



## **PMA Produce Safety Policy Conference FSMA Implementation Issue Brief**

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PMA has identified “FSMA Implementation” as one of its key “Issues Leadership” activities and it is providing value to its membership regarding FSMA implementation by:

- 1) Advocating for** sound and practical policy regarding; the who, what, when, where, and how of FSMA implementation, as well as its funding.
- 2) Working in Partnership** with allied produce trade organizations, federal and state government agencies, and academic institutions to be ready to assist members in understanding the new business requirements and how to implement the new FSMA regulations irrespective of where they are in the supply chain or located in the world.

### **Meeting Objectives**

The goals of this meeting are to foster science and risk based produce safety policy discussion and to build consensus on key produce policy issues among produce industry policy thought leaders and government policy makers. The specific objectives of the FSMA Implementation portion of PMA Produce Safety Policy Meeting are to:

- 1) Catalog and prioritize industry and government needs regarding FSMA implementation.
- 2) Identify and prioritize possible actions to address identified FSMA Implementation needs.
- 3) Develop FSMA implementation policy and funding recommendations.

### **Background**

The Food Safety Modernization Act (FSMA) is a comprehensive top-to-bottom overhaul of the United States food safety regulatory framework. Passed by Congress in late 2010 and signed into law by President Obama at the start of 2011, there is an expectation that the regulations associated with FSMA will soon be finalized, meaning that the food industry will soon have to implement new business requirements, and government agencies will soon be verifying compliance to the new regulations. FSMA is often referred to as “comprehensive change.” However, it will in fact be “transformative” in how the U.S. food safety regulatory network functions, and it will touch every segment of the produce business supply chain from farm-to-fork. Since 2011, the U.S. Food and Drug Administration (FDA) has proposed seven major FSMA regulations, and PMA has provided detailed comments on each, because they will affect how produce is grown, packed, processed, shipped and imported into the United States. It is anticipated that a number of these FSMA regulations will be finalized in August and October 2015. Details regarding the proposed FSMA regulations and finalization can be found on the PMA FSMA homepage at:

<http://www.pma.com/topics/food-safety/fsma>

**Table 1. Status Summary of FDA FSMA Rules**

<b>FSMA Proposed Rule</b>	<b>Anticipated Final Rule</b>
Produce Rule	October 31, 2015
Preventive Controls for Human Foods	August 30, 2015
Preventive Controls for Animal Feed	August 30, 2015
Foreign Supplier Verification Program	October 31, 2015
Mitigation of Intentional Adulteration	May 31, 2016
Sanitary Transportation of Human & Animal Food	March 31, 2016
High Risk Food Designation	TBD
Traceability	Proposed Rule Pending
Consumer RFR ANPR	TBD

## **FSMA Implementation**

The public discourse regarding what should and shouldn't be in the first seven FSMA regulations has largely ended. However, the discussions and policy decisions on FSMA implementation and budgetary needs are just beginning.

### **FDA's Proposed Implementation Plan**

In May 2014, [FDA issued a document](#) outlining FDA strategies for implementing FSMA which includes capacity building, training, and operational plans for the Agency. FDA explicitly states that "food safety depends primarily on the food industry, with top-level management commitment and working in a continuous improvement mode, to:

- *Implement science- and risk-based preventive measures at all appropriate points across the farm-to-table spectrum.*
- *Manage their operations and supply chains in a manner that provides documented assurances that appropriate preventive measures are being implemented as a matter of routine practice every day."*

Key aspects excerpted from the proposed FDA FSMA Implementation Plan for the Produce Safety Rule, Preventive Controls for Human Foods Rule and Foreign Supplier Verification Rule are as follows:

### **FDA Guiding Principles for Implementation of the Produce Rule:**

*"Effective implementation and oversight of produce safety standards poses distinct challenges for FDA due to the scale and diversity of the produce sector, the large number of produce farms, and their lack of familiarity with FDA regulatory oversight. Moreover, Congress envisioned a different role for FDA on produce farms compared to food facilities, as reflected in the lack of an inspection*

*frequency mandate in FSMA for farms, the directive to coordinate education and enforcement activities with state and local officials, and the mandate to USDA to provide technical assistance grants to support implementation, especially for entities such as small growers.*

*Another reality shaping FDA's approach to produce safety is there is no reasonable expectation FDA will have the resources to make routine on-farm inspection a major source of accountability for compliance with produce safety standards. FDA's implementation of produce safety standards will entail a broad, collaborative effort to foster awareness and compliance through guidance, education, and technical assistance, coupled with accountability for compliance from multiple public and private sources including FDA and partner agencies, USDA audits, marketing agreements, and private audits required by commercial purchasers. FDA will focus its efforts on:*

- Deploying a cadre of produce safety experts in headquarters and the field with the depth and breadth of capacity to develop the guidance needed to support implementation and provide technical support to government and industry parties working to foster compliance.*
- Actively supporting education and technical assistance for growers, primarily through collaboration with other public and private parties.*
- Supporting public and private parties involved in audits and other accountability functions with technical assistance and other collaborative support.*
- Conducting targeted on-farm surveys and inspections to understand current practices and identify gaps in compliance.*
- Taking administrative compliance and enforcement action when needed to correct problems that put consumers at risk.*
- Responding to produce outbreaks effectively to lessen impact on public health.*
- Conducting in-depth environmental assessments where appropriate to identify root causes of outbreaks associated with produce and to inform future prevention efforts.”*

## **FDA Guiding Principles for Implementation of the Preventive Controls Rule**

*“Implementation of FSMA's preventive controls mandate in food facilities will build on FDA's experience implementing Hazard Analysis Critical Control Point (HACCP) in seafood and juice processing operations, specifically FDA's familiar roles in issuing rules and guidance and conducting inspections to assess and enforce compliance. Implementation of preventive controls must differ, however, due to the much larger number and diversity of covered facilities, FSMA's new records access and administrative enforcement tools, and FDA's commitment to the expanded tool kit for strategic and risk-based industry oversight outlined in the operational strategy.*

*FSMA provides FDA for the first time an inspection frequency mandate for food facilities, but FSMA's public health prevention framework demands transformative change in how FDA uses its inspection authority and traditional and enhanced enforcement tools to carry out its oversight responsibility and protect public health in the most efficient manner possible.*

*FDA will significantly expand its inspection and surveillance tools to include a wider range of inspection, sampling, testing, and other data collection activities conducted through its own field force and through collaboration with partner agencies and the food industry.*

### **Inspection and Surveillance**

*The types and purposes of inspection and surveillance will include:*

- *Efficiently screening firms for food safety performance to guide risk-based inspection priority, frequency, depth, and approach.*
- *Providing firms incentives for compliance through enhanced presence in and targeted scrutiny of high-risk firms and products and reduced scrutiny of firms with records of demonstrated good performance.*
- *Assessing the compliance of individual firms through a range of inspection and sampling techniques used in a strategic, risk-based way to maximize coverage of priority sectors and firms.*
- *Making in-depth assessments of individual firms when needed to increase the incentive for compliance and determine the need for compliance or enforcement actions.*
- *Collecting data to inform understanding and analysis of sector-wide hazards, practices, and preventive control deficiencies.*
- *Collecting data on compliance rates to evaluate program performance and plan future efforts.*

### **Administrative Compliance Tools**

*FSMA's public health prevention focus and new administrative enforcement tools mean that FDA's primary tools for correcting preventive control deficiencies and resolving problems that put consumers at risk will be administrative compliance actions, rather than court enforcement cases including:*

- *Voluntary correction of problems at the facility level, achieved immediately during the course of an inspection through communication with firm management by investigators and, as needed, Center technical staff.*
- *Voluntary correction achieved at the District level through deficiency letters, issued within days after an inspection with Center back up, to document significant safety-related deficiencies and request correction within a specified period, with immediate inspection follow up to verify correction.*
- *Administrative detention of product if needed to provide immediate public health protection or for other appropriate purposes.*
- *Voluntary and mandatory recalls removing potentially hazardous food from the market.*
- *Administrative suspension of registration when other administrative compliance measures have failed or are inadequate to achieve correction of significant deficiencies that put consumers at risk.*

### **Judicial Enforcement Tools**

*Enforcement includes judicial actions when necessary to complement non-judicial compliance actions and address matters for which there is no adequate administrative remedy such as:*

- *Seizure actions that are needed to back up administrative detentions.*
- *Injunction actions when suspension of registration or other measures are inadequate to prevent future non-compliance.*
- *Criminal prosecution for falsifying records, lying to FDA, knowingly putting consumers at risk, or in other appropriate cases."*

### **Guiding Principles for Implementation of FSMA's New Import System**

*"FSMA provides FDA with a multi-faceted new tool kit for import oversight that is intended to ensure that imported foods are produced using modern preventive measures that achieve the same level of food safety protection as FSMA's new preventive control and produce safety*

*standards. FDA will use the new tool kit to build a prevention-oriented import system that provides much-heightened assurances about the safety of imported food.*

*Rather than relying primarily on FDA detecting and stopping food safety problems at the border, the new system relies primarily on importers providing documented assurances that their foreign suppliers have taken proper steps to prevent problems. To complement FDA's oversight of importers, FSMA directs FDA to strengthen private audit systems, increase its overseas presence, and work in partnership with foreign governments to strengthen and capitalize on their capacity to help ensure the safety of food destined for the United States, all in keeping with the collaboration and leveraging elements of our operational strategy for FSMA implementation.*

*FDA will use all elements of the FSMA tool kit to provide the heightened assurances of food safety, called for by Congress and expected by consumers, in a manner that makes efficient use of FDA's resources and leverages the resources and efforts of others.*

*Key features of FDA's import implementation effort will include:*

- Developing the skills, capacity, and processes to audit foreign supplier verification programs and hold importers accountable for effectively managing their supply chains in accordance with FSMA.*
- Reconfiguring current import screening and field exam activities to complement oversight of FSMA's foreign supplier verification requirement and ensuring that FDA is making strategic, risk-based use of its import oversight resources.*
- Implementing the voluntary qualified importer program and other measures to expedite entries for good performers and thereby allowing more resources to be directed toward high-risk imports.*
- Developing the skills, capacity, and processes to audit accrediting bodies and accredited third-party certifiers, with the goal of enhancing the rigor, objectivity, and transparency of private audits and their contribution to assuring the safety of imported food.*
- Developing the skills, capacity, and processes to conduct comparability assessments of foreign government regulatory systems as the basis for relying, where justified, on foreign oversight, minimizing duplication of effort, and improving risk-based resource allocation.*
- Building data integration and analysis systems and harnessing all available sources of relevant information to strengthen risk-based targeting of resources."*

### **FDA's Proposed FSMA Budget**

The FDA's FY 2015 budget allocated \$280M in funds to the FDA's Center for Food Safety and Applied Nutrition and \$623M for FDA field activities. President Obama has proposed a \$109.5 M increase in the FDA's FY-2016 budget and a \$191.8 M increase in user fees for FSMA implementation. These funds will be used to build FDA capacity and to assist the food industry with training to achieve compliance with the new FSMA regulations. Information regarding how FDA is proposing to use these funds is detailed on the [FDA website](#).

In an April 2015 joint letter sent to Congressional leaders, the Produce Marketing Association (PMA) publicly voiced its support for increasing the U.S. Food and Drug Administration's (FDA) food safety budget by \$109.5 M, for Food Safety Modernization Act (FSMA) implementation. The letter is signed by a cross-section of food organizations from across the nation and underscored that the Food Safety Modernization Act (FSMA) appropriately makes prevention a cornerstone of our nation's food safety strategy and the new rules should be appropriately funded. However,

PMA, along with other major segments of the food industry, has taken the policy position of opposing the significant increase proposed in user fees.

## **Summary of the FDA FY '16 Proposed \$109.5M Increase in Budget Authority**

### **I) Inspection Modernization and Training - \$25 million**

#### **A) New FDA Inspection Model**

- From evidence of violations / enforcement cases to assuring firms are implementing systems that effectively prevent food contamination
- Specialized inspectors, supported by FDA technical experts, to assess the soundness and performance of a facility's overall food safety system
- Data to guide risk-based inspection priority, frequency, depth, and approach

#### **B) Training FDA Inspectors and Compliance Staff (≈2000)**

#### **C) IT systems**

- Identify & track risk
- Assess & track inspection efficiency and inspector competency

### **II) National Integrated Food Safety System - \$32 million**

- Education and technical assistance to provide compliance support and oversight
- Build state partnerships and capacity to provide education and technical assistance to growers
- Inspection grants, contracts, and cooperative agreements
- Training State Inspectors and Compliance Staff (≈1000)
- Assure nationwide quality, consistency and efficiency
- Investing in state laboratory accreditation and competency

### **III) Education and Technical Assistance for Industry - \$11.5 million**

#### **A) Financial support to state agencies and public-private-academic collaborations:**

- Produce Safety Alliance
- Sprout Safety Alliance
- Food Safety Preventive Controls Alliance

#### **B) FDA Food Safety Technical Assistance Network**

#### **C) USDA NIFA FSMA - mandated compliance grants to provide technical assistance to small, sustainable, and organic farmers and processors**

### **IV) Technical Staffing and Guidance Development at FDA - \$4 million**

#### **A) Building FDA's Cadre of Food Safety Experts:**

- 12 Preventive Controls SME's
- 8 Produce Safety SME's
- 60 Compliance Support Staff SME's

#### **B) FDA Food Safety Technical Assistance Network**

- Technical assistance to industry,
- Technical support for FDA and state inspectors / compliance staff

### **C) Guidance Development**

- PC: Hazard Analysis, Allergen Controls, Environmental Monitoring
- Produce: Packinghouse, Sprouts, Animal Intrusion, GAPs
- Small Entity Compliance Guides

### **V) New Import Safety Systems - \$25.5 million**

#### **A) Develop & Implement FSVP regulatory procedures & infrastructure.**

#### **B) FDA staffing & training including SME compliance support staff.**

#### **C) Guidance, outreach and technical assistance to industry**

- Hazard Analysis
- Risk Evaluation
- Appropriate selection of verification activities

### **VI) Risk Analytics and Evaluation - \$4.5 million**

#### **A) Operations and Data Sharing (ERP)**

- System to link FDA-wide public health risk priorities to budgets, program performance, resource allocation data

#### **B) Data Structure & Gathering**

- Targeting data collection to make risk informed decisions and resource allocation

#### **C) Data Analysis & Evaluation**

- Risk ranking, prioritization, and attribution tools

### **VII) FDA Infrastructure Improvements - \$7 million**

## **Key Aspects of the FDA Proposed FSMA Implementation Strategy for Consideration**

### **Group 1: FSMA and the National Integrated Food Safety System:**

FDA has stated that “Congress envisioned a different role for FDA on produce farms compared to food facilities, as reflected in the lack of an inspection frequency mandate in FSMA for farms, the directive to coordinate education and enforcement activities with state and local officials, and the mandate to USDA to provide technical assistance grants to support implementation.” Additionally, FDA stated “There is no reasonable expectation FDA will have the resources to make routine on-farm inspection a major source of accountability for compliance with produce safety standards.” Hence it is anticipated that state government (Departments of Agriculture and Public Health) will play a significant role in produce safety rule implementation and compliance. As such, PMA staff has developed strong working relationships with both the National Association for State Departments of Agriculture (NASDA) and the Association of Food and Drug Officials (AFDO). This public policy discourse is critically important as it is anticipated, as noted above, that many of the routine FSMA compliance inspections will be performed by the States.

### **Group 2: FSMA Guidance, Industry & Govt. Outreach/Training**

#### **FSMA Guidance Development: Needs & Funding**

FDA should not take a one size fits all approach to guidance development as procedures, policies and practices vary significantly based on produce commodity, growing region and practices. It is also imperative that FDA guidance documents acknowledge that while guidance documents can provide a “safe-harbor” of practices that are in compliance with the new FSMA regulations, other

means of compliance may also be appropriate and in compliance. It is reasonably foreseeable that federal or state regulatory agencies will encounter unanticipated or novel preventive controls, procedures, processes and practices when performing routine inspections. As it is impossible for every possible hazard and preventive control combination to be identified in FDA Compliance Guidance (CG) documents, should FDA consider routinely convening a group composed of industry, academia and government (State, Local, Territorial and Tribal) subject matter experts, to draft and update model CG's for each of the FDA FSMA implementing regulations, make recommendations to the agency as to what preventive controls, policies, procedures or practices would address the identified hazard appropriately and deem the firm to be "in-compliance" with applicable regulations.

### **FSMA Industry & Govt. Outreach/Training: Needs & Funding**

PMA has also publicly advocated for increasing funding for industry education outreach and training to assist industry to understand and comply with the new FSMA regulations. The administrations proposed FY 2016 Federal Budget requests appropriation of \$11.5M for industry education and technical assistance. As per FDA's proposed FSMA Implementation Plan: "Approximately 300,000 entities could be subject to the final FSMA rules." This means that \$38 per regulated business have been requested for FSMA education outreach and technical assistance. The FDA proposed financial expenditure for FSMA education outreach and training is woefully inadequate given the sheer number of regulated business that will be affected by the FSMA regulations. FDA has proposed that the primary means of delivering FSMA industry education outreach and training will be via the Land Grant University Cooperative Extension Service and through State Departments of Agricultures. However, Land Grant University Cooperative Extension Services have been financially decimated in recent years with significant reductions in funding for cooperative extension personnel appointments, as well as reductions in financial resources that provide the means for cooperative extension specialists to provide food safety information, education and training materials so urgently needed by the food industry.



**FSMA Implementation  
Discussion Guide  
PMA Issues Leadership  
Produce Safety Policy Conference**

Arlington, VA  
June 16-17, 2015

**Day 1 – Tuesday June 16, 2015**

**Discussion Group 1: FSMA and the National Integrated Food Safety System (Gorny)**

- What roles should FDA, State Departments of Agriculture and State Departments of Public Health play regarding FSMA Implementation (Produce, PC and FSVP Rules) especially regarding education, compliance and enforcement:
  - Compliance Guidance Development
  - Education Outreach Re: FSMA Compliance
  - Routine Inspections
  - For-Cause Inspections (Foodborne Illness Outbreak, Food Sample Positives & Recalls)
  - Produce Surveillance Sampling
- What assistance should the produce industry be asking for, from Federal and State regulators?
- Would a non-regulatory pre-assessment of FSMA Compliance be of interest to the farming (Produce Rule), food facilities (PC rule) and Import (FSVP rule) regulated stakeholders?
  - How would this be done most effectively?
  - What do you recommend regulators take into consideration when designing a pre-assessment program to support moving the FSMA regulated entities towards compliance with the FSMA rules?
- What factors should Federal and State regulators take into consideration when developing an inspection program? For example, should regulators consider market access audits, marketing agreement compliance, business schedules (peak/non-peak), inspection frequency, etc.?
- What are regulated entities recommendations for inspections in terms of what should happen before, during, and after an inspection?
- What information would regulated entities find useful in advance of, during, and/or at the conclusion of an inspection?

## Discussion Group 2: FSMA Guidance Development: Needs & Funding (Whitaker)

- What types of technical assistance and outreach will industry most likely be needed for
  - Farms? (Produce Rule)
  - Food facilities (packing houses & fresh-cut processors)? (PC Rule)
  - Importers (FSVP)
- How can useful technical assistance and outreach be best provided?
- Is there particular information that needs to be provided?
- Are there different ways to provide technical assistance depending upon enterprise size, location, and produce commodity? (Guidance documents, webinar presentations, toolkits, and on-site technical assistance)?
- What educational information/topics would be most useful to the farming community (Produce Rule)?
- What kinds of guidance documents, or other technical assistance and outreach tools would be most helpful in developing a Food Safety Plan (PC Rule)?
- What kinds of guidance documents, or other technical assistance and outreach tools, would be most helpful in meeting the FSMA rule requirements?
  - Practical guidance that provides practical advice on the selection of target microorganisms microbiological testing for verification programs for end product, in-line, and environmental sampling, including guidance on the underlying assumptions and relative performance of such indicators. Where there is uncertainty concerning the relation between proposed indicator microorganisms and pathogens of concern, should research be commissioned to determine the effectiveness of proposed target microorganisms?
  - Practical guidance that provides advice on the selection of sampling sites in relation to end product, in-line, and environmental sampling, including guidance on the underlying assumptions for various selection sites and potential interpretation of data that are likely to be encountered?
  - Practical guidance regarding testing for process control?
  - Practical guidance regarding of environmental sampling of the food facility environments for an appropriate microorganisms so as to provide a statistically based verification that the sanitation programs are achieving the appropriate level of microbiological control of the environment of the food facility?
- What resources and where should the resources come from to provide for successful FSMA implementation by industry and government?

## FSMA Industry & Govt. Outreach/Training: Needs & Funding

- What do you see as the biggest challenges to inspection and compliance under the new FSMA rules?
- What resources and where should the resources come from to provide for successful FSMA implementation by industry and government?
- What are the resource priorities for FSMA implementation, and chronologically, when are they needed?
- What assistance should the produce industry be asking for from Federal and State regulators and governments?

The PMA Science & Technology team will continue to be engaged and striving to assure that FSMA implementation policy is sound and practical as well as delivering membership value in year around communications and education outreach, to keep members abreast of important food safety regulatory developments. If you have further questions please do contact any of the members of the PMA Safety and Technology Team Produce Safety team, and/or visit the PMA FSMA homepage at: <http://www.pma.com/topics/food-safety/fsma>.

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