



# Introduction to Sage ERP X3 FDA Compliance and Product Recalls



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## Managing Product Recalls to Reduce Risk and Minimize Cost

Few industries are as challenged as food and beverage producers to effectively address the impact of industry-specific requirements and legal mandates on their businesses. Not only must they effectively fill customer orders, manage recipes, control inventory and plan production in an increasingly competitive environment, they must also deal with the myriad complexities resulting from increasing federal government regulations.

From the start it's important to note that there's no such thing as FDA compliant business management solutions such as ERP. In the case of Sage ERP X3, it can support FDA-compliant processes, yet as with any modern ERP system, it's very flexible and can perform business functions a number of different ways. Put another way, Sage ERP X3 will only enforce processes that customers have identified and configured to work the way they want to work. It is ultimately customers' responsibility to configure Sage ERP X3 (or any ERP solution) to be compliant with their internal or regulatory compliance requirements.

### Importance of Being "Emergency Ready"

Since the primary intent of regulations such as the Public Health Security and Bioterrorism Preparedness Act and hazard analysis, the Food Safety Modernization Act and critical point (HACCP) compliance is to enable rapid response and containment in case of an emergency, the greatest legal impact has been felt in the critical process of handling product recalls.

Rarely a week goes by without the FDA reporting a product alert on their "Recalls, Market Withdrawals and Safety Alerts" website, based on problems reported by food and beverage producers of all sizes. With the potential for food contaminants to not only adversely affect customer and market confidence, but even corporate viability, it's no wonder food and beverage producers are diligently exploring their options on how best to minimize and eliminate these threats to their business.

Food and beverage producers who are "emergency ready" and completely in control of their information processing systems are not only best positioned to meet FDA mandates, but also avoid sanctions in case of an actual or mock recall. They also have controls in place that help prevent the introduction of contaminated food into the supply chain. Moreover, they also gain the trust and confidence of their customers and business partners, turning a seemingly nonproductive business activity into a competitive differentiator that contributes to the success of their businesses.

### A Modern Business Management Solution Can Help

How can a food or beverage producer accomplish this emergency-ready status? Certainly not by introducing manual paper records and spreadsheets to an older business system, a procedure that can only lead to inaccuracies and time delays that ultimately defeat the purpose of maintaining such information in the first place. Streamlined and seamless capture of traceability data can only be useful when all processes of material planning are fully integrated within the context of a modern enterprise system— one that not only controls business operations but also provides a complete "business picture" that can be quickly re-enacted in case of product recall. That's where Sage ERP X3 plays a major operational role.

Sage ERP X3 is a business management solution that addresses the unique and specialized needs of food



and beverage producers. In addition to managing manufacturing, distribution, customer service, warehouse management and accounting functions, the system includes industry- specific capabilities such as recipe management, quality control, regulatory compliance and lot tracking.

### Quickly Determine the Scope of the Recall

With Sage ERP X3, electronically-stored information can be returned in minutes, allowing companies to judge the scope of a recall, identify which items are at risk to consumers and halt the product at any point in the supply chain. It also supports bi-directional tracking – the ability to register a customer complaint and track it backwards to all other affected customers, manufacturing processes, produced intermediates and raw ingredients. Alternatively, it offers the ability to trace forward based on a supplier’s recall or advisory notice.

Sage ERP X3 can also link production with quality management testing – an integral way of detecting what other products might also be at risk because they use the same equipment or production method.

Lot control is not only an essential means for tracking information related to production batches, it can also become a potential time-saver when associating ingredients and intermediates with lot-specific attributes. Since common ingredients can be used in a multitude of intermediates, the scope of a potential recall can be limited to specific sub-processes associated with these so-designated items.

### Prevent Contaminated Foods from Entering the Supply Chain

Additionally, Sage ERP X3 provides a fully integrated quality control process that can help avoid the introduction of contaminated foods into the supply chain. The system rigorously enforces inspections to assure item conformance to any required product characteristics, operational tolerances or expected results.

The inspections can be conducted at key event points such as during receiving or at any stage of the production and packaging processes. Suspicious items or those that fail any inspection rules are automatically quarantined and designated for further inspection or disposal. The rules-based orientation of Sage ERP X3 assures blockage of any item from being used if it doesn’t have an acceptable quality status.

With a complete and integrated information backbone, FDA compliance comes naturally to Sage ERP X3 users since it maintains a full audit trail and archive of historical transactions for the mandated timeframe. The information is readily available in case of emergency or mock recall and it is accurate, assuring the FDA and customers that the problems can be isolated and contained based on the completeness of the provided information.

### Did you Know?

**81%** of respondents deem financial risk from recalls as **significant to catastrophic** according to a recent report by Ernst & Young for the Grocery Manufacturers Association.

**56%** of those same respondents have been affected by a product recall in the **past 5 years**.



### One System to Manage Industry-Specific Requirements and Product Recalls

With an integrated enterprise system like Sage ERP X3, food and beverage producers can use the same system to address industry-specific requirements and product recalls. Order management, forecasting, scheduling and inventory control enable food processors to reduce the overall cost of business while simultaneously improving customer service.

When combined with features supporting industry-specific and regulatory requirements, food producers can achieve “emergency ready” status, with features such as:

- Effective recipe management that captures detailed item attribute information used throughout the operational system to ensure the accuracy and coherency of product data
- The ability to account for by-products, which provides another level of traceability throughout the production process
- Automated data collection that eliminates the need for keying data into the system (which leaves room for errors and delays) and helps meet the goals of having accurate, readily-available information
- Finite capacity scheduling that can adjust the schedules for equipment using dedicated processing lines and side-by-side machines to help avoid potential cross-contamination of products
- Key performance indicators (KPIs), which provide added business intelligence for exposing suspected problems and signifying potential areas for improvement.

Product recalls, traceability, quality assurance and lot management are not isolated business activities or even the only functions needed to successfully operate a food and beverage manufacturing company in today’s legally-challenging business environment. They are inter-related business processes that, when combined with other food industry-specific requirements, work together in a way that only a business management solution like Sage ERP X3 can address.

As stated earlier, it is important to note that business management solutions like Sage ERP X3 are not inherently responsible for complying with the FDA. Ultimately, it is up to companies to define the necessary procedures and controls so that production-related problems do not occur, using a business management solution such as Sage ERP X3 as a compliance enabler.



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