

Connecting the Dots

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Is it time to completely connect the food traceability dots?

When the FDA published in December 2004 the record keeping rules for the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the government indicated that organizations involved in processing, manufacturing, distributing, selling or transporting food (with a number of notable exceptions) were now required to

“... establish and maintain... records to identify the immediate previous sources and immediate subsequent recipients for all food they receive and release...”

This requirement is typically referred to as “one forward, one back” or “one-up and one-back” and provides one type of food traceability. If a tainted food product is found in the marketplace, by working backwards and forwards for a specific product shipment from the point of discovery, other tainted product can be found, and the potential negative impact is reduced from the food-borne threat.

The government didn't dictate how these data should be collected or stored but indicated that the required information for both the immediate previous source and the subsequent recipient include:

- Name, address, telephone number and, if available, fax number, and e-mail address of both the source and recipient of each shipment;
- Adequate description of the product in each shipment;
- Date the shipment was received or released;
- Lot or code number or other identifiers for the product on the shipment and how the food is packaged when reported by a processor or manufacturer; and
- Quantity of product in the shipment.

Most food processors we've worked with are implementing the new rule by keeping a list of their suppliers and the specifics of each incoming shipment, and a separate list of their customers and the specifics of each outgoing shipment. They aren't, however, connecting the dots to show which incoming products are included in which outgoing shipments.

Many packing plants, for example, keep records about which feedlot supplies them product, noting the supplier information for each received shipment. They also keep records about the customers to whom they ship for each outgoing product shipment. What they typically don't do is have an internal plant traceability system that connects outgoing product to incoming animals or to an incoming receiving lot, providing a fully linked traceability pedigree on the products they subsequently ship. Moving “one-back” from the meat processor, cattle feedlots also typically know from whom they buy animals

and they know to whom they sell product, but they don't always know an animal from this purchase was sold to that meat packer. The meat industry is not unique. This lack of a full pedigree is typical of most food sectors, and is fully compliant with the FDA rule.

The FDA explicitly indicated that processors didn't need to connect these dots within their plant. The FDA wrote,

"FDA acknowledges that certain business practices are not amenable to linking incoming ingredients with outgoing product and that it may not always be possible to identify the specific source of an ingredient that was used to make a lot of finished product. It is not FDA's intent to mandate reengineering of long-standing existing processes. Accordingly, the final rule requires linking incoming with outgoing product only when this information is reasonably available."

The big question each of us in the food industry must ask ourselves is whether this is wise. The purpose of the "one-up, one-back" rulemaking is to provide rapid response in the face of a threat to the country's food supply, whether intentional or not. Does "one-up, one-back" provide this protection?

The downside risk is huge from too slow a response. That's at least the view of most who review the standard operating procedures for responding to a specific food-borne threat such as FMD (Foot and Mouth Disease). However, the FDA felt they couldn't go overboard and adopt a rule that would be too onerous to the multi-segmented and highly diverse U.S. food industry. They needed a rule that would balance risk with the cost to the industry, and minimize cost to consumers. Hence, they developed an initial rule that would speed up traceability investigations while minimizing the operational impact on the nation's food suppliers.

But does "one-up, one-back" provide a fast enough response potential? Today, investigations launched by the FDA and USDA typically are multi month projects which often are hampered by not having sufficient basic information about the source of supply or the recipient of food shipments. In their December rulemaking, the FDA noted that fully 20% of their investigations are terminated because they lacked even basic traceability information (e.g., who shipped what to whom). Other investigations are lengthened when this elementary information is lacking. To illustrate their point, the FDA pointed to the 2003 green onion contamination which caused a record number of Hepatitis A infections. In their write-up, the FDA noted that in Pennsylvania where basic records existed, the traceback investigation took only a week. For the same investigation in Georgia where the records were not as thorough as in Pennsylvania, it took a month and for North Carolina where records were lacking, the investigation was terminated after two months as being "inconclusive".

Is even a one week response fast enough? Monitoring of past food-borne threats in the U.K. and elsewhere has shown that to effectively limit massive downside risks, traceability must be completed within the first few hours and at most a few days. This is the reason why the USDA for their animal identification project has set the bar at a 48-hour traceback. Some epidemiologists believe the response time must be much faster, but 48-hours was deemed to be achievable with existing technology.

Can "one-up, one-back" provide the 48-hour response? Reviewing historical FDA and USDA traceability projects strongly suggests that with only the basic "one-up, one-back"

information, investigations will take much longer than 48-hours. The Pennsylvania investigation into the green onion contamination, where the records exceeded the minimum “one-up, one-back” requirement took a week. Can we afford to wait that long? The FDA, in their rulemaking concluded that

“In scenarios where time is of the essence to prevent serious injuries or death on a large scale, having records available becomes even more critical.”

As key stakeholders in the global food supply, each of us needs to ensure we balance our own company’s need with the larger industry and societal need. As an industry, we can not afford to tip too far to any one side. It is in no one’s best interest to have a catastrophic failure that vastly erodes consumer confidence in the safety of U.S. food, nor prevents that food from reaching consumer tables. Most consumers will not understand the details of “one-up, one-back”, and today they already assume that all the dots are connected on the food they eat. A failure to respond quickly enough to a threat will surely focus adverse public attention on our industry.

Katrina, Wilma and other recent disasters underscores all too clearly the downside risk of not properly planning for various catastrophic contingencies. It is our belief that a good insurance policy against a catastrophic failure is to revisit what it takes to connect the dots within specific processing and manufacturing operations.

The good news is that within the last few years, automated, low-cost traceability tool solutions have been developed to provide in-plant traceability – tying incoming product with outgoing shipments. These solutions can even be bolted onto existing ERP systems to minimize cost and disruption, and can be brought online in a matter of a few months, even in high-speed modern plants. There are always challenges in introducing this technology, and the traceability, especially in continuous batch operations, will never be 100%. But it will be much better than exists today and it will lay the foundation for a credible, rapid response to food borne threats.

There are good and valid reasons to move forward with programs that connect the dots and link incoming product with outgoing shipments beyond just the catastrophic insurance policy such a system would provide. Many customers, especially foreign customers, are requiring that the dots be connected. Having a more robust system in place can provide this assurance to these foreign buyers. Likewise, connecting the dots within the plant allow plants to substantiate label claims, ensuring that some of the new, specialized ingredients (e.g., Omega 3 enhanced soybeans and trans fat-free oils) are truly being used where they are being claimed on the label. And finally, providing this level of internal traceability has a big payback because plants can improve profitability by understanding the impacts of certain incoming materials on their plant efficiencies.

Connecting the dots not only allows provides the protection and rapid response required by the Bio-Terrorism legislation, but it adds protection to each food company and to the industry. It also satisfies customer requirements, especially requirements from overseas. And, most importantly, it can very rapidly pay for itself and ultimately add to profitability. It is time to re-evaluate the most recent traceability tool offerings for connecting the dots within our plants, and to determine how we best position our companies.

Further information can be found at www.aginfolink.com.