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# **Bioterrorism Act Record Keeping Compliance Guidelines**

By Craig Nelson  
CTO and Founder



 *Regulatory Compliance*

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## Checklist for Bioterrorism Trace Readiness

How ready are you for a serious recall? The guidelines discussed below are taught to FDA and USPHS ratings officers to help them quickly narrow the search for an adulterated food product. The issue of adulteration has special significance in the case of dairy and food products manufactured in environments where lots are mixed and byproducts are created, and product is reused or sold to other manufacturers.

A good adulteration search system should be able to:

1. *include* all products that *could* be affected.
2. *exclude* products that *could not* be affected.
3. prove dilution or concentration of affected products.

### **1. Inclusion of affected products.**

Of most importance, when conducting an investigation the FDA wants to see that the manufacturer can accurately *include* all products that *could have been* adulterated by the incident being investigated. This should include:

- residual product left in a tank, silo, or processing equipment between qualified, full washes or CIP's (Clean In Place);
- residual product that could have been left in pipes or valves, even in minor amounts, between qualified, full washes on that CIP circuit;
- residual product left in a transport container including tanker trucks, totes, and bins;
- any points of possible contamination with cross connections of pipes, overflows, pressure relief valves, or bypasses.

Manufacturers can comply at the most basic level by including all products that could have been in storage or processing during the suspected period of the adulteration. While this provides essential knowledge, it does not build confidence, in and of itself, that the correct products have been specifically identified. It also does not allow the investigators to quickly identify the common factor in all the ingredients across multiple manufacturers. And, it does not contain recall in much detail.

### **2. Exclusion of unaffected products.**

It is equally important for the manufacturer to be able to *exclude* all products that *could not* have been adulterated. This should consist of:

- bulk dry or liquid materials added to a storage tank or silo after a downstream destination has changed;
- products made in any equipment after a full wash or CIP has been completed;
- product that could not have physically co-mingled. (Mix-proof routing valves and physical pipe connections are examples of physical breaks that make cross contamination impossible.)

The ability to *exclude* products will not only reduce the affect of the recall, but will allow isolation of suppliers and customers; this could be the main factor in returning the plant to business after an event.

### **3. Dilution or concentration of affected products.**

This is typically the most difficult information for manufacturers to furnish, but will reduce the impact of the investigation and recall to the greatest degree. Being able to quickly and accurately tell the investigators which products have the highest concentration of the suspected ingredient, which products have lower concentration, and which products have none will give the investigators confidence. This can be accomplished by:

- electronic tracking of all movement of materials and products in manufacturing,
- placing meters in strategic locations to meter flow of bulk materials, and
- accurately tying the metered flow to the lot genealogy.

With meters in the right places, investigators can closely estimate the dilution percentages for each scenario. Specific suspect products can then be tested and the recall appropriately managed, with expectations built on knowledge. The investigative system in place must enable such capabilities within a few hours to establish confidence in the outcome.

Ratings officers and inspectors are learning these three simple guidelines and their training is constantly updated with new detail and substance. Installing a capability to comply with the trace and track requirements of the Bioterrorism Act not only protects our business, but more importantly, it helps us truly protect our community's food and beverages.

*Craig Nelson has been teaching within the FDA and US Public Health Service for over twelve years. He is recognized as an expert on federal regulatory affairs and on regulatory impact on dairy and food manufacturing automation. He was an author on the 2005 PMO (Pasteurized Milk Ordinance) "Criteria for the Evaluation of Computerized Systems for Grade 'A' Public Health Controls." Craig addresses and teaches regularly across the US for the FDA and its ratings officers.*

*Craig is Founder and Chief Technology Officer of Vigilistics, Inc. a provider of software for dairy and food plant tracking, Bioterrorism Act compliance, and production improvement information.*