A Look at FSMA Inspections

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Based in Washington, D.C., the Grocery Manufacturers Association is the trade organization representing the world's leading food, beverage and consumer products companies and associated partners.

About the Grocery Manufacturers Association

Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and the products consumers rely on and enjoy every day. We pride ourselves in serving large, international brands and regional brands, as well as foodservice companies and industry service providers from consulting, technology, logistics and other sectors.



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Preventive Controls for Human Food Inspections Arrived



GMA's Goal for FSMA Inspections

- FSMA inspections should take a "systems approach" and focus on whether the facility has designed and implemented effective systems to ensure food safety.
- Inspections should also reinforce behaviors that promote food safety, such as implementing robust environmental testing programs.
- Inspection process should be transparent in both its planning and decision-making
- Efficient inspections

Some Learnings on Both Sides



Some Feedback



Appendix 1:

- Trend: Investigators are generally using Appendix 1 as a checklist. More importantly, they are telling plant personnel that because a hazard is listed in App1, then you must have a PC for that hazard. This is not the case.
 - Hazards listed in App1 are <u>potential</u> hazards that could be IDENTIFIED as potential hazards in the hazard analysis. The HA will then determine if the hazard is one requiring a preventive control and what the appropriate PC will be.
 - HA has to play itself out and NOT be pre-determined

Environmental Monitoring

 Inspectional approach should continue to encourage the seek and destroy approach to environmental monitoring.

 During inspection focus should be on whether the facility took appropriate steps in response to the positive samples.

Supply Chain Documentation for Supply Chain PCs:

- When audits are used as a supplier verification procedure, some investigators were asking to see the ENTIRE audit report. In the case of the annual audit, 117.475-c-7 states, "Documentation of the conduct of an onsite audit. This documentation must include:
 - (i) The name of the supplier subject to the onsite audit;
 - (ii) Documentation of audit procedures;
 - (iii) The dates the audit was conducted;
 - (iv) The conclusions of the audit;
 - (v) Corrective actions taken in response to significant deficiencies identified during the audit; and
 - (vi) Documentation that the audit was conducted by a qualified auditor;"
 - The actual audit is not required, just the above 6 elements. There is similar language in FSVP 1.506

 Electronic Records: Some investigators have told facilities that electronic records are not acceptable, that those records must be printed out and physically signed by the appropriate individual. Electronic records are acceptable according to the regulation. Reference § 117.305 for the general requirements applying to records.

Other Feedback

- Engagement with Corporate Subject Mater
 Experts (SMEs) during an inspection is important
 - Many programs, such as supply chain management,
 are managed at corporate. Beneficial to have these
 SMEs involved in inspectional process.



Last but Not Least--Photos



THANK YOU!

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