FDA Inspection Readiness: Before, During & After Your FDA Visit

March 28, 2017 | Shawn K. Stevens, ESQ, Founder, FoodIndustry Counsel

Questions/Answers

Q: Are DNA strains always specific to each facility? ie. My facility won't match another facility.
A: the DNA collected from your facility could match DNA from a person, another product or another facility. Or none if it is a rare strain.

Q: Should the "do not sign" policy extend to 3rd party audit documents?
A: No. Not usually.

Q: Can we shut down production, initiate a cleaning cycle and then have the FDA swab to prevent a recall due to zone 1 swabbing positive result?
A: Yes, in a perfect world that would be possible. But, the FDA likely will not allow that. Rather, the agency in most cases will insist that it be permitted to sample after production has commenced.

Q: Do you recommend and is the industry now performing direct contact environmental Listeria Sp swabs?
A: The new FDA guidance recommends that companies do this, but the underlying decision to do so or not do can vary wildly by individual circumstance.

Q: Or do you recommend LM swabs not Listeria species?
A: I typically recommend species, unless you're testing finished product, then we may want to test for LM.

Q: interesting and agree that careful documentation of sample location....pictures are the best way...recommendation of how else to be so accurate?
A: That usually is sufficient.

Q: Even though apples/cherries are RTE, we don't cut them, they remain whole. Will they take that into account?
A: Yes, that fact may be significant, depending upon how the cherries are then used or processed by your customer.

Q: even with Attorney Client privilege can FDA still get the records?
A: Not always. Depends upon the circumstances surrounding the assertion of the privilege. Ultimately, if there is a fight, a judge will be required to decide.

Q: How do you think the swab-a-thon will affect a distribution facility with no processing areas?
A: FDA will likely not swab those areas, unless ready-to-eat foods exposed to the environment while being held.

Q: Is there a "recommended" number of people that should make up a food safety/ food defense team? How many individuals within a facility should acquire the PCQI training?

A: No recommended size. Depends upon the type and size of the organization.

Q: I am sorry I came late but I would like about certificate of training of FSPCA is mandatory?
A: No. Unless, you do not have the requisite experience to qualify as a QI.

Q: The foreign supplier verification plan has to be implemented at 100%?
A: Yes.

Q: I may have missed this at the beginning, but will these FDA inspections be random? I currently have two foreign inspections scheduled next month. FDA did advise of the inspections for these.
A: Domestic inspections are unannounced and random.

Q: If you are under Alternative 3 of 9CFR 430.4 can you do Zone 2 instead of Zone 1 to comply with the CFR but focus more on Zones 3 and 4?
A: Zone one is not required for FDA testing, only recommended.

Q: In regards to the "Do Not Sign" Policy, can we include the 483 form in this policy? Or should this be specific to any documents other than a 483?
A: Yes, the form 483 could be included.

Q: Is environmental monitoring required for storage facilities that do not own the product they store?
A: Only if the product is ready-to-eat and exposed to the environment.

Q: My auto cut in and out on the part about not signing any documents. Can you recap it again?
A: There is no legal requirement for a company to sign any documents, statements or affidavits the FDA provides.

Q: Question for Shawn - would a statement of "Client Confidential" be sufficient to protect records from FOIA or is there other recommended language to be used? Thank you. Awesome webinar!
A: Use this: "THIS DOCUMENT AND THE INFORMATION CONTAINED HEREIN CONSTITUTES TRADE SECRET, CONFIDENTIAL AND PROPRIETARY COMMERCIAL INFORMATION PURSUANT TO 5 U.S.C. 552(b)(4), AND SHALL BE STRICTLY PROTECTED AS SUCH FROM ANY DISSEMINATION AND/OR DISCLOSURE." FDA will be able to see those records, but they will be protected from further public disclosure by the agency.

Q: We manufacture acid/acidified sauces that are heat treated in a cook tank before being hot filled & held into glass jars or PET bottles. The products are considered commercially sterile and are under vacuum. Will FDA swab our facility with this type of product?
A: FDA may swab some areas, but likely less than in those cases where the finished product is exposed to the environment for lengthy periods of time.

Q: What documentation/records are we as food companies required to show to the FDA investigators and how much can we push back on their requests?
A: FDA can generally access all food-safety-related documents, and any documents the company is required by law to maintain.

Q: What does zone 2/3 mean?
A: Zone 2, on the one hand, and then Zone 3, on the other.

Q: will the FDA be swabbing during inspections if none of our products are suspected to make people ill?
A: Yes. They will swab during EVERY inspection.

Q: Will the swab a thons only apply to finished goods ore RTE foods? We are an industry additive not a final food good...
A: Ingredient companies will be swabbed as well.

Q: If we have a "do not sign" policy, will this apply to 483 forms after the inspection?
A: Yes.

Q: Will the FDA expand this process into the kitchens/restaurants?
A: Likely within the next few months and years, I predict yes.

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299 South Main Street, Suite 2300 | Salt Lake City, Utah 84111 | 888-327-6187