

It's the 24th Hour:

Do you know where your food product is?



ERP: The Key to Managing Bioterrorism Act Record Maintenance

Establishing, maintaining, and making records available as outlined in the Bioterrorism Preparedness Act can be overwhelming for manufacturers. Because of this, many companies have not followed through with complying with these regulations. Unfortunately, these companies could face serious consequences if action is not taken, and taken quickly. Being prepared for any type of disaster is the key to minimizing the potential adverse effects on businesses and consumers. A solid ERP is the necessary tool to meet the bioterrorism record requirements without being overwhelmed.



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Bioterrorism History

It may come as a big surprise, but bioterrorism has been a method of attack since the beginning of time. Members of the ancient Roman civilization threw dead and rotting animals into wells in order to contaminate the water supply of their enemies. The bubonic plague was introduced as a bio-weapon in the 14th century. By the 15th century, when smallpox was used during the Revolutionary War, methods of controlling and refining the use of the virus proved effective in intentionally contaminating specific targets. Since then, the use of biological warfare has become more and more sophisticated, and today we have growing concerns about anthrax, salmonella, ricin, and others.

A bioterrorism attack is the deliberate release of viruses, bacteria, or other germs used to cause illness or death in people, animals, or plants. These agents are typically found in nature, but it is possible that they could be changed to increase their ability to cause disease, make them resistant to current medicines, or to increase their ability to be spread into the environment. Biological agents can be spread through the air, through water, or in food. Terrorists may choose to use biological agents because they can be extremely difficult to detect and do not cause illness for several hours to several days.

Manufacturers and regulatory agencies paid little attention to the potential threat of bioterrorism until the attacks of 9/11. Since then, Congress responded by passing the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which President Bush signed into law June 12, 2002.

It's important to point out the distinction between "food security" and "food safety" as the Bioterrorism Act specifically addresses security. Food safety deals with accidents such as cross-contamination or processing failures. Food security is much broader and pertains to issues dealing with *intentional* threats. However, both food security and food safety plans have a common goal: to prevent problems that would compromise the safety of the end product to consumers.

To achieve this goal, the Bioterrorism Preparedness Act directed the Food and Drug Administration (FDA) to implement regulations:

- Registration of foreign and domestic food facilities (finalized October 2003).
- Prior notice of food shipments imported or offered for import into the US (finalized October 2003).
- Establishment, maintenance, and availability of records (finalized December 2004).
- Administrative detention of food for human or animal consumption that may pose a threat of serious adverse health consequences or death (finalized May 2004).

A Closer Look at Record Requirements

This paper specifically addresses the establishment, maintenance, and availability of records portion of the Bioterrorism Preparedness Act. Because of the overwhelming nature of this task, many companies have not followed through with record requirements. These companies must take action to comply, and they must do so quickly.

Section 306 of the final ruling requires persons, foreign or domestic, who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records. Food must be meant for human or animal consumption, including pet food, in the United States. Any persons that fall into these categories must be able to identify the immediate previous source of all food received and the immediate subsequent source of all food released.

What is required on the records? For incoming shipments, the records must identify the immediate previous non-transporter source of all foods, either foreign or domestic. Information on this record must include the name of the firm (i.e. supplier), the responsible individual, address, telephone and fax numbers, and email address.

Recording the type of food is also a requirement. This information must be very specific. For example, when describing the variety of food that was received, it is unacceptable to label a product 'cheese'. The records must have descriptions that include a particular brand or food type such as Kraft® Cheddar Cheese. In addition to describing the food variety, the records must also include the date the product was received, the lot number assigned or the vendor identification, the quantity received, and the type of packaging. Again, the packaging type must be specific. Instead of identifying the packaging as a box of product, it is better to categorize the packaging as a 12 count carton or 30 pound case.

Lastly, the incoming document record must depict who delivered the shipment. The name of the company, the responsible individual, address, phone and fax numbers, and email (if available) have to be included. Outgoing shipments have all the same requirements as incoming, except that they are relevant to the next immediate non-transporter food source in the food distribution chain.

Establishment and Maintenance of Records

The FDA does not specify exactly how the records should be maintained as long as all of the required information is tracked. The records should be retained at the location at which the documented activities occurred, or at a reasonably accessible location. Records should be created at the time the food is released, received, or transported, and maintained for a period of one or two years, depending on the food type. Records for perishable food not intended for processing into non-perishable foods and records for animal food should be retained for one year from date of creation. All other food records should be retained for two years post date of creation.

The burden of responsibility in maintaining these records falls upon the person subject to regulations. If the FDA has reasonable evidence to suspect that a food product has been tampered with, the required records must be available for inspection and photocopying as soon as possible, but not to exceed 24 hours. Some states have different guidelines; each business is responsible for checking with the state for current

requirements.

Some examples of the types of records that are kept include: purchase orders, bills of lading, invoices, certificates of analysis, and shipping documents. Manufacturers understand that “Cradle to Grave” traceability is the key to compliance. Producers of food products must have a solid procedure in place where every lot of material is quickly accounted for, whether the substance is a raw material or finished good. Lastly, the manufacturer must also be able to quickly identify where the lot of a finished product was shipped.

The Record Challenge

Having incomplete records or records that are not accessible in the event of an audit or product recall can result in devastation for a company. Any interruption in a company’s ability to produce and deliver products can have serious long-term consequences on its sales or market share. Consider this: nearly *half* of all companies that experience a natural or man-made disaster never re-open for business; in addition, *95%* of the disasters that a company faces are man-made. These man-made disasters include mislabeling, process failures, and employee tampering.

In addition to a potential disaster, a company not in compliance with the regulations subjects themselves to serious consequences should an auditing firm make an unannounced inspection. The federal government can bring civil or criminal action against the person or persons who committed the prohibited act. These actions could result in confiscation of company assets.

Being prepared for any type of disaster, including bioterrorism, is the key to minimizing the resulting damage of such a crisis for both the manufacturer and the consumer. By requiring companies involved in the manufacturing and packaging of food to track where raw materials came from and subsequently who the food was sent to, the FDA can more quickly track and contain food that may be contaminated. In the event of a terrorist attack on the food chain, traceability will be the key to decreasing or eliminating the number of people adversely affected by the attack.

Facing the Challenge

Though all manufacturing companies in the US are required to be in compliance with the FDA regulations as of December 2006, not all companies are. Manufacturers have difficulties facing the lot tracking, paperwork, and reporting challenges in a cost effective, timely manner. So, what’s a producer to do?

All across the country, no matter the food product, manufacturers are investing in ERP solutions to help them maintain FDA compliance. Specifically, these companies are utilizing the tools of integrated ERP systems that link the required documents listed earlier: purchase orders, bills of lading, invoices, and shipping documents.

For example, the Inventory Control component of the ERP should automatically track inventory balances, serial numbers, lots, and product line information. The most advanced inventory control will track unlimited inventory locations and at least two types of storage divisions within each location. The finished goods lot tracking must have the capability of recalling all customers who purchased a finished good lot. A superior system should also track serial numbers and lotted items when the product is

ordered, produced, and shipped. With a fully integrated system, this information is linked to and automatically available for the bill of material, bill of lading, batch ticket, and more thus simplifying the documentation process.

A solid ERP that truly assists manufacturers with FDA compliance will also have Lot Tracking capabilities. A Lot Tracking report has all the necessary information required by the FDA to locate a product in less than the 24 hour minimum limit. In addition to being able to quickly identify where the lots came from, what products the materials went into, and who the finished product was sent to, the ERP system will also be able to identify who transported the products to and from the manufacturing facility.

A Final Word

The bottom line is that each individual is liable to some degree for his or her own food safety. Consumers, however, rely heavily upon the manufacturer to shoulder most of that responsibility. Consumer confidence is built through brand loyalty with companies that are proactive in protecting the food supply. Choosing the right ERP can be an effective tool to help manufacturers comply with the regulations of the Bioterrorism Act. Stop bioterrorism history in its tracks; the time to act on record compliance is now.

- Shanon Odegaard

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