Article | July 25, 2014

FSMA Fridays: Traceability Requirements And Best Practices (Part Four Of Four)

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On the last Friday of every month, Barbara Levin of SafetyChain, a leading provider of food safety and quality assurance automation and compliance solutions, hosts FSMA Fridays™, the leading online forum for the food and beverage community to learn the latest information about the FDA's Food Safety Modernization Act (FSMA). Featuring Dr. David Acheson, the popular monthly interactive pod/webcast is sponsored by SafetyChain Software and The Acheson Group.

In the third portion of *FSMA Fridays: Traceability Requirements And Best Practices*, Safety Chain's Barbara Levin and the Acheson Group's panel answered questions from the pod/webcast's live audience regarding what companies should do to prepare for upcoming traceability requirements, what companies should do to track direct-contact packaging and how FSMA affects these practices. Here, in the fourth, and final, installment on the topic, the group will continue answering the live audience's questions.

Barbara: David, let's stay with you here, for a moment. Tomas is asking, "What are current lot numbering requirements, and will FSMA change them?

David: That's the question that certainly should have gone to Jennifer, but let me give it a shot, and then she can clean up my mess. My belief is that there are no current lot numbering requirements. The FDA — of you've got lot numbers — they want them in regard to the one up, one back, but the requirement to keep lot numbers, no, I don't believe that's a requirement right now. Will FSMA change them? Yeah. I think it will. As Jennifer pointed out, the new record-keeping requirements around high-risk food, that's precisely what they want to do; to put in much tighter requirements which I think will include lot numbers. Jen, did I get that right?

Jennifer: For the most part, David. I'll add a few details to your comments. David is correct that there are some loopholes that are currently on the books that don't strictly require the recording of lot numbers. What the current rule says is that manufacturers need to record lot numbers of ingredients into finished products, if available. That's the loophole, and it only does apply to manufacturers, so distributors and others in the supply chain do not need to maintain lot numbers. That's crystal clear. It's just that one up, one back — who did you get it from? Who did you send it to?

That was one of the key things that we looked at in the pilots, was it a necessity to record lot numbers. How much does it help if, supply chain-wide, there was a recording of lot numbers. I can tell you it helps an awful lot. I think it's pretty obvious, but there is a cost associated with that and infrastructure changes that would need to occur in order for, especially high-volume facilities such as distribution centers, warehouses to maintain lot numbers.

What we then looked at was, "Could we use other numbers that are currently recorded as a proxy or estimation?" Things like purchase orders, they worked so-so. Bills of lading could work. Invoices, not quite as much, but bills of lading that did have additional information on them; those could be used, in some cases, sort of in lieu of lot numbers.

It's up to the FDA to determine how to best strike that balance between protecting public health and getting the information that they need and the cost to industry. When we looked at using these other numbers — purchase orders and bills of lading — the thing that really helped in the analysis was the use of technology.

Trying to establish these links between those types of documents by hand was extraordinary difficult, and fortunately, we had a person on our team whose background was in computer science, and he was able to build some models to look at the impact of requiring lot numbers, using other numbers, and so it's to-be-determined how the FDA will or won't require lot or other discriminating numbers.

Barbara: Okay, great, thank you, David and Jennifer. David, a question from Paula. “Does the FDA have access to all the record-keeping documents today?”

David: Wow, that's a very astute question. The way the regulations are written, and the this statute was written, is that the FDA basically has the authority, today, if they have a reasonable probability that your product is linked to a serious adverse health consequence or death, then they have access to all your records. That's extensive. If that trigger is tripped, then they can get at pretty much everything except personnel, financial, and the detailed recipes, and they can continue to roll that down moving from one product line to another product, from one facility to another if they start pulling on loose threads.

What we are seeing is that the FDA is showing up and saying, “Show me all your records,” and I think there is a questionable authority around that right now, because that's not for cause. Now, FSMA will change that in the context of the preventative control rule, because the inspectors are at least based on the statute and the way the regulation was laid out in the proposed rule will have the authority to come in and say, “Show me your food safety plan,” and more importantly, “show me that you can document through record-keeping that it's working.”

They jumped the gun a little bit on that — a t least, I think they have — but I'm not an attorney, and I certainly wouldn't recommend anybody challenge them on it, because it's coming down that road. But, if you don't have those records, then I'm not sure that they would be officially able to ding you and get away with it, but this is definitely a really good question, because frankly, I think right now it's a gray zone. It's going to head that way, as I've just said, when FSMA becomes final, which is little over a year from now if they stick to their time-line, and I think they will. But if it's for cause, then we're better off, and they can get at pretty much anything they want with those minor exceptions.

Barbara: Great. Jen, I'm going to come to you. Question from Ruth: “What do you do about bulk grain?”

Jennifer: That is a great question, and it's something that people often bring up. Bulk grains, other bulk products — how can you trace something that's bulk? My response is generally, you don't just throw your hands up in the air and just say, “We can't trace it definitively, so we are just not going to keep any records.”

I think the prudent thing to do is to still capture what's going into the silo, so that you know the dates, the times, the inputs into the system. What I would really recommend is, there is an individual professor at – I think it's Iowa State, and I will look it up while we are talking here, Chuck Hurburgh — he is an expert in grain traceability and has been doing a lot of work, and is developing some traceability information specific to grains. He's one of the individuals that I've worked with and that I've looked to when it comes to the issue of tracing grains, because it and other bulk products do present some unique challenges.

Barbara: This next question is related. You've probably covered most of it, but is there anything to add? We see this question here, “How about bulk materials stored in tanks? How much detail is required for those mixing lots?”

Jennifer: One thing I should add is whether or not there will be some exemptions for raw, agricultural products. There may be instances where the FDA recognizes where traceability is not achievable, especially in looking at the cost of trying to trace these types of products versus the benefits of traceability and looking at where in the system problems typically occur. Where is it most important to trace products, and how critical is it to trace at the bulk level when it would be extremely difficult to do so? I think that’s part of what the FDA will need to deal with, and I wouldn't be surprised, when a proposed rule comes out, if FDA seeks public comment on these types of issues. I don't know, David, if you have anything you'd like to add in that regard.

David: No. I think you covered it, Jen. I think these are tough areas. Those are very pertinent questions, and I totally endorse what you said about, “don't throw your hands up and do nothing,” but it is not well-defined.

Barbara: David and Jen, thank you so much for joining us today, and of course, to everybody, thank you for joining us. We hope that we see you next week, August 1, where we will be discussing high-risk food methodology.

Did you miss the first three parts of *FSMA Fridays: Traceability Requirements And Best Practices*? You can check out the first part here (http://www.foodonline.com/doc/fsma-fridays-traceability-requirements-and-best-practices-part-one-of-four-0001), the second portion here (http://www.foodonline.com/doc/fsma-fridays-traceability-requirements-and-best-practices-part-two-of-four-0001), and the third installment here (http://www.foodonline.com/doc/fsma-fridays-traceability-requirements-and-best-practices-part-three-of-four-0001).