



May 26, 2015

U.S. Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: The Food and Drug Administration Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards (Docket No. FDA-2015-N-0797)

To Whom It May Concern:

On behalf of our members, Produce Marketing Association (PMA) respectfully submits the attached comments to the FDA's Food Safety Modernization Act (FSMA) proposed implementation work plans (Docket No. FDA-2015-N-0797). To assist both FDA and PMA membership in reviewing the comments, we have organized them into an executive summary followed by discussion of specific issues categorized as follows:

- 1) Overarching Comments Regarding FDA's Proposed FSMA Implementation Work Plans
- 2) Inspection Modernization and Training
- 3) National Integrated Food Safety System
- 4) Education and Technical Assistance for Industry
- 5) Technical Staffing and Guidance Development at FDA
- 6) New Import Safety Systems
- 7) Risk Analytics and Evaluation
- 8) FDA Infrastructure Improvements

PMA is the largest trade association representing companies in the fresh fruits and vegetables industry. Our association represents more than 2,700 member companies located in 45 countries. In the U.S., our members operate throughout the supply chain from growing to shipping, processing/manufacturing, distribution, wholesaling, retail and foodservice. Collectively, our members handle more than 90 percent of fresh produce sold to domestic consumers. Regardless of member size or scope of operations, our members are committed at every level in the supply chain to food safety.

PMA's vision is to strengthen and lead the global produce community to increase produce consumption. Fruits and vegetables are an integral part of a nutritious and healthful diet, offering great public health benefits. PMA believes that produce safety, taste, convenience, and nutrition are the cornerstones of increasing fruit and vegetable consumption and fighting obesity.



PMA has long been a champion of produce safety and has relied upon the expertise of produce safety professionals who serve as volunteer leaders on the PMA Science & Technology Committee and PMA members at large to develop the comments that follow. In preparing our comments, PMA engaged in numerous and frequent in-depth discussions with PMA member companies that grow, pack and ship fresh produce both domestically and internationally and companies that represent the diversity of produce commodities American consumers expect to be available to them year around. Throughout the discussion, PMA members carefully discussed and deliberated each aspect of the FDA proposed FSMA implementation strategy to assure that the recommendations put forward are practicable and easily implementable solutions to enhance the safety of fresh produce. As a result, our comments provide perspectives from the collective experiences of those who work diligently in the produce global supply chain to provide safe and nutritious produce to consumers daily.

PMA has participated in the congressional debate about FSMA and has provided comments to FDA at every opportunity regarding proposed FSMA rules and now the FDA proposed FSMA implementation work plan. We greatly appreciate those earlier opportunities and the opportunity here to provide detailed comments regarding FDA's FSMA implementation work plans. Attached are those comments.

Respectfully,

A handwritten signature in black ink that reads "James R. Gorny".

James R. Gorny, Ph.D.
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Executive Summary

Food safety is a top priority for the global produce industry. Implications of the FDA's FSMA proposed implementation work plans (Docket No. FDA-2015-N-0797) are critically important to PMA members' businesses and to the industry's overall objective of increasing produce consumption. PMA strongly supports advancing produce safety in ways that are meaningful for industry members and that also protect public health, including through the implementation of the Food Safety Modernization Act. PMA supports the implementation of science- and risk-based regulations throughout the supply chain that require the use of preventive controls that correspond with risks associated with the commodity, and practices and procedures employed during the production, handling, and holding of fresh produce.

Key issues from the perspective of PMA members regarding FDA's FSMA proposed implementation work plans (Docket No. FDA-2015-N-0797) are as follows:

1) Overarching Comments Regarding FDA's Proposed FSMA Implementation Work Plans

PMA in general concurs with FDA's approach to FSMA implementation and supports increased funding for the U.S. Food and Drug Administration's (FDA) food safety budget, including but not limited to appropriation of an additional \$109.5 million in new budget authority. PMA understands that FDA needs sufficient budgetary resources for food safety tools, infrastructure and personnel, to appropriately implement FSMA. However, PMA believes that these financial resources should be derived from the Federal budget as the implementation of FSMA benefits the health and wellbeing of all American consumers, and the cost of FSMA implementation should not unfairly and disproportionately fall on the food industry sector. As such, PMA is opposed to the imposition of user fees, inspection fees or registration fees by Federal or State governments to fund FSMA implementation.

2) Inspection Modernization and Training

Technical Assistance & Regulatory Inspections: PMA applauds FDA's inspectional approach of fostering dialog during inspections regarding matters of non-compliance and deployment of a technical assistance network to provide real-time technical assistance to industry and compliance officers. However, FDA has proposed that the Agency play dual roles: educational outreach (via technical assistance) and the role of assuring compliance verification through inspections. This duality is likely to place FDA in "conflict-of-interest" situations, in that inspectors would be providing technical solutions to non-compliant procedures, processes and practices during the verification inspections. The duality could place both FDA and the inspected party in a difficult situation, and FDA must consider how the agency will clearly provide industry with a portfolio of solutions and separate technical assistance from the FDA's verification role via inspections.

Adjudication of Compliance Status: It is reasonably foreseeable that there will be differences in professional opinion between the regulated fruit or vegetable operation and the federal or state regulatory agency during an inspection regarding the compliance or non-compliant status of particular procedures, policies or practices implemented by the regulated firm. PMA respectfully requests that FDA consider development of administrative procedures to quickly and justly adjudicate differences in professional opinion between a regulated firm and federal or state regulatory agency personnel regarding the firm's compliance status. The administrative procedures should be permitted to be initiated by the firm and difference of opinion resolved by the FDA in a timely manner.

Harmonization of Produce Safety Market Access Audits & the FDA FSMA Produce Rule: Numerous types of market access food safety audits are currently used by buyers to qualify produce suppliers; as these produce safety market access audits assure food safety awareness by produce suppliers and verify implementation of produce safety programs. PMA encourages FDA to work with all standard holders, accreditation bodies and certification bodies engaged in produce safety market access audits to harmonize independent third party produce safety market access audit requirements with FDA FSMA standards. Additionally, FDA should strongly consider the results of market access produce safety audits to reduce redundant inspections by FDA or States that are verifying compliance with the FSMA produce rule.

3) National Integrated Food Safety System

Role of States in FSMA Implementation: PMA supports the role of state governments as entities that would assist with education outreach to produce growers and perform routine FSMA produce rule compliance inspections because state governments are best positioned to have in-depth working knowledge about produce growers' procedures, policies and practices in their state. Produce farms to date have not been pervasively regulated regarding produce safety practices and procedures. PMA also respectfully requests that FDA provide sufficient time and resources to train growers so that they can comply with final rules, as well as training FDA and state regulatory officials regarding agricultural practices and the various means by which growers may comply with this new set of food safety regulations. Additionally, state or federal marketing agreements and marketing orders which are comparable to, or exceed the requirements of the FSMA produce rule requirements, should also be recognized by the FDA for their comparability.

4) Education and Technical Assistance for Industry

Inadequate Funding for Education & Technical Assistance to Industry: The Administration's Federal Budget appropriations request of \$11.5M for industry education and technical assistance is woefully inadequate given the sheer number of regulated business that will be affected by the FSMA regulations. PMA believes that greater federal

government resources need to be authorized and appropriated for FSMA education and technical assistance to industry.

Land Grant University Cooperative Extension Programs are Woefully Underfunded & Under-resourced for FSMA Implementation: 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. However, Land Grant University Cooperative Extension Services have been financially resource-constrained 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. PMA respectfully requests and would support FDA seeking increased Federal Budget funding for industry FSMA education outreach and training in future administration budget proposals for FY 2017 and beyond. It is imperative that sufficient resources be allocated to educate industry before FDA regulates.

All Industry Sectors Need Assistance with FSMA Compliance:

PMA's vision is to strengthen and lead the global produce community to increase produce consumption. Therefore, PMA supports all types of produce production practices (e.g. organic, conventional) irrespective of enterprise size (small business to large business). It would be short-sighted for FDA to limit or focus education outreach and technical assistance to any one business sector or enterprise size. As such, PMA respectfully requests that the FDA consider and implement education and training for all produce business sectors irrespective of their size or production practices employed. A healthy food sector is a diverse food sector with all types of operations providing an abundant and safe food supply to American consumers.

5) Technical Staffing and Guidance Development at FDA

Stakeholder Engagement to Develop FSMA Compliance Policy Guidance: PMA wishes to express a strong desire to engage early, often and repeatedly with FDA on the development of applicable guidance documents for produce industry operations and provide an opportunity to explain and discuss current industry best practices and preventive controls to address identified "significant hazards." We also request that FDA consider routinely convening an expert group composed of industry, academia and government (State, Local, Territorial and Tribal) subject matter experts to draft and update model CPG'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.

6) New FDA Import Safety Systems

Verifying the Safety of Imported Food: FDA's new import safety systems must create a level regulatory playing field for both domestically and imported produce while providing for an equal level of public health protection. We have great expectations that preventive control assurances brought about by the new FDA import safety system will speed border crossings and facilitate international trade, while providing consumers with assurances that produce entering the United States has been safely grown, packed, processed and held under standards that are comparable to produce that has been domestically grown, packed, processed or held. We also have great expectations that the new FDA import safety system will provide for a more preventive approach to import produce safety and significantly reduce the frequency of produce testing at the border, which often causes severe and significant economic losses of perishable commodities. Recognizing the profound impact the new FDA import system will have on the produce industry, PMA offers its support to the FDA to assist with guidance development and educational outreach to the produce industry to assure implementation the new FDA import system.

7) Risk Analytics and Evaluation

Implementation of FSMA Rule and Improved Public Health Outcomes: PMA supports the finalization and implementation of FSMA regulations. However, it will be important for FDA and industry to work collaboratively to quantify how effective or ineffective particular preventive controls provisions made requisite by the FSMA regulations, perform at meeting the FSMA stated public health goal of reducing food adulteration and subsequent illnesses or deaths. It will not be sufficient for FDA to rely solely on the measurement of improved public health outcomes resulting from FSMA rule implementation. It will be critical to quantify how effective specific mandated preventive controls provisions are at reducing produce adulteration, recalls and foodborne illnesses. This approach will help determine if the regulatory standard for particular provision areas has been set "too high" or "too low."

8) FDA Infrastructure Improvements: PMA in general supports FDA's budget authority request for an additional \$7M for necessary infrastructure costs at the Agency.



Produce Marketing Association Comments

**“The Food and Drug Administration Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards”
(Docket No. FDA-2015-N-0797)**

Produce Marketing Association (PMA), on behalf of its members, respectively submits the following comments in response to the U.S. Food and Drug Administration’s (FDA) Federal Register Notice entitled, “The Food and Drug Administration Food Safety Modernization Act: Focus on Implementation Strategy for Prevention-Oriented Food Safety Standards, Public Meeting and Establishment of Docket” (Docket No. FDA-2015-N-0797) published on March 23, 2015. PMA is the largest trade association representing companies that market fresh fruits and vegetables. We represent 2,700 companies in 45 countries including members that handle more than 90 percent of fresh produce sold to consumers in the United States. Member companies are representative of the U.S. produce industry supply chain. They vary in size from small to large and their operations range from supermarket retailing, wholesaling, and distribution, to shipping and growing. PMA’s members of every size and at every level in the supply chain are committed to food safety and share the FDA’s focus on food safety.

PMA applauds the FDA for the tremendous effort made in developing a proposed FSMA implementation work plan. PMA supports the use of science-based standards in the produce industry. Recognizing the profound impact the final FSMA rules currently under development will have on the produce industry, PMA offers its support to the FDA, our membership, allied trade associations, USDA and state and local agencies on implementing the final rule and all of its provisions. PMA understands and supports the important role that FSMA implementation can play in reducing produce-associated foodborne illnesses and we remain committed to enhancing the safety of fresh produce.

PMA’s comments are provided below on select topic areas set forth in the FDA’s proposed FSMA implementation strategy.

- 1) Overarching Comments Regarding FDA’s Proposed FSMA Implementation Strategy
- 2) Inspection Modernization and Training
- 3) National Integrated Food Safety System
- 4) Education and Technical Assistance for Industry
- 5) Technical Staffing and Guidance Development at FDA
- 6) New Import Safety Systems
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1) Overarching Comments Re: FDA’s Proposed FSMA Implementation Work Plans

PMA applauds FDA’s forthright and transparent approach in communicating to stakeholders the agency’s proposed FSMA implementation work plans and its openness and call for stakeholder comments regarding the proposed work plans. FSMA has often been referred to as being “comprehensive change” but 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. Overall, PMA concurs with FDA’s approach to FSMA implementation; however, PMA respectfully requests that FDA consider the following issues and proposed solutions by PMA.

A. Roles & Responsibilities

The food industry is responsible for producing safe food and the FDA is responsible for: setting food safety standards, conducting inspections, ensuring that standards are met, and maintaining a strong enforcement program to deal with those who do not comply with standards (FoodSafety.Gov). As per FDA’s Operational Strategy for Implementing the FDA Food Safety Modernization Act issued in May 2014, *“FDA will play a central public health leadership role as a catalyst for innovation and action to improve food safety and as a primary source and repository of the science and expertise needed to understand and prevent food safety problems.”*

PMA Comment: PMA acknowledges that FDA will play an important role in public health leadership and that FDA is “a” source and repository of science and expertise needed to understand and prevent foodborne illnesses. However, it’s highly unlikely that FDA will be the “primary source and/or be a catalyst for innovation.” As the food industry has the primary role of assuring the safety of products they produce, it is most likely that industry will likely play a leading role in innovation. It is also unlikely that FDA will be the primary repository of technical knowledge regarding produce safety as this collective knowledge is dispersed among industry food safety practitioners, academia and government subject matter experts. While the FDA public health statement may be aspirational in nature it is recommended that FDA consider acknowledging the varied knowledge and experiences among stakeholder groups and facilitate collaborative and collegial engagement on food safety policy and verification activities.

B. FSMA Implementation Funding:

The Administration has proposed in the FY 2016 Federal budget, an increase of \$109.5M in budget authority and \$191.8M in user fees for FSMA implementation.

Specifically, the increase of \$109.5M in budgetary authority would be used for:

- Inspection Modernization and Training - \$25 million
- National Integrated Food Safety System - \$32 million
- Education and Technical Assistance for Industry - \$11.5 million
- Technical Staffing and Guidance Development at FDA - \$4 million
- New Import Safety Systems - \$25.5 million
- Risk Analytics and Evaluation - \$4.5 million
- FDA Infrastructure Improvements - \$7 million

Specifically, the increase of \$191.8 in user fees would be used for:

- Food Imports,
- Food Facility Registration,
- Food Facility Inspection,
- Food Contact Substance Notifications, and
- International Couriers.

PMA Comment: FDA Budgetary Authority

PMA supports increased funding for the U.S. Food and Drug Administration's (FDA) food safety budget in the Fiscal Year 2016 Agriculture/FDA Appropriations legislation. The overarching goal of FSMA is to modernize and enhance food safety practices across the supply chain, bolster consumer confidence and eliminate unnecessary risks to public health. To accomplish these goals FSMA encompasses transformational reform of our nation's food safety laws and how FDA operates.

FDA's operational focus on prevention and expanded authority as granted by Congress necessitates that FDA be provided with the resources for food safety tools, infrastructure and personnel, to appropriately implement FSMA as it was envisioned by Congress. This year, the FDA will begin to finalize and implement the new rules, regulations and guidance documents necessary to clearly define industry compliance under FSMA. We look forward to working with the agency, as they finalize the rules, and with Congress to ensure that FDA's final rules target risk and follow congressional intent, and that they have the resources necessary to implement them.

Produce safety is a high priority for the industry and PMA member companies work hard at implementing produce safety best practices on a daily basis, because maintaining consumer confidence in the produce supply is absolutely critical. As such

our commitment to produce safety is steadfast and we strongly support FDA regarding implementation of FSMA including but not limited to appropriation of an additional \$109.5 million in new budget authority. We also welcome congressional oversight; not only to ensure these investments are implemented effectively, but also to make certain that the agency's regulatory implementation of FSMA is consistent with what the law requires, and what Congress intended in adopting the law.

PMA Comment: FDA User Fees

PMA understands that FDA needs sufficient budgetary resources for food safety tools, infrastructure and personnel, to appropriately implement FSMA. However, PMA believes that these financial resources should be derived from the Federal budget as the implementation of FSMA benefits the health and wellbeing of all American consumers, and the cost of FSMA implementation should not unfairly and disproportionately fall on the food industry sector. Additionally, PMA would also be opposed to the imposition of user fees or registration by State governments to fund FSMA implementation.

2) Inspection Modernization and Training

A. Technical Assistance & Regulatory Inspections

As per FDA's proposed FSMA Implementation Plan FDA will be:

- *“Fostering an on-site dialogue during inspections when areas of noncompliance are identified, seeking timely and adequate corrective actions to achieve industry compliance, and following up with timely re-inspection to verify that compliance has been achieved. When compliance is not achieved in a timely and adequate manner using this approach, FDA will deploy its enforcement tools to protect public health.”*
- *“Staffing the FDA Food Safety Technical Assistance Network that would be the cornerstone for outreach and real-time technical assistance to industry and regulators by hiring seven managerial and administrative staff.”*

PMA Comment: PMA applauds FDA's inspectional approach of fostering dialog during inspections regarding matters of non-compliance and deployment of a technical assistance network to provide real-time technical assistance to industry and compliance officers. However, FDA is proposing to play a dual role of education outreach via technical assistance and the role of assuring compliance verification through inspections. While these goals are laudable this duality is likely to place FDA in “conflict-of-interest” as they would be providing technical solutions to non-compliant procedures, processes and practices during an verification inspection. This duality is a problematic “conflict-of-interest” with the FDA inspector determining not only if a procedure, policy and practice is or is not in compliance but the inspector also playing the role of a technical consultant with regulatory authority to demand that their

recommendation be followed. FDA should consider how the agency will clearly provide industry with a portfolio of solutions and separate this technical assistance from the FDA's verification role via inspections. Food industry management must be tasked with and given discretion to determine what preventive controls, procedures, policies and practices are best suited and most effective for their specific operations and unique circumstances.

B. Adjudication of Compliance Status

It is reasonably foreseeable that there will be differences in professional opinion among the regulated firm and federal or state regulatory agency during an inspection regarding the compliance or non-compliant status of particular procedures, policies or practices implemented by the regulated firm.

PMA Comment: PMA respectfully requests that FDA consider development of administrative procedures to quickly and justly adjudicate differences in professional opinion between a regulated firm and federal or state regulatory agency personnel regarding the firm's compliance status. The administrative procedures should be permitted to be initiated by the firm and differences of opinion resolved by the FDA in a timely manner. PMA requests that FDA give consideration to development of a mechanism for industry stakeholders to outreach and immediately elevate issues to FDA subject matter experts when a difference of professional opinion occurs between the regulated firm and the FDA inspector. Additionally, PMA also requests that FDA consider development of a formal appeals process to address observations and inspectional conclusions which the regulated firm believes to be in error. Both the above suggested elevation and appeal processes would provide FDA with opportunity to have more consistent decision making by FDA field inspectors as well as provide the opportunity to identify compliance issues that warrant further clarification in communications to both the regulated industry as well as FDA and State inspectors.

Additionally, FDA should also consider as a model the USDA FSIS appeals process set forth in 9 CFR 306.5 and 9 CFR 381.35, which provide USDA FSIS regulated facilities with an opportunity to appeal any inspection decision. This USDA FSIS appeal process allows USDA FSIS regulated facilities to appeal the whole decision or part of the decision made by USDA FSIS inspectors without fear of retaliation. FDA food facilities or farms covered by the new FSMA regulations should also be provided with a similar due process and be encouraged appeal decisions they believe are unfair or are not consistent with applicable standards.

C. Harmonization of Produce Safety Market Access Audits & the FDA FSMA Produce Rule

Numerous types of market access food safety audits are used by buyers to qualify produce growers as suppliers; as these GAP audits assure on-farm food safety



awareness by growers and verify implementation of GAPs. It is anticipated that independent third party auditors, USDA AMS and States will play an important role verifying FSMA produce rule compliance on farms. Growers are, however, currently suffering from “audit fatigue,” in that, buyers often have different market access audit requirements hence growers face numerous market access GAP audits. When the FSMA produce safety rule is implemented, FSMA inspections by the FDA and States may actually accentuate this “audit/inspection fatigue” problem; as a FSMA produce rule inspection is in addition to required market access audits.

PMA Comment: PMA acknowledges that produce buyers will play a key and important role in promoting FSMA implementation. PMA applauds that USDA AMS and FDA are already working together to harmonize the FDA FSMA standards and the USDA GAP audit standards. PMA fully support USDA AMS and FDA working collaboratively to assure that USDA AMS market access audits and FSMA Produce Rule compliance inspections be performed in a harmonized and comparable manner to reduce industry audit fatigue. PMA encourages FDA to work with all standard holders, accreditation bodies and certification bodies engaged in produce safety market access audits to harmonize independent third party produce safety market access audit requirements with FDA FSMA standards. Additionally, adoption of FDA FSMA standards in produce safety market access audits will provide a means for farms that may be exempt from the FSMA produce rule to demonstrate compliance to potential buyers.

Specifically PMA respectfully requests that FDA consider the following:

- **Harmonization:** FDA should work to assure that produce safety verification activities (i.e. Market Access audits and FDA FSMA Inspections) be done in a harmonized manner (i.e. one activity), using the FDA FSMA produce rule for the inspectional standard and if required by buyers a more robust standard (e.g. CA LGMA).
- **Comparability:** FDA should work to assure that produce safety market access audits and activities will be recognized by FDA so as to reduce redundant inspections by FDA or States that are verifying compliance with the FSMA produce rule. This means that if a credible and proficient third party market access audit was performed, it would make it less likely that FDA or a State agency would follow-up with a grower FSMA produce rule inspection.

D. Non-Regulatory FSMA Compliance Assessments

PMA Comments: PMA supports the concept of FDA and State agencies providing non-regulatory FSMA compliance assessments in advance of final FSMA compliance dates. Such non-regulatory assessments in advance of rule compliance dates would serve as valuable learning experience for both industry participants and regulatory

inspectors. However, these training exercises must be voluntary, done in-person, onsite and not be a remote recordkeeping review.

3) National Integrated Food Safety System

A. Role of States in FSMA Implementation

Currently fewer than 25 state departments of agriculture have some type of on-farm produce safety authority and it is unclear if the remainder of state agency's do or do not wish to pursue obtaining state statutory authority and this decision will likely be based on available funding and their negotiated working relationship with FDA.

PMA Comments: Produce farms to date have not been pervasively regulated regarding produce safety practices and procedures. PMA respectfully requests that FDA provide sufficient time and resources to train growers so they can comply with final rules, as well as training FDA and state regulatory officials regarding agricultural practices and the various means by which growers may comply with this new set of food safety regulations.

PMA supports the role of state governments as the entity that would assist with education outreach to produce growers and perform routine FSMA produce rule compliance inspections, because state governments are best positioned to have in-depth working knowledge about produce growers' procedures, policies and practices in their state. In short it is more practical and effective to train agricultural professionals about produce safety than to attempt to train food safety professional about everything there is to know about agricultural production practices and culture. Additionally, State Departments of Agriculture are best suited to identify farms which are covered by the produce safety rule and would be subject to compliance inspections.

The use of on-farm routine inspections by State Department of Agriculture officials for compliance to the FSMA produce safety standards is also similar in approach to the California and Arizona Leafy Green Marketing Agreements which have been found to be very effective at promoting the implementation of farm food safety best practices. Additionally, state or federal marketing agreements and marketing orders, which are comparable or exceed the requirements of the FSMA produce rule requirements, should also be recognized by the FDA for their comparability. For example, the California and Arizona Leafy Greens Marketing Agreements are operated under the auspices and authority of their respective state governments, hence should be recognized as providing sufficient compliance oversight to the FSMA produce rule.

4) Education and Technical Assistance for Industry

A. Inadequate Funding for Education and Technical Assistance to Industry

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.

PMA Comments: Appropriate level Federal funding for education outreach and implementation of the final FSMA rules is a must. It is suggested that education outreach and implementation funding for the produce safety rule be formula funded with each state getting baseline funding plus additional funds based on the covered produce acreage in each state. 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. PMA believes that greater federal government resources need to be authorized and appropriated for FSMA education and technical assistance to industry. Recognizing the profound impact the new FDA FSMA rules will have on the produce industry, PMA offers its support to the FDA to assist with education and technical assistance to the produce industry to assure implementation of the new FDA FSMA rules. PMA understands the importance of the new FDA FSMA rules in preventing produce associated foodborne illnesses and is committed to improving the safety of fresh produce whether it is produced domestically or internationally.

B. Land Grant University Cooperative Extension Programs are Woefully Underfunded & Under-resourced for FSMA Implementation

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.

PMA Comment: PMA respectfully requests and would support FDA seeking increased Federal Budget funding for industry FSMA education outreach and training in future administration budget proposals for FY 2017 and beyond. It is imperative that sufficient resources be allocated to educate industry before FDA regulates.

C. All Industry Sectors Need Assistance with FSMA Compliance

As per FDA’s proposed FSMA implementation work plan, FDA will be “partnering with USDA’s National Institute of Food and Agriculture (NIFA) to administer the FSMA-mandated NIFA grant program to provide technical assistance for FSMA compliance to small, sustainable, and organic farmers and processors.”

PMA Comment: PMA’s vision is to strengthen and lead the global produce community to increase produce consumption. Fruits and vegetables are an integral part of a nutritious and healthful diet, offering great public health benefits. PMA believes that produce safety, taste, convenience, and nutrition are the cornerstones of increasing fruit and vegetable consumption and fighting obesity. As such, PMA enthusiastically supports all types of produce production practices (e.g. organic, conventional) irrespective of enterprise size (small business to large business). It would be short-sighted for FDA to limit or focus education outreach and technical assistance to any one business sector or enterprise size, and as such PMA respectfully requests that the FDA consider and implement education and training for all produce business sectors irrespective of enterprise size or the production practices that they employ. A healthy food sector is a diverse food sector with all types of operations providing an abundant and safe food supply to American consumers. PMA wishes to express a strong desire to engage early, often and repeatedly with FDA on the development and delivery of education outreach and training for produce industry operations, as we believe that leading industry trade organizations will play an important and integral role in providing technical assistance and training to our members.

5) Technical Staffing and Guidance Development at FDA

A. Stakeholder Engagement To Develop FSMA Compliance Policy Guidance

PMA Comment: PMA wishes to express a strong desire to engage early, often and repeatedly with FDA on the development of applicable guidance documents for produce industry operations and provide an opportunity to explain and discuss current industry best practices and preventive controls to address identified “significant hazards.” FDA guidance regarding preventive control validation should be a high priority for the agency and issued as soon as possible in conjunction with the final FSMA regulations. We also encourage FDA not to 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 Policy Guidance (CPG) documents, it is respectfully requested that 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 CPG'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.

Academic subject matter experts would provide access to the best available science to assure that risk-based and science-based decisions can be made regarding compliance. Industry subject matter experts would provide key perspectives regarding current industry preventive controls practices, procedures and policy's as well as what is practicable and economical to implement. State, local, territorial and tribal government officials may provide key perspectives on the unique procedures, processes and practices encountered in their locales.

Development of a model CPG for FSMA rules and specifically for the FSMA Produce Safety Rule would be very beneficial in that the process would be:

- **Deliberative:** It would provide a mechanism to discuss, deliberate, determine and recommend what is and is not appropriate compliance to FSMA produce safety rule implementing regulation provisions that are situation specific. It is likely that FDA and State inspectors will encounter unanticipated or novel procedures, processes and practices when performing routine inspections. This is due to the fact that agricultural procedures, processes or practices are constantly evolving and changing over time, as are the technologies and preventive controls employed by industry to address known hazards.
- **Consensus:** The recommended process would provide a means to develop consensus among government (Federal, State, Local and Tribal), industry and academia regarding what is and is not appropriate compliance to FSMA produce safety rule implementing regulation provisions that are situation specific. Since the FDA FSMA CPG's will likely be Level 1 guidance requiring public comment, input by stakeholders during the development of the produce rule CPG would be very beneficial to the FDA in building consensus among stakeholders.
- **Education:** Technical assistance in the form of education outreach to industry stakeholders is critical for compliance to the new FSMA implementing regulations. The implementing regulations provide only broad provision

requirements and offer few details regarding specific situations or scenarios. This would provide a means for FDA to educate the industry to harmonized and agreed upon provision requirements for all likely scenarios that are will ultimately be encountered by stakeholders during verification activities by State or FDA inspectors.

FDA Model Food Code as a Model

The model proposed above is not new. It is in fact used by the Conference for Food Protection (CFP) to develop and draft recommended changes to the FDA Model Food Code, which is a guidance document whose purpose is to harmonize food safety practices and policy among the numerous State, County and Local jurisdictions, which have authority and responsibility for verifying by inspection State, County and Local regulations regarding food service and retail establishments. Ultimately, FDA still maintains editorial authority over the FDA Model Food Code but academic, industry and government (State, County, Local, Territorial and Tribal) subject matter experts are provided a means to share stakeholder perspectives and input on the FDA Model Food Code. Changes suggested to the FDA Model Food Code are first vetted and voted on by a committee composed of academics, industry and government (State, County, Local, Territorial and Tribal) subject matter experts with FDA present and participating in the discussion but FDA does not have voting privileges. Any committee approved changes to the FDA Model Food Code are then approved or not approved as a recommendation by a plenary session of all States participating in the Conference for Food Protection scheme. It is recommended that a similar scheme be considered for development of the FDA CPG for the Produce Safety Rule for the reasons outlined above with an outside convening authority. This proposal for development and updating of FDA compliance policy guidance provides for an open transparent process for development of FDA CPG's as well as public vetting.

6) New FDA Import Safety Systems

A. Verifying the Safety of Imported Foods

As noted in FDA's proposed FSMA implementation work plan, FDA, currently on an annual basis, must address the safety of 12M line-entries to 88k consignees whom are receiving imported food shipments and this volume of food products is growing each year.

PMA Comment: FDA's new import safety systems must create a level regulatory playing field for both domestically and imported produce while providing an equal level of public health protection. As 50% of fresh fruits and 20% of fresh vegetables consumed in the United States are imported, the development and deployment of a new FDA import system is critically important to the fresh produce industry. Additionally the new FDA import safety system must allow FDA the opportunity to shift from relying

heavily on import surveillance and product testing at the port of entry, to a preventive approach of assuring the safety of imported produce. We have great expectations that preventive control assurances brought about by the new FDA import safety system will speed border crossings, reduce border crossing bottlenecks and facilitate international trade, while providing consumers with assurances that produce entering the United States has been safely grown, packed, processed and held under standards that are comparable to produce that has been domestically grown, packed, processed or held. We have great expectations that the new FDA import safety system will provide for a more preventive approach to import produce safety and significantly reduce the frequency of produce testing at the border, which often causes severe and significant economic losses of perishable commodities.

Recognizing the profound impact the new FDA import system will have on the produce industry, PMA offers its support to the FDA, to assist with guidance development and educational outreach to the produce industry to assure implementation the new FDA import system. PMA understands the importance of the new FDA import system in preventing produce associated foodborne illnesses and is committed to improving the safety of fresh produce whether it is produced domestically or internationally.

7) Risk Analytics and Evaluation

A. Implementation of FSMA Rule and Improved Public Health Outcomes

PMA Comment: Produce Rule Implementation

PMA supports the finalization and implementation of FSMA regulations; however, PMA members have very serious concerns regarding many of the proposed provisions that were set forth in the supplemental proposed produce safety rule and preventive controls rule for human food. Many of the proposed provisions will adversely affect how produce businesses operate, and the proposed provisions simply do not reflect the realities of produce production, handling and storage. It is critically important that FDA get the final produce safety and preventive controls rules right to truly enhance the safety of produce available to the consumer while not adversely affecting how produce businesses operate.

As the FSMA produce rule is implemented it will be important for FDA and industry to work collaboratively to quantify how effective or ineffective particular preventive controls provisions made requisite by the FSMA regulations, perform at meeting the FSMA stated public health goal of reducing food adulteration and subsequent illnesses or deaths. It will not be sufficient for FDA to rely solely on the measurement of improved public health outcomes resulting from FSMA rule implementation. It will be critical to quantify how effective specific mandated preventive controls provisions are at reducing produce adulteration, recalls and foodborne illnesses. This approach will help determine if the regulatory standard for particular provision areas has been set “too

high” or “too low.” If FDA does not take this hybrid approach of broad requirements in the implementing regulation coupled with situation-specific guidance, FDA risks imposing standards on the produce industry that do not enhance produce safety in specific provision areas or saddling the industry with burdensome provisions that may only marginally enhance produce safety. FDA, in the agency’s implementation framework, has stated that the agency will in the future act both as a public health agency and a regulatory agency. To act as public health agency, FDA must measure the efficacy of each provision area and have the ability to adjust produce provision areas so that improved public health outcomes can be achieved cost effectively. Without sufficient measurement of provision area efficacy to improve public health and the flexibility to adjust regulatory provisions on a regular basis, FSMA will likely not attain its goal of enhancing public health.

8) **FDA Infrastructure Improvements**

The \$109.5 million increase in the food safety budget for FDA includes \$7 million for necessary infrastructure costs.

PMA Comment: PMA in general supports FDA’s budget authority request for an additional \$7M for necessary infrastructure costs at the Agency.

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