FSMA Inspections: What to Expect and How to Prepare

Annual Food Quality and Safety Symposium

June 22, 2017

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Focus on Industry Education

- The first major FSMA compliance deadlines have come and gone
- FDA's mantra is "educate before and while we regulate"
- FDA has said its initial goal will be to work with industry to create a culture of safety and this goal will apply not just in the initial months of compliance, but going forward
  - What that really means remains to be seen
  - A "culture of food safety" will not trump situations with public health implications

FDA's Enforcement Plans

- Preventive Controls and modernized GMP inspections began in January 2017
  - A few "for cause" FSMA inspections were conducted in 2016
- 750 "FSMA" inspections the first year
  - 300 PC inspections (240 domestic / 60 foreign)
  - 450 modernized GMP inspections
- How many have been done?

FDA's Enforcement Plans

- FDA has trained a cadre of 30 inspectors (aka investigators) for Preventive Controls inspections
  - Train the trainer model to train additional inspectors
  - To perform a Preventive Controls inspection, the inspector must have attended the FSPCA course and FDA's Regulator Training Course
  - To perform a modernized GMP inspection, the inspector must attend a webinar on modernized GMPs

Who Will FDA Inspect?

- Expect inspections to be targeted based on risk
- FDA's key risk factors:
  - Known food safety risks of the food (i.e., Class I recalls, high profile recent outbreaks (e.g., ice cream));
  - Compliance history of a facility (i.e., whether there is a history of non-compliance or significant violations);
  - The type of food processed in the facility; and
  - The number of years since the last inspection.

What to Expect

- No state inspectors will conduct Preventive Controls or modernized GMP inspections on behalf of FDA
  - FDA did not update contracts with states to cover Preventive Controls inspections for FY 2017
  - States can only inspect for compliance with Part 110
- Preventive Controls inspections are also training exercises
  - Inspectors will become lead trainers
  - Other investigators from the District may be present
  - State inspectors may shadow the inspection

What to Expect

- Modernized GMP inspections are about more than just compliance with Part 117, Subpart B
  - Also covers employee training/records of training and a review of the Food Safety Plan at a high level to look for red flags around pathogen and allergen control
  - If there are red flags, it will expand to a full PC inspection
  - Typically takes 2 days
- PC Inspection
  - Budgeted for 22 hours; 4 days not unusual

What to Expect

- Based on the initial Preventive Controls inspections, expect a very regulatory approach
  - Where there is a requirement for something to be written, FDA will inspect for adequacy of the written program followed by whether it is being implemented as written
  - Inspectors will seek to determine compliance with each and every applicable regulation and sub-regulation
- If it isn't documented, it didn't happen
  - For example, if you can't find your 15 year old validation study, FDA will document that the preventive control has not be validated
  - If you document only one of two corrective actions that were taken, you won't get credit for the rest of your work

What to Expect

- FDA will expect the plant manager to be able to explain their scientific justifications underlying Food Safety Plan and provide supporting scientific documentation
  - This is applicable to each part of the plan (e.g., length of production run)
  - Based on some initial PC inspections, FDA may not accept Corporate representatives giving the answers
  - Have more than one person on the plant level who understands the Food Safety Plan and how it is implemented
- Inspectors will conduct their own hazard analysis (will use “Appendix 1”) and compare that to the facility’s hazard analysis
  - Plants need to be prepared to support the approach and decisions made in their hazard analysis (e.g., pre-requisite program vs. preventive control; why a particular control is effective)

What to Expect

- Record requests
  - Align with FSMA requirements (e.g., request for validation, environmental monitoring program)
  - Must meet regulatory requirements for content
  - Consumer complaints
- Photography requests
  - Sometimes linked to swab sites

What to Expect

- Multiple investigators will conduct the inspection
- FDA may conduct a “swab-a-thon”
- FDA may bring in a second team to perform the sampling simultaneously
  - Need to be prepared to have enough personnel available to accompany multiple teams of FDA investigators
- FDA may want to observe sanitation – even if it’s conducted during third-shift

Note: If FDA engages in sampling and facility puts product on hold, facility should ask investigator to note on sample receipt and collection form “voluntary hold” so results are conducted and communicated more quickly

What to Expect

- FDA intends to document only serious and significant observations linked to public health outcomes
  - cGMP violations and others may not be recorded on the 483 if site has a good process in place to address issues and plant manager can clearly articulate the process
- FDA is highlighting other concerns that don't make it on to the 483 as part of the close out meeting ("discussion points")
  - These will be part of the EIR
  - Need to decide whether to respond and how

Other FSMA Inspections

- Sanitary Transportation inspections will be conducted as part of routine facility inspections (starting this Fall)
- Supplier verification program inspections will begin after May 30th
  - Tiered inspections for supply chain programs is still under consideration, but the agency is leaning that way
  - FSVP inspections will focus on the FSVP Importer identified on the customs paperwork
  - FSVP provides FDA with remote access to records (will be on Form 482d)
  - FSVP violations can trigger a Form 483a, a Warning Letter, Import Alert
  - For PC supplier programs, agency remains interested in tiered inspections for corporate managed programs

What We've Been Hearing

- Few 483s issued so far
  - "Educate while we regulate" approach
- FDA is looking at records very closely
- Inspectors are conducting their own hazard analyses
- FDA is still trying to understand what's required by some aspects of the regulations
- "Swabathons" are alive and well
  - Expect Zone 1 testing based on broad FDA policy
- Requests for PCQI documentation

FDA's Feedback

- Industry could do a better job at:
  - Improving organization of documents
  - Better connecting each preventive control to its monitoring, verification, and corrective action procedures
- It's okay to get your corporate expert on the phone to discuss an issue with CFSAN
- Investigators have been told NOT to routinely copy all records; copying should be relate to a significant issue that needs to be evaluated by CFSAN
- Denying photographs should not be considered a "refusal" of inspection

How to Prepare

- Make sure your food safety plan meets FDA's regulatory requirements
  - Is it well organized?
  - Accessible?
- Are you documenting what you said you would do?
- Do you have a culture of food safety?
- Conduct a mock FSMA inspection
- Update your inspection manual

How to Prepare

- Who is going to be present?
  - Which employees will accompany the investigators?
- Who is going to be on-call to answer questions?
  - Legal support, too
- Swabathons
  - Decide your company policy on companion/sister/duplicate sampling
  - Do you have the resources lined up (personnel, equipment, lab availability)
  - Decide whether to hold product for zone 1 samples
- Develop a company policy on photography

How to Prepare

- Ensure plant manager and team are well versed in the Food Safety Plan (plant manager signs the food safety plan!)
  - Investigators are likely to ask lots of specific questions
  - Be prepared to discuss plant procedures and scientific justification in detail, without leaning heavily on Corporate
  - Be familiar with location of documentation
- When the inspection starts, ask FDA whether it's a FSMA inspection and, if so, whether it's a PC or modernized GMP inspection

During the Inspection

- Accompany the investigators
- Take immediate corrective actions
- Take detailed notes
- Mark records “confidential commercial proprietary information; trade secret” as appropriate

Post Inspection

- Respond to the 483, if issued, in writing
  - Be sure to develop documentation of corrective actions
- Share learnings with ABC

Questions?

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