The use of Laboratory Information Management Systems in the food sector

Colin Thurston considers the valuable role of Laboratory Information Management Systems in the dealing with food safety issues and regulatory compliance

Introduction
Over the last few years, food safety incidents in the USA have been increasing at a fast pace, generating strong public concerns about the safety of the foods they consume. Most recently, a Salmonella outbreak linked to peanut butter and products made with peanut paste sickened at least 529 people in 43 States, sent at least 116 people to the hospital and may have contributed to 8 deaths, according to the US Centers for Disease Control and Prevention. Related to this most recent food contamination incident, the US Food and Drug Administration (FDA) has recorded more than 2,100 products in 17 categories that have been voluntarily recalled by more than 200 companies, and the list continues to grow. The large number of products and brands that have been recalled as well as the large quantities of some of these products, makes this one of the largest food recalls ever in the USA. What was once considered the ubiquitous comfort food of children in many parts of the world is now suspect and the public is left wondering what is safe and what companies are trustworthy with regards to utilising the most stringent safety practices in the preparation of food items.

Regulatory framework
Historically, the management of food safety initiatives has been spread across numerous agencies worldwide. In the USA, for example, the various regulators’ staffing for food inspections has been tragically low in light of the volume required to manage safe agriculture processes, beef, poultry and pork processing, dairy and produce. For prepared foods, separate and non-aligned inspections by different agencies are required if a finished product contains meat or dairy or both. This lack of adequate manpower and the separation of responsibilities based on the type of food are only adding to the ineffectiveness of the regulatory agencies and causing further confusion and dismay amongst the consuming public. Perhaps a look at the regulatory set-up that exists in the USA and the European Union (EU) will illustrate just how complex the issue of food safety can be.

The US and EU regulatory systems
The US regulatory landscape makes a number of different government agencies responsible for various aspects of food safety: the FDA, USDA (US Dept of Agriculture), ATF (Bureau of Alcohol, Tobacco and Firearms) and EPA (Environmental Protection Agency) all have different regulatory accountability dependent upon the segment of the food supply chain.

For example, the FDA has responsibility for general food products and beverages, except for processed egg products, meat and poultry, fruits, vegetables and other plants which are under the remit of the USDA. Combination products (e.g. stew, pizza) may fall under either the FDA or USDA depending upon their make-up ingredients. All alcoholic beverages, except wine containing less than 7% alcohol, are regulated by the ATF. The EPA determines the safety of pesticides and tolerance levels for pesticide residues in food.

These complex multi-agency responsibilities result in a public perception of a confused government attitude to the nation’s food supply. Newly-elected President Obama recently declared that the current regulatory framework “… is a hazard to public health”. It is widely expected that new legislation will be proposed to overhaul the US approach to consumer safety. In the mean time, the FDA has recently received $300m in additional funding, of which half is to be used to increase the number of domestic and overseas inspectors.

The EU enforces regulations with the aim of achieving the highest possible level of protection of human and animal life and health, plant health and the environment. In addition, the regulations aim at achieving EU-wide free movement of human food and animal feed. Adopting a comprehensive, integrated “farm-to-table” approach, the regulations cover all aspects of the food production chain, with a single overarching framework. There are specific regulations applying to imported food that contains animal products, e.g. meat, meat pies, salami, poultry, fish, eggs, milk, dairy products, and honey. These products must be presented at a border inspection post accompanied by all the relevant certificates required in EU veterinary legislation. Less strict legislation is implemented for food that has no animal content such as fruit, vegetables, cereals, certain bakery products, herbs, spices, mineral water and fruit juices.
Food companies in developing nations have a general obligation to monitor the safety of products and production processes while the competent authority of the exporting country must guarantee the compliance or equivalence with EU requirements. In general terms, food products must be tested to ensure conformance to specifications and product safety whether they are destined for human or animal consumption. Testing must address the complete spectrum of food safety issues, including veterinary drug residues, pathogenic and toxigenic microorganisms such as mycotoxins and marine biotoxins, pathogens, trace elements and chemical residues including environmental pollutants. Regulatory requirements are dictated by the location of the consumer, and therefore, complex testing requirements and specifications will inevitably exist where products are provided to multiple geographic markets. This complex backdrop of laboratory analysis means that Laboratory Information Management Systems (LIMS) are an essential tool for the management and monitoring of test results and therefore play a significant role in this process.

LIMS capabilities in food safety testing

For food producers, traceability throughout all stages of production, processing and distribution is critical in the effort to monitor quality, effectively manage recalls and limit product and revenue loss. A LIMS offers a secure environment for the management of batch relationships between raw materials, processed materials and packaged goods. A LIMS automatically captures sample data, checks for out-of-specification tests, collects and processes data and re-issues whenever needed by regulatory agencies. In addition, a LIMS can help laboratories achieve full compliance with even the strictest regulatory requirements. With a LIMS monitoring the testing of samples, a producer can be assured that the samples are handled correctly and processed within allowed timeframes. A LIMS will also monitor any established requirements for instrument calibration and replacement of parts, as well as the training qualifications for all users of the equipment or software, ensuring that only authorised users are performing testing and that all instrumentation is within specified settings. A LIMS can provide a producer with the knowledge that the quality of the product they are delivering meets the highest standards set by legislation and regulatory authorities.

Sophisticated LIMS solutions are capable of integrating with instruments and other critical systems already in use within the laboratory, as well as with enterprise resource planning (ERP) systems in place throughout the organisation. By having a LIMS integrated with the existing ERP system, management can make use of the data generated in the laboratory in a way that informs their day-to-day decision making. This type of integration is especially critical when a contamination has been identified and a recall has to be issued. As a result of integrating the LIMS with the organisation’s ERP, test data are immediately available to plant personnel and control system managers, making results instantly available to managers. This will enable more efficient tracking of the source of contamination, minimise the company’s exposure to distributing contaminated product to the public and reduce the company’s loss of revenue that will result if a recall is ordered.

Application examples

**Chr. Hansen**

One of the largest food ingredient companies in the world, Chr. Hansen operates six culture production sites in Denmark, France, Germany and the USA. Following a considerable productivity boost, the company standardised on Thermo Scientific Nautilus LIMS™ across all of its six facilities to enable finest quality control in starter culture production. The system’s central server has been installed in Denmark while an infonet connection has been established between the culture production laboratories and the rest of the Chr. Hansen plants. In total, the LIMS is being used by more than 100 research scientists.

Since its implementation, SampleManager LIMS has allowed the company’s scientists to automatically enter all samples into the system immediately, eliminate redundant testing, reducing real-time results and enhancing productivity. In addition, the LIMS now seamlessly integrate with the company’s ERP system, meaning that the test results are amassed and available to all users once they are introduced and authorised in the LIMS. Identical product specifications and performance indicators are being used across all sites allowing for timely detection of global bottlenecks. Overall, this implementation has helped Chr. Hansen achieve its goal for optimum product quality.

**Sino Analytica**

Sino Analytica is a world-class contract analytical services provider, performing tests each week using 200 different samples, for food suppliers, trading companies and retailers from China and all over the world. Analysis of pesticide residues, drug residues, heavy metals, microbiological contaminants, colours, physical testing and formaldehyde release from wood composite products are just some of the many applications undertaken at the company’s state-of-the-art facility. The company required a powerful system that would automate data management in the laboratory, coping with a monthly load of more than 1,200 samples while meeting the accelerated quality control and accreditation requirements.

Following a strong recommendation by Central Science Laboratory, Sino Analytica chose Thermo Scientific Nautilus LIMS™ to replace legacy systems in both its laboratories, allowing for faster realisation of quality control and response, legislative authorities have been notified and work is being undertaken to identify and address the problem. 

**Nautilus LIMS** has been able to support accreditation activities such as audit trails and traceability, demonstrating that the company has the capability of meeting the requirements of auditors and providing documentation for processing internal QC data.

**Ingredia**

Ingredia is a top European dairy ingredient processing company performing tests each week using 200 different analytical methods to evaluate product appearance, performance, texture and taste. In total, the company processes 100,000 tons of dairy ingredients each year. In order to control the laboratory testing procedures and achieve repeatable production levels, Ingredia implemented Thermo Scientific SampleManager LIMS™.

The LIMS has enabled Ingredia to monitor all products, samples and test results in the most accurate and timely manner. Data reports follow a format that satisfies the entire organisation, allowing for continuous, uninterrupted monitoring of the data and to each sample matrix received from customers. Integration of the LIMS with the existing ERP and other critical systems has allowed for uninterrupted production.

**Conclusion**

As a result of reoccurring food safety incidents, consumers are aware and concerned about the safety of their food. Food producers, suffering enormous loss of revenue and public confidence if their products are suspected of being unsafe, are likewise aware of their responsibility to ensure safety and to prevent food fraud. In response, legislative authorities have issued a number of regulations to ensure the safety of food manufactured, distributed and stored throughout the world. As a consequence, raw materials, packaging and finished product as well as environmental and process safety testing must be conducted on a regular basis.

Competent LIMS solutions ensure that test data from all parts of the delivery chain can be captured and analysed so that the safety of consumers is guaranteed. A LIMS manages and controls the quality assurance process, organising and storing all raw data and converting this data into valuable information that can be used by management to make informed business decisions. Achieving complete automation of all laboratory operations, a LIMS provides food producers with the confidence that sample results are within regulated limits, while any failures will be highlighted to trigger follow-up actions and prevented from being distributed throughout the rest of the supply chain and ultimately to the consumer.

Colin Thornton is Director of Product Strategy, Process Industry, Thermo Fisher Scientific, 2160 Cabot Rd, Woburn, MA 01801-1086, USA. He is responsible for determining the strategy of Thermo Fisher’s current portfolio while identifying new market opportunities within the Process Industry sector.

For more information about Thermo Scientific LIMS solutions, please contact:

**Tel:** + 1 886 463 6522 (USA) or +44 (0)161 942 3000 (UK)

Email: thermo@scottpr.com.

Maha contact

Kelli Delongton, The Scott Partnership, 1 Wholesale, Station Road, Holmes Chapel, Cheshire, CW4 8AA, UK.

Email: kelli.delongton@thermo.com.

Patty McDermott, Thermo Fisher Scientific 35A Cabot Rd, Woburn, MA 01801-1086, USA

Tel: +1 781 933 4689

Email: patricia.mcdermott@thermofisher.com.

For more information about LIMS solutions, please contact:

**Tel:** +1 866 463 6522 (USA) or +44 (0)161 942 3000 (UK)

Email: patricia.mcdermott@thermofisher.com.