautilus and storage of the samples. Login of samples is now site-wide. Nautilus 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/foodandbeveragesafety
 Or visit: www.thermoscientific.com/informatics to see our entire portfolio of informatics solutions.
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