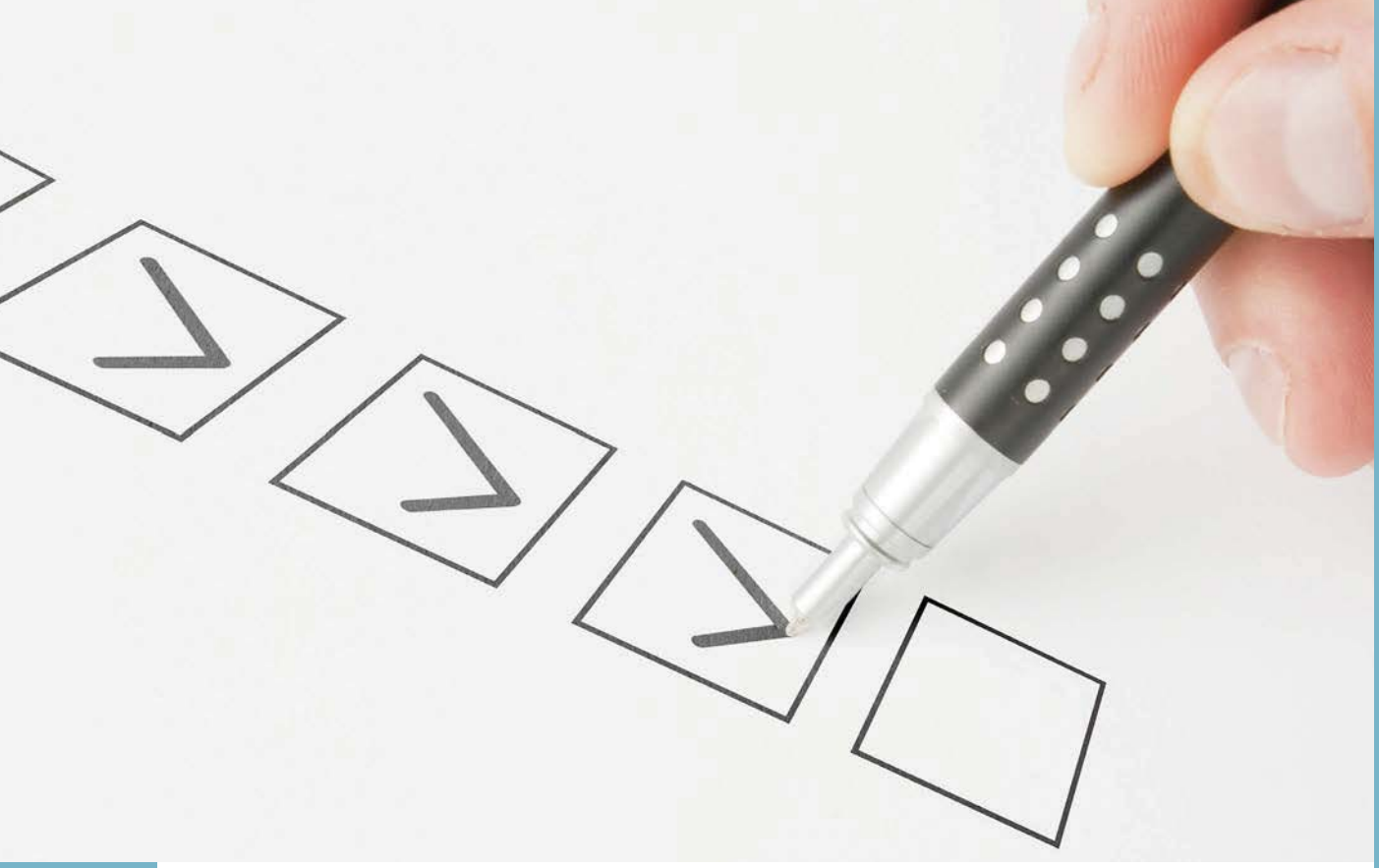

FSMA Checkup: Is Your Company Ready?

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Implementation of the FDA Food Safety Modernization Act (FSMA) has been FDA's top priority for the foods program since the law was enacted in January 2011. In 2013, FDA published six major proposed rules that, once finalized, will impose significant new food safety requirements for every company that sells food in the United States.[1] These proposed rules address preventive controls for human and animal food, produce safety, foreign supplier verification programs (FSVPs) for importers, accreditation of third-party auditors, and food defense. Another proposal, addressing sanitary transportation of food, is due in early 2014.

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When the comment periods end for the proposed rules, FDA will begin internal deliberations about whether and how to modify the regulations in the final rules. Under a court order, FDA is required to issue all seven final rules by June 30, 2015. There likely will be some significant changes to details of the proposals, based on public comments, but many aspects of the proposed regulations are not likely to change because they are based on mandates in FSMA itself.

Food companies would be well served to start getting ready for FSMA now, before FDA publishes the final rules and starts enforcing them.[2] Active engagement during the waiting period before the final rules is critical, as many requirements of FSMA cannot be implemented overnight. A good way to begin is to conduct a "FSMA Checkup" to examine your state of preparation and to identify gaps that warrant further attention. To help companies start this process, this article highlights some of the key questions to ask as part of a FSMA checkup and focuses in particular on areas where it is a good idea to start preparing now: food safety plans, supplier verification, recordkeeping, animal food, and food defense.

Food Safety Plans. The requirement to develop and implement a food safety plan is a core component of the preventive controls regulation. Although many food companies already are implementing Hazard Analysis and Critical Control Point (HACCP) programs voluntarily, some changes may still be necessary as a result of FSMA. As a starting point for the FSMA checkup, companies should think about the following issues:

- Hazard Analysis: Does your hazard analysis consider all of the different hazards itemized in FSMA (e.g., radiological hazards, pesticide and drug residues, natural toxins, decomposition, and unapproved food or color additives)? Do you have a documented scientific basis to support these determinations, even if you conclude that a hazard is not reasonably foreseeable?
- Selection of Preventive Controls: What preventive controls do you implement and which of those, if any, are CCPs? Can you document that these controls are adequate to significantly minimize and prevent the identified hazards?
- Corrective Actions: Are your corrective action procedures adequate? Do your procedures require adequate documentation? (The discussion on recordkeeping below provides additional considerations regarding corrective action documentation.)
- Validation: Have you validated your process controls and is this validation documented? It can take considerable time and resources to validate critical controls points, so it is particularly important to get started with this activity now. Additionally, validation that your process adequately reduces the presence of microorganisms of public health significance also may be critical to support an exemption for your produce suppliers from the FSMA produce safety regulation.
- Verification: What steps to you take to verify that your preventive controls are working properly? Do you verify monitoring and corrective actions within a week after the documents are created? Is this verification documented?
- Testing: Do you have a well-thought out and documented testing program? If so, can you justify your decisions about when and how to conduct environmental and product testing? Although FDA did not propose testing requirements, they will likely be included in the final rule.
- Recall Plan: Do you have a written recall plan and, if so, does it need to be updated for FSMA?

Supplier Verification. FDA did not propose a supplier verification requirement as part of the preventive controls regulation, but did set forth a proposed mandate to verify foreign suppliers as part of the FSVP proposal. The agency also stated in the FSVP preamble it recognizes the need to align supplier verification requirements for domestic and foreign suppliers, so the same requirements apply equally no matter where the food was produced. Companies should expect that the final rules will require all food suppliers, whether located in the U.S. or internationally, to be verified by their customers. To prepare for these new requirements, it is wise to consider these questions:

- Can you identify all of your suppliers? FDA has proposed requiring companies to verify the establishment that manufactures, processes, or harvests the food. Therefore, simply identifying the broker that directly supplies the food is not enough.
- Do you currently engage in verification of all your suppliers? If not, what is your justification for not doing so?
- For which imported products do you bear responsibility for supplier verification under the FSVP? This analysis likely will not be uniform for all products a company imports and requires a case-by-case analysis.
- Can you justify your decision about the appropriate verification activities you apply for each of your suppliers?
- Do you maintain documentation of your supplier verification activities?
- For which suppliers do you require on-site audits? How often are these audits conducted?
- Is the person that audits your suppliers appropriately qualified?
- If your company is a supplier, will you be able to meet your customers' supplier verification requirements? Have you been certified by a qualified third party auditor?
- Are your suppliers ready for FSMA? It is important to help your suppliers understand their FSMA obligations, so they are not caught short when FDA begins enforcement – as that would affect you as well. Supplier education and outreach are the best ways to ensure you receive safe food and prevent supply chain disruptions.

Recordkeeping. FDA's routine access to food safety records will increase significantly under FSMA. Nearly all food safety records related to in-plant operations will be available to the agency during an inspection, including monitoring-type records (e.g., CCP monitoring; testing results) and narrative-type records (e.g., corrective action reports; reactions to positive test results). During inspections, FDA will review records to determine whether companies were making safe food even when agency investigators were not present. Companies need to ensure all employees understand the core principle "If it isn't documented, it didn't happen." Preparation should focus on (1) records creation and (2) records retention.

Records Creation. Records are an essential area for thoughtful preparation because they are created in significant volumes throughout the company every day. All employees, at every level, should understand why their role in good recordkeeping is important. Record creation training should start now, be tailored to FSMA, and be repeated over time. It is particularly helpful to use real records and examples as part of training, to make the advice practical and applicable for employees.

Records Retention. FSMA requires records to be maintained for 2 years. In the preventive controls proposals, FDA allowed for records (except for the food safety plan) to be stored off-site 6 months after their creation so long as they are readily accessible (within 24 hours) upon an investigator's request. It is essential to have robust systems in place to ensure records are maintained and accessible.

As part of a FSMA checkup for recordkeeping, companies should review recent records and consider:

- Are monitoring records accurate, created in a timely manner concurrent with the activity documented, and as detailed as necessary to provide the history of the work performed?
- Are narrative records complete, containing all necessary facts to explain the situation and justify your decisions?
- Do records use unnecessary language that characterizes the facts or suggests the wrong conclusions?
- Do you maintain records for 2 years after they are created?
- Can employees readily locate all required records?
- Which records are stored at the plants versus on the corporate level?
- For records stored centrally or off-site, is it clear how to obtain copies in a timely manner?
- Can all records be accessed within 24 hours?
- Are electronically-stored records (e.g., emails) organized and accessible?

Animal Food. The animal food preventive controls proposal will affect human food companies that divert human food "waste" to animal food or feed. FDA proposes allowing these companies to comply with the current good manufacturing practices (cGMPs) and preventive controls for human food regulations, but their hazard analyses would have to address the possible hazards the food(s) may present for animal consumption. As a starting point for this hazard analysis, you should determine:

- What products are sold or donated for consumption by animals?
- To whom are these materials sold?
- Will this food be further processed? Will the processing steps address any hazards presented by the food/waste your company is supplying (e.g., foreign materials)?
- What animals will consume the food? FDA proposes requiring the hazard analysis to be tailored for each type of animal that will consume the food.
- Does your company have the necessary information and expertise to identify hazards of concern for animals?

Intentional Contamination. FDA's food defense proposed rule addresses intentional adulteration, such as deliberate acts of contamination or tampering. This is the first time FDA will issue requirements in this area, as all efforts have been voluntary until this point. At the outset, companies should ask themselves:

- Have you conducted a vulnerability assessment to identify areas at particular risk of intentional contamination?
- What mitigation strategies have you implemented in your facility and/or supply chain?
- Do you have a documented food defense plan?
- Are you familiar with FDA's Food Defense Plan Builder and did you use this tool to help develop your food defense plan?

Although the final rules are still more than a year off and FDA will allow some time thereafter before enforcement starts, food companies should start getting ready for FSMA now by conducting a FSMA checkup. As Benjamin Franklin said, "By failing to prepare, you are preparing to fail." Getting a head start on preparation will serve every food company well.

1. At the time this article was written, the food defense proposed rule was under review by the Office of Management and Budget but had not yet been published. FDA is under a court order to publish this proposed rule by December 20, 2013.
2. FDA has proposed staggered compliance dates based on business size. For businesses with more than 500 employees, the compliance date for preventive controls would be one year after publication of final rules and the compliance date for FSVP would be 6 months thereafter. FDA proposed giving an additional 1 year to "small businesses" (with 500 or fewer employees) and an additional 2 years to "very small businesses."