



NASDA Model Produce Safety Implementation Framework

**Working Document for Review and Discussion Purposes
Subject to Revision as Needed**

**Prepared by:
NASDA FSMA Technical Working Group
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Although the contents of the chapters of this framework have been discussed with FDA through a cooperative agreement between FDA and NASDA (Grant #: 5U01FD005334), we stress that this document is written from a state's perspective, with the goal of providing guidance and basic information to any state contemplating development of a produce safety regulatory program. We are thankful for the contributions of FDA staff and their significant interaction with state food safety professionals during the development of this framework. The federal/state dialog definitely improved the overall quality of our efforts.

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NASDA Model Produce Safety Implementation Framework

Introduction

The National Association of State Departments of Agriculture (NASDA) Model Produce Safety Implementation Framework (PSIF) contains the fundamental and essential components for the operation of a state produce safety program that can fully implement the FDA Produce Safety Rule (“The Rule”), published as a final rule in November 2015.

The Food Safety Modernization Act of 2011 (FSMA) required the United States Food and Drug Administration (FDA) to establish and publish a science-based, preventive rule to provide minimum standards for the safe production and harvesting of produce by domestic and foreign farms. The Rule, as well as this framework, establishes preventive actions to protect public health and is outcome-driven in nature. It is the goal of this NASDA Model PSIF to provide the foundational knowledge and support to any state considering implementation of a FSMA-aligned produce safety program.

The PSIF includes basic chapters discussing each key area required for a state to successfully implement a FSMA-aligned produce safety program including:

Chapter 1	Alignment and Consistency
Chapter 2	Foundation of Law
Chapter 3	Financial Support
Chapter 4	Outreach/Education and Compliance/Enforcement
Chapter 5	Work Planning
Chapter 6	Information Sharing
Chapter 7	Regulator Training
Chapter 8	Accessing Laboratory Resources
Chapter 9	Technical Assistance
Chapter 10	Dispute Resolution
Chapter 11	Infrastructure

Twenty-four state Departments of Agriculture and five national organizations (NASDA, the Association of Food and Drug Officials, the Association of State and Territorial Health Officials, the International Food Protection Training Institute, and the American Association of Feed Control Officials) were actively involved in the development of the PSIF in an extensive collaborative and consensus building effort through a Technical Working Group (TWG). A few states already have preventive authority for the food safety of produce; therefore, NASDA tapped state expertise in other program areas in the development of this framework. Many states, particularly those where the State Department of Agriculture has a current food safety program for manufactured foods, chose to participate in the effort by authoring specific sections or chapters. A majority of the states represented on the TWG have a feed control program; staff from many of these states volunteered to be involved in this effort. All states were involved and briefed through NASDA regarding the development of this model framework.

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The TWG authored these fundamental chapters to allow any state Department of Agriculture, Health, or other agency to have available to them a full discussion of the basic components needed for implementation of the Rule. The PSIF is written from the perspective of states taking the role as the major on-farm implementation arm for the Rule and is written for the guidance of state regulatory programs.

Although each chapter in the PSIF has been reviewed with FDA through a cooperative agreement between, FDA and NASDA (*Grant #: 5U01FD005334*), we stress that this document is written from a 50-state perspective, with the goal of providing guidance and basic information to any state contemplating development of a produce safety regulatory program. Some states may already have within their programs many of the components discussed.

Other states may need to seek fundamental changes in their programs or may choose to implement only one or some activities under the Rule (education, training, outreach, inspection, etc.). The decision on the scope of implementation completed by the state will be at the state level; however, the chapters, herein, will provide the essential core components needed for a complete program. For the purposes of these chapters, the term ‘state’ includes any state, local, or territorial agency.

The FDA’s [Operational Strategy for Implementing the FDA Food Safety Modernization Act](http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm395677.htm) (<http://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm395677.htm>) spells out some of FDA’s thinking about implementation of FSMA – from a federal perspective. While the FDA has been involved with the review of this model implementation framework, this should be viewed as a NASDA document – offering advice to the states (i.e., it is not an FDA document *per se*). We appreciate the advice, counsel and recommendations from our FDA colleagues as they measurably improved the model framework chapters.

In addition to further interactions between FDA and NASDA, discussions between State Departments of Agriculture, Public Health and other agencies regarding the PSIF have already begun. We have scheduled a meeting of state Agriculture and “Health” officials for March 2016¹, in which the FDA is invited to participate. Personnel from 81 state agencies were also invited to participate in this meeting, including all 50 State Departments of Agriculture and 31 Public Health or other agencies with food safety authority for manufactured foods. As appropriate, considering the continued need for interagency dialogue, this document is a living document, destined to be improved over time.

The interactions between NASDA, the states and FDA are facilitated by using Subgroups and Workgroups of interested staff on topical areas needing attention. A NASDA-FDA Implementation Group, which meets quarterly, serves as a clearinghouse for work products. FDA Leadership and NASDA’s Steering Committee on Food Safety serve to resolve issues where the IG hasn’t found consensus. Following is a list of our Active and Planned Subgroups (with Workgroups under some of the more complex Subgroups) for 2017 and beyond:

¹ This meeting preceded the establishment of the National Consortium for Produce Safety in 2017.

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1. On-Farm Readiness Review Subgroup
2. Regulator Training Subgroup
3. Dispute Resolution Subgroup
4. Foundation of Law Subgroup
5. National Consortium Meeting Planning Subgroup
6. State Strategic Plan Development Subgroup
7. Farm Inventory Core Subgroup
 - a. Farm Inventory Workgroup - Mobile Application Development
 - b. Farm Priority Workgroup
 - c. Aggregate Data Workgroup
8. Inspectional Approach Core Subgroup
 - a. Inspectional Approach Workgroup - Defining FDA / State Roles
 - b. Inspectional Approach Workgroup - Developing an Inspection Protocol
 - c. Inspectional Approach Workgroup - Defining Enforcement Actions
9. Recall Plans for Produce Safety
10. MOU Development

Update: February 2019. Since 2017, NASDA has organized, hosted and managed a National Consortium for Produce Safety each year, as a deliverable under the cooperative agreement NASDA has with FDA. This year's event is scheduled in Florida on March 6 – 8, 2019. The focus will be primarily on the inspection process – and accomplishing initial inspections of large produce farms that are covered by the Produce Safety Rule (PSR). In addition, NASDA is focused on the need for states to have a compliance and enforcement function (separate from the inspection process or at least an extension – a continuation – from inspection to compliance to enforcement). Given the goal of “prevention” that FSMA established the need for assuring the food is safe independent of enforcement functions is important – we stress the need to “educate before – and while – we regulate” – to seek compliance; enforcement can be a function intertwined with but often separate from compliance.

As NASDA developed this framework, we noted that it is – and will remain – a living document. It will need revision from time to time, or more likely, as time goes by, will result in additional documents consistent with this framework. We have circulated previous drafts of this framework to various stakeholders in the produce/food safety/public health arenas and have made changes to address substantive comments to improve and/or more clearly state our thoughts. We will continue to do so. The framework, however, will likely not be the only document that further explains possible means of achieving programmatic objectives needed to standup and/or administer a state food safety program consistent with FSMA. several additional appendices have been added to the document. They are available for state staff from NASDA. They are considered appendices to the Framework and include:

During the past year, NASDA and FDA have collaboratively worked together to develop a variety of inspectional documents. These documents are designed to ensure consistency and uniformity as we transition to conducting inspections in 2019 and include:

- The documents shared with states in September 2018:
 - o Standardized Approach to Produce Farm Inspector

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- o What to Expect During an Inspection
- o FDA 4056 Produce Farm Inspection Observations Form (and/or state equivalent)
- o Compliance and Enforcement Action Template
- o Compliance & Enforcement Decision Tree (new version being developed)
- o Dispute Mitigation & Resolution Procedures
- New documents added since September
 - o Produce Farm Inspection Report Summary
 - o Instruction for the 4056 Form

The mutual state and federal goal for the FSMA produce safety program is to provide public health protection through a preventive, science-based partnership and integrated regulatory program. It is the goal of this PSIF to provide the foundational knowledge and support to any state considering implementation of such a FSMA-aligned produce safety program. For those states that choose to participate with FDA in the implementation of FSMA, the framework document is intended as a roadmap to follow as they develop their state programs. It is primarily intended to help assure uniformity and consistency between state programs. States that choose to get involved will still have to develop their own programs, consistent with long-standing state procedures; the framework is intended to be sufficiently flexible to allow for these differences. The framework is not intended to tell states how to do their programs nor as anything that will affect due process (administrative procedures) requirements at the state level.

Without the commitment from the NASDA members and the voluntary involvement of the state staff members, this document would not have come to fruition. Many thanks to the NASDA members for their willingness to allow NASDA to use their staff members as technical experts on this project. Equally, many thanks to the individual contributors, who assisted us as writers, commenters and reviewers. Your knowledge and passions have made this effort more rewarding. Thank you also to the FDA staff for their contributions. The dialog definitely improved the overall quality of our efforts.

NOTES: see page 132. NASDA has received some additional comments from stakeholders regarding the Framework. Many requests found in many of the comments have been added to the framework and some additional conversation is captured in the Notes section at the end of this document.

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Chapter 1: Alignment and Consistency

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1.Executive Summary

To ensure uniform and consistent application of the Produce Safety Rule (PSR), implementing programs must be in alignment with the rule. Because so many different programs will be involved in implementing the rule, implementing programs will not all look alike or do things the same way. **However, outcomes are more significant than methods, and even though programs differ, if each one is in alignment with the PSR, it will create the consistency needed to implement the PSR successfully.**

States, local governments, and territories (all hereinafter referred to as “states”) may adopt different portions and seek different authorities because of differences in public policies, political landscapes, agricultural conditions and available resources. Each state will need to work through its own system. For the PSR to be successful, states will need options and flexibility when approaching implementation. This is particularly important for states with few or limited resources.

Preventing foodborne illness through the PSR will require work in five core areas. Programs will need basic competencies to successfully carry out the work, and through self-assessment they can identify areas where they need to act to ensure alignment with the PSR. By focusing on work areas, alignment and consistency are approached through function and can be evaluated through outcomes.

Core Work Area	Desired Outcome
1. Education, outreach, training and assistance.	An educated regulated community that pro-actively participates, complies, and adopts the rule, fully incorporating its principles in efforts to improve food safety and protect public health. Also, an educated produce safety staff and a regulatory system that promotes compliance through education and corrective action.
2. Application, identification, categorization and risk profiling of industry.	Sufficient knowledge about the regulated community to support uniform, consistent and effective implementation actions (See Work Areas 1 & 3).
3. Application of regulatory scheme.	State-wide consistency in both encouraging and requiring compliance (enforcement), resulting in the prevention of foodborne illness.
4. Evaluation of success.	A clear picture of how effective the program is, as well as its strengths, weaknesses, opportunities and threats.
5. Implementation of improvements.	The ability of the program to demonstrate continuous improvement in the effectiveness of implementing the PSR.

2.Purpose

While other chapters of this Operational Framework address individual elements, a program will need to implement the FSMA Produce Safety Rule (PSR), this chapter incorporates those elements into an overall foundation for effectively implementing the PSR and for ensuring it is uniformly and consistently applied.

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Under some circumstances, such a foundation may be created by adopting program standards. For example, the Manufactured Foods Regulatory Program Standards (MFRPS) provide a basis for quality assurance and consistency in participating programs. However, implementation of the PSR does not lend itself well to the same approach. The PSR itself is brand new; the implementing programs are in their infancy; and states, local governments, and territories (states) do not yet have policies from which to write standards. Further, when production crosses state lines and only one of those states has adopted the standard, consistency is not supported. It should be noted, however, that in the future, conditions and experience with the rule may make the development of program standards a viable option for creating a consistent approach to the PSR.

Programs implementing the PSR can be expected to vary due to the different agricultural and political conditions that exist from state to state. Programs need to reflect their consumers, stakeholders and general public, as well as protect public health. Each state will need to work through its own system. For the PSR to be successful, states will need options and flexibility when approaching implementation, including mechanisms to handle the volume of requests. Flexibility and options are particularly important for fostering innovation and for states with few or limited resources. Also, depending on various factors and internal conditions, different states may have different priorities with respect to education/outreach vs. compliance and enforcement of the new regulations, and how they carry out different elements of the PSR can be expected to differ as well.

However, alignment with the intent and requirements of the PSR is essential for uniform and consistent application of the rule for state programs to successfully prevent foodborne illness from occurring nationwide. FDA needs to know the rule is being followed and is being applied appropriately and uniformly. The produce industry needs to know what to expect and that it is being treated fairly, especially from state to state. States need to know they are focusing their resources and attention appropriately and effectively.

This chapter takes the approach that outcomes are more significant than methods, and that even though state programs differ, if each one is in alignment with the PSR, it will create the consistency needed to implement the PSR successfully.

The overall goal is compliance with the PSR. By focusing on alignment with the PSR, rather than on conformance to a set of program standards, states can give priority to function rather than to form. Public health can be accomplished through multiple approaches—e.g., education, outreach, training, technical assistance, inspection and enforcement. The outcome is what matters, so there can be flexibility in how to achieve it. This idea is acknowledged within the PSR itself by the allowance for alternatives and variances. If the PSR is to be applied uniformly and consistently, alignment with the PSR needs to be assured—among states, within a state, and even among the parts of the implementation process. Elements, structures, processes and practices all must align with the rule.

Addressing how to achieve alignment and thus create consistency is particularly important because the PSR regulates a sector that previously has not been subject to food safety regulations, and likewise, States have not had this regulatory responsibility before. States cannot simply build or expand their programs based on a previous system, because most states do not have a system for on-farm inspections. The rule itself is new and not yet tested.

The need for consistent alignment with the PSR is reflected in the need for ongoing education, outreach and training as part of a long-term strategy and commitment for making the rule effective. The bottom line: Know the rule, know how to apply the rule, and know the public health significance.

Programmatic alignment with the PSR supports the goal of compliance with the PSR, and the PSR supports a goal that the FDA and the state's share: preventing foodborne illness. This shared focus is at the core of the model processes and practices outlined in the rest of the chapter. What follows is an outcome-driven approach with public health as the ultimate goal. Focus will be on the ability to support market access for producers, the individuality and regional distinctiveness needed for marketing, and the flexibility needed for state programs to be innovative in their successful implementation of the PSR.

3.Scope

The processes and practices identified in the next section serve as a model framework for creating consistency through programmatic alignment with the PSR.

Because each state, local government, and territory (state) is different, the model takes a broad, flexible approach. Much of the model calls for self-assessment, identifying questions programs should ask themselves. The answers are not intended to verify adherence to a specific program standard; instead they are intended to point to areas where a program needs to act to ensure alignment with the PSR. And because consistency of outcomes is the intention, the model is based on the work that creates those outcomes.

The model's concept: Focusing on outcomes, use the International Standards Organization (ISO) eight guiding principles of quality management (see box,) to shape a program around **five core work areas** needed to implement the PSR:

1. Education, outreach, training and assistance.
2. Application, identification, categorization and risk profiling of industry.
3. Application of regulatory scheme.
4. Evaluation of success.
5. Implementation of improvements.

Program participation and how the ISO quality principles are applied will clearly vary from state to state, but the five core work areas apply to almost any level of implementation. For example, a program wishing to take on only education and outreach activities (Work Area 1) would still need to understand the local produce industry (Work Area 2), evaluate success (Work Area 4), and make improvements as needed (Work Area 5). And even though it would not be fulfilling the regulatory functions such as inspections (Work Area 3), the program's activities would still need to be in alignment with them.

By focusing on core work areas, alignment and consistency are approached through function and can be evaluated through outcomes.

On the following pages, the model structure for each core work area includes:

- Brief introduction – general description of the work area and why it is important.
- Desired outcome – what the work is intended to achieve.
- Related chapters – where to look in the operational framework for more information

ISO Quality Management Principles

1. Customer focus
2. Leadership
3. Involvement of people
4. Process approach
5. System approach to management
6. Continual improvement
7. Factual approach to decision making
8. Mutually beneficial supplier relationships

NOTE: Customers and suppliers vary, depending on the situation. A customer in one situation may be a supplier in another. They may be farmers, produce packers, laboratories, FDA or other agencies.

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- General attributes and functions – things an effective program will need to be able to do and examples of typical work
- Specific considerations—for alignment and consistency, with possible measures for some work areas.

4. Model Framework

Each of the five Work Areas of the Model Framework plays a key role for implementing the Produce Safety Rule (PSR) and preventing foodborne illness through compliance.

The desired outcomes, general attributes and functions, and specific considerations provided for each Work Area reveal the nature of the work to be done and what it is intended to accomplish, even what some of the work might look like. Still, the specifics of *how* the work is addressed is left up to the individual programs. Self-assessment questions are meant to point to areas where a program needs to act to ensure alignment with the PSR and the desired outcome.

When answering the self-assessment questions in the model framework, a program needs to consider the context of its work.

Context is particularly important because the PSR is intended to be part of an Integrated Food Safety System (IFSS). FDA and other state partners play key roles and need to be considered. Over time, roles may change. For example, it is expected that some state programs will start with a focus on just one work area, or perhaps with just one type of crop (e.g., tree fruit) or one region within their state. Over time, they may (or may not) expand their responsibilities.

Because the PSR is a federal rule, implementation work not undertaken by a state program will have to be done by FDA. This makes coordination and collaboration between FDA and each state program essential to success.

State programs should be able to answer the following questions regarding Work Areas 1, 2 and 3:

- What is your level of program participation? What functions are you taking on? How fully? Who is doing what you are not? How does what you are doing connect to what they are doing?
- How does the state let FDA know which duties it (the state) is willing to fulfill? And by when?
- What other information needs to be shared between the program and FDA (e.g., from inspectors to educators, and vice versa)?
- How do the state and FDA ensure they are not duplicating efforts? Or overlooking key functions? How do they close the loop?
- Do state program actions align with FDA guidance?

And because each work area is part of a larger program and each state is part of a larger region:

- Where and what kind of overlap or commonality is there among functions – e.g., need to communicate, assess resources, etc.
- Are there regional issues, efforts, solutions, agreements, variances, alliances, etc.?

It is also important to remember that although there are five separate areas of work, the areas are connected and are intended to support each other, as well as the overall goal of compliance with the PSR and prevention of foodborne illness.

Work Area 1. Education, outreach, training and assistance

This work area is HIGH PRIORITY. To follow the Produce Safety Rule, farmers and produce packers need to understand what is expected of them. Those enforcing the rule need to know what compliance looks like. And everyone has to understand and agree what that means.

Effective **education** and **outreach** for growers will require multiple approaches and more effort than is traditionally given to currently regulated facilities. Developing and distributing guidance materials, as well as ongoing education, outreach and compliance **assistance** will be needed to make the rule effective, and multiple formats will be needed for different uses and audiences. The work in Work Area 2 is important for identifying those audiences. See also Chapters 4 and 8.

Ongoing regulator **training** will be necessary to keep regulatory staff and management up-to-date and effective when working with the regulated community. See also Chapter 7.

Related Chapters

4. Outreach/Education and Compliance/ Enforcement
5. Work Planning
6. Information Sharing
7. Regulator Training
9. Technical Assistance
11. Infrastructure

DESIRED OUTCOMES: An educated regulated community that pro-actively participates, complies, and adopts the rule, fully incorporating its principles in efforts to improve food safety and protect public health. Also, an educated produce safety staff and a regulatory system that promotes compliance through education and corrective action.

GENERAL ATTRIBUTES and FUNCTIONS

An effective program will need to be able to:

- Be consistent with messages and information, regardless of audience or delivery mechanism.
- Target information for the intended audience, e.g., use farmer-recognizable terms for farmers.
- Use appropriate information delivery methods.
- Use teachers to teach.
- Ensure information is aligned with FDA guidance on how rule applies, what it means
- Show how the rule benefits industry, customers and public health.
- Notify those who are covered by the rule of the rule requirements and educational and process opportunities and options.
- Communicate who is not covered by the rule, while still promoting practices that reduce the risk of contamination.

Work in this area can be expected to typically include:

- outreach campaigns
- partnership development
- mailings
- material development and distribution
- workshops or classroom sessions
- on-site visits
- web-based resources

BOTTOM LINE

- ***Know the rule.***
- ***Know how to apply the rule.***
- ***Know the public health significance.***

SPECIFIC CONSIDERATIONS

Foundation of Law (See Chapter 2)

Does the state, local government or territory (state) have a produce safety rule program with clearly defined mission, authorities, and assignation of duties and roles upon which educational and outreach efforts and instructional materials can be based?

Suggested Practice: Identify key elements/section headings of Produce safety rule in tabular form and develop state cross walk with FDA regulations, and state agency coverage of that regulation, in addition to roles of any auxiliary groups, e.g., Extension, or third-party auditors, etc.

Outreach Activities (See Chapter 4)

What are you doing to reach the regulated community to encourage participation?

- Are constituency groups, industry, and interested parties identified? See Work Area 2.
- Are in-state producers also participants in any adjacent state organizations?
- Have the adjacent states been contacted for comparable associations sharing messages to targeted groups across state lines?
- Do you have a communication plan focused toward the specific needs of the targeted audiences?
- Does your program have a point of contact website, or person or both to provide support or communication from commodity producers?
- Are members of producer groups being motivated to participate by commodity groups/organizations and farm groups?
- Are efforts being made to identify and contact and maintain contact with small farmers, regardless of their exempt or non-exempt status under the Produce Safety Rule?

What are you doing to reach decision makers and others that may be instrumental in essential support for the state program (e.g., authority, policies, and fiscal support)?

- Are legislators and policy makers aware of these plans and breadth of impact?
- Are these entities aware of national coordination efforts through NASDA involvement?

Education Activities (See Chapter 4)

- Are educational materials tailored to the needs of the targeted group? Content should be consistent to all commodity groups, but communication methods and some details may be reconfigured. Outside expertise may be necessary for determining appropriateness of materials.

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- Are educational materials consistent with FDA guidance? Are other educational materials from any useful source, identified to service the target audiences? Are these modified or jointly re-authored to contain the appropriate commodity-specific educational materials?
- Are all possible avenues of communication and contact with the targeted audiences being fully pursued? (Confirm best communication channels with targeted audiences.)
- Are standardized educational sessions identified and made available to each targeted audience? (Are any states considering licensing and continuing education?) Are educational sessions made available to the various types of growers/packers:
 - At an appropriate price?
 - At a location reasonable for growers/packers to attend?
 - In various formats (e.g., 1 day, 2 half days, 7 -1h sessions)?
 - During times growers are likely to attend (winter)?

On-Farm Education Activities (See Chapter 4)

On-Farm Readiness Review

- Are the readiness reviews described in Chapter 4 fully developed and implemented? See also Training for Compliance, below
- Has the authority for this type of education been clearly established? Have the roles been clearly assigned? e.g., Can regulatory staff do education during inspection without taking enforcement actions, or does the extension service fill the on-farm education role? A NASDA pilot project hopes to help address the typical challenges states will face on this issue.

Incentives

- Have policy makers and legislators adopted incentives or have other incentives been developed to gain compliance with targeted audiences? Are these incentive programs being effectively communicated and funded?

Training for Compliance and Enforcement Activities (Regulator Training - See Chapter 7)

- Are regulators or other agency personnel fully trained (see Chapter 7), authorized to fully enforce the rules, or to have clear authority for on-farm readiness reviews to gain compliance?
- Is training consistent with FDA guidance?
- Do regulators and non-regulator trainers meet periodically to discuss compliance issues and interpretive issues with regard to practice and possible enforcement? Is a regular meeting time clearly established for discussions to take place?
- Do regulators and non-regulatory trainers meet with commodity producers to discuss perceived compliance enforcement issues?
- Have regulators and auditors been jointly trained, i.e., in the same room together?
- Is the same training course content being received by all participants? Although standardization in national trainings is desirable, it is not to be assumed.
- Is regional production uniqueness accounted for in the trainings? Some parts of the country do things differently due to water or soil differences, as well as the practiced culture of production.
- Does the regulatory agency have a means of appropriately addressing alternatives to the PSR as they are encountered?

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- Does the regulatory agency have a means of accepting, reviewing and submitting variance requests to the FDA?
- Do inspectors know how to determine if certain practices have already been approved and validated by FDA?

POSSIBLE QUALITY/ EFFECTIVENESS MEASURES

- Percentage of associations and industry groups representing stakeholders covered by the rule that have been contacted. Also, types of contact efforts, e.g.,
 - o Presentations at group meetings
 - o Distribution of education materials
 - o Inclusion in newsletters
 - o Other
- Number of participation obstacles identified by the regulated community, and development of strategies to overcome participation obstacles.
- Percentage of clients in the regulated community pleased with access to information and quality of training and outreach.
- Level of understanding of the rationale for voluntary compliance and production practice.
- Level of compliance being attained.
- Percentage of clients in the regulated communities generally satisfied that they are treated fairly, and with consistency from one inspector to another in the same commodity program (or from a third-party auditor, if that is an option).
- Intra-state regulatory inspections and audits consistent with those of neighboring states for the same commodities. Are they handled in the same way, allowing commerce to move back and forth?
- Are neighboring programs compatible?

Work Area 2. Application, identification, categorization and risk profiling of industry

This work area is about knowing who the rule applies to, and where and what the risks are, so that the knowledge can be used to shape the program and actual application of the rule. It lays groundwork for ensuring the rule is applied to all that are regulated by it, for supporting a risk-based approach, and for using outreach and education to help achieve compliance with the rule.

DESIRED OUTCOME: Sufficient knowledge about the regulated community to support uniform, consistent and effective implementation actions (See Work Areas 1 & 3).

Related Chapters

2. Foundation of Law
4. Outreach/Education and Compliance/ Enforcement
5. Work Planning
6. Information Sharing
11. Infrastructure

GENERAL ATTRIBUTES and FUNCTIONS

An effective program needs to be able to:

- Understand the PSR. (See Work Area 1.)
- Understand the local produce industry.
- Know who in the state the PSR applies to and who it doesn't (both groups need to know their status and requirements under all FSMA rules)

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- Know when a farm needs to comply (staggered compliance dates).
- Understand how the nature of the local produce industry affects implementation.
- Have a basis for setting priorities for implementation that reflects the produce industry and associated risks and conditions, as well as FDA priorities where applicable.

Work in this area can be expected to typically include:

- Creating a method to identify farms and their products.
- Comparing the rule to the farms/produce packers and determining if and how the rule applies.
- Compiling info on crops and commonly used practices, be they alternative or traditional. Identifying regional connections, themes, issues.
- Identifying risks associated with practices and conditions (e.g., outbreak data, consumption demographics, packaging, growing conditions (on or off ground), fertilization schemes, climate and water (irrigation and wash water safety).
- Identifying firms by risk category so that the categories can be used to schedule inspections and allocate resources.
- Keeping current and updating as needed.

SPECIFIC CONSIDERATIONS

Do you have a PROCESS for...

- Identifying and evaluating agricultural conditions and practices in your state (e.g., types of crops, irrigation systems, soil, weather, and labor)? And for identifying what conditions and practices occur at given locations?
 - o What is grown where? How often?
 - o Are there seasonal growing conditions that need to be considered for areas that may have multiple crops?
 - o What water sources are used? What are they used for?
 - o What are typical practices? Are alternative practices common?
 - o What soil amendments are used? Manure? Compost?
 - o What differences are typical to farm size?
 - o Does production cross state boundaries?
 - o Are there other farm related activities, such as holding livestock?
- Identifying all who are affected, subject to the rule? And why?
 - o Who are the farmers? Produce packers?
 - o What do they grow or pack?
 - o Do they fall under the PSR or the Preventive Controls rule? How do you know which?
 - o Farm size?
- Identifying and evaluating risks associated with the crops, conditions, and practices? Identifying research needs related to risk? Incorporating new data and research findings into risk profiles? Some of the information in this work may be provided by others, but the state still will need to be able to answer the questions:
 - o What risks are associated with what conditions and practices?

- o What is the source of the risk?
- o How can risk be mitigated?
- o Where is the most risk?
- o What is most serious risk?
- Categorizing risk? (e.g., based on practices and conditions such as outbreak data, consumption demographics, packaging, growing conditions (on or off ground), fertilization schemes, and climate, water (irrigation and wash water safety).
- Revising risk categories as outcome measures are developed (e.g., in response to sampling data)?
 - o What risks go with what farms?
 - o What conditions pose most risk? Least?
- Identifying needs and opportunities?
 - o For partnerships, collaboration
 - o For incentives for compliance
 - o For outreach and education
 - o For information sharing

POSSIBLE QUALITY/ EFFECTIVENESS MEASURES

- Extent of alignment between estimates/inventory and ground-truthing, e.g., crops grown, number of covered farms, practices used, etc.
- Usability of information for education, training and outreach; for creating risk categories; for supporting incentives and partnerships.
- How quickly new knowledge is incorporated into education and training.
- Usability of risk categories, e.g., for prioritizing work/resource use, for supporting budget requests, etc.

Work Area 3. Application of Regulatory Scheme

This work area is where uniform and consistent application of the Produce Safety Rule really takes place. This is where you determine if a farmer or produce packer is complying with the requirements of the rule or not, and the potential consequences.

DESIRED OUTCOME: State-wide and national consistency in both encouraging and requiring compliance (enforcement), resulting in the prevention of foodborne illness.

GENERAL ATTRIBUTES and FUNCTIONS

An effective program needs to be able to:

- Understand the PSR, those being regulated, and the regulatory environment (See Work Areas 1 & 2).
- Go where the action is – farm, packing shed, shipping depot, trucks. (Need authority and means.)
- Recognize what is happening and know whether it shows compliance or not.
- Get the information you need (e.g., analysis of “for cause” samples).

Related Chapters

2. Foundation of Law
3. Financial support
4. Outreach/ Education and Compliance/ Enforcement
5. Work Planning
6. Information Sharing
7. Regulator Training
8. Accessing Laboratory Resources
9. Technical Assistance
10. Dispute Resolution
11. Infrastructure

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- Perform at same “level” state-wide, industry-wide.
- Resolve disputes.
- Act on findings.
- Point non-compliant firms towards compliance.
- Act to prevent suspect produce from advancing in the market or being consumed, and to allow non-suspect produce to advance in the market.
- Be credible, accurate.
- Deal fairly with all whom you regulate.
- Respond to complaints, inquiries, and incidents.
- Assess alternative practices and the impacts of rule on local industry.
- Communicate findings, concerns, successes.
- Partner with others.
- Obtain and/or provide trustworthy lab results.

Work in this area can be expected to typically include:

- Inspections, sample taking and analysis when warranted, corrective actions, technical assistance, enforcement, investigations.
- Coordinating actions with other work areas or with other programs.
- Identifying how the rule should best be applied for the local conditions, such as through seeking variances.
- Collecting data, especially in a way it can be shared and used for risk analysis – track and trend.

SPECIFIC CONSIDERATIONS

Authorities (See Chapters 2 and 10)

Do you have, or can you get, the legal authority to do what you need to?

- Have you identified the authorities needed to implement the PSR in your state?
- Do you have the legal authority to conduct on-farm inspections, take samples? Does anyone?
- Do you need new authority to conduct inspections? Do you know the process for acquiring needed authority?
- Do you know how related authorities/legal requirements will affect your work implementing the PSR? Public records acts, etc.
- Do you have an established, authorized means of resolving disputes? Different authorities may be necessary to address disputes between: (1) FDA and state programs; (2) differences in state determinations; (3) industry and state programs; (4) differences between scientific evaluations; and (5) validation of alternatives and variances.

Resources (See Chapters 3, 4, 5 and 11)

Do you know what you need, where to get it, and how to make sure it can do the job?

- Have you assessed the work load and your resource and infrastructure needs?
- Do you have a process for assessing capacity and capability?
- Do you have the staff, equipment, data, systems, facilities needed? Including laboratories? Including administrative support?

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- 778 • Do you have a process for assessing the financial resources needed to acquire other resources? For
779 identifying the path to acquiring that funding?
- 780 • Do you have adequate funding to do what you need to do? Can you identify different kinds of funding
781 needs?)
- 782 • Do you have partners? A process for identifying and pursuing access to others' staff, equipment,
783 facilities, information or expertise?
 - 784 o Food and Drug Administration (FDA)
 - 785 o USDA Agricultural Marketing Service (AMS)
 - 786 o Other state agencies
 - 787 o Academia / Cooperative Extension
 - 788 o Industry
 - 789 o Associations
- 790 • Do you know how to and are you able to access the FDA's subject matter and food safety experts (SMEs
791 and FSEs)?
- 792 • Have you updated your assessment to reflect program status or intent?
- 793 • Do you have a process for keeping data resources up to date? **Competency and Credibility (See Chapter**
794 **4, 7, 8, 9 and 11)**

Can your program be relied upon to be accurate, honest and fair?

- 796 • Do you have a regulatory training program to ensure your staff's knowledge of the PSR and how to
797 apply it to the local produce industry? See Chapter 7.
 - 798 o Does it include inspectors, compliance and management personnel? Lab personnel?
 - 799 o Does it incorporate and align with FDA guidance and materials?
 - 800 o Does it include people skills?
 - 801 o Does it include assessment of capability?
- 802 • Do you have a process for ensuring the credibility of other resources you use, whether they are from
803 your program, privately supplied or from other states' programs? (e.g., lab accreditation, tool
804 calibration) See also Laboratory Functions, below.
- 805 • Do you have a process for ensuring execution (see below) is uniform and consistent? For addressing
806 conflict of interest within the program (e.g., inspectors that are also growers or investors)?

Execution (See Chapters 5, 6, 7 and 10)

Do you take a systematic approach to regulatory duties, functions?

- 810 • Have you identified program goals, outcomes, and level of development?
- 811 • Do you have a process for evaluating and applying education and outreach? Do you plan to be directly
812 involved? Are you on the same page with others?
- 813 • Do you have a process for developing priorities and strategies for implementing the PSR? Are the
814 inspectional priorities and strategies risk-based? (e.g., do resource allocations and inspection schedules
815 reflect level of risk indicated by risk category?)
- 816 • Do you have a process for developing protocols for inspections?
- 817 • Do you have a process for developing protocols for product sampling and analysis when needed to
818 demonstrate risk or otherwise warranted?
- 819 • Do you have a process for ensuring those protocols are followed? Updated? In alignment with PSR?
 - 820 o Do you have a process for voluntary compliance and corrective action?

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- 821 o Does it include on-farm readiness reviews?
- 822 o Does it include technical assistance?
- 823 o Does it include corrective action before enforcement?
- 824 • Do you have a trained team for rapidly investigating outbreaks and identifying and eliminating the root
- 825 cause of an outbreak?
- 826 • Do you have a process for identifying and seeking answers to regulatory problems?
- 827 • Do you have a set process for resolving disputes? Different processes may be necessary to address
- 828 disputes between: (1) FDA and state programs; (2) differences in state determinations; (3) industry and
- 829 state programs; (4) differences between scientific evaluations; and (5) validation of alternatives and
- 830 variances.
- 831 • Do you have a process for identifying and evaluating acceptability of alternative practices?
- 832 • Do you have a process for identifying and evaluating whether alternative practices are appropriate to
- 833 be addressed through a variance?
- 834 o What other states might want the same variance?
- 835 o Would a regional variance work?

836 837 **Laboratory Functions (See Chapter 8)**

838 If you have need for laboratory analysis of samples taken “for cause” (such as in investigations) ...

839 Do you have a process for evaluating the reliability, dependability, accuracy and repeatability of lab results

840 used for enforcement or for verifying compliance, regardless if the results are from your own laboratory, a

841 private laboratory or another state’s laboratory? Are results from your laboratory accepted by others?

842

- 843 • Does your lab have ISO 17025 accreditation, or is it pursuing it? Or does your lab at least follow the
- 844 following concepts:
- 845 o Documentation/transparency of all practices and policies that help achieve competency in
- 846 personnel and practice.
- 847 o Appointment of a specific, independent, accountable person to oversee the quality program
- 848 and evaluate the lab.
- 849 o Training of all personnel so that understanding of the quality plan is demonstrated.
- 850 o Creation of an organizational culture of quality assurance practice.
- 851
- 852 • How does your self-assessment reveal your lab’s credibility and trustworthiness?
- 853 o Active practice of a quality management system?
- 854 o Participation in a program that is characterized by established standards?
- 855 o Adequate staff training? Cross-training?
- 856 o Adequate resources to conduct the required analyses? Budgetary support?
- 857 o Participation in appropriate regional or national meetings?
- 858 o Ability to share data? Ability to hold data as confidential, not subject to public disclosure?
- 859 o Regular requests by other state laboratories for services, or assistance?
- 860
- 861 • What considerations do you make to engage and trust data from another laboratory?
- 862 o Do you have a process for identifying Capability and Competency -- Is it competent in the tests
- 863 you require? In accepted methods and technologies? How frequently does it run these specific

analyses? How frequently and how recently have they completed proficiency testing? What program? (FERN, AAFCO, other?)

- o Standing – Is the laboratory part of FERN (Federal Emergency Response Network)?

A backup laboratory for other state testing laboratories? A referee laboratory for other laboratories?

Communicating and understanding Good Laboratory Practices are essential in successfully facilitating the ability of SLTTs state and federal government laboratories to work together. The ISO 17025 standard is a gold standard that should be desired by all laboratories. While ISO 17025 accreditation is preferred, it is not the only way to maintain a quality assurance practice. Having a rigorous quality management plan in use, even if not accredited by third parties, is better than having nothing.

To ensure consistency concerning laboratory functions, the following pathways are offered, recognizing that some programs will not have adequate funding to pursue ISO certification but still need to improve lab competencies:

- a. ISO 17025 accreditation or other FDA recognized accreditation.

- i. This is the gold standard. You must have the ISO elements clearly and competently addressed which includes the agency or laboratory-specific administrative documentations and guidance.

- ii. Must have a person dedicated full time, or fully available to the task of maintaining accreditation and who is accountable directly to management.

- iii. Must support third party audits of your ISO accreditation status to maintain your status.

- iv. This appears to meet the basic language in concept of FDA requirement that laboratories who achieve this standard can have their data accepted by FDA for enforcement purposes.

- b. Compliance with an FDA audited standard.

- i. This standard is one maintained and audited by FDA for FDA's purposes.

- ii. As in above the ISO 17025 standards will be the basis for most of this requirement but may be selectively audited for those practices most immediately relevant to FDA purposes.

- iii. This standard of performance could be achieved in non ISO 17025 accredited laboratories under emergency situations through the use of specifically prepped FDA proficiency testing combined or not with prescriptive use of a specific method, for specific targeted analytes. Personnel and laboratories achieving acceptable levels of performance on the proficiency test can be approved by FDA to conduct that test for that analyte, using the prescribed method, if a method was prescribed. It is not a general approval of other laboratory testing. Such work has been done by USDA APHIS PPQ in quarantine situations and by EPA in working with state laboratories in emergency situations.

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- iv. Unless adopted under MFRPS and AFRPS, the use of this option is not apparent in discussions thus far with FDA. (The AAFCO Laboratory Methods Manual and the Partnership for Food Protection Laboratory Manuals are good exemplars.)
- c. Self-assessment and self-implementation
 - i. States perform self-assessments and implementation ISO 17025 standards. Work with another mentoring state or state agency that has ISO 17025 accreditation.
 - ii. Do your own due diligence. Assure that your own laboratory team is producing the most accurate results possible:
 - 1. Are laboratory professionals trained by the instrument vendor in use of the instrument? Or have personnel attended vendor workshops on this instrument offered by the vendor?
 - 2. Are laboratory personnel trained on particular methods for which they are responsible? Is this training updated and recorded?
 - 3. Does the laboratory participate in matrix appropriate proficiency testing? How does the laboratory or given personnel rank compared to their peers? Are you attempting to improve your operations based on these results?
 - 4. Is adequate backup present in your laboratory to cover an anticipated emergency, e.g., cross training of laboratory personnel to provide internal coverage if one instrument specialist is out for a period of time, or to provide added capacity including both personnel and instrumentation resources, plans for shift changes, etc.?
 - iii. Work intelligently with others. Develop a working, documented relationship with a back-up laboratory (According to ISO must have an agreement between a laboratory and any backup laboratories)
 - 1. Periodically split a non-enforcement sample with a back-up laboratory to compare results with that obtained by your own laboratory?
 - 2. Communicate annually or semi-annually on types of analytes being run, testing needs, instrumentation, discuss critical areas where back up is most likely perceived to be needed, and make sure comparable practices are in place.
 - 3. Perform cross trainings with laboratory personnel to gain new skills in methods
 - 4. Monitor each lab's comparative progress – share data (non-enforcement) – agree how to share mutually wanted data using the PFP Guidances as reference material.
 - 5. Purposefully attend joint trainings or participate in national meetings with peers.
- d. Outsourcing (Memoranda of Understanding may be necessary)
 - i. States that have particularly small programs that cannot sustain a laboratory and ISO accreditation should consider working closely with any other state laboratory and consult with their FDA state contact. An agency working within the state with

- another in-state agency may make arrangements to cooperatively fund needs-specific testing services subject to Good Laboratory Practices, and references such as the
- ii. Partnership for Food Protection Laboratory Manual:
<http://www.fda.gov/downloads/ForFederalStateandLocalOfficials/FoodSafetySystem/PartnershipforFoodProtectionPFP/UCM404716.pdf>
 - iii. or the AAFCO Laboratory Resources for Animal Feed Laboratories:
<http://www.aafco.org/Laboratory>
and the AAFCO Laboratory Manual:
<http://www.aafco.org/Publications/QA-QC-Guidelines-for-State-Feed-Laboratories>
 - iv. See also the FDA ORA Laboratory Manual:
<http://www.fda.gov/ScienceResearch/FieldScience/LaboratoryManual/default.htm>

POSSIBLE QUALITY/ EFFECTIVENESS MEASURES

- Number of complaints and conflicts regarding consistency of implementation, e.g., are neighboring states concerned about produce your program inspected entering their jurisdiction?
- Outbreaks linked to produce from your state.
- Budgetary support for program implementation and improvements.
- See Work Area 4.

Work Area 4. Evaluation of Success

This work area is about considering the effectiveness of your program. It is about measuring outcomes and about checking to see if the results you want are the results you are getting. It is about identifying what is working, what isn't, and why. It lays essential groundwork for Work Area 5 – Implementation of Improvements.

DESIRED OUTCOME: A clear picture of how effective the program is, as well as its strengths, weaknesses, opportunities and threats.

GENERAL ATTRIBUTES and FUNCTIONS

An effective program needs to be able to:

- Compare the existing to the intended.
- Identify progress made, changes in conditions.
- Identify what works; what's lacking; what needs to be retained and maintained; and what needs to be fixed, eliminated or added.
- Benchmark alignment against other state programs.

Work in this area can be expected to include:

- Monitoring.
- Measuring impact of activity.

Related Chapters

2. Foundation of Law
3. Financial Support
4. Outreach/Education and Compliance/ Enforcement
5. Work Planning
6. Information Sharing
7. Regulator Training
8. Accessing Laboratory Resources
9. Technical Assistance
10. Dispute Resolution
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- Identifying trends.
- Tracking complaints and resolutions.

All the work need not be accomplished directly by the state program itself. For some work, ISO auditors may be appropriate. Also, a state program may want to engage another program or another state as an assessment partner to provide an outside perspective.

SPECIFIC CONSIDERATIONS

Different modules or levels of implementation will require different measures, but certain themes persist: Is what you are doing working? How do you know if your program is effective? Any outbreaks? How is the produce community responding? Are they asking for help? Clarification? Are they changing practices?

Do you have measures and processes that let you answer the following questions?

Functionality – How well is the program working?

- How effective are you in analyzing the core elements for risk profiling?
- How effective are you in communicating an educational program?
- How effective are you applying your inspections to the industry?
- How effective are you in maintaining alignment with the rule and consistency?
- How effective are you in measuring the changes in industry? In evaluating changes?

Effect on industry – How effective are your strategies?

- Is industry modifying behavior to produce a safer product?
- Are you driving compliance? (as opposed to enforcement)
- What is the difference in effectiveness between in-state industry producers and covered produce distributed across state lines?
- Have produce-related outbreaks increased or decreased?

POSSIBLE QUALITY/ EFFECTIVENESS MEASURES

- How often is the program reviewed/assessed?
- Do others have the same perception of your program as you do?
- Do on-the-ground results match the assessment results?

Work Area 5. Implementation of improvements

This work area is about making programmatic changes that increase the effectiveness of implementation of the PSR. This work is part of continuous quality improvement (ISO principle #6) and connects strongly to Work Area 4 – Evaluation of Success. It's also where program expansion or enhancement takes place.

DESIRED OUTCOME: The ability of the program to demonstrate continuous improvement in the effectiveness of implementing the Produce Safety Rule (PSR).

GENERAL ATTRIBUTES and FUNCTIONS

An effective program needs to be able to:

- Identify improvements to be made.
- Show how changes will make a difference.
- Assess and acquire resources needed for those improvements—including partnerships.
- Identify the process and schedule for making changes.
- Ensure changes are made.
- Communicate about the improvements – to staff, regulators, industry, and partners.

Work in this area can be expected to typically include:

- Changing policies or protocols.
- Changing record/tracking mechanisms.
- Revising strategies, schedules, or staffing.
- Incorporating new tools and systems.

SPECIFIC CONSIDERATIONS

Preparation – Do you have a process for:

- Generating improvement ideas?
- Evaluating ideas for improvements and ensuring that those that go forward are fact-based and/or science-based and aligned with intent of the PSR?
- Identifying and acquiring resources needed? See Work Area 3 and Chapter 11, Infrastructure.
- Prioritizing improvements to be made?
- Identifying expected outcomes and how to measure effectiveness of improvements?
- Identifying how improvements are to be made, by whom and when?

Follow-through – Do you have a process for:

- Ensuring improvements are made according to plan?
- Identifying who needs to know about the changes, and how best to convey that information?
- Including changes in materials used for Work Areas 1-4?

POSSIBLE QUALITY/ EFFECTIVENESS MEASURES

- Have planned improvements been made to program materials, methods, policies, practices?
- Are the changes actually improvements? Have they been effective, achieved their goal?

Related Chapters

2. Foundation of Law
3. Financial Support
4. Outreach/Education and Compliance/ Enforcement
5. Work Planning
6. Information Sharing
7. Regulator Training
8. Accessing Laboratory Resources
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- Do improvements reflect needs identified in Work Area 4?
- Do improvements lay groundwork for future improvements?

5.Related Documents and References

The specific processes and practices outlined in the other chapters of this Operational Framework can help create programmatic consistency. In addition, the resources and standards listed below may be helpful to states, local governments, and territories (states) developing new produce programs or expanding existing programs to include produce.

6.Resources for State Programs

NASDA – FERP Template <http://www.nasda.org/File.aspx?id=4065>

NASDA – FERP Template – Supplemental Information <http://www.nasda.org/File.aspx?id=12006>

Produce GAPs Harmonized Audit - link to the USDA Harmonized GAP page:
<http://www.ams.usda.gov/HarmonizedGAP>

GAP & GHP Auditor Handbook, November 2009 – this is subject to revision to align with the requirements in FSMA: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=stelprdc5101326>

7.Standards

Grade “A” Pasteurized Milk Ordinance:
<http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM209789.pdf>

FDA Milk Safety Program:
<http://www.fda.gov/ForFederalStateandLocalOfficials/PartnershipsContracts/ucm303972.htm>

Commodity Specific Food Safety guidelines for the Production and Harvest of Lettuce and Leafy Greens:
<http://www.lgma.ca.gov/wp-content/uploads/2014/09/California-LGMA-metrics-08-26-13-Final.pdf>

Manufactured Food Regulations Program Standards:
<http://www.fda.gov/ForFederalStateandLocalOfficials/PartnershipsContracts/Overview/default.htm>

Animal Feed Regulatory Program Standards:
<http://www.fda.gov/ForFederalStateandLocalOfficials/AnimalFeedRegulatoryProgramStandardsAFRPS/default.htm>

Voluntary National Retail Food Regulatory Program Standards:
<http://www.fda.gov/food/guidanceregulation/retailfoodprotection/programstandards/ucm245409.htm>

National Shellfish Sanitation Program:
<http://www.fda.gov/food/guidanceregulation/federalstatefoodprograms/ucm2006754.htm>

Model Commercial Feed Bill and Model Commercial Feed Regulations Developed by Association of American Feed Control Officials:
aafco@agr.wa.gov

Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain
<http://fvreports.freshfromflorida.com/tomatsup2.pdf>

1117 ISO 17020 Standard:
1118 [http://www.iaf.nu/upFiles/600630.IAF-ILAC-A4_2004_guidance_on_the_application_of_ISO-](http://www.iaf.nu/upFiles/600630.IAF-ILAC-A4_2004_guidance_on_the_application_of_ISO-IEC_17020_2007-04.pdf)
1119 [IEC_17020_2007-04.pdf](http://www.iaf.nu/upFiles/600630.IAF-ILAC-A4_2004_guidance_on_the_application_of_ISO-IEC_17020_2007-04.pdf)
1120
1121 Or (general information) at:
1122 <http://www.ehsservices.com/ISO%2017020.htm>
1123
1124 Global Food Safety Initiative
1125 <http://www.mygfsi.com/schemes-certification/benchmarking/gfsi-guidance-document.html>

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Chapter 2: Foundation of Law

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1. Executive Summary

This document is an internal deliberative document not intended to provide legal advice. This document provides background materials and information for the purpose of facilitating conversation between states and their legal counsel about establishing a food safety program.

The purpose of this chapter is to provide the toolset for a state's analysis of the legal authority and considerations necessary for implementation of the Produce Safety Rule as promulgated by the FDA.

Each state has a variety of mechanisms available to adopt or develop a produce safety program, but each state must develop an individual solution (statutory and regulatory) regarding whether they intend to implement the produce safety program in its entirety, to implement only specific activities (outreach and education, inspection, compliance/enforcement, etc.), or if the state chooses not implement a produce safety program at this time.

2. Scope

The Legal Foundations chapter addresses the legal and regulatory components that must be in place for a state regulatory program to implement the Produce Safety Rule to be codified at 21 CFR part 112. This chapter will reference other pertinent chapters of the States' Operational Framework, developed through NASDA. For example, the Enforcement and Work Planning chapters' reference material covered in the Legal Foundations; likewise, this chapter refers to several other chapters. This Chapter is intended to be read as part of a compendium of resources for states to use in implementing a produce safety program aligned with the final Produce Safety Rule published in November 2015.

3. Purpose / Outcomes

Using this chapter in conjunction with an assessment of state legal authorities and analysis of the authorities necessary for state law to align with FSMA (a project expected to be completed in late 2016 by NASDA, AFDO, ASTHO and other partners under a cooperative agreement with FDA):

- A state agency will understand the steps necessary to evaluate existing legal authority and will identify the optimal approach to implement a state produce safety program.
- Second, a state will understand the preliminary requirements for establishing a program aligned with the federal Produce Safety Rule and why program consistency is crucial.
- Third, a state will be able to develop a practical timeline for obtaining authority, if necessary, and establishing a produce safety program depending upon the legal requirements of their state.

4. Responsibility & Roles

4.1 State Agency Responsibilities

Regarding existing food safety programs², States fit into several categories:

- States with existing food safety authority for manufactured foods
 - o Administered by the state department of agriculture
 - o Administered by the state department of health or other similar agency
- States with existing feed control programs
 - o Administered by the state department of agriculture
 - o Administered by the state university

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- States considering future authorities and institutional relationships
- States not yet considering future authorities and institutional relationships

Depending upon the existing statutory and regulatory food safety authority, differing analysis and action steps may be necessary. Some states may choose to expand existing programs; others may consolidate programs; some may create unique programs; and some may forgo changing authorities at this time. While the emphasis of this document is to assist states considering developing a produce safety program, states will likely want to consider creating authorities to deal with the entirety of the Food Safety Modernization Act (FSMA) changes instead of a piecemeal approach.

States will be responsible for analyzing their existing state legal authority and determining the structure under which a produce safety program, aligned with the FDA Produce Safety Regulation, can be developed. In this process, the states will benefit from an evaluation of the foundation of law and regulations in their state to verify that the state program is aligned with the authority in the federal law and the federal regulation. In this regard, states should compare their basic state food safety authority to the Federal Food, Drug, and Cosmetic Act (FFD&CA) and/or the AFDO Model Food Safety Law to determine whether basic food safety authority is present before examining the additional authorities necessary for on-farm inspections and actions authorized in the Produce Safety Regulation. In addition, some states with existing programs may benefit from a review of the voluntary retail standards; manufactured food for human consumption or the voluntary animal feed standards for guidance from these examples.

If additional legal authority is needed, the state will be responsible for drafting appropriate statutory and/or regulatory language for a produce safety program, which is aligned to the FDA Produce Safety Regulation. For more information on benchmarking and consistency, see the Alignment and Consistency Chapter. Further project work under the NASDA-FDA Cooperative Agreement should also complement and assist in the review of states' authorities.

Congress made substantial changes to existing federal food safety authority when FSMA passed, and the President signed the act into law. Food safety is in everyone's best interest. As state legislative changes seek to bring state laws into alignment with federal law, adequate resources to implement the federal law will be necessary. If a state chooses not to participate, primary enforcement authority will remain with FDA in that state. See the Financial Support Chapter for more information on the need for adequate funding to implement a state produce safety program.

4.2 FDA Responsibilities

In addition to federal rulemaking to establish science-based standards for the safe production and harvesting of produce, FDA is responsible for setting national policy related to produce safety and interpretations of the requirements of the Produce Safety Rule, including publication of guidance documents. FDA does all of this national policy development in close consultation with state regulatory partners.

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FDA has indicated that in shaping the operational strategy for gaining industry compliance with the Produce Safety Rule, state regulatory partners will serve as the front line for domestic on-farm surveillance operations including inspections, with FDA financial and scientific support.

In addition, it is desired that FDA should work with NASDA, AFDO, ASTHO, other partners as needed, and the states to develop a series of model authorities and regulations to ensure the state programs have a process for determining substantial comparability and alignment with the Produce Safety Regulation.

4.3 Other Responsibilities

NASDA and their cooperative agreement partners will coordinate with the states and be active facilitators of information and resources to assist states in adopting and maintaining necessary legal authority.

Organizations such as the National Conference on State Legislatures (NCSL), the Council of State Government (CSG) and/or the National Agriculture Law Center can assist AFDO, ASTHO, FDA, NASDA, and the states in monitoring the progress of state legislation across the nation related to the Produce Safety Rule.

5. Regulatory Foundation

The final Produce Safety Rule and the authorities in FSMA represent the regulatory floor for a state's produce safety program. The adoption of FSMA statutory and regulatory provisions or the promulgation of comparable statutory and regulatory authority should complement any existing food safety regulatory authority, if any, held by the state agency.

6. Fundamental Components of a Regulatory Program

For states that do not already have food safety regulatory authority within the agency (i.e., manufactured food program authority) and will implement the Produce Safety Rule must ensure that four primary components are present. The four crucial components include: statutory authority; ability to adopt regulations to implement the Produce Safety Rule; appropriate enforcement authority, and mechanisms for adjudicative functions.

7. Steps to Evaluate the Regulatory Foundation for a Produce Safety Program

The first decision is whether a state desires to implement the produce safety program in its entirety or in part. State departments of agriculture have historically been involved in on-farm programs; however, food safety programs (i.e., manufactured food safety) across the United States are divided between departments of agriculture, departments of health and, for a few states, other agencies. Therefore, if states seek to implement a produce safety program for the Produce Safety Rule, each state will need to determine in which department the new authority should reside.

Some states may choose to split responsibilities between agencies and develop agreements regarding the role each agency will play in the state's individual produce safety program. States may also wish to develop a formal agreement to ensure understanding of roles and responsibilities on this regulatory issue.

Each state should carefully review the existing statutory authority and current regulations to identify changes necessary to implement a produce safety program. The analysis should include additional considerations of privacy, variances, enforcement, access to property and other facets to ensure compliance. These fundamental areas are discussed in the following sections.

7.1 State Decision to Implement a Produce Safety Program

Each state should carefully review the statutory changes FSMA has created including the new authority in the Produce Safety Rule to determine whether the state will fully implement the Produce Safety Rule, or to forgo establishing a program under state authority.

In the absence of independent state authority, a state could implement a produce safety program under FDA Commissioning or Credentialing authority. By operating a program through federal commissioning and credentialing, the state would most likely only be able to use existing staff and resources. Operating a program under commissioning and credentialing may not provide the same benefit as a state's own legally authorized program. Under programs authorized by commissioning and credentialing, FDA takes a more active role in inspection schedules and priorities, rather than the state agency, and enforcement and compliance decisions are made by the FDA rather than the state.

It is likely that some states will consider the option of working under FDA authority, as seeking state authority, drafting rules, establishing a program, training staff and educating the regulated community may take more time than is available between the publishing of the Final Rule and the implementation dates for enforcement of the Produce Safety Rule. Commissioning and credentialing may be an interim solution or a longer-term solution, depending upon timing and/or interest of stakeholders at the state level.

Administrative Procedure Requirements for Rule Adoption Regardless of the adoption method, each state seeking to implement the Produce Safety Rule will need to develop it based on the state's Administrative Procedures Act (APA). Each state has its own APA and regulations, adjudicative functions, and regulatory programs must be created or modified in accord with the state APA.

7.2 Determination of Needed Agency Authorities in State Law

Traditionally, the state legislature must grant an agency the appropriate authority to establish a regulatory program. Authority in some states may be extremely broad and applicable to all food produced (or grown) in the state. Other state legislatures might provide specific and limited authority to an agency. If a state has broad statutory authority, this may be sufficient to allow a state to develop a produce safety program without obtaining additional statutory authority.

Since neither FDA nor many states have traditionally conducted routine on-farm food safety inspections in the past, a crucial aspect of authority that a state must determine is whether existing authority permits an agency to establish regulations for growing, harvesting, packing, holding and inspecting on the farm and the authority to declare a food adulterated. In addition, the state's analysis should also recognize the additional authority groups that complement federal programs and provide additional safeguards, e.g., stop sale and embargo authorities.

Review of Basic Food Safety Authority

Many states currently have basic broad food safety laws incorporating authorities similar to or identical to the FFD&CA. States should carefully review the basic provisions such as authority to take action on food adulteration.

Review for Produce Safety Authority

Since most states have not had on-farm food regulatory programs, a state needs to ensure it has the legal authority to enter the farm, to inspect against an established regulation, to determine whether food is adulterated, gather evidence, collect and analyze samples and take enforcement actions for violations comparable to federal authority and regulations.

Review Protection of Information Authority

Each state should carefully examine existing authorities regarding what information can be protected as confidential. Many states have adequate statutory authority to protect proprietary practices and confidential business information. The farmers regulated under the produce safety program may claim information should be protected from disclosure. Farmer privacy is protected in many states under other voluntary programs.

When a program becomes mandatory, the change is significant. It traditionally becomes subject to public accessibility and FOIL/FOIA (Freedom of Information Laws / Freedom of Information Acts) laws, which create perceived invasions of privacy. In addition, inconsistencies between federal and state protections of confidential information could result in regulatory partners not being able to share information, hindering the ability to protect public health.

Authority to Enter into Agreements

States should review their legal authority to enter into agreements with other state agencies, non-governmental organizations and the federal government, such as FDA. If intrastate Memorandums of Understanding (MOUs) are utilized, their underlying authority and language should be heavily scrutinized by the legal divisions of any involved state agency to ensure that they are not only appropriate but authorized by state statutes. State agencies should work to enact, through State Legislatures, additional needed legal authorities as identified.

Authority to Adopt Statutory Requirements

States differ widely on the authority to adopt federal statutory language into law. Each state should examine legal authorities and determine what options it has to expand or exercise jurisdiction and become involved in activities related to the Produce Safety Rule. For example, the state must consider whether it is in the best interest of the state to adopt FSMA in its entirety or seek only limited authority to implement a produce safety program.

Efforts are underway to craft model language that will allow states to consider methods to create state law that would align state authority with FSMA requirements. Model language will help ensure consistent state authority.

7.3 Adoption of appropriate state regulations

Authority to Adopt Federal Code and Regulations

Each state has an Administrative Procedures Act (APA) that establishes procedure and requirements for regulations and regulatory activities. Some states allow adoption of federal regulations by reference while others require specific language for adoption. Some states permit automatic adoption of critical rule changes while other states require specific consideration of each change. Each state should carefully review their ability to adopt the Produce Safety Rule to ensure there is a mechanism to keep the regulation current with federal changes.

Some states may choose to amend their existing state authority to incorporate FSMA as it amends the FFD&CA, or pass legislation that aligns state law with FSMA modified portions of the FFD&CA. Finally, others may enter into a cooperative agreement with FDA and subsequently promulgate state rules aligned with the produce safety rule.

Adoption of the US Code and the Code of Federal Regulations by Reference

Many state agencies have also adopted parts of Title 21 of the Code of Federal Regulations word for word, at the time of adoption, or adopted by reference, but have not adopted subsequent revisions. It will be important to verify which Code provision and the date of the last update of the code for the purposes of determining authority under the Produce Safety Rule. Failure to have the proper legal foundation and maintain updates as the regulations are updated or changed over time, presents significant risk of fragmented state produce safety requirements.

The authority to adopt regulations in state statutory language may impact the ability to tailor jurisdiction and regulations to the state's priorities. It is possible to adopt only certain provisions of the Produce Safety Rule; however, partial adoption could increase the complexity of the state produce safety program and could cause confusion in the regulated community. Partial adoption could also jeopardize FDA funding for a state's program.

Methods of Regulation Adoption

Since rule adoption is an integral part of developing a regulatory program, each state should carefully plan for an adoption schedule that will permit continuing alignment to the requirements of the federal Produce Safety Rule. Each state should consider the usual time required for rule adoption under their state's administrative procedures and requirements and should factor in adequate time to appropriately implement the produce safety program or to seek separate means of implementation.

7.4 Determine the State Agency Responsible

Basic food safety programs are authorized and administered by state departments of agriculture, state departments of health and in a few states by other agencies. For agencies that have not had food safety

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authority in the past, but now seek authority to develop a produce safety program, the state program making these decisions must determine who should be responsible for the major components of the produce safety program as a function of the current and potential roles of the state agencies. The major components of the program include: obtaining authority including inspectional authority on farms, establishing or adopting regulatory requirements, ensuring the proper function of an enforcement program and availability of an adjudicative program.

In determining the structure and function of the state produce safety program, state agencies should consider whether establishing an agreement between state agencies is viable and appropriate. Permutations of the division of authority and responsibility include, but are not limited to the following:

- All food safety, including produce safety, reside under one agency;
- Split authority between agencies for general food safety and produce safety; and
- Other permutations such as delegation of primary authority for inspections and enforcement for produce safety programs; creating expanded authority for food safety in a non-agriculture agency and creating an agreement for all on-farm inspections, including mixed-type facilities inspection, to be conducted by the state's agriculture agency; or compliance and outreach activities performed by one agency with inspection and enforcement by another.

Even if a state has legislative authority with respect to produce grown on farms, it is possible that a state may seek to separate the functions of an inspection program for manufactured food from a farm-based inspection with respect to on-farm mixed-type facilities. In addition, it is also feasible for a state agency to have authority and set the regulations but enter into a MOU with another state agency for the purpose of inspections, outreach, and more.

States may establish an MOU, Memorandum of Agreement, Statutory Language or other mechanism for agreement

In states where jurisdiction is split between agencies for certain functions or where the primary food safety agency does not anticipate implementing a produce safety program, an MOU may be the appropriate mechanism to transfer specific and limited authority or responsibility to another agency. Some states authorize a Memorandum of Understanding, Memorandum of Agreement, or some contractual agreement.

7.5 Develop a Timeline

Establish and execute a plan and timeline to develop a state produce safety program.

A state plan should consider the amount of time needed to obtain authority, adopt a Produce Safety Rule, ensure that enforcement mechanisms are present, and an adjudication procedure is in place. The plan should consider legal, legislative, environmental, and political situations such as the timing of state legislative sessions. Although 46 state legislatures meet annually, 4 legislatures (Montana, Nevada, North Dakota and Texas) only hold sessions every other year.

8. Other Considerations

Developing a Registry of Regulated Businesses

Farms are exempt from registration under the §415 of the FFD&C Act, the mechanism by which regulated entities are determined under many federal food regulations. FDA sought feedback under the first

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comment period for the Produce Safety Rule about whether or not FDA should establish a farm registry requirement.

A program is difficult to manage if covered farms and locations are unknown. States may or may not choose to gain or exercise authority to establish a farm registry and should consider several factors in making that decision. Although establishing a farm registration requirement could assist in identifying covered farms, the utility of any farm registration will vary based on how the registration is developed. For example, frequent changes in land leases and cropping decisions may make maintaining an accurate registration difficult.

If a farm registry is established at the state level, the state should consider: the requirements of the registry; the scope of the farm registry; whether it requires a license to operate; associated fees; required information; and more. If a state does seek authority for a farm registry, the state implementing a farm registration should also consider whether the farm registration should or can be protected from public disclosure.

Establish Variance Process

Within FSMA statutory language, the states have the authority to petition for a variance or exemption to requirements. The petition for variance is required to come through a state or foreign government entity. At this time, authority to provide this petition process at a state level generally doesn't exist. In addition to establishing authority, state programs should determine whether and how to coordinate seeking variances from the FDA and develop state procedures to support the application for a variance. Depending upon the state, variance procedures may require rule adoption. While FSMA did not spell out the state management of the variance process, the produce safety rule establishes a variance process following the petition requirements found in 21 CFR Part 10.

References, Attachments and Applicable Models and Templates (TBD) - A list of additional documents, links and templates is under development.

¹ AFDO, as a partner with NASDA in a Cooperative Agreement with FDA, has conducted a survey and rigorous analysis of existing state food safety authority. This listing is an overly simplistic representation of the state programs.

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Chapter 3: Financial Support

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This chapter has been replaced by the funding opportunity announcement issued by FDA and agreements entered into by 46 state agencies.

1. Executive Summary

State regulatory agencies will require substantial financial support to successfully develop and implement comprehensive outreach, education, compliance and enforcement programs in support of the Produce Safety Rule. Each State will elect to implement these new programs differently; this chapter will describe processes to determine the necessary financial resources to support an inspection program based on the Produce Safety Rule.

All State agencies will require resources to establish the training, outreach and education, inspection, compliance, enforcement, laboratory and administrative programs necessary to implement the Produce Safety Rule. While many State programs may have existing resources dedicated to support current regulatory activities, those resources will not be adequate to meet the additional mandates created by the Produce Safety Rule. State agencies charged with developing produce safety programs for the first time will have commensurately higher resource needs in order to develop these programs “from the ground up”.

In recognition of the resources needed to establish a produce safety program, multi-year funding using a grant, cooperative agreement or similarly designed flexible funding vehicle should be utilized to provide financial support to build the necessary infrastructure and capacity. Existing financial vehicles such as State inspection contracts will not suffice to provide the funding necessary to build infrastructure, capacity and capability to establish a produce safety program; innovative performance-based methods should be developed in order to provide funding commensurate with the anticipated resource needs of participating programs.

The proposed funding model includes provisions for tiered baseline funding combined with tiered funding for outreach and education, On-Farm Readiness Review, and inspection activities performed by the State program. Individual program funding would be based on metrics such as the amount or volume of regulated industry and burden on the State agency.

2. Background

Section 105 of FSMA directs the U.S. Food and Drug Administration (FDA) to establish science-based minimum standards for the safe production and harvesting of fruits and vegetables that are raw agricultural commodities. In response to these directives, in 2013 and again in 2014 as supplemental, FDA released the proposed Produce Safety Rule. The Final Produce Safety Rule was issued in November 2015. This rule will impact farms engaged in the growing, harvesting, packing and holding of fresh fruits and vegetables commonly consumed raw. Some farms, depending on the structure of their business or nature of their operations, will also have to comply with the Human Food Preventive Controls Rule.

The law mandates that FDA monitor compliance with the rules in significant part through the inspection process. FDA’s ability to successfully meet the inspection mandates of FSMA is dependent on strong collaboration with State agencies.

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In the context of the Produce Safety Rule, State Departments of Agriculture have institutional knowledge and expertise in the processes related to the safe production of raw agricultural commodities. This institutional knowledge is based on strong working relationships with the farming community and is rooted in mutual trust and understanding of the industry. These State agencies are well-versed in the challenges that the farming community has faced over the past decade.

The goal of the funding proposed herein will enable FDA to effectively and equitably leverage the collective knowledge and expertise of all State agencies and establish a financial basis for State agencies to develop and maintain the infrastructure, capacity and capability to develop produce safety programs to conduct outreach, education and regulatory inspections of produce farms and related facilities.

3. Purpose

The purpose of this chapter is to describe a flexible funding model that incorporates tiered funding levels based on industry volume metrics to determine financial resources for State-led produce safety regulatory programs. The goal of the proposed funding model is to establish a viable means to determine adequate funding for State agencies that is proportional to program needs and volume of regulated industry.

The funding will be utilized to develop and/or expand infrastructure, capacity and capability to conduct outreach, education, inspections, compliance and enforcement on farms and facilities impacted by the Produce Safety Rule. Chapter 4: Outreach/Education and Compliance/Enforcement; Chapter 5: Work Planning; Chapter 6: Information Sharing; Chapter 7: Regulator Training; Chapter 8: Accessing Laboratory Resources; and Chapter 11: Infrastructure provide additional detail on the processes to determine program funding and/or resource needs for successful FSMA implementation.

While this chapter does not specifically address funding for laboratories, states, in assessing the scope of a produce safety program, will want/need to consider where the necessity for laboratory capacity fits in as an integral component of a holistic produce safety program. A comprehensive regulatory assessment of the produce industry should include considerations for sample analysis; this chapter includes references to the importance of laboratory capacity in meeting the food safety and public health mandates of a responsive produce safety regulatory program.

4. Scope

One of the cornerstones of FSMA is the development of enhanced partnerships and collaborations with other government agencies; FDA is tasked with developing and implementing “strategies to leverage and enhance the food safety and defense capacities of State and local agencies”. (See: FDA’s FSMA website at <http://www.fda.gov/Food/GuidanceRegulation/FSMA/>). The mandate to integrate State resources in meeting FSMA food safety objectives is clear, and FDA has publicly stated that they plan to leverage State capacity to assist in meeting these demands.

Many State regulatory agencies already participate in established collaborations with FDA under contracts, cooperative agreements, or partnerships, e.g., Manufactured Food Regulatory Program Standards, RRT

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Cooperative Agreements and FDA Food/Feed/Egg Contracts. Current FDA contracting practices, where a participating State agency receives a fixed-price reimbursement for inspection or sampling/analytical activities based on a yearly negotiated unit cost, cannot be used to develop the infrastructure, capacity and capability necessary to institute food safety programs in support of the FSMA rules. The contracting process may have merit as currently applied to existing regulatory and compliance programs but cannot be used as a model to provide the necessary resources to build, develop and implement new or enhance existing programs to meet the FSMA mandates.

As detailed in other chapters of the NASDA Model Produce Safety Implementation Framework, FSMA produce safety programs will be resource-intensive and States will require financial support in order to successfully develop programs responsive to the mandate of increasing public health protection. See Chapter 11: Infrastructure for a more in-depth discussion of assessing State program infrastructure, capacity and capability. Participating agencies will need funding to accomplish the following, using a funding instrument such as a grant or cooperative agreement:

Year 1: Assessment of Current Capacity and Capabilities to Identify Gaps and Develop Strategic Plans:

- Assess industry volume, begin process of identifying industry, developing an inventory and establishing priorities (recognizing the need to establish a risk profile of the farm and when a farm needs to be inspected, i.e., when each farm needs to comply – may not be able to do so until after a first visit to the farm);
- Assess current infrastructure including Information Technology (IT) needs to support development and implementation of a produce safety program;
- Assess foundation of law and ability to enter into MOUs with partners as appropriate and initiate the process of establishing appropriate regulatory authority;
- Assess programmatic capacity and capability to implement a produce safety program that includes (as determined by program goals):
 - o Education
 - o Outreach
 - o On-Farm Readiness Review
 - o Inspection
 - o Compliance and Enforcement
 - o Laboratory
- Assess program goals (education, outreach, inspection, enforcement, and laboratory) and determine gaps in current capacity, capability and infrastructure to meet goals;
- For each assessment area and identified gaps, develop a strategic implementation plan with specific tasks, objectives, timelines and milestones for short- and long-term programmatic development;
- Participate in educational sessions and meetings with industry and other regulators to build awareness of Produce Safety Rule requirements; and
- Establish information sharing processes with Local, State, Tribal and Federal partners.

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Years 2 -3: State Program Development

- Continued development of Year 1 deliverables;
- Develop strategies for administrative support programs to support IT development, outreach, education, inspection, compliance and enforcement programs;
- Develop strategies and administer industry outreach and educational programs to build an awareness of and encourage compliance with the Produce Safety Rule;
- Obtain training for inspection, compliance and management personnel, and plan for implementation of these functions including:
 - Develop strategies to implement a comprehensive produce inspection program that includes provisions for significant outreach and education prior to and during compliance and enforcement;
 - Develop strategies for appropriate, uniform and consistent nationwide compliance and enforcement programs;
 - Develop strategies for product sampling and analysis protocols, to be employed as necessary during inspections or investigations, or, as an alternative, establish a relationship with a servicing laboratory to meet analytical needs;
- Establish/formalize partnerships with academic institutions, industry experts and associations as appropriate;
- Ensure regulatory authority, temporary credentialing, MOUs are in place;
- Develop and begin to deliver outreach, education, on-farm readiness review programs for industry;
- Initiate IT development for data sharing, etc.; and
- Participate in pilot programs.

Years 4 – 6: Implementation

- Continued development and implementation of Year 1 through 3 deliverables;
- Conduct extensive industry outreach, education, on-farm readiness review programs;
- Identify best management practices and mitigation strategies to facilitate industry compliance activities;
- Facilitate information sharing among impacted stakeholders to share/exchange educational materials, information on alternatives/variances, emerging scientific information, validation processes as appropriate to the industry and rule;
- Collaborate with impacted stakeholders regarding FSMA implementation; and
- Initiate inspection program including, as appropriate, laboratory support, compliance and enforcement.

5. Summary of desired outcomes

State agencies that elect to participate and are selected to receive funding should have the option to receive tiered baseline funding and additional funding specifically for: industry outreach and education; regulator training; on-farm readiness reviews: and inspectional activities including provisions for analytical support

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as necessary. Produce safety program funding should be based on programmatic needs, sustainable and multi-year, optimally providing continued funding adequate to support sustainable State programs.

Tiered funding means that funding should be offered in tiers, with States regulating the greatest number of farms being placed in the higher tiers; the number of tiers used would be based on available funding, program needs, and regulatory priorities. Individual funding instruments (grants, cooperative agreements) should offer no less than 5 years of funding to enable efficient and effective long-term planning for States and FDA.

All States will be strongly encouraged to develop produce safety programs, recognizing that there will be some variability in scope and approach among state agencies. The receipt of FDA funds by a state agency to support the development and implementation of a produce safety program should not be contingent upon participation of the agency in other FDA initiatives such as a food inspection contract.

Recognizing that States may develop components of a produce safety program at different rates or may elect to develop only certain components of a produce safety program such as outreach and education, a menu-driven concept should be considered to determine individual program funding. By utilizing a menu-driven model, state agencies can customize their funding to meet short- and long-term programmatic needs and receive funding on a timetable that mirrors their plans for developing holistic programs.

During the initial phases of developing a program, for example, a State may select tiered baseline and outreach and education funding and add On-Farm Readiness Review and inspection funding in subsequent years as appropriate to their program development. The added measures of flexibility created by using a menu driven system will allow States to customize funding which will, in turn, result in more effective utilization of FSMA appropriations.

The following is an EXAMPLE of a plan for baseline and category-based funding over a six-year period, one that could be tiered to offer funding based on the size of the program developed by each state. *For a specific illustration of how this EXAMPLE plan might work, for a state with a mid-range number of covered farms and moderate program needs.*

Funding line descriptions:

- Tiered Baseline funding:

Begins in Year 1 of funding, this is tiered baseline funding available to all state agencies that choose to develop a produce safety program, for use in developing and implementing the basic components of a produce safety program including industry outreach and education programs as detailed above.

The allocation of funds would be based on metrics that approximate the volume of regulated industry (total number of produce farms) as well as responsiveness of the state proposal. The number of funding tiers, the amount of base funding per state for each tier, and the ranges of covered farms in each tier could be

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varied based on the amount of total funding appropriated and the number of states that choose to participate. Needs for each funding category would also likely vary over time (additional base funding in early years, for example, to allow additional funding during the program development phase in each state).

- o Years 1 – 3 Baseline funding is at its highest point, to allow support for program development activities.

- o Years 4 – 5 Baseline funding is reduced, with resources shifting to other priorities.

- o Year 6 Baseline funding settles to a level that allows program sustainability.

Note that a portion of the baseline funding could be awarded, using a subcontract, to Land Grant Universities, cooperative extension programs or other entities as appropriate to support collaborative efforts such as startup of outreach and education activities.

- Tiered Education, Outreach and Technical Assistance Funding:

Begins in Year 2 of funding, provided to support efforts to develop and deliver industry outreach, education and technical assistance as well as to support regulator training. Some state departments of agriculture may have a coordinating role in education, while the education function may be completely separate from the state agencies in other states. As a general rule, funding for education will need to be available for all states; the mechanisms may differ, however, and will need to be identified and/or developed.

- o Year 1 – States receive baseline funding only.

- o Years 2 – 4 Education, Outreach and Technical Assistance funding is at its highest point, to allow support for program development activities.

- o Years 5 - 6 Education, Outreach and Technical Assistance funding settles to a level that allows program sustainability.

Note that a portion of the Education, Outreach and Technical Assistance funding could be awarded, using a subcontract, to Land Grant Universities, cooperative extension programs or other entities as appropriate to support collaborative efforts.

- On-Farm Readiness Review Funding:

Begins in Year 2 of funding, provided to support program activities to conduct on-farm readiness reviews.

- o Year 1 States receive baseline funding only.

- o Years 2 – 4 Per review, funding based on metric goals in each State, to support State personnel participation.

- o Years 5 – 6 Per review, funding based on metric goals in each State, to support State personnel participation.

- Inspection Funding:

Begins in Year 4 of funding, provided to support State personnel conducting regulatory inspections of covered farms.

- o Year 1 – States receive baseline funding only.

- o Years 2 – 3 States receive baseline and/or Education/Outreach and Technical Assistance and/or On-Farm Readiness Review funding.

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- o Years 4 - 6 Per inspection funding based on metric goals in each State, to support inspections by State personnel:
 - Full inspections of large farms at a pre-determined maximum percentage of farms (to be determined by available funding and metrics, and FDA/State goals and priorities) subject to the produce safety rule, at a per inspection rate to be determined FDA/States.
 - Targeted inspections of large farms at a pre-determined maximum percentage of farms (to be determined by available funding and metrics, and FDA/State goals and priorities) subject to the produce safety rule, at a per inspection rate to be determined FDA/States.
 - Re-inspections, up to 25% of total full and targeted inspections at a per inspection rate to be determined by FDA/States.
 - Sample collection and analysis, up to 10% of farms inspected, at a per sample rate to be determined by FDA/States.

Following is an EXAMPLE of how funding could progress over six years for a state with a mid-range number of covered farms and moderate program needs (AMOUNTS USED ARE FOR ILLUSTRATION PURPOSES ONLY – ACTUAL FUNDING AMOUNTS WILL BE COMPETITIVELY AWARDED BASED ON ACTUAL PROGRAM NEEDS AND THE AVAILABILITY AND AMOUNT OF APPROPRIATED FUNDING):

6-Year Funding for State X (mid-range number of covered farms and moderate program needs):

	YR1	YR2	YR3	YR4	YR5	YR6
Baseline:	500,000	500,000	500,000	400,000	400,000	300,000
Education/Outreach:	0	300,000	300,000	300,000	200,000	200,000
On-Farm Readiness Reviews:	0	13,500	13,500	13,500	7,500	7,500
Inspection:	<u>0</u>	<u>0</u>	<u>0</u>	<u>38,000</u>	<u>64,500</u>	<u>159,500</u>
Total Funding	500,000	813,500	813,500	751,500	672,000	667,000

Again, the specific funding amounts listed above are offered as EXAMPLES only, for illustration purposes. Actual funding amounts per state, number of funding tiers, and metrics used within each tier will vary based on the actual amount of funds appropriated, number of states that choose to participate, responsiveness of state proposals, and other factors.

Combined, the different funding components listed above provide States with the resources necessary to develop holistic produce safety programs that include industry outreach and education, inspection, compliance and enforcement.

6. Responsibilities

6.1 State Department of Agriculture (or other State agency)

The State agency should develop and maintain the infrastructure, capacity and capability to initiate and maintain a produce safety program in accordance with the requirements of any funding obligation. The

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participating State agency should be willing to coordinate and share information relative to produce safety program activities such as outreach, education, training, and inspections with Federal/State partners as appropriate. (See Chapters 5. Work Planning and 6. Information Sharing).

6.2 FDA

FDA should evaluate the feasibility of providing funding for State produce safety programs consistent with the model proposed in this document, or similar models that provide the same degree of flexibility to accommodate all permutations of program objectives, degree of participation, size of industry and expectations. FSMA mandates that FDA should provide support, guidance and oversight to the issuance of funding and ongoing project accomplishments as appropriate. FDA should readily share information with State agencies regarding the funding process (to the extent permissible by law, particularly during periods of open competition), during and throughout the duration of the project.

6.3 Associations

Associations, such as NASDA, AFDO, ASTHO or others as appropriate, will facilitate the exchange of information to assist State programs in obtaining financial support, and provide assistance as appropriate during and throughout FSMA implementation.

7. Related Documents

7.1 NASDA FSMA Operational Framework, Chapter 4. Outreach/Education and Compliance/ Enforcement

7.2 NASDA FSMA Operational Framework, Chapter 5. Work Planning

7.3 NASDA FSMA Operational Framework, Chapter 6. Information Sharing

7.3 NASDA FSMA Operational Framework, Chapter 7. Regulator Training

7.4 NASDA FSMA Operational Framework, Chapter 8. Accessing Laboratory Resources

7.5 NASDA FSMA Operation Framework, Chapter 11. Infrastructure

8. Definitions

“On-Farm Readiness Review Program”: A voluntary on-farm program in which assistance is provided to promote compliance with the requirements of the Produce Safety Rule through a pre-inspectional readiness review.

“Covered by the Produce Safety Rule”: A farm or mixed-type facility with an average monetary value of produce (as defined in 112.3(c) of the Produce Safety rule) sold during the previous 3-year period of more than \$25,000 (on a rolling basis) that conducts a “covered activity” on “covered produce” as defined in the Rule.

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of “farm” as defined in this chapter. This part does not

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1803 apply to activities of a facility that are subject to part 110 of this chapter. (Reference: Produce Safety
1804 Rule Supplemental Proposal, September 29, 2014)
1805
1806 *Covered produce* means produce that is subject to the requirements of this part in accordance with
1807 §§ 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the
1808 crop. (Reference: Produce Safety Rule Original Proposal, January 16, 2013)
1809
1810 *“Volume of regulated industry” or “Industry Volume”*: Number of farms per State covered under the
1811 Produce Safety Rule; this is inclusive of all size designations, permutations of covered commodities and
1812 farms eligible for the qualified exemption provided under §112.5.

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Chapter 4: Outreach/Education and Compliance/Enforcement

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1. Executive Summary

The Outreach/Education and Compliance/Enforcement Chapter details some of the necessary components to successful implementation of the United States Food and Drug Administration’s (FDA) rule regarding the “Standards for Growing, Harvesting, Packing and Holding Produce for Human Consumption” (Produce Safety Rule). The implementation framework includes outreach/education activities and effective compliance/enforcement program strategies. The framework’s purpose is to identify the necessary processes to ensure effective administration of and compliance with the Produce Safety Rule as well as to ensure initial education on preventive practices. The successful implementation of the Produce Safety Rule requires collaboration between regulatory agencies (state and federal), industry, academia and others to ensure standard and uniform application of the rule and the continuous identification and development of risk-based best practices to support enhanced food safety.

Outreach activities are designed to promote self-identification, encourage proactive compliance in advance of regulatory action and provide education. This requires identifying and connecting with targeted produce industry stakeholders that represent diverse commodity groups, various growing regions, farming practices, and various sizes of operations. The outreach component also aims to reach regulatory, academic, industry, 3rd parties, and other interested partners (produce safety stakeholders) to advance the content and development of the educational materials.

The education plan outlined in this chapter focuses on the creation and delivery of a core curriculum. The educational materials therein focus on understanding the public health significance, knowledge and application of the rule. These materials are created to target regulators, food safety staff, the regulated industry and other stakeholders including academia and auditors. These materials also consider the diversity of the farming industry (farm types, production methods, commodities grown, growing seasons and other regional differences). This curriculum will be delivered through various mediums and will include the availability of an educational on-site farm assessment (On-Farm Readiness Review). The primary goal of the on-site assessment is to further educate the industry by allowing them to knowledgeably assess their farms, evaluate their current food safety practices and seek alignment with existing farm practices and rule requirements. A secondary goal is to familiarize industry with existing regulatory process which includes inspection processes as well as compliance and enforcement activities.

Regulatory inspections begin when the firm is required to be in compliance based on the rule’s defined timelines and criteria. The initial inspection will have an informational emphasis; the second (routine) inspection as well as follow-up inspections will be more structured and formal; enhanced regulatory inspections will be conducted in for cause situations. In an effort to effectively and efficiently implement the rule, a program that utilizes a preventive and proactive approach with major focuses on education and effective compliance and enforcement strategies is proposed and detailed in this chapter. Finally, the framework recognizes the importance of partnering with industry, constituencies, interested parties and our regulatory peers.

2. Purpose

The Produce Safety Rule promulgated under FSMA is designed to protect public health and minimize the risk through preventive practices of foodborne illness that would result from microbially contaminated produce. This chapter is designed to address both the education and regulation components of the rule's implementation.

Education Before Regulation: Compliance traditionally has been encouraged through enforcement actions. We realize, however, that education can drive compliance as well. The education before regulation concept incorporates both of those principles -the preferential use of education to drive compliance while maintaining the ability for regulation and enforcement. Protecting public health is of the utmost importance; as such compliance must be achieved and enforcement actions should be used as necessary to assure that protection. Here we propose both the educational and regulatory plans to effectively gain compliance. The role of buyers, and their expectations, can also drive compliance and should be incorporated into effective education efforts.

3.Scope

The Produce Safety Rule promulgated under FSMA was written to protect public health and minimize the risk of foodborne illness that would result from microbially contaminated produce, through preventive practices.

Successful rule implementation efforts will include education and outreach activities which provide both the regulators and the regulated communities with knowledge of the rule's requirements and how to effectively implement the rule's various provisions. Through effective outreach and education activities, industry will be empowered to seek compliance with rule requirements and maintain the ability to conduct self-assessments and take immediate corrective actions as needed. Along with outreach and education activities, effective compliance program and enforcement strategies must be developed and implemented. These strategies will focus on education to promote compliance but also include timely enforcement actions which can be used (as needed) to achieve compliance.

This chapter details the implementation framework on how to provide outreach and education and describes a model compliance program and suggested enforcement strategies.

4.Background

FSMA

FSMA was signed into law by President Obama on January 4, 2011, to better protect public health by helping to ensure the safety and security of the food supply. FSMA embraces preventing food safety problems as the foundation of a modern food safety system. The proposed rule would set forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated.

FSMA requirements would enhance prevention activities (as they relate to food safety hazards) by ensuring preventive measures and a timely and effective response. Requirements include the creation of inspection and compliance activities, efficient and effective response to food safety emergencies, ensuring appropriate

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1908 food import activities, and continuing to develop and refine partnerships between regulatory agencies and
1909 other food safety stakeholders.

1910 Other Initiatives

1911 In 1998, the FDA published the “Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards
1912 for Fresh Fruit and Vegetables” (Guide), in an effort to provide best practices to reduce food safety hazards
1913 in the production and handling of fresh fruit and vegetable products. Cases of illness were associated with
1914 leafy green vegetables and tomatoes between the years 1999-2006, which resulted in letters from FDA to
1915 industries in California and Florida in 2004. Simultaneously, purchasers of produce (retailers and
1916 processors) started requesting documentation from producers to prove that they were following the
1917 practices outlined in the Guide. Private audit firms began offering audits to demonstrate that growers were
1918 using good agricultural practices as outlined in the Guide.

1919 The [United States Department of Agriculture](#), Agricultural Marketing Service (USDA/AMS) began
1920 conducting voluntary audits based on the Guide in 2002 after the New Jersey Department of Agriculture
1921 petitioned USDA-AMS to implement an audit based program to verify conformance with the Guide. Since
1922 2002, voluntary audit programs have evolved and include additional commodity specific guidelines,
1923 generally spearheaded by individual industries, for mushrooms, tomatoes, leafy greens, sprouts, onions,
1924 potatoes, and cantaloupes.

1925 In 2006, the Florida tomato industry, after three years of efforts crafting a program of good agricultural
1926 practices (T-GAPs) and best management practices (T-BMPs), formally adopted these GAPs and BMPs as
1927 standards. Within the year, industry cooperated with the food safety regulatory agency, the Florida
1928 Department of Agriculture and Consumer Services (FDACS), to pass legislation through the Florida
1929 Legislature in 2007, establishing the first mandatory government produce safety program in the nation.

1930 In 2009, over 100 produce industry sectors, academics and international participants from Mexico and
1931 Canada as well as USDA and FDA participated as part of the Good Agricultural Practices (GAPs)
1932 Harmonization Initiative which "harmonized" fourteen of the major North American GAP audit standards
1933 and culminated in 2011 with the release and implementation of the Produce GAPs Harmonized Food Safety
1934 Standard. The Harmonized Standard is used by both governmental and private audit groups. Additional
1935 efforts have been made to ensure international harmonization with Global GAPs and to meet the
1936 requirements of the Global Food Safety Initiative (GFSI). It is important to note that USDA and private party
1937 audits based on the Guide have been historically voluntary and are primarily buyer driven.

1938 The next step is to capitalize on the work done by all parties regarding produce safety activities and put into
1939 place science-based best practices and standards for the growing, harvesting, packing and holding of fruits
1940 and vegetables.

1941

1942 **5.Implementation Strategies**

1943 Implementation strategies ensure the successful implementation of the Produce Safety Rule and should be
1944 considered the tasks necessary to achieve short- and long-term goals.

1945

1946 Implementation strategies include:

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- 1947 • Funding model;
- 1948 • Pre-implementation risk analyses and assessments;
- 1949 • Resource needs assessment;
- 1950 • Oversight and monitoring activities;
- 1951 • Strategic planning (which include reasonable timelines, benchmarks, target dates and the
- 1952 development of project implementation schedules, GANNT charts etc.); and
- 1953 • Education of state and federal regulators and food safety staff.
- 1954

1955 **6. Outcomes, Objectives and Process Overview**

1956 The desired outcome provides for an educated food safety staff and an educated regulated community that
1957 participates, complies, and adopts the rule, fully incorporating its principles in efforts to improve food safety
1958 and protect public health. An additional outcome provides for a regulatory system that promotes
1959 compliance through education, while maintaining a structured enforcement program that is used to
1960 encourage and require compliance.

1961 **6.1 Planned Objectives:**

- 1962 • Provide effective outreach strategies and activities;
- 1963 • Develop an effective education plan (consistency and standardization of materials etc.);
- 1964 • Educate regulators, industry, and other partners;
- 1965 • Develop strategies to achieve compliance (incentive programs); and
- 1966 • Develop a consistent and standardized compliance and enforcement program to be used as needed.

1967 **6.2 Outreach Activities**

1968 Outreach efforts include identifying and connecting with targeted produce industry stakeholders that
1969 represent diverse commodity groups, various growing regions, farming practices, and various sizes of
1970 operations, to promote self-identification and encourage compliance with industry taking proactive efforts
1971 to be in compliance in advance of regulatory action. Another effort is designed to reach regulatory,
1972 academic, private companies, 3rd parties, and other interested partners to advance the development of the
1973 educational materials and leverage private resources.

1974 The Produce Safety Rule impacts an industry that has historically been unregulated regarding food safety.
1975 As such, outreach and education, inspection/audit programs, and effective compliance and enforcement
1976 activities are imperative to ensure successful implementation and compliance with the rule. Educating the
1977 industry on the Produce Safety Rule will be of major importance and will present a major challenge to
1978 accomplishing this task. Coupled with the absence of prior food safety regulation, most produce farms
1979 were not required to identify themselves to regulatory authorities. This self-identification issue will have
1980 continued programmatic impacts as inspection resources are assessed, data warehousing and processing
1981 mechanisms are created, and workload planning (commodity/region/farming practice) is being done. Thus,
1982 outreach to the farms to provide the necessary education will be an iterative process and may prove to be
1983 challenging without a comprehensive listing of farms.

1984 To reach the desired audience, partnerships will have to be formed with farming organizations and
1985 associations, land grant university extension programs, USDA AMS programs and other groups to identify

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1986 and reach the covered farming communities. Effective strategies must be developed to encourage farms to
1987 voluntarily identify themselves.

1988 Although there are farms exempt from the rule, we recognize that in the interest of public health, and given
1989 our knowledge of the fluctuation in farming business practices that could have many farms transitioning in
1990 an out of regulated status from year to year, outreach efforts should be directed towards all farms, so
1991 education can be made available to farmers across the board.

1992 **Encouraging Participation through Outreach**

1993 A well-executed outreach plan that accurately details the elements of the rule and focuses on benefits of
1994 the new requirements will maximize initial participation. Providing clarity of rule requirements will help
1995 reduce industry anxiety caused by misinformation.

1996 Key elements include the following efforts:

- 1997 1. Research and identify constituency groups, industry, including buyers, and interested parties.
- 1998 2. Develop a communication plan which is focused on targeted audiences.
- 1999 3. Motivate member participation through cooperation with commodity groups/organizations and
2000 farm groups. The involvement of buyers, and their expectations, should also be leveraged.
- 2001 4. Outreach to small farms, regardless of their exempt or non-exempt status. Small farms may not
2002 be included in the scope of the compliance plan for the Produce Safety Rule. However, in the
2003 interest of public health, voluntary early adoption of the Produce Safety Rule should be
2004 encouraged, actionable through programs, and able to be validated through certification.

2005 **6.3 Education Activities**

2006 Education is the delivery of critical knowledge needed to ensure that the rule is fully understood. The
2007 education plan outlined in this chapter focuses on the creation and delivery of a core curriculum and should
2008 serve as the foundation of knowledge which can be built upon to support future activities (trainings,
2009 implementation of new processes). Education should not be interchanged with the term “training.”
2010 Training provides instruction on how to apply knowledge and skills, ensuring consistent compliance with
2011 the rule regardless of location. Regulator training is covered in Chapter 7.

2012 Educational opportunities present themselves throughout the regulatory continuum. The educational
2013 materials therein focus on understanding the public health significance of the rule, knowledge of the rule’s
2014 components and the on-farm applicability of the rule. Educational materials will target various audiences
2015 including regulators, food safety staff, the regulated industry, and other stakeholders (including academia
2016 and auditors) and will consider the diversity of the farming industry production methods, commodities
2017 grown, growing seasons and other regional differences. This curriculum will be delivered through various
2018 media and may include an educational on-farm assessment. One goal of this assessment is to further
2019 educate the industry, allowing them to knowledgeably assess their farms, evaluate their current food safety
2020 practices and align themselves with requirements contained in the rule. Another goal aims to familiarize
2021 them with the regulatory process, which includes inspection, compliance, and enforcement activities.

2022 **Education Plan**

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The education plan should include a fundamental understanding of the Produce Safety Rule with respect to the public health significance of the rule, knowledge of the rule’s components and the on-farm applicability of the rule.

1. Establish Audience: Various audiences are targeted; regulators (food safety staff), the regulated industry (owners, farm managers, crew chiefs and farm workers), and other stakeholders including academia and auditors. Similarly, consideration is taken of the diversity of the farming industry (production methods, commodities grown, growing seasons and other regional differences). Although the information will be consistent, some audiences will have a varied delivery mode or emphasis.
2. Create and leverage existing educational materials sanctioned by the FDA.
 - a. Enlist cooperation with Produce Safety Alliance (PSA), DHRD, IFPTI, AFDO and other Subject Matter Experts (SMEs) from academia, private companies, along with other regulatory bodies on the identification or creation of educational materials.
 - b. Materials could include standardized educational packets and modules.
 - c. Materials should be audience-oriented (language, appropriate to audience, role on farm, etc.)
3. Establish appropriate notification methods of education opportunities:
 - a. Perform Outreach: Regional, Local, and Seasonal
 - i. Regulatory community
 - ii. Regulated community: Commodity Groups, Commodity Group Meetings, News Organizations, Television, Radio, Social Media.
 1. It is critical to reach the maximum number of affected growers/producers.
4. Conduct standardized educational sessions (by qualified bodies).
 - a. Education will be delivered through multiple mediums and in multiple locations
 - i. Live Sessions
 - ii. Webinars
 1. Must be available in perpetuity, updated as needed and with the opportunity for participation and completion to be documented.
 - iii. Website - Developed for ease of use, to guide regulators through requirements and to provide a central location to obtain information such as written interpretations, guidance documents for industry and regulators, template forms, procedures, policies, etc.
 1. Opportunity exists to capitalize on existing, effective resources. (Ex. Produce Safety Alliance (PSA); FamilyFarmed.org; onfarmfoodsafety.org; Academia/Extension Faculty)
5. Conduct on-farm, non-regulatory educational assessment (described in section 6.3 with example provided in *Chapter 4 Appendix 1 – available as a separate document upon request*)

6.4 Initial On-farm, Non-Regulatory Readiness Reviews

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The goal for the final stage of the education processes includes the voluntary on-farm, non-regulatory readiness reviews (On-Farm Readiness Reviews: For details, see the separate document entitled: *Chapter 4 Appendix 1 – FDA/States Produce Safety On-Farm Readiness Review Process*). These reviews are designed to ensure the farmer is: educated on regulatory inspections and the applicability of the rule to their farming operation, provided examples of food safety and produce farming best practices that are in alignment with the rule and shown examples of compliant vs. non-compliant farming activities.

Entities conducting these types of reviews will vary depending on the state. If non-compliant activities are identified, non-regulatory agents can assist in resolving areas that need improvement. If conducted by a regulator, these non-regulatory reviews should occur on the farm prior to the time the farm must come into compliance. It is likely that not all farms will get this type of review due to lack of resources (educators, regulatory entities, academia, partners, etc.); as such, the initial regulatory inspection will be conducted with an informational focus. Non-regulatory agencies may continue performing these reviews after the regulations have gone into effect.

Several models may work for this readiness review phase, but the process developed with FDA/State input is outlined in *Chapter 4 Appendix 1 (separate attachment available upon request)*. Each state must have flexibility to allocate resources and perform reviews according to their state needs and risk environment. For example, it is likely that some states will not allow regulatory inspectors to conduct these readiness reviews. NASDA encourages flexibility in the administration of readiness reviews. Some potential participants for the pre-assessment inspection model include dedicated university extension personnel, state agency marketing division personnel, third parties, or state inspection personnel who will also conduct regulatory inspections.

On-Farm Readiness Reviews for the regulated community will include several components:

1. Provide materials to simplify path to success: template safety plans, recordkeeping, and examples of compliance plans.
2. Provide examples of egregious violations that would result in a significant public health threat and subsequent failed inspection, empowering farms with the opportunity to succeed and maintain compliance.
3. Conduct On-Farm Readiness Review/ walk-through farm assessment.
 - a. Notification to farm agent that an egregious violation will result in immediate corrective action or possible stoppage of activities (e.g. observation of immediate food safety risk in operation that has not been appropriately corrected).
 - i. This step will necessitate a specific compliance and enforcement strategy for the regulator (a written improvement plan would be a valuable tool here).
 - b. May or may not be performed by same inspector who performs regulatory inspection for reasons of liability.
 - c. Include an introductory meeting to explain the process and have the farm contact participate in the readiness review.
 - d. Identify areas of improvement in operations from field to pack out using Produce Safety Rule requirements as guidelines. For consistency, it is important that the readiness reviews use the same form that will be used for the regulatory inspection(s).
 - e. Observations verbally communicated to farm as they are observed.
 - i. Identify deficiencies to farm agent as observed.
 - ii. Educate farm agent on how they might mitigate deficiencies.

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1. The line between regulatory inspection and readiness reviews must be observed.
- iii. Immediately address deficiencies that would pose an imminent public health threat.

6.5 Incentive Program

Incentives implemented in both the educational and regulatory components can promote earlier acceptance and understanding of rule requirements and encourage more effective compliance. A process to identify potential incentives and engage with the community will be developed. Examples of incentives are given here:

1. Participation in educational programs by the regulated community will make them eligible for an initial on-farm, educational readiness review in preparation for their upcoming regulatory inspections.
2. Once regulatory inspections begin, a well-defined incentive program to reduce inspection frequencies or length can be implemented. This program will be risk-based evaluating the commodity's known risk, region, and compliance history.

7.Compliance Activities

The goal of the compliance phase is to evaluate, encourage, and require compliance through regulatory inspections. Nothing in this section is meant to preclude compliance activities, for-cause investigations, and/or assignments. The authority for conducting regulatory inspections and who are to perform the same has not been determined. All states are different as to statutory authority and program structure and determination will need to be made regarding participation in rule enforcement. Trained regulators (see Training Chapter 7) conduct on-farm inspections and report on both compliant and non-compliant findings. The response to these findings results in corrective actions that could lead to follow up inspections and/or other measures.

7.1 Compliance Components

1. The inspection identifies conformance and non-conformance with the requirements established in the Produce Safety Rule and notes it on a standardized inspection form.
2. Re-inspections can be utilized to verify correction of prior non-conformances.
3. Egregious violations: stop sale, stop use, embargo, seizure or a voluntary agreement to cease operations can be utilized to stop the shipment of produce and ensure correction. Egregious violations would include those materially related to food safety with a high likelihood of rendering the produce adulterated. A follow-up inspection is conducted (requested by the farm) within 10 days of initial inspection if possible. The result is the issuance of information, warning or certified warning letters or other regulatory responses such as Voluntary Agreement to Cease Operations, Stop Sale, Stop Use Embargo or recall or request for regulatory meeting.
4. Inspections will be classified as:
 - a. No Action Indicated: farm in compliance with rule and will be inspected per routine schedule.
 - b. Action Indicated: (Two Categories):

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- i. Voluntary Action Indicated: farm generally in compliance with the rule with minor violations. Farm has indicated corrective actions will be taken; program elects whether to conduct a re-inspection to verify corrective actions.
- ii. Official Action Indicated: Egregious violations materially related to food safety have been observed and program has utilized embargo, stop use, stop sale or seizure authority and requested a recall or a voluntary agreement to cease operations. Farm may receive official correspondence, request for regulatory meeting and will be re-inspected to verify compliance.

7.2 Regulatory Inspections

Inspections begin when the firm is required to be in compliance based on the rule's defined timelines and criteria. Timing of routine inspections, follow-up and re-inspections must take into account the growing and harvesting seasons with respect to the type of commodity.

Initial Regulatory Inspection:

Initial regulatory inspections of a farm are conducted to identify conformance and non-conformance with Produce Safety Rule. The farm may or may not have had a voluntary on-farm, non-regulatory educational assessment and also may not have attended or participated in industry education or training sessions. As such, the initial regulatory inspection includes some explanation of the regulatory expectations and is conducted with an informational focus. Based on available regulatory resources, every farm may not receive their initial regulatory inspection (informational focused inspection) within a desired time frame.

A determination will be made that if a farm has not had their initial regulatory inspection within a set time frame after implementation of the Produce Safety Rule, as to whether their first inspection will be classified as "initial" or whether the routine inspection will be performed. The initial regulatory inspection is designed to explain enforcement concepts to regulated industry but is typically conducted with a focus on education.

1. Farm is issued an observation sheet (narrative) that details items that are in compliance as well as any violations.
2. The farm may conduct corrective action activities in an appropriate manner and in agreement with the regulatory program prior to increased enforcement action.
3. The regulatory program may elect to conduct a re-inspection as appropriate. Significant/egregious violations that are likely to result in adulterated product are addressed through voluntary cease operations, embargo, and recall as appropriate.
4. Development of an improvement plan to highlight improvements needed, provide a measurement for improvement for regulators and help farmers prioritize improvements.

Routine and follow-up inspections

Number of routine inspections will be performed as discussed in Work Planning, Chapter 10. Follow-up or re-inspections are performed to verify corrective actions are implemented as appropriate to the situation and non-conformances mitigated.

1. The routine inspections, follow-up or re-inspection moves industry from an informational inspection to a more structured compliance and enforcement program.
 - a. Inspection history is evaluated by regulator.

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- b. Compliance with corrective actions is followed up by the same inspector who performs initial regulatory inspection - when possible.

Any issues identified in the inspection should be corrected and addressed. If not immediately corrected, a workable timeline for correction should be established.

Repeat violations or non-conformances may result in the issuance of an information letter, warning or certified warning letters or other regulatory responses such as voluntary agreement to cease operations, embargo/stop sale; order of product destruction, recall, or a regulatory meeting will be used as necessary.

Enhanced Regulatory Inspection:

Enhanced regulatory inspections are conducted after a farm has been found to be or is suspected of being substantially out of compliance with the Produce Safety Rule or “for cause” (connection to recall or foodborne illness outbreak investigation). Proactive measures will be taken to protect public health.

Enhanced Regulatory Inspection:

1. Will include assessment of compliance with Produce Safety Rule and may include environmental monitoring and product testing.
2. Farm will be advised to identify lots (of product) and may be advised to hold product; program will expedite analysis where laboratory confirmation is necessary.
3. May be conducted prior to or in response to FDA withdrawal of exemption.

Produce Sampling and Laboratory Analysis Considerations

Detailed descriptions of laboratory needs are provided in Chapter 8. Here laboratory analysis is discussed with respect to the aforementioned compliance and enforcement activities (enhanced regulatory inspections).

Regulatory sampling and laboratory analyses of samples collected during for-cause or enhanced regulatory inspections require additional resources of a state regulatory program. States should determine their laboratory’s capacity to perform the work and the impact those additional functions have on their current operations and food safety mission. Each portion of the laboratory protocols will require specific training for the samplers and the laboratory personnel. Based on the current accreditations held by a laboratory and the type of work currently being performed there, the amount of training may differ greatly from one state’s lab to another. There is also the possibility that these protocols will have to be developed and carried out by some third party. Training needs are addressed in Chapter 7 and laboratory needs are addressed in Chapter 8.

8. Enforcement and Administrative Activities

Enforcement activities are necessary to ensure compliance with applicable Produce Rule requirements. Publicly available activities include but are not limited to:

- Advisory Notices;
- Press releases;
- Warning Letters;

2225 License/Permit Revocation;
2226 Certified Warning Letters;
2227 Stop Use Orders;
2228 Stop Sale and Hold Orders;
2229 Embargos;
2230 Recalls;
2231 Destruction of Product Orders;
2232 Seizures;
2233 Voluntary Agreement to Cease Operations;
2234 Regulatory Compliance Meetings;
2235 Criminal Prosecution;
2236 Withdrawal of Qualified Exemption;
2237 Administrative Fines; and
2238 Final Orders for Unpaid Administrative Fines.

2239 The types of enforcement activities will vary as determined by the respective enforcement authority. One
2240 of the primary goals is to gain compliance with applicable Produce Rule requirements as opposed to
2241 imposing financial sanctions for non-compliance.

2242

2243 **9. Responsibilities**

2244 Responsibilities can vary greatly based on the legal authority an entity has to participate in the regulation
2245 of this rule. Legal authority is detailed further in Chapter 2 (Foundation of Law). This section identifies
2246 regulatory and partner entities associated with the Produce Safety Rule and identifies some of the
2247 responsibilities they may assume in the implementation of this rule.

2248 **State Agency**

2249 Individual states may elect to be the lead in implementing on-farm produce safety inspections, provided
2250 that adequate resources are made available. States may need to modify existing laws, rules, regulations,
2251 policies, and procedures to accommodate the rule requirements. It is important to include this as part of
2252 the needs assessment to determine the level of effort and associated costs. Each state should determine
2253 the degree to which they adopt rule requirements and participate in rule implementation.

2254 **FDA**

2255 FDA has primary responsibility to develop and maintain subject matter experts (SMEs) over the FSMA rules.
2256 Additionally, FDA works closely with all regulatory partners to set operational priorities and processes
2257 related to inspections, developing training plans and outreach and education for regulators and regulated
2258 farms, establishing inspection work plans, and determining optimum enforcement and compliance steps
2259 when necessary.

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2261

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2263 **Others: Industry, Academia, Associations**

2264 Industry should actively participate in the Produce Rule implementation activities and empower itself to
2265 successfully implement the rule through participation in available outreach and training activities, the
2266 submission of ongoing feedback regarding the effectiveness of implementation strategies, and by taking
2267 responsibility for their production processes.

2268 Academia is seen as subject matter experts (SMEs) and as a resource for identifying best practices for
2269 regulators and industry. Academia will play a critical role in outreach, education and training of both the
2270 regulators and industry, and will provide on-going support in a multitude of roles.

2271 Industry, Academic, and Regulatory Associations will be the key points-of-contact for communications
2272 regarding the rule. These associations are also responsible for disseminating information to members and
2273 for participating actively and collaboratively in FSMA implementation.

2274

2275 **10. Definitions**

- 2276 1. Information Letter/Advisory Notice: Details violations or non-conformances and requests a response
2277 from farm.
- 2278 2. Warning letter: Details violations or non-conformances, notifies farm of violations of Act and requests
2279 response from farm.
- 2280 3. Certified Warning letter: Details violations or non-conformances, notifies farm of violations of the Act
2281 and penalties for continued non-conformance, requests response and/or regulatory meeting with farm.
- 2282 4. Voluntary Compliance: Industry taking proactive efforts to be in compliance.
- 2283 5. Voluntary Agreement to Cease Operations: Voluntary Agreement between state regulatory program
2284 and farm to temporarily cease operations during corrective action implementation. Corrections
2285 verified by program and Voluntary agreement released.
- 2286 6. Education: The delivery of critical knowledge needed to ensure full understanding of the rule.
- 2287 7. Training: Providing instruction on how to apply knowledge and skills that ensure consistent compliance
2288 with the rule
- 2289 8. Outreach: Activities geared toward identifying and connecting with the targeted industry
- 2290 9. License Revocation: As appropriate to the state program, a license can be temporarily or permanently
2291 revoked due to non-conformance (similar to PMO).
- 2292 10. Injunctive Relief: Court Order to permanently close operation.
- 2293 11. Embargo/Stop Sale: Immediately cease distribution of adulterated product.
- 2294 12. Recall: Voluntary or Mandatory (if available to state program authority) to remove adulterated produce
2295 from market.
- 2296 13. "For cause": Connection to recall or foodborne illness outbreak investigation.
- 2297 14. Stop Sale and Hold Orders, Embargo, detained means the product must be held and cannot enter into
2298 commerce.
- 2299 15. Stop Use means the piece of equipment, room or area may not be used for the production, handling or
2300 storage of food.

11. Resources/Attachments

Chapter 4 Appendix 1 – FDA/States Produce Safety On-Farm Readiness Review Process (available as a separate document upon request)

Cornell University Produce Safety Alliance (PSA):

<http://producesafetyalliance.cornell.edu/>

USDA AMS Harmonized GAP Audits:

<http://www.ams.usda.gov/AMSV1.0/HarmonizedGAP>

Florida T-GAP & T-BMP Program:

http://www.floridatomatoes.org/wp-content/uploads/2013/01/TOMATO_QA_on_T-GAP_and_T-BMP11-8-06.pdf

<http://www.freshfromflorida.com/content/download/10037/136490/TomatoBestPractices.pdf>

<http://www.freshfromflorida.com/content/download/24003/486772/5G%20Tomato%20Best%20Practice%20Manual%20June%202012.doc>

Primus Labs Web tools:

<http://www.primuslabs.com/services/Webtools.aspx>

North Carolina Produce outreach web pages:

<http://www.ncfarmfresh.com/farms.asp>

<http://ncfreshproducesafety.ncsu.edu/good-agricultural-practices/audits-plans/food-safety-plans>

On Farm Food Safety Project

<http://onfarmfoodsafety.org/>

Government Accountability Office

<http://www.gao.gov/>

Government Accountability Office Yellow Book (Auditing) Standards

<http://gao.gov/yellowbook/overview>

Association of Inspectors General (Risk Assessment/Needs Assessment Resource)

<http://inspectorsgeneral.org/>

Institute of Internal Auditors (Risk Assessment/Needs Assessment Resource)

<https://na.theiia.org/Pages/IIAHome.aspx>

NASDA Model Produce Safety Implementation Framework

Chapter 5: Work Planning

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1. Executive Summary:

Through this chapter, NASDA outlines plans to establish procedures for work planning related to on-farm inspections and all other activities related to implementation of the Produce Safety Rule. This chapter is designed for state regulatory agencies that take the lead for implementation of the rule. Some items in this framework may need to be modified from state to state based on the state agency's involvement in implementation.

Implementation of the Produce Safety Rule requires change from the current work planning procedures and processes for existing state-federal collaborations. Under the current procedures, state agencies leverage existing workloads to conduct contract inspections for the FDA. The FDA relies on an existing inventory of facilities to determine contract lists for the states, which help the FDA meet established priorities and performance goals.

Implementing the Produce Safety Rule will be very different, as states do not have existing workloads for this type of inspection and the FDA does not have an existing inventory of farms. States will need to modify laws, develop infrastructure and hire new staff as part of implementation. A uniform data strategy to develop and maintain an inventory must be created, which will most likely be done by states. The development of that type of program will require a different system for work planning that is based on partnerships between federal and state agencies.

The process outlined in this chapter reflects the priorities of state regulatory programs in collaboration with the FDA to ensure successful implementation of the produce safety rule and establish a primary role of state agencies in enforcement of the rule.

2. Purpose:

NASDA believes State agencies should play a primary role in the implementation of the Produce Safety Rule. There will be a need for some states to have a transitional period between the compliance date of the rule and the date the state agency conducts on-farm inspections under their own authority and becomes a joint partner with FDA as the on-farm regulatory authority. This transitional period is further discussed in Chapter 2: Foundation of Law. The purpose of the work planning chapter is to create a baseline for all stakeholders to use to assess resource needs and plan work activities to ensure successful implementation of the Produce Safety Rule using a risk-based approach. It is envisioned that there will be joint inspectional strategies between the state agencies and the FDA. Sharing consistent inspectional approaches and data collection strategies will help to avoid duplication of efforts and maximize use of regulatory resources.

3. Scope:

Implementation of the Produce Safety Rule will require significant planning and resources. It is important to identify the work that must be completed to gain compliance with the new rules. A method to identify firms subject to the rule must be established. An assessment must be done to categorize farms based on risk and prioritize inspections. Targets for the number of inspections to be completed should be established based on available resources and determination of which farms will be inspected from year to year should

be made. Communication between state agencies and the FDA should be established to facilitate better informed strategies for inspectional priorities.

It is envisioned that CFSAN will provide information to the states to help facilitate better informed risk matrices and jointly create a national scheme that can be utilized to prioritize inspectional objectives. Inspection results, information regarding food safety incidents and investigations should be shared among the agencies. Planning of routine inspections, state re-inspections (as needed) and sampling are included in this section as well as for cause/investigations and Disaster/emergency response. Target completion goals should be set during the work planning process.

Education and Outreach:

A common theme with implementation of the Produce Safety Rule is “education before regulation”. For states to be consistent with this theme, resources for outreach and education will be required prior to and during implementation of the rule. Outreach efforts include identifying and connecting with targeted produce industry stakeholders that represent diverse commodity groups, various growing regions, farming practices, and various sizes of operations, to promote food safety practices that are aligned with the Produce Safety Rule. Education is the delivery of critical knowledge needed to ensure that the rule is fully understood. Details on these efforts can be found in Chapter 4; education and outreach efforts should be factored into the work planning process.

4. Field Procedures:

4.1 Regulatory Inspections:

The State agency responsible for conducting on-farm inspections will work jointly with FDA to determine the workload based on available information and resources. A risk-based approach will be used to determine the number of inspections to be completed for the year. The firms that will be inspected should be determined prior to the start of the inspection year. Joint inspections between the State agency and FDA may be conducted as appropriate. Information from various agencies (state or federal) on produce from across the nation may be utilized to determine what areas the regulatory efforts need to concentrate on.

4.2 State re-inspections/Confirmation of Corrections:

During the work planning process, an anticipated number of follow-up activities should be estimated based on information from previous years. This includes on-site re-inspections or other forms of confirmation that corrections have been made. The need for follow-up actions should be determined based on findings during the routine inspection and corrective actions needed.

- States should anticipate a demand for re-inspections requested by farms for the purpose of market access. Once regulatory inspections begin, industry buyers will most likely use the results to make purchasing decisions. Therefore, farms with noted non-compliances may not be able to sell to certain buyers and will want a re-inspection to show that concerns have been addressed. States will need a system to address this demand and determine how to manage resources between risk-based re-inspections and industry requested re-inspections for market access.

4.3 Enhanced Inspections:

Enhanced regulatory inspections are conducted after a farm has been found to be or is suspected of being substantially out of compliance with the Produce Safety Rule or “for cause” (connection to recall or foodborne illness outbreak investigation). Proactive measures will be taken to protect public health. (See Chapter 4: Outreach/Education and Compliance/Enforcement)

4.4 For Cause/Investigations:

If a state agency has taken the lead role in conducting regulatory inspections, all investigations in response to produce on farms covered under the state program and in-depth environmental assessments intended to identify the root cause must be done in concert with the responsible State agency. Due to the highly perishable nature of produce, it is important to conduct investigations quickly and efficiently. Responding quickly to a complaint or illness is important to protect public health and so samples may be taken of the environment or the produce. It is also important to rule out implicated produce quickly so it can enter the market. Holding produce can render it unsalable due to rotting or loss of quality.

Prior to the investigation a conference call or in person meeting should be scheduled with inspectors and directors (or a designee) from all participating agencies. During this meeting, the reasons for the investigation should be discussed as well as any ideas for the focus of the investigation. Laboratory personnel should be included if there is a need for samples to be taken during the investigation. Multiple inspectors may be assigned to maximize efficiency of an investigation so that an inspection, record review and sampling can be done in a timely manner. All administrative compliance and enforcement actions needed to correct problems that put consumers at risk should be done with a joint State and Federal Strategy.

4.5 Ad hoc:

The state agency should anticipate inspectional or other regulatory work based on requests from other agencies (FDA), internal stakeholders in the agency or other entities.

4.6 Assignments:

The State agency will work jointly with the FDA to make decisions on yearly inspections and assignments. The state must be made aware of or involved in all assignments initiated outside the State agency that impact farms covered under the state inspection program. This includes in-depth environmental assessments to inform future prevention efforts.

4.7 Disaster/Emergency Response:

In the event of an emergency or natural disaster, the state emergency response network, including the Rapid Response Team (RRT), should be notified. The RRT has the resources and established relationships to be able to quickly respond to a variety of emergency situations. Grower groups (i.e., Fruit and Vegetable Growers Association) should also be contacted to determine what resources would be most beneficial and to help disseminate information rapidly.

4.8 On-Farm Readiness Reviews:

Educational visits and on-farm readiness reviews to farm locations are encouraged and detailed in Chapter 4 of the implementation framework. These visits could be for a variety of reasons including farm requested visits, and information gathering to determine if a farm is producing covered produce. Joint on-farm readiness reviews between the State agency, FDA and any third-party group conducting assessments may be conducted as appropriate.

4.9 Inventory Update Visits:

When an inspection is attempted, and the farm is found to be: “Out of Business” (OOB), not subject to coverage due to change in crop, relocated outside of the agency’s geographical jurisdiction, or when a complete inspection cannot be accomplished.

- It is expected that there will be a lot of Inventory Update Visits, especially in the first few years. There should be a way to incorporate that into planning and the target goals to ensure it doesn’t prevent States from reaching the inspection goals.

4.10 Brief educational visits:

When an inspector visits a farm and determines the farm is “exempt” from the Produce Safety Rule, the inspector should attempt to perform a brief educational visit with the farmer. This type of visit will take more resources than a standard “inventory update visit” and should be categorized differently for resource purposes.

5.Communication:

Chapter 6 has a more detailed discussion of information sharing, but it is important to reiterate within work planning the importance of communication.

5.1 Points of Contact:

The Director of Food Safety for the State agency or a designee will be the main point of contact. For those states in which the Director of Food Safety is in a different agency than Agriculture, that Director shall be the point of contact but a contact in the Department of Agriculture must be offered a role appropriate to their responsibility. The Director will maintain an open line of communication with other regulatory agencies, so information may be shared quickly.

5.2 Methods and Type of Communication:

States and the FDA will need to dedicate resources to various forms of communication to share necessary information in order maintain risk-based inspectional priorities. Please see Chapter 6 for specific methods of communication and the type of information that should be shared.

5.3 Timeframe and Frequency of Communication:

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It is imperative that agencies distribute information quickly to partner regulatory agencies. Information pertaining to recalls or outbreaks should be disseminated promptly upon receiving the information.

The timing for work planning will be very important due to the seasonality of the products involved. In many cases as there is a specific window of time within the year that crops are grown and harvested. Therefore, it will be essential to determine workload prior to the start of the season. If not timed properly, it will greatly reduce the number of inspections that can be conducted.

It is important to maintain continuous communication between agencies as well as industry. A ListServ format would be one way this information could be shared among states, but the method of sharing information must be flexible to allow other options in the future as new programs are developed and new technologies are available.

6.Farm Inventory:

Identifying the industry subject to the rule will be a challenging task that will require resources. Reviewing inventories is typically one relatively simple line item in the work planning process. This item will be significantly more difficult for produce farms than manufacturers as there is not a current structure or authority for creating or maintaining these inventories. Therefore, generating the farm list from year to year should be included as part of work planning to dedicate needed resources to this effort. The collaboration and cooperation of a variety of partners, like the land grant university's extension service agents, conservation district agents, and commodity groups is critical in maintaining an accurate inventory of farms per county.

The initial creation of a list of farms that grow produce subject to the rule will require a process that gathers available information from multiple sources, generates new information from various partners, and assesses the information to create an accurate list of covered farms in each state.

6.1 Current information:

Information currently available that could be utilized to create an inventory of farms includes:

- 6.1.1 Land Grant University Extension Service personnel
- 6.1.2 Water Usage Database
- 6.1.3 Pesticide Applicators
- 6.1.4 Local Health Department records (irrigation well and septic system data)
- 6.1.5 Migrant Housing Data
- 6.1.6 Plat Maps
- 6.1.7 Zoning Maps
- 6.1.8 Marketing Program Registrations
- 6.1.9 Organic Farms
- 6.1.10 USDA GAP Certification
- 6.1.11 USDA Farm Service Agency information
- 6.1.12 Farm Market vendor lists
- 6.1.13 Dunn & Bradstreet

6.2 Potential Partners:

Partners will be needed to create and maintain the inventory of farms. It should be recognized that the gathering of this list may not be very popular among many farmers. Therefore, some groups identified

below may be hesitant to take part. Being part of a project that collects information for a government regulatory agency may have a negative impact on the relationship between certain groups and the farmer and impede the other work these groups want to accomplish. Therefore, it may be a challenge to partner with some.

6.2.1 Land Grant University Cooperative Extension Agents

6.2.2 USDA

6.2.3 Conservation Districts

6.2.4 Farm organizations (i.e. Farm Bureau)

6.2.5 Commodity Associations

6.2.6 Marketing groups

6.2.7 State/Local Health Departments

6.2.8 Dairy farm lists

Maintaining the list will be another task that will require resources. Farming is a dynamic process that changes from year to year. A farm that grows a covered crop one year may grow different crops the next year. For example, when the housing market decreased, many turf farms converted to growing foods like cantaloupe in response for the decrease in demands in turf grass. If the housing market picks back up they will most likely revert back to turf farms. Many other situations like this take place from year to year across the country. It should be recognized that the inventory will be very dynamic. The dynamic nature of both farming and maintaining an inventory of covered farms should not impede the process of establishing an inspection program. Determining what farms are covered and what farms are either not covered or exempt will be another significant task in maintaining the inventory. States will also need a method to determine whether the total annual sales of a farm qualify them for an exemption. Reviewing financial records to confirm annual sales will not be the most effective use of regulatory staff time. NASDA suggests that a signed statement from the owner of the farm verifying that the farm meets the financial requirements of the exemption should be sufficient information.

There are a variety of approaches for gathering and updating farm inventories. All will require resources at the state level for maintaining the information and working with partners. The partners will also require resources for any efforts they contribute. These resources must be factored in when determining work planning.

7. Inspection Priorities:

Prioritizing inspections will be an important part of work planning. To effectively use available resources, higher risk farms will need to be higher on the priority list than lower risk farms. Therefore, a system to categorize farms by risk will be necessary. FSMA section 421 sets a mandate for FDA to inspect domestic and foreign facilities. However, this section does not apply to farms. A system must be developed to determine the total number of inspections each state will conduct. In Section 421, there is a mandate to inspect a specific number of foreign facilities in year 1 and an increased number of inspections in subsequent years. This same concept could be used for the farm inspection program. Within the total number of inspections, the percentage of high-risk farm inspections and low-risk farm inspections should be determined. Based on the number of farms subject to the rule and available resources, the number of inspections will need to be modified.

In addition to high-risk and low-risk, an “Enhanced Regulatory Inspection Schedule” (see Chapter 4) should be used for some locations that may involve more or less frequent visits based on compliance history. The

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growing season will also impact where a farm falls on the inspectional priority list and how resources are utilized. For example, a lower risk food may be grown and harvested earlier in the year when other higher risk products are not yet available for inspection. Therefore, the agency may have available resources. While the growing and harvesting season for multiple high-risk foods may overlap or occur at the same time. State agencies will need to develop a system to utilize as many resources as possible during certain growing seasons and then deactivate or divert those resources during other parts of the year.

7.1 Categorizing Risk: There are several factors that should be considered when determining what risk category a farm falls under. This could be a multi-step process based on findings during the first inspection. Some of the information may not be available until the farm is inspected.

7.1.1 Known food safety risks: History of class 1 recalls and outbreaks.

7.1.2 Evaluation of practices in handling produce categorized by FDA's qualitative risk assessment as providing greater food safety risk

7.1.3 Growing conditions: The crop itself should be a big part of determining risk. How the crop is grown (on the ground or in a tree), whether there is direct contact with irrigation water, assessment of farm environment and adjacent land use, and method of harvest should all be factors.

7.1.4 Source of irrigation and wash water

7.1.5 Soil amendments: Type of amendments used by the farms should also be a factor

7.1.6 Volume of covered produce

7.1.7 Compliance history (once the program is established).

7.1.8 Sample Results

7.1.9 Third Party Audits

7.1.10 Marketing Agreements

7.1.11 Geography

7.1.12 End User

7.1.13 Weather Conditions (drought, flood, etc.)

7.1.14 Reportable Food Registry Notices

7.1.15 Recalls

8. Inspection Authority:

Many states do not have inspection authority for farms under current State laws. Many States may also not be able to adopt the applicable sections of Title 21 of the Code of Federal Regulations (CFR) prior to the implementation phase of the produce safety rule. Under current FDA contracts, State inspectors must be credentialed as officers of the Department of Health and Human Services (DHHS), FDA in order to conduct inspections in this situation. NASDA covers this topic in more detail in Chapter 2: Foundation of Law.

9. Responsibility:

9.1 State Department of Agriculture (or other state agency)

The state regulatory agency will assess resource needs through work planning to meet current and anticipated requirements for being the lead agency for outreach, education and on-farm regulatory inspections for the Produce Safety Rule and develop a strategic implementation framework to address any identified gaps. Sharing of inspection results, information regarding food safety incidents and investigations with the FDA and other state regulatory agencies will also be necessary.

2653

2654 **9.2 FDA**

2655 FDA can provide assistance in the form of guidance documents and other technical sources of information
2656 to state regulatory agencies seeking to assess the impact of the proposed Produce Safety Rule on the
2657 resource needs and developing joint work plans, as appropriate to the situation. Communication of a
2658 national scheme for prioritization of inspectional objectives, FDA assignments, inspection results and other
2659 information regarding food safety incidents will be important for states during the work planning process.

2660

2661 **9.3 Others: Industry, Academia, Associations**

2662 Industry, academia and associations will play a role in developing and maintaining an accurate inventory
2663 of farms, communicating public information, and education/outreach.

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Chapter 6: Information Sharing

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1. Executive Summary

The produce safety operational framework must establish a clear, mutual understanding on communications and information sharing roles, responsibilities and expectations among state and federal partners, including public and private partners. This chapter documents processes that are foundational to achieving the broader goal of having effective and robust partnerships between federal and state partners for protecting and promoting public health.

FDA's Field Management Directive (FMD) 50, "[FDA-State Communication](#)" provides the framework for effective communication between State and FDA for routine activities, work planning, and emergency situations. NASDA recommends fully implementing FMD 50 to improve communications and information sharing between states and FDA Field Offices, Headquarters and Centers. NASDA recognizes that the existing mechanisms for sharing non-public information will remain the standard: confidentiality agreements, commissioning and credentialing. NASDA proposes alternative methods of sharing non-public information to enhance and insure effective and timely information between state and federal regulatory partners in the implementation of the produce safety rule. These alternative methods will supplement the standard agreements.

The sharing of public information plays a very important role in the implementation of the new FSMA Produce Safety Rule due to the regulated community's unfamiliarity to regulatory requirements and expectations. NASDA supports building a network of expertise for science-based information and outreach at both the regional and national level utilizing existing models such as University Resource Centers, Produce Safety Alliance and other similar entities. FDA and USDA have proposed and funded a collaborative effort to administer a National Coordination Center for food safety training, outreach and technical assistance with four regional centers. These entities can provide a repository for research on produce safety alternatives and variances, educational outreach for producers and commodity groups and training for regulatory professionals to help facilitate compliance with this new regulation as long as adequate federal funding continues.

2. Background

An effective process to promptly share information is a critical component of the FSMA State Operational Framework to ensure successful implementation of the FSMA Produce Safety Rule. Congress recognizes the importance of information sharing to ensure the safety of the food supply chain in FSMA and expresses the need for information sharing among FDA and other federal agencies, states and local entities. Included in this is the need to share laboratory results, electronic data, surveillance information and non-compliances with US food safety requirements. FSMA §205 specifically speaks to sharing information "on a timely basis among public health and regulatory agencies, with the food industry, with health care providers, and with the public."

The timely sharing of information among state and federal agencies must be addressed, recognizing each may require a different process due to the type of information that can be or is likely to be shared. Effective implementation of the FSMA Produce Safety Rule will require information sharing with groups such as academia and cooperative extension staff not consistently associated with regulatory programs. This chapter will cover the sharing of non-public information with regulatory partners and the sharing of public information with all parties. A critical consideration is the sharing of information with regulated communities that do not have access to electronic media.

2.1 Sharing of Non-Public Information

The ability to leverage the expertise of state public health authorities can be optimized through policies, procedures and regulations that allow for streamlined sharing of non-public information. Without the rapid exchange of information, an integrated national food safety system in partnership with state authorities will be unworkable. Although the regulatory framework for communications of non-public information with state government officials is well defined in 21 CFR §20.88, FDA should assist state governments in developing and implementing proper policies and practices to facilitate the speedy exchange of information among all appropriate public regulatory health officials.

[21 CFR§ 20.88](#) provides that confidentiality is maintained when FDA discloses information to a commissioned or credentialed state official, and when the disclosure relates to regulatory enforcement activities undertaken pursuant to an FDA contract. (21 CFR §20.88(a)-(b)). Most state agencies have used these methods to facilitate ready discourse; however, it can be difficult, time consuming and costly to become commissioned with credentials.

State officials that are not commissioned are treated like members of the general public. (21 CFR §20.88(c)). The only exception to that provision allows FDA to maintain confidentiality in certain situations when a state official voluntarily discloses confidential information as part of an investigatory report compiled for regulatory enforcement, or when the FDA is working cooperatively with the state official for regulatory enforcement. (21 CFR §20.88(c)(1) -(1) -(2)). Even when confidentiality agreements are signed with state officials, there still remain challenges in the timely exchange of information between FDA and state partners.

FDA has the authority under [21CFR §20.91](#) to share (without needing a confidentiality agreement) information otherwise exempt from public disclosure to take regulatory actions such as effectuate a recall. The CFR grants broader authority to FDA to share information it addresses in any administrative or court enforcement action. FDA is encouraged to take advantage of the information sharing authorities provided under 21CFR §20.91 and share information otherwise exempt from public disclosure with state and local counterparts to enhance overall public health protection goals.

NASDA conceptually recognizes the recent “Long-Term Food Information Sharing Agreement” (ISA) that FDA proposed regarding 21 CFR §20.88(d). The agreement should be used to help FDA readily identify, contact, and involve pertinent individuals within each state in the event a food safety incident occurs. It is important to recognize and eliminate impediments to initiating contact between FDA and state officials. Furthermore, the agreement provides FDA ample discretion to decide when information should be shared.

Memorandums of Understanding (MOUs) are another vehicle that FDA has used to share and protect information between federal agencies and national associations. This mode of sharing is very complicated, cumbersome and not necessarily timely. MOUs are not likely to be used in the case of information sharing between individual states and FDA. NASDA may consider utilizing this mode of information sharing with FDA to address communication issues related to the timing of media releases with state notification similar to the one NASDA developed and implemented with USDA APHIS (state notification no later than one hour prior, with preferably 24-hour notice).

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Clear parameters regarding information sharing and cooperation among FDA Centers, Headquarters and District Regional offices are critical to the successful implementation of the Produce Safety Rule. The FDA policies related to information sharing impact the outcome of any process adopted and there must be reciprocity in information sharing.

State laws have provisions to protect confidential and trade secret business information. These are statutory provisions which are not impacted by state sunshine laws. State laws that do not protect confidential and trade secret information should consider adopting such provisions. These state provisions further allow a state to exchange information of a regulatory nature with duly appointed representatives of the United States Government, or of other States, who are similarly prohibited by law from revealing this information.

State laws also provide provisions that a state may cooperate with and enter into agreement with government agencies of their state, other states, agencies of the Federal Government, and private associations in order to carry out the purpose and provisions of their respective law. State programs for the most part freely share information with their local, state and federal trusted regulatory partners. Reciprocity in information sharing among local, state and federal partners is critical and must be ensured in order to optimize public health protection.

NASDA has identified a number of alternative mechanisms of sharing non-public information between other federal agencies and state regulatory officials. The alternatives include restricted access web files, non-disclosure agreements maintaining federal possession, treat as critical infrastructure information, new federal legislation and a model state confidentiality statute. The alternatives offer options states can utilize to address the protection of non-public information. Not all states are in the same situation and not all states have the same laws.

2.2 Sharing of Public Information

Sharing public information with academia, associations, industry, producers, and state/federal regulators will be a major component of implementing the FSMA Produce Safety Rule. Public Information will include educational outreach documents, compliance assistance templates, research on alternatives and variances and investigational findings with non-public information redacted. The ability to separate confidential and trade secret information from inspectional information in a timely manner to share with non-regulatory partners is fundamental to the successful implementation of this rule.

Leveraging the National Coordination Center and associated regional centers, provides a network of expertise for science-based information and outreach at both a regional and national level. These centers can assist the produce industry in understanding and navigating the changing regulatory landscape, help producers in implementing best management practices related to produce food safety, improving the security of our food system and emergency response. These centers can also serve as a source of focused training and education to regulatory professionals on the latest science and techniques.

NASDA will recommend processes to improve information sharing and pre-establish, to the extent possible, clear channels of communication for implementation of the FSMA Produce Safety Rule that will, with some modification, be applicable to any FSMA or other FDA inspection programs. The processes will establish the path forward in building the partnership needed for implementation of these programs between FDA and state programs and recommending information sharing improvements between states at both the national and regional levels.

3.General Scope

This section will outline the core attributes of information sharing, the types of information to be shared, the routes of communication, the partners to share information, the modes of agreement, the means to ensure consistent data collection and an evaluation to report the effectiveness of information sharing and recommend improvements.

A. Information sharing must be built on core principles.

- Mutual trust/respect to achieve positive public health outcomes.
- Reciprocity and information sharing must move both ways between partners.
- Timeliness – information sharing must occur in real world time, not after the incident occurred.
- Efficiency – sharing must be effective, fluid and eliminate redundant data entry.

B. Types of information to be shared

Non-Public information

- Distribution Information
- Establishment inventories
- Planning information (including inspection strategies and schedule)
- Pre-assessment/inspection data and results of inspection sampling assignments
- Pre-decisional information (compliance strategies, policies)
- Assignments
- FDA CORE reports
- State Emergency response preliminary documents
- Emergency response events – FDA CORE function
- Food borne illness investigations reports, preliminary and final
- Consumer complaints
- Sample results of laboratory analytical testing (including presumptive results)
- Inspection reports (completed)
- Inspectional findings
- Results of recall audit
- Pre-notification of compliance actions
- Pre-notification of removal of qualified exemptions
- After action reports from outbreak investigations – must be done with state involvement

Public Information

- Compliance Program
- Guidance
- Import alert information
- Final laboratory results
- Updates on approved variances
- Repository of relevant scientific information
- Outreach/education/training materials
- Recall notifications
- Aggregated Data
- Redacted inspectional reports

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C. Routes of information sharing

- FDA FSMA Technical Assistance Network (TAN)
- Database to collect inspectional and analytical information (not facts or whatever is replacing it). Seamless sharing of information. More robust Reportable Food Registry (RFR) where states have access to more than their state information. (The intent is for states to have information that may impact them.)
- FDA Produce ListServ – similar to the FDA Feed ListServ
- FoodShield or Knowledge Vault for informal and formal collaboration on problems and archiving data.
- NASDA and AFDO can facilitate information sharing to include 50 state, regional and district calls
- AAFCO can facilitate information sharing online in a secure environment designed to interface with industry, when desired, using feed BIN website. This AAFCO example is expandable to include other groups (produce, food, and feed) or separate domains can be established for each group.
- Timely FDA information release on 50 state, regional or district calls
- State Food Safety Rapid Response Teams (RRT) can facilitate information sharing
- State food safety/defense task forces can facilitate information sharing
- Extension facilitates information sharing through publications and meetings
- Consumer oriented Public website
- Food Manufacturer/Farmer oriented Public websites
- PFP Resources

D. Information sharing partners in a two-audience program, for instance:

- Regulatory –
 - i. Federal/State, between states (national & regional), intra-state (agriculture/health, USDA or other), federal/federal, FDA (Field, Centers, Headquarters), national regulatory/public health associations (AFDO, AAFCO, APHL, ASTHO, NASDA)
 - 1. Criminal – US Attorney, OCI, State AG and IG.
 - 2. Regulatory
- Non-Regulatory
 - i. Produce, Sprout and Preventive and Preventive Controls Alliance
 - ii. Academia – Cooperative Extension, University Resource Centers
 - iii. Industry/Public – producers, commodity groups, industry associations, consumer groups and general public.
 - iv. GAP certifiers

E. Modes of agreement in non-public information sharing.

- Confidentiality Agreements
- Commissioning
- Credentialing
- Memorandum of Understanding (MOUs)- commonly used between federal agencies and associations
- 20.88 agreements between FDA and others.
- Other mechanisms – restricted access web files, nondisclosure agreements, critical infrastructure, new federal legislation and model state confidentiality statute

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F. Consistent and Appropriate data collection

- Consistency in data collection to facilitate sharing of inspection, compliance and results of sample analysis.
- Foundational database to collect and share basic information on produce industry which will have utility in developing uniform and consistent establishment inventories and tracking exemptions (PFP Workgroup IT Workgroup model project). This database should include the collection of research studies supporting alternatives under the Produce Safety Rule, to facilitate sharing that information to a broader audience as appropriate.

G. Reporting and evaluation process

- Pilot program to assess the success of proposed information sharing for the Produce Safety Rule by region and at the national level.
- Metrics for the utilization of information processes to measure successes of processes established.
- Report on successes or failures - evaluation will determine the need for changes in information sharing.

4.Outcomes and Process

The goal of this section is to enhance produce safety and public health information sharing and collaboration between regulatory partners, promote efficient utilization of interagency expertise, technologies, and tools to improve product risk identification, validation, and analysis, and build an information sharing infrastructure and processes to increase food safety compliance under the FSMA Produce Safety Rule.

- Develop national and regional information sharing networks and processes on producer audits and inspections, recalls, import alerts, laboratory findings or methods, and other food safety procedures. A foundational database approach that allows information to be rapidly and effectively shared is recommended. Alternative methods of information sharing will need to be considered as part of the recommendation.
- Collaborate in the development of produce safety capabilities, including training, joint inspections, meetings and conferences, risk communication, assessment and risk management, and appropriate emergency preparedness and response plans. NASDA will work with associations through their regional network to coordinate with FDA, training and meeting opportunities for implementing the Produce Safety Rule. State and Federal Food Safety Centers and other resource centers will play a pivotal role in training regulatory partners in produce safety requirements.
- Coordinate effective communication among health and other state officials with state agriculture departments. NASDA will work with associations to establish a model framework for state agriculture, health and other agencies to collaborate and coordinate their regulatory programs to enhance public health.
- Improve communication and information sharing among and between FDA Districts and State regulatory programs. NASDA requests FDA to fully implement FMD 50 to effectively communicate and share information with state regulatory partners. Establish metrics to determine the effectiveness of the improvements. FDA should seek to enhance and continuously improve their internal communications between the Field, Centers and Headquarters to achieve better sharing of information.
- Identify additional federal, state and university centers of excellence and agriculture resource centers to enhance public information delivery to producers. These would include the FDA/USDA

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proposed National Coordination Center and associated regional centers and other similar alliances and centers which can support and enhance compliance with the produce safety rulemaking. NASDA will work with CDC to ensure agriculture interests are encompassed within the Food Safety Centers of Excellence.

- Improve the release of enforcement actions and media briefings between federal and state regulatory officials. NASDA would enter into a MOU with FDA establishing an information sharing agreement that FDA would provide notification whenever possible to NASDA prior to a media or public release information regarding the event that would be shared with state departments of agriculture not less than one (1) hour but preferably twenty-four (24) hour when possible.
- Promote alternative ways of sharing non-public information which could include restricted access web files, non-disclosure federal agreements, critical infrastructure information, new federal legislation, or a model state confidentiality statute. Restricted access web files would allow states to view non-public and proprietary information without taking possession, resulting in the states having the information needed. Non-disclosure federal agreements would protect federal information from being subject to state disclosure provisions. Classifying food safety investigational information as critical infrastructure information (CII), would not allow states to disclose information. New federal legislation could provide and enhance protection of non-public information. NASDA should draft and recommend the adoption of a model state statute that assures the confidentiality of necessary information.
- NASDA and associations will facilitate regional platforms that encourage states to share experiences and information that can enhance public health opportunities in produce safety. This can be accomplished through routine regional and/or national phone conferences and state to state collaboration/coordination to ensure consistency and uniformity in implementing the Produce Safety Rule.
- Develop and maintain a repository for information dissemination for regulatory, scientific and technical information, including information on alternatives and variances. For example, the National Coordination Center for Food Safety and the Regional Food Safety Centers could serve as that repository of information.
- Information sharing must be accomplished on a timely basis. NASDA will recommend processes that ensure an understanding exists between all impacted parties that information is shared rapidly and effectively.

5.Responsibilities

5.1 State Department of Agriculture (or other Local/State/Other agencies) Responsibilities

- Provide access to local and state food safety information within existing security constraints and proprietary information requirements.
- Must protect all non-public information shared and restricted to employees, agents and officials who require access to perform their official duties.
- Share public information with non-regulatory partners including educational outreach and research information on alternatives and variances.
- Compliance with confidentiality requirements.

5.2 FDA Responsibilities

- Provide access to FDA food safety information within existing security constraints and proprietary information requirements.

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- Must protect all non-public information shared and restricted to employees, agents and officials who require access to perform their official duties.
- Share public information with non-regulatory partners including educational outreach and research information on alternatives and variances.

5.3 Produce, Industry, Academia, Cooperative Extension, Commodity Group, Farm Bureau and other Farm Organizations Responsibilities

- Disseminate public information provided by regulatory partners to enhance compliance with the Produce Safety Rule.
- Share research on alternatives and variances to improve produce safety.
- Cooperative Extension, Farm Bureau and other Farm Organizations provide a critical role in providing information to regulated communities that do not have access to web based electronic media.

6. Definitions

Center for Produce Safety

The fresh produce industry is responsible for supplying a safe food supply to the world's consumers. Government expects ever-safer food, and companies continue to invest millions of dollars creating and implementing food safety initiatives. Since effective regulation and implementation of food safety programs should be founded in science-based research, it is imperative that the key stakeholders work together to identify research needs, conduct research and implement appropriate solutions.

The Center for Produce Safety (CPS) is a collaborative partnership that leverages the combined expertise of industry, government and the scientific and academic communities to focus on providing targeted research needed to continually enhance food safety. This level of collaboration allows CPS to fill the knowledge gaps on produce food safety. CPS is gaining visibility and respect for:

- Funding research. CPS has compiled an impressive six-year body of work, awarding \$13.6 million and funding 85 one- to two-year research projects at 22 universities and organizations.
- Identifying the priorities for targeted research by the CPS Technical Committee to provide the produce industry with practical data that can be used at all levels of the supply chain and providing a repository for produce safety research information.
- A hands-on approach to research management from competitively awarding RFPs to monitoring the researcher's progress, CPS maintains research timelines, eliminates research roadblocks and identifies needed resources.
- Outreach to and education for the research community. CPS provides knowledge of industry processes, applications, varieties and conditions to academia and the research community to better target and direct research that will have immediate application in the produce industry.
- Translation of scientific research through reports, symposia, webinars and direct access to experts to support industry-wide food safety programs.
- Partners in Research Program with matching funds from commodity groups, CPS leverages and maximizes research resources.

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3043 CPS is a partnership that is creating targeted research; streamlining costs and maximizing research output
3044 by combining industry, government and academic resources; and translating research into action – all to
3045 enhance food safety and protect your business.

3046 **CDC Food Safety Centers of Excellence**

3047 CDC has designated five Integrated Food Safety Centers of Excellence to help fulfill its role in the Food Safety
3048 Modernization Act (FSMA). After a competitive process, five state health departments and their affiliated
3049 university partners were selected and notified: Colorado, Florida, Minnesota, Oregon, and Tennessee. With
3050 CDC's leadership, these Centers will provide technical assistance and training on epidemiological,
3051 laboratory, and environmental investigations of foodborne illness outbreaks and associated analyses.
3052 Centers will identify and implement best practices in foodborne disease surveillance and will serve as a
3053 resource for public health professionals at state, local, and regional levels.

3054
3055 The new legislation recognizes that robust foodborne illness surveillance data are needed to inform
3056 targeted prevention interventions. Relying on CDC's expertise in this area the FSMA directs the agency to:

- 3057 • Improve coordination and data sharing with public health partners and the public;
- 3058 • Increase state and local participation in national surveillance networks;
- 3059 • Expand and integrate national surveillance systems;
- 3060 • Enhance laboratory and epidemiological methods for agent identification, outbreak
3061 detection and investigation; and
- 3062 • Improve the attribution of specific illnesses to specific foods

3063 Other provisions of the FSMA require or will be enhanced by CDC leadership and participation. These
3064 activities include, but are not limited to the following:

- 3065 • Developing the Joint Food Safety and Food Defense Research Plan;
- 3066 • Designating high-risk foods based, in part, on the history of foodborne illness outbreaks
3067 attributed to such foods
- 3068 • Establish a work group to advise on the improvement of surveillance data collection, access and
3069 use;
- 3070 • Developing guidelines for individuals to manage the risk of food allergy and anaphylaxis in
3071 schools and early childhood education programs.

3072 CDC has many ongoing activities which pertain to this section. Some of the additional activities needed to
3073 fulfill the components of this section include:

3074 "Improve the collection, analysis, reporting and usefulness of data on foodborne illnesses"

- 3075 • Enhanced pathogen testing and genotyping methods
- 3076 • Increased participation in national surveillance networks and systems
- 3077 • Enhanced IT infrastructure for electronic laboratory reporting and data integration

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- 3078 • Customized attribution to agency specific food commodities, attribution by source and point
3079 of processing
- 3080 • Systematic collection and advanced testing of samples from outbreaks of unknown etiology
- 3081 • Reference database for standard pathogen information from public health laboratories
- 3082 • Extramural funding for scientific research by academic institutions
- 3083 • Establishing a "Working Group" to recommend improvements in foodborne disease
3084 surveillance
- 3085 "Improve the collection, analysis, reporting and usefulness of data on foodborne illnesses"
- 3086 • Increased participation in FoodCORE
- 3087 • Standardized investigation data elements and enhanced IT infrastructure for communication
3088 and data integration
- 3089 • Extramural funding to implement best practices in outbreak response and containment
3090 nationally
- 3091 • Conduct a review of state and local capacities
- 3092 **Produce Safety Alliance – Cornell University**
- 3093 The Produce Safety Alliance (PSA) is a collaborative project between Cornell University, United States
3094 Department of Agriculture, and the Food and Drug Administration. The overarching objective of this project
3095 is to provide the produce industry and associated groups with training and educational opportunities
3096 related to current best practices and guidance, and future regulatory requirements by establishing the
3097 Produce Safety Alliance (PSA).
- 3098 The curricula will include GAPs and other preventative controls including co-management. Outreach efforts
3099 will focus on fresh produce growers, packers, and grower cooperatives with special emphasis on small and
3100 very small-scale farms and packinghouses. Small operations may be defined as those who currently direct
3101 market to consumers, have gross sales of under \$500,000, or have an immediate need of assistance in
3102 understanding and implementing food safety practices.
- 3103 There are four main objectives:
- 3104 1. Providing educational outreach assistance to fresh produce growers and packers, including
3105 grower cooperatives, to increase their understanding of the critical role they play in public
3106 health via implementation of on-farm and packinghouse GAPs, on-farm environmental
3107 coordinated management (co-management), and other preventive controls;
- 3108 2. Developing a standardized, multi-format training and education program to assist the
3109 produce industry including growers and packers and regulatory agencies with the
3110 implementation of FDA's requisite produce safety regulation;
- 3111 3. Developing a standardized, multi-format, training and education program to assist the
3112 produce industry including growers and packers and regulatory agencies in understanding
3113 the environmental benefits of co-management and to integrate food safety and

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3114 environmental co-management principles while implementing FDA's produce safety
3115 regulation; and

3116 4. Being a repository for and providing easy access to stakeholders of up-to-date scientific and
3117 technical information related to FDA's produce safety regulation, on-farm and
3118 packinghouse produce safety, and related environmental co-management.

3119 **Pennsylvania Agriculture Resource Centers (Animal Care, Food Safety & Plant Health)**

3120 Penn State and the Pennsylvania Department of Agriculture have partnered to address high-priority issues
3121 for Pennsylvania and the public. The Centers are focused on helping food and animal industries navigate
3122 and understand the changing regulatory landscape, assist the agricultural industry in implementing best
3123 management practices related to food safety; improve the security of our food system and emergency
3124 response to a crisis through joint planning among all parties; providing focused training to regulatory
3125 professionals on the latest science and techniques; and enhance the ability to attract private or public
3126 funding to address vital agricultural industry issues.

3127 The mission of the Food Safety Resource Center is to maintain and improve the safety of food and feed
3128 produced, processed, distributed, and consumed in the Commonwealth. The Center will carry out this
3129 mission through synergistic collaboration among the Pennsylvania Department of Agriculture, Penn State
3130 College of Agricultural Sciences and other state, federal, and private partners.

3131 The Food Safety Resource Center has established informational kiosk stations at six (6) produce auction
3132 houses across the state. These kiosk stations will provide valuable educational outreach material on food
3133 safety issues and regulations, as well as plant health issues. The produce auctions are weekly gathering
3134 sites for the Amish and Mennonite communities. The Center has also provided Advanced HACCP training
3135 to food safety regulators and Feed HACCP training for feed safety regulators.

3136 **7.Equipment/Materials/Resources**

3137 FDA FSMA Technical Assistance Network (TAN):
3138 <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

3139
3140 Field Management Directive (FMD): FDA-State Communication Field Management Directive –
3141 [http://www.fda.gov/ICECI/Inspections/Field Management Directives/ucm056669.htm](http://www.fda.gov/ICECI/Inspections/Field%20Management%20Directives/ucm056669.htm)

3142
3143 RRT manual: Contains a chapter on joint inspections and investigations. Available at AFDO –
3144 [http://www.afdo.org/Resources/Documents/6-](http://www.afdo.org/Resources/Documents/6-resources/The%20RRT%20Manual%202013%20FINAL.pdf)
3145 [resources/The%20RRT%20Manual 2013 FINAL.pdf](http://www.afdo.org/Resources/Documents/6-resources/The%20RRT%20Manual%202013%20FINAL.pdf)

3146
3147 Overview of information sharing from FDA/ORR Office of Partnerships: Overview of different
3148 type of arrangements for FDA to share non-public information.

3149
3150 Overview of information from FDA/ORR Office of Policy and Risk Management: More detail on
3151 non-public information sharing.

3152
3153 Regulatory Procedures Manual: Chapter 3. Commissioning

<http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074334.pdf>

8. References/Attachments

Section 702 of the Federal Food, Drug and Cosmetic Act (21 USC 372) – Examinations and Investigations, (a) Authority to conduct.

Section of the Act regarding Commissioning in (a)1(A)

<http://www.gpo.gov/fdsys/pkg/CFR-2013-title21/pdf/USCODE-2012-title21-chap9-subchapVII-partA-sec372.pdf>

21 CFR§ 20.88 Communications with State and local government officials.

Section regarding information sharing with state officials, commissioning and limitations on information sharing

<http://www.gpo.gov/fdsys/pkg/CFR-2013-title21-vol1/pdf/CFR-2013-title21-vol1-sec20-88.pdf>

Agriculture Biotechnology Information Disclosure: Accommodating Conflicting Interests Within Public Access Norms http://www.pewtrusts.org/news_room_detail.aspx?id=36772

FMD 50 - FDA-State Communication Field Management Directive (FMD) -

<http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/UCM056669>

CDC Integrated Food Safety Centers of Excellence an important resource/means to improve information sharing practices - <http://www.cdc.gov/foodsafety/centers/>

Center for Produce Safety as a resource or route of information sharing -

https://cps.ucdavis.edu/global_research_database.php

Pennsylvania Agriculture Resource Centers - <http://agsci.psu.edu/resource-centers>

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Chapter 7: Regulator Training

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1. Executive Summary

This chapter outlines a model Produce Safety Training Plan and an analysis of costs for training state and federal officials in carrying out responsibilities under the Produce Safety Rule. This plan encompasses the steps from identifying competencies and developing training, effectively delivering training to a varied audience, and supporting the costs of maintaining such a system. The plan identifies stages for implementation due to the fact that setting up a training system based on competencies will require a significant level of effort over time. Therefore, existing training programs have been identified that can be used to begin the regulatory agency training process in preparation for Produce Safety Rule implementation.

The degree to which states implement the Produce Safety Rule will depend upon the parts or components of the produce safety program the states elect for participation. Their selection, along with existing program resources, will in turn impact the type and amount of training that will be needed. The training needed will be based on the competencies required to conduct the produce safety activities that a state plans to implement. The current FDA effort to create a competency-based National Regulatory Curriculum will be leveraged – thus saving time and cost. A competency framework and a curriculum framework will be developed for produce that will identify the training states will require to effectively implement a program.

The purpose of the training plan is twofold:

1. To identify the immediate steps that can be taken to prepare staff at different levels and program functions for implementation of the Produce Safety Rule, and
2. To understand the FDA process for developing a long-term National Curriculum and training system for food protection professionals that will include produce safety training.

The overall system approach is designed to create a comprehensive, coordinated training system to address regulatory capacity. The training plan will examine the development of a training system that will assist in the immediate operationalization of FSMA produce safety requirements while at the same time build long-term competency obtainment.

The proposed system will allow state agency decision-makers to identify the most cost-effective produce safety training options that meet their programmatic needs. The produce safety training paths and specific courses will be vetted (through a formal course review process) and placed in a curriculum so that a standardized approach is used across the U.S.

The produce safety training program can be applied broadly across the food and agriculture sector and include regulatory officials, auditors, non-regulatory agency staff, extension specialists, and even farmers. States are actively engaged in many capacities in the FDA process to create a National Curriculum that will include produce safety. States currently participate through the Partnership for Food Protection (PFP) and some state personnel are members of the PFP's Training and Certification Work Group which is helping to direct the process.

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The training in this plan will be phased in based on the rule implementation provisions and the components a state chooses to implement. The first phase will identify existing course material that could feed into a program to meet the needs of the varied audience. Instructor skills training will be given to federal and state instructors along with course-specific instructor training in order to create a cadre of skilled trainers.

The next phase would be to broadly disseminate existing training and build capacity. During this phase, online and instructor-led courses will be delivered that include on-farm activities. Deliveries will include existing produce safety alliance courses, GAPs courses, produce farm investigation courses, and other courses meeting curriculum foundations (e.g., ORA-U courses).

In the third phase a clear training pathway will be in place for state and federal personnel. Training efficiencies will be built-in including online and blended learning activities along with the growing number of instructor-led skills courses. Training material produced by various entities will be reviewed and approved for placement within the curriculum. Delivery of specific regulator training for On-Farm Readiness Reviews and inspections would occur during this phase.

The goal of the produce safety training regimen is to develop a competent workforce that can consistently and uniformly conduct inspections, laboratory analysis, and other produce safety tasks across the U.S. Implementing a competency-based training program for produce safety will help meet the goal for the education, outreach and inspection activities required under the Produce Safety Rule.

As funding is identified and budgets are developed, there is a number of training cost figures that will inform the process. A spreadsheet tool was developed to create an estimate of the costs for a two-day, three day, and five-day face-to-face training course. The spreadsheet tool has been built so that any assumption can be changed, and overall costs change will change accordingly. This tool can be used for budgeting purposes and is available upon request.

2.Introduction

The degree to which states implement the Produce Safety Rule will depend upon the parts or components of the produce safety program the states elect for participation. Their selection, along with existing program resources, will in turn impact the type and amount of training that will be needed. It is unknown at this point what level of participation states will choose. Some states may choose to develop a comprehensive program to include outreach, education, On-Farm Readiness Reviews, producer compliance inspections, laboratory capacity, and enforcement of the produce safety rule, while other states may limit their involvement to specific components such as outreach, education, and On-Farm Readiness Reviews.

Some states may have to enact specific legislation modeling the Produce Safety Rule to develop their own programs, while other states may decide to conduct produce rule activities under an agreement with FDA with state officials serving as FDA agents using FDA credentials. Additionally, States may be able to conduct outreach, education and possibly On-Farm Readiness Reviews within their existing authorities.

Nationally, food regulatory programs are divided between departments of agriculture and departments of health, where only one of the agencies may have a regulatory food inspection program. Other states have food regulatory authority divided within the state, with manufactured food and dairy inspection overseen by the department of agriculture and retail food service inspection overseen by the department of health. Some state departments of agriculture do not conduct any food inspections and may not have the

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infrastructure to implement the produce safety rule without a substantial internal investment to develop a regulatory program.

Clearly, food protection regulatory programs in states can vary significantly as far as the agencies responsible for implementation; as a result, training needs and requirements will be different from state to state, agency to agency, and program to program. This variation between states will require a flexible approach to identifying and delivering the specific training a state will need to implement the components of the state's chosen produce safety program.

States that don't have a regulatory infrastructure will need the information and funding to develop such an infrastructure, while states that already have a food inspection program generally have an infrastructure to support the level of effort. The "States Helping States" approach is one way to provide information and advice to states that don't have a regulatory program. This approach has been used with the Rapid Response Teams (RRT) cooperative funding and the Manufactured Food Regulatory Program Alliance (MFRPA) funded by FDA.

NASDA has begun development of a plan for training state and federal officials in carrying out responsibilities under the Produce Safety Rule. This plan encompasses the steps from identifying competencies and developing training, effectively delivering training to a varied audience, and supporting the costs of maintaining such a system. The plan will identify stages for implementation due to the fact that setting up a training system based on competencies will require a significant level of effort. Additionally, there will be an ongoing need, especially in the interim, to continue utilizing existing training courses and instructors until the new training system can be fully implemented.

The training needed will be based on the competencies required to conduct the produce safety activities that a state plans to implement. The current FDA effort to create a competency-based National Regulatory Curriculum will be leveraged – thus saving time and cost. A competency framework and a curriculum framework will be developed for produce that will identify the training states will require to effectively implement a program. The curriculum will include pre-requisite training to provide the necessary background in regulatory programs and a decision tree for the training needed to conduct the specific produce safety components chosen by the state. The intent is to develop a national standardized produce safety training curriculum that meets the open-source quality and content standards. This will ensure the training instills the competencies required for state officials to perform effectively in a produce safety program.

3.Purpose

The purpose of this training plan is twofold:

1. To identify the immediate steps that can be taken to prepare staff at different levels and program functions for implementation of the Produce Safety Rule, and
2. To understand the FDA process for developing a long-term National Curriculum and training system for food protection professionals that will include produce safety training.

The overall system approach is designed to create a comprehensive, coordinated training system to address regulatory capacity. The training plan will examine the development of a training system that will assist in the immediate operationalization of FSMA produce safety requirements while at the same time build long-term competency obtainment. Ultimately, the current FDA curriculum development process will

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incorporate all produce safety training; so, priorities that meet foundational, short term goals can be the initial focus for NASDA and the states.

The proposed system will allow state agency decision-makers to identify the most cost-effective produce safety training options that meet their programmatic needs. The produce safety training paths and specific courses will be vetted (through a formal course review process) and placed in a curriculum so that a standardized approach is used across the U.S. and can be supported financially as required by FSMA. The value proposition includes system-wide comparability, uniformity, quality, improved public health, and economic savings through targeted, competency-based produce safety training across states, federal agencies, and ultimately across the food and agricultural community.

4.Scope

The produce safety training system proposed in this training plan can be applied broadly across the food and agriculture sector – including regulatory officials, auditors, extension specialists, and even farmers. The system can expand and contract as resources permit or as needs emerge. States are noted for their innovative approaches to assure food safety compliance including pre- and post-harvest outreach, education, and assistance performed by a variety of state agency personnel. For example, environmental services program staff often disseminate food safety information while performing routine farm assistance visits. Components of the overall program may be conducted by personnel with various existing skills as well as different training needs.

The system can also be phased to align short-, mid-, and long-term training decisions that support capacity development efforts. In the short-term, the system will meet current demands for highest priority training. Mid-term the system will create a framework for planning, prioritizing and expanding training capacity. In the long-term, a sustainable and cost-effective national training program will support continuous and measurable food safety improvement across the sector.

Specific State Tasks

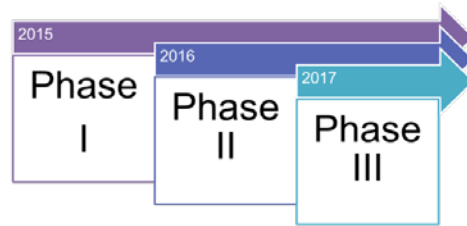
States will be actively engaged in many capacities in the FDA process to create a National Curriculum that will include produce safety. States currently participate through the Partnership for Food Protection (PFP) and some states are members of the PFP's Training and Certification Work Group.

In addition, there are many specific tasks that will need to be conducted by states to quickly implement training to support the Produce Safety Rule. State involvement will include:

- Providing input in stakeholder advisory groups for strategic direction and training priorities;
- Forming teams of subject matter experts to make training recommendations that support implementation decisions, identify produce safety staff competencies and curriculum content areas, developing guidance documents, and serving on course development teams;
- Helping develop a decision tree that identifies the training needed for specific produce safety program components such as education, outreach, pre-assessments, inspections, compliance and enforcement;
- Providing recommended, existing training to appropriate staff;
- Tracking staff training and managing records;
- Identifying and sharing best practices with other states; and
- Creating mechanisms to measure impact of training.

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3381 The training will be phased in based on the rule implementation provisions and the components a state
3382 chooses to implement:



3383 **Phase I (2015)**

3384 One of the first foundational training events needed for states that do not have experience in operating
3385 food protection programs will be developing or identifying existing courses and/or other learning events
3386 that will provide the background necessary for establishing a produce safety program. Another initial
3387 component for states will focus on training staff on the rule applicability and the requirements for
3388 conducting education and outreach to the produce industry. Existing Good Agricultural Practices training
3389 such as offered by the Produce Safety Alliance and UDSA's Agricultural Marketing Service are suggested as
3390 good preparatory courses for produce safety regulatory professionals.

3391
3392 Existing course material will be identified at this phase that could feed into a program to meet the needs of
3393 the varied audience. Instructor skills training will be given to federal and state instructors along with course-
3394 specific instructor training in order to create a cadre of skilled trainers. Duties and tasks will be identified
3395 along with the competencies necessary to conduct produce safety activities so that new training can be
3396 developed. Various audiences will be identified based on tasks and a produce safety training curriculum will
3397 be created at this phase that fits into the national curriculum being developed by FDA. The regulator
3398 training being developed by FDA will require input from states in order to assure appropriate learning
3399 objectives are included for the target audiences.

3400

3401 **Phase II (2016)**

3402 The next component would be to broadly disseminate existing training and build capacity. During this
3403 phase, online and instructor-led courses will be delivered that include on-farm activities. New courses and
3404 online, pre-requisite material will begin to be developed. Deliveries will include existing produce safety
3405 alliance courses, GAPs courses, produce farm investigation courses, and other courses meeting curriculum
3406 foundations (e.g., ORA-U courses). It is expected that produce farm investigation training would be a
3407 separate training program area from the basic produce rule related regulator inspection training.

3408

3409 Training courses/modules to be developed would include developing the infrastructure for a produce safety
3410 program, understanding basic farm practices and on-farm inspector etiquette, regulator courses on how to
3411 conduct On-Farm Readiness Reviews, compliance inspections, and enforcement procedures. On the
3412 curriculum side, gap and depth analyses for existing material will take place. Development teams will be
3413 formed to build out new training and redevelop exiting material to meet competencies and curriculum
3414 content areas. Many development and delivery initiatives currently underway will be leveraged during this
3415 phase including the Produce Safety Alliance training and programs identified by the National Coordination
3416 Center.

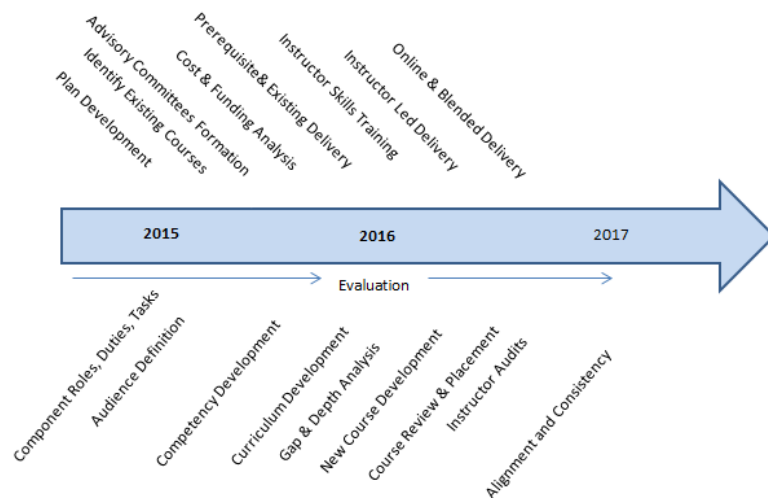
3417

3418

Phase III (2017)

This phase will put all components of the system in motion to achieve a steady-state. A clear training pathway will be in place for state and federal personnel. Training efficiencies will be in place including online and blended learning activities along with a growing cadre of instructors for each course. Training material produced by various entities will be reviewed and approved for placement within the curriculum. Evaluation of training outcomes will take place and metrics will be captured and reported. Methods to monitor alignment and consistency will be considered and program audit processes identified. Training records will be linked through learning management systems.

Figure 1. Phased Timeline of Produce Safety Training System



5. Background

FSMA introduced new mandates for FDA to provide training and support to states. Section 209 of FSMA (Section 1012 of the FDC Act or 21 USC 399c) is clear in the mandate for training:

“§ 399c. Improving the training of State, local, territorial, and tribal food safety officials

(a) Training

The Secretary shall set standards and administer **training** and education programs for the employees of State, local, territorial, and tribal food safety officials relating to the regulatory responsibilities and policies established by this chapter, including programs for—

- (1) **scientific training;**
- (2) **training** to improve the skill of officers and employees authorized to conduct inspections under sections 372 and 374 of this title;
- (3) **training** to achieve advanced product or process specialization in such inspections;
- (4) **training** that addresses best practices;
- (5) **training** in administrative process and procedure and integrity issues;
- (6) **training** in appropriate sampling and laboratory analysis methodology; and
- (7) **training** in building enforcement actions following inspections, examinations, testing, and investigations.

(b) Partnerships with State and local officials

(1) In general

The Secretary, pursuant to a contract or memorandum of understanding between the Secretary and the head of a State, local, territorial, or tribal department or agency, is authorized and encouraged to conduct examinations, testing, and investigations for the purposes of determining compliance with the food safety provisions of this chapter through the officers and employees of such State, local, territorial, or tribal department or agency.

(2) Content

A contract or memorandum described under paragraph (1) shall include provisions to ensure **adequate training** of such officers and employees to conduct such examinations, testing, and investigations. The contract or memorandum shall contain provisions regarding reimbursement. Such provisions may, at the sole discretion of the head of the other department or agency, require reimbursement, in whole or in part, from the Secretary for the examinations, testing, or investigations performed pursuant to this section by the officers or employees of the State, territorial or tribal department or agency.”

In addition, FSMA §210 (Section 1009 of FDC Act or 21 USC 399) calls on the agency to make grants to eligible entities to (among other things):

“(2) **train** to the standards of the Secretary for the examination, inspection, and investigation of food manufacturing, processing, packing, holding, distribution, and Importation, including as such examination, inspection, and investigation relate to retail food establishments;”

These FSMA components set the stage for the utilization of state resources in an integrated fashion to accomplish the food safety and public health goals set by the Produce Safety Rule.

Since the fifty-state meeting hosted by FDA in 2008, the creation of a competency-based training regimen for regulatory food protection professionals has been a strategic goal for successfully establishing a nationally integrated food safety system (IFSS). A national regulatory training plan is a critical component in developing a competent workforce across all levels of government to successfully achieve an integrated system and improve the overall safety of the food safety system.

A sustainable model is required to address the critical role that training plays in building state agency workforce capacity around produce safety. While many of the needs for produce safety training are new, a number of initiatives already underway can be leveraged such as the:

- Produce Safety Alliance
- Sprout Alliance
- National Coordination Center ³
- FDA’s National Curriculum Standards and curriculum development process
- Partnership for Food Protection
- USDA GAP auditor training and the national GAPs training program

³ Announced via RFA-FD-15-003

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NASDA has begun the development of a plan for training state and federal officials including laboratories in carrying out responsibilities under the Produce Safety Rule. This plan encompasses the steps from identifying competencies and developing training, effectively delivering training to a varied audience, and supporting the costs of maintaining such a system. The plan will identify stages for implementation due to the fact that setting up a training system based on competencies will take a significant level of effort. Additionally, there will be an ongoing need, especially in the interim, to continue utilizing existing training courses and instructors until the new training system can be fully implemented.

6.Leveraging Current Initiatives

There are already initiatives underway that can be leveraged so that NASDA’s training plan can maximize efficiency and avoid duplication.

1) The Produce Safety and Sprout Safety Alliances have developed courses aimed at producers that address the learning objectives to comply with the Produce Safety Rule. Much like the Seafood HACCP Alliance training courses, government officials can use the produce training courses and material as a foundational part of a regulatory curriculum.

2) The establishment of a National Coordination Center and Regional Centers to provide training, education, outreach, and technical assistance across the country. The National Coordination Center will oversee the development and evaluation of training for small producers and will play an instrumental role in integrating crop-specific research into practical training that can also be used to meet identified regulator competencies.

3) FDA’s National Curriculum Standards currently under development and the curriculum development process will form the foundation of the NASDA approach to align learning with the attainment competencies necessary to perform produce safety tasks. Utilizing the existing process that streamlines training development will greatly speed the delivery of the curriculum while ensuring measurable outcomes. This will occur as a parallel process to continued utilization of existing training courses until the standards are in place. New course development will occur using the standards developed and existing courses will be compared to the standards and redeveloped if gaps exist. The Partnership for Food Protection is participating in the development of the National Curriculum Standards and will play a role in steering produce training prioritization. NASDA may also have a workgroup to assist in development and prioritization of training for produce safety.

4) USDA GAPs Auditor Training and the national GAPs program training courses are existing courses that would provide excellent background on produce farm issues for state regulatory produce safety professionals.

Beyond these important initiatives, other means to leverage activities will be undertaken. NASDA will identify ways to establish partnerships with training institutions, associations, land grant universities and cooperative extension programs to coordinate development and delivery of training. Regional and state-based training will make content more relevant and minimize travel. Additional partner leveraging will be used to:

- Incorporate on-farm practical training;
- Use existing learning management systems to track training accomplishments;
- Identify means to assure consistency of training between federal and state inspectors;
- Identify timing (seasonality will dictate the need for off-seasonal training);

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- Ensure modular training (basic training + commodity specific modules at multiple levels);
- Co-train with producers or industry when appropriate;
- Use train-the-trainer concepts as a means to broaden distribution of standardized curriculum;
- Incorporate best practices from industry, associations, USDA, and local produce safety task forces;
- Use multiple delivery nodes and connect the course completion data to a centralized or linked data systems (e.g., learning management systems); and
- Track assessment of knowledge and skills attained and require and formalize the effective evaluation of training.

7. Overview of the Process

A competency-based training regimen for regulatory food protection professionals is strategically important to the success of a nationally integrated food safety system and in meeting the requirements of FSMA. Achieving many of the goals of FSMA is dependent on the nation's ability to properly and consistently train the estimated 45,000 federal, state, local, tribal, and territorial regulatory and laboratory food protection professionals. The goal of the produce safety training regimen is to develop a competent workforce that can consistently and uniformly conduct inspections, laboratory analysis, and other produce safety tasks across the U.S. Implementing a competency-based training program for produce safety will help meet this goal for the education, outreach and inspection activities required under the Produce Safety Rule.

To achieve this end, a Produce Safety Curriculum Framework will be developed to identify the training content areas and the competencies needed by regulatory and laboratory personnel to conduct produce safety activities. Since states may choose the depth of engagement in implementation of the Produce Safety Rule, a system for identifying training needs will be used to determine and prioritize the delivery of training. Some states may choose to participate in outreach and education only, while other states may choose to develop more comprehensive programs including compliance inspection and enforcement activities. Since the implementation will be phased in, the initial focus will be on forming advisory councils and workgroups, developing the training on the rule requirements, increasing instructor skills to conduct education, conducting outreach activities, and delivering the Produce Safety Alliance course.

NASDA proposes the formalization of a national produce training program in concert with FDA that:

1. Provides career-specific and career-spanning skills training and continuing education for food protection officials engaged in produce safety activities – entry level, core job training, intermediate level, advanced level training in specialized areas of produce safety on the farm, training of elite or expert level food protection officials, and leadership development.
2. Develops and uses multiple and advanced training approaches to reach food protection officials engaged in produce safety activities including face-to-face courses, on-the-job training and learning, multi-media approaches, distance learning, web-based courses, blended learning, and other innovative and effective methods.
3. Develops criteria and assesses measurable training outcomes.
4. Develops assessment for instructor curricula and training delivery.
5. Expands the availability of training through the use of state and/or other competent instructors to complement federal instructors.
6. Establishes methods to provide timely training in response to emerging produce safety events in order to minimize public health impacts and aid recovery.
7. Establishes a system to predict and continuously report state training needs

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8. Provides training at no charge to state agencies and funding to states and other eligible entities to be used for meeting workforce training requirements and sharing instructors with other states. A sustainable funding system will need to be developed to provide the training needed for implementation of the Produce Safety Rule.
9. Promotes cooperative integration of advanced technical knowledge throughout the food supply chain among regulatory officials, industry, and academia.
10. Actively participates in the promotion, attainment, and advancement of uniform program standards supporting a national, integrated food protection system in order to build domestic capacity in produce safety regulation.

Specific steps in the process that will be developed to support these main objectives include:

- Identifying competencies needed by state personnel to conduct produce safety outreach, education, pre-assessments, inspections, and laboratory analyses;
- Building a competency framework that will form the measurable basis for training development. A competency framework is a structure that identifies the knowledge, skills, and abilities (KSAs) required to perform a specific job or task, at a specific professional level (entry, journey, etc.) and competencies within a specific domain (communication, core, critical thinking, organizational awareness, and technical);
- Building a produce safety regulatory curriculum framework in alignment with the national curriculum framework. The National Curriculum Framework is a platform/system to catalog and organize learning events, similar to a library where learning events are like books categorized into sections or content areas.);
- Identifying existing training material that can be leveraged and performing a gap and depth analyses on this material;
- Forming teams consisting of state and federal officials to develop needed training based on the national curriculum and using scientific methods;
- Developing an instructor cadre and course-specific instructor training;
- Identifying online courses as needed based on appropriate knowledge, skills, or abilities identified in the development plans;
- Identifying the various employees (audiences) who will conduct produce safety tasks;
- Performing a formal job/task analysis of produce safety work;
- Identifying training gaps and ongoing course redevelopment plans; and
- Developing assessment and evaluation tools to determine the effectiveness of training outcomes.

The FDA process is already in place to develop a system for ensuring that all food protection training is standardized, properly formatted, peer reviewed, policy and regulatory compliant, and updated on a regular schedule. This process will be leveraged to identify competencies and ultimately training courses for the regulatory and laboratory workforce engaged in implementing the produce safety rule. The process is an instructional systems' design model commonly used by instructional designers and training developers to develop training in five stages: analysis, design, development, implementation, and evaluation (ADDIE Model).

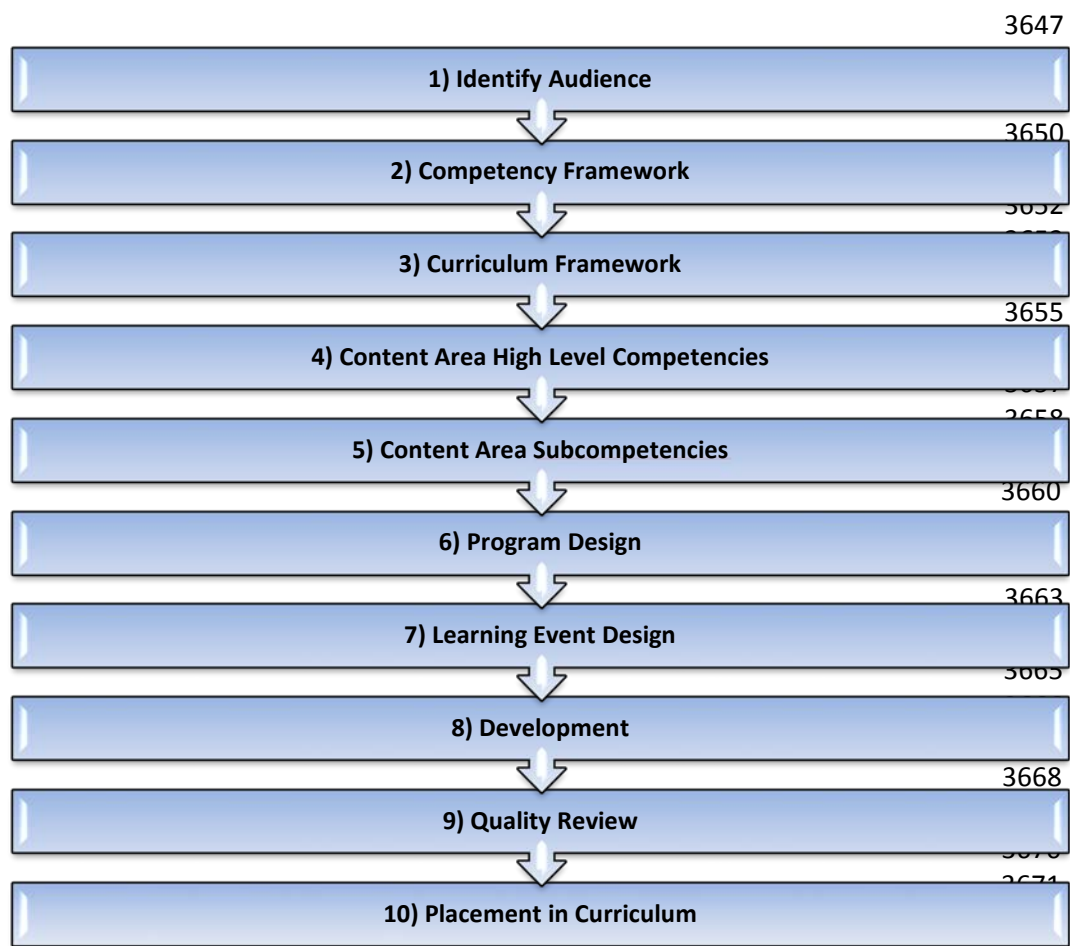
While FDA has conducted analyses of some federal food protection positions in order to establish a body of knowledge upon which training can be built, a specific analysis and comparison to state food protection positions will need to be conducted to verify competencies identified for the various tasks and levels of personnel anticipated to conduct produce safety activities. Once completed, it can be determined if current

training is effective in imparting the knowledge, skills, or abilities needed to perform key produce safety tasks.

Through a Cooperative Agreement, FDA-DHRD and IFPTI have designed a comprehensive approach to tackle the challenge of putting in place a solid foundation for a comprehensive training system while at the same time quickly developing treatments, evaluation metrics, and delivering training to the workforce. When complete, the National Curriculum Standards will cover all aspects of food safety training in a farm to table integrated food safety system.

The curriculum development process comprises a total of ten distinct steps, as depicted in Figure 2.

Figure 2. The Curriculum Development Process



It is anticipated that many existing courses may meet the National Curriculum Standards that are under development or may need some revisions to meet these standards after the courses are adopted. Depending on timing, some of the existing training courses applicable to produce safety may be used until the courses can be evaluated on meeting the curriculum standards. Specifically, the Produce Safety Alliance course, existing Good Agricultural Practices auditor courses, and the FDA's produce farm investigation course will be readily available prior to completion of the standards.

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The process will identify standards and outcomes as benchmarks to use to evaluate existing courses and serve as an open source for the development of new courses to fit into the Curriculum Framework content areas.

Given the decentralized nature of the sector, multiple approaches to gathering stakeholder input will be considered. This will include utilizing existing needs assessments and engaging stakeholders to provide information to fill in gaps as needed to prioritize training needs.

Surveying key stakeholders (FDA, USDA, state regulators, the produce industry, and academia) will identify the most pressing training needs. This will be accomplished through 1) a NASDA committee of state agency representatives who will provide direction to the federal agencies on addressing the needs of state agencies, and 2) creating a Produce Training Advisory Council made up of stakeholders from across the food & agriculture sector to advise NASDA on overall sector needs.

NASDA recognizes that a system of this magnitude and complexity will require a comprehensive approach using multiple training partners. The system that NASDA proposes includes key stakeholder subject matter experts to develop: sector competency and curriculum frameworks, plans to conduct specific Job/Task Analyses, a produce safety curriculum, public/ private co-training plans for cross sector Leadership/ Fellowship Programs, and emergency response protocols. AFDO and IFPTI will play a critical role in assisting NASDA to meet its objectives.

8.Benefits of a National Produce Safety Curriculum

The benefits of NASDA's approach to build a National Produce Safety Curriculum are numerous. The curriculum framework can, for example, guide professionals in planning their career paths; help supervisors create career improvement plans for their employees; foster the efficient use of resources—training time can be spent on courses that actually address specific competencies; provide a road map and standards for an open-source of public, private, and academic organizations seeking to offer food safety training; foster integration of the food safety system by encouraging greater collaboration among all stakeholders; and help professionals prepare for certification exams.

Certification is an element of the overall Partnership for Food Protection Strategic Plan for ensuring a competent workforce.

The overarching goal of the training and certification components is to improve consistency and uniformity of produce safety education, outreach, inspectional and laboratory efforts across the country.

Training/ Learning Events

A comprehensive approach will be used to identify treatments that are the most effective to address the identified competencies. These events include different modalities of: training, education, experience, coaching, mentoring, networking, workshops, conferences, job shadowing, standardization, and performance audits, and will cover specific content areas related to produce safety, some examples of which can be seen in Figure 3.

Figure 3. Possible Curriculum Content Areas

Waste	Water	Wildlife	Equipment
Environment	Chemicals	Employees/ Hygiene	Organic Practices
Management Practices	Biotechnology	Produce Grading	GAPs
Soil Amendments	Storage	Farm Safety	Transportation
Food Safety Plan	Jurisdiction	Enforcement	Compliance
Pre-Assessment	Farm Inspection	Produce Traceback	
Pre-Harvest	Post-Harvest Processing	State Program Development	

9. Identifying Target Audiences

Identifying the appropriate target audiences of training helps to design and align learning events to achieve the desired outcomes for the target groups. Not all employees conducting produce safety tasks will be regulatory officials. States will likely use a variety of personnel for different components of the Rule such as those carrying out outreach, pre-assessments, audits, compliance visits, and laboratory analyses. For the anticipated audiences carrying out the various functions and tasks under the Rule, characteristics that need to be considered include, but are not limited to: scope of work, required knowledge, skills, abilities, behaviors, attitudes, and attributes, work environment, tools, resources, learning styles, personality types, organizational culture, and professional culture.

10. Course Development and Delivery

Course development and delivery is the foundation for effective produce safety training. High quality courses must use professionally accepted design and formatting procedures; have a system for updating and maintaining conformance with current regulatory requirements and policies; use course development tools that are recognized as effective for learning and retention; prevent course duplication and conflicting information through a gap and depth analysis and needs assessment program; undergo a strict peer-review process; and ensure instructors are qualified to conduct and teach classes.

Existing produce safety related courses will be utilized as much as possible. These courses will need to be evaluated based on the National Curriculum Standards to determine if any gaps exist and revisions are needed. To ensure that training can begin in a timely manner, existing courses will likely be utilized in their existing form until the standards are completed and the courses can be evaluated. Essentially, this will be a parallel process of utilizing available courses to meet training needs until the formal course review process can be implemented and courses can be re-developed, modified, or newly created.

11. Instructor Development

There are two essentials for successful training - course quality and instructor quality. The NASDA approach will seek out the best instructors, and the instructor pool will comprise recognized experts from around the nation. Each instructor applicant will undergo a vetting process to ensure that his/her qualifications meet the requirements of the course being delivered. Further, to meet strict instructor requirements, all instructors will be required to successfully complete an accepted instructor development/skills course that focuses on best training practices and enhances and understanding of instructor competencies. Emphasis

will be placed on the active, adult learner-centered style of delivery and student experience. Courses using technical or special skill level training may require instructors to undergo additional preparatory training prior to instruction. An instructor pool will be maintained, and instructors will be periodically assessed and evaluated on their instructor skills during course delivery.

The NASDA approach will leverage instructional capacities and capabilities through Train-the-Trainer (TTT) or Course Specific Instructor Training (CSIT) programs. Potential instructors participating in the program will be required to successfully complete the TTT or CSIT prior to teaching. The TTT or CSIT will include performance assessments. Instructor development training will be standardized and delivered by trainers who have completed the TTT and CSIT process. States that want to establish their own cadre of instructors to deliver training within their jurisdiction will need to complete the instructor development requirements when established.

Again, this is a parallel implementation process. Until the instructor vetting process is implemented, existing instructors and new instructors may be utilized based on qualifications and experience. The instructor development component is extremely important as qualifications and experience alone are not sufficient to determine if an individual is a competent instructor.

12.Assessment and Evaluation

The NASDA approach calls for formal evaluation of training programs and participant acquisition of knowledge. The approach will implement a systematic and standardized process to assess participant learning and the effectiveness of all accepted courses within the curriculum. As part of the course development process, a standardized process will be used to develop clearly defined learning objectives for each module or component of a course to assess participant mastery of objectives. Depending on the level of the course, the assessment methodology chosen may vary and innovative formative and summative assessment techniques will be required.

At a minimum, all courses will include an assessment of the learner's mastery of the material and will determine whether the overall course goals and outcomes are being met. Comparisons of post-test results (when used) and utilization of standardized course evaluation forms will provide data on course effectiveness. All test questions will be analyzed as part of the course development process to ensure validity and to determine an appropriate pass-fail rate. This is one methodology that is recommended and suitable for courses seeking accreditation through certifying and standards bodies. Other assessment methods can be used depending on pre-determined participant learning objectives.

All assessment information will be reviewed to identify needed adjustments to course materials (formative). Follow up will be conducted with all course participants' post-course completion to evaluate retained knowledge and impact on performance in the work environment (summative assessment). Data will be evaluated using statistical software and reported to NASDA quarterly for use in tracking training objectives, maintaining a situational awareness of completed trainings and ensuring an awareness of competency levels of participating regulators. Quarterly progress reports will include information on progress made towards identified goals and a summary of all relevant course data (number of deliveries and performance metrics).

Through its stakeholder committees and Training Council, NASDA will establish metrics to support an annual program evaluation process. Metrics will be developed to focus on desired outcomes and will not just focus on course metric data such as number of deliveries and participants. Desired outcomes may be the ability

to conduct certain types of inspections or meeting certain quality standards for food handling procedures. Program evaluation will include evaluating the progress in meeting these outcomes by looking at specific identified criteria. Periodic program evaluation will also examine progress towards all identified goals and will identify any barriers to implementation.

If any barriers are identified, a plan will be developed to facilitate the process of meeting program tasks and activities prior to the next evaluation. Evaluation will include an internal evaluation using defined performance metrics as discussed, and will include an external evaluation of activities, which will incorporate feedback from stakeholders. Mechanisms for input from external stakeholders will include feedback from advisory councils and may include targeted surveys of defined stakeholder groups.

The assessment process will also include an opportunity for course participants to evaluate both the course and instructors to help identify training material or delivery concerns or issues.

13.Ensuring Success

NASDA sees the need to build into the training system those principles that will ensure success. NASDA understands the needs of states and has committees and communication processes in place to gauge changing state needs.

The training plan that NASDA will implement will assure quality on a number of fronts:

- Development against nationally recognized competencies;
- Transparency – identifying the basis for deciding how to allocate scarce training resources;
- Demand driven – addressing the needs of front-line food and agriculture responders, aligning and prioritizing development and deployment of deliveries with national priorities;
- Coordinating funding sources to prioritize development and avoid duplication;
- Allowing for customization by agencies to better address local and regional needs and accessibility;
- Recognizing interdependencies within and between food and agricultural systems and sector stakeholders;
- Supporting incremental capacity development at multiple levels (entry, journey, specialist, etc.), at other levels including rapid response teams, programmatic, agency, regional, commodity-based, interstate, cross-sector (government, producers, industry, academia), and at all levels of government (federal, state, local, tribal, territorial);
- Using multiple delivery nodes and connecting the course completion data to a centralized or linked data systems (e.g., learning management systems);
- Tracking assessment of knowledge and skills attained; and
- Formalizing the effective evaluation of training.

14.Suggested Initial Roles for Key Training Partners

14.1 State Responsibilities

- Develop and implement a training strategic plan detailing how to meet training and competency requirements
- Participate on NASDA training/oversight committees
- Share instructors
- Cooperate with other states
- Share subject matter expertise

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- Train with producers and industry, where appropriate
- Participate in training needs assessment surveys
- Participate in online training needs assessment reporting when the system is adopted.

14.2 FDA Responsibilities

- Utilize a network of training entities to build training development/delivery capacity
- Adequately fund state agency training through cooperative agreements and other vehicles
- Support instructor development and quality auditing of state and federal instructors
- Include produce safety components in the ongoing development of the National Curriculum Standards
- Participate in curriculum development and training needs assessments.

14.3 Other Responsibilities

The produce industry, academia, cooperative extension, commodity groups, and the USDA all will play a responsible role in assuring the ongoing success of the training plan.

15. Baseline Costs

As funding is identified and budgets are developed, there are a number of training cost figures that will inform the process. NASDA is conducting surveys and interviews to help determine these costs. Considerations include:

How much does it cost for states to train their staff?

- Time, travel, facilities costs for states to attend training
- Time away from the job to complete training
- Cost of computers and IT systems used for training
- Time to track training records and cost of learning management software
- Time & travel for state instructor training
- Materials costs
- What about states that can't travel?
- Field standardization activities
- Time & travel for state attendees on curriculum teams and committees
- Indirect costs

How much does it cost for training system development and maintenance (much of this will be borne directly by FDA)?

- Competency identification
- Curriculum development
- Course development costs
- Grants for training partners to develop courses
- Course review SMEs
- Online development costs
- LMS costs
- Instructor development
- Instructor management/ audit
- Instructor led delivery
- Online course maintenance
- Evaluation and audit costs

- Reporting
- Advisory council meetings
- Standardization costs
- Communications and marketing
- Catalyzing professional expectations

Figure 4. Depiction of the Degree of Training Anticipated Based on the Program Component Performed

Program Component	Prerequisite Foundational Training	Core, Spanning Produce Curriculum Content	Inspection Component Required Training	Comprehensive Regulatory Program Curriculum
Outreach				
Education				
Pre-Assessment				
Inspection				
Enforcement				
Laboratory				

The purpose of Figure 4 is to show that the type and amount (and cost) of training that is anticipated will vary with the component of the produce safety program that is performed by a given state. The Produce Safety Curriculum will accommodate these differences. Obviously, training costs will be greater for components that have a broader scope. However, for full regulatory programs, much of the cost for produce safety training will be combined with overall program costs to administer a regulatory system. Training costs for state regulators will also include the costs for training laboratory staff that will be involved in implementation of the produce safety rule. Laboratory staff involved in testing produce would benefit from taking some of the same courses as the produce regulatory professionals to help them better understand the nature and scope of the produce safety regulatory program. Laboratory staffs in a number of states are trained in the food safety regulatory programs and in some states participate in field inspection sampling activities at manufacturing and retail food facilities.

As NASDA collects baseline cost information from states, consideration will be given to:

- Estimated salary ranges for component staff
- Anticipated number of staff needed
- Staffing basis (number of farms, geography, location, combined duties)
- In-course training hours
- Travel
- Type, duration, and complexity of training
- Facilities and on-farm activities
- Required training program (number of learning events)

- 3938 • Turnover
- 3939 • Continuing education
- 3940 • Etc.

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Chapter 8: Accessing Laboratory Resources

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1.Executive Summary

Laboratory resources are a critical component of any regulatory program implementing the rules promulgating the Food Safety Modernization Act (FSMA). While the Produce Safety Rule does not require environmental or product sampling as a part of routine compliance, the access to an appropriately accredited laboratory for analysis of samples from for cause investigations or other FSMA rule requirements is essential.

The primary goal of a laboratory is to provide meaningful and actionable data to regulatory agencies, whether local, state, or federal. In order for a state regulatory program to have the greatest impact on food safety, the laboratory program should operate under the ISO/IEC 17025:2005 standards or comparable quality system. For states that elect not to establish in-house laboratory capabilities, other options include establishing partnerships with other State, local, or academic laboratories, or contracting with private, third party servicing laboratories if appropriately accredited. The accreditation body of the laboratory must be a full member of the International Laboratory Accreditation Cooperative (ILAC) and a signatory to the ILAC Mutual Recognition Arrangement (MRA). The main component is to provide access to appropriate laboratory resources.

A full discussion of essential laboratory structure and components will be made available as a supporting document to this Chapter. However, since routine sampling and analysis of products or the environment on farms and on-farm packinghouses is not part of the Produce Safety Rule, agencies will have to consider the individual needs of the programs to support other regulatory requirements of other rules and the necessity to have laboratory resources available when observed conditions and environments mandate sampling and analysis for investigative and confirmatory purposes. Laboratory access is an essential part of an overall operational FSMA implementation plan.

One of the key components of an Integrated Food Safety System (IFSS) is data sharing that would enable federal agencies to use state or local laboratory results for regulatory purposes. To do this, a laboratory program should have a quality system in place and utilize reference or standard methods for food testing. Several factors have a key role in a laboratory's ability to provide reliable data to regulatory programs: (1) quality system which includes quality manual, documented business process, corrective of action; and document control process; (2) laboratory capacity and capability; (3) laboratory contingency planning; and (3) good communication between the regulatory and laboratory personnel.

For states with existing food safety laboratories and for states without existing laboratories, each state should consider the cost of setting up and maintaining a produce safety testing program. Factors that will determine whether a regulatory enforcement program will perform in-house laboratory analysis includes: capacity needs of the program and the ability to provide timely information. The ability to perform laboratory analysis is only one aspect of developing a regulatory program.

2.Purpose

This chapter will provide an overview on the important role laboratories play in developing an IFSS and to the produce safety regulatory program. A forthcoming, supporting document will describe the broad considerations for a laboratory's role in the IFSS which will include acquiring ISO/IEC 17025:2005 accreditation or establishing relationship with an accredited laboratory, method standardization, federal and state acceptance of data and information sharing.

Second, the chapter and supporting document (still to be developed) will provide an introduction to the important functions, capabilities, and costs of developing a state laboratory program, as well as alternate opportunities for states to obtain necessary resource analysis to support their state produce safety regulatory program (equipment, personnel, training, capability, capacity, cost, space, load, surge, demand, and timeliness of response) whenever for cause investigations require sampling.

3.Scope

State Laboratory Analysis - Outcomes Desired

FSMA shifted the focus of food safety from responsive to preventive. Although the shift from responsive to preventive food safety system will not drastically change the role of the laboratory, there are many significant and costly changes a laboratory program will need to undergo in order to perform the necessary testing when required by any of the FSMA rules.

The produce safety regulatory program will likely include laboratory analysis as a component of an investigation which could include but not be limited to water quality testing, environmental sampling, and/or product sampling.

Not all states have the same agency involved in a food safety program. Food safety testing is performed in departments of agriculture laboratories in some states, while other states may have their laboratories in a department of health. Each state implementing the produce safety regulation will be responsible to have an appropriately accredited laboratory available to them for investigational sampling where warranted. Review the forthcoming supporting document for a full discussion of laboratory resources and structure.

4.Summary of Desired Outcomes and Process Overview

This chapter and the supporting document will provide best practices to ensure a state implementing the FSMA produce safety regulation is aware of the considerations for successfully obtaining actionable data from an ISO/IEC 17025:2005 accredited laboratory (ISO accredited laboratory) if such is required by needed investigations, as well as the larger role that laboratories play in an IFSS environment. In addition, it will provide an existing laboratory with tools and considerations to develop a program geared toward improving the state's ability to respond to foodborne outbreaks and investigations associated with produce. States will determine whether an accredited laboratory within the agency is necessary or whether access to such a laboratory is sufficient.

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Desired Outcomes - Resources on how a laboratory can reduce costs and duplication of analysis through unified and coordinated action (both state and federal agencies) on the basis of data acceptance from ISO accredited laboratories.

- Appropriate understanding by a state of the implementation needs for an ISO accredited laboratory to support regulatory action and determination of what standard method is suitable for produce testing.
- Accurately assess short-term and long-term needs within a state to sustain an ISO accredited laboratory program.
- Provide resources to prepare a state program for utilizing/leveraging laboratory resources effectively and in a manner to further developed an IFSS.
- Improve timeliness of decisions and activities related to food safety by ensuring state and federal agencies are able to collaboratively rely on the results from an ISO accredited laboratory for enforcement action.
- Improve communication between laboratories and state regulatory programs.

Process Overview

First, each state implementing the produce safety regulation under FSMA should understand the scope of the role laboratories will play in the enforcement of the regulation. Second, a state should analyze agricultural production within the state to determine the extent of regulated activities engaged in at the state level and the potential level of observed conditions that might cause sampling and investigation. Finally, if adequate laboratory resources are not available or it is not financially feasible to develop a state laboratory program only for produce safety, the state should consider alternatives to obtain access to the appropriate services from ISO accredited laboratories located in a university, the private sector or other states. Review the forthcoming, supporting document on Laboratory Resources as well as other Chapters in this Operational Framework for further details.

5.Responsibilities

State Regulatory Agency

- Determine which agency will be testing investigational produce or environmental samples according to agency jurisdiction. If state laboratories from different agencies have responsibility for food safety testing (Agriculture or Health), use a Memorandum of Understanding (MOU) to document the agreement. Sharing and acceptance of laboratory data should also be discussed and documented accordingly.
- Work with state laboratory to ensure staff, supplies, equipment and other resources are available prior to sending samples to the laboratory.
- Develop best practices applicable in for cause investigational sampling, in collaboration with the laboratory, concerning sample collection, aseptic techniques, sample type, size or quantity, sample storage and transportation conditions.
- Develop a plan or network to enable the produce regulatory program to have adequate communication systems in place to obtain timely results and reports from the laboratory.
- Seek for ISO accredited laboratories to test the limited produce or environmental samples using standard analytical methods.

FDA

- Continue to provide financial assistance to laboratories seeking ISO accreditation as through the current FDA ISO Accreditation Cooperative Agreement.
- Ensure laboratory meets the overall best practices for laboratories detailed in the forthcoming, supporting document.
- Promote development of information sharing platforms.
- FDA should work with state, local, and private ISO accredited laboratories in procedures to accept the analytical results of laboratory analysis associated with a state regulatory program.

Others: Industry, Academia, Associations

- Associations such as APHL, AFDO and AAFCO through cooperative agreement will provide assistance for laboratory seeking ISO accreditation and will develop best practices manuals. One example of this cooperation is the PFP Food/Feed Laboratory Testing Best Practices Manual. Refer to each and the supporting document of this Chapter for best practices.
- Other laboratories such as land grant university laboratories may be able to meet the ISO/IEC 17025:2005 accreditation standards of the produce safety regulatory program in the longer term because of their ability to increase staffing to meet demand. This could be accomplished through an agreement to maintain base training and laboratory capacity.

6.Laboratory Resources

Laboratories play an essential part of an IFSS as well as a key role in the implementation of any of the rules under FSMA including the Produce Safety Rule. Key components include:

Information Sharing

Program Development Resources

Capacity of the Laboratory – Both Physical and Personnel

Communication and Relationships

Laboratory Program Costs – Devoted to implementation of each rule including possible contracting costs with a non-regulatory laboratory

7.References

Best Practices Manual Developed by the Partnership for Food Protection Laboratory Task Group

[Food/Feed Testing Laboratories Best Practices Manual \(Draft\)](#) November, 2013

Water Testing Manual – [Standard Methods for the Examination of Water and Wastewater, 22nd Edition](#)

Laboratory Quality Management System – [ISO 17025 Laboratory Accreditation Standards](#)

Association of Public Health Laboratories – [APHL Food Safety](#)

Food Laboratory Directory – [FoodShield](#)

USDA – AMS Microbiological Data Program <http://www.ams.usda.gov/AMSV1.0/mdp>

Accrediting Organizations

- ANSI-ASQ National Accreditation Board - <http://anab.org/> and their associated brands ACLASS, FQS, and ANAB
- [American Association for Laboratory Accreditation \(A2LA\)](#) <https://www.a2la.org/>
- Laboratory Accreditation Bureau <http://l-a-b.com/>

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- 4115 • Perry Johnson Laboratory Accreditation (PJLA) <http://www.pjlabs.com/>
- 4116 • American Industrial Hygiene Association <https://www.aiha.org/Pages/default.aspx>
- 4117 • International Accreditation Service <http://iasonline.org/>
- 4118 • National Voluntary Laboratory Accreditation Program (NVLAP) - <http://www.nist.gov/nvlap/> -
- 4119 technically part of the US government and only accredits a few narrow disciplines.

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Chapter 9: Technical Assistance

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1.Executive Summary

Through this chapter NASDA highlights the importance of technical assistance and ensuring that FSMA stakeholders have access to the scientific information necessary for successful implementation of the Produce Safety Rule. All FSMA stakeholders will benefit from having access to technical assistance/information. FSMA stakeholders include, among others, both domestic and foreign produce industries as well as state, federal and foreign government regulators. (See: *Definition: “FSMA Stakeholders”* at the end of this chapter.) This chapter aligns with the processes, roles and responsibilities detailed in Chapter 6: Information Sharing; clear lines of communication and processes to rapidly share information are critical to providing technical assistance.

In addition to the information available to states highlighted in this chapter, FDA has also opened the FSMA Technical Assistance Network (TAN), which is currently operational and designed to provide technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation. The TAN will address questions related to the FSMA rules, FSMA programs, and implementation strategies after each rule is finalized.

FDA is implementing the TAN in two phases: Phase 1 addresses inquiries related to the publication of FSMA rules and is operational. Phase 2 will provide technical assistance to FDA and state staff performing inspections and supporting compliance activities; it will be implemented by 2017 when preventive controls inspections are targeted to begin.

Features of the TAN will include:

- Inquiries answered by FDA Information Specialists or Subject Matter Experts, based on the complexity of the question.
- Notification of receipt and a case number to be referenced in future correspondence, once a question is submitted.
- Questions tracked and trended using a Knowledge Management System (KMS) to assist FDA in prioritization; repeat questions will be addressed in Frequently Asked Question or guidance documents posted on FDA’s website.

2.Background

Historically, the fresh produce industry has little routine interaction with federal or state regulators outside of limited emergency response, outbreak investigations or surveillance assignments. The demand for technical assistance will only increase as each final rule is published; industry will be challenged to obtain the level of assistance necessary for successful implementation.

The Produce Safety Rule establishes science-based standards for the safe production of covered fruits and vegetables. The rule includes the processes and/or practices necessary to minimize the introduction of reasonably foreseeable microbial hazards in covered produce. While many produce industry stakeholders have been exposed to many of the risk management concepts contained within the Produce Safety Rule, compliance with the enforceable standards found in the rule is entirely different than compliance with the

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voluntary standards found in GAP/GHP programs based on FDA guidance/best practices. The Produce Safety Rule establishes, for the first time, routine inspections for many segments of the food supply (such as produce farmers) against a federally mandated and enforceable food safety standard.

In order for industry to successfully implement the Produce Safety Rule, they should have access to technical assistance to better inform decisions related to growing, harvesting, packing and holding of their specific commodities. Industry will require assistance to determine cost effective, practical and reasonable solutions to issues that may arise as a result of new inspection programs. Applying food safety regulations to the produce industry will be a new regulatory paradigm for both federal and state agencies tasked with enforcing the Produce Safety Rule. As this is a new arena for routine regulatory activities, there are few precedents on which to build compliance and enforcement programs; access to technical information is necessary to ensure national uniformity and consistency in determining industry compliance with the rule.

It is essential that all stakeholders have access to technical information to better inform and guide the decision-making process by industry during implementation and regulators during the development of compliance and enforcement programs. It is of everyone's vested interest that implementation of the various FSMA related rules is successful. An effective system to provide technical assistance will ensure that consumers have access to fresh, locally grown produce, as well as safe imported produce. In order to ensure an adequate, reasonably priced and safe food supply, it is essential that industry has the tools necessary to successfully implement these rules.

The ultimate goal of each of the rules promulgated in support of FSMA is to provide an additional measure of safety and public health protection. Public health is best served when all stakeholders have access to the technical information in an effective and timely manner.

3.Purpose

The purpose of this chapter is to establish the importance of technical assistance; the need for easily accessible and credible scientific information available to all impacted stakeholders; and the various means of providing technical assistance. "Information sharing", as detailed in Chapter 6 of this Operational Framework provides the framework and basic processes for sharing the information needed to provide technical assistance. "Dispute Resolution", as detailed in Chapter 10 establishes the processes to resolve differences in opinion related to technical assistance provided to industry or regulatory stakeholders.

4.Scope

The fresh produce industry has a long standing and well-established working relationship with cooperative extension programs and land grant universities to obtain assistance/guidance in optimizing operational processes but has limited experience working with State or Federal regulatory agencies. The issuance of the Produce Safety Rule introduces, for the first time, routine food safety regulatory inspections on many produce farms. It is critical that the means to provide technical assistance are established as soon as possible after the issuance of each final rule to better assist industry, both domestic and foreign, during ongoing operations and FSMA implementation.

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The need for technical assistance encompasses the entire gamut of operations at a produce farm; not only for routine operations but also for situations such as natural disasters that impact food safety (e.g. extreme drought or flooding). The produce industry impacted by the rule will include a wide range of operations along the size continuum from very large operations to smaller producers; each with different needs for technical assistance. Due to the variation in practices and technical assistance needs along this continuum, the system designed to provide technical assistance should be sufficiently flexible in nature to accommodate the requests of all stakeholders from large to small operations.

Just as the Produce Safety Rule incorporates elements of flexibility to accommodate all sizes and types of operations, the system created to support industry should be equally flexible and adaptable to all sizes of industry and manner of requests. Consideration should also be given to providing access to technical assistance to those sectors of the produce industry that do not have access through electronic media. Traditionally, these types of operations (domestic) have been served by the cooperative extension network.

The Produce Safety Rule includes provisions for alternatives to specific requirements and variances to one or more requirements of the rule to allow for flexibility in implementation. While measures that provide flexibility are welcomed, a caveat to the use of an alternative or variance is that they must provide the same level of public health protection as the original requirement of the rule. Demonstrating that an alternative or variance provides the same level of public health protection will represent a substantial challenge to industry (or regulators) seeking to take advantage of these provisions. In addition to ensuring that industry has access to credible scientific information, it is equally important that scientific research centers (Universities, cooperative extension programs) receive funding to conduct the research necessary to support these processes.

Industry will require access to known alternatives and assistance in determining if their chosen alternative meets the requirements of the rule as appropriate for their commodity or operation.ⁱ The National Coordination Center for Food Safety Training, Education, Extension, Outreach and Technical Assistance Program and associated Regional Centers can be used as a resource to provide a repository for up-to-date scientific and technical information which could include alternatives and variances. Chapter 6 Information Sharing also offers several other options to maintain and share information. The establishment of technical centers and development of readily available FAQs for industry and regulators should be considered to facilitate the dissemination of technical assistance.

FDA has traditionally relied on the issuance of guidance documents to “explain the agency’s interpretation of, or policy on, a regulatory issue” in lieu of providing individualized technical assistance to industry or other stakeholders. Per the FDA Fact Sheet on Good Guidance Practices, guidance is prepared:

“...primarily for industry, but also other stakeholders and its own staff, and uses them to address such matters such as the design, manufacturing, and testing of regulated products; scientific issues; content and evaluation of applications for product approvals; and inspection and enforcement policies.”

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Requests for technical assistance from FDA are frequently handled on an ad hoc basis. FDA's Produce Safety Team is developing guidance documents and other reference materials that will be available to both domestic and foreign stakeholders. It is anticipated that FDA will continue to rely heavily on the issuance of guidance to provide technical assistance to industry but, with the magnitude of changes to industry anticipated by the issuance of the FSMA rules, general guidance documents alone may not adequately support industry or regulatory stakeholders. FDA is currently also developing region specific guidance documents to address practices and processes specific to certain regions; these, in addition to general guidance documents, will provide technical assistance to a wider range of industry.

For technical and regulatory issues requiring a prompt and scientifically supported response, regulators will need a mechanism to access FDA's Centers in order to receive a response in a timely manner. Regulators tasked with making timely, uniform and consistent compliance decisions including those related to alternatives and variances will benefit from access to technical assistance that can include comprehensive FAQs available through a web-based application or through FDA's regional produce safety centers currently under development. Industry stakeholders will need timely access to technical assistance via food safety experts from Produce Safety Alliance, Center for Produce Safety, Cooperative Extension Network and related associations.

As outlined in the Executive Summary of this chapter, FDA's FSMA Technical Assistance Network (TAN) is anticipated to become the primary mechanism for providing technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation. The TAN will address questions related to the FSMA rules, FSMA programs, and implementation strategies after each rule is finalized.

5.Summary of desired outcomes and overview of process

5.1 Desired Outcomes

The desired outcome is the establishment of effective, uniform and consistent technical assistance for industry and regulators in order to implement (and regulate) existing and upcoming federal food safety rules. A responsive technical assistance system should provide reliable, consistent, real-time scientifically supported responses to inquiries; timeliness is particularly critical when dealing with highly perishable, short shelf life commodities. It is recognized that industry and regulators have different technical assistance needs and would follow different paths to obtain that information.

Industry will need access to technical assistance to assist in determining best practices or operational responses during routine operations and emergency response activities. Industry typically will not seek this type of information from a regulatory agency but instead will likely obtain this type of support from cooperative extension programs, local Universities, commodity groups, associations, industry experts or Alliances. However; during inspection, compliance or enforcement activities, it can be anticipated that industry will seek technical assistance from various resources as appropriate to the situation.

Regulators will need access to technical assistance in order to participate with industry in determining best practices or operational responses; determine compliance with the rules; evaluate alternatives and pursue

variances. While regulators will need access to the same scientific technical information as industry, regulators will also need access to technical experts located in FDA’s Centers in order to make inspection, compliance and enforcement determinations.

5.2 Process overview

To maximize efficiency and reach, technical assistance should be delivered through a system that utilizes multiple modes of accessing or distributing the information to include: meetings/teleconference/webinar/video chat/email functionality with food safety or subject matter experts; web-based repository of information (FAQs, guidance documents); and email broadcast systems (such as “List Serves”) or similar web-based applications. The system should include flexibility in order to reach all segments of industry, including those that have limited access to technology.

5.2.1 Identify Subject Matter Experts (SMEs) and Food Safety Experts (FSEs)

Subject Matter Experts (SMEs) and Food Safety Experts (FSEs) should be identified utilizing a multidisciplinary, multiagency approach by an independent board or committee charged with establishing the selection criteria and the creation/maintenance of a topical registry of SMEs/FSEs. The SME/FSE registry could include representatives from FDA/Center for Food Safety and Applied Nutrition; other FDA Centers as appropriate to the rule; FDA/Office of Regulatory Affairs; State Departments of Agriculture; State Departments of Public Health; commodity associations; national associations; Academia; Cooperative Extension Programs; USDA; industry experts and members of FDA Alliances. SME/FSEs will provide technical/scientific information in response to stakeholder requests for technical assistance using various methods of delivery described in 5.2.2 of this Chapter. It is recognized that FDA representatives may, under certain circumstances, be limited in their ability to act in a SME/FSE capacity and will participate to the extent permissible.

5.2.2 Establish Methods of Delivery

A web-based repository of scientific and technical information (including FAQs) should be created and maintained; this can be accomplished by leveraging existing resources through a cooperative agreement with an external entity such as an association, University or Alliance. The web-based repository should be accessible to all FSMA stakeholders and should consider functionality to send email blasts to rapidly disseminate information as appropriate to target audiences. As needed, access to certain information can be restricted to the regulatory community to allow State and Federal regulators to freely exchange technical information regarding inspection, compliance and enforcement actions. As mentioned earlier in this chapter, consideration should be given to those sectors of the produce industry that lack access to electronic media. Chapter 6: Information Sharing offers a number of options for delivery of technical assistance and repositories of technical information. Again, as mentioned earlier in this chapter, FDA’s FSMA Tan is anticipated to meet many of the needs for web-based exchange of technical assistance information.

For high priority issues requiring immediate response, FDA should consider establishing a call or response center (such as a FSMA hotline) for real-time communication with FDA Center technical

experts. “List Serves” or similar web-based applications serving as repositories of FAQs or similar guidance documents could be established as an alternative means for State regulators to obtain technical assistance directly from FDA Center technical experts. A precedent for a regulatory agency providing effective technical assistance can be found in USDA/FSIS Policy Development Division (formerly the Technical Service Center); FSIS has successfully established a system to provide technical assistance to agency personnel, industry and other stakeholders using both call-in and web-based applications.

Priorities should be established to ensure that timely and adequate responses are provided. Consideration should be made to prioritize responses based on criteria such as the public health risk associated with the process or commodity and intended use of the product; regulatory or enforcement consequences; perishable nature of the commodity or product involved and volume of impacted product or area of impacted region. In addition, response priorities should be balanced to ensure that all parties have equal access to technical assistance with all segments of the industry and/or individual stakeholders availed an equal opportunity to receive information.

Many of the FSMA regulations, notably the Produce Safety Rule, represent the first-time industry will be regulated against a federally mandated food safety standard and the demand for technical assistance has the potential to exceed the capacity to deliver technical assistance.

It is anticipated that extensive resources will be required to meet stakeholder’s demands for technical assistance in the initial years of FSMA implementation. A tiered technical assistance system should be developed that can effectively provide support to the various stakeholders; no one single agency or entity will be adequate to meet the anticipated demand. A privatized or third-party entity should be considered to handle the technical assistance requests that do not require immediate responses in order to reserve critical resources for high priority/high consequence requests such as those related to regulatory or enforcement issues.

5.2.3 Implement Pilot Programs

Pilot programs should be established to measure the effectiveness of the aggregated systems for providing technical assistance. Resource prioritization and risk-based modelling would be used to identify the pilot programs. It can be anticipated that smaller entities will require more technical assistance in the initial years of implementation and targeted pilot programs can provide valuable data regarding the effectiveness of both technical assistance and educational programs proposed in this Operational Framework. The use of pilot programs to measure effectiveness of technical assistance programs would in no way limit the overall availability of technical assistance to all stakeholders. (See Chapter 4: Outreach/Education and Compliance/Enforcement for information on education phase of regulatory programs.)

5.2.4 Develop Metrics

A means of measuring the effectiveness of technical assistance requests should be established to measure and continuously improve the effectiveness of technical assistance delivery systems and

the suitability/utility of response. These types of performance measures are necessary to continuously improve and optimize the systems and ensure that industry stakeholders are receiving the appropriate levels of technical assistance. State Departments of Agriculture should be included in the process to review these metrics and associated data gathered from pilot programs to provide recommendations on process improvements.

6.Responsibility

6.1 State Department of Agriculture (or other State agency)

The State Departments of Agriculture or other State agencies will work with industry (through outreach and education programs) to facilitate requests for technical assistance. State Departments of Agriculture are uniquely positioned to provide this type of assistance by utilizing both marketing and regulatory capacities to assist industry.

The State Departments of Agriculture or other agency will maintain confidentiality of FDA or industry information as necessary and will contribute relevant information to the information repository or SME registry as appropriate.

6.2 FDA

FDA should prioritize funding in the following areas: to support the scientific research needed to build the foundation of technical information necessary to support FSMA implementation, and to establish and maintain a web based technical information repository (including FAQs) and SME/FSE registry. FDA should participate in the SME/FSE registry and provide technical assistance as appropriate to stakeholder's request.

FDA should collaborate with industry to prioritize and expedite the validation and approval of rapid testing methods in support of the issuance of the FSMA rules to ensure that stakeholders have a way to provide (and receive) rapid, supportable analytical results for microbiological testing conducted in support of the rules.

FDA should quickly and efficiently respond to requests for technical assistance from industry and State regulators.

6.3 Industry, Academia

6.3.1 Industry

Industry will use the technical assistance resources to assist in developing best practices, operational processes and response strategies as appropriate to the individual operation.

6.3.2 Academia/Cooperative Extension

Academia/cooperative extension programs will provide input to the web-based repository of scientific information, conduct research to support industry implementation of FSMA rules (supported by FDA funding); provide peer review of scientific information, assist industry, provide

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technical assistance and participate in the SME registry as appropriate. Cooperative Extension programs play a critical role in providing technical assistance to those regulated communities that do not have access to web based electronic media.

6.4 Associations (Commodity and national)

Associations will assist industry in seeking technical assistance; provide input into technical information registry and assist in disseminating information as appropriate. The Produce Safety Alliance and the Center for Produce Safety are critical to coordinating the research and delivery of educational and training programs and coordination research efforts.

7.Related Documents

7.1 NASDA FSMA Operational Framework, Chapter 4. Outreach/Education and Compliance/Enforcement

7.2 NASDA FSMA Operational Framework, Chapter 6. Information Sharing

7.3 NASDA FSMA Operation Framework, Chapter 10. Dispute Resolution

8.Definitions

FSMA Stakeholders: Industry (domestic and foreign); regulators (State, Federal, and Foreign Government); academia; cooperative extension programs; commodity associations; national associations (e.g. NASDA, AFDO, ASTHO, APHL); industry experts; USDA and Alliances (Produce, Preventive Controls and Sprout).

9.Equipment/Materials/Resources

N/A

10.References/Attachments

10.1 FDA Field Management Directive (FMD) 50 – FDA State Communication

10.2 Center for Produce Safety, Global Research Database:

https://cps.ucdavis.edu/global_research_database.php

10.3 Produce Safety Alliance: <http://producesafetyalliance.cornell.edu/>

10.4 Food Safety Preventive Controls Alliance: <http://www.iit.edu/ifsh/alliance/>

10.5 Sprout Safety Alliance: http://www.iit.edu/ifsh/sprout_safety/

10.6 USDA/AMS Harmonized GAPs: <http://www.ams.usda.gov/AMSV1.0/HarmonizedGAP>

10.7 FDA FSMA Technical Assistance Network (TAN):

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>

ⁱ As an example, under the preventive controls rule (human food), a facility with hazards reasonably likely to occur must have a food safety plan which includes a requirement to validate the preventive controls implemented to control the identified hazards. In order to validate a preventive control, a facility must collect and evaluate scientific and technical information to ensure that the preventive control will effectively control the hazard. As this is a new concept for many facilities (including on-farm mixed type facilities) subject to the rule, it can reasonably be anticipated that industry will have an increased need for technical assistance in this area. As firms work to implement their compliance to each of the rules, many initially may not know which rule applies (Produce Safety or Preventive Controls) and requests for technical

4482 assistance from produce farms may also encompass provisions of the preventive controls rules. Regulators,
4483 both State and Federal, tasked with determining the completeness of a food safety plan, and effectiveness
4484 or validation of a preventive control will need access to technical assistance.

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Chapter 10: Dispute Resolution

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This chapter has been modified by the development of:

Dispute Mitigation and Resolution

For the produce inspections being conducted by FDA, the agency has developed a Dispute Mitigation and Resolution procedure, which is formalized as Field Management Directive 152. This provides a process for resolving differences between FDA and state regulatory authorities during inspections.

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This chapter, considered vital to the Framework, is still in development, but has as its goal the development of a process to resolve disputes between states, and between states and FDA, that arise during the implementation of produce safety regulatory programs. Some background and summary information is provided to establish context and indicate the importance of this chapter to our overall development of state programs to implement FSMA. This topic will be one of the focuses of the NASDA-FDA year 2 Cooperative Agreement priorities.

1. Background

The Food Safety Modernization Act (FSMA) is the most sweeping reform of our food safety laws in more than 70 years. FSMA creates a new system with the goal of preventing food safety problems instead of reacting to them. FSMA also has multiple mandates to promulgate new food safety regulations in regard to most aspects of the foreign and domestic food supply, some of which will present new challenges. The mandate to establish science-based minimum standards for the safe production and harvesting of certain types of produce, to minimize the risk of serious adverse health consequences or death, will pose unique challenges for several reasons.

First, the United States Food and Drug Administration (FDA) has years of experience in regulating processed foods, as do many states. In most cases FDA and state inspection of produce farms has traditionally been limited to instances when there is a for cause food safety investigation. In a broader sense, however, state departments of agriculture, in general, have significant on-farm experience through various regulatory and non-regulatory programs. In this new environment, created by FSMA, the state agencies are in a unique position to bring helpful compliance perspectives to the forefront, enabling and extending FDA's efforts. Because of their past experiences and relationships, states (including state extension, in the case of education and outreach) will likely be the most effective and efficient resource to conduct outreach, education, technical assistance, inspection, and enforcement activities. It is important that the integrated food safety system fully consider the role of state and local public health and agricultural officials in the success of FSMA.

Second, while many farms have been subject to voluntary audits for Good Agricultural Practices (GAP), Good Handling Practices (GHP), Tomato Good Agricultural Practice (T-GAP) [Florida], or the California Leafy Green Products Handler Marketing Agreement (LGMA), very few have ever been subject to a regulatory inspection and, as mentioned above, those that have been inspected are primarily, if not exclusively, farms suspected of being a source of a foodborne incident. Since these are new regulations that will affect a group of stakeholders that have never been subject to regulations promulgated by FDA before, and FSMA requires us all to adopt a new culture focused on preventing foodborne illness, we are essentially "plowing new ground." It is a great opportunity for public health officials to work together in order to achieve food safety goals.

This is a new area of potential collaboration and cooperation that will help us create an integrated food safety system, build domestic capacity, leverage resources, learn from each other, and focus on education, a core principle of FSMA's preventive approach. As our food safety system is revamped, this is a moment

in which public health officials can rise to the occasion and create new models that will fit the needs of FSMA, and our new regulatory efforts.

2.Executive Summary

The development of an entirely new regulatory system for a newly regulated community will likely face many issues throughout the education, outreach, implementation, and enforcement stages. A partnership between states and FDA will provide an advantage in achieving compliance, and that partnership could benefit from a safe avenue for open discussion in order to agree on the appropriate way to address a variety of issues.

Initially, there are several aspects of an integrated food safety system that will prevent conflict from occurring. Several of the chapters in the draft Model Produce Safety Implementation Framework address aspects of our food safety system that have caused disputes in the past, whether from a breakdown in communication, lack of contact or other information, or inadequate technical resources and/or understanding. Additionally, FDA is currently developing new ways to address communication, information, and technical assistance that will be considered and evaluated as they are put in place. There is a good chance that in the future, the efforts currently being put forth by States and FDA will be more effective at preventing conflicts before they occur.

Ideally, in the future, we will not have any issues with communication, information sharing, real time access to information, or consistency among regulatory partners; however, being realistic, we need to have a plan/process in place to quickly and effectively resolve disputes or conflicts between states, and between states and FDA, when differences of opinion do occur. Developing a plan/process for these up-front processes that adequately addresses these concerns is of vital importance.

Initially, disputes that arise should be resolved to the extent possible through established means such as through the use of FDA produce safety experts, informational databases, FDA District Offices and Centers, an ombudsman office, or other methods. It will be important to determine readily accessible and direct lines of communication to pertinent FDA officials, so that there are not “choke points” in the system that inundate a few individuals with an unreasonable amount of work. In order to avoid a flood of work to a few decision-makers, clear communication pathways should be established and shared, and conflicts and disputes should be addressed at the lowest level possible.

When lower-level and up-front processes are not able to address an issue of concern between states, or between a state and FDA, however, NASDA proposes the development of a dispute resolution process. Development of such a process would provide an opportunity for real-time discussion and would promote consistency. Current administrative procedures are not designed to accommodate the level of collaboration between FDA and states that is necessary for the successful implementation of the Produce Safety Rule.

In looking at existing processes, they help inform us; however, they do not adequately address some issues we recognize could be useful for us to agree beforehand to a process to deal with future conflicts. In

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addition, there may need to be different processes to address different situations. For example, if a regulator discovers a food safety issue during the growing season, there may be more time to find the solution than when an issue is discovered during harvest.

The FDA and state partnerships can achieve success and consistency if the process for conducting dialogue related to areas of disagreement is clearly understood and established. The process should be accessible, fair, and transparent to avoid the appearance of arbitrary or detached decision-making, while providing an atmosphere conducive to achieving compliance with the Produce Safety Rule and protecting the public health. The partnerships will be more successful and consistent if all parties feel that their concerns are adequately considered, and full explanations of decisions are shared. A process for discussion that is accessible, fair, and transparent will open dialogue and provide an atmosphere of mutual respect, helping achieve higher rates of compliance with the Produce Safety Rule.

The process needs to be accessible and efficient to provide quick resolution. Information sharing, infrastructure, training, and technical assistance will be important to prevent disputes; however, in the event that a dispute is not solved at a lower level, the process should have flexibility and a framework to be nimble in order to address disputes as quickly as possible, especially in regard to perishable products.

Most importantly, NASDA recommends that a dispute resolution process be:

- Independent;
- Neutral and impartial;
- Credible;
- Equitable and transparent; and
- Confidential, when appropriate.

There are multiple processes and frameworks that lend themselves as good examples for managing conflicts and resolving disputes. The demands of a novel regulatory Produce Safety Rule on our integrated food safety system, however, demands a new level of dispute resolution that will need to be continually evaluated and reconsidered. We are in the process of a large undertaking, not only through the creation of new regulations for a newly regulated industry, but also in regard to the fact that our entire food safety focus is changing from reactive to preventive. This is a tremendous opportunity for states and FDA to work together and establish working processes that will pave the way for FSMA's success.

NASDA has endeavored to find direction and models to meet the objectives of this process but has not been able to identify a current model that completely and adequately fits the tenets of this new regulatory environment. NASDA, working with FDA, will continue to develop the direction of this effort within the scope and purpose of the chapter. In addition, the value of developing and/or creating a dispute resolution process for industry is equally important. As a result, in order to evaluate potential approaches, NASDA proposes that FDA and NASDA establish a subgroup to collaboratively work on finding useful and meaningful options to accomplish these goals within an integrated food safety system.

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Chapter 11: Infrastructure

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1.Executive Summary

Infrastructure requirements are an essential part of an operational plan for any agency involved in food safety regulatory programs associated with FSMA. The term “infrastructure” refers to the physical and organizational structures necessary for the successful operation of an entity; it describes the basic and fundamental facilities and systems (such as personnel, facilities and equipment) necessary to carry out functional activities. The need for investments in infrastructure can be anticipated when initiating new operational activities or expanding existing operations to include new activities.

Developing and implementing regulatory programs in support of the proposed FSMA regulations such as the proposed Produce Safety Rule will be resource intensive in terms of personnel, facilities, materials/supplies, and laboratory capacity. State agencies tasked with developing new produce safety regulatory programs will first need to assess existing infrastructure to identify gaps that will slow or impede the process of successfully initiating the new programs. In the majority of situations, existing infrastructure will not be adequate and significant systematic expansion will be necessary to meet the demands of instituting new programs. The assessment of existing infrastructure should include a determination of immediate and long-term programmatic needs and timelines for addressing any identified gaps; the assessment should be followed by the development of a strategic implementation plan to delineate priorities, timelines, and metrics to guide, track and measure progress in filling any gaps identified in the assessment.

Assessing infrastructure should occur very early in the process of implementation as the development of a uniform and consistent regulatory program will be contingent upon adequate infrastructure to support the necessary programmatic activities. Ongoing or periodic re-assessments of infrastructure should be conducted to determine capability to meet emerging needs with revisions to the strategic implementation plan as appropriate to ensure continuous progress in program development.

In order to successfully implement any of the FSMA rules, state agencies should ensure that they have adequate infrastructure and a careful assessment of existing resources should be conducted before any significant implementation activities can occur. Assessing infrastructure is best accomplished using a systematic approach that clearly identifies and prioritizes the steps needed to enable the state agency to protect public health and support industry implementation efforts. It is important to recognize that there is variability among state programs and variability in levels of existing infrastructure that may be cross utilized to support a produce safety program; the infrastructure assessment needs to account for this variability and be adjustable; one size does not fit all. The assessment not only serves to identify what resources are needed but will also have utility in determining the level of financial support required to be successful. There is no question that extensive financial investment will be necessary to accomplish the goal of establishing a produce safety inspection program.

Through this chapter, states can identify the core areas of infrastructure needed to support the development and implementation of a produce safety program. The assessment of these core areas of infrastructure should be tailored to the individual program needs and objectives of the state agency, taking

into account the volume of industry covered by the rule in terms of number of farms; relative risk and volume of covered commodities; and seasonal nature of production.

2.Background

State agencies will play a primary role in implementing the Produce Safety Rule, published in November 2015.

While there are many components to a produce safety regulatory program as detailed in the various Chapters of this Operational Framework; the development of outreach and education programs should precede the development of inspection and compliance programs. With the advent of the sweeping reforms to the regulation and production of food established in FSMA, the importance of education and outreach remain the highest priority for state agencies embarking on developing and implementing produce safety inspection programs. Priority should be placed, to the extent possible, on staffing/training/developing outreach and education programs before the issuance of final rules and on an on-going basis thereafter.

Determining infrastructure and programmatic needs are intrinsically linked to obtaining the resources and funding necessary to develop and implement produce safety inspection programs. (see Chapter 3: Financial Support) State agencies should be cognizant of increased facilities and administration costs associated with implementing new programs; while these costs may not be directly captured in the infrastructure assessment, they can have a financial impact on the overall operation of a produce safety program. Consistency among state agencies engaged in produce safety outreach/education or inspection programs will enhance the national goal of increasing public health protection. Accurate assessments of infrastructure coupled with systematic growth in food safety programs will contribute to the consistency and uniformity needed to successfully implement the FSMA Produce Safety Rule.

3.Purpose

State agencies, regardless of whether or not they currently operate food safety regulatory programs, will not be capable of incorporating new FSMA regulatory mandates without substantial resources, funding and strategic planning. The infrastructure and programmatic needs will be far greater for those programs initiating produce safety regulatory programs for the first time. In these cases, where there is no existing infrastructure to support a produce safety program, one will be developed “from the ground up”, requiring extensive dedicated resources in the form of full time equivalent (FTE) employees and capital investments.

The process of assessing program infrastructure would ideally be initiated as soon as a decision is made to implement a produce safety program and on an ongoing basis during implementation of the rule and during the process of establishing a produce safety program. State agencies, many serving as stewards of food safety in their states, should ensure that the right processes are in place to provide the highest level of public health protection while securing the viability of agriculture. Assessing infrastructure is best accomplished using a systematic approach to identify and address gaps in programmatic capabilities and

capacities to conduct the outreach, training, technical assistance, inspection, compliance and laboratory activities relative to the Produce Safety Rule or any other FSMA related regulatory program.

4.Summary of desired outcomes and overview of process

4.1 Desired Outcomes

The desired outcome is for state agencies to have sufficient infrastructure to establish responsive produce safety inspection programs under FSMA. All states will approach FSMA implementation from a different starting point; through affiliations with the NASDA FSMA Technical Working Group, mentorship relationships can be utilized to assist in determining infrastructure needs. Existing collaborations such as those between or among state programs or the Food Emergency Response Network (FERN) should be evaluated to determine if they can be leveraged to meet infrastructure needs or gaps. In order to determine the infrastructure needed for the level of program in which they desire to participate, the state agency should:

- Assess existing infrastructure to determine suitability to meet immediate and long-term programmatic needs; and
- Develop a strategic implementation plan with priorities, timelines and metrics to guide, track and measure progress in developing a produce safety inspection program.

4.2 Process overview

4.2.1 Infrastructure Assessment

An infrastructure assessment consists of an evaluation of immediate and long term needs in regard to the core program areas identified below, taking into account existing resources and partnerships/collaborations; the assessment of these core program areas can be accomplished concurrently or sequentially as best determined by programmatic needs.

- Staffing: Determine FTEs needed to accomplish program goals based on volume of industry and anticipated demands (time and effort) in the following areas:
 - o Outreach and education for Industry (including on-farm readiness reviews);
 - o Risk prioritization and risk management;
 - o Inspections/Investigations/Re-Inspections/Surveillance activities (including sampling conducted by the state agency) (see Chapter 4. Outreach/Education and Compliance/Enforcement and Chapter 5. Work Planning);
 - o Support for the submission and management of variances or alternatives;
 - o Laboratory analysis, methods development, instrumentation;
 - o Administrative support (Including, as appropriate, project management and liaisons to external partners);
 - o Inventory management;
 - o IT support;
 - o Legal support; and
 - o Compliance and Enforcement.
- Staff development (see Chapter 7. Regulator Training): Determine the core skills, knowledge and training needed to conduct:

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- 4763 o Industry outreach, education and technical assistance;
- 4764 o Regulator training for staff;
- 4765 o Risk analysis training;
- 4766 o On-Farm Readiness Reviews;
- 4767 o On-farm Inspections/Investigations/Surveillance and sampling;
- 4768 o Emergency response (outbreak investigations, disaster response);
- 4769 o Post response recovery, restoration and resumption of operation monitoring;
- 4770 o Laboratory analysis, methods development, instrumentation; and
- 4771 o Compliance and Enforcement.
- 4772 • IT support/equipment:
 - 4773 o Support Staff (database development/maintenance, equipment set up/maintenance,
 - 4774 data entry);
 - 4775 o Database development, support for data sharing and assistance to industry;
 - 4776 o Training;
 - 4777 o Equipment (video conferencing equipment, cell phones, laptops, handhelds, GIS/GPS
 - 4778 units); and
 - 4779 o Recurring costs associated with equipment upgrades or monthly service fees.
- 4780 • Equipment/Materials/Supplies: General equipment needs to support field, administrative, IT
- 4781 and laboratory activities to include:
 - 4782 o Training materials, AV equipment, Smart Boards;
 - 4783 o Sampling kits, on-farm bio-security kits (personal protective equipment such as
 - 4784 coveralls, boots and cleaning materials);
 - 4785 o Motor vehicles fit for off-road use, safety and communication equipment;
 - 4786 o Laboratory instrumentation, materials, supplies; and
 - 4787 o Recurring costs associated with laboratory equipment maintenance and replacement
 - 4788 costs when equipment becomes obsolete.
- 4789 • Establishing and leveraging collaborations with other state agencies, FDA, other federal
- 4790 agencies such as USDA, local universities, cooperative extension programs, commodity
- 4791 associations, FDA Alliances and National/Regional Coordination Centers for Food Safety
- 4792 Training, Education, Extension, Outreach, and Technical Assistance to facilitate:
 - 4793 o Education, training, and outreach;
 - 4794 o Information sharing related to emerging issues, alternatives and variances; and
 - 4795 o Shared or split regulatory authority for on-farm inspection and enforcement programs
 - 4796 with other state agencies.
- 4797 • Legal support (see Chapter 2. Foundation of Law): The implementation of one or more FSMA
- 4798 regulation will require extensive review and amendment of existing authorities and on-going
- 4799 legal support during implementation in the following areas:
 - 4800 o Review of existing authorities;
 - 4801 o Adoption of federal statutes/regulations and/or promulgation of state authority
 - 4802 aligned with FSMA statutory or regulatory requirements;

- o Facilitate sharing or transferring on-farm inspection authority with/to other state agencies;
 - o Establish legal foundation for information sharing agreements;
 - o Support petition process for variances; and
 - o Support administrative penalty processes (as appropriate to the state program with consideration to first seek other measures to gain compliance and protect public health).
- Laboratory support (see Chapter 8. Accessing Laboratory Resources): To provide the analytical capacity and capability to administer a regulatory program that may include product (including source water) and environmental testing.
- Facilities: The expansion into new regulatory arenas will require additional space to accommodate increased staffing and laboratory activities:
 - o Expansion of existing or building-out new administrative, field and laboratory facilities; and
 - o Training facilities (in collaboration with University /Cooperative Extension or FDA).

4.2.2 Strategic Implementation Plan

After the completion of the assessment and evaluation to determine opportunities for leverage existing collaborations and partnerships, state agencies should then establish priorities and timelines for the resolution of gaps in infrastructure that will impede the development of a holistic produce safety regulatory program. Each program should establish, as appropriate for their long term FSMA implementation strategy and anticipated volume of regulated industry, priorities for developing the components of a produce safety program as detailed in the chapters of this Operational Framework.

The strategic implementation plan should delineate priorities, and timelines, to guide, track and measure progress in filling any gaps identified in the assessment.

5.Responsibility

5.1 State Department of Agriculture (or other state/local agency)

The state agency will initially (and on an ongoing basis thereafter) assess infrastructure to meet current and anticipated programmatic needs of a produce safety program and develop a strategic implementation plan to address any identified gaps. Regulatory and non-regulatory components of state agencies may play different roles in implementing a produce safety program and should cooperatively assess infrastructure to ensure the adequacy of resources to support new programs.

5.2 FDA/other federal agencies

FDA or other federal agencies such as USDA can provide assistance in the form of guidance documents and other technical sources of information to state agencies seeking to assess the impact of the Produce Safety Rule on the infrastructure and programmatic needs, as appropriate to the situation. FDA should share information regarding the validation and approval of rapid testing methods to assist in determining inspection, laboratory and compliance resources.

5.3 Others: Industry, Academia, Associations

5.3.1 Produce Industry

Industry should collaborate with state agencies, academia/cooperative extension and associations to assist in determining research priorities; fund research; determine resource demands for outreach and educational programs as well as resources needed to support the pursuit of variances and alternatives.

5.3.2 Academia/Cooperative Extension

Academia/cooperative extension programs should collaborate with state agencies, industry and associations to provide input into determining infrastructure and programmatic needs to develop and deliver outreach and education programs; On-Farm Readiness Reviews; and research necessary to support alternatives and variances and rapid testing methods validation. The state agency, in cooperation with the cooperative extension service should determine who will deliver the needed outreach and education in addition to determining the infrastructure needs to carry out this activity.

5.3.3 Associations (Commodity, national and regional)

National and local food safety and/or commodity associations may assist state agencies, academia/cooperative extension and industry in determining the infrastructure and programmatic needs of a state lead produce safety program. This assistance can be in the form of collaborating to gather information on the volume of industry, types of commodities and potential risks or mitigation strategies.

6. Related Documents

6.1 NASDA FSMA Operational Framework, Chapter 2. Foundation of Law

6.2 NASDA FSMA Operational Framework, Chapter 3. Financial Support

6.3 NASDA FSMA Operational Framework, Chapter 4. Outreach/Education and Compliance/Enforcement

6.4 NASDA FSMA Operational Framework, Chapter 5. Work Planning

6.5 NASDA FSMA Operational Framework, Chapter 7. Regulator Training

6.6 NASDA FSMA Operational Framework, Chapter 8. Accessing Laboratory Resources

7. Definitions

Infrastructure (Merriam-Webster): the basic equipment and structures (such as roads and bridges) that are needed for a country, region, or organization to function properly.

8. Equipment/Materials/Resources

N/A

9. References/Attachments

N/A

Notes

The following are comments and answers to the input NASDA has received as a result of the review of the framework by industry and interested parties. The input is accurate through February 2018; NASDA has not received additional comments since that time.

This update isn't intended to be a laundry list of the comments we have received; some comments have resulted in editing of the language in the document for clarity. In addition, however, some topics that deserve to be captured have been raised beyond those addressed by the framework.

We will continue to listen to those who are willing to take the time to provide constructive feedback. As such, this document will remain a living document throughout its useful lifetime, while states are considering developing produce safety programs consistent with FSMA; the framework will remain a reference document thereafter.

External Review. Once the draft framework was available, NASDA began seeking comments from external reviewers. For the most part, comments have supported the document. Several comments were seeking clarification of statements; in those instances, edits were made. In addition, several comments asked questions and/or raised topics that are germane to the overall program but may not fit into one of the chapters of the framework. Recognizing the potential importance of these topics the following list of topics has been created. This information is being shared with Chapter Leads for the Framework and included in the Introduction of this version of the Framework. Many of these topics will be discussed in future forums. State program developers should also be aware of these topical areas of concern or interest. NASDA can help to facilitate dialog on these and other topics as well. Some comments are better suited to FDA than to NASDA or the states. Others emphasize outreach and education and therefore include Cooperative Extension. Brief answers and/or perspectives are provided within the list below – they are not intended to replace more substantive dialog as states develop their programs.

The following topics were raised by external reviewers:

- **Risk versus Safe:** one reviewer pointed out that the emphasis on determining a risk profile / basing inspections / potential farm visits based on risk may lead the public to think that any farm that is inspected is “unsafe.”

This is a conundrum and a perennial issue faced by any government program that bases its program on an assessment of risk. While risk analysis, management and communication have developed as parts of categorizing risk – and, as an extension, safety, a potential for misunderstanding the connotation of these concepts as a part of a governmental process or a scientific characterization also has occurred. This point highlights the importance of state programs developing communications strategies to help assure that the public recognizes the value of programs – and processes – used to meet public health goals. It is this view of risk – as a tool to help set priorities, based on implementing best practices that increase the likelihood of preventing a foodborne outbreak – that is used throughout this document. Communications efforts regarding the implementation of FSMA should be tailored to clarify these messages.

- **How will programs be funded:**
 - Long-term funding
 - Farmers should not have to pay for FSMA inspections

Congress passed the federal law. Congress needs to fund it. States cannot accept unfunded mandates. If Congress and FDA are not able to maintain adequate funding, states will likely return the program to the federal government.

While the drug side of FDA is primarily funded by user fees, neither the food industry nor the states support creating user fees to fund FDA. NASDA has stressed uniformity and consistency with the states; however, we have heard that some states – with the support of their states' food industry – may create state "value-added" programs that may require revenue streams consistent with existing state programs.

- **Means to assure the state programs do not become ends to a mean** – lose sight of the food safety value and become simply a bureaucratic process

A reasonable recommendation.

- **Value of states and /or FDA creating a Produce Safety Advisory Board** or some other appropriate process
 - Value of including non-governmental, non-regulatory agencies in outreach
 - Use similar organizations, including industry groups and individual farmers in evaluation of implementation at the state-level
 - Use similar organizations to assess training & education programs

A worthy suggestion.

- **Value of a model bill – consistency and uniformity**

Our foundation of law chapter stresses this point. We are working on it. FSMA is not a standalone law and states' procedures are not always similar; however, the desire to be uniform and consistent is valid – processes and procedures to get there may differ state to state.

- **Criteria for risk characterizations –**
 - How will states stay involved / aware of / consistent with new science of produce safety
 - Risk profiling should not be public –
 - Can results of third-party audits be included in characterization of risk? –

A topic that NASDA and FDA can establish a subgroup to discuss. While everything is a priority, this one will likely fit within the inventory and the inspectional procedures subgroups and is a topic already of interest to FDA and NASDA.

- **FSMA doesn't require inspections** – if they are done, should take into account:
 - Demonstrated compliance
 - No redundancy of records – same as for audits

- o Etiquette – comply with farms food safety protocols – should leave, unless requested to stay, if the farm is exempt
- o Courtesy – unless requested to provide information, regulators should leave exempt farms
- o Scheduled
- o No fees
- o Only high-risk farms should be inspected
- o Reject the idea that if it is not documented it didn't happen.

FSMA fills an interesting niche in the regulatory framework of the nation. As a lot, farmers are compliant. They would never purposefully produce “bad” food. The standards that we know today (promulgated in FSMA rules) require farmers to maintain a minimum standard of protection. These are new requirements, although not new areas of attention for many producers. However, we do not know everything we could or possibly should know when it comes to the possibilities of contamination of produce. As a result, FSMA established a “prevention” standard to assure that the food supply is safe now and into the future. It also requires that current farmers know – and implement – best practices on their farms. Education is mandated as a basic level of knowledge of reasonable practices. This also requires that producers have an avenue to acquire “new knowledge” on a regular basis (educate before you regulate; continuing education; continuous improvement). While inspection carries a negative connotation to some, it also is a part of a process to determine the status quo and to prepare for the future. Congress set the laws / FDA established rules and guidance. Standards of accountability require that states implementing programs determine compliance, understanding the standards and implementing them in a manner that assures food safety. For every person who may be offended by the thought that an inspector may come on their farm [because the farmer has already implemented best practices] there are some other farmers who have not correctly implemented practices and/or are unaware of the requirements. While regulation and inspection to some farmers seems to be an accusation of wrongdoing in-and-of-itself, it also may well be the only cost-effective means of determining compliance.

Depending upon funding levels, inspecting only high-risk farms may be all that state programs can accomplish. This narrow focus, however, results in potentially missing out on observing best practices that farmers have developed that should be shared with others. Assuming the only reason for an inspection is to “bust” someone results in missing the importance of moving to a “preventive approach.” This also speaks to a lack of trust, real or perceived, in the regulatory process and/or agencies.

Regarding documentation. In the early years of implementing the program, it seems useful to focus more on the practices being used to assure food safety than on recordkeeping. A dilemma exists, however, if something goes wrong. If a farm is identified as a source of an outbreak, records may help to reduce liability.

- **Farm Inventory** – Farms are exempt from registration by FDA – that said, it is understood that some way to identify produce farms at the state level must exist.
 - o Fairness – all farms included (include all farms that produce more than \$25,000 produce sales)
 - o Privacy – information should not be available to the general public
 - o Minimal information collected –
 - o No fees

- Anti-regulatory mindset becomes a self-fulfilling prophecy – farms avoid education to avoid being on a list – be aware of the concerns to stay off of lists, but make education programs available to everyone growing produce

- **Sharing of non-public information**

- Can FDA refuse to provide a cooperative agreement to a state that cannot assure it will keep certain information confidential?
- Is non-public information FOIAable? Can conditions be set?

While most prefer privacy and not being on lists, accountability within a governmental context requires that state agencies will need to assure the public – and as things have evolved – the market place (buyers) that farms are meeting minimum standards for food safety. Most states have laws requiring the release of information – sunshine laws, open records, etc. State agencies are bound by those provisions. Generally, state laws allow agencies to hold confidential “confidential business information,” but state agencies are hamstrung by whatever requirements the state already has. Industry will be well-served to make their concerns known to state legislators, as state authorities are being formulated. FSMA does not specifically allow FDA to protect information unless it is confidential business information under federal statutes and that protection will not necessarily confer to state programs.

- **Staff Knowledge**

- Background – requires both food safety and agricultural production background
- Knowledge – rules & produce industry, fruit & vegetable production / how farm operation works / harvest / packing
- Federal priority for training state personnel

FSMA will require many more staff knowledgeable in food safety than currently exists. The Produce Safety rule will require many more staff members that are also knowledgeable about agricultural production. The training curriculum developed by FDA will need to be robust. The transition between now and implementation will be difficult. The importance cannot be overstated.

- **National Coordination Center & Regional Centers** (role as providing consistency from state to state)
 - Important for training, education, outreach, technical assistance

Coordination between regulators and educators is imperative. The importance cannot be overstated.

- **Education before Regulation**

- Use initial “visit” to a farm as an informational / educational contact with the farm
- Use an “all-farm” approach to education
- On-farm readiness reviews (OFRR) should be non-regulatory and voluntary.
- OFRR should continue – be an ongoing service available

Education and technical assistance will remain critical areas as FSMA is implemented. Prevention, as a principle, requires continuing education. Efforts must maintain the need for education as an early form of achieving compliance. Without this approach, enforcement replaces prevention as an organizing principle.

NASDA proposed the idea of OFRR. It has always been touted as a voluntary, non-regulatory program. NASDA also believes the OFRR process should be a long-term effort.

- **Technical Assistance**

- Creating a responsive technical assistance program is important. Is technical assistance binding? How will technical assistance be updated to reflect emerging science? Will there be any hotline for farmers and/or regulators to call in real time?

FDA has recognized the value of technical assistance and guidance. FDA has stood up a Technical Assistance Network (TAN) and hired specialists to assist in developing means to answer questions from the regulated communities. The concept of “real-time” conversations among the regulated community, regulators and technical assistance personnel is a priority. This concept, in practice, may take some time to prefect.

- **How will NASDA include others in its discussions?**

NASDA supports having open dialog with interested parties. The current priorities, of assuring current objectives are met, state programs are advancing and NASDA – FDA projects are progressing, have taken precedent over increasing dialog with interested stakeholders. As more staff is added and activities become more routine, additional dialog is anticipated. In the meantime, NASDA continues to meet with a wide array of stakeholders on an ad hoc basis. A most important avenue for input is through the state programs as they are developed. NASDA is committed to capturing ideas from the states and sharing them among the state program developers. Also, FDA and the states are participating in a quarterly meeting of the ad hoc “Produce Industry Coalition,” where a wide array of issues are raised and discussed.

- **Third-party audits.**

An issue paper is forthcoming.... Major observations:

- *GAP and related audit schemes filled a void in food safety policy over the past two decades.*
- *FSMA doesn’t provide a role for domestic audits.*
- *FDA doesn’t have clear authority to establish criteria to assess audit schemes for “adequacy” in meeting FSMA goals (Congressional action needed, if this is to occur).*
- *Several foodborne illness outbreaks occurred from produce from audited farms.*
- *Even recognizing the aforementioned sources of outbreaks, establishing a value for participating in an audit scheme and receiving “certification” seems appropriate. Farmers understanding the value of accessing food safety practices on a farm through an audit scheme should qualify for a reduced risk profile – with perhaps less frequent inspections.*

- **Novel programs for assessing compliance.**

Approximately 20 state departments of agriculture administer their state’s food safety program for manufactured foods. NASDA relied heavily upon the states with existing food safety programs when the Technical Working Group was established to comment on the 7 major rules and then to begin developing this framework document. Feed officials, who are mostly housed in state departments of agriculture, and several agricultural policy staff from the state agricultural departments also volunteered their time to these efforts. As time went by, representation from state health departments and other national associations of

states officials joined the discussions. With this preponderance of expertise from within existing state programs it is no surprise that program characteristics for new Produce Safety programs at the state level mirror existing state programs, with an emphasis on establishing traditional program inventories, inspectional protocols and compliance options. Representatives from the smaller-scale farmers and some smaller-scale farmers themselves – those farmers, a majority of which will either be fully exempt or have qualified exemptions from provisions of FSMA – raised concerns about using traditional methods to involve them. They don't want any registration requirements and do not support "routine" inspections. NASDA's advice to the states has been couched in, if a registration is considered, here are some things to take into account. FDA's funding opportunity for states, however, requires states to spell out how the state will achieve a farm inventory and FDA has been working with NASDA on developing an inspectional protocol.

Congress passed FSMA as a result of concerns over illnesses and deaths occurring as a result of foodborne outbreaks. Compliance dates for many of the rules are looming close at hand. While developing new, novel, better program administration means and inventive means to involve small-scale farms in advancing food safety principles are attractive, implementation of complex and complicated programs do not happen overnight. While following traditional means of program development will not satisfy those who can envision holistic, cooperative means of achieving compliance, better understanding and harmony among growers, educators and regulators, they are consistent with other food safety programs administered by the states.

One of the goals that FDA has agreed with is the value of educating all produce growers, whether exempt or not, is important. The fact that the market place seems to require that farmers show that they are in compliance may drive the fact that even though exempt under the law, the value-added of being "inspected" will need to occur in order to open markets and increase sales for farmers regardless of size.

Funding is always a reason for state programs to streamline activities. Subscribing to traditional means of program development is one means of showing accountability – something all funding sources will expect. NASDA is open to continued dialog.

- **Farmers will stop growing covered produce – at least until the Produce Safety programs get sorted out**

This is a potential consequence with an importance to food safety and the availability of fresh fruits and vegetables. If farmers perceive that the regulations are too burdensome it is likely some will choose to raise non-covered crops rather than endure inspection and oversight and risk enforcement actions. Over regulation in other areas can be seen as too costly and bureaucratic. Over regulation of fresh fruits and vegetables can result in nutritional and food security concerns. We have to get the balance right – the food must be safe, and it must be available. Driving fruit and vegetable sources overseas is not a supportable strategy.

- **Policies need to support farmers – not police them**

Right. NASDA's actions are not limited to the development of the framework. The last Farm Bill was signed in 2012. We are gearing up for the discussions on the next farm bill now (2017). The framework was developed in 2014 and early 2015. Farm Bill topics are not germane to this regulatory program (programs

administered by FDA). The following is a list of some initial topics NASDA will seek to discuss within the context of the farm bill dialog:

FSMA will place a financial burden on fruit and vegetable producers. While we all seek and will benefit from safe produce, the cost to comply will not necessarily be trivial. It is under these circumstances that some farmers may look to the Farm Bill for assistance. There are a number of areas that may be worth considering as we begin our dialog on Farm Bill priorities. A number of USDA program areas may have programs and/or have/develop similar programs to assist farmers to amortize debt incurred in meeting compliance and/or defray costs of certain investments. The following are captured as possible ideas to be explored and added to regarding potential Farm Bill assistance to produce growers, if such a priority evolves.

- *FSA - Farm Storage Facility Loans - see attached. Perhaps additional loans through FSA and/or other programs may help farmers [facility = a USDA definition, not an FDA one].*
- *NRCS - when conservation and food safety are one, i.e., conversion to drip irrigation - NRCS may provide assistance. Perhaps additional programs through NRCS may help farmers.*
- *RD - Rural Development \$\$ may be available for infrastructure development. FDA regulates some packing sheds as facilities, under the PC: Human Food Rule. Perhaps some farmers /packing shed owners will re-think whether farmer owned packing sheds simplify the regulatory burden. Development of packing shed designs and/or retrofitting may assist food safety and streamline regulatory responsibilities.*
- *RMA - inadvertent contamination of produce and some people's belief that any contamination of food should be handled under strict liability has raised the possibility of Risk Management insurance for produce growers. Can it be done? Would it be cost prohibitive?*

Limited liability. Much of the emphasis of FSMA places a burden on the producers – fresh produce and manufacturer of products – and little emphasis on the other parts of the supply chain. Traceability will also likely result in identification of a farm or facility without necessarily the ability to determine the actual source of the contamination. We need food and we need farms. In those instances where the actual source cannot be determined or when the source is in doubt, farmers should not be punished for a situation that may not have resulted from growing, harvesting, packing or holding the produce. Multiple costs result from reports of foodborne illness. Commodity sales plummet affecting other growers in addition to the farm(s) accused of being the source.

- **Assure that the regulated industry is involved at every step of the process**

For the most part, external reviewers have supported NASDA's approach to implementing the Produce Safety Rule. NASDA has remained concern over some details of FSMA rules, e. g.,

- *agricultural water standard,*
- *packing house requirements under the Human Food PC rule versus requirements under the Produce Rule and*
- *parity regarding standards for and inspection of imported and domestic foods*

to name three. These areas have resulted in continued dialog as we seek to improve the regulations and to assure the safety of the food supply. Opposition to using traditional means for program administration has come only from small-scale users and those representing them. For the most part, these farms or at least many of them will be exempt. We support, as they do, the need for education regardless of size. Conventional means of developing a farm inventory and determining whether a farm is covered by the rule will likely irritate those who believe that they should be able to self-declare that they are exempt; however, this process should not be particularly burdensome while still assuring others that the system is accountable.

This does not negate a value to finding alternative means to involve small-scale producers in better ways to educate and achieve high-levels of compliance. These goals will not be first order priorities, however, as the programs for larger farms and greater potential for exposure to contaminated products will take precedence. Funding for such activities will also have to be secured.