PMA FSMA Overview
By Dr. Jim Gorny

The Food Safety Modernization Act (FSMA) is a comprehensive top-to-bottom overhaul of the United States food safety regulatory framework. FSMA is often referred to as “comprehensive change” but it will in fact be “transformative” in how it will touch every segment of the produce business supply chain from farm-to-fork. The U.S. Food and Drug Administration (FDA) has proposed seven major FSMA regulations and PMA has provided detailed comments on each. These proposed regulations will affect how produce is grown, packed, processed, shipped and imported into the U.S. FSMA regulations will begin to be finalized as soon as the August to October 2015 timeframe and more details about these proposed FSMA regulations and finalizations can be found on the PMA FSMA homepage.

Food Safety Modernization Act (FSMA) – The New Regulations

FSMA Proposed Rules – The U.S. Food and Drug Administration (FDA) has proposed seven major FSMA proposed regulations. FDA and PMA have prepared summaries on each of these originally proposed regulations and proposed supplemental regulations to help you understand how they are likely to affect your business. Additionally, PMA has submitted in-depth comments to the FDA regarding each of these proposed rules with the intent of enhancing public health, while searching for practicable and easily implementable solutions to enhance the safety of fresh produce.

1) Produce Safety Regulation: This regulation affects both international and domestic produce growers, in that it will establish science-based standards focused on the growing, harvesting, packing and holding of produce on-farms. The key provision areas include agricultural water quality standards and testing, standards for using raw manure and compost, training, control of domestic and wild animals, equipment, tools, buildings, sanitation as well as worker health and hygiene. This on-farm produce safety regulation is significant in that FDA will now put in place an enforceable implementing regulation which explicitly articulates on-farm standards of conduct for the safe growing, harvesting, packing and holding of fresh produce. It is anticipated that FDA after review of stakeholder comments, will publish a final produce safety regulation by no later than October 31, 2015.

PMA Produce Rule Summary
- Original Proposal Summary
- Supplemental Proposal Summary

PMA Produce Rule Comments
- Original Proposal Comments
- Supplemental Proposal Comments
2) **Preventive Controls (PC) for Human Food Regulation:** This regulation sets standards for firms which manufacture, process, pack or hold human food. As currently proposed this includes produce businesses throughout the supply chain such as packing operations that are FDA registered facilities and fresh-cut processors. It proposes that firms covered by this rule would be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results and specify what actions will be taken to correct problems that arise. It is anticipated that FDA after review of stakeholder comments will publish a final PC regulation by no later than August 30, 2015.

3) **Preventive Controls for Animal Food Regulation (Animal Feed Rule):** This regulation focuses on improving the safety of animal feed by preventing its adulteration. This regulation would apply to domestic and imported animal food, including pet food, animal feed, and raw materials and ingredients. Facilities producing animal food would be required to have written plans that identify hazards, specify the steps that will be put in place to minimize or prevent those hazards, identify monitoring procedures and record monitoring results, and specify what actions would be taken to correct problems that arise. The proposed rule would also establish certain Current Good Manufacturing Practices (CGMPs) that specifically address animal food. The produce industry has a limited role in the production of animal feed; however produce of insufficient quality is routinely culled from a harvest or process operation and may be used for animal feed. It is anticipated that FDA after review of stakeholder comments will publish a final animal feed regulation by no later than August 30, 2015.
PMA PC Rule Comments
  - Original Proposal Comments
  - Supplemental Proposal Comments

FDA Animal Feed Regulation
  - Supplemental Proposal Summary:
    - English Language Version
    - Spanish Language Version

4) Foreign Supplier Verification Programs (FSVP) Rule: This regulation addresses import safety and is closely tied to the preventive controls and produce safety requirements. In that, importers would be required to verify that food imported into the US has been produced to the same food safety standards that are required of US producers. Food importers will be required to develop Foreign Supplier Verification Programs (FSVP) that comply with U.S. standards, including FDA’s proposed produce safety and preventive controls regulations. It is anticipated that FDA after review of stakeholder comments FDA will publish a final FSVP regulation by no later than October 31, 2015.

PMA FSVP Regulation Summary
  - Original Proposal Summary
  - Supplemental Proposal Summary

PMA FSVP Rule Comments
  - Original Proposal Comments
  - Supplemental Proposal Comments

FDA FSVP Regulation
  - Supplemental Proposal Summary:
    - English Language Version
    - Spanish Language Version

5) 3rd Party Accreditation of Auditors: This proposed regulation aims to establish a comprehensive, credible and reliable program of oversight based on third-party audits and certification of foreign food facilities to help FDA make decisions regarding the admissibility of imported foods. Importantly, this proposed rule does NOT set forth the exact criteria to which firms will be held accountable to during audits, as those proposed criteria have been put forward in the proposed produce safety rule and the proposed preventive controls rule. It is anticipated that FDA after review of stakeholder comments will publish a final 3rd party accreditation regulation by no later than October 31, 2015.

PMA FSVP Regulation Summary

PMA FSVP Regulation Comments
FDA 3rd Party Accreditation Regulation
  o Proposal Summary:
    ▪ English Language Version
    ▪ Spanish Language Version
    ▪ Portuguese Language Version
    ▪ French Language Version

6) Mitigation Strategies to Protect Food Against Intentional Adulteration Regulation:
This regulation would require the largest food businesses (i.e. businesses with $10M or more in total annual food sales) in the U.S. and abroad to take steps to prevent FDA registered food facilities from being the target of intentional attempts to contaminate the food supply. Intentional adulteration of the food supply with intent to cause public health harm is unlikely to occur. However, acts of intentional adulteration may take several forms, including those where the intention is to cause large-scale public health harm; acts of disgruntled employees, consumers, or competitors; and economically motivated adulteration. This proposed regulation may or may not apply to produce businesses that are FDA registered food facilities such as fresh-cut processors, packinghouses and distribution centers depending on enterprise size and the types of activities in which they are engaged. It is anticipated that FDA after review of stakeholder comments will publish a final Mitigation Strategies to Protect Food Against Intentional Adulteration regulation by no later than May 31, 2016.

PMA Intentional Adulteration Regulation Summary

PMA Intentional Adulteration Regulation Comments

FDA Intentional Adulteration Regulation
  o Supplemental Proposal Summary:
    ▪ English Language Version
    ▪ Spanish Language Version
    ▪ French Language Version
    ▪ Portuguese Language Version
    ▪ Chinese Language Version

7) Sanitary Food Transportation Regulation: This proposed regulation would require certain shippers, receivers, and carriers who transport food that will be consumed or distributed in the United States, to take steps to prevent the contamination of human and animal food during transportation. Specifically the regulation will establish criteria for sanitary transportation practices for shippers, carriers and receivers regarding; vehicles and transportation equipment, transportation operations, information exchange, training and recordkeeping. This regulation fulfills FDA’s statutory obligation to issue and implement provisions of the 2005 Safe Food Transportation Act as well as the requirements in section 111 of FSMA. FDA will coordinate with the U.S. Departments of Agriculture and Transportation in this rulemaking process. It is anticipated that FDA after review of
stakeholder comments will publish a final Sanitary Food Transportation regulation by no later than March 31, 2016.

**PMA Sanitary Food Transportation Regulation Summary**

**PMA Sanitary Food Transportation Regulation Comments**

**FDA Sanitary Food Transportation Regulation**
- Supplemental Proposal Summary:
  - English Language Version
  - Spanish Language Version
  - French Language Version
  - Portuguese Language Version
  - Chinese Language Version

These are the seven major rules of the FSMA regulatory framework overhaul, which is intended to implement preventive measures across the food system. These FSMA rules will significantly affect how PMA members and the produce industry conduct business in the future. PMA staff in concert with the PMA Science & Technology Committee, allied trade organizations, commissions and commodity boards will continue to monitor and stay engaged in the FSMA rule finalization process.