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Food Safety Measures Pending in 2010

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Introduction

Even before the largest food recall in U.S. history -- where this year half a billion eggs have been recalled -- new food safety laws have been working their way through the legislative process. If enacted in their current form, the focus of our food safety system will shift dramatically toward proactive prevention measures, with regular inspections and increased government involvement for inspection failures or recall incidents.

Pending U.S. Food Safety Regulations

The following food safety proposals are pending in the U.S. Congress at the time of this publication:

- *Food Safety Modernization Act of 2009* (HR 875, referred to subcommittee April 2009; S 510, put on Senate legislative calendar Dec. 2009)
- *FDA Globalization Act of 2009* (HR 759, referred to House Committee July 2009)
- *Safe Food Enforcement, Assessment, Standards & Targeting (FEAST) Act of 2009* (HR 1332, executive comment requested from USDA, HHS, April 2009)
- *Consumer Product Safety Solutions Act of 2009* (HR 1815, referred to house committee on energy and commerce, Mar. 2009)
- *Consumer Product and Food Safety Information Act of 2009* (HR 3076, referred to House Committee June 2009)
- *Relief to small and family-owned businesses* (S. 374, HR 968, Feb. 2009)
- *Food Safety Enhancement Act of 2009* (HR 2749 passed House in July 2009)
- *Food Safety Rapid Response Act* (S1269, Referred to Committee June 2009)

These competing food safety proposals contain many of the same concepts and sometimes identical language. And globally, similar legislation is being considered as countries modernize their regulatory system to address twenty-first century challenges.

Legislative Framework

The *Food Safety Enforcement Act* (HR 2749), sponsored by Rep. John Dingell (D-MI), passed the U.S. House of Representatives more than a year ago. A similar Senate bill (S 510), which is a companion to *The Food Safety Modernization Act* (HR 875), was placed on legislative calendar in December of 2009. A bipartisan senate committee, poised to release a Manager's package and Congressional Budget Analysis, recently issued the following statement:

"Any 100-year-old plus structure – like our nation's food safety system – needs improvements. With this announcement today, we aim to not just patch and mend our fragmented food safety system, we hope to reinforce the infrastructure, close the gaps and create a systematic, risk-based and balanced approach to food safety in the United States."

Broad consumer and industry support is reported for this legislation, including from the Center for Science in the Public Interest, the Consumer Federation of America, the Grocery Manufacturers of America, the National Association of County and City Health Officials, the National Restaurant Association and the Trust for America's Health (Scott-Thomas, 2010) as well as from the Obama administration.

The current drafts will, if approved, place more emphasis on prevention of food borne illness and provide new tools to respond to food safety problems. They contemplate the following:

Safety Plans and Records Retention

Food facilities will implement food safety and food defense plans. Hazard Analysis and Critical Control Points plans would become mandatory. Companies are required to create and maintain records that can be inspected using modern information systems and best practice.

Traceability

Information systems will track the origin, movement and reporting of food in the supply chain. The recall of adulterated or misbranded articles of food becomes mandatory. The technologies and methodologies used must meet requirements of the FDA.

Imports and Supply Chain Management

Importers will be subject to the same safety standards as domestic food producers (existing law and the changes noted above). Processed food labels will indicate the country where the final processing occurred.

Inspections of Facilities

Registered food facilities will be inspected by the FDA and required to comply with mandated documentation. Refusing, impeding or delaying inspections is prohibited.

Recall Authority

The FDA would have authority to mandate recalls of tainted food, and companies would have to pay the FDA's costs. Businesses with food safety weaknesses could be significantly affected by FDA intervention.

Information Systems Must Capture Key Process Steps to Ensure Food Safety

Information systems should reflect best practice, not because of a government mandate, but because it's the right thing to do. Additionally, enterprises that employ scalable business intelligence software enjoy a significant competitive advantage.

Some businesses are meeting this challenge by using enterprise resource planning (ERP) software, RFID, and other technology applications to track materials received and delivered. These solutions are helpful – and required -- but do not sufficiently monitor and document the key steps in the manufacturing process. Additional technology is still required in order to ensure food safety and efficiently comply with regular FDA inspections, as these new regulations come about.

Effective Automation Systems Require Deep Customization, Modularity

Plant automation systems control equipment and can be programmed to collect data internal to a plant. Yet each plant has a different physical layout, is built to meet different environmental considerations, at a different time and location and with different business goals in mind. As a result, there are endless varieties of equipment, operating nuances and plant design choices to support, and plant automation systems end up requiring highly customized, technically intensive integration efforts. The software not only reflects physical differences between plants, but differences among automation platforms, development goals given to the system integrator, and

the skill level and technical bias of the individual system integrator.

As a result, while plant automation systems can be configured to generate some of the data needed for compliance, they are not typically deployed with this purpose in mind. They will have to be significantly augmented in order to achieve this goal. Before attempting to reconfigure an existing plant automation installation for a second purpose, consideration should be given to the total cost of achieving compliance goals for the entire enterprise. Nuances of data collection methods among all plants and automation systems should be documented and understood. The complexity and cost of data integration efforts between multiple automation platforms should be assessed. Accountability for both regulatory and operating requirements should be clear, as modifications to the installation for one purpose may have implications on the other. Each custom integration requires a unique validation effort, with a rigid change control process.

The Role of Enterprise Manufacturing Intelligence Software

Food and beverage processing plants, and the enterprises that own them, should evaluate the role of enterprise manufacturing intelligence ("EMI") software in their food safety planning.

Newer and more powerful EMI applications offer significant advantages that have not been available in the past. This software can be licensed with a smart architecture that is highly configurable to the requirements of food and beverage plants. Modular solutions allow quick installation, without time consuming and risky integration efforts. For example, a paperless records module can be implemented for the entire plant in less than 2 weeks.

Information system managers also appreciate that configurable software products have a forward-looking product roadmap. The product can evolve over time to stay current with best practice in the industry. This is a key criteria when regulatory requirements are evolving.

EMI software can pull information at every key process step directly from the plant floor. This is necessary to establish the highest quality in data

collection integrity. It will immediately compliment existing ERP, GRC and accounting systems, while preserving full compatibility with all plant automation software platforms that may be used within the enterprise.

The processes and systems of configurable software products are repeatable and highly scalable across an enterprise. This enables dramatic simplification of the validation steps needed in a multi-plant enterprise wide food safety plan or risk analysis, whether measured at the time of initial installation, following a modification to the plant, in response to an audit by federal or state regulators, or in response to a product recall. It also dramatically simplifies data management throughout the enterprise, lowering lifetime cost.

An EMI solution should offer a traceability module that provides the highest quality lot genealogy, from every raw material to final product. This will allow the plant (or a multi-plant enterprise) to identify the distribution of all food products made and sold within just a few minutes, with full traceability to all raw material mixtures, washes and other key process steps. The traceability solution appropriate for a company shipping cartons of eggs is very different from a manufacturing plant that uses egg as a raw ingredient in some of its product. Most traceability solutions are not designed to meet this more stringent requirement.

The data collected using EMI software should also be presented graphically and combined with powerful analytics tools that enable food processors to drive efficiencies, achieve their compliance and sustainability goals, actually contributing to the bottom line through loss savings and improved operating efficiencies, creating a significant competitive advantage.

Summary

Food safety regulations are being overhauled, and the legislation currently pending will require that food and beverage processing plants implement written food safety and food defense plans. This dictates a need to modernize information systems and processes that are used to collect and maintain the records to be inspected, or that are needed in response to a food safety incident. A highly configurable software product that is designed specifically for food and beverage processing plants will scale inexpensively across an enterprise and offer a forward looking product life cycle, with real time proof of compliance that meets the requirements of regulatory inspectors, auditors, and internal management.

Bibliography

Scott-Thomas, C. (2010, August). Senate Food Safety Bill Edges Toward Vote. *Food Production Daily* .

About Vigilistics

Vigilistics, Inc. is a leader in providing real time business intelligence solutions to manufacturing plants. Its patented vEMI Application Suite combines powerful analytics tools with intuitive graphical visuals, and a smart architecture that installs quickly and easily to any existing plant hardware and software. The vEMI Application Suite may be licensed as a comprehensive solution or as one or more separate software modules, including: Product Loss Management, CIP, Equipment Efficiency, Variable Cost Management, and Traceability.

**Transform the Way Your Business Uses
Manufacturing Information**

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