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## **EXECUTIVE SUMMARY**

Today's food and beverage manufacturers, processors, distribution and storage operators face more rigorous regulatory and industry requirements than ever before. Project teams are challenged with information management related to ever-changing food safety compliance mandates. This paper outlines the information needs of the sector, the challenges of compliance, and the role played by modern Enterprise Resource Planning (ERP) systems.

# **CONTENTS**

Information Management Needs	3
The Challenge of Compliance	3
Regulatory/Trade Management Systems	4
Holistic ERP Systems Approach	4
Realizing the Opportunity	5
Tighter Controls	5
The Ultimate Goal: Safe Food	6
Food Safety and ERP – Final Thoughts	6
Food Safety and ERP from Ultra Consultants and Kestrel Management	7

Food and beverage (F&B) manufacturers, processors, distribution and storage operators have been challenged with information management related to their food safety compliance programs since the onset of both regulatory and industry requirements.

Much of this attention on documents and records management was originally emphasized by the industry requirements of the Global Food Safety Initiative (GFSI) Standards.

Today, document management is central to the benchmarked standards (i.e., BRC, FSSC 22000, IFS and SQF), as well as many customer-specific requirements and various rules under the FDA's Food Safety Modernization Act (FSMA).

This has sparked a food safety revolution in the supply chain across the U.S. and globally, including at major retailers like Walmart and Costco.

#### INFORMATION MANAGEMENT NEEDS

With the seemingly endless rollout of regulatory statutes, industry certifications, and global requirements, the need for documented programs continues to evolve, leaving F&B companies seeking the right solutions.

"Food and beverage manufacturers must be able to meet many regulatory and certification requirements to be competitive in today's food industry supply chain. This results in the demands to maintain various programs, data and records that must be consistent within their information requirements, and both a challenge and opportunity to align systems, functionality, documentation and records for food compliance and business purpose. (Ultra Consulting, 2018)

The information requirements are comprehensive and complex, with specifications that are unique to each company needing to comply. It becomes even more complicated to implement information management systems by participants at different levels, as system functionality and configuration must meet specific requirements for each company. Further, certain legal and trade requirements for programs are "must do" imperatives for legally compliant operation as part of the F&B supply chain.

## THE CHALLENGE OF COMPLIANCE

The problem lies in how companies meet the requirements for data and records that are accurate, up-to-date, and accessible at all times for their documented programs.

As a further complication, both deviations and corrections must always be fully validated and verifiable. Not properly managing data and records can lead to potential non-compliance to both legal and trade laws and significant business risks.

These information system conditions and requirements create several questions for F&B companies:



Which systems will best support company needs?



Which solutions should be implemented to alleviate risks?



How can all the necessary information requirements be addressed?

#### REGULATORY/TRADE MANAGEMENT SYSTEMS

Recent history shows that much effort has been placed on various regulatory and trade management systems.

This puts the focus on special systems for compliance purposes that are independent of other business systems, such as Enterprise Resource Planning (ERP) and or Manufacturing Execution Systems (MES). These unique systems offer specific regulatory or trade capability but are not based on the overall manufacturing process.

Enterprise Resource Planning (ERP) and Manufacturing Execution Systems (MES) offer specific regulatory capabilities for compliance."

The outcome is that the regulatory-based systems focus on information that is reported from manufacturing systems like ERP but are likely not aligned or integrated. In many cases, the information shared must be downloaded and possibly exported without complete visibility of its integrity or accuracy. With the focus on regulatory compliance as an independent requirement, the potential benefit of using integrated process information is not commonly seen within the F&B market.

#### HOLISTIC ERP SYSTEMS APPROACH

A more holistic use of ERP systems for the support of regulatory requirements is often overlooked. However, these systems have evolved to address controls and records of items, specifications, supply, manufacturing, and quality/food safety through sales and distribution. Much of the existing functionality is present and can eliminate much processing sought by specific regulatory systems.

Some examples of both large and small organizations show that ERP presents a significant opportunity to meet food safety regulatory requirements. This is especially true for the implementation of new systems that can be properly configured to meet the needs of food safety regulations. This avoids much of the need for specific regulatory and trade systems, while creating efficiencies regarding data entry and more standardized data.

The lack of alignment of food safety information within ERP is likely one of the organizational issues regarding the food safety and quality level of involvement or lack thereof based on who in establishing documented requirements within a system during implementation.

With food safety a new level of requirement to many organizations, the confidence for meeting these requirements within a business process level of decision-making of food processing may be lacking. This area is relatively new, so quality and food safety might be looked at as being outside of the core functional requirements of a new system, even though the implementation of a new system is the best time for such an alignment of information.

#### REALIZING THE OPPORTUNITY

By integrating compliance information into an ERP, processors have an opportunity to better align food safety activities, information, and data with operational activities.

This allows for time-sensitive information from one common information source to include the range of transactional data required. For example, at each point the condition of a material changes, this can be represented, changed, released or disposed with records, as required by food compliance traceability requirements.

# The use of data aligned with process provides the capability to better support food documentation requirements."

Ultimately, the use of data aligned with process provides the capability to better support many of the food document requirements, including procedures and work instructions, and can be managed within the same systems framework. The core processes supported by ERP provide the process-level details, in conjunction with the material status level required by food safety.

The process of planning and deploying new products or materials provides the means and records for establishing and managing specifications resulting in the data, records and deviations or changes that can occur within this process area.

The key is maintaining an item of any type to a specification level based on process change or resulting conditions, such as the level of food safety for the item. The use of configuration to meet food safety requirements can solve the food safety dilemma of multiple systems and databases.

#### TIGHTER CONTROLS

Manufacturing operations that plan and deploy physical product through the work order system can provide the key manufacturing process controls and records needed to assure the release of pure and unadulterated food.

This functionality can provide the information and records documenting the cause of adulteration, the proper segregation of material, and a record certifying proper disposal of contaminated goods. In both of these ERP functional areas, the process and the approval condition of the various ingredients and products can be managed, monitored, and controlled with all of the necessary tracking information.

Within storage and distribution, the required storage and handling criteria, including refrigeration, can be managed and tracked to ensure food condition is properly maintained through these activities.

Similar to the manufacturing processes, the functionality supports the management and tracking necessary for the release of product and any conditions, with records for not releasing certain food product and meeting specification for safe distribution.

Master file information for items, suppliers and manufacture provides for complete recordkeeping and user controls, supporting only the release of safe food, while managing the disposal of contaminated product, as needed.

This status-level tracking is a key requirement to meet traceability and recall requirements. It is important to note that the time-based capability within ERP provides for the level of information, quantity, and status of food product for recall compliance purposes.

ERP functional features streamline the process and the approval conditions of the various ingredients and products to better manage, monitor, and control necessary tracking information."

#### THE ULTIMATE GOAL: SAFE FOOD

Ultimately, FDA FSMA and industry certifications require complete records for all food products shipped to consumers. This is difficult to accomplish with existing information systems used within the F&B supply chain. Even companies with robust systems commonly lose track of the traceability information necessary for effective resources due to the limitations of their systems or that of their various suppliers, holders and transporters.

The use of disparate systems that are not integrated and do not support real-time information only leads to more confusion and issues, as has happened with some of the most recent food recalls.

Compliance, supply chain, trade and quality systems are common. But this often results in the implementation and maintenance of a variety of systems that do not provide common data access.

## FOOD SAFETY AND ERP - FINAL THOUGHTS

Information systems such as compliance, supply chain, trade and quality systems have the potential to provide a greater level of integration.

Without exception, the food safety status, release of product and control of non-conforming products and materials must demonstrate all product meets food safety and that questionable products are properly controlled.

Use of complete systems like ERP offer not only the full status level for all materials, products and activities, but also the time-based and quantitative data of real-time information controls.

A best option for the F&B industry is to seek the use of ERP functionality that is properly configured for safe food processing, the release of safe food, and the accurate quantitative traceability of non-conforming product.

# FOOD SAFETY AND ERP FROM ULTRA CONSULTANTS AND KESTREL MANAGEMENT

Ultra Consultants, Inc., an independent research and enterprise solutions consulting firm serving the manufacturing and distribution industries, and Kestrel Management, a consulting firm that helps companies achieve food safety regulatory and certification standard requirements, partner to provide food safety compliance and remediation advisory services to North American food and beverage processors. The expanded services draw upon proven methodologies to integrate compliance programs into core business processes and systems.

Visit Ultra Website to learn more about the expanded food safety ERP advisory services >

Visit Kestrel Website to learn more about the organization's food safety advisory services >



William Bremer is a Principal with Kestrel Management and heads the company's food safety consulting group. In his food compliance roles, he has led compliance and assurance activities to help many food industry companies meet FDA/FSMA, GFSI (i.e., BRC, IFS, FSSC22000, SQF), HACCP, EHS, and overall operations management requirements. Bill has been involved as a GFSI standard stakeholder and delegate on Technical Working Groups, working with GFSI schemes and standards. He has conducted a number of food safety workshops for clients and a variety of industry organizations and is the founder of the Food Safety Professional Group.



