The FSMA’s New Mandates:
Obstacle or Opportunity for Industry?
Background

The Food Defense Series is produced by Tyco Integrated Security in cooperation with Clareo, Inc. as a forum to discuss and share insights about the key issues facing security and supply chain practitioners in the Food and Beverage Industry.

In Part One of our series, we will review the key requirements of the Food Safety Modernization Act (FSMA), progress and challenges to its implementation and what we can learn from Food and Drug Administration (FDA)-issued rules and tools announced in the six months since its enactment.

In subsequent installments of the series, we will explore: whether the FSMA has more potential to harm or help protect the health of the food industry, what kinds of companies are most likely to prosper under the FSMA, the specific components of a proactive food defense program and a comparison of food protection in the U.S. with the efforts of other nations.

Expanding Scope

The FDA is responsible for regulating $417 billion worth of domestic food and $49 billion worth of imported food.¹ This translates to about 80% of the foods Americans consume, including upwards of 15% of the U.S. food supply ² (20% of vegetables, 60% of fruits and 80% of seafood) sourced from outside the United States.³ In fact, almost “25 cents of every dollar spent by Americans are spent on products regulated by the agency. FDA-regulated products account for about 10% of all imports into the U.S., arriving from more than 300,000 facilities in 150 different countries.”⁴

FDA’s Increased Authority and Responsibilities

The enactment of the FSMA expanded both the authorities and responsibilities of the Food and Drug Administration. The legislation’s key requirements call for developing preventive controls across the food supply, holding industry accountable for producing safe food through inspection and compliance, ensuring imported food is as safe as domestically produced food, improving the FDA’s ability to intervene and respond to outbreaks, and enhancing partnerships among all agencies that share the responsibility for the food supply. Notably, the legislation empowered the FDA to mandate the recall of food products, suspend the registration of food facilities, and increase its inspection authority, access to records and capacity to remove potentially unsafe foods from commerce through administrative detention.

The FSMA further tasked the FDA with the development and implementation of dozens of standards, guidance documents, communication and training plans to support the goal of reducing and mitigating the risks of both unintentional and intentional adulteration to the nation’s food supply.

² Statistic does not include foreign-sourced spices consumed in U.S.
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The Price of a Safer Food Supply?
The Congressional Budget Office estimates the cost of implementing the FSMA at approximately $1.4 billion over five years. As of this writing, it is unclear what percentage of the legislation will be funded. In June 2011, the House of Representatives passed Agricultural Funding Bill H.R. 2112 with more than $285 million in proposed cuts to the FDA's 2012 budget. Given these budgetary challenges, the FDA’s ability to build effective relationships with foreign and domestic partners, engage food industry stakeholders and focus its efforts on the percentage of program costs it can recoup through new fees and penalties for noncompliers will be crucial to FSMA’s success.

While the FDA cautions that funding cuts would impact the Agency’s head count and present challenges “in implementing the legislation fully without compromising other key functions,” it would be unwise for food industry noncompliers to count on a “free pass” under the potentially underfunded law. Further, savvy food industry members will recognize that many of FSMA’s key requirements draw from prior FDA program guidance and initiatives, using tools already under development before the Act’s passage.

Inspection and Compliance: the FDA’s Risk-Based Approach to Targeting
Section 201 of the FSMA requires that the FDA identify and allocate resources to inspect all high-risk domestic facilities within five years of enactment and no less than every three years thereafter.

The FDA’s FY2011 Domestic Risk-Based Model for Prioritizing Inspections weights and assigns a value to each component of a domestic food establishment’s risk profile. The model scores an establishment’s inherent risk factors, such as foodborne outbreaks, Class I recalls and adverse events within a particular food category and the FDA’s risk ranking of a particular industry code. The model also scores firm-specific factors, such as compliance history and length of time since last inspection. Establishments that are new, have never been inspected by the FDA or have not been inspected within the last five fiscal years are assigned a higher relative risk score. The combination of inherent risk factors and firm-specific compliance factors produces a total relative risk score. Establishments with higher relative risk scores are assigned a higher priority ranking in the FDA’s inspection queue. While the introduction of weighted risk criteria is new for 2011, the inspection priorities reaffirm earlier guidance on inspection priorities. “Firms covered by this program, should be considered under the following criteria for coverage” and “firms never inspected by the FDA or never inspected under the Domestic Food Safety Program should be given precedence over firms previously inspected.”

The FDA plans to evaluate the risk model annually and may, at its discretion, calibrate the model periodically to adjust scoring or address emerging threats to the food supply.

6 Vote was 217 ayes, 203 nays, 12 not voting. Currently under review by Senate Committee on Appropriations.
7 FDA estimates that $110.1M can be recouped through FSMA user fees (including voluntary qualified importer program user fees, export certification user fees, reinspection user fees, and recall user fees).
9 Risk algorithm based on FDA and State agreed criteria developed (pre-enactment of the FSMA).
What Does the FSMA Require Businesses to Do?

The FSMA increases the regulatory requirements for companies that manufacture, supply, process, pack or hold food products. By requiring food facilities to evaluate hazards in their operations, implement and monitor effective measures to prevent contamination, and have a plan in place to take corrective actions when needed, the FSMA shifts the focus of the FDA from response to prevention.

The law also allows the FDA to recoup certain program costs from food facilities:

- Imports and exports
- Administrative costs of the Voluntary Qualified Importer Program (VQIP)
- Costs associated with issuing food export certifications
- Costs to establish and administer the third-party accreditation program
- Costs associated with domestic and foreign facility reinspections
- Failure to comply with recall orders, and certain importer reinspections13

To date, only the hourly rates for facility and importer reinspections and failure to comply with recall orders have been published.

“Think of it as supply chain management written into law.”

Michael Taylor
Deputy Commissioner for Food, FDA
February 17, 2011

## Summary of the FSMA’s Key Requirements

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<td>101</td>
<td>Make records available for inspection. FDA can access and copy all records related to an article of food that is “of interest,” and articles of food that are “likely to be affected in a similar manner.”</td>
<td>January 4, 2011</td>
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<td>102</td>
<td>Facilities required to register under the FDA will have to re-register every two years during the period beginning on October 1 and ending on December 31 in even numbered years.</td>
<td>October through December 2012</td>
</tr>
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<td>103</td>
<td>Facilities required to conduct hazard evaluation to identify known or reasonably foreseeable hazards, including “biological, chemical, physical, and radiological hazards, natural toxins, pesticides, drug residues, decomposition, parasites, and unapproved food and color additives,” and “hazards that occur naturally or may be unintentionally introduced.” Includes intentionally introduced adulterants, including by acts of terrorism. Each registered facility is then required to implement preventive controls to provide assurances that the identified hazards would be significantly minimized or prevented, and that the food will not be adulterated or contain an undeclared allergen. Preventive controls specified include: • Sanitation • Training • Environmental controls • Allergen controls • Recall contingency plan • Good manufacturing practices • Supplier verification activities Facilities required to: • Monitor the controls • Establish corrective actions • Maintain records of monitoring, instances of nonconformance, and corrective actions.</td>
<td>July 3, 2012</td>
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<tr>
<td>105</td>
<td>Introduction of produce safety standards including “hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced, including by acts of terrorism.”</td>
<td>January 3, 2012</td>
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<td>106</td>
<td>FDA, in consultation with the United States Food and Drug Administration (USDA) and the Department of Homeland Security (DHS), to promulgate regulations within 18 months to protect food against intentional adulteration.</td>
<td>July 3, 2012</td>
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| 204     | Enhanced tracking and tracing pilot. List of “high-risk foods” and issue of any high-risk foods additional records requirement. | October 3, 2011 (pilot)  
January 3, 2012 (list)  
January 3, 2012 (records) |
| 207     | Administrative detention of food when FDA has “reason to believe” that the food “is adulterated or misbranded.” | July 3, 2012 |
| 211     | Grocery store chains (15 or more physical locations) required to print and post notifications for products carried within 24 hours of notices posting to FDA’s website, in a prominent location for 14 days. | January 3, 2012 |

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14 Requires FDA to conduct a study of the transportation of food for consumption in the United States.


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Food Category Exclusions and Definition of “High-Risk” Food Establishments

The FSMA does not apply to products overseen by the USDA. It also excludes certain alcoholic beverages, foods operating under the seafood, juice and low-acid canned goods Hazard Analysis & Critical Control Points (HACCP) programs.

Section 204 of the FSMA mandates that the FDA will designate high-risk foods for which additional record-keeping requirements will be required “as appropriate and necessary to protect the public health” not later than January 3, 2012. While this list has not yet been published, and FDA’s identification of high-risk food establishments under the FSMA will evolve with the agency’s understanding of new threats to public health, food safety or food defense, prior enforcement efforts and earlier Agency guidance documents also provide useful insight about potential areas of concern.

The FDA’s Compliance Program Guidance Manual “Domestic Food Safety” explains that “High-Risk Foods” may present hazards, which the Agency believes may present a high potential to cause harm from their consumption. Examples include custard-filled bakery products; dairy products, including soft, semi-soft, soft ripened cheese and cheese products; ready-to-eat sprouts, fresh fruits and vegetables, and processed fruits and vegetables; spices; shell eggs; sandwiches; prepared salads; infant formula; and medical foods, products containing or made in facilities where there are common allergenic substances, such as milk, eggs, fish, crustaceans, tree nuts, peanuts or soybeans.
Import Safety

Perhaps the most dramatic changes to how our food supply is regulated under the FSMA are contained within the import safety provisions of the law. A summary of these provisions is outlined below:

**Summary of FSMA Import Safety Provisions**

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<td>201</td>
<td>Targeting of Inspection resources, including increased inspection of foreign facilities.</td>
<td><em>(FDA must double the number of foreign facility inspections each year for five years)</em> January 4, 2012</td>
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<td>207</td>
<td>Administrative detention of food.</td>
<td>July 3, 2012</td>
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<tr>
<td>301</td>
<td>FDA to issue guidance to importers to ensure that suppliers use risk-based preventive controls that provide the same level of protection as U.S. requirements.</td>
<td>January 4, 2012</td>
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<td>302</td>
<td>Voluntary Qualified Importer Program (VQIP) “fast track” with facility certification.</td>
<td>July 4, 2012</td>
</tr>
<tr>
<td>303</td>
<td>Certification for high-risk food imports: FDA has discretion to require assurances of compliance for high-risk foods.</td>
<td>Discretionary</td>
</tr>
<tr>
<td>304</td>
<td>Prior notice of imported food shipments to the U.S. Names of any country to which article has been refused entry to be added to notice submission.</td>
<td>July 3, 2011</td>
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<td>305</td>
<td>Expand technical, scientific and regulatory food safety capacity of foreign governments and industries exporting to the U.S.</td>
<td>January 4, 2013</td>
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17 “Foreign supplier verification activities may include monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plan of foreign supplier, and periodically testing and sampling shipments.” 21 U.S.C. § 384 a(b)
## Import Safety, cont.

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<td>306</td>
<td>Increased inspection of foreign food facilities. Can deny entry if FDA access for inspection is denied.</td>
<td>January 4, 2012 (increased inspection); 30-day rebuttal period (denied entry)</td>
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<td>308</td>
<td>Submit selection basis to Congress for offices abroad to provide food safety assistance on food destined for the U.S. market.</td>
<td>October 11, 2011</td>
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<tr>
<td>309</td>
<td>Identify and prevent smuggled foods from entering the U.S. and posing a threat to national security and consumer safety.</td>
<td>July 3, 2011</td>
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Preventive Controls: Exactly What Is the Inspection Team Looking for?

Many security practitioners have asked us whether there is a comprehensive list available detailing exactly what items FDA inspection teams will be looking for at their facilities. The answer is no, not exactly. However, Form FDA 483 is a document used by FDA inspection teams to record and communicate concerns discovered during facility inspections. While Form 483 observations do not represent the Agency’s formal position on a facility’s compliance, they may be a useful indicator of the trends inspection teams are viewing in either the food industry as a whole, or at a particular facility before more formal action is taken. The current risk-based approach encourages the concentration of resources in the areas that have yielded the most serious threats in the past. The results of Form 483 are publicly available.

For example, HACCP Plan implementation topped the list of Form 483 observations during food facility inspections in both 2006 and 2007. In 2008 and 2009, salmonella-tainted peanuts at Peanut Corporation of America (PCA) triggered the most extensive food recall in U.S. history. Pervasive pest control failures were indicated by inspectors at PCA’s facilities. In August of 2010, salmonella found in eggs from Iowa producers Wright County Egg and Hillandale Farms triggered a recall of 500,000 eggs. Form 483 observations again indicated pest exclusion failures. Not surprisingly, “Lack of Effective Pest Exclusion” observations have more than doubled (from 197 to 443) between 2008 and 2010 topping the Form 483 observation in both 2009 and 2010.

Other Useful New Tools from the FDA

In March 2011, the FDA launched the Food Defense Mitigation Strategy Database “designed for companies that produce, process, store, package, distribute, or transport food or food ingredients. It provides a range of preventive measures that companies may choose to better protect their facility, personnel and operations. These safety measures are specific to individual categories that impact every step of the food production and distribution process” at http://www.fda.gov/Food/FoodDefense/ucm245544.htm

In April 2011, the FDA launched a web search engine for recall information. The new search engine may be accessed at http://www.fda.gov/Safety/Recalls/ucm2005683.htm

In August 2011, the FDA posted the Food Related Emergency Exercise Boxed set (FREE-B), a series of scenario-based training simulation exercises that companies may download and use “to test their own plans, protocols and procedures independently.” The FREE-B is available at http://www.fda.gov/Food/FoodDefense/Training/ucm216741.htm

“An ounce of prevention is worth a pound of cure.”
Benjamin Franklin
Starting Points: What Can Companies Do While Waiting for the Rest of the Rules?

- Identify who is in charge of Food Protection (both Food Safety and Food Defense) efforts at your facilities.
- If your company does not have a written hazard analysis plan in place, now is the time to start!
- If you have a written plan, how recently have you evaluated it? (Hazards, Critical Control Points, Auditing and Documentation)
- Find out how your firm qualifies and audits its suppliers.
- Determine your firm's ability to trace products “one up” and “one down.”
- Identify which additional records you may need to present to regulators under FSMA, and make sure they are inspection-ready.

While some of the FSMA's specific implementation guidance for industry has not yet been released by the FDA, it is still possible — and advisable — to take steps to prepare. By reviewing and testing facility plans in light of recent food outbreaks and FDA guidance documents issued both before and after the passage of the FSMA, the savvy food industry security practitioner can get a head start on protecting the value of his or her firm.

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