

Produce Safety Summit

Implications of Mandatory Safety Standards



The views and recommendations expressed in this document represent the combined insights of the participants of the Produce Safety Summit, held March 5, 2009, in Washington, DC. They do not reflect the views or opinions of any single attending organization, the Produce Safety Project, or Booz Allen Hamilton.

Produce Safety Summit

Implications of Mandatory Safety Standards

Every year in the United States, foodborne illnesses cause sickness, death, and significant economic and social costs that extend beyond the immediate victims. In January 2007, the Government Accountability Office designated federal oversight of food safety as a high-risk area because of the need to reduce risks to public health as well as the economy. In March 2009, President Obama announced the creation of a Food Safety Working Group to address the need to reduce foodborne illness.

A number of actions are being proposed to address these issues, including mandatory safety standards for foods such as fresh produce. However, there are significant inherent challenges in the implementation and enforcement of safety standards, primarily due to multi-stakeholder involvement, increased complexities in the food production and distribution chains, and fragmentation of oversight responsibilities.

Introduction

The Produce Safety Summit: Implications of Mandatory Safety Standards, sponsored by Booz Allen Hamilton and the Produce Safety Project at Georgetown University, took place on March 5, 2009, at the Woodrow Wilson International Center for Scholars, Washington, DC. The Summit brought together over 50 participants, each with an active interest and unique perspective in produce safety and drawn from across the federal government, producers and growers, academia, state and local governments, retailers and food manufacturers, and consumer and public health organizations. They represented the community of stakeholders with both shared and unique interests and responsibilities related to produce safety standards implementation, compliance, and enforcement.

Mandatory safety standards for produce appear to be on the horizon. The Food and Drug Administration

(FDA) has developed voluntary guidance documents for produce safety standards, as have various coalitions and organizations in the produce industry. Congress has introduced a number of bills with provisions that would direct the FDA to establish standards for the safe production and harvest of fruits and vegetables. Additionally, public interest groups are vigorously advocating for the government to adopt and enforce mandatory safety standards.

In recognition of this growing movement toward mandatory produce safety standards, the Summit featured an interactive simulation to stimulate a forward-looking dialogue among stakeholders about the implications of such standards and develop considerations that could be used to inform the standard-setting process today. One specific type of commodity—domestic fresh leafy green produce—was used in the simulation for the purpose of encouraging focused and meaningful discussions; however, participants examined issues that are truly applicable across all commodities throughout the course of the Summit. The simulation was designed to focus exploration on the challenges of standards implementation, compliance, and enforcement rather than delving into specific content or factors within the mandatory standards themselves. The objectives of the simulation were to:

- Assess the potential implications of mandatory produce safety standards; and
- Identify insights for how standards could be best shaped today as a result of exploring these implications.

Simulation Design

The concerns surrounding produce safety are issues that no single party can address independently. The simulation, in which teams communicated,

coordinated, and made decisions, was designed to encourage building and enhancing a mutual understanding for the various standards implementation and enforcement challenges faced amongst the stakeholders. Participants worked within and across teams to better understand the cascading effects of actions on different stakeholders, and how subsequent actions and assumptions could compound or alleviate problems.

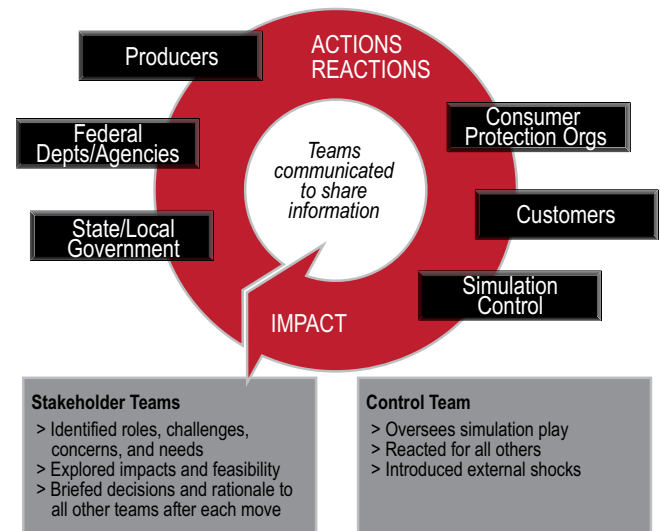
In stakeholder teams (see Exhibit 1), the participants considered the challenges of a future environment in which mandatory safety standards have been implemented to explore impacts on their operations, as well as impacts on others (e.g., within the supply chain, to end-consumers, to enforcement agencies). While each team contained a mix of participants, most participants were from the team’s actual stakeholder group (e.g., most of the participants assigned to the Federal Government Team were from actual government agencies). This team structure offered an opportunity for “cross-organizational” dialogue throughout the simulation.

The participants examined such key questions as:

- What are the challenges associated with implementation?
- Are such standards enforceable? If so, how?
- What resource outlays are associated with standards implementation (e.g., compliance and enforcement)? Who must bear the burden?
- How might such standards be modified to mitigate challenges and improve enforceability?

During the simulation, “moves” represented periods of team interaction. In Move One, mandatory standards requiring safety measures from pre-harvest activities through final processing prior to retail were introduced. These standards included microbial testing requirements for irrigation water, soil amendments, and crop treatments. Risk management planning for domestic fresh leafy green produce and detailed record keeping were also critical standard components.

Exhibit 1 | Stakeholder Diagram



Source: Booz Allen Hamilton

Equivalent safety standards were also put in place for imported fresh leafy green produce.

Move Two began with more stringent standards and enforcement, which resulted from an outbreak involving a leafy green commodity that caused several deaths and a large number of reported illnesses around the nation. New requirements around food protocols and additional employee handling guidelines were included. Inspections and records review became a minimum twice-a-year requirement rather than only once yearly.

Through this type of engagement, participants were able to gain invaluable insights into each others’ perspectives.

Considerations for Future Standards

As a result of stringent, mandatory standards presented as part of the simulation scenario, participants were forced to confront a very challenging and complex compliance and enforcement environment. The focus of the simulation was not on the standards themselves. Rather, the standards were

developed to drive participants to learn from analyzing what attempting to implement and enforce them could reveal.

As each team presented its responses (e.g., actions and concerns) to the simulation scenario to the larger group, common themes consistently emerged. The following sections summarize key insights articulated by participants during the course of the Summit.

Standards should be universal and ensure a “level playing field”

Standards for produce, including those covering imports and produce sold only within a state, must be universally applied and enforced to the extent feasible.

Different standards, such as standards affecting only domestic produce, will create inequities, as there will be advantages for those not subject to the standards and disadvantages for those who must expend resources to adhere to them. The inequities of standards may cause a perceived lack of legitimacy within the industry and serve as a disincentive to comply with the regulations.

The interconnectedness of the produce industry makes it difficult to successfully incorporate standards at only one stage of production (e.g., harvest or packaging). Standards developed in isolation from one another for different stages of production or segments of the supply chain may be inconsistent, likely making

What are our concerns regarding the enforcement of standards? One is the lack of standards for intrastate producers. People can get sick within a state as well. So without a doubt, there needs to be application of these standards to intrastate producers.

Consumer Protection Organizations Team

it impossible to ensure the safety of produce. Consequently, standards should not only be applied horizontally but also vertically to the supply chain from produce growing through distribution.

Standards must take into account differences between specific commodities and growing regions

Although standards should be uniformly applied and enforced, they must reflect differences from one commodity to another, and from one growing region to another. Different commodities have different growing characteristics and, consequently, have different associated risks, concerns, and responses. Different regions also have unique considerations. For example, irrigation practices are different in California,

There are different processes for different regions. We do need a uniform standard, but at the same time, we have to recognize that leafy greens in California may have different growing methods than leafy greens in Colorado. These differences must be taken into account.

Producers Team

Arizona, and Florida. These differences must be taken into account to create standards that can be successfully implemented by producers.

A scarcity of resources complicates effective implementation and enforcement of mandatory standards

Given the current scarcity of resources available to address food safety in general, significantly greater investments would be required to meet the requirements of standards like the ones described in the simulation. Resources are needed at every level, from the creation of infrastructure to support standards to the development of technical capabilities.

Infrastructure: Equipment, laboratory facilities, information technology, and records/data processing capabilities are examples of just a few of the areas in which infrastructure capacity would need to be significantly expanded, if mandatory standards are adopted. An enhanced infrastructure would enable more effective data sharing across multiple parties.

All parties may be willing to share data provided that several items are well defined and communicated, including the requirements and/or justifications for the usage, transmission and proprietary protection, and appropriate access authorization.

Technical Capabilities: Enforcement of mandatory standards requires a cadre of specialists specifically trained in the complexities and nuances of produce safety. For example, these trained personnel would be required to conduct inspections, review data, maintain records, ensure overall compliance with the standards, and conduct educational and outreach activities to encourage compliance with

Right now, we don't have enough experts to address these needs. We need training programs to meet these standards and help people understand how to follow them. These programs must be tailored state by state.

State/Local Government Team

the standards. Detailed knowledge of specific commodities bolsters their enforcement and compliance capabilities. This highly specialized cadre does not exist today in sufficient numbers, and will only be more difficult to obtain as the complexities and specialization within commodity-specific standards increase.

The issue of produce safety requires a science- and risk-based approach

Scientific research and risk analysis can be lengthy processes, and situations may arise, such as outbreaks, in which interim measures may need to be adopted quickly. However, a careful, methodical, overall approach, based on science and analysis of current risks, should be adopted with regards to produce safety to the fullest extent possible.

Science and risk analysis should determine the setting of specific requirements and guide how standards

When developing standards, a cost/benefit analysis would be helpful. Anything that will reduce risk sounds like a good thing, but we have to look at the consequences of enforcing those actions as mandatory.

Producers Team

should be appropriately implemented and enforced. Standards created using this approach will better ensure that the standards will be effective in protecting public health. This is an area in need of immediate investment, as there are gaps in scientific knowledge.

Standards must be nimble and continuously updated Agricultural and manufacturing practices, as well as scientific knowledge of health risks, continually advance. Once mandatory standards are in place,

We need a risk-based approach and to maintain focus on the important standards. If you chase all the standards, you may miss things you were doing before that were important.

Customers Team

a slow and cumbersome regulatory system could impede continuous improvements and even discourage research and development.

Standards should instead be crafted to be nimble and flexible, providing an overall framework for implementation and reflective of evolving science. The standards should also be supplemented with a rich set of commodity-specific guidelines for compliance and enforcement. For the standard-setting process to occur in a timely manner, built-in processes to refine/revise/re-publish the guidelines periodically based on feedback and developments are needed. There is also a need for particular caution when including numeric

measures in standards, as they are the most rigid type of requirements.

Standards need to be implemented using a phased approach

A carefully designed phasing-in of mandatory standards will be important if they are to succeed. Introducing standards in phases allows for differences in capacities in different sectors. For example, phasing might require larger businesses to implement standards at a certain point and provide additional time for smaller businesses with limited resources. Additionally, a phased approach will allow for feedback to be received from all stakeholders at each stage of implementation. Course corrections will occur during the process, building a solid foundation for each

We have to be careful not to introduce characteristics that we don't want in a system through standards, such as a static and fixed nature that is inflexible and not iterative or capable of being updated.

State/Local Government Team

standard that will subsequently be introduced. Voluntary demonstrations and pilot programs could also be considered.

The standards development process must be transparent and engage all stakeholders

Because all stakeholders in the standards environment have unique perspectives, they each need to have an active voice and participate in the formulation of standards from the beginning of the process. A productive, multi-stakeholder dialogue to help define an implementable plan to resolve conflicts and competing priorities will lead to the creation of optimal standards that are ultimately more likely to succeed. Involving all stakeholders in the process will also create transparency and is more likely to generate support from stakeholders from the onset.

We need standards that are implementable—that are something that is achievable. To get there, we need...rich consultation with diverse groups. We're all saying the same thing in different ways, but we need to come to that understanding.

Federal Government Team

Conclusion

The Produce Safety Summit offers a view into a potential future of mandatory produce safety standards and, more importantly, an understanding of the drivers and implications of that evolution. By experiencing this simulated future together, participants have developed a shared appreciation of the implications and impacts of potential mandatory standards, which can serve to bring new value and viewpoints to the current standard-setting dialogues.

During the course of the Summit, it became evident that, although the participants may have used different words or come from different backgrounds, they expressed similar concerns and suggestions. While mandatory standards are foreseeable and will serve to enhance the overall integrity of our food safety system, there are critical issues that must not be overlooked. The balance between universal application of standards with an accounting for differences between commodities and growing regions is a critical aspect of standards development. Additionally, while a science- and risk-based approach to standards implementation is required, we must not “hide behind science,” avoiding potential interim solutions in the quest for the most scientific answer.

As with the development and review of standards in any industry, the ability to remain adaptable and flexible to new information and new approaches will serve well in ensuring that standards continue to meet real requirements over time. In the quest to expeditiously implement new safety practices, we must not lose sight of the complex innerworkings of this

industry or overlook the need to ensure a thoughtful, phased approach to better address just such challenges.

Stakeholders have had numerous past dialogues around the development of mandatory standards for leafy greens, for produce, and for food in general and will continue to drive these efforts going forward. This Summit has provided a unique opportunity to consider and reflect on the implications of standards while engaging in future standards-shaping. The lessons learned provide pragmatic suggestions for ways in which standards can be better crafted to be both implementable and enforceable for produce and other commodities.

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The Produce Safety Project at Georgetown University seeks the establishment by the Food and Drug Administration of mandatory and enforceable safety standards for domestic and imported fresh produce, from farm to fork. Our families need to have confidence that federal food-safety regulation is based on prevention, scientifically sound risk assessment and management, and coordinated, integrated data collection.

To learn more about the project, please visit www.producesafetyproject.org

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