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From The Editor | June 29, 2015

## Why Thorough Traceability Systems Are Crucial To The Food Industry



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**Obviously, food producers, manufacturers, and processors are facing enormous challenges creating traceability systems that meet an ever-growing list of requirements. Here, Nye Hardy, a former director of food safety at Dole Fresh Vegetables, answers my questions about FSMA, traceability systems, electronic recordkeeping, and how to tie all of those things together to keep consumers safe, your supply chain well managed, and your company on top of the latest regulations.**

**Food Online:** Tell us about FSMA's stance on traceability. What do food makers need to know to comply with the criteria?

**Hardy:** At this point, FSMA's Section 204 on Traceability **does not** concentrate on what producers should do; rather, the entire section is a mandate to the FDA to figure out what to do about traceability. The section requires the Secretary of Agriculture to commence pilot projects, research and consult with experts, and have public discussions — all to formulate future rules on how your company will report traceability documentation to the FDA for food safety issues.

This is what FSMA is working on right now:

- What sort of system should the FDA set up to collect traceability information from domestic and international companies quickly?
- What are the current traceability practices used by the food industry?
- Should there be additional traceability reporting requirements for high-risk foods?

Eventually, FSMA may ask for companies to have traceability documentation available, and there is a good chance that such documentation will look similar to what the industry is using now. The requirement will probably be more on **how** and **when** you need to turn over your documentation to the FDA when there is a suspected contamination or outbreak.

A big focus of this traceability mandate is **timeliness**. In general, FSMA wants records kept in a central location for at least two years. When the FDA asks to see those records, it wants them within 24 hours. So, the priorities for producers should be:

1. Creating a system that accurately shows where your products came from and where they went so you can ...
2. Give that information on any request as quickly as possible, preferably within that 24-hour time limit.

In writing, those are fairly simple requirements. However, in practice, it can become an entirely different and rather surly beast.

**Food Online:** Why is the FDA taking this stance on traceability? What is the driving force behind it?

**Hardy:** It is not FSMA's intent to mandate how your company runs a traceability program. Instead, it only intends that you have one that gives accurate results. FSMA's real goal is to allow the FDA to monitor and respond to food safety events and outbreaks in a timely manner.

If you don't know where something came from or where it went, all the other work you have done to keep food safe has been utterly lost. The FDA got a very hard lesson on this in 2008 when it was unable to correctly identify the source of a large salmonella outbreak. Tomatoes were first suspect, but then it was found eight weeks later to be cilantro. This was extremely harmful for consumers and businesses alike. I think this one incident in particular has affected the new rulings as no one wants that kind of confusion to happen again.

**Food Online:** What should food makers consider when implementing traceability and inventory management systems?

**Hardy:** I like to think of traceability as a "Reality Monitoring System." Here is what you are monitoring:

- What is actually happening: what did you get, how is it identified, where did you keep it, and where did you send it?
  - This is different from what you think is happening or what you told people to do.
  - To know what is happening, you need to physically see product come in, get stored or processed, and go out. If you don't know this, you are missing an important part of the reality your entire traceability system should be based on.
  - This task is arduous, but necessary. It can take a long time to do, especially if you receive product from multiple producers or make products from several producers. But, if you don't invest that time, your traceability system is more likely not to be based on reality.
  - Does the identity of a product get lost at any time? What can you do to maintain product identity?
- How do you document each of these steps? What records do you keep, where do you keep them, and how do you find them again?
  - Records should reflect each time there is a **change** — in physical location, splits in lots, combined lots, etc...
  - Documents need to reflect what is actually happening; not what you think is happening or what you want to happen.
  - Names used to identify products and lots need to stay consistent throughout the process. It's just easier that way.
  - If your records don't reflect the reality of where and what things are, what do you need to change to make them more accurate?
  - My personal rule is, "If you don't document it, it never happened" and "If you can't find your documentation, it also never happened." This is where electronic recordkeeping comes in as really helpful.
- What are your rules for making sure the correct steps and documentation is done?
  - Once you know how things move through and how you need to document it, your rules/plans/policies/SOPs need to reflect this perfectly as possible. Again, if you leave things out, you are losing what is really happening, which means that you may be ignoring food safety or food quality issues.
  - How do you test your system to make sure it actually gives you the information when and where you need it? Mock recalls are part of these tests, but are you testing everything you need to test? It's another way of confirming what reality is.
- What are your employees doing?
  - Employees do not always do what they are supposed to do. Shocking, but true.
  - In many companies, the least-educated and least-paid employees are overseeing the steps that will make or break your traceability system.
  - "Training" is not enough. If you really want to know what employees are doing, you are going to need to **spend an entire shift** watching work be done. It takes a lot of time, and it can be boring, still, working a shift is the best way to see if your traceability system is being done correctly.
  - Further, employees feel more valuable when they get your attention. They will also take their jobs more seriously because you are taking their job seriously.

So in summary, the closer all these separate realities — processes, documents, rules, and employees — resemble one another, the stronger and more effective your traceability system is. After this is all in place and working, then it is time to improve or bring in electronic recordkeeping and traceability solutions.

**Food Online:** Obviously, electronic recordkeeping and electronic traceability solutions are not a necessity for FSMA compliance, but implementing them will surely benefit food makers. What kind of benefits will these types of technologies provide?

**Hardy:** Electronic recordkeeping and monitoring systems can be wonderful, but just like the upcoming requirements for reporting, they are only as good as your actual traceability system. Have you heard the saying, "Trash in, trash out"? Your recordkeeping system is only as good as what you put in it. I think it's important to remember that any recordkeeping system, recall plan, or mock recall exercise **is not** a traceability system.

No software company is going to be able to "give" you a traceability system; you need to have that in place for a database company to be able to work with you. However, effective electronic data management can make the entire traceability process so much easier to wrangle. After all, there is a lot of data there and storing and retrieving documents are just two cherries on the top of your business cake.

Even without a recall looming over your head, electronic technology is yet another way of ensuring you know what the reality of your entire business is. These systems can help preserve your business by simplifying managing inventory, preventing unidentified product from continuing through your process, and creating streams of data that will allow you to see expensive or dangerous inefficiencies. So, they are important tools for efficient information management. If you don't know what is real and what is not, how can you run a good and safe business?

**Food Online:** What does the future of traceability look like? What technological capabilities will food makers who implement electronic traceability solutions have to look forward to?

The future of your traceability system should be absolutely based on the reality of what your business does, so I think it is going to be unique for everyone in the industry. Knowing your processes, documents, rules, and employees will allow you to acquire the exact amount of electronic support you need — not less, and not more. The good news is that these systems are becoming not only more and more adaptable to individual business needs, but they are coming down in price, as well.

For all business's future traceability systems, I think lot size will be a crucial component. Defining and minimizing what product lots are critical to controlling the extent of a recall. If the FDA knocks at your door and says, "We think you have a salmonella contamination. What products were included in this lot over this period of time?" and you reply with, "I don't know," you will be required to recall everything. However, if you can say, "We received three lots, made these 10 products out of it, and shipped it to these customers in Vermont," you will be doing a much smaller, and likely less publicized, recall.

Traceability is all about seeing and responding appropriately to reality.

## **About Nye Hardy**

With 22 years of experience in production agriculture, a B.A. in biology, and a Master's degree in Food Safety, Nye Joell Hardy was most recently the director of food safety at Dole Fresh Vegetables. She now works privately as a food safety technical and regulatory writer, specializing in writing training classes, food safety plans, and more. If you have questions or comments, you can contact her at [badwolf@redshift.com](mailto:badwolf@redshift.com).