

# **Strategic Plan for Improving Small and Very Small Establishments' Food Safety Programs to Further Protect Public Health and Ensure Regulatory Compliance**

**Facilitated by:  
The International HACCP Alliance**

**December 2005**

## Table of Contents

Table of Contents.....	2
Introduction.....	3
Key Need #1..... Acceptable Supporting Documentation for HACCP and Other Food Safety Programs.	4
Key Need #2..... Summary of Questions and Answers and FSIS Information.	5
Key Need #3..... Development of Additional Guidance Documents.	6
Key Need #4..... Provide educational opportunities for both FSIS and industry personnel.	7
Key Need #5..... Ensure a Consistent Message is Being Delivered.	8
Key Need #6..... To ensure that small and very small plants understand the appeal process and their right to appeal.	9

# **Strategic Plan for Improving Small and Very Small Establishments' Food Safety Programs to Further Protect Public Health and Ensure Regulatory Compliance**

## **INTRODUCTION:**

This document is an outcome of a strategic planning meeting for small and very small establishments that was hosted by the International HACCP Alliance on December 7-8, 2005. The participants represented industry associations, universities and federal and state government agencies. The goals of the meeting were to:

1. Determine the needs of the small and very small establishments.
2. Identify the best methods/tools for meeting these needs.
3. Identify specific actions to be taken by the parties involved.

During the opening remarks Dr. Richard Raymond, USDA's Under Secretary for Food Safety, discussed the plan for further implementation of a more robust risk-based inspection system. He noted that the goal of accomplishing a more robust risk-based inspection system requires that all inspected establishments (Federal and State) must have solid HACCP and food safety programs. Dr. Raymond indicated that while FSIS has done outreach for the past six years for the small and very small plants that he recognized it might be time to reassess that outreach. He wanted to be certain that FSIS is providing the right type of assistance when and where possible, but he also made it very clear that FSIS has regulatory responsibilities and would not back away from those. He also noted that he sensed a widening gap between the large and the small and very small plants, and that this is not acceptable. Dr. Raymond stated that there are two ways to deal with this — regulate or educate. By re-energizing FSIS' outreach efforts, more education can be provided to help plants have sound HACCP and food safety programs that comply with the regulations and would help further protect public health.

To address the first goal, there was a significant amount of discussion on the fact that many small and very small plants have very successful HACCP and food safety systems that are in compliance with regulatory requirements, while other plants may have specific areas that need improvement to strengthen their programs and comply with the regulations. It was noted that some plants are making extra efforts to ensure they are staying current and complying with the regulations, while other plants either do not understand what is needed to have a successful program that complies with the regulations or they do not want to know what is needed. Therefore, it was agreed that the needs are not the same for all small and very small plants.

One of the key phrases used during the planning session was the need to "Educate before you Regulate." It was clearly noted that education will not replace enforcement of regulatory requirements, but that outreach and educational activities should be available to those plants seeking assistance and trying to comply with the regulations. FSIS will continue to take all necessary enforcement actions to protect public health. The ability to communicate, collaborate, and cooperate was emphasized by Dr. Raymond during the opening remarks, and was reflected in many of the needs and activities that were identified.

Representatives from FSIS, FDA, and APHIS provided a brief update on activities related to trying to address the needs of small and very small establishments. All three agency representatives noted that a variety of methods have been tried to reach all of the small and very small establishments. Dr. Barbara Masters, FSIS Administrator, discussed the importance of

ensuring that outreach programs are effectively addressing the real needs of the establishments. Dr. Brett Koonse, Chief, FDA's Programs and Enforcement Branch, provided information on the development of the Fish and Fisheries Products Hazards and Control Guide, which has been a tremendous help for facilities implementing HACCP program. Dr. Jerry Diemer with APHIS described the success they had with educational efforts related to BSE. Throughout the discussion, the representatives from FDA and APHIS provided insight into their experiences in working with small and very small producers and processors.

After each of the updates, the participants were challenged to address each of the previously identified goals. As a result of the thorough and extensive discussions, six key needs were identified and specific action items were developed to address each need. It was agreed that the needs and activities could change as additional input is provided. All involved parties expressed a commitment to make available to all small and very small plants the appropriate information and/or tools needed to develop an effective HACCP/food safety system that will ensure regulatory compliance. However, it was also noted that all establishments, regardless of size, should be held accountable for utilizing the available information and/or tools to successfully implement the programs in each establishment. The participants also agreed that all of the needs and activities must address the cultural diversity of the industry. Therefore, the materials may need to be available in multiple languages and various formats (printed and electronic) to ensure that all plants can benefit.

The overall success of this strategic plan relies on two points:

- (1) The ability to fulfill the key needs by achieving the identified action items, and
- (2) The willingness of the establishments to address the areas within their HACCP and food safety systems that need improvement.

## Key Need #1

### Acceptable Supporting Documentation for HACCP and Other Food Safety Programs.

#### Overview<sup>1,2</sup>:

This need was based on the concern that some small and very small plants have difficulty finding/obtaining/developing documentation to help them develop and implement the decisions that they have made in their HACCP and food safety programs. Some of the scientific articles supporting interventions and food safety programs are based on more complex systems and are not directly applicable to small and very small establishments, so it is difficult to use them to support their decisions. Needs for supporting documentation to meet the HACCP regulatory requirements could relate to decisions made in a hazard analysis; the process of selecting critical control points (CCPs) and/or critical limits; and information to help support monitoring and verification procedures and frequencies. Needs for supporting documentation for other food safety programs could relate to *Listeria* control programs; design and development of sanitation programs, including operational SSOPs; and information to help develop an effective recordkeeping system for these programs.

#### Specific Action Items for Key Need #1:

1. Industry associations will survey their members to identify the areas for which supporting documentation is needed.
2. FSIS will obtain information from repetitive enforcement actions, historical data from recalls and/or outbreaks, and testing data that could identify areas where supporting documentation is needed.
3. Identify existing scientific/technical/regulatory information that can be used to address each area for which supporting documentation is needed.
4. Ensure that information is provided in a clear and concise manner that can be easily understood and applied within small and very small establishments.
5. Develop a review process using experts from academia, industry and FSIS to determine acceptability of supporting documentations.
6. Develop a dissemination process using industry associations and/or FSIS personnel for the documents to ensure easy access to all establishments that are seeking information.

---

<sup>1</sup> While not discussed at the meeting, the needs identified are similar to those in foreign countries. Many of the action items throughout the document will be useful in working with countries that export to the United States.

<sup>2</sup> While not discussed at the meeting, the needs identified are similar for outreach in the area of food defense. Where practical FSIS should leverage resources to use similar outreach efforts to educate small and very small plants on efforts they can take to protect their products from intentional contamination.

## **Key Need #2**

### **Summary of Questions and Answers and FSIS Information.**

#### Overview:

This need was based on the concern that some small and very small plants have difficulty obtaining consistent responses from FSIS personnel and in obtaining some FSIS responses in writing. For example, many states have conducted “Roundtable” sessions that bring industry, academia and FSIS personnel together for a few hours to provide a forum for discussing concerns/issues and obtaining input on regulatory issues, and yet these discussions are generally not captured in writing to allow establishments that are not able to attend to benefit from the information. Roundtables are often organized by academic institutions to help stimulate discussion between industry and FSIS personnel from the district offices, and they have served as useful tools for providing assistance to plants.

#### **Specific Action Items for Key Need #2:**

1. Contact states that are currently conducting “roundtables” to request previous questions that may have been captured and to request that all future questions and answers are captured.
2. Post commonly asked questions sent to FSIS’ Technical Service Center in a location that is easily accessed on the FSIS website.
3. Utilize an e-mail address within FSIS that questions can be sent to ensure a coordinated response to each question is provided. (Make the e-mail address known to State agencies, industry academia, and Extension personnel.)
4. Develop a “roundtable” instruction piece (schedule, who is invited from the FSIS, how to set ground rules, etc.).
5. Encourage additional “roundtable” sessions across the country.
6. Develop IKE scenarios for appropriate situations that require more than a simple question and answer (for food safety and food defense issues).
7. Provide access to all questions and answers by posting them on the FSIS web site.

### **Key Need #3**

#### **Development of Additional Guidance Documents.**

##### Overview:

Guidance documents are intended to provide establishments with recommendations and/or suggestions on how to comply with specific regulatory requirements. For example, FSIS issued the Compliance Guidelines to Control *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products to help establishments develop their *Listeria* control programs. It was noted that guidance documents are useful, provided they are clearly written and as concise as possible. It was agreed that additional guidance documents would be beneficial.

##### **Specific Action Items for Key Need #3:**

1. Identify existing compliance guidelines and determine if any of them should be revised to more clearly address small and very small establishment issues.
2. Utilize industry associations to survey their membership to obtain areas where guidance documents would be useful for food safety and food defense.
3. Develop new easily understandable guidance documents for identified areas.
4. Provide a mechanism for distribution of guidance documents.
5. Develop a mechanism for obtaining feedback from small and very small establishments on the usefulness of the guidance documents.
6. Utilize industry associations to survey small and very small establishments to determine what infrastructure needs related to food safety and food defense that they have where small business loans and/or Rural Development Assistance would be beneficial.

#### **Key Need #4**

#### **Provide educational opportunities for both FSIS and industry personnel.**

##### Overview:

The need for additional educational opportunities for both FSIS and industry personnel was identified as a need due to the importance of ensuring that small and very small plants have the opportunity to understand the regulatory requirements. It is important that establishments are given an opportunity to learn what the requirements are and how to meet them, and that some FSIS personnel can help disseminate educational information to small and very small establishments. It was clearly noted that FSIS has responsibilities for enforcing the regulations and those actions will be taken to protect public health.

#### **Specific Action Items for Key Need #4:**

1. Explore options for “joint” training through FSIS’ regional training offices.
2. Allow EIAOs to participate in industry training sessions.
3. Utilize EIAOs to deliver information to establishments on educational opportunities.
4. Provide opportunities for EIAOs to visit establishments to provide information and discuss the process for conducting a Food Safety Assessment.
5. Explore options for additional delivery mechanisms to allow for broader participation, such as webcast and interactive training.
6. Discuss educational needs with CSREES to determine opportunities for funding and identify an effective mechanism for communicating with university Deans that have programs related to food safety and/or food defense.
7. Develop a mechanism for FSIS to provide updates/training for Extension personnel and other individuals who are providing industry educational programs and serving as a resource for small and very small establishments.

## **Key Need #5**

### **Ensure a Consistent Message is Being Delivered.**

#### Overview:

One of the areas that had been identified during the FSIS listening sessions was a concern over the inconsistency of responses received from the Technical Service Center and from FSIS personnel. It was agreed that the messages must be consistent.

#### **Specific Action Items for Key Need #5:**

1. FSIS' Office of PEER is conducting an evaluation of the Technical Service Center to determine areas to make continual improvements. FSIS is looking for ways to include industry in the evaluation.
2. FSIS will identify other entities/groups that serve as models for addressing questions and serving as a technical resource to determine how they address consistency.
3. FSIS will implement a "virtual representative" or "Ask Harry HACCP" hotline on the FSIS website to answer technical questions similar to the current "Ask Karen" that answers consumer education questions.
4. Ensure that all tools for delivering information are as concise and clear as possible.
5. Develop a mechanism for assessing the effectiveness of the message to ensure that the responses are addressing the needs.

### **Key Need #6**

**To ensure that small and very small plants understand the appeal process and their right to appeal.**

#### Overview:

Based on the discussions, some small and very small establishments do not fully understand the appeal process for NRs, NOIEs, suspensions or other enforcement actions. It was also noted that others are hesitant to appeal the findings of their in-plant inspector. It was noted that establishments have the right to appeal and that an appeal should not be taken personally by the inspection force.

#### **Specific Action Items for Key Need #6:**

1. FSIS will develop an IKE for appeal situations to help explain the process and the outcomes.
2. FSIS will develop an informational tool for what can/should be appealed and the step-by-step process for appealing.
3. FSIS will identify the number of appeals that are upheld and those that are overturned.
4. FSIS will determine if the information from the overturned appeals can be used to develop training materials to educate FSIS' workforce.
5. FSIS will re-emphasize to all FSIS personnel that industry has the right to appeal any inspection decision.