WHITE PAPER

THE HIGH COST OF A PRODUCT RECALL

USING PROCESS ANALYTICS SOFTWARE TO MAXIMIZE SAFETY, PRODUCTIVITY AND PROFITS

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Introduction

Why have domestic food-and-beverage recalls more than tripled since 1999? The top reasons include globalization with increasingly complex supply chains. Where at one time, ingredient-suppliers were longstanding and fairly regional, today they can be changed frequently and may reside halfway around the world.

In response governments around the globe are stepping up the complexity and scope of regulations that apply to food and beverage companies. In the United States, the FDA is also requesting significant increases in its 2011 budget. So where does this leave a business?

More than ever, the onus is now on businesses to proactively evaluate their food safety standards before a catastrophic contamination incident occurs. The quality and accessibility of manufacturing records is at the core of this effort, and paper based compliance systems are no longer an industry best practice. When an outbreak does occur, businesses must be ready to provide a rapid and effective response.

Recall Considerations

At the time this paper is being written the F.D.A. is still sorting through how two Iowa farms managed to produce the largest egg recall in U.S. history. The bigger picture, however, is that every year 76 million Americans get sick from foodborne illness. According to
the Centers for Disease Control and Prevention, more than 300,000 are hospitalized and 5,000 die.

And the numbers have only gotten worse over time. Given an increasing population, global markets and a more complex supply chain, a three-fold increase in the number of domestic food-and beverage-related recalls since 1999 is not altogether unpredictable. More eyecatching is the rate at which these recalls have increased in the last few years, jumping from

240 in 2006, to 565 in 2008, and up to 926 in 2009. (Oehl 2010).

The top two causes of food product recalls in recent years are Salmonella contamination and unknown ingredients. To put the complexity of a major recall in perspective, consider that a single recently publicized incident involved more than 70 companies and over 3,900 specific products due to a peanut-related Salmonella outbreak at a Georgia manufacturing plant. The economic impact of this outbreak is estimated to be more than $1B USD.

The human cost associated with product recalls can be even more profound. Nine people died and hundreds became sick from the Georgia peanut plant incident. 1400 are already reported sickened by the recent egg recall incident. When human lives are lost, or significant numbers of people become sick as a result of food safety negligence, the incident may be politicized, greatly increasing media attention and damage to the brand and business. In those instances publicity can continue through multiple years, with increased regulatory and media scrutiny, and possible criminal sanctions for those deemed responsible.

In 2008 a highly publicized salmonella outbreakin salsa was initially linked to tomatoes.
The FDA ultimately found that the salmonella had originated in Mexican jalapeno and serrano peppers. By that point, the tomato industry had lost an estimated $100m. (Scott-Thomas 2010). This underscores the responsibility that government and business share to prevent outbreaks and, when they occur, to respond effectively and accurately in the public's interest.

A recent study reported that "76% of respondents indicated that they are more concerned now than they were 5 years ago about the foods they eat and 57% have stopped eating a specific food because of a food recall (for an average length of about 6 months)." (Oehl 2010). Clearly, a business will be hit hard when a food or beverage product is recalled. The direct hit will include (on average) a full quarter of profits for the recalled product, marketing to repair long term brand damage, spillover negativity that reduces sales of other products, product liability claims and the cost of restoring status within distribution channels. This is in addition to the recalled product value.

Self Regulation Can Avoid Increased FDA Intervention

For fiscal year 2011, the FDA has proposed a 30% budget increase for new safety standards, traceability frameworks, import safety checks and better risk analysis under the Transforming Food Safety Initiative. One of the proposed changes would give the FDA authority to mandate recalls of tainted food, and require that firms pay the FDA's costs associated with recalls. Some control over mandatory recall authority would shift away from companies to the FDA, affecting a company's ability to quickly contain a recall. (Gunther 2010).

Stepped up regulatory involvement prior to a recall is also contemplated. Food processing plants registered with the FDA would become subject to inspection. The inspections require compliance with mandated documentation requirements and give the FDA greater access to records. Refusing, impeding or delaying inspections is prohibited. Non-compliance fines would be levied in greater numbers as the FDA takes proactive steps aimed at reducing the number of recalls.

It's not clear that these regulations will reduce the number of recall incidents. What is clear is that companies with food safety weaknesses will be significantly affected by FDA intervention. It is therefore in the best interests of companies to pro-actively self regulate, even going above and beyond what is or may soon be required.

(continued)

Best Practice Can Reduce Brand Damage in a Product Recall

Viewed through a positive lens, self regulation is a way to help build customer goodwill and loyalty and convey the impression that the company is making higher quality and safer products. Studies demonstrate that consumers are increasingly aware of a company's sustainability and social responsibility initiatives, and that food and beverage companies can effectively use this information in marketing campaigns.(Forward 2008).

Effective branding is always important but never more so than in troubled economic times. Consumers are inclined to scrutinize each purchase more closely, particularly in terms of branded versus private label products. For a consumer to justify paying more for a product, they have to believe that the product is safer, of higher quality, or tastes better. Food and beverage companies expend tremendous resources in order to clearly differentiate their products from competitors'.

Nothing will differentiate a product more (and more quickly) than a product recall. It is highly destructive to brand value, at a cost that is vastly disproportionate to the cost of implementing best practice. The lack of best practice in records retention can be a direct cause of the product recall. In other situations, a deficiency in records retention or traceability solutions may increase the recall scope, delay the remediation effort, or cause unnecessary resources to be expended. The mere existence of a best practice deficiencyexposed publicly in a highly negative context will have its own destructive impact on the public's view of the product and company, and on the company's view of management.

Digital Records are No Longer Optional for Food and Beverage Plants

Digital Records retention for highly regulated operations such as clean-in-place and material traceability is no longer optional for a business operating in this environment. The high cost of product recall, the increased safety risks inherent in an extended global supply chain, a less tolerant consumer combined with evergrowing (and global) regulatory pressures, have already created competing and greatly more complex demands on the record systems. While the government may never mandate a digital records system, the requirements that are mandated cannot be efficiently met using traditional paper based processes.

Companies that invest in the right technology to help them manage these records can more promptly respond to or even avoid a food safety incident. They are better positioned to meet the emerging regulatory challenges, domestically and internationally. They have a significant competitive advantage going forward.

Digital records can be created in many different ways. For example, paper documents can be scanned or manually entered into ERP systems. An existing automation software installation, highly customized to the physical plant layout, can through custom integration work be programmed to pull certain data. Newer, more advanced solutions can rapidly configure directly to a plant floor, providing a continuous stream of the data needed and permanent digital record.

In selecting an information technology best practice for a food or beverage processing plant, the following criteria should be considered:

- *Data Collection:* Real time data pulled directly from the plant floor. In a recall incident, the company will need to quickly isolate the contaminated product. The ability to collect information directly from the plant floor will allow the company to respond quickly. It also reduces the likelihood of data entry or translation error.

- *Process Standardization:* Consistent process definition across the enterprise, for all process steps that are subject to regulation, with a repeatable data collection process. Differences between plant

installations and data collection should be documented with implications on validation and audit understood.

- *Business Intelligence*. Dashboard reporting and business intelligence analytics tools that help drive operating improvements in the organization.

- *Data Management:* Ease of integration with enterprise resource planning, accounting and information services. Repeatable data collection, traceability, interfaces across the enterprise.

- *Product Lifecycle Management*. The lifetime cost of maintaining the product, including installation, maintenance, and interfaces with other systems necessary to capture and share the data.

- *Traceability:* The ability to track and trace lot genealogy for the type of product being manufactured, with full two way traceability from all raw materials through the final product.

To illustrate, consider a processing plant that combines various raw materials in liquid form to produce a finished product. If a contaminated raw material is introduced from a supplier into several product lines at multiple plants, the time required to isolate the contamination and initiate a product recall is a function of the quality of the records kept, and their accessibility; paper records (or an ERP system lacking current data) will add significant delay and is error prone. The time required for the FDA to declare that the problem is resolved (or approve the recall if the FDA is managing the process) is a function of process standardization across the contaminated plants (if each plant has a custom integration then the differences will need to be understood and factored into the response). The scope of recall will be determined by the accuracy of the traceability genealogy through all of the process seps and mixtures, through the point in time that the contamination was removed.

Business Intelligence Solutions Should be Repeatable, Agile and Forward-Looking

Business Intelligence Solutions used in food and beverage processing plants must allow plants to evolve and remain agile while, at the same time, satisfying the need for scientific hazard analysis across an enterprise.

A food safety plan that relies on data collected from multiple plants requires a highly repeatable data collection process. If this is accomplished by custom integration work, then the enterprise will achieve a rigidity around the business intelligence that is counter purposes to the end goal. It is also highly unlikely that a custom integration effort will yield a repeatable data collection effort. Even if it does, the cost and inertia required to adopt process and equipment innovations will be significant and, over time, erode the company's ability to compete.

This need can be filled by a solution that rapidly configures to the individual variations among different physical plant. Such a solution would take information in real time, directly from the plant floor, without need for lengthy and technically intensive integration efforts. The traceability and regulatory records are free to evolve with best practice and regulatory changes, because there is a forward looking product roadmap. The plant is also free to evolve and remain agile, as the configuration will easily update to reflect changes to equipment, product lines or processes, without engaging custom integration efforts across an enterprise.

Companies who achieve this will be able to continuously monitor and record process information at key process steps, without human intervention, establishing the highest quality in data collection integrity. Their data collection processes and systems will be highly repeatable across the enterprise, enabling a fundamentally simpler validation approach to the emerging FDA requirements, and to their own

evolving food safety goals. They will also enjoy much simpler integration with ERP, accounting and information systems, while immediately eliminating compatibility issues between variants of plant automation software platforms.

In response to a product recall, these businesses will be able to quickly isolate all affected products. They will have complete visibility into the processing plant, with real time data that was collected the same way across an enterprise. Within a few minutes of learning about a material contamination from one of their suppliers, they will be able to isolate every food product made and sold that may have been contaminated, with full traceability to all raw material mixtures, washes and other key process steps.

Summary

Business Intelligence Solutions for food and beverage processing plants can provide dynamic, real time proof of compliance that meets the requirements of regulatory inspectors, auditors, and internal management, without costly or technically intensive integration efforts. These solutions are an indispensible tool for helping to prevent the potentially catastrophic consequences of a failed safety audit or otherwise high cost of product recall, and they will also help companies to create a meaningful long term competitive advantage for their business.

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About Vigilistics

Vigilistics, Inc. is transforming the way food and beverage operations use manufacturing data. Our software solutions monitor, record, analyze and optimize production and cleaning processes used in manufacturing operations, to deliver actionable real-time intelligence to managers and executives.

Our software is now in use by some of the largest food manufacturers in the world, and validated by the FDA for paperless compliance reporting. Our secret is a novel and patented data model that unlocks an ability to configure data collection to the nuances of each plant, and monitor every process step and parameter the same way, without using highly technical engineering resources. We offer solutions for receiving, pre-op inspections, CIP management, traceability, yield, and more.