

The Power of Code: Traceability Compliance

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The recent outbreaks of animal health and food-borne illnesses in all parts of the globe have created a heightened awareness of food-related safety and traceability issues. In response to these outbreaks, the European Union (EU) has already enacted stringent requirements for traceability on both United States and EU-member food manufacturers. Canada, Japan, and Australia are following suit and considering imposing more strict traceability requirements on food manufacturers.

It should be no surprise to manufacturers that the U.S. would soon weigh in with similar programs. Recent food safety regulations issued by the Food and Drug Administration (FDA) will be placing new requirements on both domestic and foreign food and feed manufacturers as a part of the Public Health Security and Bioterrorism Preparedness Act of 2002. These national and international regulations, coupled with the evolution of a more educated and informed consumer, have created a demand on food processors to verify the source of products as they are used throughout the entire supply chain.

U.S. Regulations Requiring Food Traceability

President Bush's fiscal 2004 Federal budget earmarked \$116.8 million in *new* spending to protect the U.S. food system and consumers – an increase of \$19M or 19% over 2003 for bioterror-related food safety programs at the FDA. Part of that budget will be used to enforce the Public Health Security and Bioterrorism Preparedness Act of 2002. On May 6, 2003, the final two proposed Food Safety Regulations created from that Act were published for public comment and consideration. One of these two regulations has the potential to have the most impact on the food industry. It requires establishing and maintaining a chain of custody for ingredients and finished product.

The objective of the record-keeping rule is to help the FDA track foods implicated in future emergencies, such as terrorism-related contamination. Under this rule, manufacturers, processors, packers, distributors, receivers, holders, and importers of food, including pet food, would be required to keep records identifying the immediate source from which they received the food as well as the immediate recipient to whom it was sent².

Not only are all U.S.-based companies subject to this new rule, but foreign facilities that manufacturer, process, pack, or hold food intended for human or animal consumption in the U.S. are also required to abide by this regulation. Pet food companies that are not subject to the record-keeping provisions of the *Animal Proteins Prohibited in Ruminant Feed* regulation are excluded from conformance to this regulation.

Although the rule states that records can be kept in any format (paper or electronic), the type of information, response time, and length of retention is detailed. Information is required to be established at the time the activity occurs and includes:

- The name of the company and/or individual representative of the firm that was the immediate previous source or immediate subsequent recipient of the food
- The address, telephone, fax numbers, and e-mail address (if available) of the individual representative
- The date the food was received or released
- The lot number or other identity, if available
- The quantity and type of packaging
- The contact information for the carrier that transported the food

While certain food processors are required to retain the information for two years after the activity, pet food processors are only obligated to retain the records for one year from time the information is collected.

The regulations are earmarked for final approval in June 2004 and will become effective 6 months later, in December. All businesses are required to comply, but smaller businesses, those with fewer than 500 people but more than 10 full-time equivalents, will have 12 months after final approval to comply, and very small businesses (less than 10 full-time equivalents) will receive 18 months to comply.

Companies may quickly discover that while the cost to capture and retain this information manually seems feasible and appears to be less costly, the requirement that the information be made available to the FDA within 4 hours of a request¹ should prove automation of manufacturing process traceability to be a shrewd consideration.

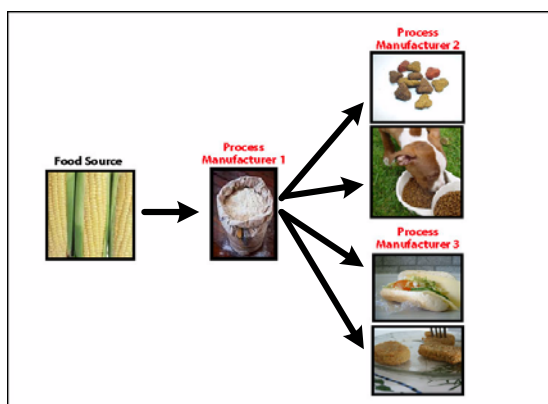
Manufacturing Process Traceability

Traceability has become a 'buzz word' with regard to food safety, and these recent national and international regulations have made it an unavoidable concept. Traceability is the ability to track a food, feed, food-producing animal, or substance through all stages of production and distribution from core genetics to the dinner plate. It involves identifying and documenting all procedures and practices that impacted the life of a

given product and making this information available to the purchaser or other supply chain participant. With respect to the new FDA regulations, traceability is a must.

Traceability Systems

As shown below, traceability *systems* are record-keeping procedures that capture the path of a particular unit or batch of product or ingredient beginning with supplier(s) and continuing through each intermediate step that processes and combines ingredients into product supplied to customers, and ultimately to consumers.



According to new proposed regulations, a manufacturer must provide specific FDA-requested information within 4 hours of a request. A manufacturer's ability to accomplish this depends on the traceability systems in place.

In the event of a product recall, manufacturers must have the same ability to determine what foods are potentially affected and to rapidly respond in order to minimize the health, economic, and other effects of such contamination. The speed at which this can be accomplished and the amount of product impacted, again, hinges on the traceability systems in place.

Traceability systems have been shown to be weak or absent during a number of recent food safety incidents. They were proven to be slow or simply unable to assure consumers of the safety of their food. There is a wide range of traceability systems in place today, from manually recorded information in paper-based systems to data gathered electronically through Information Technology (IT) enabled systems. All of these systems are critically reliant on the accurate recording of information. As a result, handwritten or printed labels are being replaced or supplemented by more effective systems that use machine-readable identification (e.g., bar codes and radio frequency ID tags).

Next Steps

Food manufacturers do not ignore food safety issues and they cannot afford to ignore the traceability issue either, even if they have been lucky enough to avoid a high-profile contamination incident. With the FDA's newfound focus and authority, not automating traceability is a gamble. Regardless of the regulations, since trust is the foundation for acquiring and keeping customers, making food safety and traceability a well-

documented priority is an easy way to keep and increase a loyal customer base in this volatile economy.

Adopting strict standards and ensuring that enterprise and supply chain systems support the full range of food safety and traceability requirements will protect companies from a potential disaster and additional cost of non-compliance with new regulations. Automating traceability is just one step in this process. It requires that quality control and lot traceability be integrated into processing and warehousing systems. These capabilities are an integral and intuitive part of operations and should be reflected as such in the systems that support operations.

Traceability is also greatly enhanced through the use of bar codes or radio frequency identification (RFID) for automated data collection. When supplier lot numbers are associated with a unique ID (bar code or RFID) as product is received, and that ID is then scanned as the product is introduced into the manufacturing process, the product and lot information can be easily traced if needed. Likewise, capturing the lot number of bulk products at receipt and usage, although prone to more uncertainty based on products mixing in a bin, helps quickly pinpoint what lots may have gone into which finished products. In the race against time in a recall or an FDA request for information, automated systems beat a spreadsheet every time. **That's the power of code.**

Conclusion

Manufacturers need to find the optimal balance between streamlining their operations and providing the required level of traceability. Information Technology solutions must be selected based on the specific traceability obligations of the food and feed industry. Tracking lots through bar-coding, RFID, and other automated means is required to meet the new traceability and timing guidelines being imposed by governments around the globe. Finding someone to provide a solution designed for the complexities inherent to food processing and governmental regulations is crucial.

The primary role of traceability is to **protect** public health by facilitating the rapid withdrawal of products from sale and minimizing potential impacts of bioterrorism. The drive for traceability in food manufacturing has been accelerating outside the U.S. and is quickly becoming a domestic requirement. Government and food companies are counting on traceability to support “end-to-end” food safety, thereby improving customer perception, ensuring their confidence, and protecting consumers. Automating traceability should not be seen as a challenge, but rather an opportunity to send out a positive message that you care about, and are committed to, protecting the people you feed.

¹ The 4-hour window is for requests made within business hours. Requests made at other times require an 8-hour turn around of information.

² FDA News, *FDA Issues Final Two Proposed Food Safety Regulations*, May 6, 2003.

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