Growers' Understanding and Implementation of FDA's GAPs Guidance

Mental Models Research Report

FINAL REPORT

Prepared for FDA
Linda Verrill, Ph.D., Project Officer

By Decision Partners

Sara Eggers, Ph.D., Steve Ackerlund, Sarah Thorne and Gordon Butte

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Executive Summary

Introduction, Background and Method

Decision Partners was asked to conduct research that will support FDA in improving its communications related to the 1998 Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables[1] (updated in 2008[2] and hereafter referred to as the FDA GAPs Guide, or Guidance, or the Guide). The goals of this research were to: 1) gain an understanding of Growers' awareness and knowledge of, and attitude toward, "good agricultural practices (GAPs)" in general and the FDA Guide in particular; 2) understand whether, how, and why growers are currently implementing GAPs using the FDA GAPs Guide; and 3) identify opportunities to facilitate Growers' adoption of the FDA GAPs Guide.

The researchers conducted confidential, in-depth telephone interviews with: 22 Growers: individuals who serve in a management capacity on farms where tomatoes (Florida) or leafy greens (primarily California and Arizona) are grown, with annual revenues over $250,000 and distribution in multiple states; 19 Trainers and Auditors: individuals who provide training on food safety and to produce growers, packers or handlers, or who are actively engaged in auditing farm food safety practices; and 4 Buyers: individuals who serve in a management capacity for organizations that purchase produce from growers. Data analysis consisted of content analysis of the interviews and assigning codes (according to an *expert model* developed in advance of the analysis) to discrete segments of the transcribed interviews. Coded segments of each interview were then combined into a database and analyzed to: assess key themes corresponding to the codes in the expert model, explore relationships among themes and to identify other emerging themes not anticipated in the expert model. See Appendix A for background on the methodology.

The researchers experienced significant recruitment challenges, specifically, getting people to agree to, or follow through with, the telephone interview. Given the geographic sample frame (Growers in Florida and California), as well as the volume of non-response, the sample of Growers interviewed may not be representative of produce growers across the nation. The sample is mainly comprised of Growers who already have established GAPs programs on their farms and who may be more supportive of GAPs, GAPs standardization, and GAPs regulation than their non-participating counterparts.

This project was built upon similar research conducted with small-, medium- and large-scale produce growers in 2007– 2008.[3] Relevant findings from that study are also included in this Report.

[1] See http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm

[2] See http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm

[3] That research supported a U.S. Department of Agriculture (USDA) National Integrated Food Safety Initiative special emphasis grant on microbial risks to fresh and fresh-cut produce. For more information, contact Sarah Thorne (sthorne@decisionpartners.com).

Results

Awareness and Understanding of the FDA GAPs Guide

This research identified substantial differences among Growers in terms of awareness and knowledge of the FDA GAPs Guide. Most of the Growers interviewed for this study were familiar with and apply some kind of GAPs, but not necessarily those of the FDA GAPs Guide. Some Growers confused FDA's authorship of the Guide with that of USDA, and a few said they were unfamiliar with it. Growers were generally aware that the federal government (FDA and/or USDA) are promoting GAPs; however, they believed that the key drivers of GAPs development and adoption are large-scale produce buyers, state governments and industry associations, all of whom tend to have their own GAPs standards and guidelines.

When **Growers** were asked to identify their primary source of information related to GAPs, none spontaneously mentioned FDA or the Guide. Growers said that they prefer to seek information and support on GAPs adoption through agricultural extension agents and university experts (primarily for Florida Tomato Growers), private auditors and consultants, professional or trade associations, and/or commodity groups. Results from the Trainers and Auditors interviews, as well as from previous research, suggest that smaller growers: a) have less familiarity with formalized GAPs; b) are generally less proactive in seeking information on GAPs; and c) rely heavily on the agricultural extension agencies for information on food safety.

Trainers and Auditors had a detailed understanding and appreciation of the FDA GAPs Guide. However, they said that they generally rely on and communicate GAPs information from other sources (Cornell University, for example), preferring a format that they feel is more accessible and relevant to growers. Trainers and Auditors believed FDA's role is to focus on scientifically-supported GAPs development; their own role is to find ways to effectively communicate that information to growers and support growers' adoption of GAPs.

Buyers generally had detailed understanding of the FDA GAPs Guide. However, they believed that FDA's Guidance lacks specificity, accessibility and relevance to farming operations and broad stakeholder buy-in that they felt was necessary to make GAPs adoption practical, relevant and aligned with their own food safety needs. Buyers cited other programs, such as the California Leafy Greens Marketing Agreement (LGMA), as an appropriate model for future development of produce-specific guidance because it is a broadly accepted GAPs program.

Interviewees in all cohorts commented that they would like FDA to conduct further research that will lead to more produce-specific and scientifically-supported GAPs. While they viewed FDA Guidance as providing a technically sound basis for GAPs, they believed that universities, extension offices, and private companies have the long-standing, in-depth relationships with growers that are needed to motivate, communicate and support growers in their GAPs adoption.

Attitudes Regarding Food Safety and Risk Prevention

This research suggests that Growers' current food safety goals and activities are driven primarily by customer expectations and buyer requirements and, to a lesser degree, by regulations, concern for legal or financial liability resulting from a contamination event, and moral obligation to protect people's health. The research, however, also suggests that the food industry (including growers and buyers) is interested

in promoting a broader and more integrated "food safety culture," by encouraging more proactive food safety attitudes and behavior among growers.

Large-scale Growers recognized the value of adopting GAPs programs (generally and not specifically the FDA's GAPs Guidance). However, they believed that certain GAPs and related audits are onerous and/or unproductive, and they did not always see the value of GAPs in terms of real risk reduction on the farm. They were frustrated by the inconsistency in the GAPs Guidance and other standards across government and industry. They believed these guidelines should extend to other players in the food system, including retailers and suppliers. They would like more uniform and specific standards of performance than what the current guidelines contain, and specifics on how GAPs should be implemented.

The research suggests that smaller-scale Growers may not see the value in adopting GAPs, largely because they do not see the public health need to change "what they've always been doing."

Opportunities to Facilitate Adoption of GAPs

Most of the Growers interviewed in this study were motivated to implement GAPs in order to meet customers' expectations and to protect their own financial interests. For these Growers, the transition to GAPs as a legal requirement appears to be largely achievable and even welcomed because they want all Growers to share in the costs of providing safe food and because an outbreak caused by one grower affects the entire industry.

However, results of this research and previous research suggest that a regulatory requirement to implement GAPs will present a real or perceived financial challenge for smaller-scale Growers. Trainers indicated that growers struggle in the early stages of GAPs awareness and implementation. They believed that growers on farms without formalized GAPs programs need training to help them recognize the need for GAPs programs and to become more knowledgeable about specific GAPs practices. Once they understand what they need to do, they believed the growers will need support in developing and initially implementing GAPs programs specific to their farms. The research suggests that once implemented, GAPs programs can become accepted and embraced on the farm.

Over the course of the interviews, Growers, Trainers and Auditors, and Buyers, suggested a number of potential opportunities for FDA to help implement the adoption of the FDA GAPs Guidance. These opportunities included:

- Clarifying FDA's role and responsibilities in promoting food safety, including its relationship with other regulatory partners at the federal (e.g., USDA) and state level.
- Continue to better understand and recognize the complexity of the produce industry, and the "food safety system" more broadly when developing and communicating GAPs. Coordinate with stakeholders in the development of GAPs policies, standards and communications.
- Facilitate stakeholder dialogue to clarify stakeholder roles and responsibilities, as well as their priorities and objectives for food safety. Promote the design and adoption of common food safety standards across the industry.
- Facilitate scientific research needed to advance GAPs development and implementation across the industry, with an emphasis on developing produce-specific, simple standards that growers can understand and implement.

- Partner with and support trainers, auditors and others in the industry to better support growers. Use existing communication networks and channels to support GAPs adoptions.

- Promote the value of the FDA GAPs Guidance to consumers, emphasizing the value of food grown by growers adopting GAPs.

- Gain further insight into other key stakeholders' decision-making processes and information needs. Other stakeholders may include small growers, large growers in states without established GAP programs; suppliers of goods and services to growers; packers and handlers; and consumers.

Growers' Understanding and Implementation of GAPs
Mental Models Research Report

A. Introduction

FDA is responsible for ensuring the safety of all domestic and imported fresh and fresh-cut fruits and vegetables consumed in the United States. In 1998, FDA issued a guidance document to industry entitled Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables[4] (updated in 2008,[5] hereafter referred to as the FDA GAPs Guide, or Guidance, or the Guide). The FDA Guide sets the foundation for a variety of practices and programs commonly referred to as Good Agricultural Practices (GAPs) and Good Manufacturing Practices (GMPs). Growers, packers, and shippers and others can use GAPs/GMPs to address common risk factors in their operations and thereby minimize potential food safety hazards. However, there is evidence that growers have not fully implemented GAPs to reduce potential risks to fresh produce, despite intensive GAPs training programs and other efforts to promote adoption of GAPs.

Decision Partners was asked to conduct research to support FDA in improving its communications related to the FDA GAPs Guide. The goals of this research were to: 1) gain an understanding of growers' awareness and knowledge of, and attitude toward, "good agricultural practices (GAPs)" in general and the FDA Guide in particular; 2) understand whether, how, and why growers are currently implementing GAPs using the FDA GAPs Guide; and 3) identify opportunities to facilitate growers' adoption of the FDA GAPs Guide.

B. Research Method

The researchers used an expert model/mental models research approach. This approach is well-established in the fields of risk analysis and decision sciences. Mental models research seeks to discover people's thinking in-depth on a particular risk issue or decision and is well-suited to address complex, multi-stakeholder,[6] risk management and risk communication challenges.[7] The method begins with the development of an *expert model,* which summarizes and integrates the knowledge of experts on a given topic, typically in a graphic form. The expert model serves as the analytical framework for the design, implementation and structured analyses of in-depth, semi-structured interviews, known as *mental models* interviews, conducted with a sample of individuals representing a stakeholder population of interest. Detailed information on this approach can be found in Appendix A.

[4] See http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm

[5] See http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064458.htm

[6] For the purpose of this research, a stakeholder is defined as any individual, group or organization that may affect, be affected by, or perceive itself to be affected by a potential risk.

[7] A person's "mental model" can be thought of as a complex and tacit web of values and beliefs, affect how he or she defines a problem, interprets information, and makes decisions. See Fischhoff, B. et al. (1997) Risk perception and communication. In: Detels, R. et al. (eds.) Oxford textbook of public health. London: Oxford University Press, 1997. Pp. 987-1002.

Building on Previous Research

For this project, the researchers built upon similar expert models/mental models research conducted by Decision Partners and collaborators at Ohio State University in 2007 – 2008 with small-, medium- and large-scale produce Growers (hereafter called the OSU Study).[8] As part of that project, the researchers and its collaborators conducted interviews with 12 large- and medium-scale Growers, 20 small-scale Growers and 12 Amish Growers (all Growers were located in the U.S. Mid-West.) The researchers worked with the FDA Project Team to adapt the Expert Model that was developed for that prior project.[9] The Expert Model served as base for the research design and analysis of the in-depth interviews with produce Growers, GAPs Trainers and Auditors, and large-scale Buyers conducted as part of the current project.

Note: Select findings from the OSU Study are included in this Research Report in order to further support the research findings and/or offer evidence to suggest potential variability among growers depending on size, geographic location and type of produce. Doing so enables discussion of smaller-scale farmers in particular (under $250,000 in annual revenue), who were not included in the FDA study.

Research Design

The research scope focused on microbial contamination of fresh and fresh-cut produce, and on tomatoes and leafy greens, in particular. The three cohorts for this study were:

- ***Growers:*** Individuals who serve in a management capacity on the farms where tomatoes (in Florida) or leafy greens (California and Arizona) are grown. Eligibility criteria included operations with annual revenues over $250,000, and whose products are widely distributed in multiple states.

- ***Trainers and Auditors*:** Individuals who provide training on food safety to produce growers, packers or handlers, or individuals who are actively engaged in auditing farm operations to provide independent assurance that GAPs are being followed. These individuals provide these services through private companies, agricultural extension programs, universities, the USDA, or trade associations. The researchers sought to interview from a range of organizations, geographies and professional backgrounds.

- ***Buyers:*** Individuals who serve in a management capacity for large-scale organizations that purchase produce from growers. These organizations may sell produce as retail, package the produce and/or may transport the produce to other retail customers.

Interviewees were offered an agenda of topics to discuss in a way that allowed for free expression. Interviewees were also encouraged to raise additional topics spontaneously and to elaborate on their perspectives. Discussion topics included: the Interviewees' farming operation and their specific role on

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[8] The research supported a U.S. Department of Agriculture (USDA) National Integrated Food Safety Initiative special emphasis grant on microbial risks to fresh and fresh-cut produce. More information on this project and its research results is available upon request. Please contact Sarah Thorne (sthorne@decisionpartners.com).

[9] See Wilson, R.S., J. Parker, D. Kovacs, D. Doohan, and J. LeJeune (2009). "Contamination prevention and response related to fresh and fresh-cut produce: An expert perspective on the farmer decision-making process." *Journal of Food Protection Trends*. The Expert Model was developed based on input from an expert elicitation workshop held March 2007 with approximately 20 academic, industrial and governmental experts who spoke to a range of issues related to microbial food safety, GAPs and agricultural management.

the farm; microbial contamination types and sources; GAPs programs and other food safety practices designed to address microbial contamination; challenges and barriers to implementing GAPs; information sources on GAPs; and opportunities for FDA to further support growers' adoption of GAPs. (See Appendix B for a copy of the interview guide.) Similar interview guides were developed for the Trainer and Auditor and Buyer cohorts, with additional questions included to address their respective roles in managing food safety and other specific issues.

In-depth interviews were conducted by phone with 44 individuals in 3 cohorts: Growers, Trainers and Auditors, and Buyers. See Table 1. Appendix C provides more detailed demographic information. Interviewees' identities and personal information were kept confidential to Decision Partners. Interviews were transcribed and then coded against the Expert Model by trained coders who followed a standard set of coding and analysis procedures. Coded interviews were transferred to a database where detailed analyses were performed to identify detailed themes and their relationships.

Table 1: Summary of Interviewee Demographic Characteristics

	Growers (Leafy Greens; Tomatoes)	Trainers / Auditors	Buyers	Total
Number of Interviewees	22	19	4	45
Interview Lengths	38 min – 107 min. Average: 60 min.	29 min – 75 min. Average: 56 min.	51 min – 75 min. Average: 65 min.	29 min. – 107 min. Average: 58 min.
Male/Female	14 / 8	16 / 3	3 / 1	33 / 12

Note: The researchers experienced challenges in getting people to agree to conducting a research interview and in following through with scheduled interviews.[10] Given the narrow sample frame (focusing on mid- to large-scale growers in Florida and California), as well as the volume of non-response, and on the basis of the research findings, it appears that the sample of Growers interviewed may not be representative of the broader set of produce growers across the nation. The sample may be biased toward growers who already have established GAPs programs on their farms and who may be more supportive of GAPs, GAPs standardization, and GAPs regulation. For example, the Growers interviewed all said that they had established GAPs programs implemented within their organizations. However, other data, including the interviews with Trainers and Auditors and Buyers, as well as the research findings from the previous OSU Study with small to medium-scale farmers in the U.S. Mid-west, suggest that many operations (particularly smaller operations) across the U.S. do not have formalized GAPs programs on their farms.

[10] Approximately 200 contacts were attempted by phone and email to acquire the 44 interviews obtained for this research. Many Growers, Trainers, and Auditors declined to participate, citing lack of time, the need to obtain permission, lack of interest, lack of financial incentive (Interviewees were not offered an honorarium for participation) and not wanting to get involved in "politics."

C. Top-line Research Findings

Interviewees offered rich insight and a broad range of perspectives on the complex issues surrounding the adoption of GAPs designed to reduce risk of microbial contamination in fresh and fresh-cut produce. This research revealed current levels of understanding and practice of GAPs, as well as Interviewee perspectives on future needs and directions for improving and expanding GAPs as an industry standard. The following is a summary of key findings from the research. It includes a set of considerations based on these findings. As mentioned, select findings from the OSU study are included to add further context. More detailed research findings, including illustrative quotes for context, are summarized by cohort (Grower, Trainer and Auditor, and Buyer) in Sections D, E and F.

Growers' Adoption of GAPs

The majority of the Growers interviewed in this study (representing mid- to large-scale farms) said that they had some kind of established risk prevention or GAPs program implemented on their farm. They described having "a food safety plan," "standard practices" and "operating procedures," and commented on conducting "risk assessments" and "field inspections." These Growers said that they are generally satisfied with how their programs are working.

However, the results of the interviews with Trainers, Auditors and Buyers, as well as the previous findings from the OSU Study suggest that many small- and mid-scale growing operations do not have comprehensive GAPs or auditing programs on their farms. Rather, they tended to describe specific practices that they believed reduce risk of contamination (e.g., not using manure).

Growers tended to express more concern about sources of contamination that they viewed as being "outside of [their] control." This includes contamination from wildlife, visitors and trespassers, source water and environmental contamination (e.g., flooding, run-off from a neighboring farm). Growers expressed less concern about (but attached no less importance to) sources of contamination that they considered "manageable," including worker hygiene and equipment sanitation. Trainers, Auditors and Buyers did not appear to make this distinction, citing irrigation water, worker "compliance" and equipment sanitation and as contamination sources of concern.

Growers appeared to be generally confident about the effectiveness of their risk prevention activities, regardless of the degree to which they had established and formalized GAPs programs. They tended to offer general comments to explain their confidence: *"Everything's pretty clean and sterile around us," and "we don't have contamination so far, we have not failed an audit."* Growers stressed, however that there are "inherent limits" to "achieving 100% prevention record," given the nature of the food risks and limits on testing. Trainers and Auditors also emphasized the difficulty of evaluating the success of GAPs, "since outbreaks are such rare occurrences."

Growers generally believed they were prepared to take immediate action in response to a contamination incident, and some cited having "trace back processes" and "mock recalls." The results of the OSU study suggest that small-scale growers are somewhat confident in their ability to respond to a contamination incident, while acknowledging that they had little or no experience with an actual incident.

The research findings suggest that Growers' current risk prevention goals and activities are primarily driven by customer expectations and buyer requirements and, to a lesser degree, by regulations, concern for legal or financial liability resulting from a contamination event, and moral obligation. Growers

commonly described their food safety practices as a collective set of requirements given to them by buyers.

This research, however, also suggests a movement toward a broader "food safety culture," by encouraging more proactive food safety attitudes and behavior among growers. A few Growers who have established GAPs programs described this culture, which they believed took hold after the "spinach outbreak of 2006." These Growers, as well as Trainers, Auditors and Buyers, stressed the need to for a cultural shift away from "old school growers who have done it this way for so many years without problems." As one Grower, commenting on "old school" growers, said:

> *"I think the opportunity to come up with a systematic plan that changes their culture on the farm… changing the way that they think about the overall management of the farm. It's going to be a different culture for them and once they start thinking in those terms, then I think a lot of these things will automatically be taken care of."*

Awareness and Understanding of FDA Guidance

This research identified large differences in current awareness and knowledge of FDA GAPS Guide. The Growers interviewed for this study (who represent mid- to large-scale farming operations) were generally aware that the federal government (FDA and/or USDA) promotes adoption of GAPs. However, they believed that the key drivers of GAPs development and adoption are large-scale produce buyers, state governments (e.g., Florida's T-GAP program), university extension programs (e.g. University of Florida) and industry associations (e.g., the Leafy Greens Marketing Association), all of whom have their own standards and guidelines for GAPs.

Many Growers lacked a detailed understanding of the FDA Guide. When asked to identify their primary source of information related to GAPs, none spontaneously mentioned FDA or the FDA Guide. When prompted to comment specifically on the FDA Guide, many Growers confused its authorship with that of USDA. A few said they were unfamiliar with it. Results from the Trainers and Auditors interviews, as well as the previous research with smaller-scale Growers, suggest that smaller growers appear to have even less familiarity with the FDA Guide.

Trainers, Auditors and Buyers had a detailed understanding of FDA Guide. Most appeared to appreciate the general principles and foundation on GAPs provided in FDA Guidance, especially those principles and practices they perceived to be supported by science. They commented that many GAPs programs are based on FDA Guidance. However, they also noted that FDA's Guidance still lacks specificity, accessibility, relevance and broad stakeholder buy-in that is necessary to make GAPs adoption practical, relevant and in alignment with their needs. Buyers cited other programs, such as the Leafy Greens Marketing Association, as an appropriate model for future development of produce-specific guidance, that is, broadly accepted GAPs programs.

Challenges and Barriers to Adopting GAPs

The Growers interviewed in this study generally recognized the value of adopting GAPs programs (generally and not specifically FDA's GAPs). However:

- They believed that certain GAPs and related audits are onerous and/or unproductive.
- They did not always see the value of adopting specific GAPs, in terms of real risk reduction. They would like scientific evidence regarding which GAPs are effective. Some believed that many

GAPs "are not supported by empirical inquiry" and/or "do not make common sense." Some Trainers, Auditors and Buyers made similar comments. As one Buyer said: *"Strictly, there's no science to many of the metrics we have … like why a mile from a feedlot sounds good."*

- Growers were frustrated by the inconsistency in the various GAPs guidance documents and standards from government agencies and industry; for example, the need to respond to different standards imposed by different Buyers, which they believe are often needlessly stricter than government standards.
- They believed these guidelines should extend to other players in the food system, including retailers and suppliers.
- They sought more uniform and specific standards of performance than are contained in current guidelines and more specificity regarding how GAPs should be implemented to achieve effectiveness.

The research suggests that smaller-scale growers may not see the value in adopting GAPs, primarily because they do not see the need to change "what they've always been doing" in the interest of public health. For example, one larger Grower (who has an established GAPs program) offered his perception of smaller growers:

> *"You don't know how many times I get 'Well you know it never made anybody sick before so why do we have to do this now? We never had this problem in the past.' Well, we probably did, we just didn't have the communication that we do now. We didn't have the Internet; we didn't have the CDC that reported people being sick."*

Growers with established programs anticipated few significant barriers to implementing or sustaining their GAPs programs. They commented on changing requirements, unclear standards and costs as challenges they continue to address. They also appeared to be confident in their ability to identify the information they need on GAPs. They generally commented that they did not have any specific information needs related specifically to GAPs. Some mentioned the need for more science to support or "back up" the specific GAPs practices they were already applying.

Interviewees in all cohorts (particularly Trainers) commented that growers who have not yet implemented formalized food safety programs are either not yet familiar with GAP programs, do not recognize the value in implementing programs on their farm, or do not have the resources to implement a program. The results of this study and the previous OSU Study suggest that growers struggle most in the early stages of GAP awareness and implementation. The research results suggest that smaller-scale growers are generally less proactive than larger growers in seeking information on GAPs, and are generally more reliant on the agricultural extension agencies for information on food safety. Trainers and Auditors generally believed that training efforts have made a noticeable difference in implementation of GAPs by these smaller-scale growers. Trainers and Auditors indicated that growers without formalized GAPs programs need more training to help them recognize the need for GAP programs and to become more knowledgeable about specific GAPs practices. Growers then need help in applying general GAPs knowledge into a farm-specific plan that meets their unique needs. The research suggests that once their GAPs program is implemented, GAPs can become an accepted and embraced culture for the farm. They also believed that training needs extend to other players in the industry, such as labor contractors, packers, and handlers. Trainers and Auditors described the challenges they face in reaching out to large number of small growers and devising GAPs that are effective for small growers' needs.

Thoughts on FDA's Role in Food Safety

Most Growers were unclear about FDA's role and responsibilities in designing, implementing and enforcing GAPs. They often confused FDA and USDA's roles.

Interviewees in all cohorts saw a major role for FDA to support the development of GAPs, particularly the needed science. However, Interviewees did not necessarily see a role for FDA in communicating directly to growers about GAPs. Growers preferred to seek information and support on GAPs adoption from other sources including: agricultural extension agents and university experts (primarily for Florida Tomato Growers), private auditors and consultants, and professional or trade associations and commodity groups. Likewise, Trainers and Auditors commented that FDA's role is to focus on scientifically-supported GAPs development; their role is to find ways to effectively communicate that information to growers and support their adoptions of GAPs.

Interviewees in all cohorts expressed desire for consistent standards for the produce industry nationally and internationally, as well as others in the food distribution and retail sectors. They believed the adoption of consistent standards will enhance consumer perceptions of product safety and establish a fairly-distributed cost basis across the industry. (Note: We did not find evidence in our prior OSU Study, conducted in 2007 – 2008, that would suggest that smaller-scale growers desire adoption of consistent food safety standards.) Interviewees expressed a variety of perspectives on how these standards should be achieved or implemented, including whether GAPs should be a regulatory requirement or a voluntary standard, and who should pay for implementing GAPs.

The Growers interviewed in this study (representing mid- to large-sized growing operations) appeared to be motivated to implement GAPs in order to meet customer expectations and to protect their own financial interests. For these Growers, the transition to GAPs as a formal requirement appeared to be largely achievable and even welcomed. Growers, Buyers, Trainers and Auditors all tended to recognize a need for national and even international standardization of GAPs, though perspectives differed on whether GAPs should be a regulatory requirement. However, results of this research and previous research suggest that a requirement to implement GAPs will present real or perceived financial challenges for smaller-scale growers.

Opportunities to Facilitate the Adoption of GAPs

Over the course of the interviews, Growers, Trainers and Auditors, and Buyers, suggested a number of potential opportunities for FDA to help implement the adoption of the FDA GAPs Guidance by growers and promote safer produce more broadly. These opportunities may become particularly salient in the event the FDA GAPs guidance becomes mandatory. They included the following:

- **Clarify FDA's role and responsibilities in promoting food safety:** The research findings identified an opportunity to more clearly define and communicate FDA's roles and responsibilities, as well as the Agency's goals and objectives pertaining to food safety. In particular, there is an opportunity to clearly articulate FDA's regulatory role in relation to other federal and state regulatory agencies and industry organizations.
- **Continue to better understand and recognize the complexity of the produce industry when developing and communicating GAPs:** The research demonstrates that decisions and communications about food safety affect varied needs and interests of multiple stakeholders throughout an established food supply system.

- **Partner with and support trainers, auditors and others in the industry to better support growers:** While growers may appreciate FDA as a credible source of scientific information on food safety, they do not generally turn to the FDA for support on specific "how-to" questions. Rather, growers rely on an established network of industry and trade associations, university and university extension agents, USDA officials, private auditors and consultants, and buyers, who have long-standing relationships with growers, and who they believe to be more familiar with their day-to-day needs and better able to translate general GAPs principles and objectives into farm-specific practices. Thus, the research suggests that while FDA Guidance can provide a technically sound basis for GAPs, others at universities, extension offices, and private companies appear to have the kinds of long-standing, in-depth relationships with growers that are needed to motivate, communicate and support growers in their adoption of GAPs.

- **Facilitate scientific research needed to support GAP development, refinement and implementation across the industry:** Interviewees in all cohorts believed that more science is needed to demonstrate the need for and effectiveness of GAPs at reducing health risks. These Interviewees perceived the FDA as a credible source for scientific knowledge. However, they believed that FDA needs more knowledge about how farming works in order to conduct studies and apply their findings more effectively. Interviewees emphasized the need for produce-specific, simple standards that Growers can understand and implement.

- **Collaborate with Stakeholders in the Development of GAPs Policies, Standards and Communications:** Stakeholders appeared willing to collaborate with FDA in the development of regulations or standards. For example, Trainers and Auditors expressed interest in working with FDA to translate scientific findings into methodologies that work for growers and to develop the methods of communication that can be effective. There also appeared to be support for FDA, as a trusted source, to convene a process for multi-stakeholder dialogue aimed at improving food safety.

- **Promote the design and adoption of common food safety standards across the industry:** The research suggests a role for FDA as a facilitator and coordinator of any further expansion or development of standards or regulations.

- **Promote the value of food safety to consumers:** One of the key reasons Growers appeared to be motivated to implement GAPs was that they recognize that a publicized outbreak linked to their farm or other farms in their industry could be financially devastating. However, Interviewees expressed concern that consumers do not fully understand (or appreciate) the added cost and value of ensuring food safety through the adoption of GAPs. They also believed that consumers need to be taught more about food safety and how to protect themselves.

Research conducted by Decision Partners and its collaborators to date has included small, mid-sized and larger Growers, Trainers and Auditors in public and private practice, and Buyers. The research has largely focused in areas where GAPs for produce are already well established: tomatoes in Florida and leafy greens in California and Arizona. Small-scale Growers were interviewed as part of a prior project with a focus in Ohio, Michigan, Indiana and Kentucky. Because of the complexity of the produce industry and the food system, there is an opportunity to gain further insight into other key stakeholders' decision-making processes and information needs. Other stakeholders may include small-scale and mid-scale growers; larger-scale growers in states without established GAP programs; smaller-scale buyers; suppliers of goods and services to growers; packers and handlers; and consumers.

D. Detailed Summary of Research Results for Growers

This section presents more detailed research findings of the interviews conducted with 22 Growers, which supplement or add details to the Top-Line research findings presented in Section C. Select quotes are added for context. It is organized into the following sub-sections:

D.1. Grower Characteristics

Growers were asked to describe their farming operations, including farm size, revenue, and number of workers. Growing acres ranged from 5 acres (for a hydroponic tomato operation) to 15,000 acres. Total annual revenue ranged from $250,000 to over $10 million per year. Those earning more than $10 million per year appeared to be earning substantially more than $10 million per year. (See Appendix C for a more detailed summary of demographic characteristics of the Growers and their operations.)

All of the tomato Growers were in Florida. The majority of the leafy greens Growers were located in California and/or Arizona. A few leafy greens Growers had operations in multiple states. One leafy greens farm was located in Illinois and one was located only in Florida.[11] The majority of Growers sold their products for consumption regionally, nationally, and even internationally. Many grew multiple crops, including squash, radishes, strawberries, cantaloupe, cucumber, eggplant, watermelons, oranges, grains, grasses, cotton. Nine Growers (three Tomato and six Leafy Greens) reported producing some organic or "naturally grown" products.

Business Models: Growers described a complex network of businesses that support the production and distribution and sale of produce. Growers from smaller operations (in terms of acres and revenue) tended to consist primarily of a growing operation. Growers from larger operations tended to include a complex array of growing, packing, distribution and buying operations in multiple states; for example, farms with buying operations may own and operate some farms directly but get some or all of the produce they sell through contract relationships with other growers.[12]

Growers' Roles in their Operations: Growers interviewed for this study generally held two different categories of roles within their organizations:

- Many, particularly those in larger operations, held roles such as food safety specialists or managers. Among these, tomato Growers said they focused on one or a few operations within a small geographic location and generally had direct contact with field workers. Those who were Growers of leafy greens said they often worked with multiple operations over a large geography (including California, Arizona and international locations) and had less direct contact with field workers.

[11] This Grower is counted as a tomato Grower; however, comments specific to leafy greens food safety were included in the analysis of the leafy greens Grower cohort.
[12] Interviewees who indicated that significant revenue comes from buying operations are included in the buyer cohort addressed in Section E of this report.

- Some referred to themselves as Operations Manager and/or described broader leadership or management or responsibilities within their organizations, such as environmental compliance and occupational health and safety. A few Growers in smaller operations were the owners – and key decision makers – of a family-run farm.

The research results suggest an association between the Grower's role within the organization and his or her perspectives on food safety risks and risk management. For example, Growers with broader management roles and responsibilities tended to describe food safety and GAPs in more general terms and provided a broader context of the priorities, challenges and opportunities for their organization and the produce industry at large. Those with more specific food safety responsibilities tended to focus more specifically on food safety priorities, technical and procedural aspects of GAPs "compliance," and the associated challenges and opportunities.

D.2. Growers' Goals and Objectives

Growers' Objectives for the Farm: Growers were asked to describe the key goals or objectives for their farm. The primary objective mentioned, particularly by those in a more general management role, was profitability or economic survival. For example, one Grower commented:

> *"Seems like we're in dire circumstances anymore, whether it's the price that the consumer's willing to pay, or the middle guys, or the weather or increasing costs. Balancing that [being profitable] and able run our program… it's not that easy."*

In addition to economic goals, many Interviewees commented on "providing a quality product," "meeting customer expectations," "increasing stakeholder value," and/or "marketing our produce to a loyal customer base." Many, particularly food safety specialists, cited food safety or "achieving high food safety standards" as key goals. Other goals mentioned primarily by Growers with smaller operations, included "being stewards of the land," treating employees well, participating in the community, and employee safety.

Throughout the interview, Growers described a number of regulatory pressures (e.g., environmental, food safety, occupational health and safety) that challenge their ability to meet their operations' key goals and objectives. As one commented:

> *"My biggest* problem *is the government. We are saddled with all kinds of regulations … I'm required by law to keep [my land] out of production for water retention and I must keep it in a pristine state, less than 5% invasive species, so that we keep all the native flora and fauna happy … [We also have] immigration issues, food safety requirements. We have OSHA, we have EPA, we have pesticides, we have our taxes and it goes on and on and on … My biggest competitor is south of the border, who doesn't have the same regulations.*

Some Growers commented on the challenges in meeting food safety requirements. These are described in more detail in Section D.3. Other challenges included: uncertain weather, pest control, international competition, labor shortages, increased customer demands, unexpected events and workforce quality.

Growers' Food Safety Objectives: Growers were asked to describe their specific goals for reducing the risk of microbial contamination on their farm. They expressed their food safety objectives in various ways:

- Nearly all indicated that the buyers, or "customers," drive their food safety programs. They commented that customers *"are very strict"* and *"demand that the product we're selling them is as*

safe as possible." Growers indicated that many buyers will dictate specific GAPs or audits that must be implemented, and that these requirements can be much more stringent that those required by government agencies, or other industry associations.

> *"Yes, [customers] want a quality product, but when they send their people out here to check us out… their first question isn't 'how is your product doing'? No. Their first question is 'how is your food safety program'? Before it was 'how is your quality, how were your yields'? Not any more."*

> *"I think originally we just governed our food safety practices with the Guide to Minimize Microbial Risks. Over time, different companies have added their own requirements into that and they have made their own types of risk assessments based on probably what their lawyers are telling them."*

- Throughout the interview leafy greens Growers described the role of the Leafy Greens Products Handler Marketing Agreement (LGMA)[13] on their food safety programs. (Their comments on the LGMA are described in further detail in Section D.4.)

- Some mentioned one or more regulatory requirements as driving their food safety programs. In particular, Florida Growers commented that they are directly accountable for meeting the Tomato Good Agricultural Practices (T-GAP)[14] regulations promulgated by the State of Florida. Growers' comments throughout the interview suggested some uncertainty about whether enforcement authority for food safety lies with the USDA, FDA or state agricultural departments. (Their thoughts are described in further detail in Section D.4). However, many of these Growers described regulatory requirements as a secondary driver to Buyers' demands on growers to perform specific GAPs.

- Some Growers expressed concern about liabilities or economic impacts in the event on a contamination incident or outbreak as influencing their risk prevention programs. (See Section D.4.) These Growers commented that the industry is very vulnerable to significant economic impacts resulting from an incident.

- A few mentioned moral or ethical reasons for preventing food contamination or ensuring safe food, such as, *"You don't want anyone to get sick or be responsible for illness or death …"* A few Growers stressed that their food safety programs are primarily driven by their own goals to produce a safe product rather than external forces.

Growers were asked how significantly a contamination incident at their farm would affect their operations. Many indicated that the impact would be "devastating": *"It would probably shut me down."* Some

[13] The California LGMA is a voluntary industry association created in 2007 that sets food safety requirements for its members. Over 100 handlers, representing approximately 99% of the volume of leafy greens grown in California and Arizona, are LGMA members. LGMA membership requires verification of compliance with the accepted food safety practices through mandatory government audits. See: http://www.caleafygreens.ca.gov/about/lgma.asp.

[14] Florida was the first state in the country to adopt a comprehensive food safety program with mandatory government inspection and audits for tomato handling, production and packing. These Good Agricultural Practices and Best Management Practices were adopted as state regulations on July 1, 2008. See: http://www.floridatomatogrowers.org/). Known as the T-GAP, it was developed by the Florida Tomato Exchange (representing the industry), the University of Florida's, Institute of Food and Agricultural Sciences (UF/IFAS), the Florida Department of Agriculture and Consumer Services (FDACS), and the U.S. Food and Drug Administration (FDA). See: http://www.floridatomatoes.org/FoodSafety/TOMATO_QA_on_T-GAP_and_T-BMP11-8-06.pdf.

commented that the outcome would depend on the nature of the incident, and whether the source could be quickly and accurately identified. Interestingly, Growers offered varied beliefs on the impact an incident would have on consumer confidence. Some believed that *"The whole industry is based on customer confidence."* A few, however, believed that the impact on consumer confidence in their products would be mild because *"people are not that afraid of food borne illness,"* outbreaks generally involve mild cases of upset stomach that people are familiar with, or the number of people adversely affected is "infinitesimally small."

D.3. Growers' Thoughts on Food Safety Risks

Growers were asked to describe in detail the food safety threats they face on their farms. This included types of potential contamination (e.g., *E.coli*) as well as the potential sources (e.g., worker sanitation). When talking about food safety threats, Growers generally did not make a clear distinction between types of contamination and their sources. Their comments focused more on contamination sources.

Types of Contamination Mentioned: Growers commented in general terms on the types of contamination they face. Most mentioned *E.coli* (particularly Leafy Greens) and Salmonella (particularly Tomatoes). A few mentioned hepatitis, HIV/AIDS, and "blood pathogens." Interviewees spontaneously included non-microbial hazards as well, including pesticide residue, fungus and spores, oil leaks from equipment, and other environmental risks.

Sources of Contamination: The most common source of contamination mentioned was wildlife; for example, birds, mammals and reptiles. Growers believed that controlling wildlife is largely "out of their control." Interviewees also identified worker hygiene and worker training as a potential source of contamination, noting workers are "more in contact with the product." In contrast to wildlife, however, Growers believed worker hygiene was generally more "manageable." A few identified potential contamination of source water for irrigation and washing and cleaning equipment. A few Growers commented that they cannot control regional water and environmental quality. Other potential contamination sources mentioned included farm visitors and trespassers, particularly those adjacent to more urban areas or major roadways, rotting produce, adverse weather, and contamination from pesticides and petroleum products.

D.4. Growers' Adoption of GAPs

The majority of the Growers interviewed in this study (representing mid- to large-scale farms) said that they had some kind of established risk prevention or GAPs program implemented on their farm. They described having "a food safety plan," "standard practices" and "operating procedures," and commented on conducting "risk assessments" and "field inspections." These Growers said that they were generally satisfied with how their programs are working.

However, the results of the interviews with Trainers, Auditors and Buyers, as well as the previous findings from the OSU Study, suggest that many small- and mid-scale growing operations do not have comprehensive GAPs or auditing programs on their farms. Rather, they tended to describe specific practices that they believed reduce risk of contamination (e.g., not using manure).

Growers were asked to describe the practices they use to prevent contamination. When discussing their practices on a general level, Growers used various terms, such as "food safety plan," "standard operating procedures," "daily operating procedures," and "daily checklists." As one Interviewee indicated, *"It's pretty industry standard stuff."* Some Growers described their practices as a collective set of requirements given to them by Buyers.

Growers also described a number of specific practices, which appeared to have many similarities. For example, to control contamination from water sources, most Growers mentioned that they test their water, and those who described the kind of test mentioned generic *E.coli* testing. Some mentioned their water sanitization procedures, "risk assessments" or "field inspections" as methods for avoiding the use of unsuitable water. A few mentioned other practices, such as storing irrigation pipes off the ground, or drip irrigation to keep potentially contaminated water off produce. One (small growing operation) Grower mentioned the use of sanitized water for washing as the "final line of defense."

Many Interviewees expressed confidence that they were effectively preventing risk on their farm. They generally appeared to base their confidence on their level of understanding of GAPs, their compliance with requirements or guidance, and/or on their lack of incidents. For example:

- *"We really don't face contamination here. We have to comply with such stringent rules and regulations… A contamination issue has never occurred under my management just because of the rules and regulations that are set in place to prevent that."*
- *"[Growers in] Arizona and California have been doing [food safety] for several years. We have a fairly good handle on it over here and have been working with the FDA to pull together a national program."*
- *"Everything's pretty clean and sterile around us."*
- *"We don't have contamination so far, we have not failed an audit."*

A few Growers spontaneously commented throughout the interview on what they saw as limitations to achieving a one hundred percent prevention record and/or believed that there would always be room for improvement. They noted that "microbes cannot be seen," that there are many ways that contamination can enter into the food production or distribution system, and that testing programs have inherent limits to identify any and all contamination. For example:

> *"Most microbial testing programs are looking for a needle in a haystack. Unless you had gross contamination of a field, a microbial testing program just doesn't take enough samples to statistically find a problem in the field. It's more of a customer requirement that makes them feel warm and fuzzy, but occasionally these testing programs do find problems prior to harvest."*

Growers were asked about their level of preparedness and ability to respond to a contamination incident on their farm. The majority indicated that they were "very prepared" to deal with produce contamination if it occurs, and a few indicated they were "somewhat prepared." Growers cited having "trace back" processes and conducting "mock recalls" as a measure of confidence in their preparedness. None said they were "not at all prepared."

Sources Relied Upon to Develop Farm-Specific GAP Programs: Growers were asked to identify any specific organizations' GAPs programs they used to develop their GAPs program. They identified several sources. Some cited the FDA as a source of information. A few specifically mentioned the FDA Guide. (About half of these spontaneously identified the USDA as the author.) Some Growers, particularly leafy greens Growers in California commented that their GAPs programs are built on FDA GAPs. For example:

> *"The CA/AZ leafy greens programs are both based on the FDA's guide for reducing microbial risk and cited in their literature as something that you should use. Our own farming operations have been using this since it first came out 10 years ago or so. We have been using that from the very beginning of what we looked for when we first designed our first food safety program. Since then, every customer has developed their own set of GAPs."*

"Our program is based on The Guide to Reduce Microbial Contamination as well as the LGMA. We have taken the guidelines and suggestions of those different programs and we have incorporated them into our food safety program so that the program we have in place not only fulfills the requirements of the FDA and the USDA LGMA but also combines together and creates a comprehensive program."

Some Growers identified government and private auditors as an important resource in the development of their GAPs program. Primus, a private company, was most frequently mentioned. About half of the leafy greens Growers identified the LGMA as the basis for their GAPs program. A few of these Growers commented that the development of the LGMA standards was supported by FDA's Guidance. A few mentioned the USDA, State Extension Programs (Florida Growers only), state agricultural departments in Florida and California, and trade associations. A few were non-specific saying they follow "everything that is out there right now." Of these, many mentioned two or more specific sources on which their farm-specific GAPs programs are based.

Perspectives on T-GAP and LGMA: Growers were asked to give their thoughts on T-GAP (if they grew tomatoes in Florida) or LGMA (if they grew leafy greens in California or Arizona). Many Growers indicated that the GAPs programs of these organizations are a necessary and good approach for improving food safety. California and Arizona leafy greens Growers' comments about the LGMA were generally positive. A few offered detailed thoughts on the value of the program. For example:

"*Previously … we had our own guidelines… but we had so many and companies that used to grow or buy or whatever and had their own rules but were very lax, meaning they weren't very strong and there were no set rules for everybody. When the LGMA came in, everybody had to be on the same page and everybody cleans everything. And everything is a 100 times better… With these voluntary guidelines we tightened up on everything, and it helped us because we weeded out some growers who didn't want to follow the rules, because they said it was too expensive and they weren't making a lot of money."*

Florida tomato Growers' comments about T-GAP were mixed. Some voiced overall support for the standards. Some expressed more negative overall sentiments, citing "excessive paper work," poor quality audits, specific standards as "silly" or "impractical," and lack of flexibility to meet specific growers' needs. All offered suggestions for how the T-GAP regulation or program implementation might be improved, including setting minimum standards for ongoing worker training and ensuring that the standards are the same for everybody nationally.

Challenges and Barriers to Adopting GAPs: Growers were asked to identify any challenges or barriers to adopting microbial contamination prevention measures. Many Growers with established programs generally said there were few significant barriers. For example:

"There really aren't any significant barriers at all. They're not so much of a financial burden and most people individually are cooperating because they have to. There are a few minor barriers where you run into specific growers that really are trying to push back on a lot of these requirements, but they aren't very successful because they know they won't stay in business for long if they don't cooperate."

"I don't really feel that there are any barriers out there. It's a pretty simple system right now. There are rules and regulations set and people in place to pass them down to us and there are people in place

to make sure we're kept up to date and, as I said, we pack year round without any problems so I think the system we're put in place right now is working fine."

Many Growers described the challenges they face in implementing and maintaining their GAPs programs:

- Some commented on the challenges in responding to changing, and increasing stringency of government regulations, industry standards and/or buyer requirements: *"Every time we turn around … there's a new law or regulation that's coming into effect."*

- Some also mentioned the challenges in implementing a broadly recognized "food safety culture," which is necessary due to the complexity and interdependency of the wide range of players in the food industry. For example:

  "I would say the biggest barrier is a group or individual or supplier who has showed or expressed that they aren't totally willing to accept the practices. Everybody has to be committed from the seed to the fertilizer supplier. Everything that goes into growing a product is an input and the supplier of the inputs needs to be 100% dedicated to food safety and practicing a implementing procedures and policies focused on food safety and if everyone isn't then committed to that you have a weak link."

Some commented on the challenges associated with worker quality and worker training, citing worker adherence to the requirements (e.g., "employees who feel the rules don't apply to them"), and the need to overcome language barriers when providing worker training and oversight. Some identified cost as a burden, but the Growers with established programs generally did not see cost as a prohibitive barrier. Other challenges cited included: cooperation with neighbors; cooperation with suppliers and contractors who participate in the growing and delivery food production system; and inherent challenges to managing risk in an outdoor environment, including the uncertainties of weather and the numerous potential sources of contamination.

D.5. Seeking Information on Food Safety

Growers were asked if there are any particular contamination risks or prevention activities about which they would like more information at this time. Many said no, suggesting a level of comfort and satisfaction with the food safety programs they had in place. Some mentioned the need for more science to support or "back up" the specific GAPs practices they were already applying. They seek more science to: monitor and protect water quality, verify value for specific practices (i.e., not smoking in the field), identify "*where all the contamination risks are*," and to identify technologies or procedures that could be implemented in packing houses. A few, particularly those who appeared to have less-established food safety programs, mentioned the need for more general awareness and training*:* "*I probably don't know what I don't know. So I am constantly reading and have a good network out there*."

When asked where they go for information on food safety:

- Many cited commodity groups, including: United Fresh, GAP Harmonization Group, Florida Fruit & Vegetable Association, Produce Marketing Association, and the Western Growers Association. They noted these organizations: "do a lot of research," "have the most up-to-date information," and are "accessible and relevant."

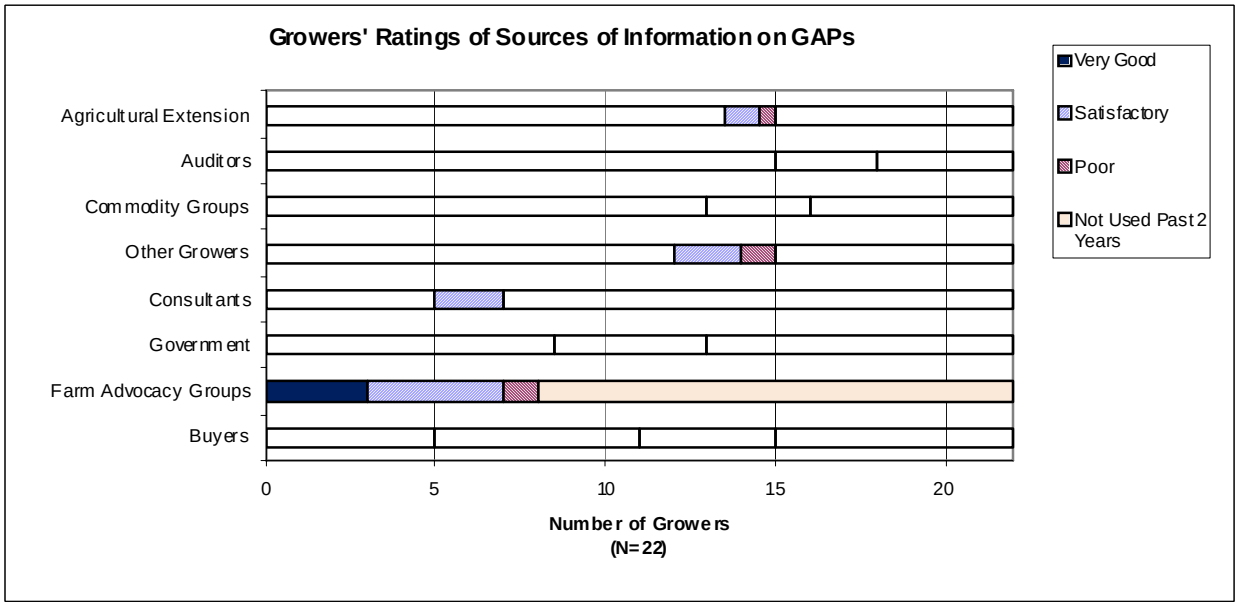
- Some, particularly the Tomato Growers, mentioned universities (e.g., University of Florida, Cornell) or more specifically the agricultural extension services tied to the universities (e.g., Florida IFAS).

- Some mentioned the FDA, and some mentioned the USDA, or simply government sources in general. Growers described using these sources to "keep aware of what others are doing" or because they provide information in a format that is helpful.

- Other sources mentioned were Buyers, third-party consultants (such as Primus), the Center for Disease Control, research conferences, meetings with guest speakers, self-help by reading self-audits or GAPS information available online, consulting with other food safety experts internal to the company, or generally "looking anywhere and everywhere."

A similar hierarchy of preference was indicated when Growers were asked to rate various sources of information they had used to learn about GAPs in the past two years as either "very good," "satisfactory," or "poor." The results are presented in Figure 1.

Figure 1: Growers' Ratings of Sources of Information on GAPs



Growers were next asked to identify the sources of information they found most useful. Some mentioned agricultural extension (primarily Florida Tomato Growers), some mentioned consultants, and some mentioned professional or trade associations. A few mentioned USDA. No Growers mentioned FDA.

D.6. Growers' Thoughts on the Role of FDA in Food Safety

The interviews ended by asking Growers about their most important needs for food safety and what they think FDA's role in food safety should be. Their comments are summarized below.

- **Regulations and Requirements:** Some identified the need for a national GAPs standard, to have GAPs apply to more crops, and to have food safety guidelines apply to transportation and retail sectors. Concern was expressed that GAPs should "*not be used as a marketing tool by*

large farmers," that GAPs should focus on how crops are harvested and sold rather than how crops are grown, and that effective corrective action/enforcement provisions be established.

- **Science:** Some noted they would like FDA to provide more science to demonstrate which GAPs really work. They suggested that FDA consider sources of risk throughout the entire "farm to fork" process, and identify where the real problems are:

  "Whatever comes out of government needs to be science-based not emotional-based, and … they need to be able to convince me of the practical reasons why it's good...If they want to come at me with legislation, come at me with practical, realistic and economically viable legislation and don't come at me with feel good, emotional crap. [It is] absolutely hard for them to do because they don't come down here to see it for themselves."

  "The preamble on most of these agreements cites the 2006 spinach incident, yet the FDA still has not determined the cause…"

- **Communication and Training Needs at FDA:** Some identified the need for more communication and training within FDA. They would like FDA staff to have a better understanding of farm practices so they can be more effective in promoting GAPs that are recognized as useful. They are not sure that the focus is always in the right place along the "farm to fork" process:

  "I think the FDA needs to learn how the food and food chain works and who does what. They need to become more educated."

  "I just wish the FDA would get it more on the farm level."

  "I think the FDA has to start with really understanding all the processes. I don't think you can find a solution until you understand all the steps. As I said, from the field to the tomato house to a re-packer or food service, to the customer…and to educate themselves in the sense of understanding that we have systems in place."

- **GAPs Standards:** A few mentioned the need for improvements in GAPs standards. There was a desire for a single standard, rather than having to meet differing expectations and standards of multiple buyers. They wanted the standards to be feasible to implement and flexible enough to work on different sized farms or otherwise meet the needs of different farms. They also wanted the audit process to be more efficient and effective.

- **Communication and Training:** A few commented that a more consistent level of understanding about food safety is needed between various stakeholders in food safety: e.g., growers, consumers, retail businesses, industry associations, and auditors. Growers recognized that the consumer needs assurance that the products are safe. Growers want the rest of the food industry to operate at the same high standards to which they are held.

  "People need to be taught more about food safety and cross-contamination. Restaurants and stores need to be taught… [The FDA] needs to show the American people how hard we're trying out here to ensure they're receiving a safe product."

"I think right now most of the companies, 99 percent of the companies out here, are doing a fantastic job as far as food safety…The people who are slamming us, they don't even have a clue about what we do out here."

"I think we need to do a better job of communication with the Leafy Greens Marketing Board per se, and the auditors that are out there in the field."

- **Enforcement:** A few expressed a desire for FDA to be more careful, consistent and vigilant in its enforcement role. They commented on the challenge of FDA balancing a more open relationship with growers with the need for more enforcement:

  "I'd tell them to continue what they are doing, but be more vigilant. I'm talking from a policeman's point of view."

  "Not to blow the industry up because every time they move in, that hurts everybody here in the industry."

  "Recognize the authority that [the FDA] brings with them and how that may intimate the grower or handler. It is like your local police. You might never want to have contact with them but that is not true because they are a public service entity…and if they want to develop the consumer confidence – that they are protecting the consumer's health by being involved in GAPs and investigating contamination – then they need to try to forge relationships, and not just in regulatory [ways] but [by promoting] education and learning."

- **Promotion of Safe Food:** One Grower suggested that FDA conduct a communications campaign to drive consumer demand for safe food and earn farmers a premium for a safer product:

  "We've got all these different programs that we have to be in compliance with, but we have no way to gain more money back to the farm to pay for those. There needs to be a better promotion…we've got to be able to promote the fact that we're in a global market and we're competing with hothouse tomatoes out of Canada, we're competing with Mexican product… driving our prices down while all our costs are just skyrocketing. There's got to be a way, when you go through all this process and we grow as good a product and as safe a product as we do, to get more money back to the farm to afford to keep doing this."

E. Detailed Summary of Research Results for Trainers and Auditors

This section presents the research findings for the Trainer/Auditor cohort that are most relevant to the current objectives of this study. Nineteen Trainers and Auditors were interviewed who have worked on GAPs with tomato and/or leafy greens growers in the past two years. Section E is organized into the following sub-sections:

E.1 Trainer/Auditor Characteristics
E.2 Trainer/Auditor Thoughts on Food Safety Risks
E.3 Trainer/Auditor Thoughts on GAPs Programs
E.4 Auditors' Thoughts on Growers' Implementation of GAPs
E.5 Trainers' Experiences in Training Growers
E.6 Trainer/Auditor Assessments of Food Safety Needs and FDA Role

E.1. Trainer/Auditor Characteristics
The Trainers and Auditors provided a diverse range of services to growers. These services varied depending on whom they worked for and in which state they worked.

Trainer Descriptions: The Trainers worked in the following capacities:

- **University Faculty:** Six Trainers worked for universities located in Florida, New Jersey, North Carolina, or Wisconsin. These individuals conducted research, developed teaching aids and curricula related to food safety, taught, and provided applied training classes for growers. Florida Trainers appeared to take a lead role in providing a comprehensive range of training programs that included designing classes, integrating new research findings into training programs, developing on-line instruction programs, and other such training development functions. In Florida, Trainers interviewed were associated with the University of Florida and the agricultural extension program. In California, the universities tended to be centers for specialized expertise, rather than a resource for the development of comprehensive training programs. The Buyers in California described a prominent role in conducting training for growers and farm laborers. As a group, university-based trainers indicated they have limited available time for training that involves direct contact with growers.

- **Agricultural Extension Agents:** Three Trainers worked for the extension programs in Florida affiliated with the agricultural programs located at both the universities and county governments. The extension agents were located throughout the state and provided various technical assistance services to growers. These Trainers provided support on many topics other than food safety and indicated they had limited time to dedicate to food safety.

- **Trade Association Representatives:** Two Trainers worked for agricultural trade associations. One worked for a national agricultural trade association comprised of companies that represent the entire food supply chain: growers, packers, shippers, distributors, warehouses, terminal markets, food service companies and retail markets. The other worked for a grower-supported trade association in Florida that supports the development of training and auditing services for growers.

- **Private Consultants:** Two Trainers worked for private consulting companies that provide technical assistance to growers. One also provided food safety auditing services to growers.

- **Regulator:** One Trainer worked for the Florida Department of Agriculture and had responsibilities relating the implementation of the T-GAP regulation in Florida. This individual had oversight involvement in training and auditing services.

Auditor Descriptions: The Auditors interviewed work in the following capacities:

- **State Agencies:** Four Auditors worked for either the Florida Department of Agriculture or the California Department Food and Agriculture. These government Auditors provided audits to growers for a fee. In California, leafy greens growers must be audited by the California Department Food and Agriculture for compliance under the LGMA.

- **Trade Association Representatives:** Two Auditors were the same individuals described under Trade Association Representatives above. They provided both training and auditing services.

- **Private Consultants:** Two Auditors worked for private consulting companies, one of which also provides training services.

E.2. Trainer/Auditor Thoughts on Food Safety Risks

Food Safety Objectives: Trainers and Auditors were asked to describe their goals and objectives regarding microbial food safety. Most indicated that they were working to reduce health impacts from contaminated produce, such as "reducing the incidents of food borne illness." While some spoke about "supporting a safe product to the consumers," others stressed the challenges: "*We want to make sure it is as safe as it can be recognizing that there are no guarantees in fresh produce* …" A few focused more on the business advantage and/or liability protection needs of growers (e.g., *"protect the market for the commodities that are grown in the state of Florida"*). A few focused on ensuring a reputation for food safety: *"[The consumer] should never look at produce and worry about whether this is going to safe to serve to my family."*

Food Safety Threats: Trainers and Auditors, like Growers, focused their comments more on sources of microbial contamination than on the types of microbial contamination (e.g., *E.coli*). However, throughout the interviews most discussed Salmonella and many discussed *E.coli.* Cryptosporidium, Listeria, Shigella, Campylobacter, Hepatitis and Staphylococcus aureus. Norwalk-type viruses were also mentioned.

Trainers and Auditors were asked to identify the greatest opportunities for growers to reduce contamination risks. The most commonly cited sources were water, particularly water used for irrigation, and worker training or hygiene. Some mentioned produce washing, sanitation of packing operations, proper application of manure (when applicable and admitting that manure is not as widely used as it once was), control of wildlife to prevent wildlife droppings from contaminating produce, and farm visitors. Uncontrollable environmental influences such as flooding or hot weather were also mentioned.

Some focused more on compliance issues. Rather than identify a source of contamination, they expressed the need to require more farms to implement GAPs. Others commented that growers were already undertaking appropriate practices, but needed to better document their GAPs practices. As one Auditor noted: *"There's a small minority out there that just don't want to do anything and they've been doing it for 50, 60 years and they don't think they need to change."* One Trainer, however, suggested an opportunity to gain broader compliance by "changing the culture":

> *"I think the opportunity to come up with a systematic plan that changes their culture on the farm is the way I would see it. I don't know if it's any one specific thing but I think just changing the way that they think about the overall management of the farm. It's going to be a different culture for them and once they start thinking in those terms, then I think a lot of these things will automatically be taken care of; the way that they address restrooms and hand washing facilities and just the nature of keeping the farm clean and the way they store materials and those kinds of things."*

E.3. Trainer/Auditor Thoughts on GAPs Programs

Nearly all Trainer/Auditors spontaneously commented that a key goal of their work is to increase growers' awareness and knowledge about food safety risks and ways to prevent or manage those risks. One Trainer described the basic starting point of the educational process for many: *"You have to make them aware of what Salmonella is first, to understand that's it's an invisible microbe they cannot see."* Some identified the need to help growers implement the knowledge about food safety that they gain through training. They believed that it is not enough to simply educate growers – there are numerous competing demands for growers' time, and growers need help assimilating food safety knowledge into a plan that makes sense and can be implemented on their farm. As one said:

"We've got a little over 47,000 farms in Florida and over 44,000 of them would be in that small farm category.[15] So the challenge, number one is just in sheer numbers. How are we going to be able to reach that less identified and less traditional type of farmer? So not only is it a huge group, it's less organized in Florida. We don't have an organization such as the Small Farmers Association of Florida. So finding these folks is going to be a major challenge … And at the Listening Session we kind of got a flavor of them indicating that they are willing and understand the necessity for them to participate in this whole national initiative and yet are concerned about the expense of implementing a program on a small farm where it's usually just the family group that is doing everything from producing and marketing and everything in between ."

Familiarity with GAPs Programs: Trainers and Auditors were asked to identify the GAPs programs they were familiar with or used in their training. The majority described multiple GAPs programs. Some spontaneously mentioned the FDA and/or the 1998 Guide produced by FDA. When specifically prompted to rate their familiarity with FDA's Guidance on GAPs, nearly two-thirds said they were "very familiar," and nearly one-third indicated they were "somewhat familiar." One Trainer said he/she was not familiar with the FDA Guidance. Trainers and Auditors also indicated their familiarity with: T-GAP, LGMA, GAPs promoted by various trade associations, GAPs promoted by various universities (particularly Cornell University and University of Florida) and private consultants or auditors (principally Primus where specific names were mentioned). The USDA and the Florida Department of Agriculture were mentioned less frequently.

Trainers and auditors generally believed that the various GAPs programs are similar. Some commented that the various GAPs programs "*are all built on the same 1998 [FDA] document*." As one Trainer commented:

"The FDA Guide to Minimizing Microbial Contamination is just a basic guideline. You have to build way beyond that. The FDA GAPs are a very good outline and a starting point and primarily we use them because we're going to have to deal with them eventually [laugh]."

When asked to speak about the quality of FDA's Guidance:

- Most appreciated the general principles provided in the FDA Guidance, especially those they perceived to be supported by science: *"It's been the bible, so to speak, for developing GAPs programs or T-GAP programs or food safety programs throughout the country*." FDA Guidance was generally recognized as having set certain baseline principles that can be applied broadly.

- Some indicated that the FDA Guidance was more generic than other information sources they use. This was not intended as a criticism. Rather the FDA Guidance was recognized as providing general principles upon which others add in specificity as needed for a specific crop, region, or other basis of need.

  "[The Guide] is probably better on the big picture part of things and less friendly in terms of the day to day operational part of a farmer actually being able to take the information and implement or develop their food safety plan."

[15] Decision Partners did not verify this information. The statement is believed to reference farms of all kinds, not just tomatoes.

- Some suggested that the Guide could be improved by making it shorter and simpler, and that those general principles must be translated into specific, relevant and simple procedures. As one Trainer said: *"You have about five minutes to catch growers' attention."* They suggested Cornell University and others organizations do provide these necessary translations to meet the needs of those who are in the business of communicating directly with growers.

- A few indicated that FDA Guidance was very good: *"The [FDA] program is fine, it does an excellent job. The [FDA] Guidance document is well written and very good."* Another Auditor elaborated on why FDA does a good job while recognizing certain limitations:

  > *"The thing with FDA, and the good thing with FDA, is that they stick with science and there's not a lot of good science. What's good water, what's good microbial quality of water for agriculture? …a lot of this stuff is general. Use good water; well, what the heck does that mean? Where some programs say the same thing, some programs say it has to be a certain level. FDA is good but, it's not their fault. There are a lot of things lacking in science. And so there are a lot of different audit GAPs programs out there that have all these different parameters …"*

- One Trainer thought that the FDA Guidance was not written in language accessible to the typical farmer. This Trainer identified the work by Cornell, which he/she said turned the FDA guidance into *"easy to understand language."*

Effectiveness of GAPs: Both Trainers and Auditors were asked how effective they thought their programs were in helping growers reduce the risks of microbial contamination. Of the 14 who provided a rank score, about two-thirds ranked risk reduction effectiveness as "excellent," and about one-third responded with a rank of "good." They cited "major observed changes on farms," "very few incidents" when GAPs are used, and an effective "start to the educational process." None rated "fair" or "poor."

A few refrained from providing a ranking, saying that they could not state with confidence the impact training has on food safety outcomes, since outbreaks are such rare occurrences, and there is limited data on "what's really going on day-to-day on the farm." Selected quotes illustrating these concerns are:

> *"I'd rather say that they're kind of undefined because the data is just not there. I don't think we have enough evaluation of how well people are implementing GAPs."*

> *"I teach statistics, so from a statistical standpoint, actually producing a number of reduced outbreaks versus the number that would have happened is impossible…Maybe we are doing great because we have not had any outbreaks, but it's hard to take credit for all this. Realistically though, we have seen changes in attitudes, changes in practices, but since we don't know the source of most of the contamination for most of these outbreaks – we're assuming it's on the farm and that's what GAPs is all about – but there is still the potential it's coming from third-party processors, slicers-dicers, even retail."*

> *"I really couldn't answer that because … these people are all putting on hair nets today and putting on the jackets, well because they have a third-party coming in to do an audit that day … and the next day we're back to the same old thing."*

E.4. Auditors' Thoughts on Growers' Implementation of GAPs

Growers' Understanding of GAPs: Auditors were asked to rate the degree of growers' understanding about GAPs as they related to microbial contamination. Of the six Auditors providing a rank score, four indicated that growers have a "high degree" of understanding, and two indicated that growers have a "medium degree" of understanding. Those ranking high attributed recent educational efforts for improving grower understanding of GAPs. Auditors who rated medium said that although they did not see "violations," there were opportunities for growers to "better understand what they are doing," to adopt a more optimal approach, and to improve documentation. For example:

> *"The problem is, you can have very specific guidelines but there's always left some discretion. You can't cover every single situation. There's got to be some reasonable discretion involved."*

> *"They do [adopt GAPs] but they don't have a record and records are just part of GAPs ... If they understand why they're doing it and why it's important, then the execution and the compliance becomes much higher."*

Growers' Implementation of GAPs: When asked to rate the extent to which growers are implementing GAPs, Auditors indicated there is widespread implementation. Four out five Auditors who addressed this question indicated a "high degree" of implementation by growers, while one indicated a "medium degree" of implementation. Those giving a high rating identified grower understanding, existing requirements, and market demand as the reasons for high level of implementation. The one medium score focused concern on the small growers:

> *"Small growers … may do some mitigations to protect food, but unless there's some format of requiring this, I don't know how we would get to a high category."*

Opportunities and Barriers to GAP Implementation: When asked to identify where the greatest opportunity exists to improve GAP implementation:

- Most indicated that more education for growers was required. Sometimes the response was just a general call for more or continued education of growers and auditors alike. However, some specifically mentioned the need for more Trainers, and some specifically mentioned the need for improved outreach to others in the business, such as growers' associations, labor contractors, and packers. As one Trainer stated, "*We're all broke; anything you do involves money to provide these services."*

- Some identified opportunities for improving the audit process, such as providing grant money to growers so that third-party Auditors can both audit and provide education. Another expressed the need to sort out what is reasonable from what is not in the current practices, and to recognize that GAPs must be sufficiently flexible to consider the type of produce and regional/geographic influences on sources of risk.

- Some mentioned the need to mandate GAPs. One thought mandating GAPs would overcome the cost-related hesitation of some growers. Another commented that a mandated program is necessary to ensure compliance.

E.5. Trainers' Experiences in Training Growers

Settings and Methods of Trainings: When Trainers were asked how they generally approached training, most described classroom training as their primary or sole training mode:

- Many stressed the importance of conducting training in local and familiar settings such as extension offices. Many preferred to keep classes small so that dialogue could be encouraged.

- A few described training sessions beyond, or in lieu of, the classroom. One Trainer stressed the importance of field demonstrations, on-site training and one-on-one interactions. This three-part approach was described as:

  > *"[We'd start with a] mid-sized or large-sized groups … for the initial exposure to the topic … Phase two would break it down into smaller groups where we can provide more one-on-one attention. That's where we would actually work with them to help them develop their food safety plan … The third phase of that would be working with them on their farms as maybe a follow up to some specific issues that they have …"*

  Other Trainers stated that on-site training is particularly important with migrant and low-wage workers.

The differences in approach may reflect the scope of Trainers' goals, which may be constrained by their position and/or availability of resources. Those who indicated a focus on classroom training tended to be located at the universities and were trying to reach large numbers of people in a limited amount of time, while those working for the extension service or as consultants had more opportunity to work with growers on a personal basis.

Interviewees described a number of training approaches. A few mentioned using guest speakers, namely local extension agents, regulators, or experts in a particular topic area. A few said they focused their training to meet certain needs, like special needs for hydroponic growers, or packing houses versus field workers. Other topics mentioned included using: personal experiences from the field; hands-on demonstrations; films and approaching growers to retrain workers on a seasonal basis, with an emphasis on documentation.

Use of FDA Guidance in Training: Trainers were asked what topics they tend to include in their training. The responses generally indicated that training courses were tailored to meet the needs of either farm management or workers. There was an emphasis on keeping the training to one day or less, and within that limited time, to develop understanding of the need for and benefits of GAPs.

After allowing for spontaneous comments on information sources, Trainers were asked if FDA Guidance specifically was incorporated into their GAPs training. Their responses underscored how they assemble information from numerous sources to meet their needs:

- Many responded in vague ways. Some indicated that they did not know, while others stated that FDA Guidance describes *"the same GAPs we have",* that it does *"not differ appreciably from other materials readily available"* or that it is *"the basis for a lot of what we do."*

- Some specifically stated "yes" they do incorporate FDA Guidance into their training, but still described the manner of the inclusion in fairly non-specific ways. One Trainer said he/*she "talks about FDA Guidance during in-service training."* Another stated, *"I've read through it all and if it looks like it says something better than or presents information in a way that I think is more understandable then I'll bring it in."* Another said: *"I've got a nice big picture of [the FDA document] that I use in a lot of my presentations."*

- A few stated that FDA materials are not preferentially sought or promoted to support training needs. A characteristic response in this category was, *"No, other than we follow their general outline and examples of what GAPs comprises."*

Impact of Training on Growers' Implementation of GAPs: Overall, Trainers provided high scores on the effectiveness of training on GAP implementation by growers. One-third indicated that the training had an "excellent" impact on GAPs implementation by growers, and half indicated that training had a "good" impact. Two Trainers indicated that training was fair or poor because it was not reaching small growers. Some explanations for the ratings were:

> *"I would say it's been excellent because it's been the basis upon which everyone has built their compliance program for food safety audits …"*
>
> *"I'd say somewhere between good and excellent, definitely improved over previous years ... because it's mandatory."*
>
> *"In Florida I would say it would be excellent among the large growers; fair among the small growers. Large growers are more easily identified and accessible within the industry and sort of have no way to escape, they must be involved with the program as they're shipping out of that so I think the concern among the tomato industry itself has really supported to make sure that the large growers all are going to implement the T-GAP program. The small growers are less easily identified; there may be growers out there we don't even know exist to let them know what is required. So I think just the information getting to the smaller grower is a lot more difficult."*

Greatest Opportunities and Barriers to Improve Training: Trainers were asked to identify the challenges they face in providing training and the greatest opportunities to improve GAPs training. Most Trainers indicated that there was a lack of skilled staff and a shortage of money to provide training to all growers. They mentioned the lack of time available for trainers to help growers develop farm-specific plans. Some indicated that financial support to growers is needed to enable them to get the training they need and otherwise implement farm-specific food safety plans. Here they were referring to training provided on a fee-basis, rather than that being provided free of charge through government-run programs, and were thus seeking some kind of relief, particularly for small growers. They noted that most trainers were originally trained in another field and have become food safety experts over time, and that more train-the-trainer programs were needed.

Many Trainers also mentioned the need for new science or new training information and procedures to be developed in support of better GAPs programs, including:

- Brochures that clearly communicate the benefits of GAPs.
- More information in Spanish and other languages and in picture form for illiterate workers.
- Providing GAPs that are more specific to the needs of individual growers.
- Streamlining training programs to reduce training time needs for growers.
- More science on the causes of contamination and how to prevent it.
- DVDs or on-line methods for teaching growers how to put together their own food safety plan.

A few Trainers suggested promoting GAPs by identifying compliant farms online, or by promoting food safety at national and state meetings of food producers. One suggested that making GAPs mandatory is needed to increase implementation.

E.6. Trainer/Auditor Assessments of Food Safety Needs and FDA Role

Trainers/Auditors Thoughts on FDA's Role: Trainers' and Auditors' thoughts on what role FDA should have in supporting the management of risk of microbial contamination varied:

- Many mentioned that FDA was doing *"an excellent job"* or a *"good job,"* citing such achievements as doing a *"great job in terms of putting together the written GAPs"* and supporting research and education:

  "FDA is doing a fine job at what they're doing and that being research, education, training and promoting good GAPs practices."

  "They've been more than willing I think from my perspective to work with the industries."

- Some identified areas where they believed FDA could put more focus, including support more training, conduct more outreach, put more specific metrics into future GAPs guidance so that procedures are less subject to different interpretation, provide more research and development, and better understand the farming business.

- Some focused on facilitative and consultative themes that ranged from somewhat critical to neutral or positive about FDA current performance in this area:

  "A lot of times the only time you see the FDA is when there's outbreaks. They're not setting up outreach programs that I'm aware of."

  "I think cooperation with other agencies, working with growers in a voluntary [way] rather than trying to impose from the top down would be a better way of going about things and ensuring that growers were eager to adopt what was being proposed."

  "I don't think any one entity should be moving forward on the development of anything affecting first line growers without everybody that's in the middle and that being packers, shippers, regulatory agencies that have been involved with their processes for many years along with what FDA can bring to the table in terms of their efforts with food science."

  "They have certainly indicated a willingness to reach out"

  "I think the FDA's role really is to partner with all the groups that are already out there working on this and try to help facilitate those efforts so they're most effective."

- A few commented that GAPs should be mandatory to ensure better overall industry performance in avoiding outbreaks.

- A few others indicated that there should be common standards, but did not indicate whether these should be regulations or voluntary agreements.

- A few mentioned the need to have consistent standards that apply to produce from other countries, or urged caution about making U.S. produce more expensive through excessive standards, which thereby encourages import of international produce that may not be as safe.

- A few others were expressly opposed to regulatory action.

What Trainers/Auditors want from the FDA: Trainers and Auditors were asked to provide one piece of advice to the FDA regarding GAPs programs and GAPs communications. Their responses offered rich insights into quite varied perspectives. Generally they indicated that more communication and dialogue among the various parties in the industry would foster a more commonly shared understanding of future needs and directions for food safety.

- Many identified a need for FDA to provide more science by:
    - Identifying where the real risks are and focus the development of prevention actions on addressing those risks :

        "Do we really know that if we make GAPs universal and all fresh produce farms have to go through it … that is going to reduce the risk of people getting sick from fresh produce, or because we live in a big complicated world where lots of people touch our food before it gets to us that we really can't have that big of an impact."

    - Better understanding the "complex produce industry" so that the science can be applied in meaningful ways in support of regulation.

    - Recognizing that the produce industry is different than the meat packing industry and does not have the same kind of "critical control points where you can prevent the contamination from happening."

    - Doing more to share the information that is gathered by the FDA in a timely way*: "The outbreak investigations are typically published [by FDA] a year to sometimes close to two years after the event and the investigation reports typically say nothing was found. They don't describe the issues uncovered."*

- Most offered advice on how FDA could improve its role in the further development of food safety programs, including:
    - Clarify the purpose of food safety programs. Specific thoughts offered were, "*Keep the produce industry in the U.S. thriving," "Nobody has the right to produce unsafe food in this country regardless of their size,"* and *"Be clear about what you want, make sure it's consistently applied from state to state, and make it easy to understand, and make it doable."*

    - Clarify FDA's role in food safety. One noted that *"It doesn't appear [the FDA has] decided what their role is."* Another identified the challenges that growers have in tracking regulatory developments at the federal level and questions whether it is the FDA's or the USDA's role to communicate developments to the local level and at growers' Association meetings. Another saw a distinction between teaching and regulatory roles, and thought that FDA's role and enforcement authority is limited to responding: *"Only once has something bad happened."* Yet another suggested that FDA recognize that government is the right entity for ensuring compliance with food safety standards through audits, and that the roles of USDA and FDA in this process need clarification.

    - Partner with Growers in the development of any standards so that the standards are *"user friendly."* Engage growers in *"true listening and give and take sessions."*

- Partner with other stakeholders such as state regulators and academic institutions in the development and dissemination of information, while clarifying who is responsible for what. Trainers and auditors believed that they are best positioned to communicate with growers, as indicated by the following statements:

  > "*If FDA can provide the information to the trainers, they will have a good chance of getting the information out to industry through that mechanism."*
  >
  > *"The extension people have farm experience and expertise. They have advanced science degrees so they understand these simple food safety requirements and GAPs. They also understand what makes the farmers tick, what the constraints are for the farmers to do their work and are able to bridge in any communication gaps there might have been between the science of food safety and the execution on the farms."*

Different perspectives on the need for and approach to regulation were expressed in the interviews. Views range from a call for *"standardization of what GAPs is across the US and internationally"* to *"allowing it to continue to evolve … allowing it to … be a decision-based program as opposed to 'this is what you have to do.'"*

F. Detailed Summary of Research Results for Buyers

This section presents the detailed research findings of the interviews conducted with 4 Buyers who have worked on GAPs with tomato and/or leafy greens growers in the past two years. Select quotes are added for context. Section F is organized into the following sub-sections:

F.1. Buyer Characteristics

Two Buyers interviewed worked for large companies that have operations through the U.S. and internationally. These Interviewees had 30 or more years experience in the fresh produce industry, specifically in food safety, oversaw operations involving leafy greens, tomatoes and numerous other kinds of fresh produce.

The two other Buyers worked for mid-sized businesses that grow some of their own crops and purchase other produce from Distributors. These Interviewees oversaw food safety of growers and processing facilities for leafy greens in California and Arizona. They both started their jobs in food safety after the spinach outbreak in 2006, and previously worked in various capacities in the produce processing plants.

All Buyers indicated that they were involved in developing food safety programs for their companies. The food safety programs were designed to meet the food safety demands of customers such as restaurants, schools, and the military. To administer their programs, they meet regularly with owners and food safety managers of the growers, distributors and haulers with whom they contract. Most mentioned they host annual training for those they do business with. One mentioned the use of internet-based training as a supplement to other forms of training. All Buyers also conducted audits of growers. As a variation to an

audit, one Buyer mentioned the use of a risk assessment questionnaire that helps him/her establish a process flow for the farm, followed by product testing, water testing, pre-planting site inspections, and periodic site inspections.

F.2. Buyers' Thoughts on Food Safety Threats

Food Safety Objectives and Challenges: All Buyers indicated that the top goal of their food safety program was to prevent contamination and *"make sure that the consumer has the safest product that can possibly be produced."* Another stated objective was to be a "leader" in food safety within the produce market. For example:

> *"I was right there when the original industry led GAPs, and then worked with the FDA to bring them into fresh cut plants and state-of-the-art first built safety design plant. We brought the FDA in and said 'here is the future of fresh cut'."*

Another Interviewee provided some description of the risk assessment methods he/she uses to *"look at the land and environment and … the surroundings and the effect those can have [on food safety]."*

Another Buyer emphasized the need for consistent global standards:

> *"We are a global company and we're very concerned about making sure that our standards are in lock step with the countries we are dealing with in trying to sell product into. We want to see this globalized situation so that everybody knows what the rules are and everybody participates and does the best that they can do in terms of prevention."*

Greatest Opportunities to Reduce Risk: Consistent with Growers and Trainers and Auditors, Buyers did not consistently distinguish between types of contamination and sources of contamination. When asked what types of contamination were of greatest concern, they commented primarily on Salmonella and *E.coli.* Buyers identified multiple sources of contamination, primarily wildlife, water sources, worker hygiene, domestic livestock manure or compost and processing equipment. One Buyer mentioned the possibility of contamination through pesticide application. One Buyer clearly described how worker training permeates all aspects of operations:

> *"Frequently the guys meet in the field and everybody is being trained. The irrigators know what to look for. Every level of employee knows what to look for and what to do."*

Most also described a "risk assessment" approach they applied to address the multiple potential sources of contamination and to respond to changing conditions like weather events:

> *"I'd say there's no one silver bullet. It's a net of safety. What we do here, we do watch weather change, weather affects animal activity. Weather and environment affects the growth of bacteria. I'll give you an example. If we've got a field that just had a heavy rain event, we go out, we concentrate on that area. If we're in an area where we've got high humidity, we start looking at those areas a little more closely."*

One Buyer also focused on the need for clear standards and metrics rather than more subjective statements about reducing risk:

> *"Some of these things [in FDA Guidance] are risk – consider this or consider that. I'd rather see metrics; then I'll tell them what to do. When it comes to food safety, if it's black and white they'll do it."*

Buyers also described how important it is to know the growers and work with them individually:

> *"Growers, you just have to get to know them and find the right way to communicate with each one, just like anybody I guess. Turn an idea around and make it their idea, if that works. Give them a little time to think about it a little at a time."*

> *"Growers are very independent people, so obviously you have to be very cautious how you deal with growers. They know the business better than anyone. They don't like somebody trying to tell them how to do their job."*

F.3. Buyer's Thoughts on GAPs Programs

GAP Program Familiarity: Buyers generally described multiple sources of information they have used to construct their company's GAPs program:

- Two mentioned FDA guidance.
- Two mentioned the LGMA and one mentioned the T-GAPs. One Buyer described the LGMA as a collaborative effort involving about 30 signatories, including "*food safety scientists to food safety directors from most of the processors to, I believe they even invited some of the heads of the regulatory agencies.*"
- One mentioned Davis Fresh as a source of GAPs specific to processing facilities.
- Two mentioned prior farm practices that pre-date FDA Guidance on GAPs.
- One mentioned integrating customer's needs and expectations.

FDA GAPs Guidance Familiarity: Three Buyers indicated they were "very familiar" with FDA Guidance (the other Buyer was not asked specifically, but appeared to be familiar with the Guidance.) When asked to comment on the Guidance, Buyers said that it lacked "specificity" or quickly becomes "outdated" as new methodologies are developed. These comments were not necessarily critical of FDA's Guidance, but rather an indication that Buyers perceived the Guidance as a starting point from which various other programs like the LGMA and T-GAPs were developed to meet more specific and evolving needs. In contrasting FDA Guidance with the LGMA, one Buyer stated:

> *"I think, generally speaking, it was time to update [FDA Guidance]. I think what we did from an industry perspective [in developing the LGMA] was try and give more of the reality of what implementation on the ground is and try to straighten out some things that may no longer be practices out there in the field and try to give the benefit of our practical working knowledge of how these things have been operating."*

When asked to specifically comment on the February 2008 Guidance, Buyers seemed to generally appreciate the progress FDA had made since the 1998 Guidance was published:

> "*[The 2008 FDA Guidance] is better than a lot of the global programs that are out there and they are trying to come up to speed. We in the United States have had these issues and dealt with the issues, so I think the FDA is in the right spot.*"

"I like the fact that [the FDA] is starting to get a little more specific – the use of the term permeable gloves was a lot better than just saying think of ways to reduce contamination. That's really what the biggest push in the [development of the LGMA] was. The growers said 'please be specific' and 'prove to me that that works'.

GAP Program Effectiveness: All Buyers rated their organizations' GAPs programs as being effective: "*Best out there. The only one with clear requirements*"; and "*Very successful, we haven't had an incident.*"

One Buyer noted the interdependency of multiple efforts in making GAPs work by stating that, *"science, government audit and independent audit [are needed] to make things work."*

One Buyer provided a more detailed description of the food safety requirements his/her organization requires of growers, which included: monthly water testing; documentation of soil amendments; testing compost ("wild manure" and biosolids are not allowed); pre-season and pre-harvest inspections; and third party audits for every field. The Buyer described specific requirements for tomatoes, including wash water temperatures (10 degrees warmer than that of the tomatoes, in order to prevent tomatoes from drawing in contaminants) and monitoring and controlling handling and packing of tomatoes picked from multiple fields.

Requirements for leafy greens included restrictions on use of land within a mile of a feed lot or 800 feet of grazing land, with some adjustments made based on prevailing wind direction. A justification was provided for the stringency of their standards that clearly reflects why Buyers think more science is needed to support the development of improved GAPs metrics:

"We minimize risks. Strictly, there's no science to many of the metrics we have … like why a mile from a feedlot sounds good. I've been near some really big feed lots like down in Arizona and you can truly smell, strongly smell that feed lot a good mile away. And to me if I can strongly smell it, I'm wondering what's drifting in the wind. You kind of go along and just kind of be a little more cautious. … In case of rain, you don't know how far something will wash down, especially if there's a hill slide. I have seen soil washing away into a field so we've had to go and take a little extra precaution …. All of it probably developed from one-upmanship. Somebody says we'll start and the next guy says we're better so we go this far. Some of it is overkill. I personally don't think the feed lot is overkill but I think 800 feet from two horses is overkill. But hey, it's just work and we're going to keep it. It would be nice if somebody came up with some kind of standard."

Another Buyer also commented on the need for more science in the development of metrics for GAPs as applied on the farm:

"Getting more science and basing the standards and making any changes that we need to make, based on good, solid science that emerges from research that's going on."

F.4. Buyers' Thoughts on Growers' Implementation of GAPs

Growers' Understanding of GAPs: Buyers were asked to rate the degree to which the growers they work with understand GAPs. The Buyers provided scores of high to medium levels of understanding. Lower scores were attributed to growers in states other than California and Florida and more generally to growers that simply have not yet been exposed to GAP education programs:

"The vast majority probably have a high degree [of understanding about GAPs], but there are some that not as much that, they need a little help. That's the language, the way it's written, that's why, it is harder for some people."

"If there's any group that we feel is somewhat unfamiliar, we go out and we educate them."

"I think that the leafy greens folks, I think they get it, they get the whole big picture. Tomatoes, like I say, I think in the states other than California and Florida, they're trying to, a lot of them have a lot of good Ag Practices in place, but putting a whole coherent program together is probably going to take a little while, a year or two for them to get up to speed."

"We had a bean grower from Ohio or somewhere in the Midwest and he just wasn't getting it. He didn't see why he had to invest in these food safety practices, because 'this is the way I've always been doing it'. Well you have to have the best, safest product, otherwise you aren't going to be able to survive in a global economy because that's the way the world is going."

Growers' Implementation of GAPs: Three of the Buyers were asked to rate GAPs implementation among growers and distributors, and all responded with a "high" rating.

When asked to identify influences on implementation or barriers that prevent GAPs implementation, Buyers responded by indicating overall satisfaction with the way GAPs programs were being implemented, while noting the need to get more growers involved. Buyers working for mid- to larger-sized companies, like those we spoke with, may not work regularly with smaller growers. As one Buyer admitted, *"We're very selective about the growers we pick."* With this caveat in mind, select statements were:

"*Some of them get really confused because everyone of us out there asks something different. But there's always above and beyond that. They should get it; I don't really think there's that much of a problem with it. Sometimes the questions stump them. Yes, they do it. Really they do anything."*

"I really don't see any area to recommend improvement. I'm actually quite satisfied with the level of participation in the programs that we've set forth."

"Sure you've got to get to all the farmers out there, that's not an easy job. If you put the emphasis behind it and engage the county agents and go all the way up and down the chain and get that educational material out there, it's going to take a while, but I think we've got a lot of resources, we've just go to tap into them."

"Everybody knows what GAP's are, and the more involved things like County Extension Groups are, they've been very beneficial in helping the farmers understand and follow GAPs."

Buyers indicated that they tend to get few questions from growers about GAPs. When they do, growers are seeking "examples and practical ways to get things done," or wanting to know "why everybody wants something different." While one Buyer indicated that growers "rely upon" Buyers for information on GAPs when they need it, another Buyer indicated that growers are "always looking for what the new science" and that they reach out to the universities and use the internet in addition to contacting buyers for information.

When asked to identify what can be done to improve GAP implementation, Buyers stressed the need for practical and accessible information, for example: "*making it practical, prescriptive and clear*," providing *"a*

simple, bullet point checklist for them, a summary checklist." One Buyer commented on the need for a strong "educational effort" and "outreach."

Buyers' Training of Growers: Buyers indicated that they work closely with the growers they contract to make sure they understand the need for GAPs and how to implement them in practical ways. Buyers provide regularly scheduled training sessions for growers, typically seasonally. Also, the Buyers have teams of auditors that are constantly out in the fields and working with growers. Growers are informed of new science when it comes out. When issues are identified during audits, the auditors take the time to work through issues in ways that enhance understanding, as indicated by the following statements:

> *"Whenever we doing a ranch survey or a harvester audit, we don't just say 'that's wrong, fix it'. We say 'that's wrong because this could happen and you've got to fix it'. So it's an educational effort every time we do an audit with the grower, harvester, cooler, whoever we're doing it with."*

> *"We're really dedicated to doing the process, kind of that way, in an educational manner. It takes us more time to do it, but in the long run everybody wins because the growers tend to get it, they do things right and any changes that have to happen often happen immediately."*

F.5. Buyers' Assessments of FDA Role

Two of the Buyers specifically mentioned that FDA is doing a good job in developing guidance and in working with industry, while simultaneously indicating that there is more that could be done. Buyers mentioned the need to conduct more research that would support more specific metrics in future guidance or regulations. Concern was expressed that ongoing regulatory development efforts may be driven more by politics and fear of risk than by high quality information. For example:

> *"Lately there has been more political pressure so emphasis on what the consumer thinks is right rather than what the science is saying is right. FDA role seems to be confused with police force and they are not."*

> *"I think they're doing fair in dissemination; I think they could do a whole lot more in helping with funding some research and incorporate the industry in helping them guide that research."*

> *"I think the dissemination of good science-based information [is needed]. I think also in supporting the industry in getting some more science done; getting us some answers to the questions we don't have all the answers to. I think … basing the standards on good science is going to be absolutely critical because the more we look at the questions, the more questions that pop up that we didn't think about."*

> *"We just hope that we don't implement some unsound science like the Feinstein bill, [that] wanted finished product testing. Well that's not going to do you any good and it's expensive and it's not practical."*

Two Buyers expressly supported the idea of making GAPs mandatory in order to gain wide-spread, consistent implementation. One Buyer specifically indicated that the FDA and/or USDA should conduct audits because *"third party auditors can be biased."* Select statements supporting a uniform national standard were:

> *"We can't afford to put consumers at risk and put our whole food safety system at risk with lack of consumer confidence if somebody got sick from that two loads of tomatoes that the guy sold to*

the fast food place without any food safety practices in place, without any traceability. We can't afford to do that."

"If everybody understands that the one program that we have is sufficient then we can all concentrate on it and we can all accept it as a food safety program. That's what I'm hoping that the FDA will do, is automatically make the buyers' minds feel safe."

To support effective science and effective regulation, multiple Buyers indicated that it is important for FDA to work collaboratively with industry. The LGMA was promoted by one Buyer as an effective model for how multiple parties can be brought together to develop an effective and broadly supported GAPs program. This Buyer suggested that the LGMA be used as a basis for a national standard (without expressly stating that it should be mandatory). The benefits of a collaborative approach to developing an informed and practical national standard were clearly expressed in the following statement:

"*I think we've got a lot of practical experience and great expertise in the industry. We can and should be a part of helping guide what research is done and where we need the research done. Let's not make this an ivory tower exercise, or you spend a lot of money and don't get any real answers that are practical. I think it needs to be a public/private partnership somehow, where you leverage our experience out here in the field knowing what issues we see as emerging or where we need help."*

For More Information

For more information about this project please contact Sarah Thorne or Gordon Butte, Decision Partners, LLC., 1-877-588-9106 (gbutte@decisionpartners.com), or Linda Verrill (linda.verrill@fda.hhs.gov)

Appendix A: Background on Mental Models Approach

Behavior is Guided by Mental Models

Decades of research have shown that tacit webs of beliefs that have come to be called "mental models" guide people's behavior. People draw on their mental models to make inferences about problems that come to their attention through various communications. In the past 15 years, Decision Partners has used the mental models orientation to address challenges presented by lay-people's understanding of complex issues and processes, such as risk and risk management. This work, and other research, has shown that to change people's beliefs and behaviors, one must understand and change their mental models.

What Are Mental Models?

The concept of mental models is a well-established theory in psychology and has been the focus of extensive research.[16] A person's "mental model" can be thought of as a complex web of deeply held beliefs that operate below the conscious level. Mental models affect how an individual defines a problem, reacts to issues, and makes decisions about messages and options concerning topics that come to his or her attention through communications. Mental models tend to prevent people from seeing alternative perspectives and define the boundaries of thought and action. As such, they limit people to familiar patterns of reasoning and action.

Effective analyses of mental models can identify how different groups of people think about and respond to a variety of topics, including benefits and risks associated with activities, plans or proposals. The method relies on data collected from experts and stakeholders, typically through focused interviews with individuals conducted in person or by telephone.

The Challenge of Effective Communication

Experts and laypeople alike have challenges associated with their thinking about how to communicate on topics related to choice, risk or change. For instance, research and experience have shown that experts' beliefs about what to communicate on issues, to whom, and how can represent barriers to effective communication. Experts may predict that laypeople will:

- Be "irrational" about risks and, therefore, be inherently difficult to "reason" with.
- Need to be educated in order to judge risks and benefits appropriately.
- Be unable to add to the expert task of defining and solving problems.
- Have information preferences and biases for interpreting communications that can be easily predicted.
- Want to erode authority in order to shift power away from experts.

However, over the last 30 years, it has become evident that:

[16] For example: Johnson-Laird, P. N. (1983). Mental Models. Cambridge, MA: Harvard University Press. Atman, C.J., et al. (1994) Designing risk communications. Risk Analysis 14(5): 779-788; Bostrom, A. et al. (1992) Characterizing mental models of hazardous processes. J. Social Issues 48(4): 85-100; Fischhoff, B. et al. (1997) Risk perception and communication. In: Detels, R. et al. (eds.) Oxford textbook of public health. London: Oxford University Press, 1997. Pp. 987-1002.

- When designing communication strategies, speculation about people's interests and priorities is naïve at best and often risky.
- Laypeople typically address decisions from a different conceptual framework (mental model) than experts and use different terms.
- They often want and expect to participate in the process of defining options and making tradeoffs.
- Neither experts nor laypeople can ignore scientific uncertainty.

It is well established that people's mental models vary in important, but often unpredictable ways, and that their decisions are strongly affected by these mental models.[17] Through mental models research, we can discover:

- What people know that is correct and essential to making an informed decision.
- What they misunderstand that is consequential.
- What they do not know that is consequential.
- What they want to know and is important to them.
- What criteria they use to judge the trustworthiness and competence of people, organizations, and communications.

The Mental Models (or "dialogue") Method – involves individual, one-on-one interviews, leading participants through a jointly determined agenda of topics. The one-on-one situation helps to approximate the decision-making environment within which most people form their attitudes toward an organization or industry.

The method allows free expression and encourages elaboration on topics in order to reveal individual perspectives at considerable depth. Interviewees can readily raise topics that most interest them, but which may be outside of specific questions. Because a full set of beliefs is elicited from each Interviewee, structured analyses are possible. When done well, analysts can identify what people believe and why they believe it. They are also able to compare analyses over time and provide insights into why beliefs may have changed.

Properly done, the mental models method can produce rich results more efficiently than can the equivalent time and effort invested in opinion polls or focus groups. Twinned with a structured approach to developing an interview sample, it can help characterize communication networks in communities where it is applied. It can also be used effectively in combination with opinion surveys and focus groups. In such cases, mental models research is done first in order to design properly constituted focus groups and opinion research instruments.

Expert Models – Integrating Expert Knowledge

If initiatives and communications are to be well informed and authoritative, they must reflect current understanding among the experts in the relevant fields. Experts can include managers in various functions and at different levels in organizations. They can also include subject matter experts across a wide range of fields. To that end, the first step in organizing initiatives or determining the content and

[17] Fischhoff, B. and Downs, J.S. (1997) Communicating foodborne disease risk. Emerging Infectious Diseases 3(4):489-95.

focus of communications is integrating the knowledge of experts in a ways that can be focused and managed over time.

To be effective, expert modeling sessions must encourage and enable participants to think systematically about their knowledge, that of others, and the system in which the knowledge must be applied. They must stimulate experts to look at what they know in new ways. They must also carefully focus knowledge sharing. Since they compel close collaboration, expert modeling experiences can build positive relationships among participants and long-lasting coalitions.

Done well, each session produces a model and relationships with staying power; that is, a model that can be used by many different people in different ways and adapted far into the future on the topic as new issues arise or new information becomes available. So, expert models usually become valuable assets for client partners.

Use of Influence Diagrams

One technique that is well suited to many expert modeling tasks is influence diagramming. Decision Partners has used this technique extensively over the past decade on a wide range of topics with impressive results for client partners.

Influence diagrams were developed by decision analysts as a convenient way to summarize information about uncertain situations. They are common devices in many technical fields.

They are directed graphs with arrows or “influences” linking related “nodes”. An arrow between two nodes means that the node at the arrow’s tail exerts some “influence” on the node at the arrow’s head. More formally, knowing the value of the variable at the tail node helps one to predict the value of the variable at the head node.

Properly done, influence diagrams:

- Allow effective communication among experts and between experts and non-experts.
- Ensure no critical knowledge is missed or overlooked.
- Allow a mutually respectful way for communicators and technical experts to ensure they understand one another.
- Ensure only decision-relevant information is included.
- Can be applied to virtually any situation.
- Are compatible with experts’ conventional way of thinking.
- Make communication with non-experts more tractable to skeptical experts by deconstructing the task into manageable pieces.
- Fit with a decision-making perspective.
- Provide a strong, flexible framework for obtaining systematic assistance from experts as well as documenting the assumptions’ underlying information.
- Can be readily subjected to peer review.

There is no simple recipe for converting critical expert knowledge into an influence diagram. In general, the process works from a simple model to more detailed versions. It is iterative as experts review one another’s work and reflect on their own.

Related Reading:

Morgan, M.G., Fischhoff, B., Bostrom, A., Atman, C.J., (2001) Risk Communication – A Mental Models Approach. New York: Cambridge University Press.

Fischhoff, B. (1995) Risk perception and communication unplugged: Twenty years of process. Risk Analysis, 15, 137-145.

Morgan, M.G., Fischhoff, B., Bostrom, A., Lave, L., & Atman, C.J. (1992) Communicating risk to the public. Environmental Science and Technology, 26, 2048-2056.

Fischhoff, B., Bostrom, A., & Quandrel, M.J. (1997). Risk perception and communication. In R. Detels, J. McEwen & G. Omenn (Eds.), Oxford textbook of public health (pp.987-1002) London: Oxford University Press.

Appendix B: Grower Interview Guide

Grower's Understanding and Implementation of GAPs
(Task Order #5 – Contract # HHSF223200510007I)
Mental Models Interview Protocol

Solicitation
[Ask for the person in charge of food safety, food quality assurance and/or good agricultural practices.]

Hello, this is <name> with Decision Partners. We are working with agricultural experts from the FDA on a research project to better understand how to communicate effectively with produce growers about microbial food safety hazards of fresh and fresh-cut produce and good agricultural practices to minimize those risks. As part of this project, we're contacting growers like yourself to see if you would be interested in participating in a research interview. If you are interested, we would conduct an interview over the phone at a time that is convenient to you. The conversation will be confidential and would take about 45 minutes. Would you be willing to participate in a research interview?

Interviewer make arrangements to call at the scheduled time.

Interviewer, additional information, if requested:

- The sample list was developed through references by FDA and organizations, or through publically-available lists of businesses fitting the research criteria--- operations with estimated revenues over $250,000 per year that grow [tomatoes in FL/ leafy greens in CA or AZ.] Leafy greens include lettuce, spinach, herbs, etc.
- The participant will be asked to provide information based on their professional experience and knowledge and the experience and practices of their operation.
- *Offer to have Sara Eggers, Decision Partners Research Director contact the person if they have any questions about the research.*

Introduction
Hi, this is <name> with Decision Partners. As I explained when I set up this interview, we are working with agricultural experts from the FDA to talk to growers about their understanding and awareness of the food safety hazards of fresh and fresh-cut produce and the things that growers might do to minimize these risks. This research will be used to help improve communication and education activities.

I have a list of questions to help guide our discussion, but please feel free to raise anything that comes to mind as we go along. In this kind of an interview, there are no right or wrong answers. All of your comments add value to the research. I also want to assure you that we will not identify you as the specific source of any comments in our report. Instead, the report will consolidate the responses of everyone we interview.

Before we start, in order to ensure that my notes of our conversation are accurate and complete, I'd like to ask your permission to record our conversation, but I would like to stress again that your responses will be kept confidential. The recording will only be used to create better notes and will be destroyed at the

conclusion of the project. No personally identifying information will be passed along to the FDA or any other government agencies. May we proceed on that basis?

Opening
Our discussion will have four main parts. First we'll talk generally about your operation's growing and handling practices. Next, we'll talk about your thoughts on produce contamination the steps to minimize those risks. Then we'll discuss communications on food safety hazards. We'll finish by allowing you to provide any final thoughts you might have and some questions about you.

Notes to interviewers: Growers may mention other types of contamination (e.g., chemicals, pesticides). Reiterate that we're focusing here on microbial contamination.

If time is an issue, follow the "if not mentioned" instructions and skip questions they've already mentioned or, when appropriate, acknowledge what they've already mentioned and move to follow-ups.

Part 1: Farming Activities
First, let's begin by talking generally about the kinds of farming that you do. So, to start off,

q1. Please *briefly* tell me about your farming operations.

If not mentioned:
- What crops are produced by your growing operation? (*If it's a large number of crops:* What are your primary crops?)
- How many acres are farmed on your operation?
- About how many workers are on your farm?
- How many years have you been involved in farming? How long has your farm been around?
- Are you "organic" or "certified naturally grown"?
- Where do you sell your produce? Is any of your produce sold fresh?

q2. How would you describe your most important roles on the farm – that is, what duties are you personally responsible for?

q3. In general, what are your operation's key goals or objectives for the farm?

Optional prompt (brief):
- How would you define success?

If they mention contamination issues here, note, but don't go into too much detail, and say:
- We're going to get into more detail on the issue of contamination and goals for contamination in just a moment. For now, are there any other, non-contamination goals?

q4. What are the most significant challenges or obstacles that you face in trying to achieve these goals for the farm?

Part 2: Thoughts on Contamination Hazards, Prevention & Response
Now I am interested in hearing from you about safety hazards on the farm that affect fresh produce. I will begin by asking you to think about contamination in general, how it relates to activities on your farm, and what you might do if a source of contamination was discovered on your farm.

Hazards

Interviewer note: This section is primarily to get context to discuss the operation's contamination prevention and response activities later on, so try to keep the discussion in this section somewhat short.

Interviewer note: Here we ask in terms of "types of contamination" (E.coli, salmonella, etc.). They may respond in terms of sources of contamination (contaminated water, manure from wildlife, sick workers, etc.). Allow them to answer in the way they perceive contamination – in terms of the type or the source. However, be sure to probe for both if only one is supplied. Also, we are concerned with hazards on the farm and not down the line in the supply or delivery chain.

q5. First, thinking about the crops grown on your farm, what types of contamination do you face? Anything else?

If not mentioned, for each:

- What is the type of contamination you're talking about, the microbe that is coming from this source?
- What is the source of this contamination?

If not already mentioned:

q5a. Are there any contamination hazards that specifically affect your [tomato / leafy greens] crops?

q6. Are there any other sources of contamination?

If not mentioned, for each:

- What is the type of contamination you're talking about? What is the microbe that is coming from this source?

If not mentioned:

- What about water used for irrigation? What kind of irrigation system do you use?
- What about water used for washing?
- What about manure used as fertilizer?
- What about droppings from livestock or wildlife?
- What about contamination from unsanitary farm equipment?

If already mentioned, acknowledge, but still ask:

q7. How might contamination of produce be caused by people?

[If contamination they are talking about is from farm workers]

- What is the worker's role on the farm [*if not obvious]*?
- What are they doing that causes the contamination?

If not mentioned:

- How might contamination be caused by people who visit your farm?
- Why are they on the farm?
- What are they doing that causes the contamination?

q8. You've mentioned [*list the contamination types they've mentioned*]. Of these potential types of contamination, which are you most concerned about?

- Why do you say that?

Prevention

Now I'd like to ask you about how contamination can be prevented. For this part of the discussion, we want to focus primarily on [tomatoes / leafy greens], however feel free to discuss prevention of contamination in other crops as well.

q9. What would you say are your goals for reducing the risk of contamination on your farm?

- Why are these goals important?
- Anything else?

q9a. Who external to your farm influences your goals for prevention?

If not mentioned:

- What about your wholesale buyers what influence, if any, do they have on your goals for preventing contamination?
- What about your *other* customers, what influence, if any, do they have?
- What about local, state or federal government agencies, what influence, if any, do they have on your goals for preventing contamination? *[note: e.g., Agricultural extension, health departments, USDA, FDA] Probe deeper if FDA is mentioned.*

q9b. How much influence would you say food industry organizations or commodity groups have on your goals for preventing contamination?

For Florida Tomato growers:

q10. [Priority Q] Recently the Florida Dept of Agriculture and the Florida Tomato industry have adopted Tomato GAPs and Best Management Practices to be used by most Florida tomato growers. Can you tell me about your thoughts and experiences with that? *Note: There are some exceptions (e.g., if only selling on farm or at farmers markets). Probably not likely for our participants given our $250K/year minimum.*

- Which organization's GAPs program do you follow? Why them?
- How did you find out about them?
- How have you incorporated GAPs on your farm? How has it changed the way you farm?

For Leafy greens growers

q10. [Priority Q] Some organizations such as the FDA or university extensions suggest a formalized set of farm practices with record-keeping requirements. These are designed to reduce the likelihood of contamination and may be known as "Good Agricultural Practices" or GAPs. Are your prevention activities based on one or any of these programs?

If yes:

- Which organization's GAPs program do you follow? Why them?
- How did you find out about them?
- How have you incorporated GAPs on your farm? How has it changed the way you farm?

If specific GAPs or preventive actions have not been mentioned earlier: [otherwise skip to Q11a]
Only read bracketed text if they use GAPs

q11. [Priority Q] What [GAPs or other] actions do you take to prevent contamination?

- Why do you do this as opposed to something else?

- Are there any other [GAPs or other] prevention activities that you take?

If specific GAPs or preventive actions have been mentioned earlier: [otherwise skip to Q11b]

q11a. [Priority Q] You've already mentioned [*list, one at a time, GAPs/prevention activities mentioned previously, ask follow-ups of each*].
- Why do you do this as opposed to something else?
- Are there any other [GAPs or other] prevention activities that you take?

Now I'm going to ask you about a number of specific areas of specific prevention activities, some of which you may have touched on already. If so, we'll just touch on those briefly and move on.

q11b. [Priority Q] First, what [GAPs or] prevention activities, if any, do you do related to water contamination?
- Why do you do this as opposed to something else?
- Anything else?
- If nothing: Why don't you do anything in this area?

q11c. [Priority Q] Next, what [GAPs or] prevention activities, if any, do you do related to contamination from manure?
- Why do you do this as opposed to something else?
- Anything else?
- If nothing: Why don't you do anything in this area?

q11d. [Priority Q] Next, what [GAPs or] prevention activities, if any, do you do related to contamination from wildlife droppings?
- Why do you do this as opposed to something else?
- Anything else?
- If nothing: Why don't you do anything in this area?

q11e. [Priority Q] Next, what [GAPs or] prevention activities, if any, do you do related to contamination from farm equipment?
- Why do you do this as opposed to something else?
- Anything else?
- If nothing: Why don't you do anything in this area?

q11f. [Priority Q] Next, what prevention activities, if any, do you do related to contamination from people?
- Why do you do this as opposed to something else?
- Anything else?
- If nothing: Why don't you do anything in this area?

q11g. [Priority Q] We've discussed preventive actions related to water quality, manure contamination, equipment sanitization, and worker hygiene. Which of these would you say is <u>most</u> effective at preventing the contamination of produce? Why?

If they use GAPs [otherwise skip to 12a]:

q12. [Priority Q] What are your general thoughts on the GAPs prevention program that you employ, specifically with respect to [tomatoes / leafy greens]? *Probe in more detail if FDA is mentioned.*

If not mentioned:

- What about prevention programs for your other crops do you have any different thoughts? *Probe in detail if FDA is mentioned.*

If they don't use GAPs [otherwise skip to 12b]:

q12a. [Priority Q] You mentioned that you do not follow a particular set of GAPs, Is there any particular reason why you haven't adopted a GAPs program?

- Would you consider adopting a GAPs program in the future? Why/Why not?
- What would encourage you to adopt a GAPs program?

If not mentioned:

q12b. [Priority Q] What barriers, if any, make it difficult for you to adopt contamination prevention measures particularly with [tomatoes/leafy greens]

If not mentioned:

- What about access to technology or specialized equipment, would that be a barrier? Why? [e.g., special testing or cleaning equipment]
- How might these barriers be addressed?

Response

Now I'd like to talk about how you would respond to a contamination incident on your farm.

q13. First, how would you know if you had contamination on your farm?

q14. What steps would you take if you discovered contamination on your farm?

- Why would you do this as opposed to something else?
- Anything else?

q15. How prepared would you say you currently are to deal with produce contamination if it occurs? Would you say very prepared; somewhat prepared; or not at all prepared?

- Why do you say that?

q16. [Priority Q] Are there other people, not part of your farm operations, who would help your operation deal with contamination if it was discovered on your farm? Anyone else?

If not mentioned:

- Who are they?
- How would they help you? What is their role?

If not mentioned:

- What about government agencies? How would they help you? What is their role?
- What about agricultural extension agencies? How would they help you? What is their role?
- What about Commodity groups? How would they help you? What is their role?
- What about your Suppliers (e.g. seeds, chemicals fertilizers, etc)? How would they help you? What is their role?
- What about your wholesale buyers? How would they help you? What is their role?

q17. How significantly would a contamination incident at your farm affect your operations?
If not mentioned:

- How would it affect you from a customer relationship standpoint?
- How would it affect you financially?

q18. How significantly would a contamination incident involving [leafy greens / tomatoes] at another farm affect your operations?

q19. How would a contamination incident affect consumers or society in general?

Part 3: Risk Communication

In this last section of the interview, I'd like to ask your thoughts on sources of information and the role of communications in running your farm.

q20. [Priority Q] Where do you go for general information, not specific to contamination, about ways to improve how you run your farm? Why do you go there?

q21. [Priority Q] If you wanted to learn more about the safety of fresh and fresh-cut produce and the ways to prevent contamination, where or to whom would you go for information? Why?

q21a. [Priority Q] Right now, are there any particular contamination risks or prevention activities that you would like more information on?

q21b. How would you like to receive that information (e.g., written materials, training classes, in-person visits)?

q21c. [Priority Q] Would you look for or consider specific GAPs training program? Why or why not?
If yes,

- From where?

Now I'm going to mention a number of sources that growers might use for information on produce safety and ask you to rate each one.

q22. First, Agricultural Extension. In the past 2 years, have you approached Extension to learn about produce safety and contamination?

- How would you rate University Extension on their outreach and communications to growers? Would you say it is very good, satisfactory or poor? Why?

q23. Next, government sources. In the past 2 years, have you approached any government agencies or departments to learn about produce safety and contamination?
If so, which government sources?

- How would you rate government sources on their outreach and communications to growers? Would you say they are very good, satisfactory or poor? Why?

q24. And commodity groups like your state's Produce Growers Associations or United Fresh. In the past 2 years, have you approached commodity groups to learn about produce safety and contamination?

- How would you rate commodity groups on their outreach and communications to growers? Would you say they are very good, satisfactory or poor? Why?

q25. How about farm advocacy groups like the American Farm Bureau? In the past 2 years, have you approached farm advocacy groups to learn about produce safety and contamination?

- How would you rate farm advocacy groups on their outreach and communications to growers? Would you say they are very good, satisfactory or poor? Why?

q26. How about your buyers? In the past 2 years, have you approached your buyers to learn about produce safety and contamination?

- How would you rate buyers on their outreach and communications to growers? Would you say they are very good, satisfactory or poor? Why?

q27. And third-party farm auditors, such as university farm analysis. In the past 2 years, have you approached farm auditors to learn about produce safety and contamination?

- How would you rate third-party farm auditors on their outreach and communications to growers? Would you say they are very good, satisfactory or poor? Why?

q28. How about, private consultants? In the past 2 years, have you approached private consultants to learn about produce safety and contamination?

- How would you rate private consultants on their outreach and communications to growers? Would you say they are very good, satisfactory or poor? Why?

q29. Finally, how about other farmers? In the past 2 years, have you talked to other farmers to learn about produce safety and contamination?

- How would you rate other farmers on their knowledge or helpfulness? Would you say they are very good, satisfactory or poor?

q30. Are there any other information sources I haven't mentioned that you have approached in the past 2 years to learn about produce safety and contamination?

- *If so,* which sources?
- How would you rate this source on their outreach and communications to growers? Would you say they are very good, satisfactory or poor? Why?

q31. Of all the information sources that we've discussed, which would you say is the most useful to you when it comes to produce safety and contamination? Why?

q32. Do you participate in any continuous learning programs or training activities to learn about produce safety?

If so:

- Which programs or activities?
- How would you rate these programs or activities? Would you say they are very good, satisfactory or poor? Why?

Closing

You've been very helpful and I appreciate the time you've taken to speak with me today. To finish up,

q33. Is there anything else that came to mind while we were talking that you would like me to include in our research?

q34. If you could offer one piece of advice to the FDA regarding the safety of fresh and fresh-cut produce, what would that be?

Demographic Questions

q35a. What is your approximate age? Are you in your 20s, 30s, 40s, 50s, or 60 and above?

q35b. What is your approximate range of revenue that you generate from your crops annually?

- under $250,000/year
- $250,000 to $1 Million/year
- 1 Million to 2.5 Million/year
- 2.5 Million to 5 Million/year
- 5 Million to 10 Million/year
- Over 10 million/year

q35c. May I ask what is the highest level of education that you have completed? Below high school, high school graduate, some college or university, college or university graduate, post-graduate education.

q35d. *Interviewer, record gender*.

I'd like to thank you once again for the time you've taken to share your knowledge and expertise on this issue. Your thoughts and ideas will be very valuable to our team in learning about the safety of fresh and fresh-cut produce and the best ways to communicate with growers.

If you have any questions about this research or about Decision Partners, you can get in touch with Sarah Thorne or Sara Eggers through the Decision Partners' office at (877) 588-9106 (or take their number and say that we will have someone contact them).

Appendix C: Grower Interviewee Demographic Summary