Food safety plan expectations and overview of preventive controls

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In the United States, lawmakers, regulators, consumers and the media are more focused on food safety than ever before. On 4th January, 2011, President Obama signed the Food Safety Modernization Act (FSMA) into law, which represents the largest change of the food safety regulatory environment since the passage for the Food, Drug, and Cosmetic Act in 1938.

The new legislation will bring significant changes to an already shifting food safety landscape, with a focus on prevention. This paper will outline:

- Who needs to prepare for FSMA and what preventive controls entail.
- Our analysis of expectations of a food safety plan.
- How to prepare for these prospective changes.

Although HACCP and other forms of preventive controls have been required for some FDA-regulated food products before, FSMA fundamentally shifts FDA's approach, requiring FDA to establish science-based standards for conducting a hazard analysis, and implementing and documenting preventive controls.

Preventive controls

FSMA substantially shifts FDA's approach from one of being reactive to food safety events to being proactive in trying to prevent problems from occurring. Although several FDA-regulated industries have been required to practice HACCP or some other formal preventive control program (for example, juice, seafood, infant formula, low acid canned foods), FSMA enables FDA to require the same philosophy of prevention to all FDA-regulated food products.

Who is affected?

With the exception of those industries that were already required to have preventive controls in place, most facilities that manufacture, process, pack or hold food will be required to conduct a hazard analysis and have preventive controls in place. In the proposed rule, FDA outlines a number of facility and activity level exemptions, including exemptions based on size.

What is expected?

Section 103 focuses on two related elements: hazard analysis and preventive controls. As written in the Act "preventive controls means those risk-based, reasonably appropriate procedures, practices and processes that a person knowledgeable about the safe manufacturing, processing, packing or holding of food would employ to significantly minimise or prevent the hazards identified under the hazard analysis."

How does this section relate to HACCP? Although not called 'HACCP' the description of the process required for firms to conduct a hazard analysis is very much HACCP like:

- Identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility, including biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, allergens, and unapproved food and colour additives; any hazards that occur naturally, or may be unintentionally introduced.
- Identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism.
- Develop a written analysis of the hazards.

These steps, combined with the validation, verification, monitoring and documentation requirements sounds like the basics of HACCP.

Much of the food industry has already adopted some form of HACCP, so this paper will focus on some of the FSMA-required preventive control programs that might be less formalised in food companies.

FSMA notes that preventive controls include:

- Sanitation procedures for food contact surfaces and utensils and food-contact surfaces of equipment.
- Supervisor, manager, and employee hygiene training.

Fig. 1. The food safety plan.

- An environmental monitoring program to verify the effectiveness of pathogen controls in processes where a food is exposed to a potential contaminant in the environment.
- A food allergen control program.
- A recall plan.

Current Good Manufacturing Practices (cGMPs) under part 110 of title 21, Code of Federal Regulations (or any successor regulations).

- Supplier verification activities that relate to the safety of food.
- Food label review and control program.
- Written records of control programs.

However, FDA did not include all of these elements in the proposed rule.

Validation and verification

An important component of a well functioning food safety control plan is the supporting scientific evidence that demonstrates the foundational effectiveness of each of the various programs and the continual monitoring of in-coming raw materials, in-process materials, finished products, and processing environment for factors that affect final product safety.

As your food safety partner, Eurofins offers a full array of testing, consulting, and auditing solutions to help meet these expectations.

At the 1.5 year mark FDA was to have promulgated regulations stating the minimum requirements to conduct a hazard analysis.

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A challenge for the food industry was that FSMA states that food must be in compliance with the preventive controls provision within 1.5 years of enactment.

This puts the compliance date in July 2012. FDA officially clarified that they will not take enforcement action until the rules are published and the proposed rules were only released in January 2013.

Regardless of the issue date, small and very small businesses will be given additional time to be in compliance with the new requirements.

Expectations of a plan

As indicated above, there will be several areas firms will have to consider, and the food safety plan is the place to document the thought process used during the evaluation, the processes and systems that the firms will use, and the corrective actions that will occur if deviations are found, as illustrated in Fig. 1.

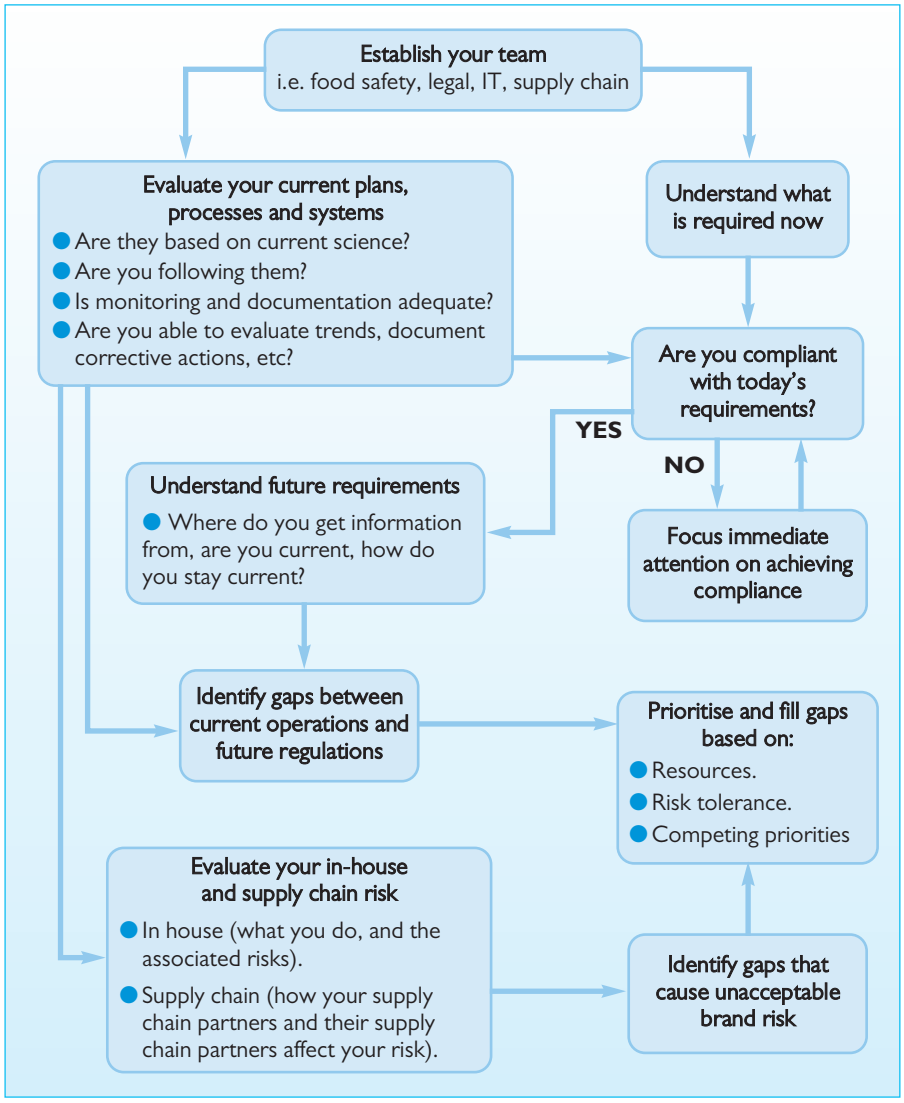
For each component of the food safety plan, a five-step approach is needed:

- Identify hazard.
- Understand the cause.
- Implement preventive controls. Data will be needed to validate that the preventive controls are effective.
- Monitor effectiveness. Firms will need to verify that the system is functioning as designed. Testing can play an important role in monitoring.
- Review and adjust. Significant changes or the identification of new hazards should prompt a re-evaluation of the food safety plan (which should be documented). At a minimum, the plan should be re-evaluated every three years.

It is important to note that while FSMA requires firms to ensure that their processes and practices reflect the state of the science and are designed to protect food from contamination, it is also important to note that without the corresponding documentation, it will be impossible for FDA, or your customers, to assess that the rules are being followed.

The food safety plan and all related documents must be made available to FDA during inspections, so again, the importance of accurate documentation, and a match between what the plan says you do and what you actually do cannot be overstated.

Fig. 2. The key points to consider when preparing a food safety plan.



How to prepare

Multiple drivers are currently impacting the food safety landscape and many changes are in motion, independent of the new legislation.

The implementation of the new legislation will take time and is largely dependent on funding and how FDA drafts the regulations. However, we see customer demands increasing in anticipation of the new requirements.

So how can a company prepare for what is to come? Leavitt Partners recently published a white paper addressing exactly this issue.

The key points are summarised in Fig. 2, and suggest that a team approach is needed to first assess the current state of the various aspects of preventive controls within an operation, and then evaluate where there may be needs – either in fulfilling current requirements and expectations, or in anticipation of what is coming in the future.

With the implementation of the new legislation, there will be changes in the food safety landscape across the supply chain. It is important that every company stays informed on the implementation of the new law and ahead of changes to ensure a position as a food safety leader.

The new legislation will not change the food safety landscape overnight, but there is a unique opportunity for industry leaders to share best practices with FDA, participate in shaping the new regulations and guidance, and position themselves to have the solutions to meet the needs created by the new requirements.

Summary

By following the developments in US regulatory policy over the coming years and evaluating your business practices against current standards, you can provide the necessary assurances to FDA – and your customers – that a protective and reliable food safety system is in place for your products.

Eurofins and Leavitt Partners can work with you to ensure that your company is properly aligned with all necessary requirements so that you maintain your firm's leading edge.

To help you ensure regulatory compliance they provide strategic analysis, customised updates, audits, and testing services that will help you protect your brands and expand your global market share. ■

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Since this article was written, FDA has released the proposed rule outlining in more detail the expectations of a food safety plan. Visit leavittpartners.com/fsma for an updated analysis