

Risk-Based Inspection Systems Focus Group Sessions

Final Summary Report

The Food Safety and Inspection Service (FSIS) is enhancing its outreach efforts, particularly to small and very small plants. We need to ensure that everyone meets the published regulatory requirements. One of the key agency priorities is to enhance the risk-based inspection system (RBIS). FSIS recognizes that properly designed and fully implemented food safety systems are fundamental to RBIS. All establishments (regardless of size) must have properly functioning HACCP systems, and FSIS has a role in educating as well as regulating industry to meet this outcome.

The Agency realizes that each step taken toward risk-based systems must further protect public health. In spring 2006, FSIS carried out this effort through a transparent process of listening to the ideas and suggestions of its own field employees who will be responsible for carrying on a successful RBIS. Focus groups of no more than 12 persons were held in Atlanta, Georgia, Beltsville, Maryland and two over the internet through Verizon's Net Meeting software. The four-hour sessions were audio-recorded and each participant was granted anonymous commenting by their assignment of a number between one and 12. When a participant desired to make a comment, they were referred to as "participant one," "participant two," etc.

The four-hour sessions were organized into six issues that relate to RBIS. The issues stem from a PowerPoint presentation that was recorded by Phil Derfler with the help of the Center for Learning in College Station, Texas. The presentation allowed the participants to gain some working knowledge of where the RBIS currently stands and to where the Agency would like to see it evolve. The six issues are:

- Anticipating Problems
- Risk-Based Inspection Factors
- Work to be Done
- Design of Inspection Activities
- Response to Findings
- Continuing Communication with Employees

A Moderator's Guide was drafted to bring consistency to all sessions. During the sessions the assigned moderators worked from the guide which contained at least one question related to each specific issue and prompts to guide the participants in answering the questions in case the participants needed clarification.

This summary will not list verbatim comments of each participant. Rather, it will display the overall comments on each issue so that the reader can have an understanding of FSIS employees' opinions on RBIS.

Issue #1 - Anticipate Problems

We believe risk-based inspection will allow us to identify problems that are likely to occur in the process before they actually become serious. As part of risk-based inspection, we will capture and analyze data across plants. We will also look to see whether there are any patterns of breakdowns, findings, or even hints of major problems.

Q1.1 – What information should we be capturing so we can easily identify emerging problems?

The four groups varied in their responses, however there was a general consensus that FSIS needs to capture and analyze more information, especially from plant records. The following types of information were recommended.

- **Sanitation**

Sanitation information, from both FSIS and plant records was stressed by all focus groups as under-used for identifying problems early. This included the Sanitary Performance Standards data. Some felt that a lot of plants will correct problems but not keep records because they don't want to tell the inspector about the problem.

- **Plant testing results**

The groups stressed that results of plant testing and laboratory results of sampling should be obtained and analyzed by FSIS. One commenter stressed that analysis was critical for identifying early indications of problems before there was any non-compliance. A participant commented that they do not believe in perfect plants and FSIS should investigate plants whose microbiology sampling results never indicate a problem. The participant also added, "If you see perfection—there is a problem."

- **Consumer complaint information**

Consumer complaint information was considered as very important. One commenter also pointed out that plants receive more consumer complaints directly from consumers and this information would be very valuable to FSIS.

- **Human cases of foodborne diseases**

Access to information on human illnesses associated with plants should be maintained, even when FSIS takes no actions. A Net Meeting participant added that FSIS should investigate methods for obtaining this information from foreign plants that export products to the United States. Currently this information is not available.

- **Other Agencies, federal, state, and local**

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The suggestion was made that FSIS encourage other Agencies, federal, state, and local, to provide information relevant to food safety. As an example, the commenter described a situation in a plant where the local agency evaluating water potability did not pass the information that the plant's water supply had been determined to be un-potable. The Inspector-in Charge only learned of this through other channels. Another person stressed that information on emerging diseases should be received from APHIS as soon as possible.

- **In-transit and storage records of product**

At one session the participants overwhelmingly felt that data on in-transit shipping and temperature records should be available. Logs of temperature monitoring of products in storage are also important for protecting foodsafety and need to be examined.

- **Facilities and equipment**

A commenter stated that facility and equipment information was under reported and/or under used. Another recommend was made that everything under 06D01 (Facilities and Equipment) was very broad and more specific instructions would help. Records of any plant construction or remodeling would be useful.

- **Foreign plants**

Some felt that more information needs to be obtained from foreign plants and countries exporting product to the United States. An example was given that U.S. plants were required to have letters of guarantee from suppliers in some cases but foreign plants are not. There was the impression that FSIS seems to take action *after* a problem is reported. There was a desire to “boost up our own testing and ask questions to see if they [international plants] know that they have a problem.”

- **Suppliers**

The identities and foodsafety history of suppliers of food ingredients, packaging materials, and cleaning compounds should be available.

- **Foodborne diseases**

FSIS needs any available information on the known and potential causes of foodborne diseases. This includes basic scientific information and current disease problems.

Q1.2 – In regard to food safety, what risks in the establishments do you believe are not adequately addressed?

Foodborne illness and consumer protection were the top two answers from the four groups. Foodborne illness included sanitation issues such as employee hygiene, product distribution issues, pathogens such as *Campylobacter* and *Salmonella*, and farm-to-table issues. Consumer protection issues included product labeling.

- ***Salmonella* and *Campylobacter***

Several participants voiced the concern that FSIS is unable to address the issue of *Salmonella* and *Campylobacter* on carcasses and raw ground product. One participant stated that the plants seem to have no concern at all about *Campylobacter*. Another participant said that the Centers for Disease Control reports indicate *Salmonella* is not adequately addressed. One example given was the emerging problem of *Salmonella* in ground beef causing foodborne illness that is difficult to regulate since *Salmonella* is not considered an adulterant in raw products. Another person described the problem of *Salmonella* and *Campylobacter* being primarily addressed in their poultry plant only by regulating the presence of visible fecal material.

- ***E. coli* O157:H7 in slaughter plants**

Comments indicated that more testing should be performed for *E. coli* O157:H7 in beef slaughter plants to more effectively control foodborne illness. Currently it is only addressed as an adulterant in ground beef.

- **Temperature abuse of product in storage and during transit**

Distribution issues that many participants stated need to be addressed included the shipping of product in dirty trucks that lacked refrigeration. Many participants expressed concern about temperature abuse of product during storage and shipping because the temperatures of product aren't monitored or recorded.

- **Allergens**

One participant noted, and others agreed that plants have not adequately addressed the control of allergens in products. Inadequate labeling of possible allergens in product can lead to human health problems in consumers with allergies.

- **Farm-to-table**

The participants agreed that more needs to be done to promote farm-to-table issues associated with foodborne disease.

Issue # 2 – Risk-Based Inspection Factors

The factors considered to drive RBIS are:

- (1) Inherent hazard, which is a function of species, processing, interventions and production volume;
- (2) The intrinsic effectiveness of the establishments risk-management system (design);
- (3) How well establishments implement their risk management system;
- (4) Evidence of pathogen control effectiveness (FSIS sampling results); and
- (5) Evidence of post-shipment problems (recalls, consumer complaints).

Q2.1 – What do you think of the factors and are these factors appropriate for risk-based approach?

All four groups agreed with the factors. Several commented that the factors were broad enough to cover all considerations. One participant felt that the points are overlapping, but that better management leads to better effectiveness.

Q2.2 – What are the other factors that we should be considering?

Various comments were made, but the areas most often mentioned were as follows.

- **Deployment of FSIS resources**

Participants expressed concern over how the new roles of the inspection force will be assigned. Clear definitions of roles, methods of assignment, and who makes the decisions must be in place from the beginning.

It was suggested that the flexibility and speed that will be necessary to apply increased inspection to areas of greatest risk may be much more expensive and require increased staffing. FSIS will need to plan on the increased costs and administrative problems of getting well-trained, experience personnel to the sites where they are needed quickly.

Several different questions were posed as to how FSIS will develop the systems for gathering the necessary information and adequately analyzing it.

- **Plant employees**

A common concern among participants was the importance of ensuring that plant employees are given adequate background screening. It was pointed out that this is critical for protecting the food supply. The plants must ensure that employees are honest and have high ethical standards. The employees also must be able to be trained in proper foodsafety procedures.

Issue # 3 – Work to be Done

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Traditionally, HACCP allows 70 percent of inspectors' activities to be focused on food safety matters. The remaining 30 percent is focused on other consumer protection activities. In a risk-based system, we foresee a much more flexible allocation of inspectors' time. We would try to free up our inspectors to spend as much time as they need to fully explore their inspectional findings that relate to food safety. We are proposing a decision tree to help inspectors in their work.

Q3.1 – Are there additional or better ways to guide inspectors as they perform their activities?

- **Current systems are best**

Several participants stated that they didn't feel that anything was wrong with the system and that the system works well. As one person commented, "we like the system that we're in."

- **Clearly define roles**

Other participants pointed out that as FSIS moves to RBIS, it will become more important to clearly define everyone's roles and who makes decisions.

Many participants expressed the need for inspection personnel in plants to have more freedom to use their discretion to adapt inspection systems to changing conditions in their plants quickly. They agreed that more flexibility and training to empower the inspectors was needed.

- **FSIS resources**

The topic of the lack of resources came up after one participant said, "How can you adequately cover assignments by covering three or four facilities in one day?" Participants agreed and noted that FSIS would need to plan to meet future resource needs under RBIS. Another participant added, "Let's try to free up the inspectors' time to really protect the consumer."

- **Data analysis systems**

The important of developing systems for collecting and analyzing data was emphasized by many participants. One person pointed out that FSIS doesn't have adequate systems to collate and analyze the data presently available. Also, one person noted that the data based system's [RBIS] success in making good decisions is contingent on good data. The participant desired to see a system with little to no flaws with the data system and added this is especially important for inspection personnel making decisions in the plants. As one participant stated, there is the problem of "creating a lot of data that often doesn't mean much."

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- **Relief Inspection Personnel**

One participant highlighted the problem for relief personnel. It will be necessary to provide methods to enable relief people to move into different plants with different levels of inspection. One participant suggested that a guide be developed to assist relief inspectors and “make it easier to transition in.”

- **Foreign plants**

The question of how RBIS will apply in foreign plants was raised.

- **Communications**

Comments were made that FSIS will need to develop methods to improve rapid communications between inspection personnel and between them and District Offices, Headquarters, etc. Some participants discussed stovepipe systems that do not communicate across programs. It was noted that more communication and cohesiveness should occur between programs.

Issue #4 – Design of Inspection Activities

Try to focus on those aspects of the plant’s process where loss of control is most likely to occur. Also focus on where a loss of control has more serious public health implications. These are the points of the process where the Agency’s inspection and verification attention is most critical. Using the recently developed Hazards Control Guide should help inspectors identify these critical aspects of an establishment’s operations.

Q4.1 – What additional ways do you suggest that FSIS incorporate into its risk-based inspection activities and why are they helpful?

Very few of the participants had any prior knowledge of the Hazards Control Guide. One participant was concerned that EIAOs and DMVs have more resources, such as the Hazard Control Guide, and information on their plants than the inspection personnel in the plant.

Issue #5 – How Should Risk-Based Systems Respond to Findings

Traditionally, the evidence of compliance or non-compliance had no effect on the intensity of the inspection. Non-compliance has always potentially led to enforcement actions (NOIEs) and that would continue under RBIS. However, under this system, non-compliance could also lead to a greater level of inspection.

Q5.1 – Is the general approach satisfactory or are there other ways to respond?

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The general response of the participants was that the approach was satisfactory and that RBIS would improve inspection. Others felt that “the theory is good but not workable.” One participant said that they agreed that the approach is satisfactory but wanted to know what made good control or bad control. There were many questions as to how RBIS will be achieved.

- **Currently**

One participant pointed out that inspectors already increase their focus on areas of problems in the plants. Another person pointed out that the current system for processing NOIEs takes too much time to quickly respond to foodsafety problems. Inspectors in the plant will need to have the flexibility to increase inspection as soon as problems arise.

- **Data quality**

Many participants were concerned that RBIS will be dependent on the quality of the data available. As one person stated, “A data driven system depends on accurate data with checks and balances.” Currently most FSIS data is entered by personnel who are not qualified to assess the accuracy and validity of the data and there are no reviews to check the data.

- **Inspection resources**

A common question was how FSIS will achieve the personnel and resources to adequately implement RBIS.

Issue #6 – Continuing Communications with Employees

Dr. Barbara Masters has placed a great deal of emphasis on improving internal communications with employees at all levels—especially those in field locations.

Q6.1 – How do you suggest that we keep Agency employees informed on our progress of implementing an enhanced risk-based system?

All groups agreed that the FSIS News and Notes, internet, and the Beacon are adequate ways for most employees to stay informed. Many suggested using more listening sessions similar to the RBIS focus group sessions and town hall meetings to not only ease the fear of employees, but to let people feel that they have a voice. All-Hands meetings were commented on as being very effective.

However, problems with the current methods of Agency communication with employees were noted.

- **Lack of time**

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One participant remarked that inspectors on the “kill floor” do not have access or time to walk off the floor and go to a computer, so direct mailings from the Administrator work well for that population. Others pointed out that while the All-Hands meetings and Town Hall meetings are very effective, they do not “trickle down” or are not accessible to most employees. Keeping first line supervisors informed was suggested as a method to keep line inspectors informed.

- **Inadequate computer resources**

A major problem occurs when information is solely given on the internet. A lot of the plants either have dial-up access (which makes it harder to download documents and PDF files) or no access at all. Employees in more rural areas (outside the Atlanta and Beltsville commuting areas) felt that communications were not as quick as they should be. They felt that they wasted a lot of time just trying to access the documents online and that there should be more resources in the field so dial-up access is not the norm anymore.

- **Information overload**

Several participants mentioned that the amount of information currently sent to employees, Directives, Notices, newsletters, etc. is too much for them to read in the time available. One participant suggested quarterly mailings to employees of information.

- **Employee input**

Several comments were made recommending giving employees more opportunity for input. One person also recommended that FSIS drop the “need to know system” and make information freely available to all.

One participant suggested an ombudsman because the possibility of one being hired by FSIS had been discussed in 2003 or 2004. The participant said that, “people feel intimidated so there needs to be an anonymous way to give info.”

Wrap-Up

What idea or thought heard today is most important to enhancing our risk-based system in FSIS?

- **Inspection resources**

Many of the responses were focused on how FSIS resources will meet the demands of RBIS. The budget was a concern and many participants wanted to know why FSIS was so under funded year after year. Others felt that the inspectors' duties were overlapping and that that was taking away from their ability to do their jobs well.

- **Communication**

Participants in all four groups commented that they want to be heard and listened to more by upper management. There were concerns that some of the Agency's decision-makers have not been out in the field and have no connection to the employees and the decisions that they make for them.

Participants also were concerned that employees need to be informed on an on-going basis of how RBIS will affect their roles in the future.

Some suggested that the computer systems in the field receive some updating to improve communications.

- **Data quality and integrity**

Many participants were concerned that RBIS will depend upon improved data systems of collection and analysis to be successful. They recommended many sources of useful data.

- **Empowerment of in-plant inspection personnel**

A common comment was that empowerment of in-plant inspection personnel will be key to the success of RBIS. Others highlighted training and that "the inspectors need to be empowered because knowledge is key."

Conclusion

Risk based inspection will provide more uniform adoption of performance standards across the industry. FSIS can implement this system and focus on ready-to-eat products and use the inspection workforce where they are most needed.

The summary report shows that field employees want to be heard and to receive all FSIS information in a timely matter. They have concerns about the checks and balances in the inspection process and desire to see an even more successful farm-to-table process. They

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were concerned about lack of resources and the budget crunch in the field and how inadequate internet access impedes their participation in agency events and prevents them from receiving important information in a timely manner. The suggestions and comments from the RBIS focus group sessions are the heart of what our employees say and think about this revamped system. Their valued opinions will only boost our programs and improve communication. The end result will be not only a success for FSIS, but an improvement in the nation's public health.