US Food Safety Modernization Act:

Food Safety Plan Expectations and Overview of Preventive Controls

November 2012

This paper covers important updates related to the US Food Safety Modernization Act (FSMA) and recent changes that will impact food shipments to the US. If your company exports food to the US or if you are a US importer of food, this document will contain valuable information for your business.

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Who are Eurofins and Leavitt Partners and why are they working together?

Eurofins is a leading international group of laboratories providing an unparalleled range of testing and support services to the pharmaceutical, food, environmental and consumer products industries and to governments. With over 160 laboratories in 32 countries, Eurofins offers a portfolio of over 100,000 reliable analytical methods for characterizing the safety, identity, purity, composition, authenticity and origin of products and biological substances.

Leavitt Partners Global Food Safety Solution is comprised of an experienced team with regulatory, public health and scientific backgrounds that can use our network of global and domestic relationships to assist our clients in navigating the new challenges around producing and selling safe food in the context of managing risk in a cost conscious environment.

Together, Eurofins and Leavitt Partners believe that existing and prospective clients will find value in a new service that combines the expertise of both organizations to provide regulatory insight regarding new challenges around imported FDA regulated food into the U.S. along with expertise on validation and verification of preventive control programs that utilize robust testing strategies.

Introduction:

In the United States, lawmakers, regulators, consumers and the media are more focused on food safety than ever before. On January 4, 2011, President Obama signed the **Food Safety Modernization Act** 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 **(1) who needs to prepare for FSMA and what preventive controls entail, (2) our analysis of expectations of a food safety plan, and (3) 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.

(1) Preventive Controls: Who is affected and what is expected?

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 (e.g., 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, any facility that manufactures, processes, packs or holds food will be required to conduct a hazard analysis and have preventive controls in place. Very small facilities- which are to be defined by FDA- also may be exempt from these requirements.

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 minimize 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 color additives; and
    - hazards that occur naturally, or may be unintentionally introduced; and
- identify and evaluate hazards that may be intentionally introduced, including by acts of terrorism; and
- 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 formalized 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.
- 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

Validation and verification of control measures

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. Subsequent editions of this newsletter will provide useful examples.

When will this start?

The preventive control rule has not yet been published. White papers can be written speculating as to why the preventive control rules are delayed. Without a doubt, they will come out eventually. At the 1.5 year mark FDA was to have promulgated regulations stating the minimum requirements to conduct a hazard analysis. 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. Regardless of the issue date, small and very small businesses with be given additional time to be in compliance with the new requirements.

(2) Expectations of a Food Safety 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 Figure 1.

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

1. Identify hazard
2. Understand the cause
3. Implement preventive controls
   -Data will be needed to validate that the preventive controls are effective
4. Monitor effectiveness

-Firms will need to verify that the system is functioning as designed. Testing can play an important role in monitoring.

5. 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 reevaluated every three years.

Figure 1.

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.**

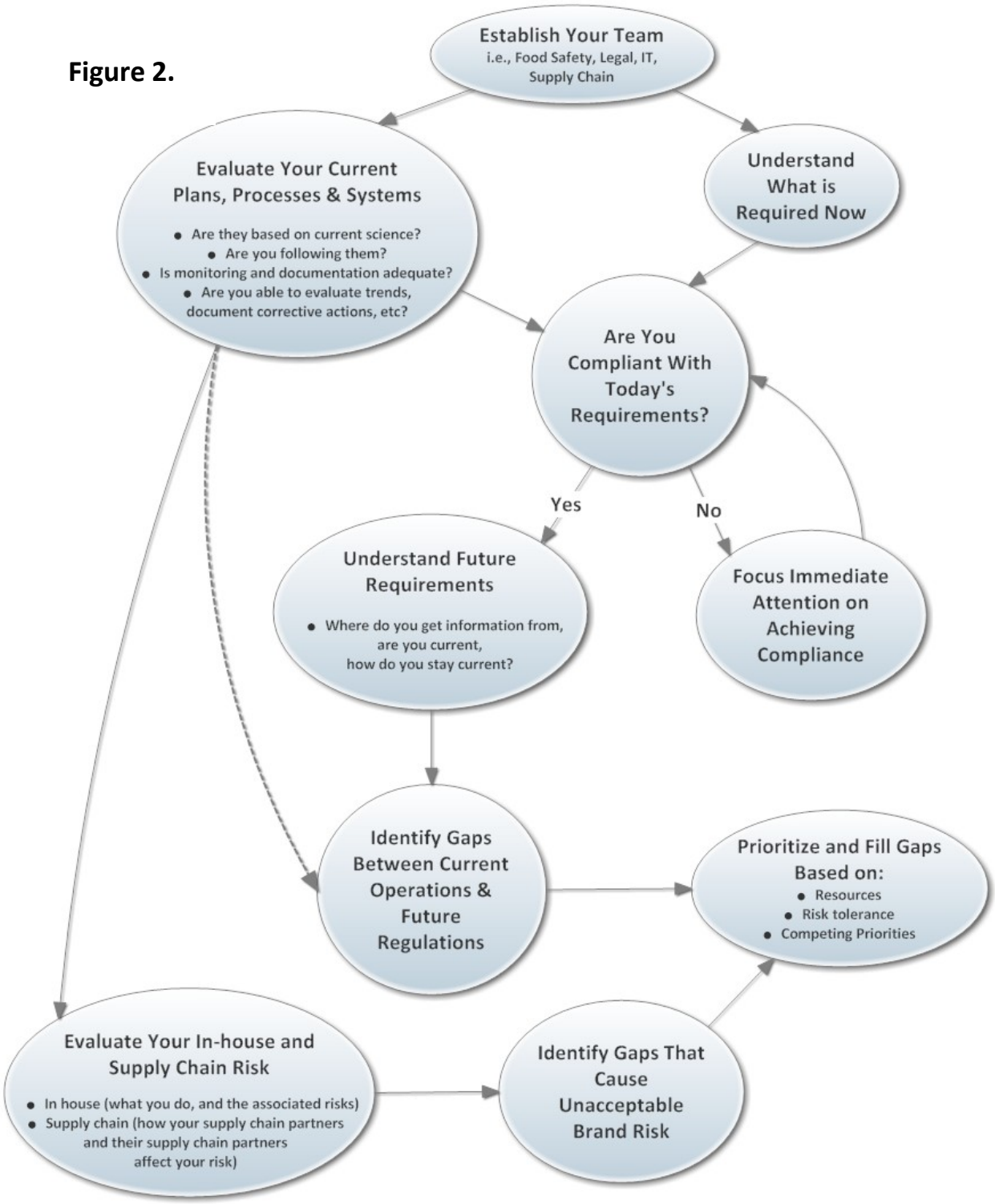
(3) How to Prepare

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 summarized in Figure 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.

Figure 2.



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 won't 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.

(4) Summary

By following the developments in U.S. 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 look forward to working with you to ensure that your company is properly aligned with all necessary requirements so that you maintain your firm's leading edge. Please contact us to learn more about how we can help you meet the new requirements of FSMA. To help you ensure regulatory compliance we provide strategic analysis, customized updates, audits, and testing services that will help you protect your brands and expand your global market share.